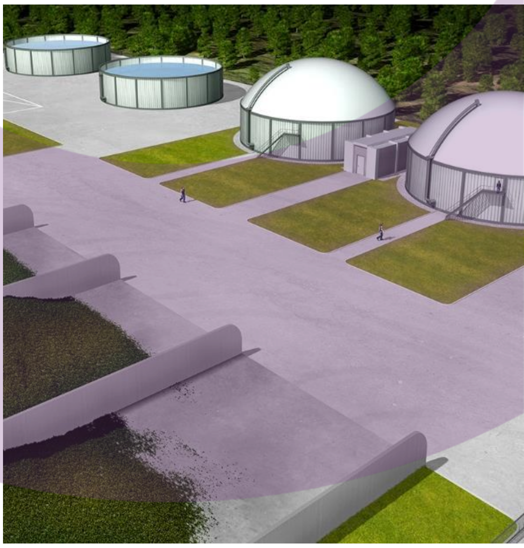
European Commission

Digestate and compost as fertilisers: Risk assessment and risk management options

Final Report



Wood Environment & Infrastructure Solutions UK Limited – February 2019

Report for

Valentina Bertato
Policy Officer
European Commission
Directorate General - Environment
Directorate B - Circular Economy and Green Growth
Unit B.2 - Sustainable Chemicals
BU 9 B-1049 Brussels

Main contributors

Caspar Corden (Wood)
Kastalie Bougas (Wood)
Ellen Cunningham (Wood)
David Tyrer (Wood)
Julius Kreißig (Wood)
Elisabeth Zettl (Ramboll)
Edgar Gamero (Ramboll)
Ros Wildey (Peter Fisk Associates)
Mike Crookes (Peter Fisk Associates)

Issued by

J. Krei

Julius Kreißig

Approved by

Caspar Corden

Wood

Floor 12
25 Canada Square
Canary Wharf
London E14 5LB
United Kingdom
Tel +44 (0) 203 215 1610

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Document revisions

No.	Details	Date
1	Draft final report	5 November 2018
2	Final report	22 January 2019
3	Revised final report	8 February 2019

Executive summary

Purpose of this report

This is the final report for a project on "*Digestate and compost as organic fertilisers – Risk assessment and risk management options*" (reference FC/2015/0010 - SR3 under Framework Contract ENV.A.3/FRA/2015/0010), prepared by Wood with partners Peter Fisk Associates and Ramboll for the European Commission, DG Environment.

The aim of the project was to prepare an environmental and human health risk assessment and a risk management options analysis (RMOA) to provide a sound basis for decision making on the need to propose any regulatory measures to control the risks associated with contaminants in compost and digestate (hereafter referred to as C/D) used as a fertiliser and soil improver. This included a socio-economic analysis of the impacts of possible risk management action.

Market analysis

Approach

The market analysis involved collecting available information on all uses and related tonnages of digestate and compost in the European Union, as well as their input materials. The analysis involved a combination of a targeted stakeholder consultation and a review of relevant literature and statistical sources.

Results

For **compost** we estimate that the current annual EU production of compost amounts to **17.3 million tonnes** per year as a central estimate (with a possible range of 13-18 million tonnes). The vast majority of this (ca 14 million tonnes) is derived from green waste and separately collected biowaste, while some 800,000 tonnes are produced from sewage sludge[1]. Some sources suggest that compost is (or at least has been) produced from mechanical biological treatment (MBT) of mixed MSW in some smaller countries, but a current EU-wide figure could not be derived. It is estimated that the majority (ca. 85%) of compost is used as a fertiliser or soil improver in agriculture, gardening, horticulture and landscaping.

For **digestate**, our analysis suggests that around **180 million tonnes** of digestate are produced in the EU28 per year, almost half of this in Germany. With 120 million tonnes, the majority of digestate produced in the EU is agricultural digestate (typically a mix of manure and plants, particularly energy crops). About 46 million tonnes are produced from the organic fraction of mixed MSW (mechanical biological treatment – MBT), at least 7 million tonnes from source separated biowaste and smaller quantities (ca. 1.7 million tonnes each) from sewage sludge and agro/food industry by-products. The vast majority of digestate is used directly as a fertiliser.

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[1] It should be noted that the sum of compost produced across input materials is lower than the total quantity of compost produced in Europe estimated above. This is due to different data sources available for quantities by country and by input material. The mismatch suggests that either the quantities of compost by country (and in sum for the whole EU) are somewhat overestimated, and/or the quantities of compost by feedstock are somewhat underestimated.

Substance identification

Approach

The objective of the substance identification was to identify potential critical contaminants in C/D for the subsequent risk assessment and risk management options analysis (RMOA).

A set of criteria was developed to decide whether a substance (or a group of similar substances) present in compost or digestate should be further investigated. These criteria include "presence in specific substance lists", "human toxicity", "environmental toxicity", "harmonised classification", "mobility in water bodies", "concentration found in compost/digestate", "intrinsic properties" and "limit values exceeded". A matrix was created to collect relevant information from scientific literature. The substances were then classified into one of three priority levels based on a combination of the above criteria.

Results

17 substance groups were identified, covering more than 94 single substances and 4 sub-groups[2], based on the information retrieved from 50 relevant publications. Based on the priority levels and discussion with the project steering group, the **following substances were then taken forward for further risk assessment**:

- Heavy metals – represented by cadmium, nickel, lead, copper, zinc and mercury.
- Bisphenol-A.
- Phthalates – represented by di(2-ethylhexyl)phthalate (DEHP).
- Pharmaceuticals – represented by 17α-Ethinylestradiol (EE2).
- Hexabromocyclododecane (HBCDD).
- Dioxins, furans and dioxin-like PCBs – represented by 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD) and 2,3,4,7,8-pentachlorodibenzofuran (2,3,4,7,8-PCDF).
- Other PCB – represented by 2,4,4'-Trichlorobiphenyl (PCB-28).
- Nonylphenol isomers and ethoxylates – represented by nonylphenol.
- Polycyclic aromatic hydrocarbons (PAH) – represented by benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene and indeno[,2,3-cd]pyrene.
- Perfluoralkyl substances (PFAs) – represented by perfluoroctanesulfonic acid (PFOS) and undecafluorohexanoic acid (PFHxA).
- Physical impurities – represented by microplastics.

Risk assessment

Approach

Realistic worst case risk assessments[3] have been carried out for selected priority contaminants. The focus of the exposure assessments was the environment and humans exposed via food and drinking water. Exposure

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[2] Sub-group = two or more individual substances are addressed together, e.g. PAH-16 or PCB7.

[3] It is important to note that a relatively simplistic realistic worst-case approach has be used in the risk assessment in order to simplify the process, and the results are subject to a number of uncertainties considered and discussed in the risk assessment.

and risks for two local scale scenarios have been characterised. These scenarios consider (1) the use of compost and digestate as a fertiliser and soil conditioner, and (2) the use of compost as a growing medium.

The risk assessments combine an assessment of exposure with an analysis of hazard in order to determine the likelihood of negative impacts. Were possible the significance of the estimated exposures derived by modelling has been assessed by comparison with available measurements of soil and water quality and/or from estimated exposures arising from the industrial lifecycle where this has previously been assessed in an exposure assessment. Where appropriate, estimated exposure levels are also compared with e.g. no-effect levels for relevant hazards, in order to derive a ratio of the exposure level to the no-effect level (a risk characterisation ratio (RCR)).

Results

The identified risks are summarised, by scenario, below:

- **Container growing:** Potential risks (and safe limits) specifically for compost used in container growing have been identified for the heavy metals **Nickel** (safe limit of 7.9 mg/kg dw) and **Copper** (safe limit of 200 mg/kg dw). For both substances, the main sources of this contamination are not entirely clear. From different input materials, most measured concentrations are broadly similar. However, for Nickel the highest maximum concentrations have been reported in biowaste compost, greenwaste compost and MBT compost. For Copper, sewage sludge compost and MBT C/D display generally higher concentrations than C/D from other source materials. Manure is a known source of Copper but is not the only possible source.

- **Application to agricultural land:** Potential risks (and safe limits) specifically for digestate and/or compost applied to agricultural land have been identified for **Mercury** (safe limit of 0.2 mg/kg dw). As above, most measured concentrations from different input materials are broadly similar. However, the highest maximum concentrations have been reported in biowaste compost, greenwaste compost, MBT compost and sewage sludge compost.

- **Both scenarios (container growing and application to land):** Potential risks (and safe limits) for both container growing and application to agricultural land have been identified for **Zinc** (safe limit in container growing of 70 mg/kg dw, safe limit for application to agricultural land 600 mg/kg dw). Generally higher concentrations of Zinc were measured in sewage sludge compost and MBT compost. However, on average Zinc concentrations were higher in digestate compared to compost.

- **For Nonylphenol,** to the extent that risk characterisation has been possible, unacceptable risks are indicated for the **container growing** scenario (with a 3.5 mg/kg safe limit). Risk characterisation for humans exposed via the environment was not quantified, as nonylphenol is an endocrine disruptor. However, the predicted local total daily intake associated with the application of C/D is comparable with the daily human intake for local exposures associated with the various industrial use scenarios set out in an EU risk assessment from 2002. Few measurements of nonylphenol concentrations were reported in the literature. Of the tested C/D, municipal sewage sludge-derived products exhibited the highest concentrations, followed by green waste compost. Agricultural digestate (manure and energy crops) exhibited far lower concentrations.

For substances where conventional quantitative risk characterisation is not appropriate, exposures at the steady state are discussed. Due to the hazards (Non-threshold or unclear threshold, SVHC, POP, PBT) associated with some substances, their presence in compost/digestate itself may be of concern, but no risk characterisation ratio can be calculated. This includes the following substances:

- **Lead** is a non-threshold neurotoxic substance and the contribution from C/D to the total background levels of lead in soil from all sources is significant. On the other hand, the realistic worst case has yielded no risk characterisation ratios (RCRs) >1 for the endpoints where conventional quantitative risk characterisation is appropriate (soil, sediment, water and secondary poisoning). Generally higher concentrations of lead were measured in compost (compared to digestate in general), with MBT compost exhibiting the highest reported average and maximum concentrations.
- **BPA and DEHP** are reprotoxins and endocrine disruptors (SVHCs).
  - For BPA, the regional scale predicted environmental concentration (PEC) in agricultural soil is well below the background concentration arising from the industrial life cycle. The predicted local total daily intake for humans does not exceed the DNEL used by EFSA and RAC, and the PNECs adopted in the 2010 ESR risk assessment are not exceeded. BPA in C/D can therefore be considered a lower priority for further risk management.
  - For DEHP, the highest reported concentrations in composts and digestates (sewage sludge compost, biowaste-food and garden waste digestate) already appear to exceed the national limit values for C/D for several member states and the local total daily intake for humans associated with container growing slightly exceeds the DNEL defined by Danish EPA. With regards to application to land, the regional scale predicted environmental concentration (PEC) in agricultural soil and grassland is below the background concentration arising from the industrial life cycle. Upcoming risk management for DEHP (amendment of the REACH Authorisation List entry and proposed REACH restriction on DEHP in articles) may lead to a reduction of DEHP in input materials used for composting and AD. Hence, further monitoring of the development of DEHP concentrations in C/D is required to judge the need for further risk management in the future.
- **17 α -ethinylestradiol** is an endocrine disruptor with unclear safe limit thresholds. The total mass in the region + continent at steady state is low (approximately 7 tonnes), but the local total daily intake is only about four times below the therapeutic pharmaceutical dose. The only concentration measurements identified in the literature are for C/D from sewage sludge and given 17α-ethinylestradiol is a pharmaceutical, it appears likely that sewage from waste water treatment is the main source of the substance into C/D.
- **HBCDD, the assessed representative PCBs (PCB28) and of dioxins and furans (TCDD, PCDF), as well as PFOA and PFOS** are POPs. That they have been detected in freshly-produced composts and digestates at several locations in recent years is itself a concern.
  - For HBCDD, very few literature sources have identified HBCDD in C/D and the estimated regional scale exposures arising from the application of C/D are well below the anthropogenic background concentrations. Furthermore, following the expiry of the only REACH authorisation, any contribution to HBCDD concentrations in compost in digestate resulting from industrial release of HBCDD should be eliminated. HBCCD in C/D can therefore be considered a lower priority for further risk management.
  - For the assessed PCB, the highest reported concentrations in composts and digestates already appear to exceed the national limit value for C/D in several Member States (although only in a very small share of samples) and the estimated exposures are high compared with reported mean/median levels in foodstuffs. A clear distinction of PCB concentration levels between C/D from different input materials could not be established, with a wide variation of values reported for most.
  - For the assessed dioxins and furans, the highest reported concentrations in composts and digestates already appear to exceed the national limit value for C/D in several Member

States and the estimated exposures are high compared with reported mean/median levels in foodstuffs. A clear distinction of dioxin and furan concentration levels between C/D from different input materials could not be established, with a wide variation of values reported for most input materials However, the highest concentrations are reported for sewage sludge based composts and biowaste/green waste manure energy crop digestate.

  - For PFOA and PFOS, estimated regional-scale predicted environmental concentrations arising from the application of C/D appear to be low compared to the measured background concentrations. Predicted exposures of humans (local total daily intake) could exceed safe limits (in the case of PFOA only for container growing, in the case of PFOS for both container growing and agricultural application). Most measured concentrations are broadly similar across C/D from different input materials, but generally higher concentrations were measured in sewage sludge compost.

- **PFHxA** has been proposed as an SVHC and the risk assessment identified that C/D application could lead to human exposure, especially via diet and drinking water. However, no data on concentrations of PFHxA specifically (only for PFOA+PFAS) in C/D are available. Hence, further monitoring of PFHxA concentrations in C/D is required to judge the need for further risk management in the future.

Long-term gradual accumulation through repeated application (cumulative loads at steady state) or transfer over long distances may present a concern for the following substances:

- Cumulative loads at steady state are a concern for 15 of the 23 assessed substances, including most heavy metals (Cd, Ni, Pb, Cu and Zn, but not Hg), DEHP, all assessed dioxins, furans and PCBs (TCDD, PCB28, PCDF), nonylphenol and all assessed PAH16 (Benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene, indeno[,2,3-cd]pyrene).
- In contrast, for mercury, 17α-ethinylestradiol and PFAs (PFOA, PFOS, PFHxA) transfer over long distances is of potential concern.
- Note that for cadmium and PAH16 substances, long-term gradual accumulation is the only main concern identified in the risk assessment. These substances are considered a lower priority for risk management. For all other substances, the risk assessment raised other areas of potential concern which are discussed above.

Lastly, with the current methods and data available fugacity modelling is not reliable for **microplastics**, so a generic estimate of exposure to microplastics resulting from digestate and compost use is provided:

- C/D application is a potentially important source of human exposure to microplastics via the environment (via root and leaf crops in the diet). The exposures of soil and sediment arising from the application of C/D estimated in the model used are very low (several orders of magnitude smaller) compared with the PECs modelled in the recent risk assessment of exposures arising from intentional use in a range of industrial and consumer uses (not including microfibres released by washing of textiles). Upcoming risk management for intentionally added microplastic particles in products (restriction proposal) might lead to a significant reduction of microplastics in household waste water and hence in sewage sludge. Hence, further monitoring of microplastics concentrations in C/D is required to judge the need for further risk management in the future.

In summary, the **following substances were prioritised for risk management** in the remainder of this RMOA, based on the identified risks:

- Heavy metals (Nickel (Ni), Lead (Pb), Copper (Cu), Zinc (Zn), Mercury (Hg))
- 17α-ethinylestradiol

- PCBs (PCB28)
- Dioxins and furans (TCDD, PCDF)
- Nonylphenol
- PFAs (PFOA, PFOS)
- Cadmium and PAH16 substances (as a lower priority)[4]

Risk management option analysis (including socio-economic considerations)

Justification for risk management at EU-level

Realistic worst case risk assessments have identified potential risks from the use of C/D as fertiliser arising from several contaminants. Existing risk management includes notably restrictions on input materials and limit values on a range of contaminants for CE-marked fertilisers under the proposed Fertilising Products Regulation, the European Compost Network (ECN) Assurance Scheme for Compost and Digestate (non-binding) and national legislation in several Member States. However, it lacks binding and coherent requirements for all types of C/D and all EU Member States. Moreover, the production of digestate as a fertiliser is expected to increase significantly in the short to medium term. Existing risk management is therefore unlikely to adequately control the identified risks. Coherent rules across the EU could improve user confidence and help support a common market for C/D use as a fertiliser. Hence, further risk management at EU-level may be required.

Comparison of the assessed risk management options

The main risk management measures considered in this RMOA are the introduction of (further) concentration limits, restrictions on input materials, conditions of use, or the application of specific processes and techniques to reduce the concentration of contaminants in input materials (before composting/AD) or C/D itself (during composting/AD or post-treatment).

Based on the results of the risk assessment and the market analysis, as well as an assessment of the likely effectiveness, practicality, monitorability and socio-economic impacts, the following **initial considerations on the potential scope for each measure** were developed:

- **Option 1) Concentration limits:** It seems appropriate to set limit values for nickel, copper, zinc, mercury and nonylphenol equal to safe limits calculated in the risk assessment. However, due to the large share of compost currently exceeding these levels for nickel and zinc for use in container growing, it is unclear if these specific limits would be proportionate. Additional limit values could be set for PCBs, PCDD/F, lead, PFAs and PAHs based on existing limit values, unless the risks from these substances can be addressed by other types of risk management or costs for sampling of PCBs, PCDD/F and PFAs are considered prohibitive.
  The proposed limits are listed in the table below:

Substance	Safe limit concentration in C/D for application to agricultural land	Safe limit concentration in compost for container growing
Cadmium	*	*

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[4] Lower priority than the above, because the only main concern identified in the risk assessment was long-term gradual accumulation through repeated application.

Nickel	*	7.9 mg/kg dry weight
Copper	*	200 mg/kg dry weight
Zinc	600 mg/kg dry weight	70 mg/kg dry weight
Mercury	0.2 mg/kg dry weight	*
Nonylphenol	*	3.5 mg/kg dry weight
For pollutants where safe limits cannot be defined:		
Substance (group)	**Range of existing limits**	**Considered most appropriate if EU-wide limits were to be set based on existing limits**
PCBs	PCB6: 0.1-1.2 mg/kg d.m. PCB7: 0.15-0.8 mg/kg d.m.	PCB7: 0.8 mg/kg d.m.
Dioxins and furans	17 PCDD/F: 20-100 ng TEQ/kg d.m. PCDD/F + dl-PCB: 30 ng TEQ/kg d.m. for the	17 PCDD/F: 20 ng TEQ/kg d.m.
Lead	100-150 mg/kg d.m	120 mg/kg d.m.
PFAS	PFOA+PFOS: 100 µg/kg d.m.	PFOA+PFOS: 100 µg/kg d.m.
PAHs	PAH16: 3-10 mg/kg d.m. PAH11: 3 mg/kg d.m.	PAH16: 6 mg/kg d.m.

- **Option 2) Restriction on input materials:** It seems appropriate to consider prohibiting the use as fertiliser of C/D made with sewage sludge[5], with an option to allow its use in the future given improvements to its treatment at waste water treatment plants. The direct application of sewage sludge to agricultural land would have to be restricted to be coherent with the restriction of sewage sludge C/D.
- **Option 3) Conditions of use:** It appears appropriate to consider a restriction for container growing (if C/D made from sewage sludge is not restricted for use as fertiliser in general as discussed above).
- **Option 4) Obligation to use specific processes:** An obligation to use two-stage anaerobic digestion[6] could be appropriate for MBT digestate and sewage sludge digestate, and an obligation to apply post-composting[7] could be appropriate for sewage sludge digestate (if C/D made from sewage sludge is not restricted for use as fertiliser in general).

The main advantages and disadvantages identified for each option and for the specific measures proposed under each option are summarised in the table below:

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[5] Addressing the following prioritised contaminants which have been found in high concentrations in sewage sludge: Copper, Zinc, Mercury, 17α-ethinylestradiol, dioxins and furans, PFAS, PAH16.

[6] Addressing the following priority contaminants which can be reduced by two-stage AD: Nickel, Lead, Copper, Zinc, Cadmium, PAH16.

[7] Addressing the following priority contaminants which can be reduced by post-composting: PCBs, PAH16.

Proposed risk management	Main advantages	Main disadvantages
Option 1) Concentration limits	+ Directly limit pollutants to levels considered to pose no (or an 'acceptable level' of) risk. + Setting limit values only for pollutants where concentrations exceeding safe limits have been found minimises the regulatory burden (e.g. sampling costs). + Separate limit values for different use scenarios minimises the share of C/D restricted.	- Sampling costs. - Setting limit values only for pollutants where concentrations exceeding safe limits have been found does not ensure the control of risks from future increases in concentrations of other contaminants. - Separate limit values for different use scenarios are more complicated to enforce. - Main potential negative impacts: Reduced compost production; affected compost feedstocks and digestate have to be disposed of; increased synthetic fertiliser use.
Measure 1a) Limit values based on calculated safe limits for application to agricultural land (zinc, mercury)	+ Only a low share of C/D expected to be affected and potential negative impacts would be modest in scale.	
Measure 1b) Limit values based on calculated safe limits for container growing (nickel, copper, zinc, nonylphenol)	+ For copper and nonylphenol, only a low share of compost is expected to be affected and potential negative impacts would be modest in scale.	- For nickel and zinc a large share of compost used in container growing is expected to be affected, so the potential negative impacts could be significant for the container growing segment.
Measure 1c) Limit values based on existing limit values (PCBs, PCDD/F, lead, PFAS, PAHs)	+ Would ensure that the risk from these substances is limited EU-wide, while minimising the disruption to those markets where limit values are already in place. + Only a low share of C/D is expected to be affected and potential negative impacts would be modest in scale.	- It is not clear if existing limits are risk-based and if they would adequately control the risks. - Sampling costs, particularly for PCBs, PCDD/F and PFAS, may render the production/use of some C/D uneconomical, likely increasing the scale of the potential negative impacts.
Option 2) Restriction on input materials	+ Easier and less costly monitorability and enforceability compared to limit values (less comprehensive sampling). + Reinforced consumer confidence.	- Risk is not directly controlled (concentration of contaminants in input materials is subject to variation). - Some C/D that does not pose a risk may be restricted. - Not technology neutral (does not encourage innovation to enable use of restricted input materials). - Main potential negative impacts: Reduced compost production; affected compost feedstocks and digestate have to be disposed of; increased synthetic fertiliser use.
Measure 2a) Restriction on the	+ Sewage sludge exhibits particularly high concentrations for most priority substances of	- Sewage sludge could be applied directly to agricultural land instead of being digested

Proposed risk management	Main advantages	Main disadvantages
use of sewage sludge based C/D as a fertiliser	concern, including several substances for which no calculated safe limits are derivable and concentration sampling is (potentially) particularly expensive. + Only a low share of C/D is expected to be affected and potential negative impacts would be modest in scale	first, unless coherent regulation on direct use of sewage sludge is implemented. - Further regulating the direct use of sewage sludge would increase the scale of impacts related to alternative waste management for sewage sludge.
Option 3) Conditions of use	+ Aims at reducing exposure, rather than banning certain composts/digestates or input materials. + No sampling required.	- Risk is not directly controlled (only reduced by eliminating uses with highest potential for exposure). - Potential difficulties with monitoring and ensuring compliance by consumers.
Measure 3a) Restriction on the use of sewage sludge compost in container growing*	+ Addresses the risk associated with container growing, which is higher than application to agricultural land for most priority substances of concern (all except zinc and mercury). + Complementary to proposed limit values based on calculated safe limits (sewage sludge is linked to several substances for which no calculated safe limits are available). + Only a very low share of compost is expected to be affected and potential negative impacts would be very modest in scale.	- Main potential negative impacts if use on agricultural land is not feasible: Reduced compost production; sewage sludge has to be disposed of; increased synthetic fertiliser use.
Option 4) Obligation to use specific processes	+ Aims at reducing contamination, rather than banning certain composts/digestates or input materials.	- Effectiveness in reducing the risks is uncertain. - Not technology neutral (not supporting innovation and not leaving choice of most efficient process to operators).
Measure 4a) Restriction on the use of MBT and sewage sludge* based digestate as a fertiliser except when using two-stage A/D	+ Targeted at specific risks (contaminants reduced by this process are particularly linked to sewage sludge). + Associated additional costs are at least partly offset by operational benefits, so for a share of the affected operators there may be no negative net effects.	- A significant share of digestate is expected to be affected and potential negative impacts could be considerable in scale. - For a share of the affected operators, there will be a net cost. - Main potential negative impacts for operators for which the additional cost is not feasible: affected digestate (and MBT feedstocks/sewage sludge if replaced by alternatives) have to be disposed of; increased synthetic fertiliser use.

Proposed risk management	Main advantages	Main disadvantages
Measure 4b) Restriction on the use of sewage sludge digestate as a fertiliser except when applying post-composting*	+ Targeted at specific risks (contaminants reduced by this process are particularly linked to sewage sludge). + Only a low share of digestate is expected to be affected and potential negative impacts would be modest in scale.	- Associated with additional space, time and operational cost. - Main potential negative impacts for operators for which the additional cost is not feasible: affected digestate (and sewage sludge if replaced by alternatives) have to be disposed of; increased synthetic fertiliser use.

Notes:
Proposed risk management: Advantages and disadvantages associated with the main options are valid for all measures proposed under these options. The advantages and disadvantages associated with the specific measures proposed under each option are additional to those for the option in general or specify their expected magnitude for the specific measure.
*) Only relevant if sewage sludge C/D is not restricted for use as fertiliser in general.

Legal options

Possible legal options to implement the proposed risk management measures are briefly discussed. These include:

- Amendments to the annexes of the revised Fertilising Products Regulation
- A REACH restriction
- Bespoke (ad-hoc) legislation
- Defining end-of-waste criteria under the Waste Framework Directive (although this is considered unlikely to be feasible)
- In addition, there are specific pieces of legislation regulating the use of specific waste streams that are also used as input materials for C/D, such as the Sewage Sludge Directive and the Urban Waste Water Treatment Directive.

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1. Introduction

1.1 Purpose of this report

Wood Environment & Infrastructure Solutions UK Limited ('Wood') has been contracted by the European Commission, DG Environment to provide services on "*Digestate and compost as organic fertilisers – Risk assessment and risk management options*" (reference FC/2015/0010- SR3 under Framework Contract ENV.A.3/FRA/2015/0010). Wood is working in partnership with Peter Fisk Associates Limited ('PFA') and Ramboll Environment & Health GmbH ('Ramboll'), who are acting as subcontractors to Wood for the purposes of this contract.

This is the final report for the project, which takes into account feedback from the project's steering group on a draft final report. The report contains the results of the project including the market analysis, substance identification, risk assessment and risk management option analysis including analysis of alternatives and their costs.

1.2 Objectives of the study

The contract aims to prepare an environmental and human health risk assessment and a risk management options analysis (RMOA) to provide a sound basis for decision making on the need to propose any regulatory measures to control the possible risks associated with compost and digestate (hereafter referred to as C/D) used as fertiliser[8]. It will include a socio-economic analysis of the impacts of possible risk management action, relating to placing on the market and use of digestate and compost as fertilising products.

The results will be presented in the format of an Annex XV dossier for REACH restriction, but they could also be used for other regulatory actions. This format will allow the possible use of the results for potential input to the Commission's impact assessment, in line with the Better Regulation Guidelines (2017). This flexibility is required as the Commission decision on the preferred risk management option will depend (inter alia) on the outcomes of the analysis, including the potential risks to the environment or human health identified.

1.3 Structure of this report

This report is structured as follows:

- First, the approach and key results of the market analysis (Task 1) are presented in Section 2. This includes tonnages of digestate and compost produced in the European Union, as well as their uses and input materials used to produce them. Additional detailed results for specific countries are shown in Appendix A, and additional information on further processing of digestate in Appendix B.
- The approach and key results of the identification of potential critical contaminants in C/D (Task 2) are presented in Section 3. Additional detailed information on all substances identified are contained in a separate spreadsheet Appendix C.
- Then, Section 4 provides a summary of the approach to assessing the risks from priority substances and chemical families to human health and the environment (Task 3). The key findings for each individual assessed substance are presented and discussed. This summary

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[8] It should be noted that C/D, particularly compost, fulfil other functions than fertilisation, such as adding organic matter to the soil. However, for simplicity we refer to the main function as fertiliser throughout the report, except where the specific function is relevant for the analysis.

information is intended to inform the prioritisation process within the risk management option analysis. A full detailed report of the risk assessment is included in Appendix D.

- Lastly, Section 5 identifies potential regulatory instrument for possible risk management activities to address the concerns identified (Task 4). The risk management options are assessed with regards to their effectiveness to control the risks. Socio-economic considerations are assessed, including the costs and benefits of using potential alternative products and techniques to reduce the risks from contaminants in C/D (Task 5). Based on this, conclusions regarding the most appropriate (combination of) risk management options are drawn.

2. Market analysis

2.1 Introduction

The task involves collecting available information on all uses and related tonnages of digestate and compost in the European Union, as well as their input materials. Understanding the range of input materials, intentional uses and associated volumes will provide a foundation for the study. It will be critical to assessing environmental and human health risks (Task 3), considering available risk management options (Task 4) and potential alternatives (Task 5).

2.2 Approach

2.2.1 Overview

Task 1 involves a combination of a targeted stakeholder consultation and a review of relevant literature and statistical sources. The approach to each of these is described briefly below. Estimates of quantities of compost/by country and by feedstock are derived based on a comparison of all available sources. All the individual figures used to derive the final estimates are presented in Appendix A.

2.2.2 Consultation

Table 2.1 lists the stakeholders that were selected for this targeted consultation. The table also indicates whether they provided a response.

Initial contact was made by telephone, in order to identify their likely willingness to provide information for the study. A questionnaire was produced and agreed with the Commission. This questionnaire was sent to the stakeholders by email. The Commission provided a letter of introduction to assist with the consultation. This was sent to the stakeholders alongside the questionnaire. 16 March was set as the deadline for submitting responses to the questionnaire, although useful responses were received until 9 April.

Table 2.1 List of stakeholders contacted and status of their response

Organisation name	Type of organisation	Response to questionnaire received?
European Biogas Association (EBA)	Industry association	✓
European Compost Network (ECN)	Industry association	✓
European Biomass Association (AEBIOM)	Industry association	Did not respond to questionnaire but noted that the most relevant members are also covered by EBA.
European Consortium of the Organic-Based Fertilizer Industry (ECOFI)	Industry association	
Biorefine Cluster Europe	Industry association / academic	
Dutch Waste Management Association	Industry association	Jointly responded they are members of ECN which will provide data covering the Netherlands.
Dutch association of Biowaste processors	Industry association	
Orgaworld	Company	

Organisation name	Type of organisation	Response to questionnaire received?
Attero	Company	
Italian Consortium of composting structures	Industry association	✓
European waste management industry (FEAD)	Industry association	
Bundesverband der Deutschen Entsorgungs- Wasser- und Rohstoffwirtschaft (BDE)	Industry association	✓
Flemish Coordination Centre for Manure Processing (VCM)	Intermediary platform between the government and the sector	
Fédération Nationale des Activités de la Dépollution et de l'Environnement (Fnade)	NGO	
European Organic Fertilizers Manufacturers Association (EUROFEMA)	Industry association	
European Biomass Industry Association (EUBIA)	Industry association	
WRAP	NGO	
European Environmental Bureau (EEB)	NGO	Responded that ECN, which is a member of EEB, will respond on their behalf.
Friends of the Earth	NGO	
Kompostierung Nord GmbH	Company	✓

2.2.3 Literature review

We commenced our analysis with a literature review focusing on well-known sources and associated uses of C/D (above all, use as fertiliser). All data were collated along with the data received from the consultation to allow further analysis, such as comparing data from different sources, calculating totals, identifying data gaps, etc.

Once data gaps were identified after finalisation of the consultation, further targeted research was conducted to achieve data coverage for each product category across the EU28 on:

- Product quantity and value;
- Use/application;
- Quantity/percentages of input materials used; and
- Production technique used.

We used both keyword searches on internet search engines as well as searching the sites of relevant industry associations and Member State Authorities in several countries both in English and their respective languages (e.g. German, French, Spanish, Czech). The specific literature sources used are presented along with the associated results below.

2.2.4 Statistical sources

The following statistical sources were used in relation to **compost**:

- **Eurostat material flow accounts for 2014** provide estimates per country of compost 'supplied by the national economy and taken up by the natural environment'.[9] This provides a figure for the quantity of compost applied in each country as of 2014 (the latest year for which data is available), however it should be noted that the Eurostat figures are estimates and subject to some uncertainty. Therefore, these figures are compared with other data/literature sources to determine a final estimate of the tonnage of compost per country.
- **Eurostat data[10] on sewage sludge disposed of as 'compost and other applications'[11] for the last available year (2015 for most countries).** For some countries data was not available for any years. This includes Spain, which was known to produce significant amounts of sewage sludge compost according to the literature review. Thus for Spain this gap was filled with data from the Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016. The Eurostat data is provided separately for urban and other wastewater treatment plants; these have been summed up. The sum across countries of sewage sludge disposed of as 'compost and other applications' was used to estimate the tonnage of sewage sludge compost produced in Europe, using the simplifying assumption of a 50% weight reduction from sludge input to compost output[12]. Overall, this is likely an underestimate given that data was missing for several countries. This is counteracted to some extent because weight reduction could be larger than 50%.

The following statistical sources were used in relation to **digestate**:

- **Eurostat data on primary production of biogas in units of energy (Terajoule) for 2016[13].** The quantity of digestate produced as a result of this biogas production was estimated for each country based on a set of assumptions (Table 2.2) using the following steps:

    1. Converting the unit of energy from Terajoule (TJ) to kilowatt hours (kWh): 3.6×10^{-6}TJ=1kWh.
    2. Dividing the production of biogas in terms of energy (kWh) by an assumed energy density of the biogas (kWh total energy per m^3 of biogas, see Table 2.2) to yield the corresponding volume (m^3) of biogas.
    3. Estimating the quantities of input material (feedstock) used to produce these volumes of biogas. This is done by dividing the volumes of biogas (m^3) by an assumed m^3 biogas yield per tonne of input material (see Table 2.2).
    4. Estimating the quantity of digestate produced from the anaerobic digestion (AD) of these quantities of input material. This is done by multiplying the tonnes of input material with an assumed factor of Tonnes digestate yield per tonne of input material (see Table 2.2).

    Three estimates were produced for each country, showing the likely lowest possible and highest possible quantity of digestate resulting from the biogas production covered by the Eurostat data, as well as a central estimate reflecting what we judge to be the most likely assumptions.

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[9] Eurostat: Material flow accounts - domestic processed output [env_ac_mfadpo]

[10] Eurostat: Sewage sludge production and disposal [env_ww_spd]

[11] This refers to "all application of sewage sludge, after mixing with other organic material and composting, as fertilizer in parks, horticulture etc." according to the underlying questionnaire available at: http://ec.europa.eu/eurostat/ramon/coded_files/OECD_ESTAT_JQ_IWA_Master.xls

[12] This is roughly the ratio of compost weight to feedstock weight suggested by the market data submitted by the European Compost Network in their response to the consultation of this project.

[13] Eurostat: Supply, transformation and consumption of renewable energies - annual data [nrg_107a]

Table 2.2 Assumptions used to estimate digestate production from biogas production

Assumption for each step	Lower estimate	Central estimate	Upper estimate	Source:
kWh total energy per m^3 of biogas (step 2)	5.0	5.5	7.5	Fachverband Biogas e. V.: BIOGAS CAN DO IT Facts, arguments and potentials, 2011, http://european-biogas.eu/wp-content/uploads/files/2013/10/broschre_2011_en_versandversion.pdf.
m^3 biogas yield per tonne of input material (step 3)	25	250	600	Lemvig Biogas Handbook: http://www.lemvigbiogas.com/BiogasHandbook.pdf NNFCC anaerobic digestion information portal: http://www.biogas-info.co.uk/about/feedstocks/ Lower estimate refers to manures, upper estimate to grains (e.g. maize, barley), and central estimate is roughly the middle of organic waste and grain (e.g. maize), presumably the main input materials in most countries.
Tonnes Digestate per tonne of input material (step 4)	0.83	0.84	0.85	Lower: EBA consultation response Central: Midpoint between lower and upper Upper: WRAP: Enhancement and treatment of digestates from anaerobic digestion, 2012, http://www.wrap.org.uk/sites/files/wrap/Digestates%20from%20Anaerobic%20Digestion%20A%20review%20of%20enhancement%20techniques%20and%20novel%20digestate%20products_0.pdf.

Source: Wood 2018 based on the sources listed in the last column.

2.3 Results

2.3.1 Overview

This section presents the results of the market analysis, first for compost, then for digestate. For both, an overview of the following is provided:

- Total tonnage produced in the EU in total and in each Member State;
- A breakdown of EU tonnage by feedstock (i.e. the materials used in the composting/anaerobic digestion that produced the compost/digestate); and
- Details of common uses, including further processing of compost/digestate and details of how the final products are applied (e.g. application rate as fertiliser).

2.3.2 Compost

Total quantities

DG JRC's technical proposals on end-of-waste criteria for biodegradable waste subjected to biological treatment (hereafter referred to as "JRC (2014)") estimated that 14.4 million tonnes of compost were produced in the EU28 (based on country-specific estimates relating to various years between 2005 and 2009[14]). Eurostat material flow accounts[15] provide an estimate of 17.9 million tonnes of compost 'supplied by

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[14] The JRC (2014) calculates the EU total as the sum of country-specific figures for EU Members. The country figures relate to different years for different countries (2005 for France, 2008 for Germany, etc.), all of which were between 2005 and 2009. Hence, the sum cannot be attributed to a specific year, but is a combination of country estimates relating to years between 2005 and 2009.

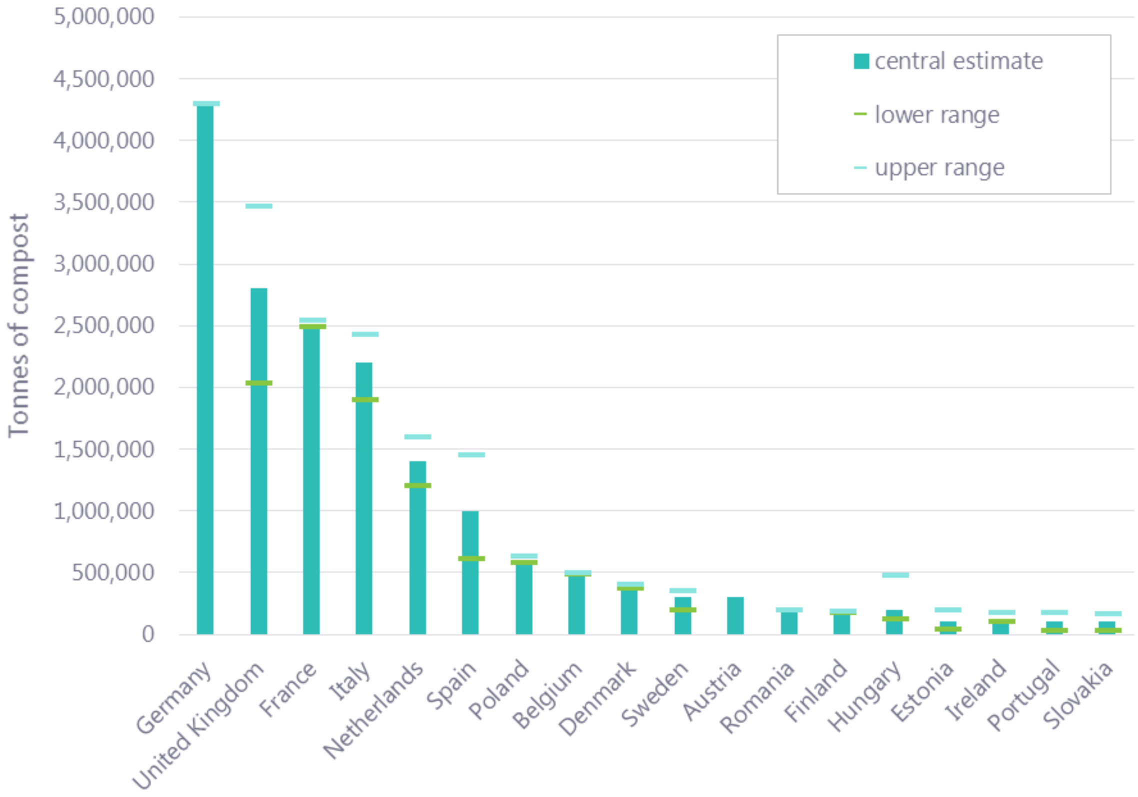
[15] Domestic processed output indicates the amounts of materials supplied by the national economy and taken up by the natural environment.

the national economy and taken up by the natural environment' in the EU28 in 2014. The response to the targeted stakeholder consultation for this project from the European Compost Network (ECN) indicated that 12.1-16.2 million tonnes of compost are produced in the EU28. However, ECN noted that this does not cover sewage sludge compost. Based on sewage sludge disposal data from Eurostat we estimate the EU production of sewage sludge compost to be in the order of 0.8 million tonnes.

As a result, we estimate that the current annual EU production of compost amounts to at least some 13 million tonnes (at least 12.1 million tonnes according to ECN plus 0.8 million tonnes of sewage sludge compost, rounded to the closest 1 million tonnes). We further estimate that at most 18 million tonnes of compost are produced annually (according to Eurostat material flow accounts, the highest figure suggested by any source)[16]. **As a central estimate, our analysis suggests that about 17.3 million tonnes of compost are produced in the EU per year.** This is the sum of estimates for each EU Member State, which are presented in more detail in Appendix A.

The largest compost producer in the EU is Germany with 4.3 million tonnes, followed by the UK (ca 2.8 million tonnes), France (2.5 million tonnes) and Italy (ca 2.2 million tonnes). An overview of estimated compost production (including ranges where available) for each country over 100,000 tonnes is shown in Figure 2.1.

Figure 2.1 Estimated quantity of compost per country, in tonnes (only countries >100,000 tonnes shown)



Source: Wood 2018 based on various data sources (see Appendix A for more details)

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[16] It should be noted that Eurostat material flow accounts refer to application of compost, not production. However, given the relatively low value per weight of compost, it is reasonable to assume that compost is applied in relatively close proximity to where it is produced and international trade of compost is low. Hence, most of the compost applied in the EU is expected to be produced in the EU and vice versa.

Feedstocks

An overview of the breakdown of compost according to the feedstocks used is shown in Table 2.3.

According to information submitted by ECN in the targeted consultation for this project, around 8 million tonnes of green waste compost, around 6 million tonnes of bio-waste compost and around 0.1 million tonnes of vegetable, fruit and garden waste compost are produced in the EU annually[17]. According to this information, there is no compost from mixed municipal solid waste (MSW). This was confirmed for some major compost producing countries by other sources[18]. However, some sources suggest that compost is or at least has been produced from mechanical biological treatment (MBT) of mixed MSW in some smaller countries (ECN 2016a, ECN 2017).[19] Based on sewage sludge disposal data from Eurostat, we estimate that additionally ca 0.8 million tonnes of sewage sludge compost are produced.

It should be noted that the sum of compost produced across feedstocks is lower than the total quantity of compost produced in Europe estimated above. This is because the total quantities of compost produced per country (and in sum for the whole EU) were derived from different sources than the quantities of compost by feedstock discussed here. Comprehensive data on compost produced by feedstock and country was not available, so it is difficult to compare the two. However, the mismatch suggests that either the quantities of compost by country (and in sum for the whole EU) are somewhat overestimated, and/or the quantities of compost by feedstock are somewhat underestimated.

Table 2.3 Estimated quantity of compost in the EU28 by feedstock used, in tonnes

Compost type	Production quantity (t)	Feedstocks type	Feedstocks quantity (t)
Green waste compost	8,000,000 (7,000,000-9,000,000)	Source separated garden and park waste.	16,500,000
Vegetable, fruit and garden waste compost (VFG compost)	100,000 (100,000-150,000)	Only separately collected biodegradable materials according to the specific input list of ECN 20144 (ECN-QAS Part CII, Annex CII 2) and the input materials listed in Table 14 of JRC 2014. 1)	300,000
Bio-waste compost	6,000,000 (5,000,000-7,000,000)	Only separately collected biodegradable materials according to the specific input list of ECN 20144 (ECN-QAS Part CII, Annex CII 2) and the input materials listed in Table 14 of JRC 2014. 1)	12,500,000
Sewage sludge compost	Ca. 800,000 1)	Sewage sludge; sometimes mixed with green waste.	Ca. 1,700,000

Sources:
Wood 2018 based on the consultation response from ECN (all compost types except sewage sludge), Eurostat Sewage sludge production and disposal data for the last available year (2015 for most countries), and the Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016.
Notes:
1) Excluded: organic fraction from mixed municipal household waste, separated through mechanical, physicochemical, biological and/or manual treatment; sewage sludge; sludges from paper industry and non-biodegradable materials.
2) Assuming a weight reduction of 50% of the input quantity during composting.

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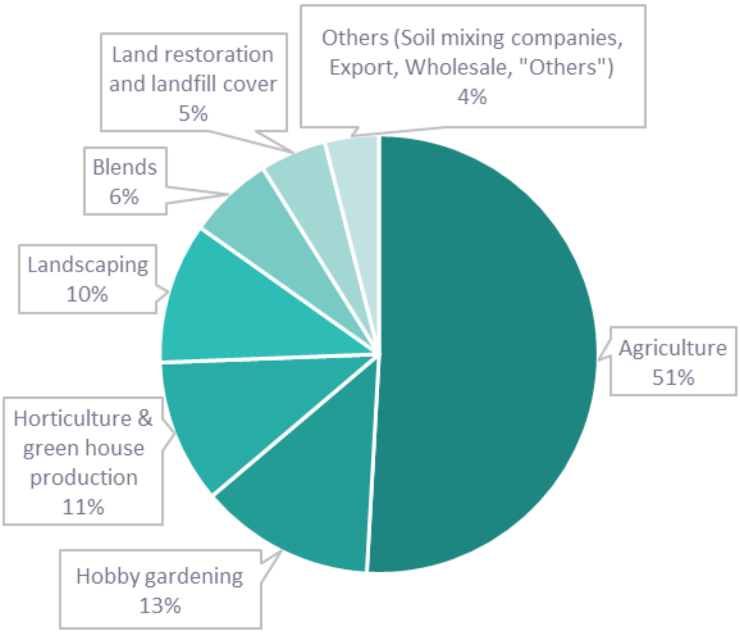
[17] Note that ECN provided ranges. We adopted the midpoints of the ranges as central estimates.
[18] For Germany by the consultation response from BDE, and for Italy by the consultation response from the Italian Composting and Biogas Consortium.
[19] ECN Country Report Lithuania (ECN 2016) suggests 384,000t of mixed MSW are treated by 9 MBT plants (4 AD, 4 composting, 1 biodrying), a breakdown of the MBT tonnage between composting and AD is not available.
ECN Country Report Hungary (ECN 2017) suggests 550,000t of mixed MSW are treated by MBT, but it is not clear if they are composted or digested.

For comparison, JRC (2014) estimated 6.7 million tonnes of green waste compost, 4.7 million tonnes of bio-waste compost, 1.6 million tonnes of sewage sludge compost, and 1.4 million tonnes of mixed waste and “Other” compost (based on country-specific estimates relating to various years between 2005 and 2009). This suggests that the production of green waste and bio-waste compost have increased since the period the JRC (2014) figures refer to, while the production of sewage sludge compost has decreased. It is not clear how the categories mixed waste and “Other” compost from JRC (2014) relate to the categories provided by ECN in the consultation for this study.

Use/application

JRC (2014) provided the use distribution (%) across 10 uses[20] for 14 major compost producing countries relating to the years 2005-2009[21]. The weighted mean average across these countries (weighted by tonnes of compost production per country) is shown in Figure 2.2. This suggests that the **majority (ca. 85%) of compost was used as a fertiliser or soil improver in agriculture, gardening, horticulture and landscaping**.

Figure 2.2 Compost use distribution (%) weighted mean average over 14 major compost producing EU Member States, according to JRC (2014)



Source: Based on DG JRC: Technical proposals on end-of-waste criteria for biodegradable waste subjected to biological treatment, 2014.

In their response to the consultation for this project, ECN listed the following uses of compost in Europe:

- Organic fertiliser and soil improver in agriculture and organic farming at a typical application rate of 6-10 tonnes per hectare per year;
- Soil improver for horticultural purposes, for landscaping purposes and in hobby gardening; and
- Mixing compound in growing media.

While our analysis could not provide a full quantitative breakdown of uses at an EU-level, it confirms the main uses quoted by JRC (2014) and the ECN consultation response:

- The consultation response of the BDE (German Waste, Water and Raw Materials Management Industry Association) stated that in Germany green waste and biowaste compost were used as organic fertiliser and soil improver; mixing compound in growing media; sewage sludge

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[20] Agriculture, horticulture & green house production, landscaping, blends, soil mixing companies, wholesalers, hobby gardening, land restoration and landfill cover, export, others.

[21] The country figures relate to different years for different countries (2005 for France, 2008 for Germany, etc.), all of which between 2005 and 2009. Hence, the average calculated in the following cannot be attributed to a specific year, but is a combination of country estimates relating to years between 2005 and 2009.

compost was used in agriculture; while residues from the mechanical and biological treatment of mixed solid waste are mainly used for energy generation or they are disposed of in landfills.

- The ECN country report for Germany suggests the following breakdown of compost uses in 2014: 59% Agriculture, 19% Soil manufactory, 8% Landscaping/recultivation, 7% Hobby gardening, 7.1% other.
- The consultation response of the Italian Composting and Biogas Consortium provided a detailed breakdown of uses per compost type for Italy:
  - Green waste compost: Soil improver for plant nursery (68%), Fertiliser for agriculture (27%), Maintenance of parks and gardens (3%), Fertiliser for domestic use (2%);
  - Bio-waste compost: Fertiliser for agriculture (72%), Fertiliser for horticulture (15%), Soil improver for plant nursery (4%), Soil improver for other usages (3%), Fertiliser for domestic use (3%), Other (3%);
  - Sludge compost: Fertiliser for agriculture (95%), Fertiliser for horticulture (3%), Fertiliser for fruit growing (2%);
- The ECN country report for the UK provides the following breakdown of compost uses in 2012: Agriculture (68%), Horticulture (12%), Landscaping (9%), Landfill restoration (3%), Other (8%). Note that other ECN country reports did not include breakdowns of compost use.

2.3.3 Digestate

Total quantities

JRC (2014) estimated that 56 million tonnes of digestate were produced in the EU in 2010. In 2013, a position paper from the biogas industry suggested that around 80 million tonnes of digestate were generated in Europe (Fachverband Biogas, EBA & BiPRO 2013). The response from the European Biogas Association (EBA) to the consultation in this project stated that no definitive data on digestate production were available, but for agricultural digestate (the largest category) they expect at least a yearly 60 million tonnes of fresh mass in Germany (the biggest EU producer) and around double that amount (i.e. 120 million tonnes) for the whole EU. This reflects strong growth in anaerobic digestion in Europe over the last decade. This is roughly consistent with Eurostat data that suggests the production of biogas almost doubled from 2010-2016.[22] We estimate that about another 56 million tonnes of digestate (in addition to agricultural digestate), are produced from other sources. This is based on several country-specific information sources and data on the digestion of material from municipal solid waste (MSW) submitted by EBA (see Appendix A for more details).

As a result, our analysis suggests that in the order around 180 million tonnes of digestate are produced in the EU28 per year. The largest digestate producer in the EU is Germany with around 87 million tonnes, followed by the Italy (up to 30 million tonnes) and the UK (ca 19 million tonnes). An overview of estimated digestate production (including ranges where available) for each country over 1 million tonnes is shown in Figure 2.3. More detail on the estimates for each country is provided in Appendix A.

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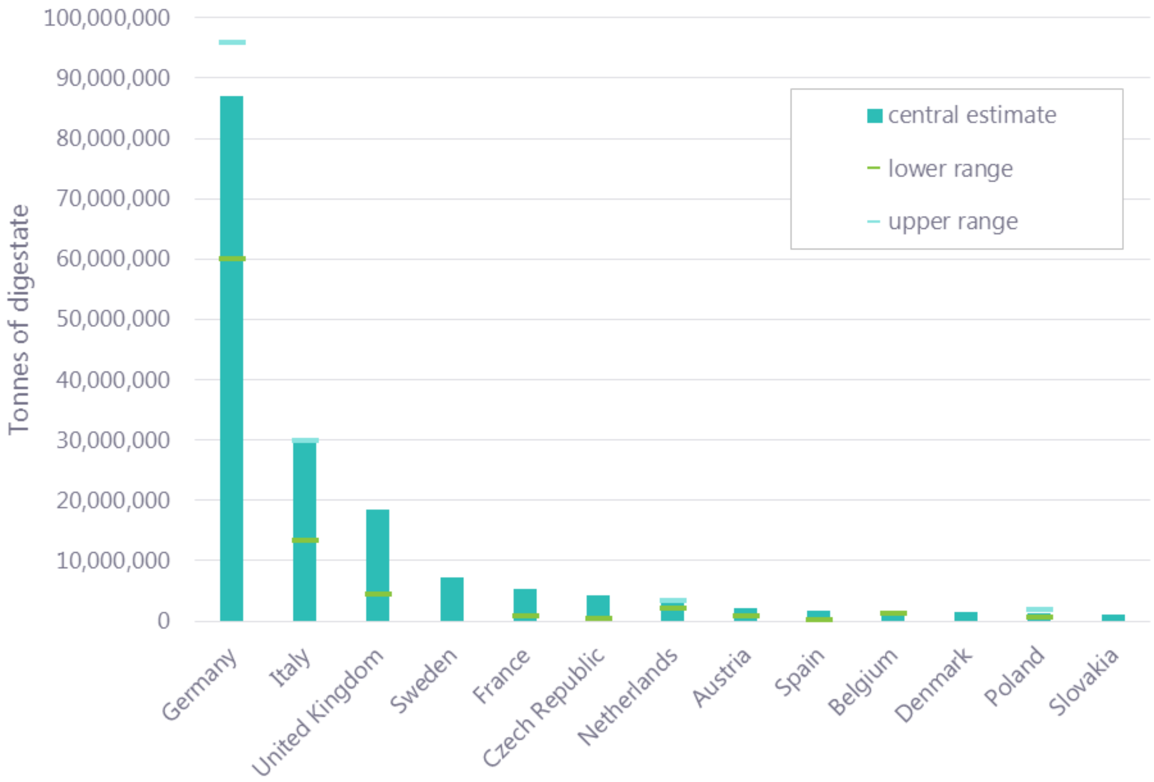
[22] This refers to the production of Biogas in the EU28 measured in terms of energy (Joule), which increased by 91% from 2010-2016. Source: Eurostat: Supply, transformation and consumption of renewable energies - annual data [nrg_107a]

Figure 2.3 Estimated quantity of digestate per country, in tonnes (only countries >1 million tonnes shown)



Source: Wood 2018 based on various data sources (see Appendix A for more details)

Feedstocks

An overview of the breakdown of digestate according to the feedstocks used is shown in Table 2.4.

According to information submitted by EBA to the targeted consultation for this project, around 120 million tonnes of agricultural digestate are produced in the EU annually. EBA further indicated that 55 million tonnes of organic material is mechanically extracted from municipal solid waste (MSW) and then digested. Based on the typical weight reduction from feedstock to digestate during the anaerobic digestion process, we estimate that this results in roughly 46 million tonnes of digestate[23]. No EU-level data on digestate from other feedstocks was available. However, country-specific data (see Appendix A) suggest at least 7 million tonnes of digestate from source-separated municipal bio-waste, 1.7 million tonnes from sewage sludge and another 1.7 million tonnes from agroindustry by-products across the EU.

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[23] The resulting amount of digestate was estimated as follows: The tonnage of feedstocks was multiplied by 0.84, the midpoint between the mass reductions from feedstock to digestate suggested by the EBA consultation response and WRAP 2012.

Table 2.4 Estimated quantity of digestate in the EU28 by feedstock used, in tonnes

Digestate type	Production quantity (t)	Feedstocks type	Feedstocks quantity (t)
Digestate from source separated biowaste from MSW	At least 7,000,000	Commonly biodegradable kitchen waste from individual housing, restaurants, caterers, offices, canteens, hospitals and schools. In some municipalities, organic material from landscaping may be used such as grass clippings.	8,300,000
Digestate from organic fraction of mixed MSW	Ca. 46,000,000	Organic fraction mechanically extracted from MSW.	55,000,000
Agricultural digestate	Ca. 120,000,000	The most common inputs are one or a mixture of the following: livestock manure; energy crops*, cover crops or secondary crops for energy use (triticale, miscanthus), straw left over from harvest. Other in-farm organic residues are not expected to be used in significant amounts.	144,000,000
Sewage sludge digestate	At least 1,700,000	Sewage sludge. In a few cases source separated biowaste from nearby MSW may be added.	2,000,000
Digestate from agroindustry by-products	At least 1,700,000	A large proportion of sewage water from households and commerce in urban areas is digested. Industrial sludge may be treated alongside urban sludge or separately.	2,000,000
Total	***Ca. 176,400,000***		***Ca. 211,300,000***

Sources:
Wood 2018 based on the consultation response from EBA (Input material types, production quantity of agricultural digestate, feedstock quantity from organic fraction of mixed MSW), as well as country-specific sources relating to anaerobic digestion of source separated bio-MSW, sewage sludge and agroindustry by-products (see Appendix A for more details). Where only the quantity of feedstocks was available it was assumed the resulting weight of digestate was 84% of the feedstock weight, based on the consultation response from EBA and WRAP 2012.
Notes:
* Plants grown with the specific purpose of being used for energy generation (e.g. to produce biogas or biofuel), mostly maize.

Use/application

According to JRC (2014), 95% of digestate was used directly in the agricultural sector as a liquid fertiliser. While no comprehensive updated data on the tonnages or percentages of digestate used for which applications was available, our analysis suggests that still the **vast majority of digestate is used directly as fertiliser**:

- According to the French Environment and Energy Management Agency (2014), in Germany 100% of agricultural digestate (by far the largest type of digestate in Germany), 30% of sewage sludge digestate, and 0% of digestate from mechanical biological treatment (mixed waste) are used as a fertiliser. In Sweden, only 24% of sewage sludge digestate (by far the largest type of digestate in Sweden), but almost all other digestate is used as fertiliser.[24]
- EBA (2015) notes that in Italy, agricultural digestate is generally directly applied as a fertiliser. Food and green waste compost in Italy are separated into solid and liquid fractions. The solid

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[24] This suggests in Sweden the general statement that the majority of digestate is used as fertiliser does not hold true. This is due to the fact that most digestate in Sweden comes from sewage sludge, which according to the EBA is a type of digestate rarely used as fertiliser (see Table 2.5). However, over the whole EU sewage sludge digestate makes up only a small part of the total digestate produced (see Table 2.4).

fraction is composted and then used as soil improver, while the liquid fraction is either recirculated in the plant or treated in wastewater treatment plants.

- WRAP (2015) reports that in the UK the majority of agricultural digestate is spread on the land of the producers or of their neighbours, while other plants had greater challenges finding suitable markets for digestate.
- CBS (2012) suggests that in the Netherlands 82% of digestate produced in 2011 were used in agriculture (while most of the rest was exported).
- According to the ECN country report for Flanders, the market for digestate products there is mainly focused on agriculture.

EBA provided information on the **typical use of digestate from each feedstock category**, which is presented in Table 2.5. This suggests that digestate from agricultural sources, source separated biowaste and agroindustry by-products is predominantly used as organic fertiliser and soil improver in agriculture, horticulture and more rarely hobby gardening. Digestate from mixed MSW and sewage sludge is incinerated or landfilled in most countries, although it is not clear if it is used as fertiliser anywhere.

Table 2.5 Typical use of different types of digestate according to the European Biogas Association

Digestate type	Typical use
Digestate from source separated biowaste from MSW	"Organic fertiliser and soil improver for use in agriculture, horticulture and in some cases hobby gardening. Whole digestate from biowaste may be liquid enough to pump, although many of the last generation plants carry out efficient dry digestion or in some cases batch digestion systems with around 70% water content or less (not pumpable). In some countries such as Italy, it is require[d] to post-compost it. This kind of digestate is usually spread in the same way as a compost."
Digestate from organic fraction of mixed MSW	"In most cases and across most European countries this digestate is not used on land, [but] generally either incinerated or landfilled. "
Agricultural digestate	"Organic fertiliser and soil improver for use in agriculture, horticulture and in some cases hobby gardening."
Sewage sludge digestate	"[...] In the vast majority of EU countries treated sludge is not spread either on land. [...] Concentrated solids of sludge [are] usually incinerated or landfilled."
Digestate from agroindustry by-products	"Organic fertiliser and soil improver for use in agriculture, horticulture and in some cases hobby gardening. The dry matter content of the digestate varies significantly depending on the product, from high water content sludge to more solid materials similar to digestate from source separated biowaste. The method for spreading will vary accordingly. "

Source: EBA response to the consultation in this project (2018).

Furthermore, EBA provided details on the **spreading and application of digestate as fertiliser**, which is reported in Table 2.6. The explanations refer to agricultural digestate, but EBA indicated that "most of the explanation below on digestate use/spreading also applies to other suitable types of digestate, including from agro-industrial by-products and sourced separated biowaste". Notably, EBA suggest that digestate is mostly used in close proximity to where it is produced. It is mostly injected directly into the soil and application rates vary across EU countries between 10m^3 and 40m^3 per hectare. EBA also suggests that some digestate is not applied as whole digestate (i.e. directly from the biogas plant), but is treated further. A brief overview of **further treatment techniques** is provided in Appendix B.

Table 2.6 Application of digestate as fertiliser according to the European Biogas Association

Application/spreading of agricultural digestate as fertiliser (also applies to other suitable types of digestate, including from agro-industrial by-products and source separated biowaste)
"Agricultural digestate is liquid in most cases (usually 70-90% water content), particularly due to the use of important quantities of manure (itself usually 90-96% liquid). The equipment used to apply digestate is mostly the same as for spreading raw slurry. It is essential to choose machinery that minimises digestate's exposure to air by injecting it rapidly into the soil, as this prevents nitrogen losses through ammonia volatilisation. Therefore, inefficient and polluting methods such as splash plate spreading should be avoided. Instead, digestate should be best applied through trailing hoses, trailing shoes or by direct injection into the topsoil. Most of the material is spread as whole digestate (i.e. as it comes out of a biogas plant) containing all input nutrients, micro nutrients, organic matter and water. In some cases digestate can be further treated to match specific needs, including: separation into liquid and solid fractions (well established); drying (also established); ammonia striping (also used) micro filtration (tested and promising); precipitation (tested in waste water treatment sector and promising in agriculture). Application doses of digestate are very variable, depending largely on mineral concentration of the mixture and plant demand. Generally whole digestate is bulky due to high water content, therefore it is advised to spread it locally as much as possible. For example, in Austria the maximum quantity allowed per hectare for a year is 25m^3. Generally application varies in EU countries between 10-40m^3. If manure based digestate is spread on a Nitrate Vulnerable Zone a limit has to be respected, usually 170kg. National interpretations vary on what is considered 'manure'."

Source: EBA response to the consultation in this project (2018).

3. Substance identification

3.1 Introduction

Digestate and compost may contain contaminants with different hazardous properties. The objective of this task is to identify potential critical contaminants in C/D for the subsequent risk assessment and risk management options analysis (RMOA). Critical substances or substances of concern are, in general terms, substances which can have negative effects on human health or the environment. Many different hazardous substances could potentially be present in C/D, depending on the input materials. Thus, it is necessary to develop criteria to decide whether a substance (or a group of similar substances) present in compost or digestate should be further investigated, i.e. a quantitative/qualitative risk assessment and RMOA.

3.2 Approach

The initial stage of Task 2 aimed to identify substances of concern for further risk assessment. In order to provide an overview of the substances reported as contaminants in C/D, an information database including information from relevant scientific literature was generated. A matrix was created to collect all potentially relevant information. The matrix identified substances and further relevant information such as the type of material in which the substance was found or the technology applied for producing compost or digestate, as well as assessment criteria according to which a substance or substance group can be identified as a substance of concern. These criteria include “presence in specific substance lists”, “human toxicity”, “environmental toxicity”, “harmonised classification”, “mobility in water bodies”, “concentration found in compost/digestate”, “intrinsic properties” and “limit values exceeded”. More details related to the assessment criteria are provided below.

The matrix was populated with information from scientific literature regarding the substances themselves, their presence in certain types of compost and their characteristics. The identification of relevant literature is described in the following:

- Relevant information was extracted from JRC (2014), which served as the main starting point for the identification of the contaminants in digestate and compost. This included substance groups, single substances and their allocated substance category; compost/digestate types in which relevant substances occur; measured concentrations; and any existing limit values. Also, the information from other relevant literature cited in the JRC report was extracted if considered relevant. In addition, conclusion chapters and the overall conclusion of the JRC report were screened for statements on the relevance of each substance group / single substances regarding the risks from contaminants in compost or digestate.
- Further literature listed in the service request for this project was evaluated and all relevant information was extracted in accordance with the approach used for the assessment of the JRC report (above). This was also added to the matrix.
- Further research was conducted to collect additional potentially-relevant scientific publications. As the JRC report only covers literature up to 2014, the research focused on publications from 2013 to present. This approach was used so that the most recent insights regarding contaminants in C/D were considered. Screened databases included GoogleScholar (https://scholar.google.de/), ScienceDirect (https://www.sciencedirect.com/), SpringerLink (https://link.springer.com/) and PubMed (https://www.ncbi.nlm.nih.gov/pubmed). Furthermore, homepages of associations and networks were screened for publications comprising

information related to contaminants in C/D (e.g. European Compost Network, Bio Refine and European Biogas Association).[25]

- Information provided via the stakeholder survey conducted in task 1 was also considered.

After having collected relevant information on substances identified in compost or digestate, the substances were evaluated according to the following methodology:

The evaluation was carried out in three steps. **Step 1** consisted of the identification of substances classified as hazardous under various regulatory lists. These are explained below:

- ECHA's **Authorisation list (REACH Annex XIV)**[26] features Substances of Very High Concern (SVHC) for which the objective is to ensure a progressive replacement by less dangerous substances or technologies where technically and economically feasible alternatives are available. Identification of these substances includes a 45-day public consultation process. Once a substance is identified as an SVHC, it is included in the **Candidate list**[27]. ECHA then recommends priority substances from this Candidate list to be included in the Authorisation list. These substances are listed in the "**Recommendation list**[28]" which is reviewed by the European Commission to decide which substances are to be included in the Authorisation list and what the respective entries should be.
- The Stockholm Convention on **Persistent Organic Pollutants (POP's)**[29] is an international treaty to protect human health and the environment from persistent and bioaccumulative hazardous chemicals. The production and use of substances featured in **Annex A** of the convention must be eliminated and/or prohibited by the participating parties, as well as their import and export. **Annex B** lists substances that must be restricted in their production, use, import and export, and **Annex C** features substances whose release through their unintentional production should be eliminated.
- The **Water Framework Directive**[30], adopted in 2000, sets requirements for the protection of surface and ground water. It aims to ensure good ecological and chemical status of water bodies. Within the scope of this directive, a list of 33 chemicals (priority substance list) has been published whose levels in water bodies is used to evaluate their status. Environmental quality standards for these substances were set in 2008. Additionally, 8 pollutants for which environmental quality standards have been set in the Environmental Quality Standards Directive, but which are not included in the priority substances list, have also been added.
- Substances under **REACH Annex XVII**[31] are substances whose marketing and/or use and release is restricted because they pose a risk to human health or the environment. The list also includes mixtures and substances in articles that do not require registration, and shows the respective restrictions for each substance.
- The **Substitute It Now (SIN) list**[32] includes hazardous chemicals whose substitution is a priority. Its aim is to put pressure on legislators to set restrictions on the substances with the highest level of concern before restrictions under REACH come into place. It aims to speed up

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[25] Homepages of associations and networks were mainly searched on European level only (except for UK and DE). However, all MS which produced 500.000 t compost or more (DE, UK, FR, IT, NL, ES, PL, BE) were covered in the literature research regarding measurement data.

[26] https://echa.europa.eu/authorisation-list

[27] https://echa.europa.eu/candidate-list-table (REACH list of SVHC intentions: https://echa.europa.eu/registry-of-svhc-intentions)

[28] https://echa.europa.eu/previous-recommendations

[29] http://chm.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx

[30] http://ec.europa.eu/environment/water/water-framework/priority_substances.htm

[31] https://echa.europa.eu/substances-restricted-under-reach

[32] http://sinlist.chemsec.org

the substitution of hazardous chemicals and offers a tool for companies to identify which chemicals to avoid in their processes.

- The **Minamata Convention** is an international treaty to protect human health and the environment from the adverse effects of mercury. It specifically targets this metal, but was also considered as part of the assessment (Minamata 2019).
- The **Fertiliser Regulation Proposal** regulates the marketing of fertilising products by setting guidelines and restrictions on their composition in terms of hazardous substances (European Commission 2016a).

The lists mentioned above were used in Step 1 for the assessment of the identified chemicals. Substances included in either REACH Annex XIV, the Recommendation list or the Candidate list, as well as those listed as persistent organic pollutants (POP's Annex A, B or C) in the Stockholm convention, were marked in red and classified as potential critical substances. If the substance appeared in more than one of REACH's lists for substances of very high concern (REACH Annex XIV, the Recommendation list and the Candidate list), only one red marking was assigned to avoid overestimating its priority, since substances in Annex XIV are also listed in the Recommendation list and the Candidate list, and substances in the Recommendation list are also listed in the Candidate list. Substances listed in the Restriction list (REACH Annex XVII), in the Water Framework Directive or in the Fertiliser Regulation Proposal were marked in yellow. Additionally, mercury (Hg) was included in this category in line with the stipulations of the Minamata Convention. This classification encompassed substances that could also be considered of concern, but for which other criteria needed to be considered for a decision on prioritisation.

Step 2 of the evaluation addressed the toxicity of each substance in terms of its effects on human health and on the environment. These two categories were evaluated separately. ECHA's classification and labelling (C&L) Inventory was used for this purpose. Substances with a harmonized classification were assigned to the "Red," "Yellow," or "Green" categories according to the hazard statements shown in this inventory and the classification criteria shown in Table 3.1 below (UBA 2017).

Additionally, substances proven to be endocrine disruptors were assigned to the "Red" category for human toxicity and substances classified as persistent, bioaccumulative, toxic/very persistent, very bioaccumulative (PBT/vPvB) were assigned to the "Red" category for environmental toxicity[33]. ECHA's Annex 15 to the final report on endocrine disruptors (BKH Consulting Engineers 2000) was used to identify proven endocrine disruptors, while information about PBT/vPvB substances was obtained from the registration dossier of each substance available in ECHA's inventory. Also, all substances listed under the Stockholm's convention POP's lists were marked as PBT substances with long range transport (LRT) potential. This information on persistency was highlighted in red letters in the substance matrix.

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[33] Chronic effects were identified as especially important criteria to assess the potential concern of substances identified in compost. They were addressed through the C&L inventory hazard statements and through PBT/vPvB classifications. All priority 1 and 2 substances showed chronic effects on human health and/or on the environment, so putting more weight to chronic effects would not change the ranking of priorities.

Table 3.1 Use and Evaluation of the Criteria “human toxicity” and “dangerous for the environment”

USE AND EVALUATION OF THE CRITERION “HUMAN TOXICITY”

Evaluation	**RED**	**YELLOW**	**GREEN**
	🟥	🟨	🟩
Sub-criterion: Dangerous by Inhalation, ingestion and eye contact	Substance may cause severe health damage	Substance may damage health	Substance is not dangerous to human health
Indicator: Classification according to CLP-regulation	H300, 330, 340, 350, 350i, 360, 360D, 360DF, 360F, 360FD, 361Fd, 362, 372, EUH32	H301, 302, 304, 314, 318, 319, 331, 332, 334, 341, 351, 361, 361d, 361f, 361fd, 37013, 371, 373, EUH029 EUH031	No classification other than “only” 335, 336
Sub-criterion: Dangerous upon skin contact	Substance may cause health damage if taken up via the skin	Substance damages skin	Substance has only light effects on skin
Indicator: Classification according to CLP-regulation	H310, 311, 314, For Substances which may be absorbed through to the skin: 340, 341, 350, 351, 360, 360D, 360DF, 360F, 360FD, 361Fd, 361, 361f, 361fd, 370, 372	H312, 315, 317 For skin-penetrating substances: 371, 373	No classification other than “only” EUH066
Sub-criterion: Endocrine disruption	Proven endocrine disruptive substance (listed in Annex 15 of ECHA’s final report on endocrine disruptors)		

USE AND EVALUATION OF THE CRITERION “DANGEROUS FOR THE ENVIRONMENT”

Evaluation	**RED**	**YELLOW**	**GREEN**
	🟥	🟨	🟩
Sub-criterion: PBT/vPvB properties	Substance is PBT/vPvB substance	Based on available information, it can be excluded that the substance is a PBT/vPvB substance*	Not a PBT/vPvB substance
Indicator: Information from testing	Mention as PBT/vPvB-substance on a list/ in the SDB or implementation of the PBT/vPvB-criteria	H410 Aquatic toxicity: LC50 < 0.1 mg/l	There are no indications that the substance is PBT or vPvB
Sub-criterion: Aquatic toxicity	The substance is highly dangerous to the aquatic environment	The substance is dangerous to the aquatic environment	The substance is not dangerous to the environment
Classification according to CLP-decree	H400, 410	H411, 412 and 413	No H-phrase beginning with 4

*it is possible that a substance is inherently not degradable and has a LogKow of more than 4. These are indications that the substance may be a PBT/vPvB. Further data is necessary for a comparison of the respective criteria (e.g. simulation test on degradability and/or study defining a BCF); **The criteria are given in the Annex of the cited document.

Source: UBA 2017: Guide on Sustainable Chemicals, A decision tool for substance manufacturers, formulators and end users of chemicals.

Substances marked in yellow fulfilled at least one criterion of the “yellow” classification criteria but none for the “red” classification. Finally, substances assigned to the “green” classification were those not considered to be dangerous to human health or to the environment.

If a harmonised classification was not available, the classification group with the highest number of notifications from the public was used instead. However, if different classifications were suggested for a substance lacking a harmonised classification, then classifications other than the most notified one were also considered - if they included information that might suggest that the substance is harmful *and* if it had a relatively high number of notifications. Classifications with comparably few notifications from the public in relation to the highest number of notifications were therefore not considered.

Step 3 considered further criteria for drawing a conclusive decision regarding the toxicity of the substances investigated. This was done for all substances and considered each substance’s mobility in water bodies. This property was addressed using the water solubility, which for most substances was obtained from the registration dossier available on ECHA’s website. For those substances for which no registration dossier was available, the water solubility was checked in other sources, including the US National Library’s Open Chemistry database and published scientific literature. When available, experimental values were preferably chosen, otherwise predicted or calculated values were used. Classification was done similarly to that of Step 2 but using the criteria shown below in Table 3.2.

Table 3.2 Use and evaluation of the criterion “mobility in water bodies”

USE AND EVALUATION OF THE CRITERION “MOBILITY IN WATER BODIES”

Evaluation	**RED**	**YELLOW**	**GREEN**
	🟥	🟨	🟩
Sub-criterion: Release potential in water	High solubility	Medium solubility	Low solubility
Indicator: Solubility in water	> 10 mg/l	1 – 0.001 mg/l	< 1 µg/l

Source: UBA 2017: Guide on Sustainable Chemicals, A decision tool for substance manufacturers, formulators and end users of chemicals.

In addition, Step 3 considered whether concentrations of the substances found in compost/digestate exceed defined or proposed limit values from regulations or guidelines. If limit values were exceeded this was marked red in the matrix. Ranges or maximum values of the concentrations found in compost/digestate were provided, where available. The matrix also specifies for each substance in which input materials, material types (compost/digestate) and output materials the concentrations were measured.

In addition to these criteria, further considerations were also used to address the priority of the substances identified. These were the reliability of sources, the measured concentration of the substances found in compost/digestate material, the type of input material, and interpretations from the authors regarding the relevance of the substance. If, for example, the author of one of the reviewed publications suggested that the substance discussed could be of concern even if the criteria for high priority substances were not met, this was noted and the substance was marked in the “Red” category.

Based on the above approach, the substances were marked in the matrix accordingly. The colour markings from Steps 1, 2 and 3 were used to classify these in various priority levels, depending on the degree of concern they pose. The criteria used for classifying substances in the different priority levels are shown below. Priority 1 constitutes the highest level of concern and Priority 3 the lowest.

1. Priority

- ≥ 1 red or 3 yellow markings in step 1, ≥ 1 red marking in step 2 and limit value exceeded; or
- ≥ 1 red marking in step 1, ≥ 3 red marking in step 2 and 3; or
- Interpretation of the author of the corresponding publication and consideration of background knowledge of the study team.

2. Priority

- ≥ 1 red marking in step 2 and limit values exceeded; or
- ≥ 1 red marking in step 1, ≥ 2 red markings in step 2 and 3; or
- ≥ 3 yellow markings in step 1, ≥ 1 red marking in step 2 and 3; or
- Interpretation of the author of the corresponding publication and consideration of background knowledge of the study team.

3. Priority

- ≥ 1 yellow marking in step 1, 2 red markings in step 2 and 3; or
- ≥ 3 red markings in step 2 and 3; or
- No or few red markings, but limit values exceeded;
- Interpretation of the author of the corresponding publication and consideration of background knowledge of the study team.

Further priorities (Priority 4 and 5) were given to other substances to distinguish them from substances without any markings. These priority levels were assigned as follows:

- Priority 4: ≥ 2 red markings in step 2 and 3;
- Priority 5: ≥ 1 red marking or yellow markings in step 2 and 3.

The substances identified as high priority according to this classification were included in the provisional list of recommendations for further risk assessment (see Excel File “Evaluation matrix_fin_20180608”).

3.3 Results

During the literature research, 50 relevant publications were identified (see the accompanying Excel file “Evaluation matrix_fin_20180608,” sheet “Literature”). The corresponding information on potentially critical substances was included in the matrix.

Based on the information retrieved from literature, 17 substance groups were identified, which include:

- AOX (adsorbable organic halogen compounds);
- Chlorophenols;
- PCDD/F (dioxins and furans) and dioxin-like PCB’s;
- PCB (polychlorinated biphenyls);
- LAS (linear alkylbenzene sulphonates);
- Nonylphenol and -ethoxylates;
- PAH (polycyclic aromatic hydrocarbons);
- PBDE (polybrominated diphenyl ethers) and HBCD (flame retardants);

- Perfluorinated surfactants;
- Phthalates;
- Physical impurities (e.g. plastic particles);
- Siloxanes;
- Polycyclic musks;
- Drugs and pharmaceuticals;
- Pesticides;
- Heavy metals; and
- Other substances not considered under the above-mentioned substance groups.

Within these substance groups, more than 94 single substances and 4 sub-groups[34] with concrete measurements were identified in the literature as contaminants present in different C/D types.

Available information from identified publications related to assessment criteria and properties (type of compost/digestate, technology applied at biological treatment plant, type of input/output material, concentration found in compost/digestate, toxicity etc.) was included in the matrix as far as available. Additionally, it was also checked whether the data collected for the high-priority substances (Priority 1 and 2) covered the Member States reported to produce the highest amounts of compost. This included all Member States producing 500 kt of compost per year or more (DE, UK, FR, IT, NL, ES, PL, BE). Overall, the sources initially checked included data from all of these countries for most high-priority substances. For Poland, only measurements of PAHs were available.

Based on the evaluation and selection criteria, the following substances were initially identified as first, second and third priority (see sheet in separate appendix "evaluation matrix"). These substances were further evaluated and discussed with the project steering group to select the final list of potential substances of concern for further risk assessment.

Priority 1 substances:

Substance group	Substance	Compost/digestate
Heavy metals	Cd	Compost/digestate
Heavy metals	Ni	Compost/digestate (highest value in green waste compost)
Heavy metals	Pb	Compost/digestate (highest value in mechanical biological treatment compost)
PCBs	Indicator PCBs (PCB 6 or PCB 7)	Compost/digestate (highest value in biowaste digestate)
Nonylphenol and -ethoxylates	Nonylphenolethoxylates (NPE) & nonylphenols (NP)	Compost from municipal sewage sludge
PAHs	PAH16	Compost/digestate (highest value in sewage sludge compost)
Phthalates	Di-isononyl-phthalate (DINP)	Compost/ digestate (highest value in liquid bio-digestate)
Phthalates	di(2-ethylhexyl)phtalates (DEHP)	Compost/digestate (high values in digestate from food and garden waste)

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[34] Sub-group = two or more individual substances are addressed together, e.g. PAH-16 or PCB7.

Substance group	Substance	Compost/digestate
Perfluorinated surfactants	Short- and long-chained PFAS	Compost/digestate (highest value in sewage sludge compost)
HBCD	Hexabromocyclododecane (HBCD)	Compost/digestate (highest value in compost)
Dioxins, furans and dioxin-like PCB's	PCDD/Fs (I-TEQ)	Compost/digestate (highest value in green waste compost)

The substances aldrin and pentachlorophenol were identified as priority 1, but measured values were below the LOD or no specific measurement data were available.

Priority 2 substances:

Substance group	Substance	Compost/digestate
Heavy metals	Cu	Compost/digestate (highest values in sewage sludge compost, biowaste digestate, biowaste compost)
Heavy metals	Zn	Compost/digestate (highest values in sewage sludge compost)
Heavy metals	Hg	Compost/digestate (highest values in biowaste compost)
PCBs	dl-PCBs	Compost/digestate (highest value in municipal solid waste digestate)
Phenols	Bisphenol A	Compost/digestate (highest value in digestate)
Pesticides	Hexachlorobenzene	Compost/digestate (highest value in digestate)

The substances DDT, 4,4'-isomer, DDT, 2,4'-isomer, alpha-HCH, beta-HCH, gamma-HCH, dieldrin and endrin were identified as priority 2, but measured values were below the LOD or no specific measurement data were available.

Priority 3 substances

Substance group	Substance	Compost/digestate
Heavy metals	As	Compost/digestate (highest value in biowaste digestate)
Heavy metals	Cr	Compost/digestate (highest value in sewage sludge compost)
PBDE	PBDE	Compost/digestate
Pesticide	Diphenylamin	Digestate from bio-food waste and garden waste
Pesticide	Imazalil	Digestate from bio-food waste and garden waste
Hormones	17α-Ethinylestradiol	Compost/digestate from sewage sludge
Hormones	Estriol	Compost/digestate
Hormones	Testosterone	Digestate
Polycyclic musks	Galaxolide (HHCB)	Compost/digestate
Chlorophenols	2,4,6-trichlorophenol	Compost/digestate
Polycyclic musks	Tonalide (AHTN)	Compost/digestate
Siloxanes	Octamethylcyclotetrasiloxan (D4)	Compost/digestate

Substance group	Substance	Compost/digestate
Drugs and pharma	Triclosan (bactericide)	Compost/digestate

The substances fluoxetine, isodrin, carbendazim and ammonium were identified as priority 3, but measured values were below the LOD or no specific measurement data were available.
In the following, the individual substance groups and substances are discussed based on the outcome of the evaluation sheet and the discussion with the project steering group. In most cases, information was provided for several input materials for compost/digestate, as well as any mention in the literature of probable sources of high-priority substances in compost material.

AOX

Measurement data on AOX in compost from municipal sewage sludge were indicated in one literature source. Other sources were not identified. No further data were provided for AOX and no individual substances were identified for this substance group. No data were available on limit values or hazardous properties of these substances. Thus, it was not selected for further risk assessment.

Chlorophenols

Measurement data were provided for several single substances in compost material from different sources (solid and liquid biowaste, green waste, renewable raw material, co-digestion, food and garden waste, manure/slurry), as well as from sewage sludge. Values measured for di-, tri-, and tetrachlorophenols were far below limit values proposed in the VLAREA Regulation[35]. Moreover, these were not classified as high-priority substances, so they were not selected for further risk assessment. According to the evaluation criteria applied, the substance pentachlorophenol was allocated to the priority 1 level. This substance is listed in Annex A of the Stockholm Convention, is highly soluble, and poses major risks for aquatic life. However, it was not selected for further risk assessment because for this specific substance no measurement data were available.

PCDD/Fs and dioxin-like PCB’s

Measurement data were provided as I-TEQ for a group of 17 PCDD/Fs, as WHO-TEQ for a defined group of selected PCDD/Fs including dioxin-like PCBs (dl-PCBs), for PCDD/F without further specifications and for dl-PCBs (PCB No. 77, 81, 105, 114, 118, 123, 126, 156, 157, 167, 169, 189) in C/D made from various input materials: municipal solid waste, manure/slurry, renewable raw materials, biowaste, renewable raw materials, fresh plant material, energy crops and a mixture of sewage sludge, straw and sawdust from wastewater treatment plants. For both groups of PCDD/Fs, defined or proposed limit values have been identified which have been exceeded in the measured samples. Therefore, and due to the identification of critical properties in step 2, the general substance group **PCDD/Fs and dl-PCBs** was selected for further risk assessment. Muñoz et al. (2018) suggest that the precursors for the formation of PCDD/F’s in compost could come from materials such as sawdust and saw used as bulking materials in composting plants treating sewage sludge. Critical properties were also identified for PCDD/F congeners. However, no measurement data were available for single congeners.

PCBs

Measurement data were provided for the indicator PCBs (group of 6 PCBs: PCBs 28, 52, 101, 138, 153 and 180; as well as group of 7 PCBs: PCBs 28, 52, 101, 118, 138, 153 and 180) in C/D made from various input materials (mainly garden waste, manure/slurry and municipal sewage sludge). For both groups of indicator PCBs, defined or proposed limit values have been identified which have been exceeded in the measured

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[35] 0.3-0.-6 mg/kg for different chlorophenol compounds.

samples. Therefore, and due to the identification of critical properties in steps 1 and 2, the **indicator PCBs** were selected for further risk assessment (PCB 6/7). Critical properties were also identified for PCB congeners. However, no measurement data were available for the single congeners. Kapanen et al. (2013) suggest that treated wastewater from industry used in composting of sewage sludge might be an important source of PCB's in compost materials.

LAS

No individual substances were identified. For the group, neither limit values nor critical properties were identified. Due to this fact and a high degradation rate, this substance group was not selected for further risk assessment.

Nonylphenols and nonylphenolethoxylates

Measurement data were provided for 3 different iso-nonylphenols, nonylphenol (surfactant precursor), nonylphenolethoxylates (NPE) and the group of nonylphenolethoxylates (NPE) and nonylphenols (NP). Samples were taken in compost from green waste, renewable raw materials and municipal sewage sludge. In compost samples from municipal sewage sludge, the identified limit values were exceeded. Due to the critical properties and the entry in Annex XIV of REACH, the group of **nonylphenolethoxylates (NPE) and nonylphenols (NP)** has been selected for further risk assessment. No information regarding the possible source of these substances in compost material was found.

PAHs

Measurement data were identified for 16 PAH substances and also for some PAH groups, including the group covering all 16 substances, in C/D made from several input materials (municipal sewage sludge from wastewater treatment plants, biowaste, vegetable, fruit and garden waste, rural and urban sewage sludge, manure, energy crops and green waste). Two PAH substances, anthracene and chrysene, are included in the Candidate List under REACH. As these two are covered by the group **PAH16** and limit values were only identified for PAH16, this group is selected for further risk assessment. Some of the measured values for PAH16 were above the identified limit values (C/D from sewage sludge, green waste, fruit, vegetable and garden waste and bio-waste). Critical properties were also evaluated for all single substances. Kapanen et al. (2013) suggest that treated wastewater from industry used in composting of sewage sludge might be an important source of PAHs.

PBDEs and HBCD

Substances in this group were measured and identified in C/D of various input materials, mainly biowaste and food and garden waste. Data was provided for PBDEs and decaBDE. The values identified are far below limit values proposed by the ESWI consortium on behalf of the EC to amend POP regulation limit values (JRC 2014)[36] and decaBDE as well as the PBDEs were not marked red in step 1 of the evaluation. It was already stated in the JRC report from 2014 that these compounds are likely to be of very low concern for compost or digestate quality. No contrary information has been identified in the literature survey for this study.

The other flame retardant, **HBCD**, which was measured inter alia in C/D from renewable raw materials, is listed in Annex XIV of REACH and in Annex A of the Stockholm Convention. As it also possesses critical properties (toxic for reproduction and for the environment), it was selected for further risk assessment, meeting the criteria for the highest priority level. No information was found in the available literature about possible sources for this substance in compost material.

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[36] 50 mg/kg d.m. for PBDE congeners and 500 µg/kg d.m. for PentaBDE

Perfluorinated surfactants

The general group **PFAS** includes several substances listed in the candidate list under REACH and having several critical properties (e.g. PFOA, PFNA, PFOS). Perfluorinated surfactants were measured as PFOS, PFOA and as a group of both (PFT) in C/D made from various input materials, mostly from sewage sludge and from renewable raw materials. Measured concentrations of PFOS and PFOA exceeded existing limit values. Moreover, it is known that short-chained PFAS remain in the environment once emitted (Brendel et al. 2018). Therefore, the whole group of substances was selected for further risk assessment. No information was found about possible sources in compost material.

Phthalates

Measurement data were provided for the phthalates di(2-ethylhexyl)phthalate (DEHP) and di-isononyl-phthalate (DINP) in C/D made of various input materials (municipal sewage sludge, biowaste and food and garden waste). **DEHP** is listed in Annex XIV under REACH and in several other substance lists. The concentrations of DEHP found in compost material from municipal sewage sludge from wastewater treatment plants exceeded the defined limit values. It is therefore selected for further risk assessment. DINP is used as a substitute for DEHP and its use is restricted for some applications (toys and childcare articles that can be placed on the mouth by children). It is already listed in Annex XVII under REACH. Even though the evaluation methodology applied suggests that this substance is classified in the highest priority level, it is not recommended for further risk assessment because RAC has analysed its toxicological profile and concluded that it will not be classified for reproductive toxicity.

Physical impurities

Physical impurities include inter alia plastics, stones and glass. Data was found for different types of physical impurities and for different types of microplastics. For glass and stones, proposed limit values were exceeded in several of the measured C/D samples, but these were not selected for further risk assessment because of the low risk they pose. In the case of microplastics, the difficulty of modelling the environmental fate of these materials limits the possibility of carrying out a detailed risk assessment. However, the increasing concern over the presence of microplastics in the environment makes it relevant to consider these materials in compost/digestate. **Microplastics** are therefore considered for future risk assessment within the limits of a feasible analysis.

Siloxanes

Measurements in C/D made of different input materials (commercial food waste, forestry residues, waste from agriculture, waste from food and beverage industry, and sewage sludge) were identified in literature for four substances within this group. One of these substances, **octamethylcyclotetrasiloxane (D4)**, has critical properties (vPvB and PBT) and is listed in the SIN list and was identified as an SVHC during the course of this study. It has therefore been selected for further risk assessment. No information was found about possible sources for this substance in compost/digestate.

Polycyclic musks

Measurement data were provided for galaxolide (HHCB) and tonalide (AHTN) in C/Ds made from different input materials (commercial food waste, forestry residues, waste from agriculture, waste from food and beverage industry, sewage sludge, and renewable raw materials). The measured values of both substances, which are listed in the SIN list and have few critical properties, did not exceed the limit values proposed by the "Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit[37]." According to literature, this endocrine disrupting substance is used for washing and cleaning products and could therefore be relevant in

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[37] 10 or 15 mg/kg.

digestate from waste water treatment. However, a rapid degradation is observed according to literature, so these substances are not recommended for further risk assessment.

Drugs and pharmaceuticals

Many drugs and pharmaceuticals, including antibiotics and hormones, were listed in the literature sources evaluated. For 53 different substances that were identified, measurements were carried out in C/D samples from different input materials, mainly sewage sludge, dairy and swine manure, slaughterhouse residues, food waste, and biowaste. Some of the hormones (testosterone, estriol, 17α-ethinylestradiol) have several critical properties (at least three red markings in step 2). Following consultations with an expert, **17α-ethinylestradiol** has been selected for further risk assessment on the basis that it is listed in the Water Framework Directive, shows a high mobility in water, and poses major risks for human health and for the environment. No information was available on possible sources for this substance.

Pesticides

Data and measurements were provided for several pesticides, including biocides, insecticides, herbicides and fungicides. Some of the substances are listed in Annex A of the Stockholm Convention (e.g. Aldrin, alpha- and beta- HCH, and DDT), are marked yellow in the evaluation matrix due to the existence in some other lists and have critical properties. However, only for hexachlorobenzene were measurement data above the limit of detection provided. Therefore, this pesticide was initially suggested for further risk assessment. However, after discussion with the steering group, is has not been selected, because it was banned a long time ago.

For the JRC report, 54 samples had been taken for several pesticides. They include 2,4-D, Dichlorprop, Mecoprop, MCPA, 2,4,5-T and Bentazone, 2,4-D also being listed in the Stockholm Convention (JRC Report 2014). The sum of the concentration values for these 7 pesticides was in all cases lower than 50.1 µg/kg. One limit value of 500 µg/kg for the sum of 10 organochlorine pesticides was identified in Austria. No further limit values were identified. It was stated in the JRC Report (2014) that “the measurement data suggests that pesticides are likely to be of very low concern for compost/digestate quality.” Therefore, this group was not selected for further risk assessment.

Heavy metals

Besides the typical heavy metals Cd, Cr, Cu, Hg, Ni, Pb and Zn, other17 metals have been measured in C/D materials made of different input materials (solid and liquid biowaste, green waste, renewable raw material, food and garden waste, and manure/slurry). For Cd (which is on the candidate list for SVHC substances under REACH), Cr, Cu, Ni, Pb and Zn, values above defined or proposed limit values were observed. **Cd, Ni,** and **Pb**, which also have critical properties, were selected for further risk assessment. The JRC (2014) report mentions leaching from glass as a possible source for Cd in compost, while the use of leaded fuels could account for the presence of lead. In the case of nickel, only natural sources such as ultramafic rock are mentioned. **Zn** and **Cu**, which are classified to the priority 2 level according to the methodology applied, are also recommended for further risk assessment due to their high concentrations found in compost materials. As discussed by the steering group, these substances are commonly found in manure/slurry because they are present in veterinary drugs. Finally, **Hg** is also recommended for further risk assessment due to its severe effects on the environment and on human health. The inclusion of Zn, Cu and Hg was recommended by experts. No information was found on possible sources for these metals. Cr would be further relevant if Cr(VI) is the source of measured Cr concentration. However, this could not be further verified.

Others

The category “others” includes phenols with the substances bisphenol A, sweeteners (3 substances), ammonium and mineral oil (C10-C40). Out of these substances, **bisphenol A** is listed in the candidate list for SVHC substances and has critical properties. It was found in C/D, inter alia from renewable raw materials, and was therefore also selected for further risk assessment. Literature sources suggest the widespread use of bisphenol A in the production of plastics as the most significant source of this substance in compost material.

Based on this discussion, a final list of substances for further risk assessment has been selected.

In general, substances assigned to the Priority 1 and 2 categories were selected for further risk assessment with the following exceptions (see Excel File "Evaluation matrix_fin_20180608"):

- Di-isononyl-phthalate (DINP), identified as a Priority 1 substance using the evaluation method used, was not selected as it was recently assessed by RAC for its toxicity for reproduction, but it was not finally proposed for classification.
- Octamethylcyclotetrasiloxane (D4), allocated to the Priority 3 level, is identified as an SVHC (vP/vB and PBT), so it is recommended for further risk assessment.
- 17α-ethinylestradiol, also classified as a Priority 3 substance, shows a high mobility and is included in the Water Framework Directive. It was thus recommended for further risk assessment.
- Hexachlorobenzene was classified as a Priority 2 substance but was not selected because its use has already been banned long time ago. It is not expected that this substance will pose a major risk.

Microplastics will be further considered for risk assessment, but a detailed analysis is not possible due to absence of limit values and the difficulty in evaluating the properties of these materials once they are released. Even though they do not fulfil the prioritisation criteria, they were selected due to an increasing concern over their presence in the environment. Microplastics intentionally added to products (such as detergents and cosmetics) are more likely to concentrate in sewage sludge (ECHA 2018a).

Table 3.3 shows the final list of substances selected for further risk assessment.

Table 3.3 List of substances recommended for further risk assessment

Substance group	Substance/family	Compost/digestate
Dioxins, furans and dioxin-like PCB's	17 PCDD/Fs (I-TEQ)	Compost/digestate (highest value in green waste compost)
PCB's	Indicator PCBs (PCB 6 or PCB 7)	Compost/digestate (highest value in biowaste digestate)
Nonylphenol and -ethoxylates	Nonylphenolethoxylates (NPE) & nonylphenols (NP)	Compost from municipal solid waste
PAHs	PAH16	Compost/digestate (highest value in sewage sludge compost)
HBCD	Hexabromocyclododecane (HBCD)	Compost/digestate (highest value in compost)
Perfluorinated surfactants	Short- and long-chained PFAS	Compost/digestate (highest value in sewage sludge compost)
Phthalates	di(2-ethylhexyl)phthalate (DEHP)	Compost/digestate (high values in digestate from food and garden waste)
Siloxanes	Octamethylcyclotetrasiloxane (D4)	Compost/digestate
Hormones	17α-Ethinylestradiol	Compost/digestate from sewage sludge

Substance group	Substance/family	Compost/digestate
Heavy metals	Cd	Compost/digestate
Heavy metals	Ni	Compost/digestate (highest value in green waste compost)
Heavy metals	Pb	Compost/digestate (highest value in mechanical biological treatment compost)
Heavy metals	Cu	Compost/digestate (highest values in sewage sludge compost, biowaste digestate, biowaste compost)
Heavy metals	Zn	Compost/digestate (highest values in sewage sludge compost)
Heavy metals	Hg	Compost/digestate (highest values in biowaste compost)
Phenols	Bisphenol A	Compost/digestate (highest value in digestate)

4. Risk assessment

4.1 Introduction and approach to assessment

The approach to assessing the priority substances and chemical families is summarised below. The findings for each individual assessed substance are presented and discussed later in this section. A brief discussion on the sensitivity of the results to specific variables was also included for substances where a particular variability concern was noted.

Appendix D presents a full detailed report of the risk assessment. The summary information here is intended to inform the prioritisation process within the RMOA.

Table 4.1 Overview of specific priority substances and approach to assessing their risk

Chemical category or family	Representative substances assessed	Comments
Heavy metals	Cadmium, Nickel, Lead, Copper, Zinc and Mercury	Exposure and risk characterisation has been carried out. Natural background and active accumulation mechanisms present a challenge. The assessments are in terms of total metal although in the environmental media it could be present in different forms. This is discussed as part of the individual assessments.
	Bisphenol A	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
Phthalates	DEHP	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
Pharmaceuticals	17α-Ethinylestradiol	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
	Hexabromocyclododecane	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
Dioxins, furans and dioxin-like PCBs	2,3,7,8-TCDD, 2,3,4,7,8-PCDF, [PCB28]	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
Other PCB	PCB28	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
Nonylphenol isomers and ethoxylates	Nonylphenol	Exposure and risk characterisation has been carried out.
PAH16	Benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene, indeno[,2,3-cd]pyrene	Collectively the first two are termed PAH2 and the first four are termed PAH4. Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed and estimated human exposures are compared with the BMDL10.

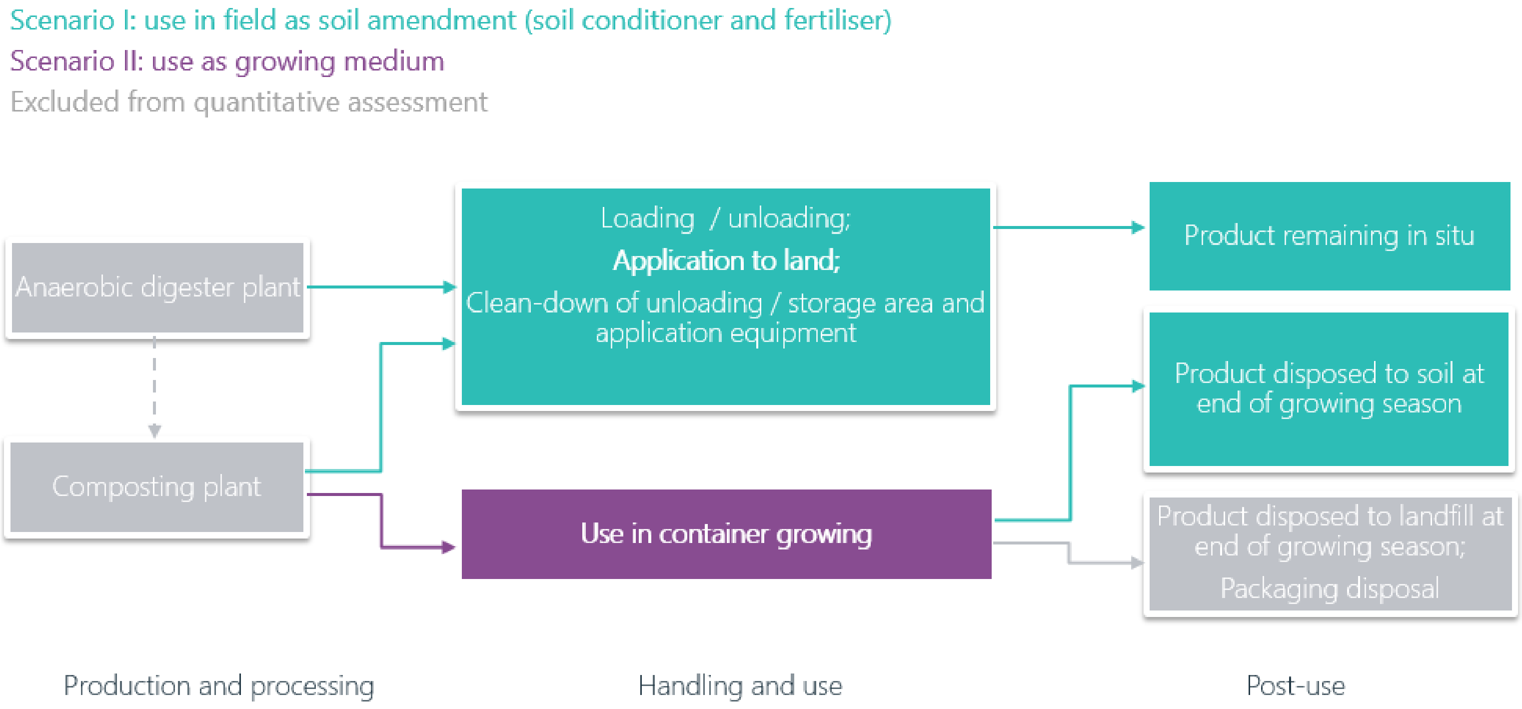
Chemical category or family	Representative substances assessed	Comments
PFAs	PFOA	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed.
Physical impurities	Microplastics	Generic estimate only – fugacity modelling is not reliable.

For the endpoints where conventional quantitative risk characterisation is appropriate, a limit below which adverse effects are not expected has been calculated. This is referred to as "safe limit" throughout the report. Note that this does not preclude possible other effects at lower concentrations, related to other endpoints for which quantitative risk characterisation was not possible.

4.2 The compost and digestate life cycle

The life cycle of digestates and composts in the agricultural context is illustrated overleaf.

Figure 4.1 Summary life cycle of composts and digestates



4.3 Defining exposure scenarios for quantitative exposure assessment

The project team gave consideration to whether additional local scenarios should be included such as transport, distribution, storage, unloading/storage/cleaning at the user site or if these were intended to be excluded. As there is relatively little firm data for the sector, it would be inappropriate to develop over-complicated scenarios. However, it is important not to neglect releases e.g. from the handling and use of products by users alongside the main mode of use.

Two separate local scenarios are discussed in the following sections:

I. Compost and digestate products, handling and application as soil amendment
    - *including application of compost; whole digestate; crude dry fibre and all liquid products;*

II. Compost used as a growing medium
    - *compost only; e.g. for consumer (hobby) and professional growers.*

Full details of the scenario have been circulated in previous progress reports and will be included in the draft final report.

4.4 Assessment of specific priority substances

4.4.1 Cadmium (Cd)

Summary of findings

Table 4.2 Summary of key findings for exposure of cadmium via use of compost and digestates

Key findings of the risk assessment of cadmium in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Median values approximately 0.2 to 0.8 mg/kg dw. The maximum values reported are 2.75 mg/kg dw in compost and 2.5 mg/kg dw in digestate.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). The highest concentrations reported are in mechanical biological treatment compost and in digestate from biowaste and green waste. It is not possible to differentiate whether natural or anthropogenic in origin[38].
Safe limit concentration in compost and digestate	No risks identified at the proposed FPR limit value. The majority of the measured data are below this limit. The safe limit would be higher than the current levels so this is not currently seen as a concern.
Main concern(s) arising	Cumulative loads at steady state.

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[38] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

Key findings of the risk assessment of cadmium in contaminated composts and digestates	
Effects considered in the main concern hazard(s)	Toxicity to kidney and bone via dietary exposure. The European Food Safety Authority (EFSA) has identified that at least in the case of children, the tolerable weekly intake of cadmium via total diet, could be exceeded (European Food Safety Authority 2012). Cadmium in compost and digest could contribute to this dietary exposure.
Uncertainties and their implications	Uncertainty over the safe threshold for dietary exposure. Small occurrence data set covering limited number of countries. The highest concentrations reported could present a risk to humans exposed via crops, however this significance of this is highly uncertain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	The contribution from C/D to the total cadmium present in soil from all sources is relatively small.

The realistic worst case analysis carried out indicates that the risks to the environment from the presence of cadmium in C/D are generally low. The contribution from C/D to the total cadmium present in soil from all sources is relatively small. For man exposed via the diet, the levels predicted are below the available toxicity threshold values. However, it should be noted that cadmium and its salts have been identified as SVHC based on mutagenicity and/or carcinogenicity and effects on kidney and bones and, according to ECHA (2013) there is some uncertainty over the safe threshold for dietary exposure. ECHA (2013) indicated that atmospheric deposition to soil was the major source of cadmium entering the diet and recommended that action should be taken at Community level to control and reduce cadmium pollution. Although the input of cadmium into soil, and hence the diet, from C/D appears to be small compared with other sources, C/D will contribute to the total dietary intake of cadmium.

At steady state, 67% of the total mass remains within the region + continent[39], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D[40]. The realistic worst case mass of cadmium in the region + continent at steady state as a result of use of C/D is estimated to be around 4.27×10^6 kg assuming that all compost contains cadmium at the mid-range of the measured concentration. This steady-state mass amounts to approximately 220 times the mass released annually via application of composts and digestates[41].

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[39] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[40] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[41] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

4.4.2 Nickel (Ni)

Summary of findings

Table 4.3 Summary of key findings for exposure of nickel via use of compost and digestates

Key findings of the risk assessment of nickel in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Typically <10 to 39 mg/kg dw. The maximum values reported are 250 mg/kg dw in compost and 40 mg/kg dw in digestate.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). The highest overall concentrations have been reported in compost samples derived from biowaste, green waste, sewage sludge and mechanical biological treatment. It is not possible to differentiate whether natural or anthropogenic in origin[42].
Safe limit concentration in compost and digestate	7.9 mg/kg dw for compost for container growing. 130 mg/kg dw for compost or digestate for application to agricultural land. The majority of measured data are below this value.
Main concern(s) arising	Human exposure through crops from use of compost in container growing. Secondary poisoning from use of compost in container growing. Cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Human toxicity based on mammalian developmental toxicity Secondary poisoning based on reproductive study in rat
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	The nickel from C/D contributes up to around 20% of the total background nickel present in soil.

The realistic worst-case analysis carried out indicates a potential risk to secondary poisoning and human exposure through use of compost containing nickel for scenario II. No risks are identified for use of compost or digestate containing nickel in scenario I based on the typical range of concentrations and the limit value from the proposal for the revised Fertilising Products Regulation (FPR) (European Commission 2018b). However, there are a limited number of measured concentrations in nickel in compost above this limit value and these would indicate a potential risk to humans via diet if the concentration exceeds around 130 mg/kg dry wt. The majority of the available measured data are below this value.

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[42] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

In order to control the risks from scenario II the level of nickel present in compost would need to be around 7.9 mg/kg dry weight or below[43]. This is would lead to a concentration in the actual growing medium of around 2.6 mg/kg dry weight. This limit value appears to be very low when compared with the reported EU background concentration in agricultural soil of 26 mg/kg dry weight (see Appendix D).

EU limit values for nickel in agricultural soil to which sewage sludge is applied are specified in Council Directive 86/278/EEC[44]. The limit value set by the Directive for nickel in soil with a pH of 6 to 7 is 30 to 75 mg/kg dry weight. The actual limit values applied in the Member States are in the range 30 to 75 mg/kg dry weight in 27 Member States (Eunomia Research & Consulting 2018). One Member State (Denmark) has set a lower limit value for nickel in soil of 15 mg/kg dry weight. Thus, the safe limit estimated for nickel for container growing in scenario II is also significantly lower than existing limit values for nickel in agricultural soil.

As discussed in Appendix D, there are some uncertainties associated with the container growing scenario used. In particular, the current calculations assume that there is no loss of the substance from the growing medium by leaching (although the analysis carried out in Appendix D suggests that this may not be so significant for nickel) and that the dietary intake from root and leaf crops occurs entirely from crops grown in such media. This latter assumption, in particular, may lead to an overestimation of the risks associated with compost and digestate containing nickel in this scenario and so the estimated safe limit of 7.9 mg/kg dry weight in compost should be seen as preliminary only.

The contribution from C/D to the total nickel present in agricultural soil from all sources is relatively small. At steady state, 77% of the total mass remains within the region + continent[45], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D[46]. The realistic worst-case mass of nickel in the region + continent at steady state as a result of use of C/D is estimated to be around 2.95×10^8 kg assuming that all compost contains nickel at the mid-range of the reported measured levels. This steady-state mass amounts to approximately 490 times the mass released annually via application of composts and digestates[47].

4.4.3 Lead (Pb)

Summary of findings

Table 4.4 Summary of key findings for exposure of lead via use of compost and digestates

Key findings of the risk assessment of lead in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Typically <2.5 to 91 mg/kg dw. The maximum concentration reported is 230 mg/kg dw in compost. The concentrations in digestate are generally lower than in compost.
Major raw material sources	The data suggests that the concentrations may be higher with biowaste and green waste, and solid and liquid biowaste as raw

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[43] Safe limit concentrations are determined for the protection target that is most sensitive for that substance. These safe limits are then protective for all endpoints.

[44] Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture. Official Journal of the European Communities L 181/6, 4.7.86.

[45] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[46] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[47] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

Key findings of the risk assessment of lead in contaminated composts and digestates	
	material sources than renewable raw materials and co-digestion as raw material sources. The highest concentration overall was found in compost derived from mechanical biological treatment. However, only very limited data are available. It is not possible to differentiate whether natural or anthropogenic in origin[48].
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Non-threshold neurotoxic substance. Cumulative loads at steady state. Significant contribution from C/D to the total background level of lead in soil.
Effects associated with the main concern hazard(s)	Non-threshold neurotoxin.
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	-

The realistic worst-case analysis carried out indicates risk characterisation ratios (RCRs) <1 for soil, sediment, water and secondary poisoning based on the realistic worst case assumptions for both scenario I and scenario II. However, lead is a non-threshold neurotoxic substance and so it is not possible to carry out a quantitative risk characterisation for man exposed via the environment (refer to Section 2.1 of Appendix D).

The contribution from C/D to the total background levels of lead present in soil from all sources is significant (estimated to be up to 66% based on the mid-range measured levels; this would be higher if the highest measured levels or the proposed FPR limit value is assumed).

At steady state, 95% of the total mass remains within the region + continent[49], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D[50]. The realistic worst case mass of lead in the region + continent at steady state as a result of use of C/D is estimated to be more than 1 million tonnes assuming that all compost contains lead at the mid-range of the levels that have been measured. This steady-state mass amounts to approximately 1,670 times the mass released annually via application of composts and digestates[51].

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[48] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

[49] This refers to the regional and continental spatial scales in the EUSES model. Refer Section 1.7 of Appendix D for further information.

[50] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[51] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

4.4.4 Copper (Cu)

Summary of findings

Table 4.5 Summary of key findings for exposure of copper via use of compost and digestates

Key findings of the risk assessment of copper in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Up to 980 mg/kg dw. More typically 50-60 mg/kg dw.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). It is not possible to differentiate whether natural or anthropogenic in origin[52].
Safe limit concentration in compost and digestate	200 mg/kg dry weight for compost for container growing
Main concern(s) arising	Soil organisms for compost for container growing. Cumulative loads at steady state.
Effects considered in the main concern hazard(s)	PNEC for soil organism is estimated statistically from a species sensitivity distribution of the available toxicity data for plants, soil invertebrates and soil microorganisms.
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Copper is an essential element. Therefore, accumulation through the food chain is not a relevant concept for copper and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out. The copper from C/D contributes up to around twice the amount of the background level of copper present in soil.

The realistic worst-case analysis carried out indicates RCRs <1 for water, sediment and soil in scenario I for both C/D. However, the highest concentration measured in compost would lead to a RCR of 1.02 for soil for scenario II. The highest concentration measured in compost is above the proposed limit value for copper reported by JRC (200 mg/kg dry wt; EC, 2014), and therefore it is unclear if this concentration represents current typical levels in soil. Most of the other available measured data show that the concentration of copper measured in C/D is below this limit value, and the resulting RCR for soil in scenario II is <1 for copper concentrations in compost ≤200 mg/kg dry wt. Therefore, it can be concluded that if the C/D meets the proposed limit value, the risk to water, sediment and soil would be low in both scenarios.

The safe limit concentration in compost and digestate estimated for copper of 200 mg/kg dry weight for container growing in scenario II would lead to a concentration in the actual growing medium of around 67 mg/kg dry weight. Similar to the case with nickel, there are some uncertainties associated with the container growing scenario as discussed in Appendix D.

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[52] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

EU limit values for copper in agricultural soil to which sewage sludge is applied are specified in Council Directive 86/278/EEC[53]. The limit value set by the Directive for copper in soil with a pH of 6 to 7 is 50 to 140 mg/kg dry weight. The actual limit values applied in the Member States are in the range 50 to 140 mg/kg dry weight in 25 Member States (Eunomia Research & Consulting 2018). Three Member States have set a lower limit value for copper in soil of 40 mg/kg dry weight (Denmark and Sweden) or 36 mg/kg dry weight (Netherlands). Thus, despite the uncertainties associated with this scenario, the limit value estimated here for copper in compost and digestate for container growing is consistent with the EU limit values for copper in agricultural soil.

Copper is an essential element and the levels within an organism are controlled by homeostasis. Therefore, accumulation through the food chain is not a relevant concept for copper and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out.

The contribution from C/D to the total background levels of copper present in soil from all sources is significant. At steady state, 84% of the total mass remains within the region + continent[54], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D[55]. The realistic worst case mass of copper in the region + continent at steady state as a result of use of C/D is estimated to be around 2.5×10^{9} kg assuming that all compost contains copper at the mid-range of the levels that have been measured. This steady-state mass amounts to 960 times the mass released annually via application of composts and digestates[56].

4.4.5 Zinc (Zn)

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is 1.1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.6 Summary of key findings for exposure of zinc via use of compost and digestates

Key findings of the risk assessment of zinc in contaminated composts and digestates	
Overall range of compost and digestate concentrations	132 to 1098 mg/kg dw. Median values typically around 200-280 mg/kg dw.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid

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[53] Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture. Official Journal of the European Communities L 181/6, 4.7.86.

[54] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[55] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[56] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

Key findings of the risk assessment of zinc in contaminated composts and digestates	
	biowaste). It is not possible to differentiate whether natural or anthropogenic in origin[57].
Safe limit concentration in compost and digestate	600 mg/kg dry weight for application of compost or digestate to agricultural land. 70 mg/kg dry weight for compost used in container growing.
Main concern(s) arising	Sediment for scenario I, related to application of compost or digestate onto agricultural land. Soil for scenario II, related to compost use in container growing. High cumulative loads at steady state and high predicted regional RCRs in sediment.
Effects considered in the main concern hazard(s)	PNEC for sediment is derived from survival and growth data for benthic organisms. PNEC for soil is based on toxicity to soil microbial processes, plants and soil invertebrates derived from species sensitivity distributions.
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Uncertainties over the risk at the regional level. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Zinc is an essential element. Therefore, accumulation through the food chain is not a relevant concept for zinc and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out. The input of zinc to agricultural soil from C/D is relatively small (around 10% of the total) compared with other sources.

The realistic worst case analysis carried out indicates RCRs <1 for water and soil for scenario I, indicating a low risk. However the realistic worst case analysis results in RCRs >1 for sediment for scenario I and soil for scenario II. RCRs >1 are also indicated for sediment at a regional level when calculated using the approximate mid-range concentration in C/D, however the regional risk assessment for zinc is highly uncertain.

When the added risk approach is used, RCRs for scenario I for sediment, water and soil are all <1 when the concentration in digestate or compost is limited to ≤600 mg/kg dry weight, which corresponds to the proposed limit value for zinc from JRC 2014 (EC, 2014). This shows that the proposed limit value would be sufficient to control the risks from this scenario. For scenario II (which relates to compost only), the concentration in compost would need to be limited to ≤70 mg/kg dry weight in order to achieve RCRs <1. This is below the proposed FPR limit value, and also lower than the approximate mid-range of the measured data.

Zinc is an essential element and the levels within an organism are controlled by homeostasis. Therefore, accumulation through the food chain is not a relevant concept for zinc and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out.

The contribution from C/D to the total background levels, including other agricultural uses and natural sources, of zinc present in soil from all sources is small. The total EU input of zinc into agricultural soil from C/D (assuming the concentration present is around the mid-range level) estimated to be around 1,700 tonnes; this compares with an estimate of the total EU input of zinc into agricultural soil of 17,000 tonnes

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[57] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

from all agricultural soil. At steady state, 54% of the total mass remains within the region + continent[58], suggesting that there is some transfer over long distances following release via the handling and application of C/D[59]. The realistic worst-case mass of zinc in the region + continent at steady state as a result of use of C/D is estimated to be around 1.51×10^9 kg assuming that all compost contains zinc at the mid-range of the levels that have been measured. This steady-state mass amounts to 130 times the mass released annually via application of composts and digestates[60].

4.4.6 Mercury (Hg)

Summary of findings

Table 4.7 Summary of key findings for exposure of mercury via use of compost and digestates

Key findings of the risk assessment of mercury in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.018-0.98 mg/kg dw
Major raw material sources	The data suggests that the concentrations may be higher with biowaste and green waste, and solid and liquid biowaste as raw material sources than renewable raw materials and co-digestion as raw material sources. However, only very limited data are available. It is not possible to differentiate whether natural or anthropogenic in origin[61].
Safe limit concentration in compost and digestate	0.2 mg/kg dry wt for C/D applied to agricultural land
Main concern(s) arising	Secondary poisoning. Transfer over long distances.
Effects considered in the main concern hazard(s)	Concerns for secondary poisoning are based on the existing EQS for biota. The effects considered in deriving the EQS are not clear.
Uncertainties and their implications	No quantitative risk characterisation for sediment or soil has been carried out. Therefore the risks to these protection goals is unclear. Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	The overall contribution from C/D to the total concentration of mercury in agricultural soil is low. European Union is a signatory to the UN Minamata Convention on Mercury.

The realistic worst case analysis carried out indicates RCRs <1 for water for scenario I and scenario II, indicating a low risk. However the realistic worst case analysis results in RCRs >1 for secondary poisoning for scenario I. In order to control this risk, the maximum concentration of mercury in compost or digestate would

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[58] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[59] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[60] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

[61] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

need to be limited to ≤0.2 mg/kg dry weight. This value is below the proposed FPR limit value for mercury. The highest reported concentration of mercury in digestate is 0.17 mg/kg dry weight and the mid-range concentration reported in compost are <0.2 mg/kg dry weight, which would not lead to a risk based on these calculations, but the highest reported concentration in compost (0.98 mg/kg dry weight) would lead to RCRs >1 for secondary poisoning.

The contribution from C/D to the total background levels of mercury present in agricultural soil from all sources is small. At steady state, ~3% of the total mass remains within the region + continent[62], suggesting that there is potential for transfer over long distances following release via the handling and application of C/D[63]. The realistic worst-case mass of mercury in the region + continent at steady state as a result of use of C/D is estimated to be around 4.24×10^5 kg assuming that all compost contains mercury at the mid-range of the levels that have been measured. This steady-state mass amounts to 10 times the mass released annually via application of composts and digestates. It is important to note, however, that a significant proportion (~97%) of the steady-state mass of mercury is predicted to have transported out of the region and continent to more remote areas.

It should be noted that the European Union is a signatory to the UN Minamata Convention on Mercury. The Minamata Convention is a global treaty to protect human health and the environment from the adverse effects of mercury and entered into force on 16 August 2017. Among other things the Convention covers control measures on emissions to air and on releases to land and water, and disposal of mercury once it becomes waste; hence it could be anticipated that levels of mercury in raw materials for composts and digestates would consequently be reduced in future.

4.4.7 Bisphenol-A (BPA)

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under ‘high water content’ conditions, and hence sensitive to leaching, is 3.7% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.8 Summary of key findings for exposure of bisphenol-A via use of compost and digestates

Key findings of the risk assessment of bisphenol-A in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Very limited data, all for one specific sampled region (2015, Bavaria) <0.01 - 1 mg/kg dw
Major raw material sources	Renewable raw materials, or not stated.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Reprotoxin and endocrine disruptor (SVHC)
Effects considered in the main concern hazard(s)	SVHC (reproduction; endocrine disrupting in relation to both human health and the environment).

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[62] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[63] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

Key findings of the risk assessment of bisphenol-A in contaminated composts and digestates	
	DNELoral for the general population available in respect of effects on mammary gland, reproductive, neurobehavioural, immune and metabolic systems. PNECs are available derived using species sensitivity distributions. Quantitative risk characterisation has not been attempted in this study.
Uncertainties and their implications	Very limited data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low. In circumstances where a) the system is watered in excess of the water holding capacity of the growing medium and b) where the container design means that excess water will drain away and not remain in contact with the container/growing medium, then a small proportion of the substance could be lost from the system in the drained water.
Other remarks	None

Bisphenol A is a SVHC (toxic for reproduction with endocrine disrupting properties in respect of both the environment and human health) and in view of these hazardous properties, quantitative risk characterisation has not been attempted in this study. However, it is noted that the predicted local total daily intake for humans does not exceed the DNEL used by EFSA and RAC, and the PNECs adopted in the 2010 ESR risk assessment are not exceeded. The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

The regional scale predicted environmental concentration (PEC) in agricultural soil arising from the application of C/D is well below the background concentration arising from the industrial life cycle, calculated in the ESR risk assessment.

At steady state, >99% of the total mass remains within the region + continent[64], of which the significant majority remains within soil. This suggests there is low mobility and little potential for transfer over long distances following release via the handling and application of C/D[65]. The total mass in the region + continent at steady state is however relatively low, less than 2 t in total even when a conservative concentration in the compost/digestate is assumed. This steady-state mass amounts to a small fraction (~0.1) of the mass released annually via application of composts and digestates[66], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

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[64] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[65] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[66] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

4.4.8 Di(2-ethylhexyl)phthalate (DEHP)

Summary of findings

Table 4.9 Summary of key findings for exposure of DEHP via use of compost and digestates

Key findings of the risk assessment of DEHP in contaminated composts and digestates	
Overall range of compost and digestate concentrations	0.6-140 mg/kg dw (or higher; the upper limit value is reportedly an average).
Major raw material sources	High concentrations associated with digestates prepared from biowaste-food and garden waste (Norway), and municipal sewage sludge from wastewater treatment plants (Finland).
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Humans via dietary exposure (container growing); High cumulative loads at steady state. Absolute concentrations in compost/digestate exceeding existing local limit values / guide values. Local PEC in freshwater (local scenario I) exceeds annual average EQS (Directive 2008/105/EC as amended (2013/39/EU)) (though regional background PEC does not).
Effects considered in the main concern hazard(s)	SVHC (toxic for reproduction, endocrine disrupting in relation to both human health and environment). Basis of the EQS (AA-QS) is not stated in the Directive but is understood to relate to secondary poisoning of predators (The Commission 2005).
Uncertainties and their implications	Concentrations in composts and digestates have high variability – local PECs would similarly be variable and could be still higher than modelled here. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Measured concentration in sludge-amended soil support the local estimated concentration.

The highest reported occurrence values in digestate exceed a national limit value of 50 mg/kg digestate dw applicable (or relevant as a guide value) in several European countries. This in itself indicates a potential issue. These high occurrence concentrations were reported in digestates prepared from biowaste-food and garden waste (Norway), and municipal sewage sludge from wastewater treatment plants (Finland).

As an SVHC (toxic for reproduction with endocrine disrupting properties for environment and human health), risk characterisation has not been quantified. However, it is noted that the local total daily intake for humans associated with local scenario II slightly exceeds the DNELoral for general population defined by Danish EPA (2016). Additionally, the predicted exposures in soil in local scenario II are approaching the PNEC value defined by EC (2008).

The estimated regional exposures in agricultural soils and grassland arising from the application of C/D are below the estimated background PECs derived from the EC (2008) ESR risk assessment based on the industrial life cycle. The estimated local exposures in agricultural soils from Scenario I is within the range measured for a sludge-fertilised agricultural soil.

The highest contribution to human exposure via the environment arising from the use of C/D in either scenario is mainly associated with dietary consumption of root vegetables.

At steady state, >99% of the total mass remains within the region + continent[67], with the vast majority of substance remaining in the agricultural soil. This suggests there is low potential for transfer over long distances following release via the handling and application of C/D[68].

The total mass in the region + continent at steady state is very high (>1000 t) based on the more conservative interpretation of the available concentration data, and still significant (90 t) even when releases are based on a less conservative, relatively low concentration of DEHP in compost/digestate. This steady-state mass amounts to 1.2 times the mass released annually via application of composts and digestates[69], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

4.4.9 17α-Ethinylestradiol

Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- BCF in fish (value 110 l/kg ± 1 log unit);
- Koc (range QSAR value 510 to RIVM 4768 (source uncertain);
- Kow (value 3.67 ± 1 log unit);
- Water solubility (value 11.3 mg/l ± 1 log unit); and
- Vapour pressure (value 2.6E-07 Pa ± 1 log unit).

The impact of varying each property within the specified range or within a suitable uncertainty range was explored independently. Refer to the figures below, which illustrate the impact on relevant predicted exposure concentrations.

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[67] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[68] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[69] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Figure 4.2 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the Koc input value: fresh water sediment

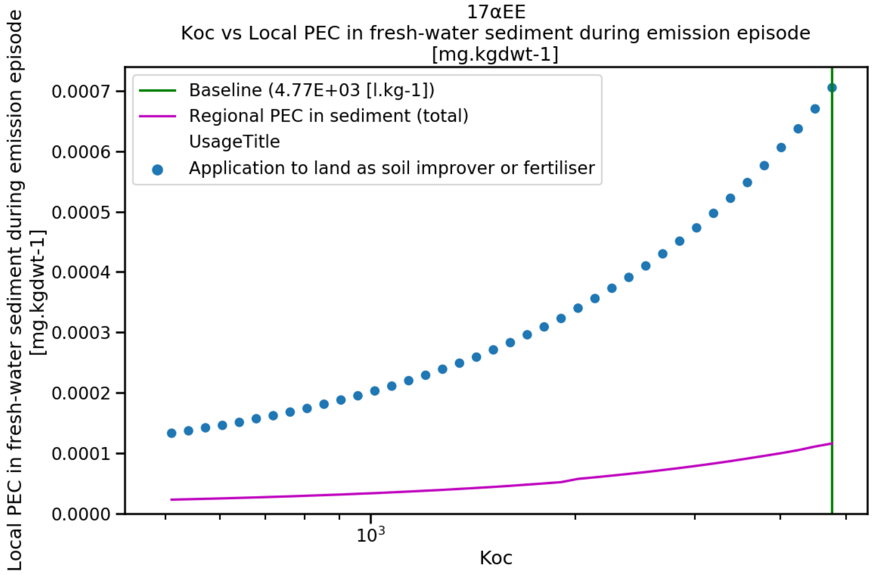


Figure 4.3 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the Koc input value: diet of worm-eating birds and mammals

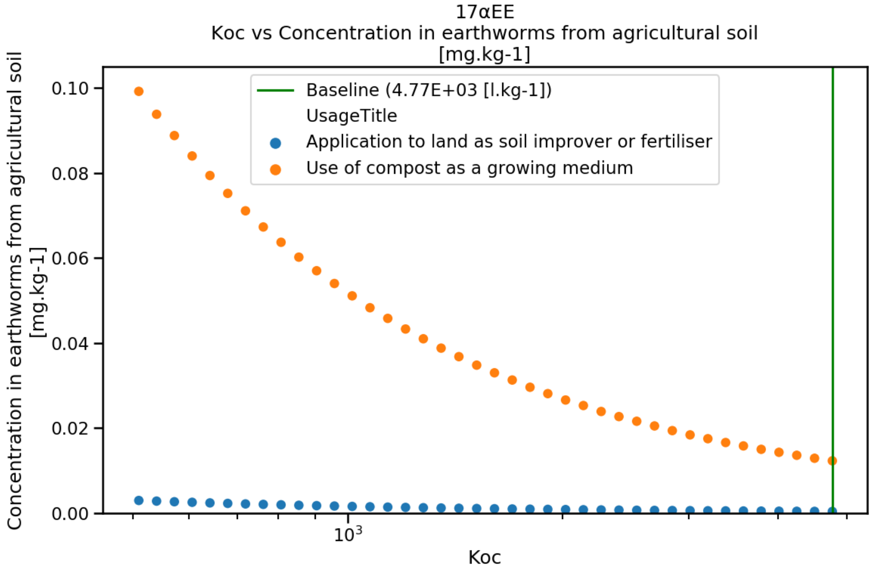


Figure 4.4 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the log Kow input value: diet of worm-eating birds and mammals

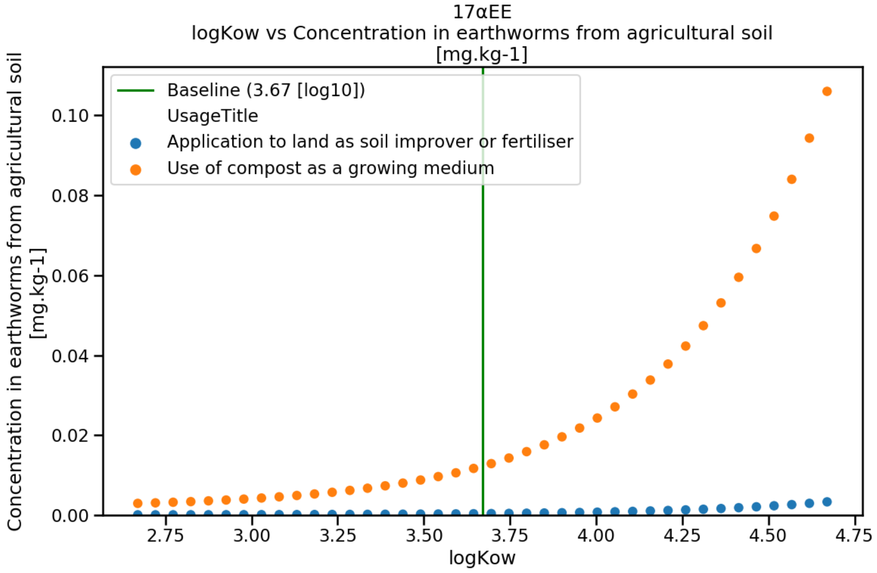
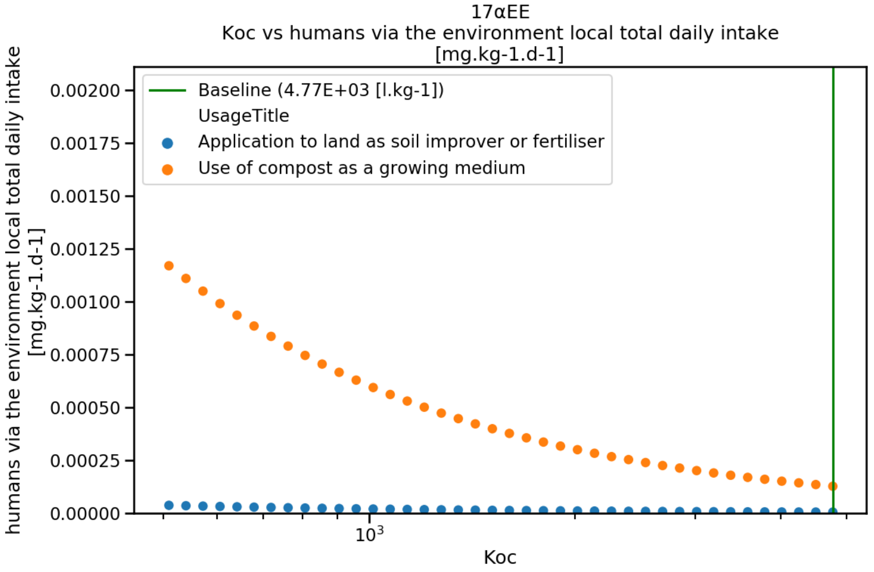


Figure 4.5 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the Koc input value: total daily intake of humans



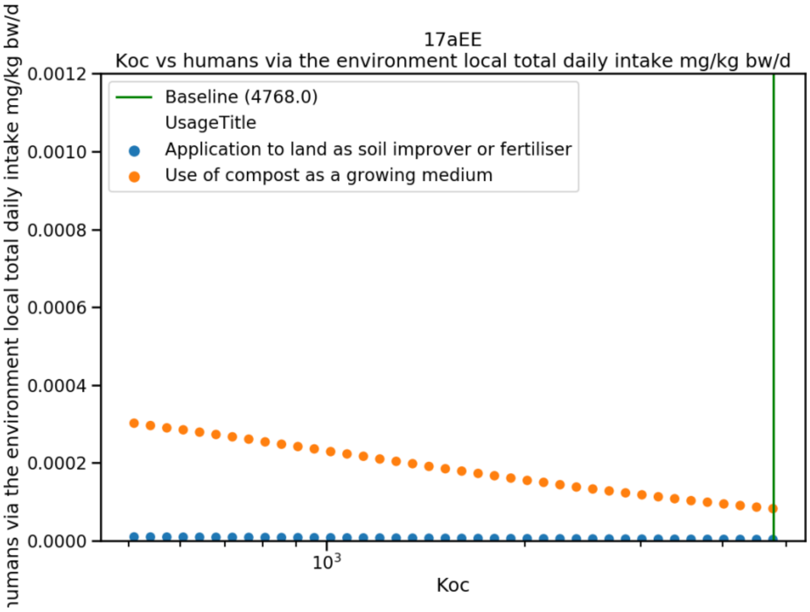
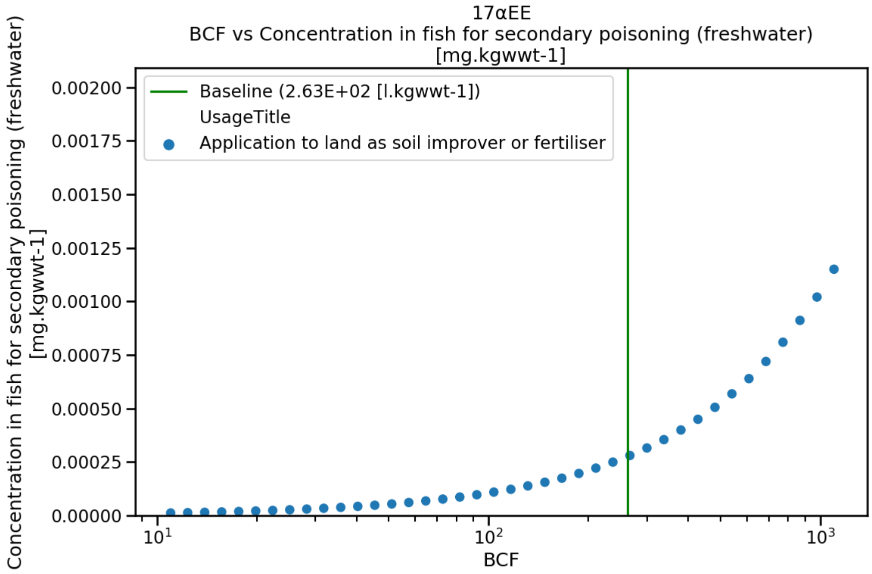


Figure 4.6 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the BCF input value: diet of fish-eating birds and mammals



It can be concluded that:

- At the Koc value used in the baseline assessment, the PNECsediment arising from the application to land scenario has been estimated conservatively.
- The secondary poisoning exposure of worm-eating birds and mammals and local total daily intake, arising from use in the container growing scenario, could have been significantly higher than estimated in the baseline assessment, if the lower value of Koc is accurate, and/or within a reasonable uncertainty range around the literature log Kow value.
- The secondary poisoning exposure of fish-eating birds and mammals (local scenario I) could be up to 5x higher within a reasonable uncertainty range around the BCF value, which is estimated in the absence of data.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.10 Summary of key findings for exposure of 17α-ethinylestradiol via use of compost and digestates

Key findings of the risk assessment of 17α-ethinylestradiol in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<LOD – 0.483 mg/kg dw
Major raw material sources	WWTP sewage sludges
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Endocrine disruptor with unclear safe limit thresholds. Modelling suggests a possibility of transfer over long distances.
Effects considered in the main concern hazard(s)	No quantitative hazard threshold available.
Uncertainties and their implications	Very limited data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model., Some uncertainties in chemical property data values which could be significant for predicted exposures. Threshold values for the environment (EQS) are not established. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	None

In view that the substance is an endocrine disruptor with unclear safe limit thresholds, risk characterisation has not been quantified in this assessment.

Both the BCF and Koc values used in the exposure assessment are associated with some uncertainty. The sensitivity to these as uncertainty sources has been checked and the local predator exposure (secondary poisoning) could be higher than estimated here.

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables. The local total daily intake is well below the therapeutic pharmaceutical dose even when the exposure model assumes relatively conservative concentrations in the compost/digestate. Again the sensitivity assessment indicates that exposures could be higher within the uncertainty range of the BCF and Koc values.

At steady state, only around 6% of the total mass remains within the region + continent[70], suggesting there may be relatively high mobility and potential for transfer over long distances following release via the handling and application of C/D[71]. Global scale modelling within EUSES suggests that at the steady state, the majority of the substance would be found in global tropic waters, (53%), moderate waters (24%) and arctic waters (16%). In view of the pharmaceutical use, it is noted that the absolute exposure of aquatic

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[70] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[71] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

environments arising from the use of C/D containing 17α-ethinylestradiol is likely to be small compared to the exposure of receiving waters from municipal wastewater treatment plants.

The total mass in the region + continent at steady state is low (approximately 7 t total) even when the exposure model assumes relatively conservative concentrations in the compost/digestate. This steady-state mass amounts to 1.3 times the mass released annually via application of composts and digestates.

4.4.10 Hexabromocyclododecane (HBCDD)

Sensitivity to specific variables

The main source of uncertainty in the assessment of this substance is the wide range in the reported concentration levels of the substance in C/D.

The impact of varying the releases within the specified range was explored. Refer to the table below, which illustrates the impact on relevant predicted exposure concentrations. The inputs used in the 'more conservative' and 'less conservative' assessments are discussed in more detail in Appendix D.

Table 4.11 Sensitivity of selected outputs in the assessment of HBCDD to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (general case)	Units
PECagricultural soil – local scenario I	1.06E-02	5.19E-03	[mg.kgdwt-1]
PECagricultural soil – local scenario II	2.01E+00	9.90E-01	[mg.kgdwt-1]
Humans via the environment: local total daily intake – local scenario I	4.72E-04	2.12E-04	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	3.77E-02	1.85E-02	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	2.15E+01	7.56E-04	[t]
Total steady-state mass fraction (region + continent)	6.73E+01	6.72E+01	[%]
Regional PEC in surface water (total)	1.51E-06	5.32E-11	[mg.l-1]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	1.16E+00	4.45E-01	[mg.kgwwt-1]
Secondary poisoning – worm-eating birds and mammals – local scenario I	3.54E-04	1.67E-04	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	9.62E-02	4.74E-02	[mg.kg-1]

It can be concluded that:

- At the local scale, the variability in HBCDD in composts and digestates is not particularly significant as the predicted exposure concentrations of HBCDD in important compartments are within a factor of 2-3. This is mainly a consequence of how close the mid-range concentrations in compost/digestate are compared to the maximum values, due to the small number of data points.
- At the regional scale, the difference between the two scenarios is much more significant for HBCDD.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.12 Summary of key findings for exposure of HBCDD via use of compost and digestates

Key findings of the risk assessment of HBCDD in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Very few reported values <1E-05 – 6.1 mg/kg dw
Major raw material sources	The type of input material is not mentioned for the higher concentration compost/digestates. Digestate produced from renewable raw materials had lower concentration of HBCDD.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP/PBT. Fresh water PEC exceeds the annual average EQS for inland surface water at both the local (scenario I) and regional scales (the MAC EQS is not exceeded); predator exposure via diet (local scenario I) exceeds the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	POP; SVHC (PBT); basis of EQS is not stated in the Directive but a background document suggests both the biota and freshwater EQS relate to effects in birds (European Commission 2011).
Uncertainties and their implications	Very limited data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	

As a POP and PBT SVHC under REACH, it is in itself a potentially important finding that HBCDD has been detected in freshly-produced composts and digestates in recent years. The raw material waste streams could be investigated further. It is noted though that very few of the literature sources has identified HBCDD. The same factors mean that the very small data set size for occurrence is not necessarily a cause of concern in respect of uncertainty in the risk assessment.

The estimated regional scale exposures arising from the application of C/D are well below the anthropogenic background concentrations modelled in the ESR risk assessment (EC 2008, which were reported to compare well with measured concentrations).

The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

At steady state, ca. 67% of the total mass remains within the region + continent[72], suggesting that there is limited redistribution following release via the handling and application of C/D[73]. Much of the remainder is modelled to distribute to global tropic (13.5%) and global moderate (12%) waters. The total mass in the region + continent at steady state is approximately 20 t. When a comparable scenario is assessed using a lower level release based on the range of occurrence data, the total mass at steady state is much lower at <1 kg. This steady-state mass amounts to 0.48 times the mass released annually via application of composts and digestates[74], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

4.4.11 2,3,7,8-Tetrachlorodibenzodioxin (TCDD) (representative of Dioxins, Furans and Dioxin-like PCBs chemical family)

Dioxins and related compounds are persistent organochlorine compounds generated during incineration and as a by-product of certain industrial processes. This group covers numerous poly-chlorinated chemical structures; theoretically there are 75 polychlorinated dibenzo-p-dioxin (PCDD) and 135 polychlorinated dibenzofuran (PCDF) congeners, and 12 'dioxin-like polychlorinated biphenyls' (dl-PCBs). One representative PCDD and one PCDF have been selected for detailed assessment of this chemical family.

Toxicity in this group is assessed based on Toxic Equivalency Factors (TEFs) and Toxic Equivalent (TEQ) expressing the weighted concentration equivalent to the most toxic dioxin 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).

Sensitivity to specific variables

The main source of uncertainty in the assessment of this substance is the wide range in the reported concentration levels of the substance in C/D.

The impact of varying the releases within the specified range was explored. Refer to the table below, which illustrates the impact on relevant predicted exposure concentrations. The inputs used in the 'more conservative' and 'less conservative' assessments is discussed in more detail in Appendix D.

Table 4.13 Sensitivity of selected outputs in the assessment of 2,3,7,8-TCDD to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (general case)	Units
PECagricultural soil – local scenario I	2.40E-04	2.15E-05	[mg.kgdwt-1]

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[72] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D and the Annex for further information.

[73] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[74] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

PECagricultural soil – local scenario II	3.96E-03	4.29E-04	[mg.kgdwt-1]
Humans via the environment: local total daily intake – local scenario I	7.75E-07	5.87E-08	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	9.98E-06	1.07E-06	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	1.59E+01	8.00E-04	[t]
Total steady-state mass fraction (region + continent)	9.91E+01	9.91E+01	[%]
Regional PEC in surface water (total)	2.65E-09	1.33E-13	[mg.l-1]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	2.58E-05	1.91E-06	[mg.kgwwt-1]
Secondary poisoning – worm-eating birds and mammals – local scenario I	1.90E-04	8.89E-06	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	1.72E-03	1.77E-04	[mg.kg-1]

It can be concluded that:

- At the local scale, the predicted exposure concentrations of 2,3,7,8-TCDD in important compartments differ by a factor of around x10-20.
- At the regional scale, the difference between the two scenarios is much more significant for 2,3,7,8-TCDD at around 4 orders of magnitude.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.14 Summary of key findings for exposure of 2,3,7,8-TCDD via use of compost and digestates

Key findings of the risk assessment of 2,3,7,8-TCDD in contaminated composts and digestates	
Overall range of compost and digestate concentrations	7E-09 – 0.0145 mg/kg dw (total PCDD/PDCF)
Major raw material sources	Highest values are reported for sewage sludge composts and biowaste/green waste manure energy crop digestate.

Key findings of the risk assessment of 2,3,7,8-TCDD in contaminated composts and digestates	
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP/PBT; significant cumulative loads at steady state; absolute concentrations exceeding previously published measured concentrations in foods; absolute concentrations in compost/digestate exceeding existing local limit values / guide values (but not exceeding EC Regulation 1195/2006); predator exposure via diet (local scenarios I and II) exceed the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	POP; basis of EQS is not stated in the Directive and is unclear
Uncertainties and their implications	Very variable data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	None.

As POPs, it is noteworthy that PCDD/PCDF and PCBs have been detected in freshly-produced composts and digestates at several different locations in recent years. Their presence may result from atmospheric deposition of emissions from combustion or municipal solid waste incineration rather than originating from the raw material waste streams. This is an area for possible future work.

The highest reported concentrations in composts and digestates already appear to exceed the national limit value for several member states, although still within the 15 µg/kg limit referenced from Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 (POPs Regulation). These high occurrence concentrations arise from composts and digestates from a range of raw materials and processing types.

The highest contribution(s) to human exposure via the environment arising from the application of compost and digestate is mainly associated with (dietary consumption of root vegetables). The estimated exposures arising from the application of C/D are high compared with reported mean/median levels of PCDD/PCDF in foodstuffs including vegetables, in Western Europe as summarised by WHO (2002). This is the case even when lower concentrations were assumed in the exposure model (for example, the 'low concentration' exposure assessment for 2,3,7,8-TCDD results in concentrations of 1E-05 mg/kg and 2E-04 mg/kg in root tissue of plants arising from application to land (local scenario I) and container growing (local scenario II) respectively. However the WHO summary reports a weighted mean of 0.003 pg PCDD/PCDF/g whole food (equivalent to 3E-9 mg/kg) for vegetable products.

At steady state, >99% of the total mass remains within the region + continent[75], suggesting that there is relatively low potential for transfer over long distances following release via the handling and application of C/D[76]. The total mass in the region + continent at steady state is 16t which is significant but not particularly high. This steady-state mass amounts to 320 times the mass released annually via application of composts

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[75] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[76] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

and digestates[77]. When a comparable scenario is assessed using a lower level release, the steady state mass is very low (below 1 kg).

4.4.12 2,3,4,7,8-Pentachlorodibenzofuran (PCDF) (representative of Dioxins, Furans and Dioxin-like PCBs chemical family)

Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- Kow (value 6.92 ± 1 log unit);
- Water solubility (value 2.35E-04 mg/l ± 1 log unit);
- Vapour pressure (value 3.51E-07 ± 1 log unit); and
- Wide range in the reported concentration levels of the substance in C/D.

The impact of varying each property within a suitable uncertainty range was explored independently. Refer to the figures below, which illustrate the impact on relevant predicted exposure concentrations. In respect of the concentration in the compost/digestate, the impact of varying the releases within the specified range was explored. In respect of the variable concentrations/releases, the inputs used in the 'more conservative' and 'less conservative' assessments is discussed in more detail in Appendix D.

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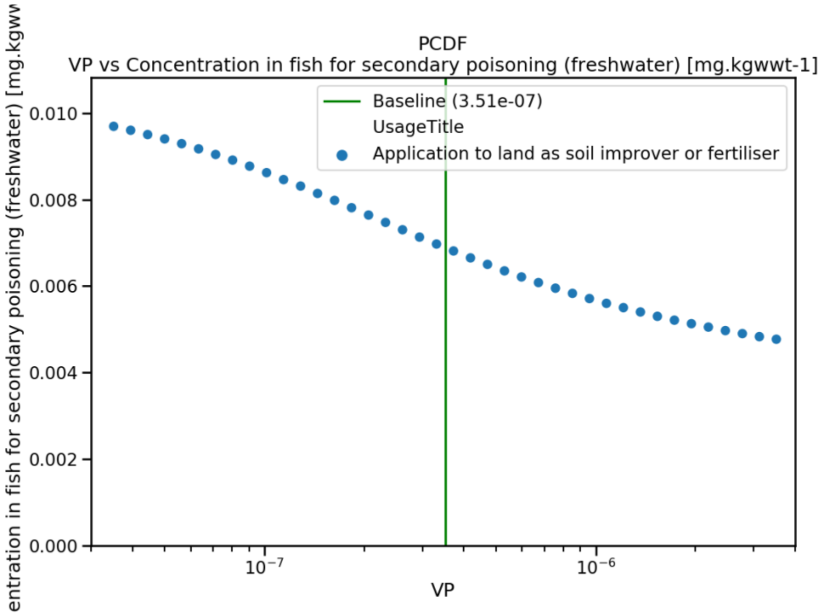
[77] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Figure 4.7 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the vapour pressure input value: diet of fish-eating birds and mammals



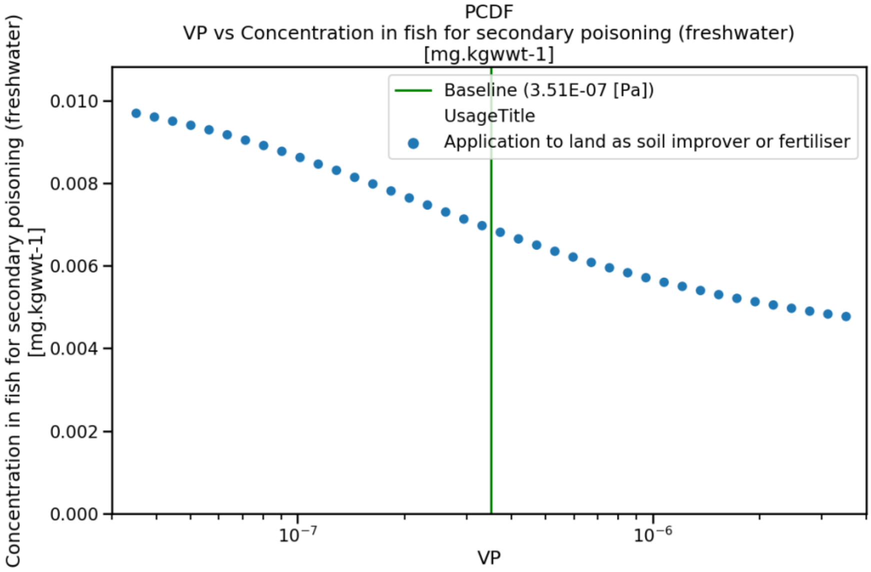


Figure 4.8 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the vapour pressure input value: diet of worm-eating birds and mammals

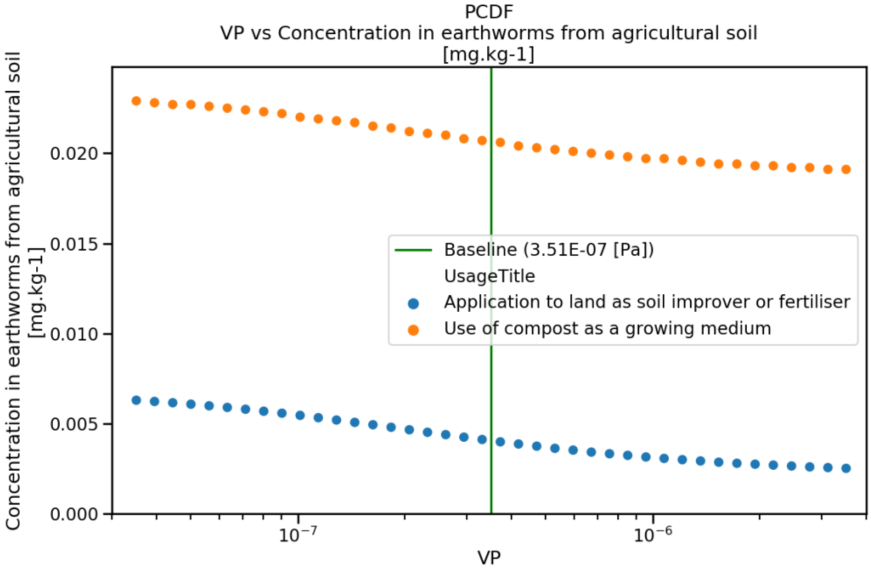
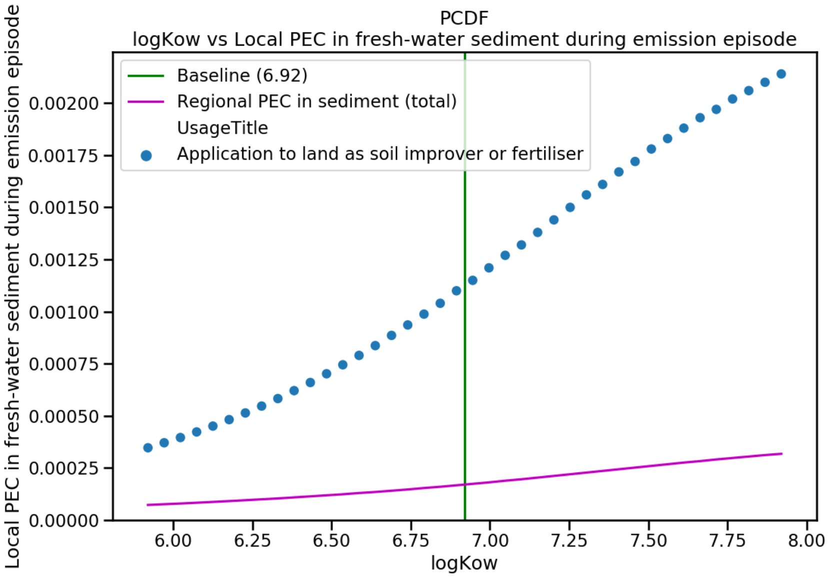


Figure 4.9 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the log Kow input value: fresh-water sediment



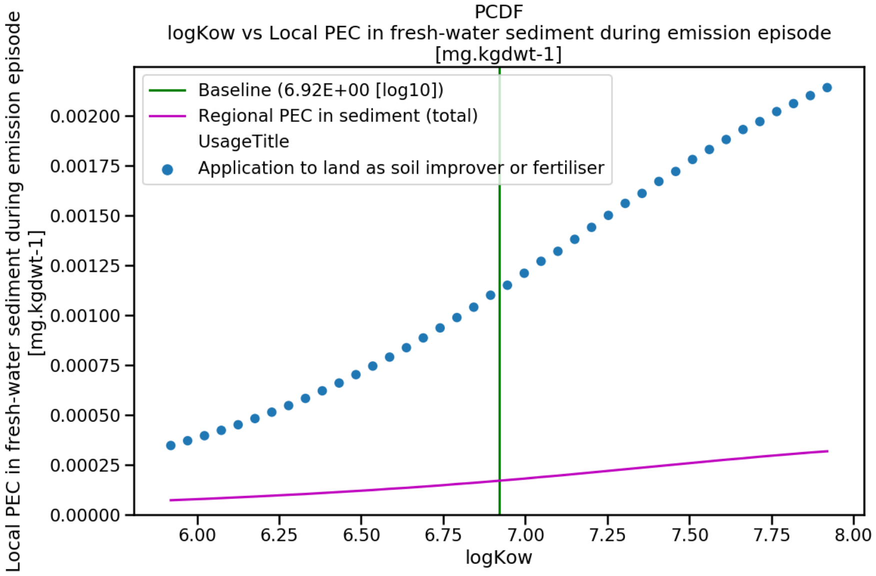


Figure 4.10 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the log Kow input value: diet of fish-eating birds and mammals

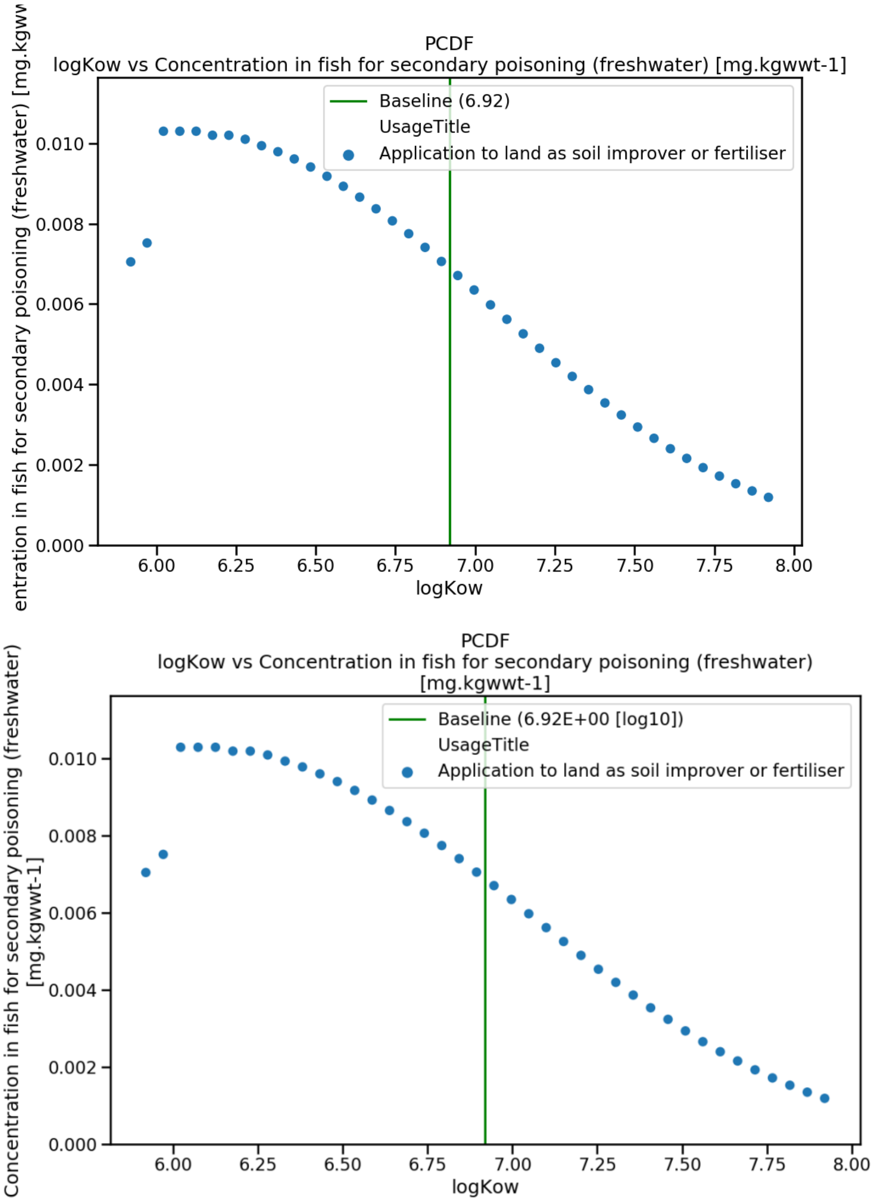
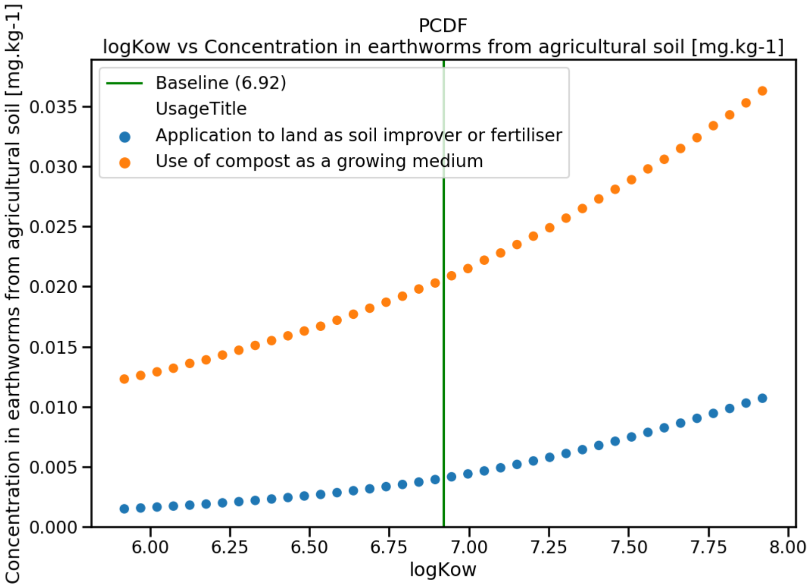
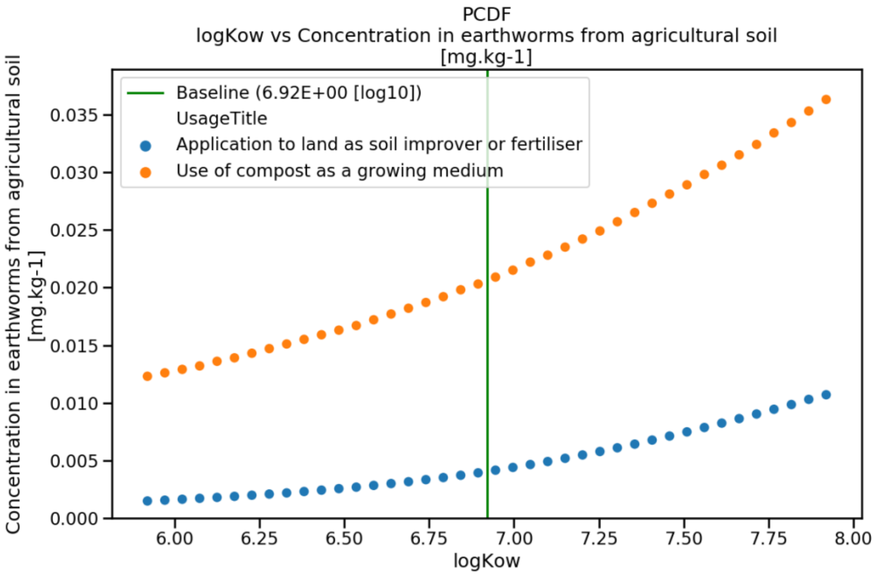


Figure 4.11 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the log Kow input value: diet of worm-eating birds and mammals





It can be concluded that:

- At the water solubility value used in the baseline assessment, all PECs have been estimated conservatively. Within the uncertainty range, some PECs could be higher, but some could be lower. The secondary poisoning exposure of worm-eating birds and mammals, and of fish-eating birds and mammals could have been significantly higher (up to 2x) than estimated in the baseline assessment, at lower Kow values and VP value or higher water solubility within a reasonable uncertainty range around the literature values.
- The local total daily intake via both exposure scenarios could have been significantly higher (up to 2x) than estimated in the baseline assessment, at lower Kow values or higher water solubility within a reasonable uncertainty range around the literature log Kow value.
- The secondary poisoning exposure of fish-eating birds and mammals (local scenario I), and sediment PECs, could be up to 2x higher at lower Kow values within a reasonable uncertainty range.

Table 4.15 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (general case)	Units
PECagricultural soil – local scenario I	3.14E-04	2.15E-05	[mg.kgdwt-1]
PECagricultural soil – local scenario II	4.03E-03	4.29E-04	[mg.kgdwt-1]
Humans via the environment: local total daily intake – local scenario I	1.08E-05	7.22E-07	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	1.17E-04	1.24E-05	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	4.88E+01	2.46E-03	[t]
Total steady-state mass fraction (region + continent)	5.87E+01	5.87E+01	[%]
Regional PEC in surface water (total)	1.40E-08	7.05E-13	[mg.l-1]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	6.89E-03	2.98E-04	[mg.kgwwt-1]
Secondary poisoning – worm-eating birds and mammals – local scenario I	4.05E-03	9.61E-05	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	2.06E-02	1.91E-03	[mg.kg-1]

It can be concluded that:

- At the local scale, the predicted exposure concentrations of 2,3,4,7,8-PCDF in important compartments differ by a factor of around x10-20.
- At the regional scale, the difference between the two scenarios is much more significant for 2,3,4,7,8-PCDF at more than 4 orders of magnitude.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.16 Summary of key findings for exposure of 2,3,4,7,8-PCDF via use of compost and digestates

Key findings of the risk assessment of 2,3,4,7,8-PCDF in contaminated composts and digestates	
Overall range of compost and digestate concentrations	7E-09 – 0.0145 mg/kg dw (total PCDD/PCDF).
Major raw material sources	Highest values are reported for sewage sludge composts and biowaste/green waste manure energy crop digestate.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP/PBT; significant cumulative loads at steady state; absolute concentrations exceeding previously published measured concentrations in foods; absolute concentrations in compost/digestate exceeding existing local limit values / guide values (but not exceeding EC Regulation 1195/2006); predator exposure via diet (local scenarios I and II) exceed the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	POP; basis of EQS is not stated in the Directive and is unclear.
Uncertainties and their implications	Very variable data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Variability in some important physicochemical input property data could be significant for PECs. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	None.

The findings and conclusions for 2,3,4,7,8-PCDF are to some extent in line with those set out for 2,3,7,8-TCDD in the previous section. However unlike for 2,3,7,8-TCDD, the models indicate that at steady state, ca. 59% of the total mass of 2,3,4,7,8-PCDF remains within the region + continent[78], suggesting that there is some potential for transfer over long distances following release via the handling and application of C/D[79]. The total mass in the region + continent at steady state is 49 t. When a comparable scenario is assessed using a lower level concentration in C/D within the reported range, the steady state mass is much lower at ca. 3 kg. This steady-state mass amounts to 970 times the mass released annually via application of composts and digestates[80].

The differences may be attributable to the apparent higher water solubility and lower Koc for 2,3,4,7,8-PCDF compared to 2,3,7,8-TCDD. The sensitivity of the assessment to possible uncertainty around the physicochemical input data confirm that the aquatic compartment and predator food chains especially may be affected by the uncertainty.

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[78] This refers to the regional and continental spatial scales in the EUSES model. Refer Section 1.7 of Appendix D for further information.

[79] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[80] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

4.4.13 2,4,4'-Trichlorobiphenyl (PCB28) (representative of PCBs chemical family)

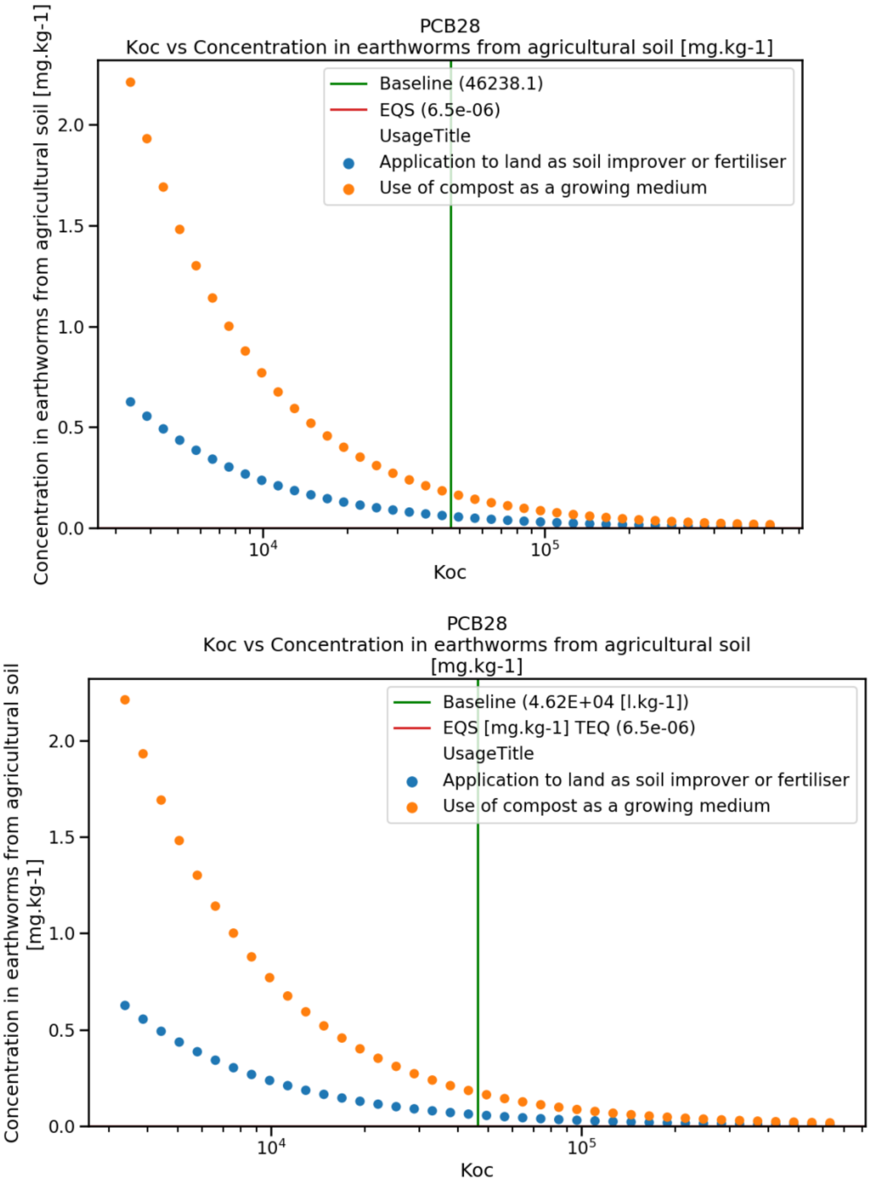
Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- BCF in fish (literature data range 2E+04 to 4E+05 l/kg);
- Koc (literature data range 3400 to 6.3E+05 l/kg); and
- log Kow (literature data range 4.4 to 5.9).

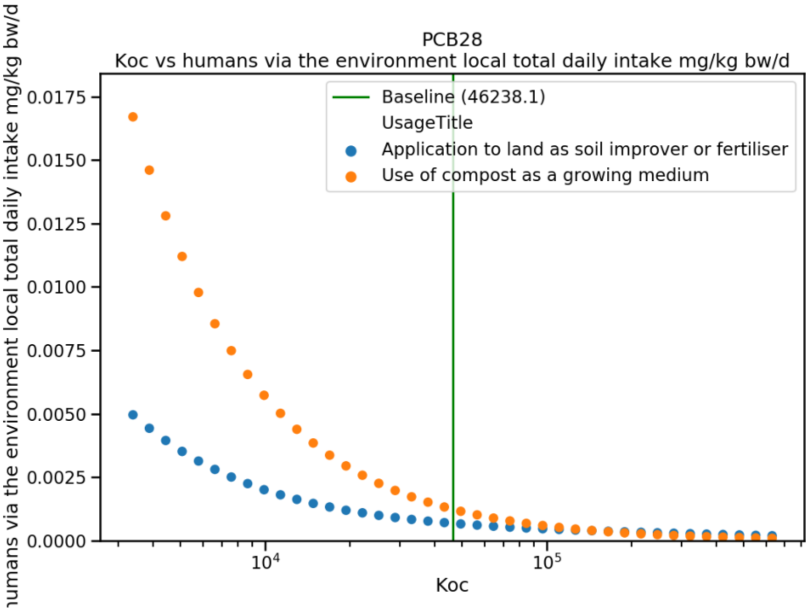
The impact of varying each property within the specified range was explored independently. Refer to the figures below, which illustrate the impact on relevant predicted exposure concentrations.

Figure 4.12 Sensitivity of selected outputs in the assessment of PCB28 to the Koc input value: diet of worm-eating birds and mammals



Note: the red line representing the EQS cannot be seen on this graph due to it overlapping the x-axis on this scale.

Figure 4.13 Sensitivity of selected outputs in the assessment of PCB28 to the Koc input value: total daily intake for humans



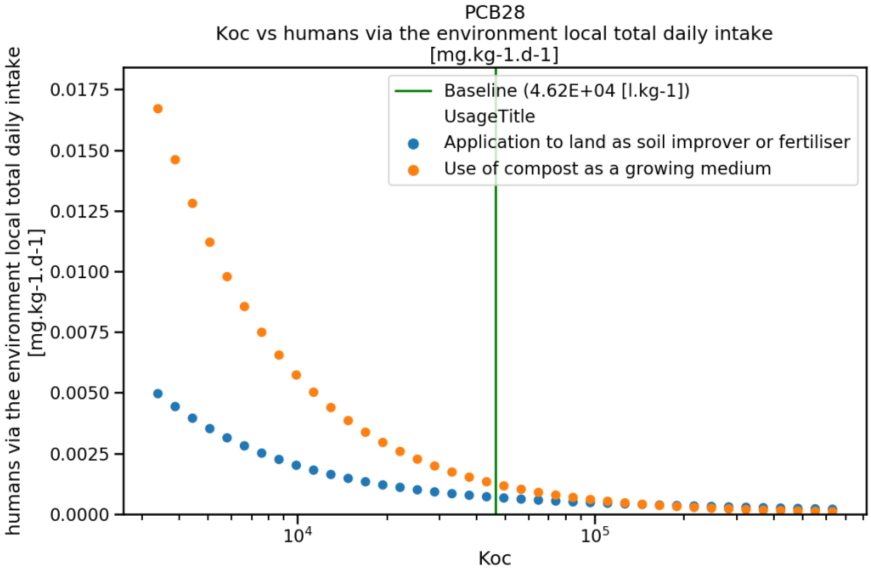
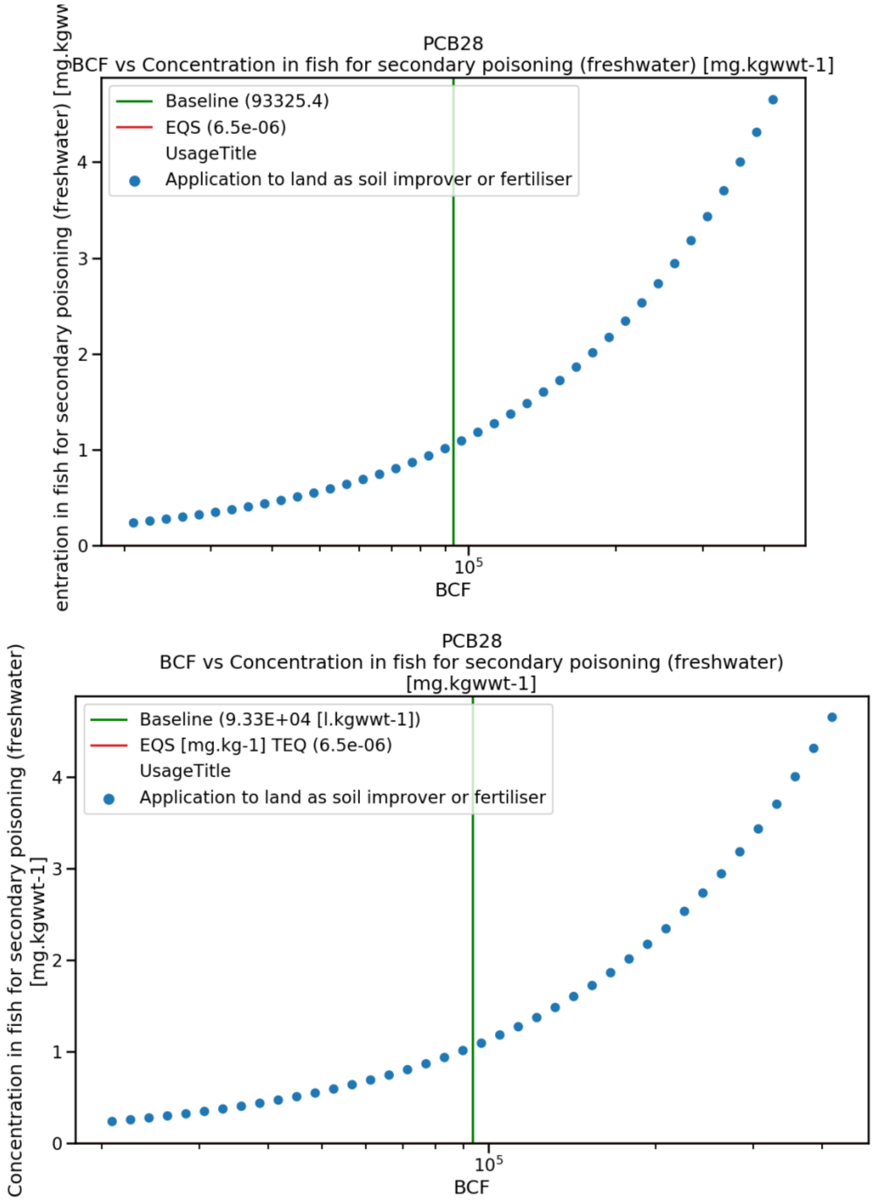


Figure 4.14 Sensitivity of selected outputs in the assessment of PCB28 to the BCF input value: diet of fish-eating birds and mammals



Note: the red line representing the EQS cannot be seen on this graph due to it overlapping the x-axis on this scale.

Figure 4.15 Sensitivity of selected outputs in the assessment of PCB28 to the log Kow input value: total daily intake for humans

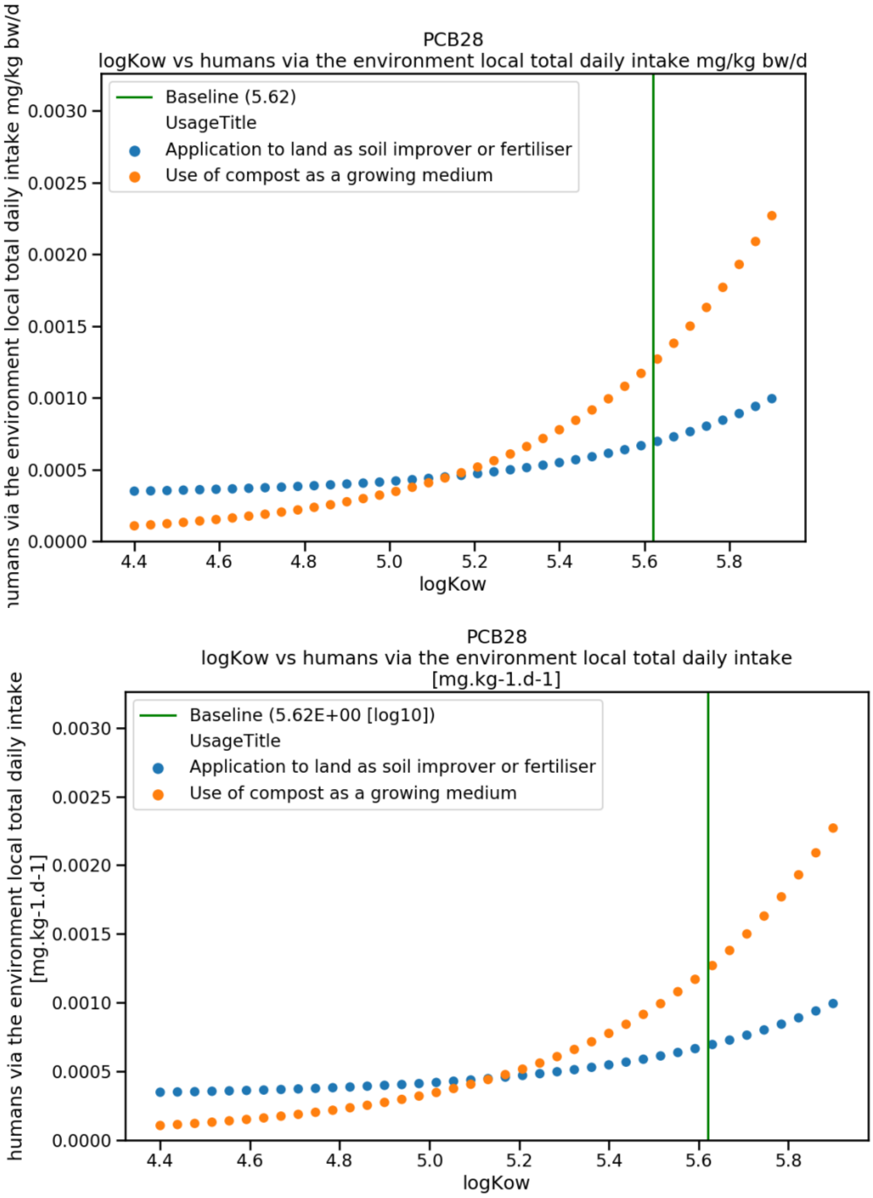
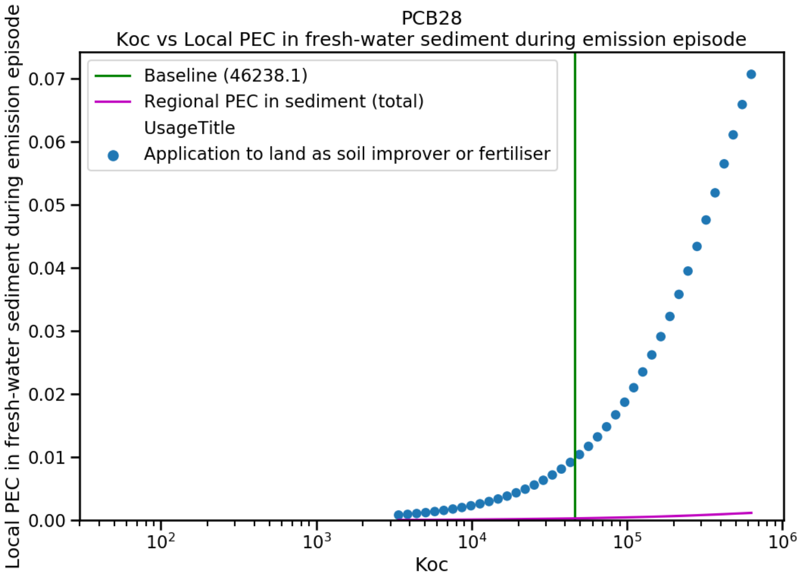
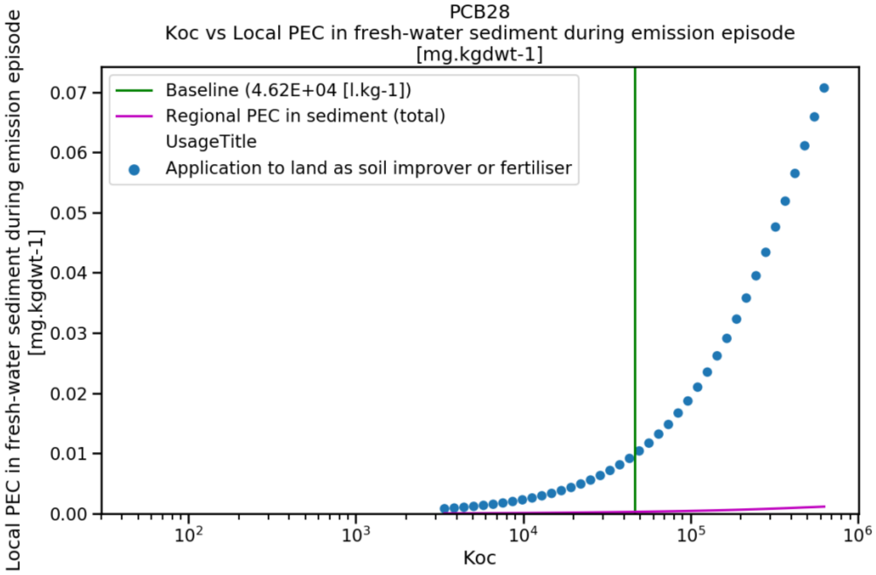


Figure 4.16 Sensitivity of selected outputs in the assessment of PCB28 to the Koc input value: fresh-water sediment





It can be concluded that:

- The variation in Koc input value is of particular significance for human dietary intake levels, sediment biota, and also predator exposure via diet (earthworms). In respect of predator exposure the modelled concentrations in prey exceed the EQS for biota at all values of Koc so the uncertainty does not affect the assessment conclusions.
- Within the literature data range of log Kow, there is an impact on the local total daily intake for humans; a relatively conservative value has been used but in the realistic worst case exposures could be up to 2x higher than modelled here.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.17 Summary of key findings for exposure of PCB-28 via use of compost and digestates

Key findings of the risk assessment of PCB-28 in contaminated composts and digestates	
Overall range of compost and digestate concentrations	0.001 – 1.2 mg/kg dw (higher values up to 9-10 mg PCB6/kg dw appear to be exceptional).
Major raw material sources	Concentrations above ca. 0.1 µg PCBs/kg dw are reported for digestates derived from biowaste-food and garden waste, biowaste and green waste compost, sewage sludge compost, C/Ds from source separation and compost made from low-grade waste wood.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP; significant cumulative loads at steady state; absolute concentrations exceeding previously published measured concentrations in foods; absolute concentrations in compost/digestate exceeding existing local limit values / guide values (but not exceeding EC Regulation 1195/2006); predator exposure via diet (local scenarios I and II) exceed the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	POP; basis of EQS is not stated in the Directive and is unclear.
Uncertainties and their implications	Range of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	None.

As POPs, it noteworthy that PCBs have been detected in freshly-produced composts and digestates at several different locations in recent years. Their presence may result from atmospheric deposition of emissions from combustion or municipal solid waste incineration rather than originating from the raw material waste streams. This is an area for possible future work.

The highest reported concentrations especially in digestates in Norway (reported by E. Govasmark et al., 2011) appear to significantly exceed the national limit value for PCBs in that region (Forskrift om organisk gjødsel; Mattilsynet, 2005; 1.2 mg/kg DM). These high occurrence concentrations seem to mainly relate to digestates prepared from biowastes food and garden wastes.

The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables. The estimated exposures arising from the application of C/D are high compared with reported mean/median levels of PCBs in foodstuffs including vegetables, in Western Europe as summarised by WHO (2002). This is the case even when lower concentrations were assumed in the exposure model (for example, the 'low concentration' exposure assessment for PCB28 results in concentrations of 2E-03 mg/kg and 0.03 mg/kg in root tissue of plants arising from application to land (local scenario I) and container growing (local scenario II) respectively. However, the WHO summary reports a weighted mean of 0.04 pg PCBs/g whole food (equivalent to 4E-08 mg/kg) for vegetable products.

At steady state, 97% of the total mass remains within the region + continent[81], suggesting that there is relatively low potential transfer over long distances following release via the handling and application of C/D[82]. The total mass in the region + continent at steady state is very high at 270 t. Even when a comparable scenario is assessed using a lower level release, ca. 15 t is modelled to remain within the region + continent at steady state. This steady-state mass amounts to 200 times the mass released annually via application of composts and digestates[83].

The consulted sources of property data show there is variation in some input properties. The sensitivity of the conclusions to this uncertainty has been investigated and it is noted that variation in the value of Koc and BCF particularly across the range given could be significant in respect of the predicted exposure concentrations in freshwater sediment, worm-eating predators via the food chain, and humans exposed via the environment. This is an important source of uncertainty in the exposure assessment.

4.4.14 Nonylphenol (representative of Nonylphenol and Nonylphenol Ethoxylates chemical family)

Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- Kow (reliable values within range 4.4 to 5.5); and
- wide range in the reported concentration levels of the substance in C/D.

The impact of varying these parameters within the specified range was explored. Refer to the figures below, which illustrate the impact on relevant predicted exposure concentrations. The inputs used in the 'more conservative' and 'less conservative' assessments are discussed in more detail in Appendix D.

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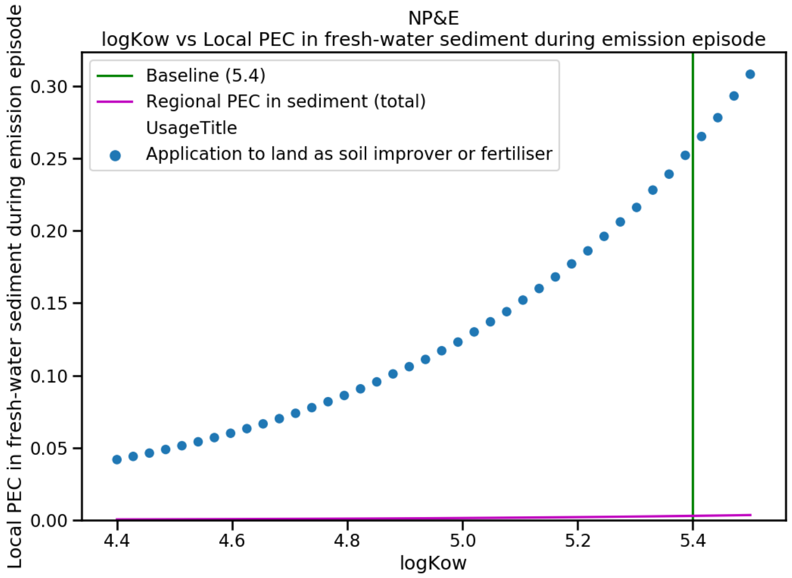
[81] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[82] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[83] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Figure 4.17 Sensitivity of selected outputs in the assessment of nonylphenol to the log Kow input value: freshwater sediment



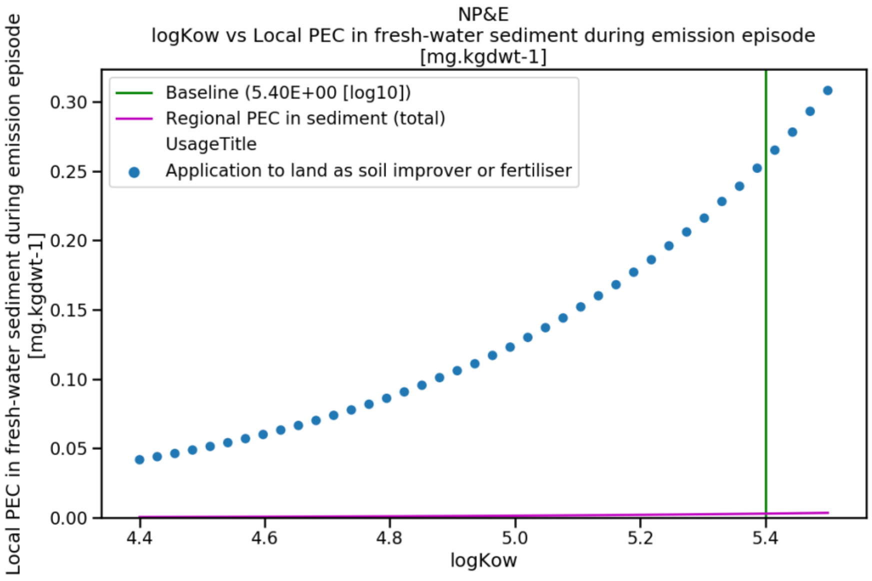


Figure 4.18 Sensitivity of selected outputs in the assessment of nonylphenol to the log Kow input value: diet of worm-eating birds and mammals

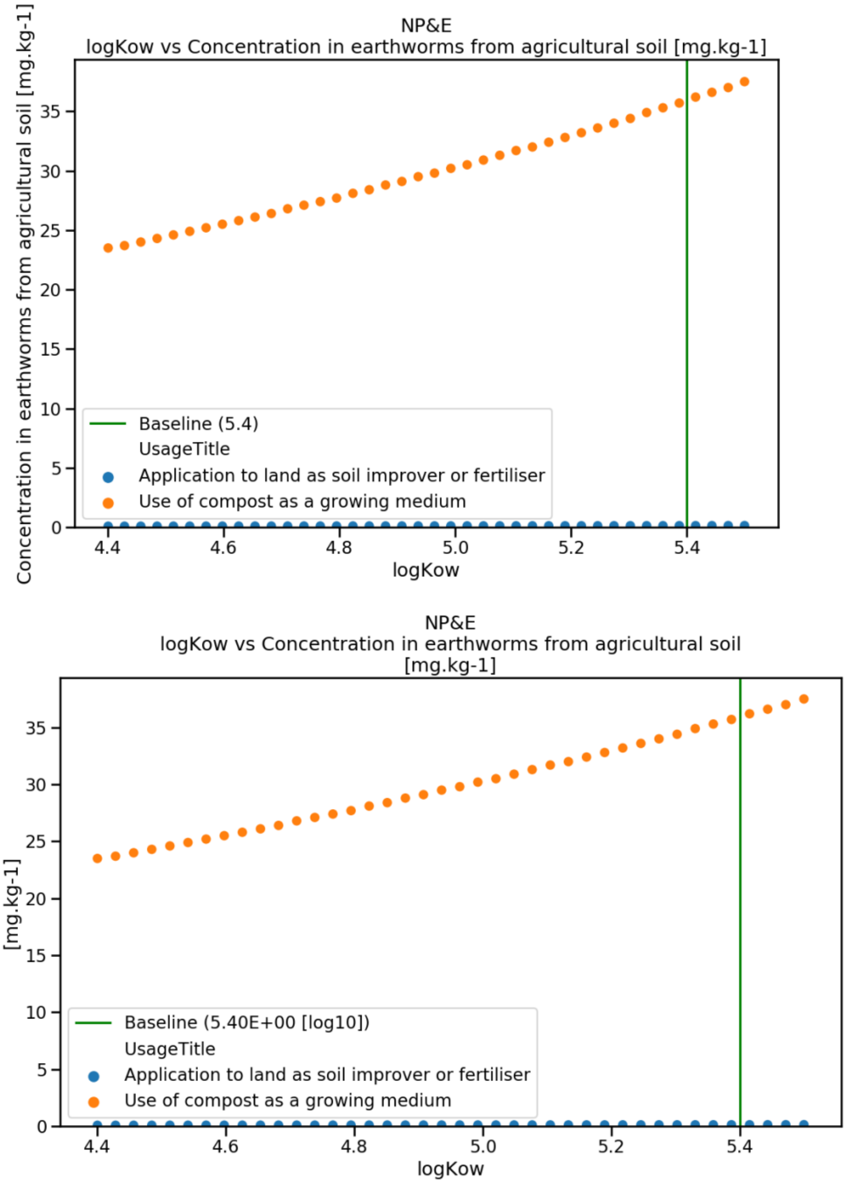


Table 4.18 Sensitivity of selected outputs in the assessment of nonylphenol to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (3.5 mg/kg dwt case)	Units
PECagricultural soil – local scenario I	8.38E-02	5.87E-03	[mg.kgdwt-1]
PECagricultural soil – local scenario II	1.55E+01	1.16E+00	[mg.kgdwt-1]
Humans via the environment: local total daily intake – local scenario I	1.15E-03	8.58E-05	[mg.kg-1.d-1]

	More conservative (realistic worst case)	Less conservative (3.5 mg/kg dwt case)	Units
Humans via the environment: local total daily intake – local scenario II	2.75E-01	2.05E-02	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	6.93E+01	6.59E+01	[t]
Total steady-state mass fraction (region + continent)	9.44E+01	9.44E+01	[%]
Regional PEC in surface water (total)	2.66E-06	2.53E-06	[mg.l-1]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	5.69E-02	6.84E-03	[mg.kgwwt-1]
Secondary poisoning – worm-eating birds and mammals – local scenario I	1.29E-01	1.09E-02	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	3.59E+01	2.68E+00	[mg.kg-1]

It can be concluded that:

1. If the lower log Kow value is correct then sediment PEC (local scenario I), secondary poisoning of worm-eating birds and mammals (local scenario II), and total local daily intake for humans could be lower than modelled. The baseline assessment is reasonably conservative.
2. At the local scale, limiting the concentration of nonylphenol in composts and digestates to a maximum of 3.5 mg/kg dwt could be expected to reduce the predicted exposure concentrations of nonylphenol in important compartments by a factor of more than 10 compared to the realistic worst case, sufficient to manage risks.
3. At the regional scale at steady state, the difference between the two scenarios is not very significant for nonylphenol.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.19 Summary of key findings for exposure of nonylphenol via use of compost and digestates

Key findings of the risk assessment of nonylphenol in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.1 - 50 mg/kg dw
Major raw material sources	Concentrations of ca. 10 mg/kg and above reported for green waste compost and municipal sewage sludge-derived products.
Safe limit concentration in compost and digestate	3.5 mg/kg dry wt for compost for container growing.
Main concern(s) arising	Soil organisms and worm-eating predators exposed via the food chain, both for compost for container growing. Significant cumulative loads at steady state. Source of exposure of humans via diet to endocrine disrupting substance.
Effects considered in the main concern hazard(s)	Soil PNEC based on enchytraeid reproductive effects. Predator PNECoral based on mammalian reproductive effects.
Uncertainties and their implications	Two alternative log Kow values are available and some protection targets are affected by the variation within the indicated range. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	It is noted that the container growing scenario is likely to be limited to exposure during a single growing season and in a container which may not be in contact with soil. It could be that the food chain envisaged by the model would not be fully established on this time scale.

The highest reported concentrations in C/D already appear to exceed the national limit value for digestates (AGW du 14/06/2001 favorisant la valorisation de certains déchets (BE), guide value of 25 mg/kg dw applicable in Belgium; Slambekendtgørelsen value 10 mg/kg dw applicable in Denmark). The high occurrence concentrations were found in digestates prepared from municipal sewage sludge (Finland, Kapanen et al., 2013) although several other similar digestates and composted sludges reported lower values (even from the same literature source).

To the extent that risk characterisation has been possible, unacceptable risks are indicated for the container growing scenario (local scenario II), specifically in respect of the local soil and secondary poisoning (in worm-eating birds and mammals) protection targets (RCRs of ca. 13 and 3.6 respectively). While risk characterisation for humans exposed via the environment has not been quantified, it is noted that the predicted local total daily intake associated with either mode of use (application on land or container growing), modelled to be in the range ca. 2E-03 – 0.3 mg/kg bw/d, is comparable with the daily human intake for local exposures associated with the various industrial use scenarios modelled in the ESR RAR (2002). Exposure of humans via the environment is significantly dominated by consumption of root crops.

The estimated regional exposures arising from the application of compost and digestate are very low compared with natural background concentrations in fresh water and sediments based on data cited in the ESR RAR (2008). The annual average EQS for inland surface waters (Directive 2008/105/EC as amended (2013/39/EU)) is not predicted to be exceeded.

It is notable that, at steady state, approximately 94% of the total mass remains within the region + continent[84], with the majority remaining within agricultural soil. This suggests that there is relatively low transfer over long distances following release via the handling and application of C/D[85].

The total mass in the region + continent at steady state is 69 t, when relatively conservative assumptions are made in regard to the concentration of nonylphenol in the compost/digestate. This steady-state mass amounts to 0.4 times the mass released annually via application of composts and digestates[86], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

The value of log Kow has been identified in the RAC/SEAC assessment (2014) as a key uncertainty, with possible impacts on various other parameters derived from it (particularly bioconcentration factor for earthworms and organic carbon adsorption coefficient Koc). In terms of the present assessment, it is noted that the two different values available for log Kow would indicate a relatively small difference in the predicted exposure concentrations in sediment (scenario I), although the PNEC is still not exceeded; and in the local total daily intake for humans exposed via the environment. This is therefore not considered to be an important source of uncertainty in the exposure assessment for these protection targets.

4.4.15 Benzo[a]pyrene (representative of PAH16 chemical family)

PAH are generated as by-products of combustion or pyrolysis of organic matter and hence almost always occur as mixtures. The PAH selected for substance-specific assessment are substances of higher molecular mass. There are precedents for assessing subgroups of PAH in regulatory contexts, and for use of certain PAH substances and small groups of PAHs as reference markers for the wider chemical family, to simplify analytical monitoring.

Sensitivity to specific variables

The main source of uncertainty in the assessment of this substance is the value of Koc. Several values covering an extremely wide range have been reported (log Koc 6.66 (LSC), Eadie et al. (1990); 6.26 (Average on sediments), Kayal & Connell (1990); 8.3 (Specified particulate), Broman et al. (1990), 4.0 (Predicted to be dissolved), Broman et al. (1990). The assessment in this project follows the approach used in the ESR RAR for coal tar pitch high temperature (log Koc 5.92, Karickhoff, 1979) but it is of interest to see how the variation across this range affects PECs resulting from these release scenarios.

- log Koc (range 4 to 8 as log values)

The impact of varying this property within the specified range was explored. Refer to the figures below, which illustrate the impact on relevant predicted exposure concentrations.

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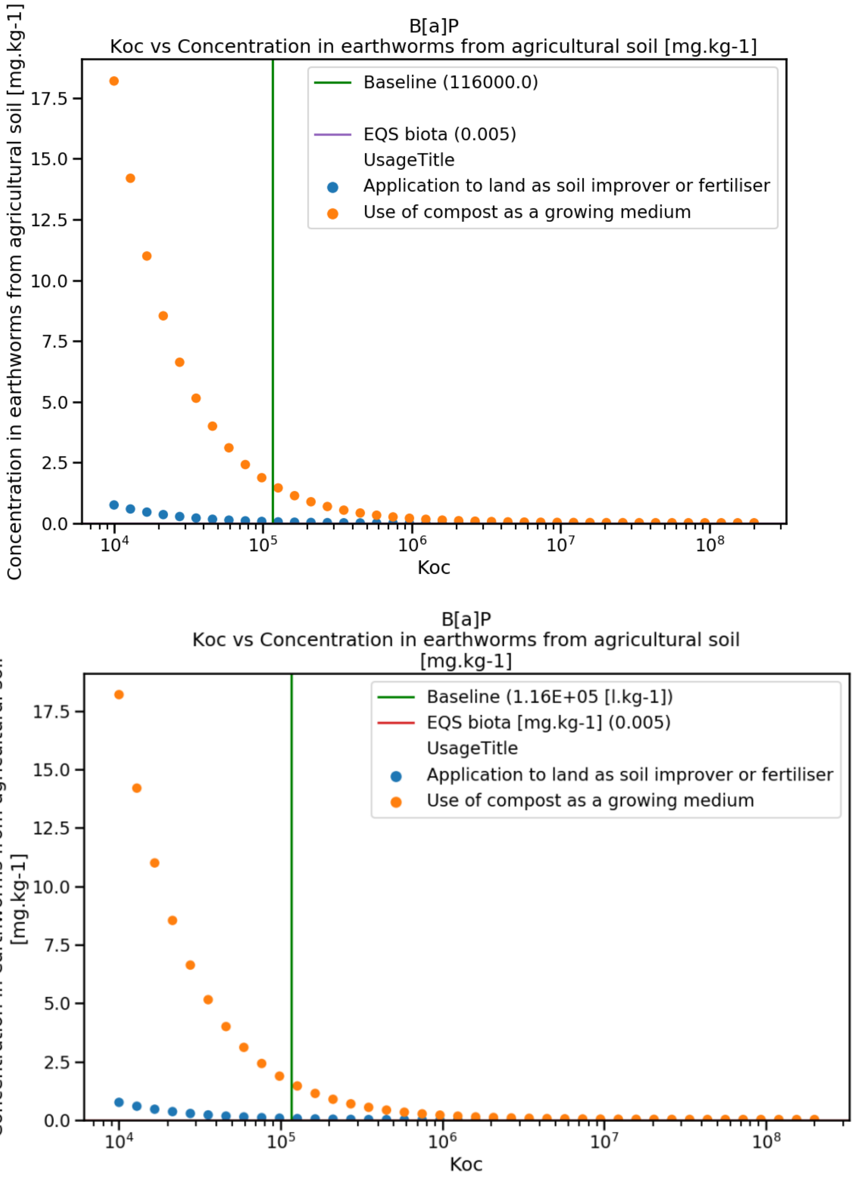
[84] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

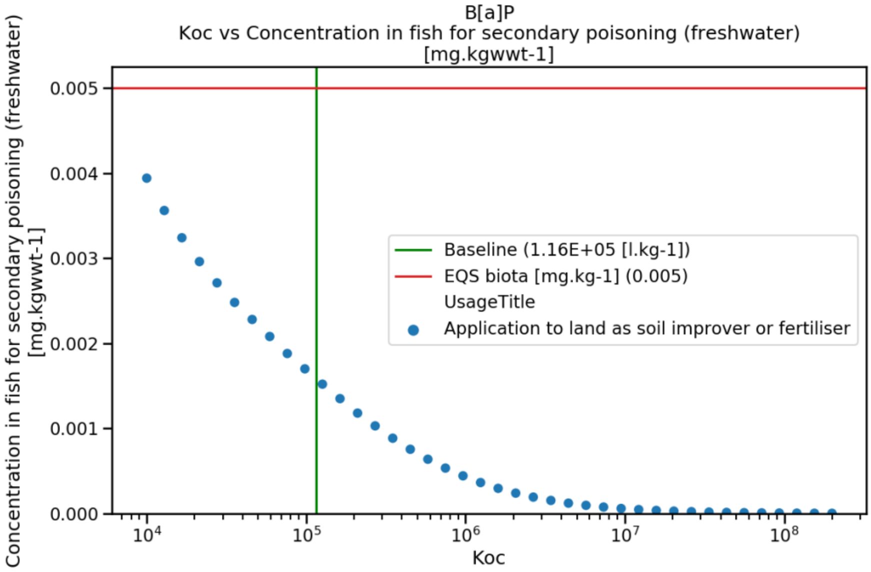
[85] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[86] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Figure 4.19 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: diet of worm- and fish-eating birds and mammals



Note: the red line representing the EQS cannot be seen on this graph due to it overlapping the x-axis on this scale.


B[a]P
Koc vs Concentration in fish for secondary poisoning (freshwater) [mg.kgwwt-1]
Concentration in fish for secondary poisoning (freshwater) [mg.kgwwt-1]
0.005
0.004
0.003
0.002
0.001
0.000
10^4
10^5
10^6
10^7
10^8
Koc
Baseline (1.16E+05 [l.kg-1])
EQS biota [mg.kg-1] (0.005)
UsageTitle
Application to land as soil improver or fertiliser

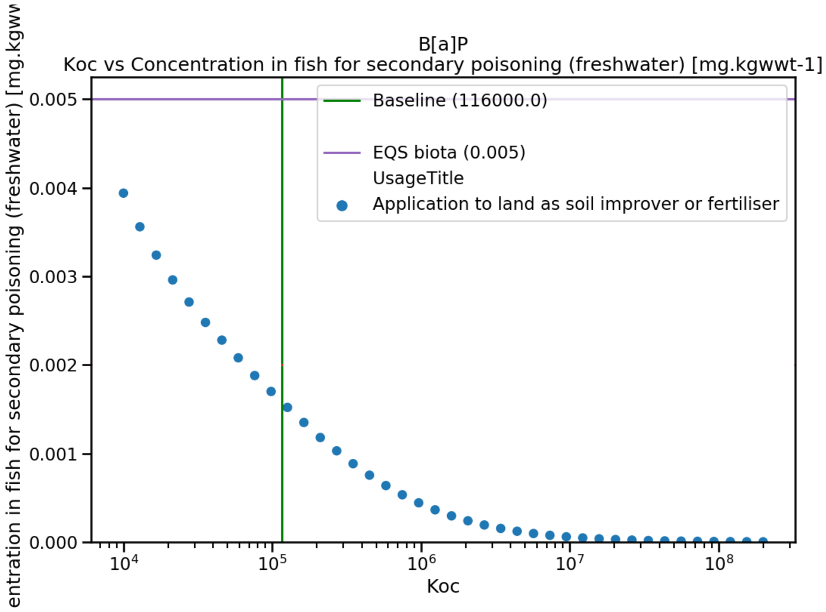
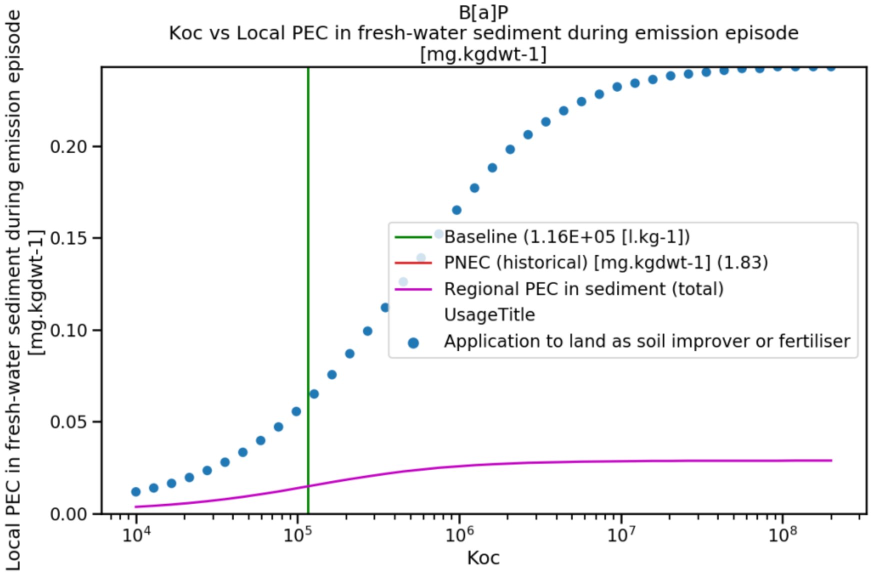

B[a]P
Koc vs Concentration in fish for secondary poisoning (freshwater) [mg.kgwwt-1]
entration in fish for secondary poisoning (freshwater) [mg.kgww
0.005
0.004
0.003
0.002
0.001
0.000
10^4
10^5
10^6
10^7
10^8
Koc
Baseline (116000.0)
EQS biota (0.005)
UsageTitle
Application to land as soil improver or fertiliser

Figure 4.20 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: freshwater sediment



Note: the red line representing the PNEC cannot be seen on this graph due to it exceeding the maximum value of the y-axis on this scale.

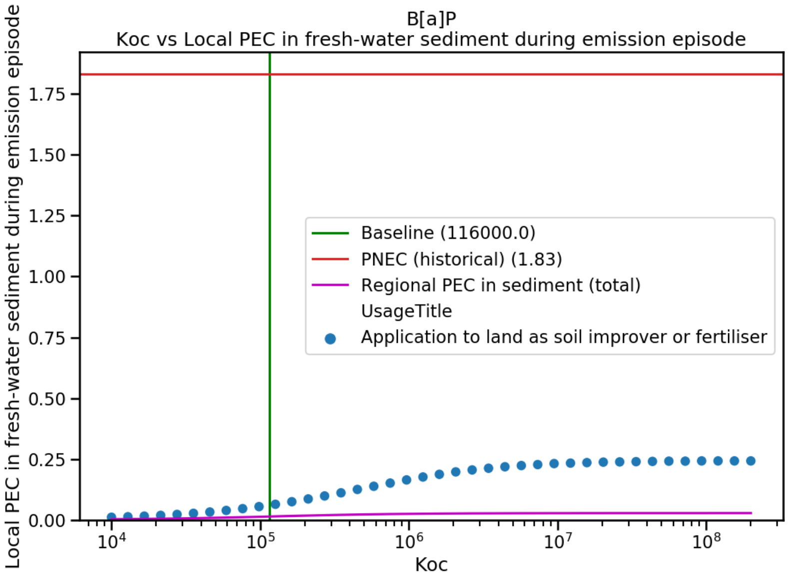
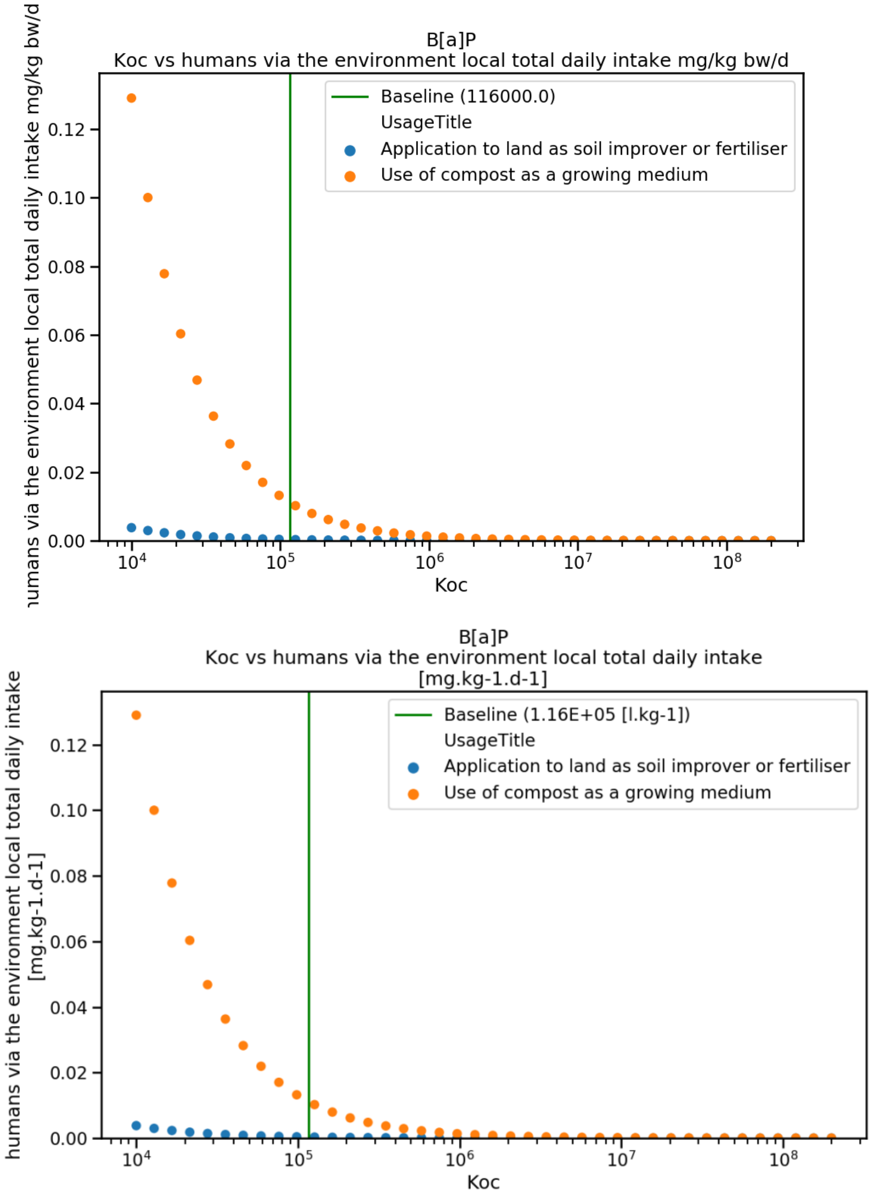


Figure 4.21 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: human daily intake



It can be concluded that:

- Secondary poisoning exposure of fish-eating birds and mammals (local scenario I) could vary significantly with the value of Koc within the literature range and could be up to 4x higher than in the baseline assessment made here, as shown in figure 2.19. However, exposure of worm-eating birds and mammals resulting from application of composts and digestates in either local scenario is in any case much higher and exceeds the existing EQS for biota.
- The local total daily intake via both exposure scenarios could have been significantly higher (up to 10x) than estimated in the baseline assessment, at lower Koc values within the literature range.
- The PEC in sediment from the application on land scenario could be significantly higher (up to 2x) than estimated in the baseline assessment, at higher Koc values within the literature range. Even the highest concentrations are however still well below the historical PNEC for sediment organisms (as applied in the ESR RAR for CTPHT, though a quantified PNEC may no longer be appropriate given the hazards of the substance).

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.20 Summary of key findings for exposure of benzo[a]pyrene via use of compost and digestates

Key findings of the risk assessment of benzo[a]pyrene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04 – 0.52 mg benzo[a]pyrene/kg dw, <0.3 – 20.8 mg PAH/kg
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, C/D from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state; PEC in surface water (at regional scale and local scenario I) exceeds the annual average EQS for benzo[a]pyrene as a marker for total PAH (2013); predator exposure via diet (local scenarios I and II) exceed the EQS for biota benzo[a]pyrene as a marker for total PAH (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for benzo[a]pyrene specifically means that the exposure levels may be under- or over-estimated by the present assessment; exposures of humans via diet, predators via the food chain, sediment organisms could be sensitive to variability in Koc value. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

While risk characterisation has not been quantified, it is noted that the predicted exposures in fresh water arising from the application of composts/digestates on soil (local scenario I) exceed the safe limit (annual average inland surface water EQS for benzo[a]pyrene as a marker for total PAH set under Directive 2008/105/EC (EU, 2008) as amended by Directive 2013/39/EU (EU, 2013)) (the MAC EQS applicable for benzo[a]pyrene specifically is not exceeded).

It is noted that predator exposure via diet (earthworms) (local scenarios I and II) exceed the EQS for biota benzo[a]pyrene as a marker for total PAH (Directive 2008/105/EC as amended (2013/39/EU)) although this biota EQS normally relates to crustaceans and molluscs.

It is noted that the human exposures to PAH arising from the application of composts/digestates on soil do not exceed the BMDL10 value either in terms of benzo[a]pyrene alone, total for PAH2 or total for PAH4.

The estimated regional concentrations in vegetables arising from the application of C/D are comparable with the background concentrations reported by WHO in the EHC monograph 202 (1998). Local predicted concentrations of all assessed PAH in root crops are notably higher than the background levels (discussed in more detail in the methodology section of the draft final report) but predicted regional concentrations are close to the reported measured concentrations. Predicted local concentrations of the assessed PAH in leaf crops are generally similar to or lower than the reported levels.

The highest contributions to human exposure of PAH via the environment arising from the application of C/D is mainly associated with dietary consumption of fish (associated with local scenario I, application on land) and dietary consumption of root vegetables (local scenario II, container growing).

At steady state, between 96-99% of the total mass of each assessed PAH remains within the region + continent[87], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D[88].

The total mass in the region + continent at steady state varies between ca 14 t (indeno(123-cd)pyrene) and ca 170 t (benzo[b]fluoranthene). The reported concentrations in composts and digestates does not cover a large range meaning that when a comparable scenario is assessed using lower concentrations in the C/D within the reported range, the steady state masses are not significantly lower. For all five of the assessed PAHs, the steady-state mass amounts to approximately 8 times the mass released annually via application of composts and digestates[89].

The variability in input properties has been considered. It is noted that variation in the Koc value of benzo[a]pyrene could suggest that the exposures of humans via diet, predators via the food chain, sediment organisms could be sensitive to the uncertainty in this value.

4.4.16 Chrysene (representative of PAH16 chemical family)

Summary of findings

Table 4.21 Summary of key findings for exposure of chrysene via use of compost and digestates

Key findings of the risk assessment of chrysene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04 – 0.61 mg chrysene/kg dw, <0.3 – 20.8 mg PAH/kg
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, C/D from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for chrysene specifically means that the exposure levels may be under- or over-estimated by the

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[87] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[88] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[89] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Key findings of the risk assessment of chrysene in contaminated composts and digestates	
	present assessment; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 4.4.15.

4.4.17 Benz[a]anthracene (representative of PAH16 chemical family)

Summary of findings

Table 4.22 Summary of key findings for exposure of benz[a]anthracene via use of compost and digestates

Key findings of the risk assessment of benz[a]anthracene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04 – 0.33 mg benz[a]anthracene/kg dw, <0.3 – 20.8 mg PAH/kg.
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, C/D from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for benz[a]anthracene specifically means that the exposure levels may be under- or over-estimated by the present assessment, particularly for digestate for which no values were found; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 4.4.15.

4.4.18 Benzo[b]fluoranthene (representative of PAH16 chemical family)

Summary of findings

Table 4.23 Summary of key findings for exposure of benzo[b]fluoranthene via use of compost and digestates

Key findings of the risk assessment of benzo[b]fluoranthene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	0.12-2.14 mg benzo[b]fluoranthene/kg dw, <0.3 – 20.8 mg PAH/kg.
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, C/D from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for benzo[b]fluoranthene specifically means that the exposure levels may be under- or over-estimated by the present assessment, especially for digestate where no values were found; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 4.4.15.

4.4.19 Indeno(1,2,3-cd)pyrene (representative of PAH16 chemical family)

Summary of findings

Table 4.24 Summary of key findings for exposure of indeno[123-c,d]pyrene via use of compost and digestates

Key findings of the risk assessment of indeno[123-c,d]pyrene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04-2.32 mg indeno[123-c,d]pyrene /kg dw, <0.3 – 20.8 mg PAH/kg.
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, C/D from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.

Key findings of the risk assessment of indeno[123-c,d]pyrene in contaminated composts and digestates	
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for indeno[123-c,d]pyrene specifically means that the exposure levels may be under- or over-estimated by the present assessment, particularly for digestate for which no values were found; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 4.4.15.

4.4.20 Perfluoroctanoic acid (PFOA) (representative of PFAs chemical family)

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is 18% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be potentially significant.

Summary of findings

Table 4.25 Summary of key findings for exposure of PFOA via use of compost and digestates

Key findings of the risk assessment of PFOA in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<2E-03 - ≤0.165 mg/kg dw.
Major raw material sources	PFOA/PFOS measured above ca 0.01 mg/kg in C/D from source separation, bio-waste & green waste compost, green waste compost, sewage sludge compost, "mechanical biological treatment compost", bio-waste & green waste manure energy crops digestate, "mechanical biological treatment digestate".
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of a POP; humans exposed via the environment (especially via diet and drinking water); possible transfer over long distances.
Effects considered in the main concern hazard(s)	Proposed POP; human TDI based on mammalian liver toxicity.
Uncertainties and their implications	Small occurrence data sets for PFOA specifically, and almost all stated values are less-than limit values. Sensitivity of exposures to variations in water management in the local container growing scenario is potentially significant. In circumstances where a) the system is watered in excess of the water holding capacity of the growing medium and b) where the

Key findings of the risk assessment of PFOA in contaminated composts and digestates	
	container design means that excess water will drain away and not remain in contact with the container/growing medium, then a significant proportion of the substance could be lost from the system in the drained water.
Other remarks	None.

As a proposed POP, it is in itself a potentially important finding that PFOA or other PFAs have been detected in freshly-produced composts and digestates at several different locations in recent years. The raw material waste streams could be investigated further. However, the reported concentrations in composts and digestates do not exceed the national limit values according to the data collected in this project.

While risk characterisation has not been quantified, it is noted that the predicted exposures of humans in the form of local total daily intake associated with local exposure when used for container growing could exceed the safe limit (TDI) based on the value derived by MST (2015).

The estimated regional-scale predicted environmental concentrations in surface water, ground water and agricultural soil arising from the application of C/D are within the range of the literature concentrations presented in this section compared with natural background concentrations based on ECHA (2014). The estimated environmental concentration in groundwater is above the Drinking Water Directive proposal limit for each individual PFAS substance in drinking water (0,1 µg/l), but below the proposed limit for the sum of PFAS substances (0.5 µg/l). The estimated environmental concentration in freshwater is well below the Drinking Water Directive proposal limits.

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables; exposure via drinking water is also high for local scenario I (application on land).

At steady state, <1% of the total mass remains within the region + continent[90], suggesting that there is high potential for transfer over long distances following release via the handling and application of C/D[91]. Global scale modelling within EUSES suggests that at the steady state, the majority of the substance would be found in global tropic waters (56%), moderate waters (26%) and arctic waters (17%). The total mass in the region + continent at steady state is <10 t in the baseline scenario. This steady-state mass amounts to 4.4 times the mass released annually via application of composts and digestates[92].

4.4.21 Perfluoroctanesulfonic acid (PFOS) (representative of PFAs chemical family)

Summary of findings

Table 4.26 Summary of key findings for exposure of PFOS via use of compost and digestates

Key findings of the risk assessment of PFOS in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<2E-03 - ≤0.165 mg/kg dw.

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[90] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[91] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[92] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Key findings of the risk assessment of PFOS in contaminated composts and digestates	
Major raw material sources	PFOA/PFOS measured above ca 0.01 mg/kg in C/D from source separation, bio-waste & green waste compost, green waste compost, sewage sludge compost, "mechanical biological treatment compost", bio-waste & green waste manure energy crops digestate, "mechanical biological treatment digestate".
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of a POP; Humans exposed via the environment (especially via diet and drinking water); possible transfer over long distances. Highest reported concentrations are limit values, but could exceed the guidance level of 100 µg/kg dw. Local and regional PECs exceed the annual average EQS.
Effects considered in the main concern hazard(s)	POP; human TDI based on mammalian liver toxicity; Basis of the EQS is not stated in the Directive but is understood to relate to accumulation in fish.
Uncertainties and their implications	Almost all stated values are less-than limit values. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	None.

As a POP, it is in itself a potentially important finding that PFOS has been detected in freshly-produced composts and digestates at several different locations in recent years. The raw material waste streams could be investigated further. The highest among the reported concentrations in composts and digestates exceed the national limit values according to the data collected in this project.

While risk characterisation has not been quantified, it is noted that the predicted exposures of humans in the form of local total daily intake associated with both types of use could exceed the safe limit (TDI) based on the values derived by EFSA (2008) and MST (2015).

The estimated regional-scale predicted environmental concentrations in surface water, ground water and agricultural soil arising from the application of C/D appear to be low compared to the measured background concentrations quoted by EA (2004). The estimated environmental concentrations in groundwater and freshwater are well below the Drinking Water Directive proposal limit for each individual PFAS substance (0.1 µg/l) in drinking water and for the sum of PFAS substances (0.5 µg/l).

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

At steady state, 5% of the total mass remains within the region + continent[93], suggesting that there is high potential for transfer over long distances following release via the handling and application of C/D[94]. The majority of the substance is modelled to be present in global tropic waters (54%) at steady state followed by moderate waters (25%) and arctic waters (16%). The total mass in the region + continent at steady state is 28 t in the baseline scenario. This steady-state mass amounts to 25 times the mass released annually via application of composts and digestates[95].

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[93] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[94] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[95] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

4.4.22 PFHxA (representative of PFAs chemical family)

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is 2.7% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 4.27 Summary of key findings for exposure of PFHxA via use of compost and digestates

Key findings of the risk assessment of PFHxA in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<2E-03 - ≤0.165 mg/kg dw
Major raw material sources	PFOA/PFOS measured above ca 0.01 mg/kg in C/D from source separation, bio-waste & green waste compost, green waste compost, sewage sludge compost, "mechanical biological treatment compost", bio-waste & green waste manure energy crops digestate, "mechanical biological treatment digestate".
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of a proposed SVHC; Humans exposed via the environment (especially via diet and drinking water); possible transfer over long distances.
Effects considered in the main concern hazard(s)	Proposed SVHC under the REACH Regulation on the basis of a large number of equivalent concern factors.
Uncertainties and their implications	No data available for PFHxA specifically, and almost all stated values are less-than limit values. Sensitivity of exposures to variations in water management in the local container growing scenario is low. In circumstances where a) the system is watered in excess of the water holding capacity of the growing medium and b) where the container design means that excess water will drain away and not remain in contact with the container/growing medium, then a small proportion of the substance could be lost from the system in the drained water.
Other remarks	None.

The estimated regional-scale predicted environmental concentrations in surface water, ground water and agricultural soil arising from the application of C/D are close to the range of the literature concentrations presented in the Occurrence data set section based on ECHA (2018).

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

At steady state, 31.7% of the total mass remains within the region + continent[96], suggesting that there is some potential for transfer over long distances following release via the handling and application of C/D[97]. A significant proportion of the substance is modelled to be present in global tropic waters (29%) at steady state. The total mass in the region + continent at steady state is 12.5 t in the baseline scenario. This steady-state mass amounts to 11 times the mass released annually via application of composts and digestates[98].

4.4.23 Microplastics

Summary of findings

In considering these findings readers should note that EUSES is not designed to model distribution of particulates which severely restricts the use in this project. Findings are indicative only.

Table 4.28 Summary of key findings for exposure of microplastics via use of compost and digestates

Key findings of the risk assessment of microplastics in contaminated composts and digestates	
Overall range of compost and digestate concentrations	14 – 146 particles/kg dw.
Major raw material sources	All reported data relate to composts and digestates prepared from household biowaste combined with green clippings and some energy crops.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	A potentially important source of microplastic exposure of the environment via wastewater treatment plant sludge (with possible consequent human exposure to microplastics via the environment).
Effects considered in the main concern hazard(s)	No quantitative assessment of hazard was applied in this assessment.
Uncertainties and their implications	Quantitative exposure of humans and predators via the food chain cannot be reliably modelled using the present methods. Steady state exposures are not reliable and not presented. Wastewater treatment digestate could potentially contain higher concentrations of particles; data were not found in this project. Sensitivity of exposures to variations in water management in the local container growing scenario cannot be modelled.
Other remarks	Other sources of microplastics release appear to be much higher than exposure via composts and digestates, although use of digestate obtained from sewage sludge could be an important source of microplastics for the soil.

The exposures of soil and sediment arising from the application of C/D estimated in the present model are very low compared with the PECs modelled in the recent risk assessment of exposures arising from a range of industrial and consumer uses (Wood 2017). However the assessment does not cover the possible release of

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[96] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 of Appendix D for further information.

[97] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[98] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

microfibres released by washing of textiles. While exposure of man via the environment arising from the use of compost and digestate is very low compared to other sources, the occurrence data used in this assessment is largely based on household biowaste-derived products rather than WWTP digestates. ECHA reports that sewage sludge could be an important source of emissions of microplastics to the soil (ECHA 2018a).

Exposure of humans via root and leaf crops in the diet is possible, however (similarly to the EC 2017 exposure assessment), the washing of vegetables and peeling of root vegetables would be expected to limit levels of human consumption.

Cattle could ingest contaminated soil adhering to the grass, and therefore the exposure of cattle will be related to the concentration in soil, however (in line with EC, 2017) the assessment assumes that this remains within gut contents and passes through the cattle without entering into meat or milk. This indicates that human exposure via these foodstuffs is negligible.

The occurrence data found in this project suggest use of composts and digestates contributes an overall total release of 3650 billion microplastic particles per year in the region plus continent, however it is not feasible using EUSES to model the multimedia fate, distribution and flux of particles following release.

4.4.24 Conclusions

A further summary and conclusion regarding the identified risks, across all assessed substances, is provided in Section 5.2 for the purpose of potential risk management.

5. Risk management option analysis

5.1 Overview

The aim of the risk management option analysis (RMOA) is to identify the most appropriate regulatory instrument for possible risk management activities to address the concerns related to contaminants in C/D used as fertilisers. As such, it covers a range of different substances and physical components (together "contaminants") present in feedstock supply for anaerobic digestion (AD) and aerobic composting plants and, consequently, as impurities in digestate and compost. This is based on the identification and prioritisation of contaminants of concern in Section 3, as well as the assessment of the risks posed by the contaminants when present in C/D used as fertilisers (Section 4).

The structure of this section is based on ECHA guidance[99] but has been adapted given its focus on a range of substances and physical components. This approach was discussed during the interim meeting of this project (17 May 2018). An adapted RMOA format was presented in a progress note (of 17 July 2018) and agreed with the European Commission. The RMOA is structured as follows:

- First, Section 5.2 briefly summarises the risks to be addressed, based on the results from the substance identification (Section 3) and risk assessment (Section 4).
- Section 5.3 puts this into the context of the European market for C/D (based on the market analysis in Section 2), in order to conclude on the geographical spread and scale of the problem.
- Section 5.4 provides an overview of existing risk management to assess the extent to which the risks are already addressed.
- Potential risk management options are presented and assessed in Section 5.5. This includes their effectiveness in controlling the risks and other regulatory considerations (e.g. regulatory consistency and practicalities of enforcement).
- Preliminary socio-economic considerations are covered in Section 5.6. Likely 'response scenarios' for producers and users of digestate and compost in the case of each risk management option are assessed. Their associated costs are estimated, including the costs and benefits of using potential alternative products and techniques to reduce the risks from contaminants in C/D.
- Finally, Section 5.7 draws conclusions based on the assessment of risk management options and preliminary socio-economic considerations.

5.2 Summary of identified risk

This section summarises the identified risks prioritised for potential management. This is based on the results from the substance identification (Section 3) and risk assessment (Section 4).

Conventional quantitative risk characterisation was carried out where possible. For some substances this has identified a potential risk. This is the case where in the realistic worst case, concentrations found in compost and/or digestate exceed safe limits[100]. The safe limits, and thus the risks, can vary for the two investigated

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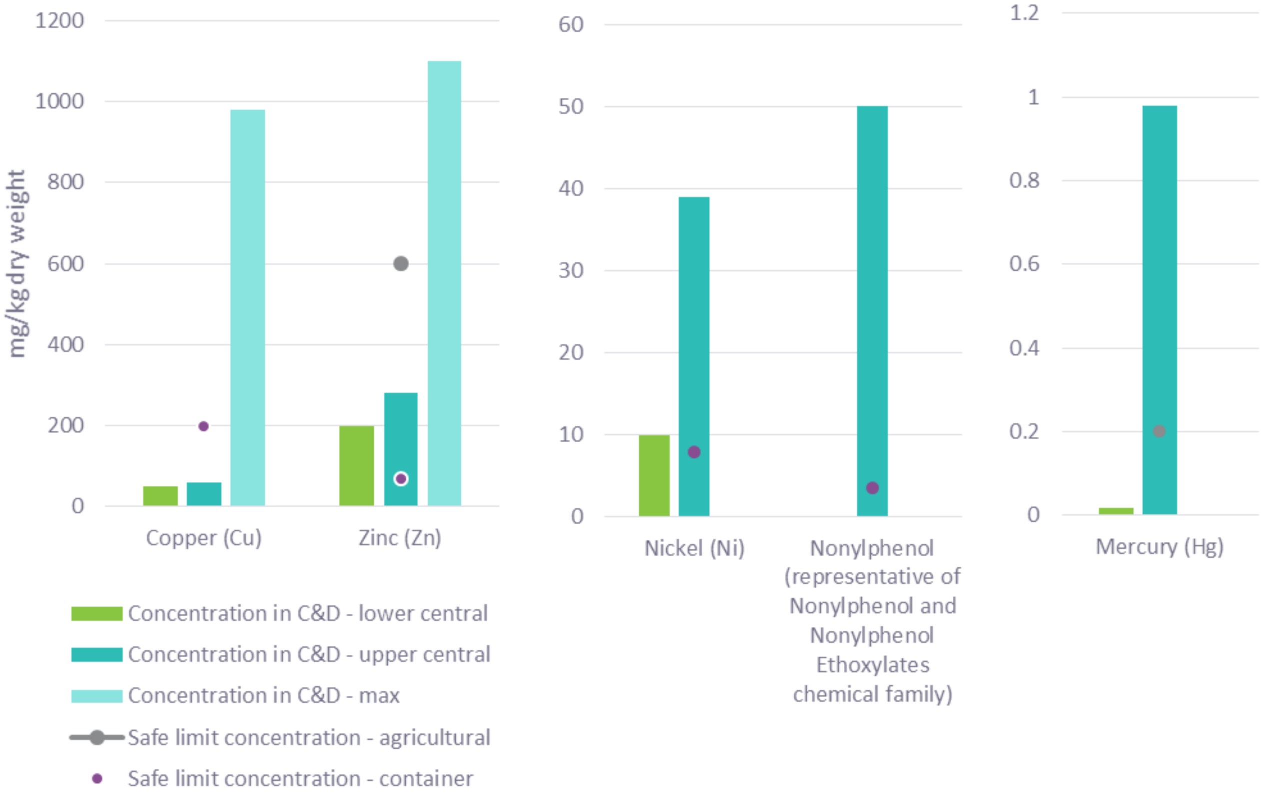
[99] Such as the internal RMOA templates used by ECHA, or Guidance on Annex XV for restriction (ECHA 2007)

[100] Note that, as explained in Section 4.1, "safe limit" in this report is defined as a limit below which adverse effects are not expected for the endpoints in question. This does not preclude possible other effects at lower concentrations, related to other endpoints for which quantitative risk characterisation was not possible.

scenarios (use in container growing, or application to agricultural land, see Section 4.3). A comparison of safe limits for both scenarios and measured concentrations in C/D is shown in Figure 5.1.

Figure 5.1 Overview of concentrations of contaminants found in compost and digestate and safe limits calculated in the risk assessment



Notes:
Concentrations in C&D: "Lower central" and "upper central" refer to the range of concentrations most typically measured in C/D, as identified in the literature in Task 2 (substance identification, see Section 3); "max" refers to the highest concentration in C/D reported in the literature but is considered an outlier and therefore an exceptional case.
Safe limit concentration: These relate to the concentration in C/D below which an unacceptable risk is not identified when applied in either exposure scenario defined in the risk assessment (I. Application to agricultural land, or II. Application in container growing; see Section 4 for more details).

The identified risks are summarised by scenario below:

- **Container growing:** Potential risks (and safe limits) specifically for compost used in container growing have been identified for the heavy metals **Nickel** (safe limit of 7.9 mg/kg dw) and **Copper** (safe limit of 200 mg/kg dw). Note that there are some uncertainties[101] associated with the container growing scenario used, as discussed in Appendix D. For both substances, the main sources of this contamination is not entirely clear. From different input materials most measured concentrations are broadly similar. However, for Nickel the highest maximum concentrations have been reported in biowaste compost, greenwaste compost and MBT

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[101] In particular, the current calculations assume that there is no loss of the substance from the growing medium by leaching (although the analysis carried out in Appendix D suggests that this may not be so significant for nickel and copper) and that the dietary intake from root and leaf crops occurs entirely from crops grown in such media. This latter assumption, in particular, may lead to an overestimation of the risks associated with compost and digestate containing nickel in this scenario and so the estimated safe limit of 7.9 mg/kg dry weight in compost should be seen as preliminary only. These uncertainties apply similarly to copper, but the limit value estimated here for copper in compost and digestate for container growing is consistent with the EU limit values for copper in agricultural soil.

compost. For Copper, sewage sludge compost, MBT C/D display generally higher concentrations. Manure is a known source of Copper but is not the only possible source.

- **Application to agricultural land:** Potential risks (and safe limits) specifically for digestate and/or compost applied to agricultural land have been identified for **Mercury** (safe limit of 0.2 mg/kg dw). As above, from different input materials most measured concentrations are broadly similar. However, the highest maximum concentrations have been reported in biowaste compost, greenwaste compost, MBT compost and sewage sludge compost.
- **Both scenarios (container growing and application to land):** Potential risks (and safe limits) for both container growing and application to agricultural land have been identified for **Zinc** (safe limit in container growing[102] of 70 mg/kg dw, safe limit for application to agricultural land 600 mg/kg dw). Generally higher concentrations of Zinc were measured in digestate from various input materials (compared to compost in general), as well as in sewage sludge compost and MBT compost.
- **For Nonylphenol,** to the extent that risk characterisation has been possible, unacceptable risks are indicated for the **container growing** scenario (with a 3.5 mg/kg safe limit)[103]. Risk characterisation for humans exposed via the environment was not quantified, as Nonylphenol is an endocrine disruptor. However, the predicted local total daily intake associated with the application of C/D is comparable with the daily human intake for local exposures associated with the various industrial use scenarios set out in the EU risk assessment from 2002 (European Commission 2005). The 2002 risk assessment concluded that (1) there was considerable uncertainty in the estimated human daily intake figures, (2) subject to this uncertainty, the industrial use scenarios could show a potential concern that needs to be addressed, and (3) further information was needed on emissions into the local environment. Few measurements of nonylphenol concentrations were reported in the literature. Of the tested C/D, municipal sewage sludge-derived products exhibited the highest concentrations, followed by green waste compost. Agricultural digestate (manure and energy crops) exhibited far lower concentrations.

Where conventional quantitative risk characterisation is not appropriate, exposures at the steady state are discussed. Due to the hazards (Non-threshold or unclear threshold, SVHC, POP, PBT) associated with some substances, their presence in compost/digestate itself may present a main concern. This includes the following substances:

- **Lead** is a non-threshold neurotoxic substance and the contribution from C/D to the total background levels of lead in soil from all sources is significant[104]. On the other hand, the realistic worst case has yielded no risk characterisation ratios (RCRs) >1 for soil, sediment, water and secondary poisoning. Generally higher concentrations of Lead were measured in compost (compared to digestate in general), with MBT compost exhibiting the highest reported average and maximum concentrations.
- **BPA and DEHP** are reprotoxins and endocrine disruptors (SVHCs).
  - For BPA, the regional scale predicted environmental concentration (PEC) in agricultural soil is well below the background concentration arising from the industrial life cycle. The predicted local total daily intake for humans does not exceed the DNEL used by EFSA and RAC, and the PNECs adopted in the 2010 ESR risk assessment are not exceeded. BPA in C/D can therefore be considered a lower priority for further risk management.

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[102] Note the uncertainties associated with the container growing scenario, as discussed above and in Appendix D.

[103] Note the uncertainties associated with the container growing scenario, as discussed above and in Appendix D.

[104] Estimated to be up to 66% based on the mid-range concentrations measured in compost and digestate. This would be higher if the highest concentrations measured in compost and digestate or the proposed FPR limit value (European Commission 2018b) is assumed.

  - For DEHP, the highest reported concentrations in composts and digestates (sewage sludge compost, biowaste-food and garden waste digestate) already appear to exceed the national limit value for several member states and the local total daily intake for humans associated with container growing slightly exceeds the DNEL defined by Danish EPA. With regards to application to land, the regional scale predicted environmental concentration (PEC) in agricultural soil and grassland is below the background concentration arising from the industrial life cycle. The European Commission is preparing to amend the REACH Authorisation List entry for DEHP (and other phthalates) to account for their endocrine disrupting effects, which means some uses previously exempted may require authorisation (ECHA 2018b). Furthermore, in December 2018 a REACH restriction was adopted on DEHP in articles used by consumers or available in indoor areas at a concentration equal to or above 0.1% w/w (European Commission 2018a). This may lead to a reduction of DEHP in input materials used for composting and AD, although food contact materials (a potential source of DEHP in input materials for compost and digestate) are not included in the proposed REACH restriction. Hence, further monitoring of the development of DEHP concentrations in C/D is required to judge the need for further risk management in the future.

- **17α-ethinylestradiol** is an endocrine disruptor with unclear safe limit thresholds. The total mass in the region + continent at steady state is low (approximately 7 tonnes), but the local total daily intake is only about four times below the therapeutic pharmaceutical dose[105]. The only concentration measurements identified in the literature are for C/D from sewage sludge and given 17α-ethinylestradiol is a pharmaceutical, it appears likely that sewage from waste water treatment is the main source of the substance into C/D.

- **HBCDD, the assessed representative of PCBs (PCB28) and of dioxins and furans (TCDD, PCDF), as well as PFOA and PFOS** are POPs. That they have been detected in freshly-produced composts and digestates at several locations in recent years is itself a concern.

  - For HBCDD, very few literature sources have identified HBCDD and the estimated regional scale exposures arising from the application of C/D are well below the anthropogenic background concentrations. Furthermore, following the expiry of the only REACH authorisation[106], any contribution to HBCDD concentrations in compost in digestate resulting from industrial release of HBCDD should be eliminated. HBCCD in C/D can therefore be considered a lower priority for further risk management.

  - For the assessed PCB, the highest reported concentrations in composts and digestates already appear to exceed the national limit value for several Member States (although only in a very small share of samples) and the estimated exposures are high compared with reported mean/median levels in foodstuffs. A clear distinction of PCB concentration levels between C/D from different input materials could not be established, with a wide variation of values reported for most.

  - For the assessed dioxins and furans, the highest reported concentrations in composts and digestates already appear to exceed the national limit value for several Member States and the estimated exposures are high compared with reported mean/median levels in foodstuffs. A clear distinction of dioxin and furan concentration levels between C/D from different input materials could not be established, with a wide variation of values reported

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[105] The upper limit of possible exposure from compost and digestate use according to the risk assessment is only approximately 4x below the lower limit of the pharmaceutical dose range if a bodyweight of 60kg is assumed for the patient. Note that the amount of data available on concentration of this contaminant in compost/digestate is extremely limited.

[106] HBCDD is listed in Annex XIV to the REACH Regulation ("Authorisation List"). The only Authorisation was for use as flame retardant additive to expanded polystyrene and expired on 21 August 2017. See: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/1602/term

    for most input materials However, the highest concentrations are reported for sewage sludge based composts and biowaste/green waste manure energy crop digestate.

    - For PFOA and PFOS, estimated regional-scale predicted environmental concentrations arising from the application of C/D appear to be low compared to the measured background concentrations. Predicted exposures of humans (local total daily intake) could exceed safe limits (in the case of PFOA only for container growing, in the case of PFOS for both container and agricultural application). Most measured concentrations are broadly similar across C/D from different input materials, but generally higher concentrations were measured in sewage sludge compost.

- **PFHxA** has been proposed as an SVHC and the risk assessment identified that C/D application could lead to human exposure, especially via diet and drinking water (ECHA 2018c). However, no data on concentrations of PFHxA specifically (only for PFOA+PFAS) in C/D are available. Hence, further monitoring of PFHxA concentrations in C/D is required to judge the need for further risk management in the future.

Long-term gradual accumulation through repeated application (cumulative loads at steady state) or transfer over long distances may present a concern for the following substances:

- Cumulative loads at steady state are a concern for 15 of the 23 assessed substances, including most heavy metals (Cd, Ni, Pb, Cu and Zn, but not Hg), DEHP, all assessed dioxins, furans and PCBs (TCDD, PCB28, PCDF), nonylphenol and all assessed PAH16 (Benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene, indeno[,2,3-cd]pyrene).

- In contrast, for mercury, 17α-ethinylestradiol and PFAs (PFOA, PFOS, PFHxA) transfer over long distances is a concern.

- Note that for cadmium[107] and PAH16 substances[108], long-term gradual accumulation is the only main concern identified in the risk assessment. For all other substances, the risk assessment raised other main concerns which are discussed above.

Lastly, with the current methods and data available fugacity modelling is not reliable for microplastics, so a generic estimate of exposure to microplastics resulting from digestate and compost use is provided:

- C/D application is a potentially important source of human exposure to microplastics via the environment (via root and leaf crops in the diet). The exposures of soil and sediment arising from the application of C/D estimated in the present model are very low (several orders of magnitude smaller) compared with the PECs modelled in the recent risk assessment of exposures arising from a range of industrial and consumer uses (not including microfibres released by washing of textiles) (Wood, PFA and EEA 2017). Note that ECHA has submitted the restriction proposal[109] concerning the use of intentionally added microplastic particles to consumer or professional use products and it is currently undergoing review by ECHA Scientific Committees (ECHA 2019). Once in place, the restriction might lead to a significant reduction of microplastics in household waste water and hence in sewage sludge. However, the occurrence data used in this assessment is largely based on household biowaste-derived products rather than sewage sludge C/D. ECHA (2018)[110] reports that sewage sludge could be an important

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[107] Generally higher concentrations are reported for MBT compost, although a few high concentrations have also been found in compost and digestate from other input materials.

[108] A clear distinction of PAH16 concentration levels between compost and digestate from different input materials could not be established, with a wide variation of values reported for most.

[109] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[110] ECHA press release, Intentionally added microplastics likely to accumulate in terrestrial and freshwater environments, ECHA/PR/18/15, 22 November 2018.

source of emissions of microplastics to the soil. Hence, further monitoring of microplastics concentrations in C/D is required to judge the need for further risk management in the future.

In summary, the following substances are prioritised for risk management in the remainder of this RMOA, based on the identified risks:

- Nickel (Ni);
- Lead (Pb);
- Copper (Cu);
- Zinc (Zn);
- Mercury (Hg);
- 17α-ethinylestradiol;
- PCBs (PCB28);
- Dioxins and furans (TCDD, PCDF);
- Nonylphenol;
- Perfluoroctanoic acid (PFOA); and
- Perfluoroctanesulfonic acid (PFOS).

For Cadmium and PAH16 (Benzo[a]pyrene, Chrysene, Benzo[a]anthracene, Benzo[b]fluoranthene, Indeno(1,2,3-cd)pyrene), the only main concern is long-term gradual accumulation through repeated application. These substances are also considered for risk management, but at a lower priority than the above.

5.3 Summary of uses and tonnages

This section combines the identified risks from Section 5.2 with the results of the market analysis (Section 2) to conclude on the geographical spread and scale of the problem. First, the extent to which it has been possible to associate identified risks with specific input materials, techniques or uses is summarised. This is then compared to the tonnages and location of these input materials, techniques or uses. Conclusions are then drawn regarding (1) what proportion of compost/digestate is affected by contaminant concentrations above levels of potential concern, and (2) where are the concerns concentrated (both geographically and in terms of the feedstocks, production techniques and application practices used)?

5.3.1 Tonnages

As discussed above (Section 5.2), the concentrations of many substances of concern (and thus risk) varies strongly between C/D, and/or between input materials used. In the following, the tonnages are presented in the context of these variations in contaminant concentrations/risk, first between C/D, and then between compost/digestate from different input materials.

Compost and digestate

Generally higher concentrations of Zinc were measured in digestate (from various input materials) compared to compost in general. Conversely, generally higher concentrations of Lead were measured in compost compared to digestate. The market analysis (Section 2) estimates a current annual EU production of some 17.3 million tonnes of compost (with a possible range of 13 million - 18 million tonnes), and in the order of around 180 million tonnes of digestate. Hence, the concern associated with Zinc (higher concentrations in digestate) could be expected to be much more widespread than the concern associated with Lead (higher concentrations in compost), considering the much higher tonnage of digestate. Note the tonnage of digestate is dominated by few Member States: almost half of the EU's digestate is produced in Germany alone (87 million tonnes), and just over three quarters in Germany, Italy (30 million tonnes) and the UK (18.5 million tonnes) together.

Input materials

For many substances, higher concentrations and thus higher risk is associated with C/D from specific input materials. Table 5.1 shows which input materials exhibit generally higher or maximum concentrations for which substances of concern, as well as the associated tonnages of C/D produced from these input materials. Note that this does not imply that a potentially unacceptable risk exists only for compost/digestate from these input materials. However, if an input material exhibits generally higher concentrations or the risk of occasionally very high concentrations of contaminants, as well as high tonnages, it could be prioritised for risk management.

About 21-25 million tonnes of C/D are produced in the EU from biowaste and greenwaste according to the market analysis (see Section 2 and Table 5.1). Biowaste and greenwaste compost/digestate exhibits generally higher concentrations, or the highest single observation of concentration, for nickel, mercury, Nonylphenol, PAHs and possibly dioxins and furans and cadmium[111].

46 million tonnes of digestate (and an uncertain but likely small amount of compost) is produced from organic fraction of mixed municipal solid waste (mechanical biological treatment – MBT). MBT digestate exhibits generally higher concentrations, or the highest single observation of concentration, for heavy metals.

A much smaller quantity, but at least 2.5 million tonnes of C/D are produced from sewage sludge. However, C/D from sewage sludge exhibits generally higher concentrations, or the highest single observation of concentration, for most priority substances of concern (copper, zinc, mercury, 17α-ethinylestradiol, dioxins and furans, nonylphenol, PFOA, PFOS, PAHs).

The majority of the total digestate and compost produced in the EU (in the order of 200 million tonnes) is agricultural digestate, with about 122 million tonnes. The input materials of agricultural digestate are typically a mix of manure and energy crops (see Section 2). Manure is a known source of copper, but the highest concentrations of copper were reported in compost/digestate from other input materials, suggesting manure is likely not the only source, and possibly not the most significant. Among the highest dioxins and furans and cadmium concentrations reported was a digestate made from a mix of biowaste/green waste, manure and energy crops. It is unclear from which of these input materials the high dioxins and furans and cadmium contents stem. Hence, agricultural digestate accounts for the largest tonnage, but cannot not be linked to particularly high concentrations of any priority substances of concern with certainty.

Table 5.1 Tonnages of compost/digestate from input materials for which generally higher or maximum concentrations were reported for substances of concern

	Biowaste	Greenwaste	MBT	Sewage sludge	Manure
Estimated tonnage of digestate produced from this input material	Separately collected organic waste (can include biowaste, greenwaste and similar waste streams such as agroindustry by-products): 8.7 million tonnes.		46 million tonnes	At least 1.7 million tonnes	Agricultural digestate (typically a mix of manure and energy crops): 122 million tonnes.

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[111] Among the highest concentrations reported was a digestate made from a mix of biowaste/green waste, manure, energy crop. It is unclear from which of these input materials the high PCB/Cadmium contents stem.

	Biowaste	Greenwaste	MBT	Sewage sludge	Manure
Estimated tonnage of compost produced from this input material	5.1-7.2 million tonnes (including Vegetable, fruit and garden waste).	7-9 million tonnes	None reported	0.8 million tonnes	None reported
Generally higher or maximum concentrations in following priority substances of concern:					
Nickel (Ni)	x	x	x		
Lead (Pb)			x		
Copper (Cu)			x	x	? [1]
Zinc (Zn)			x	x	
Mercury (Hg)	x	x	x	x	
17α-ethinylestradiol				x	
PCBs (PCB28)	*No clear distinction of concentration levels between C/D from different input materials could be established.*				
Dioxins and furans (TCDD, PCDF)	? [2]	? [2]		x	? [2]
Nonylphenol		x		x	
Perfluoroctanoic acid (PFOA)				x	
Perfluoroctanesulfonic acid (PFOS)				x	
Cadmium (Cd)	? [2]	? [2]	x		? [2]
PAH16 (Benzo[a]pyrene, Chrysene, Benzo[a]anthracene, Benzo[b]fluoranthene, Indeno(1,2,3-cd)pyrene	x	x		x	
Substances not prioritised in the summary of identified risk:					
Bisphenol-A (BPA)	BPA in C/D can be considered a lower priority for further risk management (low contribution to background concentrations, available safe limits of human consumption not exceeded).				
Di(2-ethylhexyl)phthalate (DEHP)	Further monitoring of the development of DEHP concentrations in C/D is required to judge the need for further risk management in the future.				
Hexabromocyclododecane (HBCDD)	Following the expiry of the only REACH authorisation, any contribution to HBCDD concentrations in compost in digestate resulting from industrial release of HBCDD should be eliminated. Can therefore be considered a lower priority for further risk management.				

	Biowaste	Greenwaste	MBT	Sewage sludge	Manure
PFHxA	Further monitoring of PFHxA concentrations in C/D is required to judge the need for further risk management in the future.				
Microplastics	Further monitoring of microplastics concentrations in C/D is required to judge the need for further risk management in the future.				

Notes:
[1] Manure is a known source of copper, but the highest concentrations of copper were reported in compost/digestate from other input materials, suggesting manure is likely not the only source, and possibly not the most significant source.
[2] Among the highest concentrations reported was a digestate made from a mix of biowaste/green waste, manure, energy crop. It is unclear from which of these input materials the high contamination stems, but it appears more likely that it is one or more of biowaste, green waste or manure, rather than energy crops.

5.3.2 Uses

Two use scenarios were assessed in the risk assessment (see Section 4.3): use in container growing and application to agricultural land. Table 5.2 shows for which of the two scenarios the main concerns are identified for each priority contaminant. Below, these are discussed and linked to the tonnages of different uses of C/D.

Table 5.2 Overview of concerns identified by use scenario

Substance	Container growing	Application to agricultural land	Conclusion
Measured concentrations in compost and digestate exceed safe limits for:			
Nickel (Ni)	X		Concern only for container growing
Copper (Cu)	X		Concern only for container growing
Zinc (Zn)	X	X	Concern for both use scenarios
Mercury (Hg)		X	Concern only for application to agricultural land
Nonylphenol	X		Concern only for container growing
Exposures at the steady state are higher for:			
Lead (Pb)	X		Higher concern for container growing
17α-ethinylestradiol	X		Higher concern for container growing
PCBs (PCB28)	X		Higher concern for container growing
Dioxins and furans (TCDD, PCDF)	X		Higher concern for container growing
PFAs (PFOA, PFOS)	X		Higher concern for container growing
Cadmium (Cd)	X		Higher concern for container growing
PAH16 (Benzo[a]pyrene, Chrysene, Benzo[a]anthracene, Benzo[b]fluoranthene, Indeno(1,2,3-cd)pyrene	X		Higher concern for container growing

For most substances for which conventional quantitative risk characterisation was possible, safe limits are lower for the use scenario of container growing than for application to agricultural land.[112] As a result, for several substances (nickel, copper, nonylphenol) measured concentrations in C/D exceed safe limits only for container growing but not for application to agricultural land. Hence, for these substances a potential concern has only been identified for container growing but not for application to cultural land.

For one substance (zinc), measured concentrations in C/D exceed safe limits for both use scenarios and so for both uses a potential risk has been identified. For one substance (mercury) a potential risk has only been identified for application onto agricultural land, but not for container growing.

For several substances, their presence in compost/digestate itself may present a main concern due to the hazards (Non-threshold or unclear threshold, SVHC, POP, PBT) associated with them. For all assessed substances falling into this category (Lead, BPA, DEHP, 17α-ethinylestradiol, HBCDD, PCBs, dioxins and furans, PFAS) exposures at the steady state are higher for the container growing scenario than for application onto agricultural land.

According to the market analysis, the vast majority of the 180 million tonnes of digestate produced in the EU is used directly as fertiliser in agriculture (JRC 2014). Based on this, the risk assessment has assumed that only compost is used in container growing.

For compost, the market analysis could not provide a full quantitative breakdown of uses at an EU-level, but shows the majority (ca. 85%) of compost was used as a fertiliser or soil improver in agriculture, gardening, horticulture and landscaping. This corresponds to something in the order of 15 million tonnes of compost.[113] Based on the breakdown of compost uses in 14 major compost producing EU Member States from JRC (2014)[114] we estimate that up to 34% of compost is used in container growing, while 51% are applied to agricultural land. Assuming the JRC (2014) use distribution applies to the whole EU today[115], this corresponds to in the order of 6 million tonnes of compost used in container growing, compared to some 9 million tonnes used in agriculture. Note that some additional data on tonnages per use is available for a few specific countries (see Section 2).

5.4 Overview of existing risk management

5.4.1 Objective

To evaluate the extent to which risks identified in the risk assessment may be already addressed, this section gives an overview of current risk reduction measures in the European Union. This overview is not exhaustive – it covers EU-level risk management and draws on brief case examples from selected Member States.

5.4.2 Methodology, sources and limitations

This analysis is based on the following sources:

- The targeted consultation: question 3.5 investigated actions already taken within the respondents' sector to control the risk from contaminants in digestate and compost. Responses to this question were provided by the Association of the German Waste, Water and Resource

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[112] This is because the use as a stand-alone growing medium relates to growing plants in container beds, bags, or pots, where the substance can be expected to remain in the compost and its interstitial water (soil pore-water) unless either degraded, lost by volatilisation or taken up into plants; the latter could potentially lead to human exposure if the plants are eaten.

[113] The central estimate of total compost produced in the EU (17.3 million tonnes) multiplied by 85%.

[114] Note that JRC (2014) doesn't explicitly distinguish container growing. The uses that potentially include container growing (hobby gardening, horticulture and greenhouse production, blends, "others") amount to 34% of all compost used. 51% are explicitly applied to agricultural land. Source: DG JRC: Technical proposals on end-of-waste criteria for biodegradable waste subjected to biological treatment, 2014.

[115] I.e. the use percentages are multiplied with the central estimate of total compost produced in the EU (17.3 million tonnes).

Industry[116] (BDE), the European Biogas Association (EBA) and the European Compost Network (ECN).

- Outputs from Task 2 on 'substance identification – identification of contaminants present in digestate and compost': existing defined or proposed limit values from European or national regulations or guidelines.
- Further literature review, to identify other existing measures in Member States, such as the country reports from the European Compost Network.

This review of existing risks measures is not exhaustive; we list below a series of limitations in the review:

- Information on existing risk management measures is scattered among legally binding and non-binding measures across multiple pieces of legislation.
- It was beyond the scope of this assessment to review in detail all relevant national legislation for all EU Member States.

5.4.3 Results

At EU level, certain contaminants are addressed through EU-wide legislation, including bans or limit values.

- The Stockholm Convention on POPs allows elimination and/or restriction in the production and use of chemicals such as PCB, PCDD, PCDF, some pesticides, as well as PFAS. It also proposes for listing PFOA-related compounds and PFHxS-related compounds.[117]
- A revision of the Fertilising Products Regulation (FPR) is currently under way (European Commission 2018b). The proposal specifies recovery rules for C/D which may be allowed as component materials of CE-marked fertilising products. This includes restrictions on input materials (among others, the organic fraction of mixed municipal household waste separated through MBT and sewage sludge are excluded) and limit values on a range of contaminants (including cadmium, mercury, nickel, lead, PAH, plastics) based on the recommendations made by JRC (2014). In the updated current text, it is indicated that contaminants must not be present in CE marked EU fertilising products by more than the following (European Commission 2018b):
    - Cadmium: where the EU fertilizing product has a total phosphorus (P) content of less than 5% phosphorus pentoxide (P_2O_5)-equivalent by mass: 3 mg/kg dry matter and where equal or greater than 5%: 60 mg/kg phosphorus pentoxide.
    - Other limit values are established in the document (2 mg/kg dry matter for hexavalent chromium; 1 mg/kg dry matter for mercury; 50 mg/kg dry matter for nickel; 120 mg/kg dry matter for lead; 40 mg/kg dry matter for inorganic arsenic, etc.)
- Other EU-wide initiatives include non-binding measures: the European Compost Network (ECN) Assurance Scheme for Compost and Digestate includes further risk management measures such as restriction of input materials (e.g. sludges and not separately collected waste are excluded) and limit values for heavy metals and lays down harmonised requirements for national certification bodies as well as quality criteria for recycled materials from organic sources in digestate and compost (ECN 2018).

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[116] Bundesverband der Deutschen Entsorgungs-, Wasser- und Rohstoffwirtschaft

[117] For example, its transposition as Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants[117] provides a limit value for PCBs and PFOS in waste of 50 mg/kg d.m. each; if this limit is exceeded, the waste must be treated to ensure that the persistent organic pollutant is destroyed or irreversibly transformed. Placing on the market or use of articles or mixtures containing PCBs and PFOS is fully prohibited, except as an unintentional trace contaminant (for PFOS defined as 10 mg/kg, for PCBs not explicitly defined).

Some EU-level legislation does not directly specify any risk management relating to contaminants in C/D, but concerns some of the input materials of C/D and can therefore indirectly affects potential risks from C/D use:

- The Urban Waste Water Treatment Directive establishes a requirement to collect and treat urban wastewater as well as some industrial wastewaters. The focus of this directive is primarily on the nutrient and pathogen content of waste flows, which are quantified in terms of population equivalent. Chemical substances and potential impacts from chemicals of concern are not directly included within the Directive (beyond Annex I) which indicates that for industrial waste waters, the release of treated effluent should not have an adverse effect on the environment. Article 14 encourages the re-use of sewage sludge "whenever appropriate", while "minimising adverse effects on the environment", however no targets or risk management measures are specified. The Directive also requires controlling and reporting disposal of sludge and phases out disposal of sludge to surface waters. Changes to treatment methods for wastewater under this directive may in turn affect concentrations of substances present in sludge.
- In the proposal for a revised Drinking Water Directive, new limit values for industrial contaminants were introduced by the Commission in order to ensure the safety of drinking water (European Commission 2018c). The proposal, supported by the European Parliament, suggests limits of 0.1 µg/l for each individual PFAS substance and 0.5 µg/l for the sum of PFAS substances.
  These limits can be compared to the modelled concentration of PFAS in groundwater and freshwater resulting from C/D use: PFOA concentration in groundwater resulting from C/D use is estimated to be above the Drinking Water Directive proposal limit for each individual PFAS substance in drinking water, but below the proposed limit for the sum of PFAS substances. The estimated concentrations of PFOA in freshwater and of PFOS in both groundwater and freshwater are well below both Drinking Water Directive proposal limits (for each individual PFAS substance and for the sum of PFAS substances).
  However, additional limits on PFAS in drinking water will also mean that water treatment will potentially have to filter larger amounts of PFAS which would then end up in higher concentrations in sludge, an input material for C/D.
- The Sewage Sludge Directive encourages the use of sewage sludge in agriculture and regulates its use to avoid adverse effects. In this context, limit values for concentrations of heavy metals in sewage sludge intended for agricultural use and in sludge-treated soils are in Annexes I A, I B and I C of the Directive. A study from JRC in 2012 in the context of the revision of the Directive looks further into inorganic and organic contaminants such as heavy metals, PCBs, PCDD/Fs, and PAHs, and also less investigated emerging compounds such as, for instance, brominated flame retardants, ingredients of personal care products, pharmaceuticals, some industrial chemicals, etc. in sewage sludge and treated bio-waste (JRC 2012).
  The directive also prohibits the use of sewage sludge on agricultural land unless it is injected or incorporated into the soil, or having undergone "biological, chemical or heat treatment, long-term storage or any other appropriate process so as significantly to reduce its fermentability and the health hazards resulting from its use". Hence the directive encourages the use of sewage sludge that has undergone composting or anaerobic digestion, particularly if the associated hazards are lower than for untreated sewage sludge.
- Moreover, under the new requirements from the revised Waste Framework Directive, Member States have to ensure by December 2023 that bio-waste is either collected separately or recycled at source (e.g. home composting). As of 1 January 2027, composted or digested municipal bio-waste may only be counted as recycled if it has been separately collected or separated at source, therefore MBT C/D will no longer count towards recycling targets. Therefore, MBT C/D can be expected to significantly decrease in volume in the years leading to

these 2023 and 2027 deadlines, while volumes of C/D from source-separated biowaste are likely to increase.

In addition EU Member States implement national risk management measures. Concentration limits or limit values for contaminants were the most frequent risk management measure in our review. In most cases, those limit values were mandatory (under legislation and standards); only very few cases (e.g. in Belgium) provided a guidance limit value. From all types of substances assessed, the most regulated under national legislation were PCBs (at least 8 countries out of 16), polycyclic aromatic hydrocarbons (PAHs) (at least 6 countries out of the 16), dioxins and furans (PCDD/PCDF) (at least 6 countries out of 16) and heavy metals, in particular cadmium and chromium (at least 4 countries out of 16), followed by pesticides and perfluorinated surfactants.

The highest number of risk management measures identified are in Germany, Belgium, Denmark, the United Kingdom and Austria, followed by France. Example cases are presented below:

- **Germany** implemented the EU bio-waste legislation into their national legal and policy frameworks, and subsequently implemented additional acts and ordinances regarding bio-waste. For example, the Bio-waste Ordinance (BioAbfV) covers information / requirements on suitable input materials, processes, quality and hygiene of the products and applications; it also contains obligations to provide evidence of compliance with those requirements. In addition, there are quality assurance systems used by most of compost producers as well as digestate producers for many years, i.e. BGK, RAL- Gütesicherung. These quality standards require the declaration of plant nutrients, physical and biological parameters and heavy metal content. Given the use of compost or digestate as fertiliser and soil improver, it was noted that their harmlessness must be ensured. The quality standard RAL defines quality requirements, differentiated for compost (mature, fresh, substrate), digestate (liquid, solid), digestate from renewable raw materials (liquid, solid) and compost produced from sewage sludge. The requirements of the RAL on quality standards in relation to impurities (e.g. glass and plastics) are stricter than those in the above-mentioned Ordinance. Finally, threshold values for impurities or contaminants are defined in the Fertiliser Ordinance (Düngemittelverordnung DüMV 2012, latest amendment 12/4/2017).
- In **Belgium** (**Flanders**), the VLAREMA-regulation, a Flemish regulation for sustainable management of material circuits and waste streams, provides compulsory quality certificate for the treatment of bio-waste, which is then subject to a Vlaco-certificate[118] to ensure its sustainable application and ensures that the unacceptable diffusion of unwanted or polluting substances is avoided when applied as fertiliser. The VLAREMA-regulation establishes limit values for key environmental parameters, both organic (e.g. PAH, PCB, volatile compounds, etc.) and inorganic (e.g. heavy metals). The Vlaco Quality Assurance System is based on even stricter limit values than those in the regulation.
- In the **United Kingdom**, both compost and digestate are subject to a national standard, called a 'Publicly Available Specification (PAS), published by the Brigit Standards Institute (BSI): Compost PAS 100, Specification for Composted Materials (2011) and Digestate PAS 110, Specification for whole Digestate, Separated Liquor and Separated Fibre Derived from the Anaerobic Digestion of Source-Segregated Biodegradable Materials (2014). These two specifications establish limits values for contaminants and require independent third-party certification, for which operators have to provide evidence that contaminant limit levels have not been exceeded.

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[118] In the context of the Flemish Waste Regulation (VLAREMA), Vlaco is appointed by the Flemish Waste Authority OVAM to implement quality control for the biological treatment of bio-waste.

- In **Denmark**, the Statutory Order on the application of waste products for agricultural purposes No 834 regulates the agricultural reuse of main biodegradable wastes, including compost and sewage sludge. It provides limit values for heavy metals and organic pollutants.

Risk management measures other than concentration limits, i.e. restriction on input materials, on uses or through specific processes were seldom or not applied:

Table 5.3 Examples of measures other than concentration limits

Examples of measures other than concentration limits	
Germany	In addition to transposing the EU bio-waste legislation into its national legal framework, Germany implemented additional acts and ordinances regarding bio-waste. The Bio-Waste Ordinance contains information and requirements on suitable input materials, processes, quality and hygiene of the products including their applications.
Hungary	In Hungary, the Regulation 23/2003 Technical Requirements of Bio-waste Treatment and Composting covers suitable input materials, hygiene requirements and technical specifications of composting.
Estonia	In Estonia, the Regulation on Requirements for Producing Compost for Biodegradable Waste provides quality parameters for compost, such as maximum particle size, bulk density, water content, salinity, pH, etc.
Other	In additional to national regulations (e.g. bio-waste ordinance, compost regulations, fertilisers regulations, etc.) third-party control through national quality schemes have been established in various Member States.

5.4.4 Conclusions

Geographical coverage

The current European legislative framework addresses certain contaminants. Member States must directly apply or transpose theses into their national legislation, such as the Stockholm Convention on Persistent Organic Pollutants[119] or the revised Fertilising Products Regulation, once adopted. Other non-binding measures have been established, such as requirements from the European Compost Network on recyclate from organic sources. In addition, our review found additional risk management measures implemented in 16 European countries (15 EU countries and Norway), with the most measures found for Germany, Belgium, Denmark, the United Kingdom and Austria, followed by France.

Types of existing risk management measures identified

Concentration limits, i.e. limit values for contaminants, were the most frequent risk management measures in all EU Member States. In the majority of cases found, those limit values were mandatory (under legislation and standards); only very few cases provided a guidance limit value. Other types of measures such as restriction on input materials, on uses, or reductions of contaminants through specific processes were seldom or not applied.

Substances covered

From all types of substances assessed in this review the most regulated in various national legislation were PCBs, dioxins and furans (PCDD/PCDF), polycyclic aromatic hydrocarbons (PAHs) and heavy metals (in particular cadmium and chromium), followed by pesticides and perfluorinated surfactants.

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[119] Transposed in the Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants.

5.5 Identification and assessment of risk management options

This section identifies the different options and assesses their suitability. The assessment follows relevant ECHA guidance on Annex XV for restrictions based on the following criteria (ECHA 2007):

- Effectiveness: Is the option targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk?
- Practicality: Is the option implementable, enforceable and manageable?
- Monitorability: Is it possible to monitor the implementation of the option?

Socio-economic considerations are addressed in Section 5.6 and combined with information from this section (5.5) to determine the preferred combination of) risk management options in Section 5.7.

Based on literature review[120], the targeted stakeholder consultation under Task 1, and discussions with the steering group, the following main options have been identified:

1. Directly setting **concentration limits** for the contaminants of concern.
2. Indirectly reducing the contaminants of concern by eliminating the use of potentially contaminated **input materials (feedstocks)** in composting/AD.
3. Reducing the exposure to the contaminants through the **conditions of use** of C/D.
4. In certain cases the concentration of contaminants in C/D can be reduced by applying **specific processes** *before* composting/AD (e.g. during the collection and separation of organic waste), *during* composting/AD (e.g. specific time-temperature profiles or separation of compost/digestate made from different feedstocks) or *after* composting/AD (post-processing).

Several legal instruments are available to implement each option, the advantages and disadvantages of which are discussed for each option below. The option of doing nothing ('status quo') is also briefly discussed.

5.5.1 Option 0: 'Status quo'

As set out in Section 5.4, a number of activities are already targeting known risks from digestate and compost used as fertilisers. Below the extent to which this will address the risks identified (see Section 5.2) is discussed.

The proposal for the revised Fertilising Products Regulation (FPR) is the main regulatory activity to addresses the risk from C/D used as fertilisers on EU-level (European Commission 2018b). It includes restrictions on input materials (among others, the organic fraction of mixed municipal household waste separated through MBT and sewage sludge are excluded) and limit values on a range of contaminants (including cadmium,

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[120] In particular, JRC (2014) noted the environmental and health risks from compost and digestate could be limited by end-of-waste criteria (i.e. criteria ensuring their use is safe for the environment and human health so that no regulatory controls under waste legislation are needed) "including certain product quality requirements regarding pollutants and impurities, restrictions on the input materials used to produce the compost/digestate, and process requirements to eliminate pathogens from the material." JRC concluded that 5 complementary elements should be combined in a set of end-of-waste criteria for compost and digestate:
1. Product quality requirements [minimum limit values for nutrients, maximum limit values for contaminants]
2. Requirements on input materials
3. Requirements on treatment processes and techniques
4. Requirements on the provision of information
5. Requirements on quality assurance procedures
Source: JRC 2014
JRC's Elements 1-3 are reflected in Options 1, 2 and 4 of this RMOA below. JRC's Elements 4 and 5 concern aspects related to monitoring and implementation, rather than potential standalone risk management options.

mercury, nickel, lead, PAH, plastics) based on the recommendations made by JRC (2014). These address some but not all of the risks identified in this study. For example, some substances of particular concern such as PCBs, dioxins and furans and nonylphenol are not addressed.[121] Moreover, the proposal applies only to CE-marked fertilising products. This means that other national fertilisers may still co-exist, which do not adhere to the proposal. According to personal communication with the European Biogas Association, they expect that many Member States will likely adopt national rules consistent with the Fertilising Products Regulation so that in practice its provisions will apply to the majority of the compost/digestate market, but this is currently still uncertain.

In addition, the European Compost Network (ECN) Quality Assurance Scheme for Compost and Digestate includes further risk management measures. However, quality assurance schemes are non-binding and so their ability to control the risk generally depends on their uptake. According to personal communication with ECN, they are well established in any country where there is a market for compost[122], but it is not certain if they are applied in all Member States and how well digestate is covered.

EU Member States have also implemented national risk management measures to address the issue of contaminants in digestate and compost. Although our review of existing limit values is likely not comprehensive, it suggests that limit values do not exist in all Member States, do not cover all substances of concern, and often exceed safe limits calculated in this study.[123] Other types of measures such as restriction on input materials, on uses or reduction of contaminants through specific processes were seldom or not applied in Member State regulation. Furthermore, with national-level regulation there is potential for discrepancies in the allowed input materials, their definitions, and concentration limits used in any national restrictions. This has implications not only for the degree to which the environment is protected, but also in terms of ensuring the functioning of the internal market[124].

In conclusion, this suggests some risk management is already in place in the majority of the EU C/D market, but is unlikely to adequately control the risk identified in this study. Notably, there is a lack of binding and coherent requirements for all types of C/D and all Member States. As discussed in Section 5.3, the production of digestate as fertiliser is expected to increase significantly in the short to medium term. Whether the status quo risk management will continue to provide even the level of protection it is achieving now is questionable.

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[121] In terms of input materials, the exclusion of MBT waste and sewage sludge addresses all input materials for which generally higher or maximum concentrations were reported for Lead, Zinc, 17α-ethinylestradiol, PFOA and PFOS. This means, the input materials associated with the highest concern and that are a priority for the reduction of risk from these substances are addressed by the proposal, although potentially unacceptable risk may still be posed by these substances at lower concentrations from other input materials. Furthermore, for Nickel, Mercury, dioxins and furans and Nonylphenol, generally higher or maximum concentrations were reported also for other input materials (biowaste and greenwaste) which are not excluded in the proposal. See Section 5.3.1.
In terms of limit values, some of the proposed limit values are below the safe limit concentration calculated in this study and therefore appropriately address the risk, but several proposed limit values far exceed the safe limit concentration calculated in this study. For instance, for nickel, the proposed limit value (50 mg/kg d.m.) is below the safe limit concentration calculated in this study for application to agricultural land (130 mg/kg d.m.), but far exceeds the safe limit concentration for container growing (7.9 mg/kg d.m.). For mercury, the proposed limit value (1 mg/kg d.m.) far exceeds the safe limit concentration calculated in this study for application to agricultural land (0.2 mg/kg d.m.).
For PCBs and nonylphenol, two (groups of) substances which the risk assessment of this study suggests are among the priorities for risk management, the proposal includes neither limit values, nor does it exclude the input materials for which generally higher or maximum concentrations were reported. Note that for PCBs the JRC report makes reference to the POPs Regulation limit values, which are however not specifically designed for compost/digestate use, and relatively high at 50 mg/kg d.m.

[122] For instance, in Germany >70% of compost is covered. The share is high also in Austria, the Netherlands, Flanders and others, and it is increasing in Italy.

[123] A more detailed assessment of the limit values that would be required to adequately address the risks identified in this study is provided in Section 5.5.2.

[124] Note that overcoming this issue is an objective of the ECN Quality Assurance Scheme.

5.5.2 Option 1: Additional or stricter concentration limits for specific substances in compost and digestate used as fertiliser

Concentration limits are a measure to directly limit pollutants to levels considered to pose no (or an 'acceptable level' of) risk. As discussed in Section 5.4, concentration limits for certain substances in C/D already exist (either in Member State legislation or in quality assurance schemes). JRC (2014) identified the following potential parameters for direct quality criteria on compost/digestate:

1. Quantitative minimum limits of elements providing a soil improvement/fertilising function, such as organic matter content, or nutrient (N, P, K, Mg) content.
2. Quantitative maximum limits on elements potentially toxic to human health or ecotoxic, such as heavy metals, or persistent organic pollutants.
3. Quantitative maximum limits on macroscopic foreign materials (e.g. glass, plastics, metals).
4. Limited content of pathogens (if appropriate through quantitative maximum limits).
5. Limited presence of viable weeds (if appropriate through quantitative maximum limits).
6. Minimum stability (if appropriate through quantitative maximum limits).

Taking each of the above criteria in turn: numbers one, five[125] and six[126] are not relevant in the context of risk from contaminants to the environment and health. Pathogens (number 4) were not selected as contaminants of concern for the purpose of this RMOA (see Section 3). So only criteria two and three are potentially relevant and discussed below.

The contaminants can be split into three groups:

- (1) Substances for which safe limit concentrations in C/D were calculated based on exposure and risk characterisation in the risk assessment;
- (2) Substances for which safe limits are not definable, but limit values already exist (in national legislation, quality assurance schemes, or the proposed end-of waste criteria from JRC 2014); and
- (3) Substances for which neither safe limits can be defined, nor existing limit values identified.

Group 1: Safe limit substances

For substances for which exposure and risk characterisation were completed in the risk assessment, safe limit concentrations in C/D were calculated, as shown in Table 5.4. This includes most heavy metals (Cd, Ni, Cu, Zn, Hg) and nonylphenol. For heavy metals, limit values already exist[127]. These are also shown in the table, for context. It should be noted that the existing limit values can deviate from the safe limits calculated in this study for a variety of reasons.[128]

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[125] In the context of end-of-waste criteria (which are the focus of JRC 2014), product quality criteria are also needed to check that the product is suitable for direct use (on land, for production of growing media, in addition to criteria on environmental and health risks.

[126] According to JRC (2014), the aim of minimum stability is "to avoid methane and odour emissions during uncontrolled anaerobic conditions after sales (e.g. during storage)", which are not related to contaminants.

[127] E.g. in the proposal for the revised Fertilising Products Regulation (European Commission 2018b), the ECN Quality Assurance Scheme (ECN 2018) and in many national regulations.

[128] They may reflect different assumptions and approaches to risk assessment as well as specific local circumstances (affecting the scenarios used in the risk assessment). Other factors such as socio-economic and political considerations may also have affected the choice of limit values.

Table 5.4 Overview of calculated safe limit values in compost and digestate and identified existing limit values

Substance	Safe limit concentration in compost and digestate for application to agricultural land	Safe limit concentration in compost for container growing[1]	Existing limit values
Cadmium	[2]	[2]	1.5 mg/kg d.m. (FPR), 1.3 mg/kg d.m. (ECN-QAS), 0.4 mg/kg d.m. (Norway), 1.0-1.5 mg/kg d.m. (Germany, depending on application load and input materials), 0.036 kg/ha (UK, voluntary standard).
Nickel	[2]	7.9 mg/kg dry weight	50 mg/kg d.m. (FPR), 40 mg/kg d.m. (ECN-QAS), 35-80 mg/kg d.m. (Germany, depending on application load and input materials) 1.2 kg/ha (UK, voluntary standard).
Copper	[2]	200 mg/kg dry weight	300 mg/kg d.m. (FPR, ECN-QAS), 70-900 mg/kg d.m. (Germany, depending on application load and input materials), 4.8 kg/ha (UK, voluntary standard).
Zinc	600 mg/kg dry weight	70 mg/kg dry weight	800 mg/kg d.m. (FPR), 600 mg/kg d.m. (ECN-QAS), 300-5,000 mg/kg d.m. (Germany, depending on application load and input materials).
Mercury	0.2 mg/kg dry weight	[2]	1 mg/kg d.m. (FPR), 0.45 mg/kg d.m. (ECN-QAS), 0.7-1.0 mg/kg d.m. (Germany, depending on application load and input materials), 0.024 kg/ha (UK, voluntary standard),
Nonylphenol	[2]	3.5 mg/kg dry weight [3]	25 mg/kg d.m. (Wallonia, Belgium, Guide value only, for digestate only), 10 mg/kg d.m. (Denmark).

Notes:
1) Note that there are some uncertainties associated with the container growing scenario used, as discussed in Appendix D. In particular, the current calculations assume that there is no loss of the substance from the growing medium by leaching (although the analysis carried out in Appendix D suggests that this may not be so significant for nickel, copper, zinc and nonylphenol) and that the dietary intake from root and leaf crops occurs entirely from crops grown in such media. This latter assumption, in particular, may lead to an overestimation of the risks associated with compost and digestate containing nickel in this scenario and so the estimated safe limits should be seen as preliminary only.
2) Safe limit would be higher than the current levels so this is not currently seen as a concern.
3) As per the definition of 'safe limit' earlier in this section, this refers only to the endpoint in question (for nonylphenol this is set out in Table 4.19). However, nonylphenol also has other adverse effects which can occur at lower concentrations.

The risk assessment suggests that setting (additional, EU-wide) limit values equal to the calculated safe limits would adequately control the risk, while minimising the amount of compost/digestate restricted. Where concentrations are below the safe limits, this implies no further risk management is required.

Group 2: Substances without safe limits but with existing limit values

For substances for which conventional quantitative risk characterisation is not appropriate, safe limits could not be defined in the risk assessment. Hence, it is not immediately clear at which level limit values (if any) should be set. However, safe limit values could be informed by the level at which existing safe limits (e.g. in national legislation) have been set, as presented in Table 5.5. This assumes the existing limit values are risk based, i.e. the associated risks were considered "acceptable" by the responsible organisations (e.g. competent authorities, industry associations, or JRC 2014).

Table 5.5 Overview of identified existing limit values for substances were safe limits are not definable

Substance	Existing limit values
PCBs	50 mg/kg d.m. (POPs Regulation), 1.2 mg/kg d.m. (Norway, PCB6), 0.2 mg/kg d.m. (Austria, PCB6), 0.1 mg/kg d.m. (Luxemburg, PCB6, guide value only), 0.4 mg/kg d.m. (Slovenia, PCB6), 0.8 mg/kg d.m. (France, PCB7, only for sewage sludge compost), 0.2 mg/kg d.m. (Germany, only for sewage sludge products), 0.08 mg/kg d.m. (Denmark, PCB7), 0.8 mg/kg d.m. (Flanders, PCB7), 0.15 mg/kg d.m. (Wallonia, PCB7).
Dioxins and furans	20 ng I-TEQ /kg dm (Austria, PCDD/F), 20 ng I-TEQ /kg dm (Wallonia, PCDD/F), 20 ng I-TEQ /kg dm (Luxemburg, PCDD/F, guide value only), 20 ng I-TEQ /kg dm (Switzerland, PCDD/F, guide value only), 30 ng WHO-TEQ/kg dm (Germany, maximum sum of PCDD/F and dl-PCB, in some cases additional restrictions for PCDD/F only of maximum 5 ng WHO-TEQ/kg dm)
Lead	120 mg/kg d.m. (FPR), 130 mg/kg d.m. (ECN-QAS), 100-150 mg/kg d.m. (Germany, depending on application load and input materials)
PFAs	100 µg/kg d.m. (Austria, Denmark and Germany, PFOA+PFOS).
PAHs	6 mg/kg d.m. (FPR, PAH16), 1.5 mg/kg d.m. (France, Benzo[a]pyrene), 2.5 mg/kg d.m. (France, Benzo[b]fluoranthene),), 4 mg/kg d.m. (France, Fluoranthene), 3 mg/kg d.m. (Denmark, PAH11), 3 mg/kg d.m. (Norway, PAH16), 3 mg/kg d.m. (Slovenia, PAH16), 4 mg/kg d.m. (Switzerland, PAH16), 5 mg/kg d.m. (Belgium, PAH16), 6 mg/kg d.m. (Austria, PAH6), 10 mg/kg d.m. (Luxembourg, PAH16).

Group 3: Substances without safe limits or existing limit values

For these substances neither calculated safe limits nor existing limit values can inform the choice of an appropriate limit value. Hence, additional criteria would be needed to judge appropriateness of limit values for these substances. Of the substances prioritised for further risk management (as per Section 5.2), this is the case only for 17α-ethinylestradiol.

Enforceability, manageability and monitorability of concentration limits as risk management

As discussed above, concentration limit values are included in existing risk management measures. As a result, approaches to enforce and monitor concentration limits already exist. Quality assurance schemes including limit values have achieved a high market penetration in many countries[129] which would suggest existing limits are also manageable. However, the question remains whether this would be significantly affected by additional limits. Changing the level of existing concentration limits would likely not have any significant impact on enforceability, manageability and monitorability[130]. However, setting concentration limits for additional contaminants would require additional concentration measurements.

The burden of concentration measurements for different combinations of contaminants and for different sizes of installations was discussed in detail in JRC (2014) (see in particular the section "Requirements on product testing for compost and digestate" from page 142). This is not reproduced here in detail, but the JRC concluded that whilst some concerns were raised over the burden to very small plants, the "sampling and analysis cost associated to the proposed EU end-of-waste framework [covering heavy metals and PAH16 at

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[129] According to personal communication with the European Compost Network (ECN), quality assurance systems (QAS) in compliance with the ECN-QAS (which specifies concentration limits) are very well established in any country where there is a market for compost. For instance, in Germany >70% of compost is covered. The share is high also in Austria, the Netherlands, Flanders and others, and it is increasing in Italy.

[130] The requirements would be similar in nature and the same mechanisms for checking compliance and monitoring could be used.

specified sampling frequencies] appears very reasonable compared to typical overall operating costs for most plants and that the additional cost induced by measurement of PAH16 represents only a minimal fraction of the typical operating cost of most medium-sized to large plants" (JRC 2014). Other organic pollutants such as PCBs, dioxins and furans and PFCs (which includes PFOA and PFOS) were not included in the proposed end-of-waste criteria but were discussed in JRC (2014). A key paragraph is reproduced in the box below, showing that the inclusion of further organic pollutants can increase sampling costs significantly. The magnitude of these additional costs would depend on which substances (e.g. which PCBs exactly) will be assigned limit values, as well as the sampling frequency. JRC also notes that prices for sampling are likely to decrease in the long term thanks to EU-wide standardisation of the measurements and ensuing increased competition between laboratories.

Of the substances prioritised for further risk management (Section 5.2), only the measurement of nonylphenol and 17α-ethinylestradiol were not discussed in JRC (2014). ECHA (2014) suggested a cost of about €200 per test for nonylphenol ethoxylates in textiles – costs for nonylphenol in compost/digestate could be in a similar order of magnitude but no specific data was available. No data on the measurement costs for 17α-ethinylestradiol in compost/digestate was available. Despite the limited information available it is likely that measurements of nonylphenol and/or 17α-ethinylestradiol would add significant burden.

JRC (2014): Cost of measurements for contaminant concentrations

"Several stakeholders provided cost data showing that measurement costs for heavy metals in compost/digestate were on average 129 Euro for a full metal set (range of 42 to 230 Euro), 149 Euro for PAH16 (range of 85 to 245 Euro), 201 Euro for PCB (range of 85 to 480 Euro), 481 Euro for PCDD/F (range of 300 to 741 Euro) and 150 Euro for PFC (only one data source). This shows that PCDD/F measurements are clearly the most expensive, followed by PCB, whereas PAH and PFC measurements only seem slightly more expensive than heavy metal measurements. For comparison, prices provided for the full suite of measurements for quality assured composts/digestates were generally situated between 350 and 550 Euro. Hence, adding the full set of 4 organic compound groups would roughly result in a tripling of the current analytical costs, whereas including only a PAH measurement would lead to an increase of the current measurement costs with about a third. Moreover, if only one PAH measurement would be required for every fifth sample, the average analytical cost for end-of-waste materials would only increase by 7%. In addition, other stakeholders have argued that cost increases would not be linear. As such, data were provided that showed that packages of different analytical parameters were generally more economical, e.g. 190 Euro for a full set of 8 heavy metals, PAH16 and PCB7, compared to 91 Euro for the metals alone, for a same laboratory. Moreover, it is believed that a price increase from implementing mandatory organic pollutants measurements would be partially offset by a price decrease on the long term thanks to EU-wide standardization of the measurements and ensuing increased competition between laboratories."

Source: DG JRC: Technical proposals on end-of-waste criteria for biodegradable waste subjected to biological treatment, page 133, 2014.

5.5.3 Option 2: Restriction on the input materials (feedstocks) in compost and digestate used as fertiliser

Restricting input materials aims to eliminate those materials that are the most likely or significant sources of contaminants. As discussed in Section 5.4, some restrictions on input materials already exist, but, restrictions of input materials are less common than concentration limits.

Note that the concentration of contaminants in input materials is subject to variation and so the risk cannot be directly controlled by restricting input materials. However, according to JRC (2014) the restriction of input materials is considered a potentially more workable alternative and/or additional safeguard to checking concentration limits. As discussed in Section 5.3, generally higher or maximum concentrations of substances of concern were noted in the following input materials[131]:

- Sewage sludge exhibits generally higher or the maximum observed concentrations for most priority substances of concern (copper, zinc, mercury, 17α-ethinylestradiol, dioxins and furans, nonylphenol, PFOA, PFOS, PAHs).
- Biowaste and greenwaste compost/digestate exhibits generally higher or the maximum observed concentrations for nickel, mercury, Nonylphenol and possibly dioxins and furans and cadmium.[132]
- Mechanical biological treatment (the organic fraction of mixed municipal solid waste) digestate exhibits generally higher or the maximum observed concentrations for heavy metals.

The majority of the total digestate and compost produced in the EU is agricultural digestate (manure and energy crops), which could not be linked to particularly high concentrations of any priority substances of concern with certainty. It should be noted that sewage sludge C/D only accounts for a small share of the EU compost/digestate production (at least 2.5 million tonnes), while biowaste and greenwaste compost/digestate account for some 21-25 million tonnes, and MBT digestate even some 46 million tonnes. Restricting an input material with a smaller tonnage would constitute a less disruptive effect on the compost/digestate market, but it would also control a smaller share of the risk posed by the EU-wide market.

Section 4 of JRC (2014) discusses advantages and disadvantages of granting end-of-waste status to compost/digestate from a wider or smaller range of input materials, and of using a positive list of allowed materials or a negative list of prohibited materials. This discussion is not reproduced here. However, based on JRC (2014) and discussions with key stakeholders over the course of this study, the main features of restrictions on input materials as compared to additional or stricter concentration limits are:

- Reinforced consumer confidence (by including only input materials with a proven track record of quality);
- Easier and less costly monitorability and enforceability, because of less comprehensive sampling required;
- More directly encouraging separate waste collection (if use of not separately collected waste is prohibited);
- No level playing field of standards across all C/D materials and thus not the same simplicity and clarity to producers and consumers;
- Not technology neutral and less legal certainty for long-term investment planning.

5.5.4 Option 3: Restriction on the conditions of use of compost and digestate used as fertiliser

While options 1 and 2 focus on reducing the risk by reducing the concentration of the contaminants in C/D, option 3 focuses on reducing exposure by restricting uses where the contaminants are more likely to affect people or ecosystems. This risk management option could only effectively control the risk where the risk assessment has identified a concern for specific use scenarios. These cases are marked in Table 5.2 (Section 5.3.2) and discussed further below.

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[131] Note that this does <u>not</u> imply that a potentially unacceptable risk exists <u>only</u> for compost/digestate from these input materials. However, if an input material exhibits generally higher concentrations (or the risk of occasionally very high concentrations of contaminants), it could be prioritised for risk management.

[132] Among the highest concentrations reported was a digestate made from a mix of biowaste/green waste, manure, energy crop. It is unclear from which of these input materials the high PCB and cadmium contents stem.

- For nickel, copper and nonylphenol, a potential concern (measured concentrations in C/D exceed safe limits) has only been identified for container growing but not for application to agricultural land.[133]
- For zinc, for both uses a potential risk has been identified and for mercury a potential risk has been identified for application onto agricultural land, but not container growing.[134]
- For Lead, BPA, DEHP, 17α-ethinylestradiol, HBCDD, PCBs, dioxins and furans and PFAs, safe limits could not be calculated, but exposures at the steady state are higher for the container growing scenario than for application onto agricultural land.

Hence, for all substances for which the risk assessment has found a concern - except for zinc and mercury - the risk could be reduced by restricting the use of C/D in container growing. According to the market analysis, the vast majority of digestate is used directly as fertiliser in agriculture. On that basis the risk assessment has assumed that only compost is used in container growing. While the available market data for compost does not explicitly distinguish container growing, it is estimated that in the order of 6 million tonnes correspond to uses that potentially include container growing (see Section 5.3).

To further target this risk management option, it could be combined with a restriction on input materials (see Option 2 above). This would mean that in particular composts from input materials with generally higher or highest maximum concentrations of those contaminants with a greater risk in container growing are prohibited in that use.

Little information on the implementability, enforceability, manageability and monitorability of this risk management measure was available because it was not proposed as an end-of-waste criterion (see JRC 2014)[135]. However, it appears likely that prohibiting a specific use (e.g. container growing) for a specific product (e.g. sewage sludge compost) should be simple to implement and manage through labelling and rules for distributors and retailers. Monitoring and compliance checks are likely to be more difficult, particularly for consumers (as opposed to professionals) which are likely among the users of compost in container growing.

5.5.5 Option 4: Specification of using specific processes

Specific processes and techniques are available that can reduce the concentration of contaminants in C/D. This potentially includes the introduction of additional processes and techniques:

- before composting/AD, i.e. addressing the feedstocks, their collections, handling and processing;[136]
- during composting/AD, i.e. the composting/AD processes themselves; or
- after composting/AD, i.e. post-processing.[137]

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[133] This is because the use as a stand-alone growing medium relates to growing plants in container beds, bags, or pots, where the substance can be expected to remain in the compost and its interstitial water (soil pore-water) unless either degraded, lost by volatilisation or taken up into plants; the latter could potentially lead to human exposure if the plants are eaten. Note however the uncertainties associated with the container growing scenario results, particularly for Nickel and to a smaller extent for Copper, as discussed in Section 4.

[134] This is because the main risk identified for mercury is secondary poisoning via the fish food chain, which is not relevant for the container growing scenario. Although leaching from the compost in used container growing into interstitial water may occur, this will tend to be taken back up into the compost/plant and is unlikely to lead to significant exposure of the external environment.

[135] In the context of end-of-waste criteria restrictions on the use of the product are not appropriate because end-of-waste status should imply a full-fledged product without any further waste management controls. This principle is however not critical in the context of this RMOA.

[136] Note that this does not include restrictions on which input materials (feedstocks) can be used for composting/AD, as this is addressed in Option 2.

[137] Note that this does not include the conditions of use of compost and digestate, as this is addressed in Option 3.

Processes and techniques during and after composting/AD are primarily related to the composting/AD operator or possibly other stakeholders processing compost or digestate further. In contrast, processes and techniques before composting/AD (such as waste collection and separation) primarily concern other stakeholders that are not directly handling C/D themselves (such as waste operators). Therefore in the following, processes and techniques during and after composting/AD are assessed jointly, and processes and techniques before composting/AD are assessed separately.

Processes and techniques during and after composting/AD

Table 5.6 provides a brief overview of the available processes and techniques to reduce each of the contaminants whose risk has been assessed in this report.

Table 5.6 Overview of reduction of contaminants through specific anaerobic digestion, composting, or post-treatment processes

Chemical category or family	Representative substances assessed	Relevant AD/composting processes or post-treatment
Heavy metals	Cadmium, Nickel, Lead, Copper, Zinc	Metals can be removed from digestate through a two-stage AD process (Evans 2001). The 1st stage includes hydrolysis/acidification and liquefaction of the substrate and the 2nd stage includes methanogenesis. Research results show that around 70% of the Ni, 40% of the Zn and 25% of the Cd can be removed.[138] For Cu and Pb, mobilization in the hydrolytic stage was shown to be lower (0.5% for Cu, 5% for Pb), resulting in less effective removal (Selling R., Håkansson T., Björnsson L. 2008).
	Mercury (Hg)	No relevant processes have been identified. Efforts to reduce mercury typically focus on controlling mercury in feedstock by reducing or eliminating the mercury contents in household products, particularly batteries and fluorescent lamps.
Bisphenol A	Bisphenol A (BPA)	No relevant processes have been identified. Limam et al. (2012) studied biodegradation of bisphenol A during anaerobic digestion process and no biodegradation was observed.
Phthalates	DEHP	DEHP degrades better under aerobic than under anaerobic conditions (Madsen et al., 1999; Staples et al., 1997). Therefore, DEHP can be expected to be removed from organic waste through composting to a much higher extent, compared to anaerobic digestion (Kupper et al., 2008).
Pharmaceuticals	17α-Ethinylestradiol	AD has been shown to reduce concentrations. Carballa et al. (2007) who examined pharmaceutical and personal care products. The behaviour of 17α-Ethinylestradiol in laboratory scale anaerobic sludge digesters under mesophilic conditions (37°C) with a sludge retention time (SRT) of 30 d and under thermophilic conditions (55°C) with an SRT of 20 days was examined. Removal of 17α-Ethinylestradiol was reported to be initially 60% rising to 90% with time. However, it is not clear if using a specific process could be used to reduce concentrations more than AD in general.

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[138] When the leachate from hydrolysis was circulated over a macroporous polyacrylamide column for 6 days (Lehtomäki, A and Björnsson, L, 2006).

Chemical category or family	Representative substances assessed	Relevant AD/composting processes or post-treatment
Hexabromocyclododecane	Hexabromocyclododecane (HBCDD)	AD has been shown to reduce concentrations of this contaminant. Andreas C et al. (2006) investigate whether degradation of HBCD occurs in a full-scale anaerobic digester. In accordance with the results of the laboratory incubation experiments, concentration HBCD decreased between inlet and outlet of the full-scale anaerobic digester by around 42%. However, it is not clear if using a specific process could be used to reduce concentrations more than AD in general.
Nonylphenol isomers and ethoxylates	Nonylphenol	Thermophilic digestion has been shown to be most effective to reduce nonylphenol concentrations in digestate. Paterakis et al. 2012 found a removal efficiency of nonylphenol in the mixed sludge of 92% for thermophilic digestion, compared to 58% for mesophilic digestion.
Dioxins and furans	2,3,7,8-TCDD, 2,3,4,7,8-PCDF	None found.
PCBs	PCB28	Reeh and Moller (2001) and Brändli et al. (2007) find low rates of degradation of PAH and PCB compounds during anaerobic digestion. The combination with composting as a post-treatment shows a higher rate of degradation (Reeh and Moller, 2001). PAHs with a low molecular weight are known to be biodegraded under aerobic conditions (Yuan et al., 2000) and two-stage anaerobic process (Cea-Barcia et al., 2013).
PAH16	Benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene, indeno[,2,3-cd]pyrene	
PFAs	PFOA, PFOS, PFHxA	There are no well-established treatment technologies for PFAs contaminated digestate/compost. The main post-treatment technologies that can be considered to remediate PFAs in digestate/compost include sorption and stabilization or the mobilizing/destructing of contaminants using heat (thermal technology). Thermal treatment trials conducted by Enviropacific, 2017 on PFAs impacted soils have demonstrated highly effective contaminant removal of all 20 commonly observed PFAs analytes, with >99.9% reduction in PFOS (from 172 mg/kg to 0.004 mg/kg), and PFOA (from 2.73 mg/kg to <0.0005mg/kg).
Physical impurities	Microplastics	The main process to remove microplastics in compost/digestate is mechanical screening in the pre- and post-treatment, including physical purification through ultra-filtration and reverse osmosis. In-vessel cleaning systems such as a rotating skimmer can remove floating material such as plastics (WRAP 2012).

In the following, the relevant processes/techniques identified above are assessed further, including their effectiveness in controlling the risks, practicality, monitorability and any other aspects relevant to their suitability as risk management option. Note that some product quality criteria schemes and the proposed end-of-waste criteria (JRC 2014) for C/D also specify several other processes that do not relate to any particular contaminant or group of contaminants prioritised for risk management in this study.[139]

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[139] These include:

- Time-temperature profiles (primarily address the presence of pathogens, which are not assessed in this study);
- Storage conditions to minimize emissions of greenhouse gases, odour or other compounds (does not relate to the uses assessed in this study, i.e. the application of compost/digestate onto agricultural land or in container growing);
- Plants producing end-of-waste compost or digestate should only be allowed to process approved materials; the possibility of physical contact between input materials and final products must also be prevented (do not relate to any particular contaminant or group of contaminants, and no estimates of their effectiveness in reducing contamination is available - can be considered as an addition to other risk management options, rather than an measure of their own).

- **Two-stage anaerobic digestion:** Two-stage anaerobic digestion allows higher reduction of heavy metals (Cadmium, Nickel, Lead, Copper, Zinc) and a better biodegradation efficiency of PAH16. In a two-stage anaerobic digestion system, hydrolysis/acidification and acetogenesis/methanogenesis are technically separated to maintain optimum environmental conditions for each group of microorganisms (acid and methane formers). It is associated with higher cost and space, but provides several benefits: The selection and enrichment of different microorganisms in each digester allows them to perform better and thus enhances the efficiency of the plant. It also allows to apply a higher organic loading rate (OLR) and a shorter hydraulic retention time (HRT) which ensures process stability even when input materials are highly variable.

- **Post-composting:** Aerobic conditions (i.e. composting) achieve a higher degradation of DEHP, PAHs and PCB compounds (and pesticides) compared to anaerobic conditions. Therefore, composting digestate as a post-treatment would lead to higher removal of those substances. The implementation of this process would be associated with additional space, time and operational cost.

- **Thermophilic digestion:** There are two types of anaerobic digestion systems: mesophilic (optimum temperature 37^{0}C) and thermophilic (optimum temperature 55^{0}C). All feedstock considered for anaerobic treatment is processed under either of these conditions. Removal efficiency of nonylphenol is higher for thermophilic digestion compared to mesophilic digestion. The adaptation of mesophilic anaerobic digestion to thermophilic conditions is in principle practicable to every plant[140]. Bouskova et al. (2005) showed that the required increase in temperature can be achieved directly in one step. The disadvantage of thermophilic stabilization is that more energy for the heating system is required.

- **PFAs extraction:** Heat can be used to increase the volatility of PFAs such that they can be volatilised from the digestate/compost. The resulting gases are treated at very high temperature to break down the PFAs and allow capture of the resulting fluoride in an air pollution control device. Thermal treatment requires an additional appropriately designed plant to treat the material and is associated with significant energy costs.

- **Mechanical screening:** As discussed in Table 5.6, microplastics in compost/digestate can be removed through readily available mechanical screening technologies. However, microplastics was not prioritised for risk management (see Section 5.2), so this is not discussed in further detail here.

Regarding the enforceability, manageability and monitorability of specific processes as risk management in general: Regulators could check compliance with requirements to use specific processes through inspections and/or a monitoring regime including submission of monitoring data to the regulator at regular intervals. Operators need to be able to monitor a range of parameters at different stages of the composting/AD process in order to control the process. This includes temperature, hydraulic retention time (HRT), pH, loading rate, waste composition, chemical oxygen demand (COD), dry matter (DM), flows and composition. Therefore the required monitoring infrastructure is already in place.

Processes and techniques before composting/AD

FERA (2011) has assessed in detail the potential for upstream control of contaminants in C/D (amongst other materials) spread to land. The contaminants considered included heavy metals, POPs, bulk industrial and domestic chemicals, pesticides, human pharmaceuticals, veterinary medicines, biocides and PCPs, as well as pathogens. Table 5.7 summarises the potential upstream processes and techniques (hereafter referred to as measures for simplicity) identified in FERA (2011) for the contaminants that were prioritised for risk

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[140] According to Wood internal experts on anaerobic digestion.

management in this study. As the table shows, there are a range of possible measures across various sectors. Below, for each main input material for compost/digestate, the most promising measures are listed[141]:

- Agricultural digestate (energy crops and manure) (122 million tonnes of digestate): Reducing heavy metal content in manure by controlling livestock diet.
- Mechanical biological treatment of mixed municipal solid waste (46 million tonnes of digestate): Several identified measures relate to sources that would be expected to end up in significant quantities only in mixed municipal solid waste. This includes measures such as use of metal-free inks, use of Cadmium-free or Lead-free batteries, recycling of batteries and take-back schemes for safe disposal of pharmaceuticals.
- Biowaste/greenwaste (21-25 million tonnes of C/D): Separation of woods that have received copper-containing treatment.
- Sewage sludge (2.5 million tonnes of C/D): Replace metal pipework with plastic pipework to avoid corrosion (reducing heavy metals). Two further measures addressing contaminants in sewage sludge were proposed but their effectiveness and feasibility seem currently uncertain.
- A few measures address industrial waste streams not known to be used in composting/AD. This includes separation of dyeing and post-dyeing wastes and separation of wastes from different processes in packaging.

The potential effectiveness of each measure in reducing the risk from contaminants in C/D is difficult to assess. First, it depends on the effectiveness of reducing the concentration of contaminants in the waste streams concerned. This is often uncertain because it can depend the starting concentrations in the waste streams concerned, the technical efficiency of the measure and the uptake (especially measures reliant on consumer behaviour such as recycling schemes). Second, the effectiveness depends on the share of the particular waste stream in the input materials used in compost/digestate, which is often not known in any detail.

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[141] The measures are attributed to input materials based on the “major source” and “waste type” addressed by each measure (see Table 5.7).

Table 5.7 Overview of reduction of prioritised contaminants through specific upstream (i.e. before composting/AD) processes and techniques

	Waste type	Major sources	Potential upstream control	Notes
Heavy metals (several)	Livestock manure, Abattoir waste, Chemical and pharmaceutical industry	Feedstuffs	Increase bioavailability in animal diet	With increased bioavailability of copper and zinc in animal diet, then it is likely that lower amounts are needed in feedstuffs, which would therefore effectively reduce levels in manure.
	Sewage sludge	Plumbing corrosion	Replace metal pipework with plastic pipework	
	Municipal solid waste	Batteries	Use of Cadmium-free or Lead-free batteries, Recycling (e.g. stewardship incentive schemes)	The use of Cadmium-free batteries is likely to greatly reduce Cadmium in MSW and these are already available. Lead mainly comes from batteries for which there are already available schemes for recycling.
	Paper and pulp industry	Ink	Use of metal-free inks	Using metal-free inks would reduce amount of heavy metals in the waste ink produced by a printer; in the printed materials that are landfilled or incinerated; in the sludge created during de-inking in paper recycling. However, it is unclear to what degree paper waste and sludges from this industry end up in feedstocks for compost/AD and so to what degree they contribute to the contaminants in compost/digestate.
	Food and drinks industry	Packaging	Separate the wastes from the different processes.	An effective measure to keep the different contaminants separated in the different waste streams to avoid cross contamination. However, it is unclear to what degree packaging waste ends up in feedstocks for compost/AD and so to what degree they contribute to the contaminants in compost/digestate.
Nickel (Ni)	Drinking water sludge, Food industry	Unknown	-	-
Copper (Cu)	Wood, bark and other plant waste	Wood treatment	Separate woods according to treatment received.	
Zinc (Zn)	Textile industry	Dyes, Flameproof wool	Separate wastes that contain heavy metals	Separation of dyeing and post-dyeing wastes from the other waste streams reduces heavy metal contamination of the final waste.
Mercury (Hg)	Gypsum	Unknown	-	-

	Waste type	Major sources	Potential upstream control	Notes
17α-ethinylestradiol (in FERA 2011: "Pharmaceuticals")	Sewage sludge	Urine and faeces	Urine separation (NoMix technology)	Separation between urine and faeces using the NoMix technology would significantly reduce levels of pharmaceuticals in sludge. However, this approach would not be practical for all households.
	Sewage sludge, Municipal solid waste	Improper disposal	Take-back schemes for safe disposal	
PCBs, dioxins and furans (TCDD, PCB28, PCDF)	Sewage sludge	Atmospheric deposition	Measures already in place	Measures already in place (e.g. PCBs, PCDD/Fs have been banned).
Nonylphenol	Not assessed in FERA (2011)			
PFAs (in FERA 2011: "Surfactants")	Various	Various	Substitution of persistent chemicals.	Most PFAs are already being regulated and substituted.
PAHs	Sewage sludge	Atmospheric deposition	Catch basin in motorways	PAHs could possibly be reduced by using a catch basin to recover sediments and therefore PAHs sorbed onto these.

Source: Wood 2018 based on The Food and Environment Research Agency (FERA): Assessing the potential for the upstream control of contaminants present in materials spread to land. Report produced on behalf of Defra. April 2011.

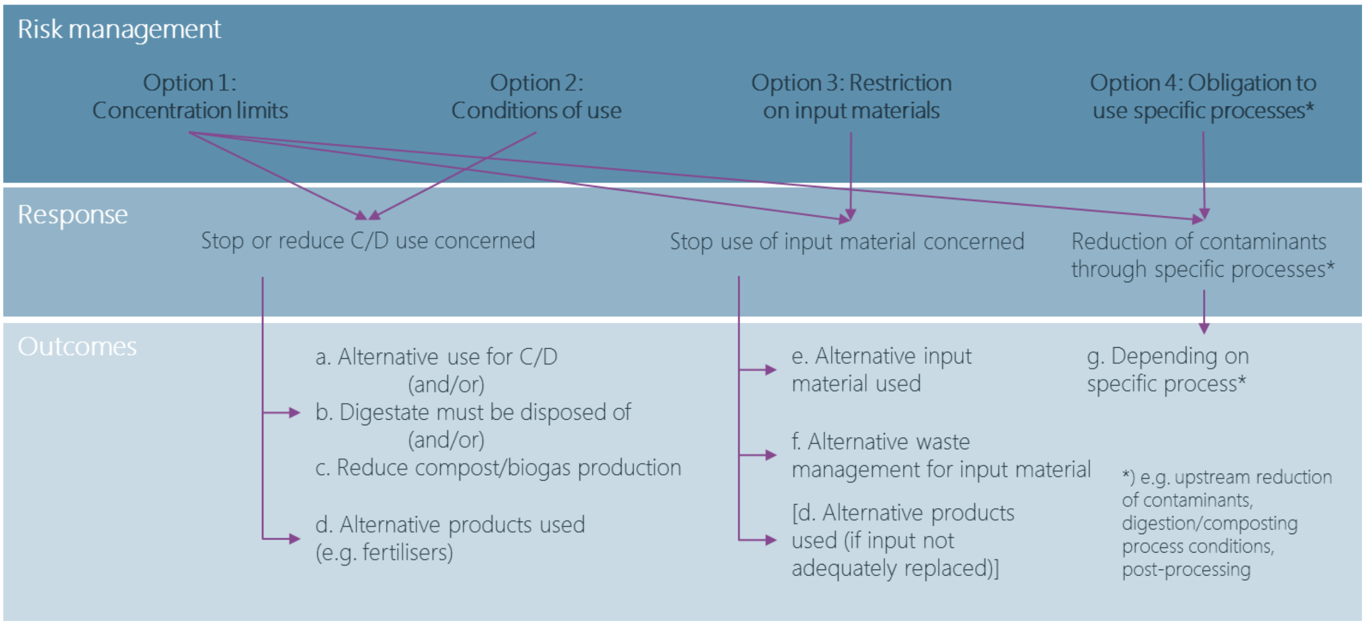
5.6 Socio-economic considerations

This section covers preliminary socio-economic considerations associated with the potential risk management options outlined above. As a reminder, these were:

1. Setting **concentration limits** for the contaminants of concern
2. Reducing the contaminants of concern by eliminating the use of potentially contaminated **input materials** in composting/anaerobic digestion (AD).
3. Reducing the exposure to the contaminants through the introduction of further **conditions of use** for compost and digestate (C/D).
4. Reduce concentrations by applying **specific processes** before, during or after composting/AD.

Figure 5.2 shows the main anticipated responses from the supply chains along with associated outcomes. These are identified based on literature review, the targeted stakeholder consultation under Task 1, and discussions with the steering group.

Figure 5.2 Response scenarios for all risk management options



Notes: "C/D" stands for compost and/or digestate.

The overall approach follows Guidance on Annex XV for restriction (ECHA 2007). In this alternatives assessment is a core component which are usually defined as *"alternative chemical substances or alternative techniques (processes and technologies) or combinations thereof that can be used to replace (partially or totally) the substance of concern in a given use or a number of uses by providing the equivalent function that the substance delivers in those uses or by making the function redundant"* (ECHA 2007). In this case, the "alternatives" derive from both the expected responses and outcomes identified in the response scenario above. These largely comprise alternative processes and technologies used to reduce the identified risks. Therefore, the four aspects described above (technical feasibility, economic feasibility, availability and human health/environmental risks) are assessed for each of the main outcomes. Table 5.8 summarises the results for all outcomes in this chapter.

Table 5.8 Summary of socio-economic considerations for the main expected outcomes of potential risk management options

Outcome	Technical feasibility	Economic feasibility	Availability	Human health/environmental risks
a. Alternative use for compost/digestate	Uncertain: There are few alternatives uses and these are in the early stages of development.	Production of digestate would likely continue largely unchanged regardless of feasibility of alternative uses. Largely not feasible for compost: production of compost that cannot be used in agriculture/landscaping would likely be stopped.	Uncertain: few alternatives uses for C/D, in early stages of development.	No significant additional risks identified.
b. Compost/digestate must be disposed of	Technically feasible: primarily relevant for digestate, most likely destination incineration or landfill.	Further waste management costs (e.g. gate fees) for digestate: <€5 to >€150 per tonne, depending the Member State as well as transport costs. Not relevant for compost (production would likely cease).	Uncertain: Depending on scope of regulatory action potential need for increases in capacity.	Considerable additional risks. Contrary to environmental policy objectives. Environmental benefits of C/D use may be lost.
c. Reduction of compost/biogas production	No relevant technical constraints.	Income from selling or using digestate often secondary to AD operators, so biogas production would likely continue largely unchanged. Reduction of compost production would result in foregone revenue from compost sales.	No relevant constraints.	Risks potentially result from alternative waste management of input materials (as per f. below)
d. Alternative products used	Partly feasible: inorganic fertilisers are a feasible alternative to C/D in terms of nutrient availability but not in terms of organic matter.	Likely economically feasible in terms of nutrient supply.	Likely no availability issue in terms of nutrient supply.	Several additional environmental risks identified: Greenhouse gas emissions, disruption of natural nutrient cycles, eutrophication

Outcome	Technical feasibility	Economic feasibility	Availability	Human health/environmental risks
e. Alternative input material used	Generally feasible, but with implications on plant design and biology, quantity (biogas) and quality of the outputs (digestate/compost).	Uncertain: Depends on a range of factors. Potentially significant impact on the economics of any composting or anaerobic digestion plant.	Likely no availability issue, constraints from implementation of separate waste collection and competing uses of cropping area (energy crops vs food production) may arise implemented at scale.	Risks potentially result from alternative waste management of input materials (see f. below)
f. Alternative waste management for input material	Technically feasible: Established waste management methods exist (e.g. incineration, landfill). Other methods in early stages of development.	Uncertain due to wide ranges of costs for each disposal method. Costs of alternatives other than landfilling appear to be at a similar or higher scale than composting and anaerobic digestion.	Uncertain: Depending on scope of regulatory action. Capacity available but constrained by legal landfill reduction targets and restrictions to incineration of bio-waste.	Considerable additional risks. Contrary to environmental policy objectives.
g. Specific processes to reduce contaminants in compost/digestate				
Measures before composting/AD	This includes a wide range of measures: Most appear technically feasible but require further research and/or the precise contamination removal efficiency unclear.	Includes a wide range of measures: Some are economically feasible, for some there is limited data available, and for other potential concerns have been identified.	This includes a wide range of measures: Some are economically feasible, for some there is limited data available, for others potential concerns identified.	No significant additional risks expected for most options, but limited data available.
Measures during or after composting/AD	Uncertain: Several measures potentially technically feasible, depending on the required removal efficiency.	Uncertain: Limited data available. Additional costs are associated with the measures, but at least partly offset by operational benefits (e.g. more efficient/faster digestion)	Uncertain: Limited data available.	No significant additional risks identified.

5.6.1 a. Alternative use for compost/digestate

Further (as yet undefined) conditions on the use of compost/digestate (Option 2) or specific concentration limits (Option 1, again undefined) may be introduced to address specific substance concerns. In the event of either risk management measure, various outcomes are possible: (a.) Downstream users may switch to alternative uses (i.e. compost/digestate is used in applications where concentration limits or use restrictions do not apply), this is discussed in this subsection. (b.) There may be an increase in the amount of digestate that cannot be used and are disposed of as waste (discussed in Section 5.6.2) and (c.) production of compost / biogas may reduce (discussed in Section 5.6.3).

Few alternatives uses for C/D other than as soil improvers and fertilisers currently exist. Those that are, are in early stages of development. Table 5.9 summarises alternative uses for compost.

Table 5.9 Alternative uses for compost

Use	Description
Covering landfills/construction	In personal communication the ECN suggested as alternative use in the worst case compost could be used for covering landfills or in construction. For example, while the Irish Environmental Protection Agency highlights how covering landfills is a potential use for compost, it is also noted that compost can have methane and odour oxidative properties and promote vegetation growth, and requires regular testing if it is used as a daily cover, as opposed to an intermediate cover. This is to check permeability and biostability as under particular conditions stockpiles of combustible matter can self-combust due to gas generation (EPA 2014). Hence, landfill cover is not the best alternative use – especially for high-quality compost – but it is feasible, subject to regular checks.
Construction of artificial wetlands	The construction of artificial wetlands can reduce erosion and sediment run-off. Compost has the potential to be used as a substrate for construction of such wetlands due to its organic matter content, permeability and ability to hold contaminants (EPA 1995).
Rehabilitation/restoration of mining sites with low quality C/D materials	Ecological restoration and mine reclamation have become important parts of the overall sustainable development strategy in many countries. Surface mining can cause soil quality deterioration in terms of biological, physical, and chemical properties. Hence, an alternative use for low-quality C/D materials is their application on damaged soil as part of the soil restoration process during remediation (Sheoran et al., 2010) (Borišev et al., 2018). For example, composted MSW has been used in the restoration is limestone quarries in Mediterranean environments (Almendro-Candel et al., 2014).

According to a WRAP report (2011) on markets for digestate, uses identified include: home garden fertiliser and soil amendment products; landscaping; commercial fruit and vegetable production; compost tea production; mushroom growing media; commercial nurseries; fertiliser for organic crops and farms; forestry; publicly owned flower beds/green spaces. Alternative uses for digestate identified by WRAP include:

- algal culture;
- construction materials;
- fuel production; and
- biopesticides production.

As highlighted in Appendix B, digestate can also be further processed by drying. The end product can be used as animal bedding and biomass for green energy as well as organic fertiliser. However, according to the European Biogas Association, digestate drying is a questionable process due to the high consumption of heat. Furthermore, during the drying process, if there is no effective air scrubbing in place, ammonium gets released into the air (EBA 2013). The report highlighted that as of 2011 technical limitations will constrain potential future demand. No further evidence was found to indicate that these alternative uses for C/D have since become established on the market. This feeds into their economic feasibility as it is possible that they are still in embryonic stages of development (WRAP 2011). Table 5.10 summaries each alternative use for digestate in turn.

Table 5.10 Alternative uses for digestate

Use	Description
Algal culture	This is a method for extracting nutrients from organic wastes via the cultivation of engineered algae ponds. This method could be used to develop algal biomass from digestate to feed biofuel production. WRAP highlighted that the Carbon Trust is researching the feasibility of increasing the yield of oil from different species of algae, and how to reduce costs associated with its harvesting. The harvested algae/macrophytes can be used as feedstock for biofuels, animal feed or as an organic fertiliser. However, it is predicted that the breakthrough of algae in the bio-based economy will take another 5–15 years, due to high costs compared to other types of biomass (Vaneeckhaute et al., 2018).
Construction materials	Dried fibres of anaerobically digestate animal manure can be blended with UF resin and pressed into wooden panels. However, this has not yet been implemented at a large scale because certain design elements still need to be tested (i.e. adherence of paint).
Fuel	Bioethanol is an alternative to petrol which is produced by sugar formation. It has previously been assumed that digestate fibre was unsuitable for processing into bioethanol. However, it has been demonstrated that AD changes the composition of manure fibres – improving suitability for the production of ethanol. For example, it was estimated that for every dry tonne of manure, 0.6 tonnes of digestate fibre could be produced which could be processed to produce 6.3m3 ethanol. As of 2011 this technology was not yet available on a commercial scale, and according to the market analysis (see Section 2), this is still not a common use of digestate. Given the developments required for alternative fuel sources due to the effects of climate change, further investment in the development of this technology is likely and could make it feasible in the future.
Biopesticides	Due to the difficulties associated with the availability of raw materials for conventional biopesticide production (i.e. soybean meal, soluble starch etc.) there may be potential for production of biopesticides from AD food and farm waste. However, the composition of digestate feedstock may have varying impacts on the effects of biopesticides on insects and detailed investigation into this topic is still required in order to conclude whether or not it is a viable alternative use for digestate.

Overall conclusion

While the uses mentioned above are potential alternatives for digestate, they are still in the early stages of development and require further investigation for further comment on their feasibility. According to personal communication with anaerobic digestion operators, the business model of the majority of installations is primarily based on biogas production or gate fees, rather than on income from selling or using digestate. The production of digestate would therefore potentially continue largely unchanged regardless of whether alternative uses are feasible.

The alternative use of compost in the construction of artificial wetlands, while viable, is a niche use and unlikely to require large amounts that are currently being produced. Compost also has some potential to be used as a landfill cover (preferably as an intermediate cover) but this is a low value application unlikely to require vast amounts being produced and, is not the best use for high-quality compost. Contrary to anaerobic digestion operators, the business model of composting operators is relying on income from selling compost. According to personal communication with the European Compost Network, the production of compost that cannot be used in agriculture/landscaping anymore would therefore likely be stopped.

5.6.2 b. Compost/digestate must be disposed of

As discussed above, (as yet undefined) conditions on the use of compost/digestate (Option 2) or the imposition of specific concentration limits (Option 1, again undefined) could lead to various outcomes. This sub-section discusses the hypothetical case where risk management leads to an increase in the amount of digestate that cannot be used and would therefore be disposed of as waste.

Technical feasibility

If compost can no longer be used as a fertiliser/soil improver, it is likely that compost would simply not be produced, or at least produced in sustainably smaller volumes.[142] So, an initial effect is likely to be increased volumes of input materials being disposed of as waste (unless viable alternative uses are found), rather than increased volumes of compost per se. The potential disposal routes for these input materials are discussed in Section 5.6.6. In addition, depending the scope and phasing of any restriction or condition, there would be a short-term increase in disposal of existing stocks of compost. Given the size of current market in the EU (central estimate of 17.3 million tonnes per year), depending on the specific concentration limits or use restriction this could amount up to several million tonnes of increased waste disposal need, per year.

The same logic does not apply to digestate, because the business model of the majority of anaerobic digestion installations is primarily based on biogas production or gate fees, rather than on income from selling or using digestate.[143] So, a rationale for continued production of digestate in large volumes would remain. Current production is large (with a central estimate of 180 million tonnes per year across the EU 28).

According to personal communication with the European Biogas Association and with a large anaerobic digestion operator, if no use for digestate is available it will most likely be incinerated or landfilled, depending on capacities of each Member State (this is discussed further in Table 5.11). Anecdotal information from the same source indicates only a very small proportion of digestate is currently incinerated in Europe. According to WRAP (2012) incineration may be the only available disposal option for digestate which cannot be applied to land due to non-compliance with legislation (WRAP 2012). JRC (2014) reported that in the Netherlands, digestate that does not meet the requirements for use as fertiliser is partially incinerated and partially landfilled.

Overall there is no inherent technical constraint in disposing of both compost (input materials) and digestate as waste, provided that moisture content is reduced/low. The most likely destination is incineration and where this is not feasible, landfill.

Table 5.11 Overview of likely waste management options and technical implications

Treatment	Notes on technical feasibility
Landfill	There is no inherent technical constraint to landfilling of digestate, except that the Landfill Directive specifies liquid waste shall not be accepted to landfill. The digestate may therefore have to be dried or the liquid fraction separated beforehand. Landfill is seen as the "final resort" in the waste management hierarchy and is contrary to various policy/regulatory targets. The revised Waste Framework Directive sets new common EU targets for recycling of municipal waste of 55% by 2025, 60% by 2030 and 65% by 2035 (Directive 2008/98/EC). Digested municipal biodegradable waste may only be counted as recycled if the resulting digestate is to be used as a recycled product, so landfilled digestate does not count towards these targets. The revised Landfill Directive sets a binding landfill reduction target of 10% by 2035 (Directive 2018/850).
Incineration	Digestate has to be dewatered prior to incineration in order to reduce the moisture content, potentially requiring additional fuel/energy input to dry the digestate. Co-incineration with municipal solid waste may provide a means of increasing the heating value. The volume of additional fuel required to initiate and sustain combustion, and whether energy recovery from the process is possible both depend on the calorific value of the digestate, moisture content and the efficiency of the incinerator.

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[142] This was confirmed by personal communication with the European Compost Network.

[143] According to personal communication with anaerobic digestion operators.

Economic feasibility

This section examines the economic feasibility of compost/digestate being disposed of as waste. This involves a brief exploration of the market characteristics of both to help determine the most likely course of action and hence the main socio-economic effects.

Composting

Table 5.12 shows that the transport and production costs of compost at least on average typically exceed its market price. On this basis, a likely outcome would be a substantial reduction in the production of compost in Europe and an associated increase in disposal of the input materials. There would be a corresponding loss of economic activity of the compost distributer/application business. Although there is no data on the size of this sector, the nature of the market described above suggests it would be comparatively small.

Table 5.12 Market characteristics of composting

Market aspect	Explanation
Transportation cost	JRC (2014) notes that generally compost plants serve a local market, supplying their product within 50 km of the plant[144]. This is the equivalent distance a 25 tonnes capacity lorry can make within an hour, at a cost of EUR 50–60. They note that transport costs and the other marketing expenses are generally covered by end compost prices of around EUR 5/tonne (EUR 125/lorry load).
Production cost	Production cost of composting depend on local conditions and the quality of the material to be composted. For example, - Estimated costs of composting source-separated biological waste is c. EUR 35–60/tonne of waste for larger 'best practice' plants in closed systems, although higher costs are noted. - The cost of low-tech windrow composting is estimated to be lower than EUR 20/tonne.
Market prices	Prices for bulk compost for use as organic fertilisers or soil improvers are lower than the production costs. Prices of composts for agricultural were rarely above EUR 5/tonne of compost, often lower or given away to farmers free of charge. A typical model used in Germany is that compost is given as part of a service that includes transport and spreading of the compost itself on land (JRC, 2014). This is broadly consistent with more recent estimates from the UK, indicating transportation costs of between £2-3 for solid organic materials, with spreading costs of between £2 and 4 per tonne (or m3), depending the vehicle type and load size (WRAP 2016).

Digestate

Table 5.13 summarises market aspects of anaerobic digestion. Overall it appears likely that if concentration limits / conditions of use were applied, additional volumes of digestate would be disposed of as waste. This would incur further waste management costs (e.g. gate fees), which range from <5 Euros per tonne to >150, depending the Member State as well as transport costs (European Environment Agency 2013). These additional costs may mean some reduction in the market size as well as a possible slowdown in the growth of the sector but appears less likely to make biogas production economically infeasible. For agricultural end users, this would also be compounded by potential losses in crop yield.

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[144] JRC also note specific cases in Germany where compost is being transported over longer distances of c.200 km.

Table 5.13 Market characteristics of anaerobic digestion

Market aspect	Explanation
Production cost	JRC (2014) notes (based on discussion with the European Biogas Association), that production costs range from 10 to 30 Euro per tonne for bio-waste treatment through anaerobic digestion. This value excludes the investment costs necessary to for start-up and costs are sensitive to technology used as well as input materials. Gate fees also vary, which reflect differences in regulation and the energy content of the feedstock. In some cases, they note anaerobic digestion operators actually pay for the input materials.
Market prices	JRC note that sales price for digestate are generally slightly lower than for compost. Often this aspect of operation runs at a loss, with average maximum price of 3 to 5 Euro/tonne for whole digestate. The digestion plants commonly pay companies or farmers for land spreading. In specific cases (solid and post-composted digestates) sales prices reach closer 10 Euro per tonne with some dry pelletized digestates reach prices of up to 150-250 Euro per tonne. Sales prices of dried digestate range from 5 - 30 € per tonne and wet digestates between 0 to 8 Euro/tonne. Composted digestates generate prices of 0 to 50 Euro per tonne. The wide range reflects differences in local demand; regions with a higher manure supply tend to reflect lower digestate prices. This is broadly consistent with more recent estimates from the UK WRAP, indicating transportation costs of between £3 and- 4 for liquid organic materials (whole, liquid or separated liquor digestate) and £2-3 for solid (e.g. separated fibre digestate), with spreading costs of between £3 – 4.50 per tonne (or m3), depending the vehicle type and load size (WRAP 2016).
Biogas production	There are no publicly available data on the economic impact of the European biogas sector, but the European Biogas Association (EBA) statistical report 2017 indicate capacity of around 18,000 plants with strong expansion between 2009 and 2014 in particular. Installed electric capacity stood at 9,985 MW in 2016.

Availability

There are both environmental, economic and technical limits to waste management capacity. In terms of landfill, there has been a 59% decrease in the volume of European waste sent to landfill between 1995 and 2016. The latest 2016 data indicates some 60 million tonnes of municipal waste was sent to landfill across the EU28 (Eurostat 2018a).

Eurostat collate data on incineration activity across Europe in line with the Waste Statistics Regulation and the Waste Framework Directive (Eurostat 2018b). Current European incineration capacity is greatest in Germany, France, Netherlands and the Nordic countries. As of 2016 European incineration capacity (total waste, both hazardous and non-hazardous), stood at some 80.8 million tonnes, up from 71.6 million in 2004, an increase of 13%. Given the 180 million tonnes of digestate produced in Europe at present, even a small increase in the amount of waste dealt with via incineration, say 5%, would imply an increase in demand of 10%, hence a potential need for increases in capacity.

Human health and environmental risks

An increase in C/D waste would be contrary to the package of waste regulation and risk management progressively adopted in the EU over the last 20 years. The Landfill Directive 1999/31/EC set out various targets to reduce the amount of biodegradable waste that goes to landfill and reaffirmed that landfilling is the least preferable option, to be limited to the necessary minimum. More generally it requires Member States set up national strategies for the reduction of biodegradable waste going to landfill (European Commission 2016b). The Directive 200/98/EC on waste (Waste Framework Directive) further established the waste hierarchy, with disposal the least preferable, alongside various waste management principles to avoid harm to human health and the environment, further legislation involves landfilling and incineration specifically as well as the shipment of waste (European Commission 2016c, European Commission 2017). More recently the 7th Environmental Action Plan (7th EAP) aims to reduced waste, limiting both incineration and landfilling to non-recyclable/non-recoverable waste alongside the 2018 waste package (European Commission 2018d).

Unless satisfactory alternatives are used, the environmental benefits of both composting and digestate use may be lost. These include increases in soil organic matter, erosion reduction, increased water retention and physical structure of soil (aggregate stability, density, pore size).

5.6.3 c. Reduction of compost/biogas production

As discussed above, (as yet undefined) conditions on the use of compost/digestate (Option 2) or the imposition of specific concentration limits (Option 1, again undefined) could lead to various outcomes. A potential reduction in the production of compost/digestate is discussed in this sub-section.

As discussed above, the business model of most anaerobic digestion operators is primarily based on biogas production or gate fees, rather than on income from selling or using digestate.[145] The production of biogas would therefore potentially continue largely unchanged, so the discussion below focuses on compost only.

A reduction of compost production would imply that likely (d.) alternative products must be used to replace it (discussed in Section 5.6.4), and the use of input materials for composting would also be reduced and so (f.) alternative waste management practices would have to be used for these input materials (discussed in Section 5.6.6). However, in addition to these outcomes, a reduction of compost production would result in foregone revenue from compost sales.

The total revenue foregone to composters would depend on the mass of compost production that is stopped, as well as the price of the affected types of compost. According to JRC (2014), typical prices of compost for farmers are up to €5 per tonne, often including transport and spreading. However, higher prices have been reported in some countries for compost made from certain input materials such as pure garden and park waste, particularly when sold in smaller bags to hobby gardeners, potentially reaching €10-300/t.

5.6.4 d. Alternative products used

Further (as yet undefined) conditions on the use of compost/digestate (Option 2) or the imposition of specific concentration limits (Option 1, again undefined) could lead to a reduction in certain uses of compost/digestate. A (again as yet undefined) restriction on input materials for composting and anaerobic digestion (Option 3) could have a similar effect, if these input materials cannot be adequately replaced, e.g. for reasons of technical or economic feasibility or availability.

According to the market analysis, the vast majority[146] of the c. 180 million tonnes of digestate produced in the EU is used as a fertiliser. The majority (ca. 85%) of compost is used as a fertiliser or soil improver in agriculture, gardening, horticulture and landscaping. This corresponds to something in the order of 15 million tonnes of compost.[147] If certain uses of certain composts and digestates are restricted through risk management their users (predominantly farmers) need to replace them with alternative products (notably fertilisers), or face losses in crop yields due to a lack of nutrients. The share of C/D affected strongly depends on the specifications of the risk management and can therefore not easily be quantified before a specific combination of risk management is chosen. Therefore, in the following the main general implications of replacing C/D with alternative fertilisers are discussed.

Technical feasibility

Digestate and compost are examples of organic fertilisers. Inorganic/synthetic fertilisers include complex N and P-fertilisers, simple mineral fertilisers (urea, ammonium nitrate, sulphate) and mineral-organic fertilisers (calcium cyanamid) (Eurostat 2015a). Fertilisation modifies soil properties (including pH, organic matter

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[145] According to personal communication with anaerobic digestion operators.

[146] For instance, JRC (2014) suggests 95%.

[147] The central estimate of total compost produced in the EU (17.3 million tonnes) multiplied by 85%.

content, soil richness, and nutrients availability). Organic fertilisers modify these qualities differently to inorganic fertilisers.

In terms of nutrient availability, inorganic fertilisers are a feasible alternative to C/D, as the latter have been shown to yield variable nutrient availability[148]. However, repeated use of compost may increase overall organic matter content and water retention in the soil which improves its workability[149]. It has also been shown to enhance environmental qualities such as biodiversity, which enhances the soil's resilience to stress.[150] Therefore, while the nutrient availability may vary depending on type of organic fertiliser and soil type, inorganic biodiversity and soil health can be improved over time due to organic matter content.

The nutrient composition of digestate can vary dependent on the feedstock and treatment (i.e. food-based digestates generally have higher nutrients than crop/manure based) (AHDB 2017). Inorganic fertilisers with well-defined nutrient concentrations may be technically preferable to farmers, as decisions related to the type/amount of nutrients applied to crops is calculated at farm level, based on the cost of fertilising products and the efficiency of nutrients in terms of yield (European Commission 2012). Due to the variation in nutrients between digestate producers, users are advised to analyse the digestate themselves, or to contact a qualified advisor/agricultural consultant (for instance, FACTS members in the UK)[151] to conduct nutrient management planning, (which may have extra costs. Integrating this kind of analysis into farm nutrient management planning would further maximise the potential of digestate to be used by farmers. According to WRAP, the available data needs to be updated to advise farmers on how to best apply digestate to crops (WRAP 2012).

Inorganic fertilisation – especially N fertilisers – contributes towards reducing the soil's pH, which enhances the mobility of micronutrients such as Cu, Fe, Mn and Zn while also adding available nutrients directly to the soil. However, conventional inorganic fertilisers – which currently supply most of Europe's soil nutrients - do not supplement organic matter content. Furthermore, simple N fertilisers and P fertilisers only add that single nutrient to the soil while organic fertilisers have variable concentrations of nutrients but also contain organic matter, an important component of healthy soil (European Commission 2012).

Given the lack of available guidelines, training and variable nutrients, it is highly likely that that conventional inorganic fertilisers may be technically preferable to farmers. Inorganic fertilisers are already commonly used, they are a technically feasible alternative to digestate and compost, but at an environmental cost (See Human health and environmental risks). Despite the high nutrient availability of inorganic fertilisers, they cannot act as substitutes for C/D in terms of organic matter.

Economic feasibility

As discussed above, compost, digestate and synthetic fertilisers contain different combinations of nutrients and other materials that benefit the soil. Therefore, these products are not ono-to-one replacements. To assess the economic feasibility of alternatives, this section first compares prices of compost/digestate with conventional fertilisers and then puts this into context of their implications for crop yields.

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[148] Digestate contains significantly more readily available nutrients than compost but this depends on how much is lost as ammonia emissions and leaching both of which can which can be reduced by the use of precision applicators during spreading and the time of year spreading occurs. Due to the highly available rates of N, digestate is also subject to no-spreading periods e.g. within Nitrate Vulnerable Zones (Eurostat 2015a).

[149] For example, the available field data indicate that compost contains little available N, yet its repeated use can increase organic matter content and water retention in the soil which generally improves workability. According to WRAP, little data has been gathered on phosphate availability from compost, but extrapolation from livestock manure and sludge suggests that ca 50% of phosphate applied is available (AHDB 2017).

[150] For example, a study conducted by Liu et al. (2016) evaluated the effects of fertiliser on soil nematode communities in croplands from over 229 data points across 54 studies. The results showed that nematode abundance increased with C input, while greater N application reduced species richness. Species richness was found to increase in organically-fertilised regimes, and decline in inorganically fertilised regimes.

[151] FACTS is a body for standard setting and training in crop nutrition, established in 1993. http://www.factsinfo.org.uk/facts/home.eb

Market prices

The data available is patchy, but Table 5.14 presents a summary of indicative values for the sales price/t of compost, digestate and examples of synthetic fertilisers used in Europe. Note that market prices for C/D are discussed in Section 5.6.2, Table 5.12 (compost) and Table 5.13 (digestate).

The latest data on sales price of synthetic fertilisers available from Eurostat is very patchy between MS and shows high variability. For example, for sulphate of ammonia, the price in Bulgaria is recorded at €1170/t, while in Czech Republic it is recorded at €170/t. Hence, the prices presented below should be taken only as indicative values.

Table 5.14 Summary of indicative sales price data on compost, digestate and synthetic fertilisers

Type of fertiliser	Indicative unit cost (€/t)
Compost	0-5
Digestate (whole)	3-5
Synthetic fertilisers	
****Sulphate of ammonia***	599
****Ammonium nitrate (26% N in bulk)***	493
****Urea***	583
****Superphosphate (18% P_2O_5)***	677
****Sulphate of potash***	772
****Ternary fertiliser 9-9-18 (NPK ratio)***	310
****Binary fertilizer 0-20-20 (NPK ratio)***	328

Source: *Denotes Eurostat 2017 data, based on average €/100kg of synthetic fertilisers across all MS converted to €/t. Compost and digestate indicative figures: JRC (2014)

Implications for crop yield

While the data on sales price highlights that synthetic fertilisers are significantly more expensive than compost or digestate when unit cost is considered, the effects of fertiliser on crop yield is likely to have more control on whether alternatives to digestate and compost are economically feasible or not. Hence, value-cost ratio (VCR) or net return from fertiliser, is, according to the FAO, a key determinant regarding fertiliser use (FAO 2006). Given the fact that the availability of nutrients and organic matter to soil also depends on local conditions (i.e. climate, terrain, soil type) (FAO 2006) the economic feasibility of using alternatives to digestate and compost will likely be different between EU Member States. Furthermore, survey data from Case et al. (2016) for 448 Danish farmers highlighted that uncertainty regarding nutrient content was a key barrier to using organic fertilisers including digestate and compost, and can therefore be interpreted as a motivation to using of synthetic fertilisers (Case et al. 2016).

Considering vegetation growth depends on the availability of nutrients, and nutrients availability is significantly more variable in digestate/compost than it is in synthetic fertilisers, it is likely that in terms of ensuring value-cost ratio/net return from fertiliser use, synthetic fertilisers may be more feasible for farmers. Therefore, despite the lower sales price of compost and digestate, there are possible trade-offs regarding net returns from fertiliser in terms of crop yield. As a result, when focusing on the provision of nutrients it seems likely that it is economically feasible to use synthetic fertilisers as an alternative to composts or digestates

Availability

Considering synthetic fertiliser as the main alternative to replace nutrient supply from compost/digestate, the synthetic fertiliser sector is a mature industry within Europe, which currently supports the majority of Europe's nutrient needs. For example, according to Eurostat N-based fertilisers accounted for the vast majority (77.4 %) of the nutrients consumed (Eurostat 2015b). Fluctuations in consumption have occurred (i.e. a dip in fertilizer use over 2009-10), which is attributed to price increases associated with the link between N fertilizers and oil prices. While the Nitrates Directive and the Water Framework Directive led to reductions in specific Member States (i.e. Croatia, Italy and Greece), overall, total N fertiliser consumption remains high in the EU (Eurostat 2018c). It should be noted that, given the environmental risks and high transport costs associated with synthetic fertilisers (See section below on Human health and environmental risks), the Commission are currently taking steps to revise EU regulation on fertilisers to promote the circulation of recycled nutrients (i.e. in digestate and compost) by developing quality standards to reduce the need for mineral-based synthetic fertilisers (European Commission 2015).

Given the fact that synthetic fertilisers already provide the majority of nutrients to European soils despite the high availability of digestate and compost being produced in the EU, a loss of a part of digestate/compost would not be likely to affect Europe's nutrient supply. However, if more policy measures are put in place to promote recycled nutrients as part of the Circular Economy strategy, the importance of digestate/compost to Europe's nutrient supply will likely increase.

Human health and environmental risks

Nutrients are essential for all forms of life and nutrients such as N and P are a principal component of fertilisers which are applied to agricultural land. However, there are a range of environmental and health risks associated with such fertilisers which are summarised in Table 5.15. This suggests if compost or digestate were to be replaced with synthetic alternatives, eutrophication and environmental risks associated with P and N fertilisers would likely become more prevalent. Whilst there are concerns regarding cadmium content of P fertilisers, it is not yet possible to provide a conclusive answer as to whether this is an additional risk to the use of digestate or compost, as quality standards are still being developed as a means of minimising health risks associated with their use.

Table 5.15 Summary of health and environmental risks associated with alternatives to compost/digestate

Risk	Explanation
Health risks	Cadmium in P fertilisers and the associated effects on human health have been identified as a potential risk within the EU (SCAHT 2015). Several Cd compounds have also been identified as SVHC under REACH and included in the candidate list for authorisation (ECHA 2018d). 90% of P fertilisers are imported from third countries (e.g. Morocco, Tunisia). The cadmium content in P rock can vary depending on where it is mined, potentially making its way into soils, foodstuffs and lead to long term adverse health and environmental effects (EPRS 2017).
Environmental risks	
Climate change	It has been estimated that in Europe for every ton of mineral fertiliser that gets produced, an average 9.7 tons of CO_2 eq is emitted (EBA 2015). Hence, the use of mineral fertiliser contributes to the overall risks associated with climate change and fossil fuel emissions as its production is energy intensive. For example, it has been estimated that 2% global energy production gets used to produce inorganic N fertilisers alone. The physical application of N fertiliser to land also releases N-emissions into the atmosphere which can also contribute to acidification and climate change (Eurostat 2018c).

Risk	Explanation
Disruption of natural nutrient cycles	Disruption of natural nutrient cycles is another environmental risk associated with the use of mineral fertilisers. For example, phosphorous is an example of a commodity which moves linearly from mines, travelling large distances where it is applied to crops as fertiliser, where a large amount may be lost to surface waters, or it may become inactive due to over application and is thus not fully taken up by the crops it is applied to (Schröder et al., 2011). For example, it has been estimated that only between 15-30% of P fertiliser that is applied gets taken up by crops – the rest may end up in the aquatic environment when soil is saturated by phosphorus, where it can contribute to eutrophication and algal blooms (in addition to N) (Weber et al. 2014). In Europe, mineral fertilisers and manure accounted for 93% of the P input to the environment (Eurostat 2018d).
Eutrophication	Regarding N, before the development of the Haber-Bosch process in the 19th century, the only natural means of forming reactive nitrogen (Nr) from N_2 was by lightning and biological N fixation (BNF) of certain bacteria. This was balanced by the natural cycle of conversion of Nr back to N_2 which ensured Nr did not naturally accumulate in the environment. Today, since the development of N-fertilisers via the Haber-Bosch process, biologically available nitrogen has dramatically increased due to increased food demands of a rapidly growing population and as such, majorly contributed to Nr accumulating in lakes, rivers and seas all over the world (Galloway et al. 2014). Excessive N fertiliser application gets lost to water and overstimulates production of algae and contributes to eutrophication in the aquatic environment. For example, according to the impact assessment for CE marked fertilisers, leaks of N and P from human activities have negatively affected European surface waters via eutrophication and led to the development of anoxic zones in coastal zones.[152]

5.6.5 e. Alternative input material used

Further (as yet undefined) restrictions on input materials for composting and anaerobic digestion (Option 3) could lead to replacement of the restricted inputs with other materials. Furthermore, the imposition of specific (as yet undefined) concentration limits (Option 1) could have a similar effect, if the concentration limits cannot be met in particular by compost or digestate from specific input materials.

Technical feasibility

Almost any biodegradable organic material can be treated by anaerobic digestion/composting. Anaerobic digestion/composting plants are currently treating a wide range of material including various kinds of organic wastes, manures, crops and other plants (see market analysis in Section 2). Therefore, in principle the substitution of one input material with another (biodegradable organic) material is technically feasible. However, the composition of input materials has significant implications on the plant design and digester biology, as well as the quantity (biogas) and quality (digestate/compost) of the outputs. These are discussed in Table 5.16.

Table 5.16 Main implications of input material choice for anaerobic digestion and composting plants

Market aspect	Explanation
Plant design and digestion biology	Each type of input material will require an appropriate pre-treatment process to transform the materials into a suitable form for digestion/composting. Depending on the chemical composition of the input material, the microbes responsible for the digestion process may need to be supplemented with trace elements, particularly selenium, cobalt, nickel and iron to perform at a peak level. But excessive concentrations of some elements and common compounds can inhibit or kill the microbes, so inputs must

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[152] Circular Economy Package: Impact Assessment (2016) Proposal for laying down rules on the making available on the market of CE marked fertilising products and amending Regulation no 1069/2009 and No 1107/2009.

Market aspect	Explanation
	be carefully planned and monitored. Hence, it is theoretically and practically possible for any plant to switch to any other commonly used input material, but each type of input material can bring different challenges (preparing material for digester feeding and impact on digester performance (biogas production).
Biogas yield (applies only to AD)	The energy content stems from methane, which accounts for about 50-75% of the volume of biogas. Different input materials yield different amounts of methane and hence biogas in anaerobic digestion, depending on their content of proteins, fats, and carbohydrates (Lemvig Biogas 2008). Therefore, to achieve the same amount of biogas with an alternative input material may require larger/smaller quantities of material, depending on the biogas yield of the different materials. Biogas yield in m^3 per tonne of fresh feedstock is provided for some typical feedstocks below:[153] - Livestock manure and slurries: Ranges between 15-100 m^3/tonne for different animals - Organic waste: This can vary widely depending on the composition of the waste, but 100 m^3/tonne is reported as a typical value. - Plant waste: from around 80 (beets), to around 200 (silage) and up to 500 (grass, leaves) m^3/tonne - Energy crops: From around 300 to over 600 m^3/tonne
Digestate/compost quality	Similarly, the quality of the resulting digestate or compost for agriculture depends on the input materials used. Table 5.17 provides and overview of nutrient value in digestate from a few different input materials, for illustration. Furthermore, the nutrient availability (the share of nutrients that are in chemical forms accessible to plant roots, an important factor in plant growth) varies across different input materials used. For instance, 80% of the total nitrogen is present as readily available nitrogen in food-based digestate, whereas the figure is lower in digestate from livestock slurries (around 50% for cattle slurry digestate and 70% for pig-slurry digestate).[154]

Table 5.17 Examples of the nutrient content (kg/m^3 fresh weight) of some input materials commonly used in anaerobic digestion

Input material	Total N	NH_4-N	Total P	Total K
Grass silage	3.5-6.9	6.9-19.8	0.4-0.8	–
Maize silage	1.1-2	0.15-0.3	0.2-0.3	4.2
Dairy waste	1.0	0.1	0.4	0.2
Food leftovers	0.8-3	2-4	0.7	Value not available

Source: Lukehurst et al. (2010). Utilisation of digestate from biogas plants as biofertiliser. IEA Bioenergy Task 37. Available at: http://www.centri-force.co.uk/wp-content/uploads/2014/07/Utilisation-of-Digestate-as-Biofertiliser-V2.0.pdf

Economic feasibility

As discussed above, using alternative input materials can affect the quantity of biogas produced per tonne of input material. Alternatively, the plant can adjust the quantity of input material to produce the same amount of biogas. In any case, this has an impact on the economic viability of the plant, because it can affect either the income through the sale or use of biogas (which is the main source of income in most cases) or the costs. The change in costs would depend on the relative prices of different input materials. Table 5.18 gives examples of values of different input materials in the UK in 2010 (values have been converted to € in 2017

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[153] A more detailed list can be found in the sources for these figures: Lemvig Biogas 2008 Handbook and NNFCC anaerobic digestion information portal (http://www.biogas-info.co.uk/about/feedstocks/)

[154] WRAP (2012): Using quality anaerobic digestate to benefit crops. The source provides nitrogen availability in pig and cattle slurry and notes that digestion of livestock slurry will typically increase availability of the nitrogen in the slurry by around 10%. This yields the figures of 50% for cattle slurry digestate and 70% for pig-slurry digestate reported here.

prices). These are 'opportunity cost' values, i.e. what the product could be sold for on the open market or transferred into another farm enterprise (such as dairy), which can be different from the 'cost of production' of the input materials. The values are for illustration only, as in reality they will vary across Member States and local circumstances as well as time. However, the values show that there is a wide variation of costs across different input materials. For instance, grains which are also associated with the highest biogas yield are also the most expensive. Manure has no value for other applications and is typically free, while for treating waste, plants can treat gate fees and hence generate an income, rather than a cost, from the input material.

Table 5.18 Examples of input material costs

Input material	Cost	Income (gate fee)
Maize/grass silage	€28-32	
Grain (wheat/barley)	€102-114	
Manure/slurry	€0	
Green waste		Ca €25
Food waste		At least €57

Source: THE ANDERSONS CENTRE (2010). A DETAILED ECONOMIC ASSESSMENT OF ANAEROBIC DIGESTION TECHNOLOGY AND ITS SUITABILITY TO UK FARMING AND WASTE SYSTEMS 2ND EDITION. Available at: http://www.organics-recycling.org.uk/uploads/category1060/10-010%20FINAL_Andersons_NNFCC_AD2010.pdf
Values converted to Euros in 2017 prices, using the 2010 annual average annual exchange rate from the European Central Bank (available at: https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/index.en.html) and the Harmonised Index of Consumer Prices (HICP) for the euro area (available at: https://www.ecb.europa.eu/stats/ecb_statistics/escb/html/table.en.html?id=JDF_ICP_ECONOMIC_ACTIVITIES_INX).

The choice of input materials can affect the nutrient content and availability of both compost and digestate. This in turn affects their value for use in agriculture/landscaping. For instance, JRC (2014) reports a range of values for C/D from different input materials, in various countries. For instance, depending on the nutrient content the price of digestate can vary from €5-30/t for dried digestate and €0-8/t for wet. Prices for compost from park and garden waste are generally reported to be higher (€8-12/t) than those for compost from for instance mixed municipal solid waste (MBT compost, €2–3/t)[155]. Note however, that of course the choice of input materials affects not only the sales price of the compost/digestate, but also the costs for input materials, as discussed above.

As mentioned above under technical feasibility, the choice of input materials can also affect the amount and type of pre-processing required. This could also have economic implications, although detailed data on cost for pre-treatment by input material were not available.

Hence, switching input materials can significantly affect the economics of any composting or anaerobic digestion plant. However, due to the amount of factors involved that are all subject to strong local variation, no general conclusion about economic feasibility could be drawn.

Availability

In principle, far larger amounts of most input materials are or could be made available than is currently used in composting and anaerobic digestion. For instance, it is estimated that, only about 25% of the 118 and 138 million tonnes of bio-waste arising annually in the EU are currently recycled into C/D (ECN 2016b). This does

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[155] The fact that JRC 2014 refers to a price for MBT compost suggests that it has been produced at some point before 2014. Note that the market analysis could not quantify MBT compost production in Europe, as some sources suggest MBT compost is not currently produced, while others suggest that compost is or at least has been produced from MBT in some smaller countries.

not include significant quantities of food residues from food manufacturing (41 million tonnes) (ECN 2016b). However, the ability to use these materials for composting and digestion depends on their separate collection, which is not yet implemented across the EU and likely challenging to establish quickly.

Whilst there are competing uses for energy crops (e.g. biofuel) and for cropping areas (e.g. growing crops for food), in 2012 it was estimated that in the EU only 3.2% (5.5 million hectares) of the total cropping area were used for bioenergy cropping, of which in turn only 7% were used for biogas crops (Biomass Futures 2012). Due to the significant growth of biogas production since that time, these figures will have increased, but biogas still likely only accounts for a small share, which suggests that small increases in the use of energy crops for anaerobic digestion would likely be feasible, provided market prices can be paid (see economic feasibility above).

Human health and environmental risks

This section assesses switching input materials in response to a risk management measure to reduce risks to human health and the environment from the use of C/D as fertiliser. No increase in other risks is expected. Hence, risks are expected to decrease overall.

5.6.6 f. Alternative waste management for input material

Further (as yet undefined) restrictions on input materials for composting and anaerobic digestion (Option 3) could lead to the restricted inputs having to be treated using alternative waste management methods. Furthermore, the imposition of specific (as yet undefined) concentration limits (Option 1) could have a similar effect, if the concentration limits cannot be met in particular by compost or digestate from specific input materials.

As discussed in Section 5.3, the majority of the total digestate and compost produced in the EU is agricultural digestate, with about 122 million tonnes. The input materials of agricultural digestate are typically a mix of manure and energy crops. 46 million tonnes of digestate (and an uncertain but likely small amount of compost) is produced from organic fraction of mixed municipal solid waste (mechanical biological treatment – MBT). About 21-25 million tonnes of C/D are produced in the EU from biowaste and greenwaste. A much smaller quantity, but at least 2.5 million tonnes of C/D are produced from sewage sludge.

The alternative waste management methods covered in this subsection are landfill, incineration, including co-firing and advanced thermal treatment, physical or mechanical treatment, use as construction materials and fermentation.

Technical feasibility

The table below elaborates on the technical feasibility of the identified alternative waste management methods for inputs material from digestate and compost.

Table 5.19 Overview of potential waste management for input materials from digestate and compost

Type of waste management	Technical feasibility
Landfill	Landfilling is considered the least preferable option in the waste management hierarchy, and it should be minimised as much as possible. Waste that needs to be landfilled must comply with legal requirements set out in the Directive 1999/31/EC on the landfill of waste, which aims to prevent or reduce the negative effects on environment. Although considered as the final resort in terms of waste management, input materials typically used in C/D, could by definition be accepted by any non-hazardous licensed landfill site; however, the decision would sit with the operator of the site, who has the final decision to accept such material.
Conventional incineration	Conventional incineration is usually applied for waste with a high content of combustible fraction, i.e. paper and plastic/synthetics, and/or where land for disposal is limited. Technically, it requires adequate equipment, infrastructure facility and trained personnel (World Bank 2000). In this treatment, waste is reduced through combustion in incinerators for material recovery or disposal in landfills as an inert inorganic ash residue. The energy is recovered to produce electricity and/or heat. The most common form of incineration is large-scale mass burn incineration, that involves little or no sorting or any other pre-treatment, however, biodegradable materials (like input materials for compost or digestate) are usually excluded by source separation given their low calorific value and high water-content (except paper and wood). Sewage sludge is typically dehydrated before incineration. This is particularly common in countries where the direct use of sludge in agriculture is banned (e.g. the Netherlands (HVC 2018)). The resulting ash can be used for a range of applications, including fertiliser production, but is currently still predominantly landfilled (Donatello and Cheeseman 2013). Although a technically feasible option, the combustible residue from burning biodegradable without separate treatment provides a lower calorific value, unlike for example refuse derived fuels (RDF) that have been pre-processed to remove several streams of recyclable materials.

Type of waste management	Technical feasibility
Co-firing	Co-firing is a type of incineration that involves two or more different types of materials at the same time. The co-firing of biodegradable waste, in particular those that classify as biomass like wastewater sludge, are thus a potential source of renewable energy. Although it is technically feasible to burn wastewater sludge with municipal waste and co-firing is recognised as a 'Best Available Technology' process for IPPC (covered under BREF), there are some technical issues highlighted in the Sludge Strategy from Scottish Water (Scottish Water 2006), for instance: The technologies associated with dried sludge applications have not proven commercially viable, unlike the technologies for dewatered sludge. Pre-treatment of waste would still be required as many organic wastes have a high moisture content and may require drying before combustion. Moreover, there are technical issues regarding the mixing arrangements, as the quantity a plant may be able to take will depend on the proportions of the sludge 'cake' to dried product suggested: there is a risk that a substantial addition of cake affect negatively the combustion. Finally, the flue gas abatement plant must be in place and adequate, to ensure compliance with the Waste Incineration Directive, as the incineration of sludge can increase the emissions of particulate and NOx. Scottish Water also recognises that if the plant is not specifically designed to take specified quantities of wastewater sludge with other waste streams at the design stage, there is a substantial risk and potential for plant failure, under performance and/or inability to accept some of the intended waste streams. Scottish Water estimates that it would take between three to eight years from planning to construction and first operation of such a plant. It is also possible to construct and operate a built multi-waste stream plant; however, it is more difficult to obtain a planning permission for such a plant compared to a dedicated sludge incinerator and there are risks from adding another different stream into an existing plant arrangement. Given that regulations such as the Waste Incineration Directive apply to co-firing in power stations, stations would have to comply with requirements to meet Annex I and II on emission limits to air, and Annex IV on emission limits for discharges of waste water from the cleaning of exhaust gases, as well as clauses 2 to 8 of Article 6 on requirements for gas residence times. It is unlikely that any power station will be able to take wastewater sludge for co-firing as, depending on the quantity of wastewater sludge co-fired, the fly ashes may be considered as hazardous. Co-firing can also take place in cement and lime kilns. The use of alternative waste derived fuels is preferable in the cement industry as it is energy intensive. The utilisation of waste as fuel source is technically feasible and is subject to the Waste Incineration Directive. However, the use of wastewater sludge is not appropriate for co-firing in line plants as it can contaminate the lime.

Type of waste management	Technical feasibility
Pyrolysis and gasification (advanced thermal treatment)	Pyrolysis and gasification are both alternative waste treatment technologies that rely on high temperatures in order to treat the biodegradable share of municipal solid waste and recover energy (e.g. under heat, electricity or fuel). These technologies usually use carbon-based waste, e.g. paper, petroleum-based wastes like plastics and organic materials, and support the diversion of biodegradable waste from landfill. Pyrolysis is the thermal degradation of a substance in the absence of oxygen, to break down waste materials. Gasification is a partial oxidation process that produces syngas: the amount of oxygen added is not sufficient to allow a full combustion to occur (Friends of the Earth 2009). Advantages from those two waste management systems, often called 'advanced thermal treatment' (ATT) are (Defra 2013). Treatment from ATT technologies recover more value from waste compared to mass burn incineration; moreover, a by-product from these technologies, the syngas, can generate energy more efficiently that mass burn incineration. ATT technologies are more flexible than mass burn incinerators, as the plants are modular: they are made of a number of smaller units that allow them to increase/reduce their size depending on the waste amounts received; moreover, these technologies are easy to build. These technologies reduce the biodegradable content of residual waste, which, in turn, reduce the production of landfill gases, when this residual waste is sent to landfill. Technical limitations exist for pyrolysis and gasification. These technologies need to use pre-sorted or processed waste as feedstock and they do require high technical experience compared to mass burn incineration.
Physical or chemical treatments	Other physical and chemical treatments for input materials for C/D include: Rendering, i.e. 'the partial recovery of materials from animal by-products, e.g. former foodstuffs, by crushing and grinding, followed by heat treatment that will reduce the moisture content and kill micro-organisms' (NIBusinessinfo). Hydrolysis, i.e. 'a process in which chemical bonds are broken by the insertion of water between the atoms in the chemical bond (…). It is particularly suited to high-risk wastes, e.g. high-level animal by-product wastes' (NIBusinessinfo). Autoclaving, i.e. 'a conventional combination of heat treatment under pressure, used as a sterilisation process (…). Organic waste such as food and vegetable residues, paper and cardboard, etc. will result in an organic 'wool' or fibre when treated in an autoclave' (NIBusinessinfo). More information on this treatment is provided below. As for pyrolysis and gasification, plants are modular and made up of smaller units that can adapt to the waste streams and subsequent volumes. Technical issues exist for autoclaving as the fibre requires a significant heat input to be dried before further processing, given its very high moisture content (up to 50%). If dried to 5-8% moisture, it can be stored for over a week, but if not, it will deteriorate and rot within 24 hours. Moreover, hazardous municipal waste may contaminate the fibre, given that there is not front-end recycling to remove such hazardous waste from the waste stream beforehand. A report from Friends of Europe highlights that in some fibres, high levels of some metals were found, which limited its potential uses (Friends of the Earth 2008). Finally, autoclaving only consists in an intermediate step and potential applications for the fibre to be recovered or recycled still include composting, digestion or creation of refuse derived fuel. Potential markets to use the fibre as a raw material in product manufacturing exist, including the washing of the fibre to extract the long cellulose fibres used in paper pulp. Another application is to convert the fibre into refuse derived fuel that will be incinerated and produce energy, however this would have to occur in another dedicated site or the same facility should plan for both purposes.
Construction materials	Scottish Water reports that a number of trials involve sewage and water treatment sludges in manufacture of lightweight aggregate and bricks, as well as in the manufacture of ceramics, cement and aggregate through wastewater sludge incinerator ash. However, brick manufacturers consulted in the context of this study reported that the water content was critical for this type of treatment and their processes could not accept wet product streams (Scottish Water 2006).

Type of waste management	Technical feasibility
Fermentation	Some of the biodegradable waste can also be used to produce biofuel through fermentation. In the past, biofuels were mostly based on crops, however waste material from food crops can also be used nowadays. To make the material fermentable, a first step is to steam crack the lignocellulose parts.

Economic feasibility

A 2001 study highlighted that the prospects for obtaining one figure for the unit cost of each treatment in given countries were remote, as costs are highly influenced by the scale and volumes of waste (Eunomia 2001). Since this further literature on the topic is limited, or scattered comprising case studies focusing on specific input materials, in given countries with certain waste treatments.

A 2012 report, provides the following comparative analysis on estimated solid waste management costs by disposal method (World Bank 2012). It compares the cost of collection by income categories and the cost of treatment by disposal method, i.e. sanitary landfill, open dumbing, composting, waste-to-energy incineration and anaerobic digestion. Note that all countries in the EU are high income countries, with a few exceptions of upper mid income countries. Costs are shown for these two income categories in Table 5.20. This suggests that due to the wide ranges of costs for each disposal method, a general conclusion on the cost implications of switching from composting or anaerobic digestion to a different method cannot be drawn.

Table 5.20 Comparison of cost of collection and disposal according to World Bank 2012

Cost of collection and disposal (US $/tonne)	Upper Mid Income Countries	High Income Countries
Collection	40-90	85-250
Sanitary landfill	25-65	40-100
Open dumping	NA	NA
Composting	20-75	35-90
Waste-to-energy incineration	60-150	70-200
Anaerobic digestion	50-100	65-150

Source: World Bank, 2012, What a Waste.
Note: Information on lower mid income and lower income countries is also available in the report; however all EU MS are either upper mid income countries or high income countries.

IA 2002 report classified various disposal treatment in a qualitative manner (see Table 5.21) (Eunomia 2002). This suggests that the costs of alternative waste management practices other than landfilling appear to be at a similar or higher scale than composting and anaerobic digestion.

Table 5.21 Comparison of cost of collection and disposal according to Eunomia 2002

Disposal method	Scale of costs
Mechanical Biological Treatment	Costs of whole treatment depends upon destination of separated / treated fractions
Compost	Low to medium
Anaerobic Digestion	Medium to high
Incineration	Medium to very high
Pyrolysis	Medium to high
Gasification	Medium to very high

Source: http://ec.europa.eu/environment/waste/compost/pdf/econanalysis_finalreport.pdf

The following figure compares the cost of landfill and incineration, with and without their respective taxes, in a series of EU Member States in 2012 and 2014 (Ademe 2017), and highlights differences in the cost structure across the EU: for instance, it shows that, in 2012, the cost of landfill including taxes was lower than the cost of incinerating in France, Catalonia, and the Netherlands. Hence, the cost implications of switching from composting or anaerobic digestion to a different method will likely depend on local circumstances affecting the costs for each method. To provide more context, the cost structure of each method (where information was available) is discussed further below. Where possible, conclusions regarding economic feasibility are drawn.

Figure 5.3 Comparison of the cost of landfill and incineration, with and without their respective taxes, in several EU Member States

Source: ADEME, 2017, Étude comparative de la taxation de l'élimination des déchets en Europe

Landfill

Typical costs of landfill can be disaggregated into the following components: acquisition costs, capital expenditure and development costs, operating costs, restoration and aftercare costs. Acquisition costs depend on the country: the site can be acquired for a fee, through royalty payment or lease. Capital expenditures will also be affected by the countries' requirements as well as by the geology of the site and proximity to aquifer. Restoration costs will also be defined depending on the area rather than on the quantity of material taken. Aftercare costs arise mainly from the Landfill Directive, that requires adequate financial provisions to be made by the operator to cover the costs of aftercare, and the magnitude of this fund is likely to depend on the Member State (Eunomia 2001).

The following factors result in differences in unit costs of landfill:

- Land acquisition;
- Requirements for engineering (geology, aquifer);
- Scale of landfill;

- The rate at which the landfill is filled;
- The costs for daily cover/restoration;
- Financial provisions / aftercare; and
- Landfill taxes.

A main constrain on landfill consists in the landfill tax. CEWEP provides an overview of landfill taxes and landfill bans (current and planned) across EU Member States, in 2017 (CEWEP 2017).

Incineration and co-firing

The costs of incineration are affected by:

- Cost of land acquisition;
- Scale (given diseconomies of small scale);
- Plant utilisation rate;
- The requirements for treatment of flue gas (differing among MS);
- The treatment and disposal / recovery of ash residues: bottom ash can be used in construction, hence preventing landfill, however the fly ash needs to be treated and its cost of treatment varies among MS and depending on legislation;
- The efficiency of energy recovery;
- The revenue received for energy delivered;
- The recovery of metals and revenues from this; and
- Taxes on incineration.

Regarding the co-firing of wastewater sludge as a fuel, Scottish Water highlights that other types of waste will possibly require a higher gate fee than wastewater sludge.

Pyrolysis and gasification (advanced thermal treatment)

Regarding advanced thermal treatment, it was noted that both gasification and pyrolysis have much higher capital and operational costs than mass burn incineration. However, biomass and bio-waste gasification can improve the efficiency of large-scale biomass power facilities and specialised facilities. A report from Friends of Europe on pyrolysis and gasification indicates that the syngas (by-product from gasification) can be used to generate energy more efficiently if a gas engine is used, while incineration will only generate energy less efficiently through steam turbines. Moreover, it highlights that the energy produced is considered as renewable energy, increasing the potential income from power generated, in some countries like the UK through Renewable Obligation Certificates (Friends of the Earth 2009).

Physical or chemical treatments

A report from Friends of Europe on autoclaving raises doubt about its cost-effectiveness. It also highlights that this process is a waste of resources, as in some cases, certain high-calorific elements of the waste stream are left in the fibre, instead of being separated for recycling (Friends of the Earth 2008).

Construction materials

In a consultation for their national sludge strategy (Scottish Water 2006). Scottish Water highlighted that brickworks manufacturers would only be interested in taking water treatment sludges at very low moisture content as drying requirements may not be cost-effective in the short-medium term, and longer-term financial viability will be subject to the material's suitability, contracts, etc.

Availability

Landfill

According to Eurostat data, around 1.1 billion tonnes of waste were landfilled in the EU as of 2014, suggesting that adding a small share of waste currently treated by composting/AD would be feasible (Eurostat 2018e). However, the European Union established strict requirements for landfills through the Landfill Directive and requires that waste is treated before being disposed in landfills; moreover, it sets out that biodegradable waste to landfill must be reduced to 35% of the levels of the total amount of biodegradable municipal waste produced in 1995. The revised Waste Framework Directive sets new common EU targets for recycling of municipal waste of 55% by 2025, 60% by 2030 and 65% by 2035 (Directive 2008/98/EC). The revised Landfill Directive sets a binding landfill reduction target of 10% by 2035 (Directive 2018/850).

Incineration and co-firing

According to Eurostat data for 2014 (Eurostat 2018e), the EU has an incineration capacity of 184 million tonnes per year, and 34% of household waste are incinerated (both for disposal and recovery of energy). This varies strongly by Member State (from 0% in Bulgaria, Greece, Croatia, Cyprus, Lithuania, Malta, Romania and Slovenia to 100% in Sweden). Hence, on EU-level sufficient incineration capacity would likely exist to add a small share of waste currently treated by composting/AD, but this capacity is concentrated in some Member States so availability would likely be an issue locally. However, note that according to the revised Waste Framework Directive, bio-waste has to be collected separately by 31 December 2023 (§22 (1)) and separately collected bio-waste cannot be incinerated (§10 (3a)), although there are derogations for environmental, technical, and economic reasons.

Pyrolysis and gasification (advanced thermal treatment)

Plants that carry out pyrolysis require a certain amount of particular types of materials to work effectively, i.e. plastic, paper and food waste; hence, this conflicts with recycling and composting as these materials are often the most valuable of the waste streams for such processes. Specific information on the availability of capacity for physical or chemical treatments or use as construction materials was not available.

Human health and environmental risks

Waste management has a key role to play in the transition to circular economy, contributing to the supply of high-quality secondary resources. Although waste avoidance is prioritised in the waste hierarchy, the reduce, re-use and recycle approaches are fundamental toward the implementation of circular economy. In this context, a major concern in this analysis of alternative waste management for inputs materials used for digestate and compost lies in related risks for the human health and the environment. The following table presents the various risks to both the environment and health by disposal method.

Table 5.22 Risks to the environment and health by disposal method

Disposal method	Potential risks to the environment and health
Landfill	• Landfilling mixed municipal solid waste without pre-treatment or separating out the biological fraction used to be a common practice in the European Union despite its negative impacts on environment and health from high greenhouse gas potential (methane), leachate and space

Disposal method	Potential risks to the environment and health
	usage. In 1995, the production of methane from bio-waste (and other biodegradable waste) decomposing in landfills accounted for circa 3% of total greenhouse gas emissions in the EU15. • Nowadays, landfilling of such waste still leads to a waste a potentially valuable resource, the exploitation of virgin resources and the reduction of the amount of land required for landfill.
Incineration	• A large amount of ash is produced during the incineration of waste, ca. 30% of the weight of the original waste, and ca. 40-50% of the volume of compacted waste. Two types of ash are produced during incineration, i.e. bottom and fly ash. Fly ash is highly toxic and has high concentration of heavy metals and dioxins – even substances with little toxicity before incineration can become hazardous after the conversation to particulates and fine particles in the ash. Moreover, the combination of pollutants within the fly ash can increase its toxicity. Modern incinerations produce less air pollution, however, the less air pollution, the more toxic the ash. Given that landfill sites are becoming less available, there is a need to develop a practicable alternative to both landfill and incineration (BSEM 2008). • There are trace elements such as sulphur and nitrogen in wastewater sludge for incineration, which can lead to emissions of hazardous chemicals to air during combustion. Sludge incineration can also result in increased particulate and NOx emissions.
Co-firing	• Sludge incineration can result in increased particulate and NOx emissions. • Co-firing in a power plant station may require fit flue gas desulphurisation and NOx abatement. Moreover, depending on the quantity of wastewater sludge co-fired, the fly ash can be hazardous.
Pyrolysis and gasification (advanced thermal treatment)	• Although fewer air emissions may be produced due to the minimum use of oxygen, if gases and oils from the process are then burnt, this can generate emissions. • Disposal of ash and other by-products may happen. • Air emissions from advanced thermal treatment may include acid gases, dioxins and furans, nitrogen oxides, Sulphur dioxide, particulates, cadmium, mercury, lead and hydrogen sulphide.
Physical or chemical treatments	• The fibre from autoclaving treatment may be contaminated by hazardous municipal waste. High levels of some metals have been found in the fibre, hence limiting its potential uses. • Note that the residual waste from autoclaving may be sent to landfill, however, this treatment reduces the biodegradability of waste, hence it is 'bio-stabilised' and is less likely to degrade in the environment and produce methane gas in landfill.
Construction materials	• Waste used in construction material also produce ash that will have to be disposed to landfill.

In conclusion, most alternative waste management methods investigated are associated with severe risks to human health and the environment, and undermine the transition to a circular economy, a priority target for environmental protection and economic development in the EU (European Commission 2018e). This is true particularly for the methods that are most common (landfilling and incineration) and therefore most likely to be used for input materials that would cease to be treated by composting/AD. Some methods (advanced thermal treatment, physical or chemical treatment, use as construction materials) are associated with lower risks and/or are more compatible with the circular economy, but as discussed above, these are more niche applications associated with higher costs and/or technical limitations.

5.6.7 g. Specific processes to reduce contaminants in compost/digestate

Figure 5.2 sets out the risk management options being assessed, the potential responses from the supply chain and the associated outcomes. This subsection considers the main socio-economic considerations of requirements for additional processes to remove specific contaminants of concern (Option 4). The precise measures are as yet undefined but are expected to comprise some combination of:

- Additional measures addressing the input material / feedstocks, *before* composting / AD processes takes place.
- Additional measures taken *during*, or *after* the composting or AD processes themselves.

Note that such additional processes before, during or after the production of compost/digestate could also be used to achieve specific concentration limits (Option 1), which could be associated with the same broad socio-economic implications.

Part 1: Measures before composting/AD

This section evaluates several measures that could, in principle, be implemented before composting or AD processes commence. The potential RMO in this study focusses on addressing the risk from several chemical containments. Hence the assessment in Table 5.7 above is organised by chemical substance. This identified several measures that address the risks from several common substances, but these arise from different sources, so different technical and economic issues may be relevant for each.

The information below is based on the scope of measures in Table 5.7 and the technical analysis on each of these is contained in FERA (2011). Below we look briefly at the measure, the substance(s) the measure would address as well as the sources of the contaminants. Any RMO would require a range of different technical measures. These measures would require action at several stages of several very different supply chains.

Technical feasibility

Measure:	**Increase bioavailability in animal diet**	**Replacement of metal pipework with plastic**	**Separation of wastes; recycling; battery replacement or “take back” schemes.**	**Substitution**	**Other specific technology**
Contaminant of concern:	**Heavy Metals; (Zn, Cu, Fe, Mn).**	**Heavy metals (Cu, Zn. Cd, Hg, Ni, Pb).**	**Heavy metals (Cu, Zn. Cd, HG, Ni, Pb)** **Pharmaceuticals** **Plastics**	**Heavy Metals (Cd, Cr, Cu, Zn, Pb)** **Pharmaceuticals** **Surfactants**	**Pharmaceuticals** **Heavy Metals (Cr, Pb, Cu, Zn), PAHs.**
Waste type or source:	**Livestock manure (and abattoir waste):** Experts cited in FERA 2011 judged that further controls on metal levels in feed are possible and increasing bioavailability in feed represents “the most effective way to reduce the amount of metal in manure”. The authors note that “more research is needed on the actual requirements of animals in different life stages, the metal bioavailability, interactions between different minerals, and the use of organic trace element formulations”[156]. Despite this, certain specific techniques are proposed. These include: • Reducing the period where high zinc content diet is	**Sewage sludge (and dredgings from inland waters):** Various contaminants present, arising from a wide range of household and industrial uses and from pipework /plumbing corrosion. • Replacement with plastics pipework considered likely to reduce sludge contamination.	**Municipal solid waste:** Batteries are a significant source of Cd, Pb. Measures include: • Cd free or rechargeable batteries. • Segregation judged one of the “best approaches” for contaminant reduction. Source separation and mechanical and biological separation. FERA 2011 notes that educating consumers also likely to be effective. • Stewardship schemes: e.g. pay by weight / recycling programmes judged effective for Pb (Car batteries). **Municipal solid waste, sewage sludge and dredgings from inland waters:** • Take back schemes for pharmaceuticals already in use for e.g. drug disposal. **Paper and Pulp waste:** • Separation of de-inking sludge from other waste. **Waste wood, bark and other plant waste:**	**Municipal solid waste and Paper and Pulp waste:** • Metal free (vegetable oil based) inks: Cr in paper is mainly from inks. Using metal-free inks expected to significantly reduce levels and aid greater paper recycling. **Sewage sludge and dredgings from inland waters:** • Change prescription practices, “greener” drug development. **Textile industry waste:** • Substituting of persistent chemical incl. surfactants. **Tannery and leather waste:** • Substitution of chromium as tanning agent and of	**Urine separation from sewage sludge:** Pharmaceuticals are released at higher concentrations in urine. Urine source separation is noted as a “new-technology that diverts faeces from urine using “NoMix-technology”. FERA, 2011 notes that whilst this technology was being studied in 38 projects Northern and Central Europe Countries, at the time of writing “a global application of this technology is not practical”. Application in specific institutions (e.g. hospitals and nursing homes) was considered more feasible. **Catch basin: for PAHs from atmospheric deposition** “could possibly be reduced” by using a catch basin on motorways to recover sediments.

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Measure:	**Increase bioavailability in animal diet**	**Replacement of metal pipework with plastic**	**Separation of wastes; recycling; battery replacement or “take back” schemes.**	**Substitution**	**Other specific technology**
Contaminant of concern:	**Heavy Metals; (Zn, Cu, Fe, Mn).**	**Heavy metals (Cu, Zn. Cd, Hg, Ni, Pb).**	**Heavy metals (Cu, Zn. Cd, HG, Ni, Pb) Pharmaceuticals Plastics**	**Heavy Metals (Cd, Cr, Cu, Zn, Pb) Pharmaceuticals Surfactants**	**Pharmaceuticals Heavy Metals (Cr, Pb, Cu, Zn), PAHs.**
	provided to animals and combining organic and inorganic mineral in feed. • Cease non-essential mineral supplements • In terms of sources of metals, specific concerns are noted in pig farming.		• Separation of woods according to treatment received. SMARTWaste[157] is a waste auditing tool used in the UK claimed to aid this process. **Textile industry waste:** • Separation of dyeing and post dyeing waste from other waste streams. **Food and drink industry waste:** • Separate highly inked/dyed wastes as well as packaging, food & drink and animal waste streams to avoid contamination. **Chemical and pharmaceutical manufacturing waste:** • Various contaminants expected – sorting to prevent cross contamination.	persistent chemicals more generally (e.g. surfactants). **Food and drink industry waste and Chemical and pharmaceutical manufacturing waste:** • Substitution of persistent chemicals more generally.	**Granular activated carbon (GAC) filter water treatment option:** GAC filters “could possibly” reduce Cr inputs into wastewater treatment – one significant source is via carwashes.
Conclusion:	**Appears technically feasible but requires further research.**	**Technically feasible but precise contamination removal unclear.**	**Technically feasible but precise contamination removal efficiency unclear.**	**Substitution is technically feasible in certain applications but has proved difficult in several applications described above[158].**	**Several measures appear technically feasible, but authors note these are at early stage. Likely up-**

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[157] See www.smartwaste.co.uk. This is site monitoring and reporting software, available for a fee.

[158] See for example A Safe Chemicals Innovation Agenda (2018) for a discussion of various technical functions performed by harmful chemical substances that, in practice, have proved difficult to substitute for a range of technical and economic reasons. https://webgate.ec.europa.eu/s.../Safe%20Chemicals%20Innovation%20Agenda.pdf

Measure:	**Increase bioavailability in animal diet**	**Replacement of metal pipework with plastic**	**Separation of wastes; recycling; battery replacement or “take back” schemes.**	**Substitution**	**Other specific technology**
Contaminant of concern:	**Heavy Metals; (Zn, Cu, Fe, Mn).**	**Heavy metals (Cu, Zn. Cd, Hg, Ni, Pb).**	**Heavy metals (Cu, Zn. Cd, HG, Ni, Pb)** **Pharmaceuticals** **Plastics**	**Heavy Metals (Cd, Cr, Cu, Zn, Pb)** **Pharmaceuticals** **Surfactants**	**Pharmaceuticals** **Heavy Metals (Cr, Pb, Cu, Zn), PAHs.**
	🟧	🟩	🟩	🟨	🟨 **scaling requirements / challenges.**

Economic feasibility

Taking each measure in turn:

- Increasing bioavailability in animal diet: requires amending animal diet to reduce metal content in manure. As noted above further research is required so that elves can be reduced without adversely affecting the animals' physical development and hence prices that farmers can command. It is not clear whether farmers would be able to retain existing feed mixtures, simply feeding less, or whether the feed recipe itself will need to be changed by suppliers. Feed is the largest single source of cost in pig farming, representing upwards of 60% in several European countries (AHDB 2016). Recent data suggests that pig feed prices have increased, reflecting recent droughts, alongside a decrease in pork prices putting pressure on margins (Farmers Weekly 2018). Overall, a reduction in feed will be economically feasible – if animal growth is not adversely affected and assuming a change in feed recipe that increases costs further is not required.
- Replacement of metal pipework with plastic: such as PVC is economically feasible, such pipes are commercially available and in widespread use. Their use in certain circumstances can reduce costs, given that plastic pipes are more amenable to repair in Situ, rather than require roadworks (Epoxy Resins Committee 2015). However the process of replacing pipework, including old pipe and plumbing can be extremely costly, given they are generally inaccessible. Appropriate phasing and replacement criteria would be required.
- Separation of wastes; recycling; battery replacement or "take back" schemes: Examples of pre-sorting of waste streams as well as take back or other stewardship schemes already exist (Resource 2018). They require no scarce resources so are generally available. As discussed above, Cd free/ rechargeable batteries are already commercially available (Which 2019). The majority of the world battery market is Cd free. Overall, in general terms such activities are likely to be economically feasible. Pre-sorting of waste steams is currently carried out, but the precise technical solution and additional cost is not currently clear.
- Substitution: Heavy metals, pharmaceutical and surfactants are the subject of several regulations (such as REACH) aiming to address their use in specific applications. These undergo detailed assessment of economic feasibility in each case. Substitution is a wider technical and economic challenge recognised in recent strategy published by ECHA (ECHA 2018e).
- Other specific technology: Of the three specific technologies noted above, two are commercially available[159] however there is limited recent data on the capital and operation cost of installation and the precise technical requirements to address the presence of PAHs (and their safe disposal is not known). Information suggests that since the FERA report noted above was drafted, the NOMIX system has been discontinued, reflecting "commercial risk" and challenges associated with consumer preference (Treehugger 2014, BBC 2014).

Availability

Taking each measure in turn:

- Increasing bioavailability in animal diet: As noted above, further research is required so availability is currently difficult to assess.

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[159] See for example: http://www.health.state.mn.us/divs/eh/hazardous/topics/gac.html#types / https://www.ndspro.com/shop/drainage/catch-basins.html

- Replacement of metal pipework with plastic: as discussed above, PVC pipes are commercially available and in widespread use, although appropriate phasing of the replacement would be required.
- Separation of wastes; recycling; battery replacement or "take back" schemes: There are already examples of pre-sorting of waste streams and take back or other stewardship schemes. Cd free/ rechargeable batteries are already commercially available and Cd free batteries account for the majority of the global battery market (Battery University 2016). Overall, in general terms no availability issues are expected for these activities.
- Substitution: As for economic feasibility, the substitutions of heavy metals, pharmaceutical and surfactants undergo detailed assessment of availability in the context of regulatory action (such as REACH).
- Other specific technology: As discussed above, of the three specific technologies noted, two are commercially available[160], however the NOMIX system has been discontinued and little information is available on the catch basin for PAHs from atmospheric deposition.

Human health and environmental risks

All of the measures listed above have the objective to reduce human health and environmental risks. For most of them, no additional human health or environmental risks have been identified. However, for the substitution of heavy metals, pharmaceutical and surfactants, the risks depend on the specific alternative chosen. Again, where these are used these undergo detailed assessment of availability in the context of regulatory action (such as REACH). Similarly, the risks of the substitution of metal pipework with plastic depends on the plastic chosen. Some sources [161] suggests pipes from specific plastics are more sustainable in a full life cycle assessment and pose lower human health or environmental risks than concrete or metal pipes.

Part 2: Measures during or after composting/AD

Technical feasibility

The specific processes are identified in "Identification and assessment of risk management options", Option 4, in Section 5.5.5. These are discussed in turn below.

Two-stage anaerobic digestion

As noted in Section 5.5.5, two-stage anaerobic digestion allows improved removal of heavy metals (Cadmium, Nickel, Lead, Copper, Zinc) and better biodegradation efficiency of PAH. Two-stage systems are usually applied for input materials with high concentrations of chemical pollutants.

- In terms of PAH, evidence cited in Cea Barcia et al, 2013 noted that "some" PAHs can be degraded under AD conditions. But noted in the cases where sewage sludge is the growth substrate, PAHs removal strongly varies based on the characteristics of the sludge (Cea Barcia et al. 2013).
- For heavy metals, using two-stage digestion can result in heavy metals being transferred to the leachate, where the first stage includes hydrolysis/acidification and liquefaction of the substrate. These can then be removed from the leachate by absorption. A study from Selling et

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[160] See for example: http://www.health.state.mn.us/divs/eh/hazardous/topics/gac.html#types / https://www.ndspro.com/shop/drainage/catch-basins.html

[161] For instance, for PVC: https://www.uni-bell.org/files/Reports/Life_Cycle_Assessment_of_PVC_Water_and_Sewer_Pipe_and_Comparative_Sustainability_Analysis_of_Pipe_Materials.pdf. Note this report was commissioned by the PVC piping industry and subject to independent peer-review.

al, 2008, noted removal from maize of up to 70% of the Ni, 40% of the Zn and 25% of the Cd, although this process took six days, and removal of Cu and Pb were lower, further refinements were proposed that were expected to increase heavy metal removal efficiency (Selling, Håkansson and Björnsson 2007). Other studies have note that two stage AD can remove heavy metal presence, but removal efficiency is not quantified (Lehtomäki & Björnsson 2010).

Overall, the limited evidence suggests two stage AD can reduce heavy metal and PAH content, although the technical feasibility will depend on the specific removal efficiency judged necessary in the risk assessment.

Post-composting

As noted in Section 5.5.5, composting digestate as a post-treatment would lead to higher removal of DEHP, PAHs and PCB compounds and pesticides.

- Reeh et al 2001, notes that DEHP were reduced to "safe" levels in less than two weeks via composting of sewage sludge and MSW. The same study also noted PAH degradation (not quantified), but at comparatively slower rates (Reeh and Møller 2002).
- Brandli et all (2011) note that "in lab studies, some compounds (e.g., low molecular weight (LMW polycyclic aromatic hydrocarbons (PAHs)) were observed to decrease during composting, whereas other compounds (e.g., polychlorinated biphenyls (PCBs), high molecular weight (HMW) PAHs) remained stable". They note that, conditions (e.g., availability of the pollutants, nutrients, temperature) need to be "appropriate" (not defined) for the process to work successfully. They note the need for further research, with a "probably more promising" approach to single out particularly contaminated input materials (Brandli et al 2007).
- Yuan et al 2000 evaluated the biodegradation of PAHs by an aerobic mixed culture which used phenanthrene as its carbon source. They note the efficient degradation of pyrene and acenaphthene, but that "it failed to degrade anthracene and fluorene". Further, in samples containing a mixture of the five PAHs, treatment with the aerobic culture increased degradation rates for fluorene and anthracene and decreased degradation rates for acenaphthene, phenanthrene and pyrene (Yuan et all 2000). *(N.B only the abstract of this source was available).*

Overall, the limited evidence suggests post composting may be technically feasible for reducing DEHP, PAH content, although the technical feasibility will depend on both the fuel type – the extent of contamination of input materials – and the specific removal efficiency judged necessary in the risk assessment. There appears rather more limited data on removal efficiency of PCBs.

Thermophilic digestion

As noted in Section 5.5.5, feedstock for anaerobic treatment is processed under: mesophilic (optimum temperature 37^{0}C) and thermophilic (optimum temperature 55^{0}C) AD systems. The removal efficiency of nonylphenol is known to be higher for thermophilic than mesophilic digestion. In Paterakis et al (2012) the authors note that the "removal of nonylphenol ethoxylates was greater in mixed sludge digestion (>58%) compared with primary sludge digestion…". They conclude that anaerobic digestion reduces the concentrations of […] and would therefore be expected to confer a degree of protection against exposure and transfer of [nonylphenol ethoxylates] to the receiving/re-use environment". Specifically, they examine the effect of temperature and note that the removal efficiency of nonylphenolics in the mixed sludge evaluated in the study was 92% for thermophilic digestion compared to 58% for mesophilic digestion (Paterakis et al 2012). According to discussions with Wood internal anaerobic digestion technical experts, this adaptation is in principle applicable to all plants.

Overall, the limited evidence suggests this may be technically feasible process for reducing nonylphenol contamination, although this will depend on the specific removal efficiency judged necessary in the risk assessment.

As noted in section 5.5.5, no relevant processes (or no scientific data has been identified) to address contamination of Bisphenol A (BPA).

Economic feasibility

No specific data has been found on capital and operation cost implications nor on process efficiency, however the available information indicates additional costs would be incurred in all these processes. The (limited) information identified is below.

Two-stage anaerobic digestion	Post-composting	Thermophilic digestion
• **This process requires an additional reactor vessel, with the associated capital investment costs, space, pumping and control complexity. However, this may be offset by the higher overall energy recovery from a two-stage process (IPPTS Anaerobic Digestion Community 2018).** • **There is also evidence that the presence of certain heavy metals (mercury, cadmium and trivalent chromium) decreases the overall efficiency of the AD process (Abdel-Shafy and Mansour 2014).** • **The gross/net effects on cost or efficiency were not quantified.**	• The implementation of this process would be associated with additional space, time and operational cost. • The extent of additional cost depends on local conditions and likely to exhibit considerable variation (Reeh and Møller 2002). The primary driver of process cost is whether the composting occurs outside in open air (c. €20 per tonne) or within a plant (c. €45 per tonne) (Eunomia 2002).	• Bouskova et al 2005 note that adaptation from mesophilic conditions is in theory applicable to all AD plants, although they note that post transition stabilisation might take c.30 days. Whilst more energy for is required for heating systems, (given the higher operating temperatures required), it is understood that thermophilic digestion is up to 8 times faster (Bouskova et al 2005).

Availability

AD is a growing sector with capacity and plant increases experienced over the last decade. Data on the availability of specific process are rather limited but noted below.

Two-stage anaerobic digestion	Post-composting	Thermophilic digestion
• **The European bioplastics association indicates there as of 2015 there were between some 290 plants in Europe, of which c. 100 (Germany); and c., 30 in each of Switzerland, France and Spain (European Bioplastics 2015).**	• No data has been identified on current capacity for post treatment of digestate for composting.	• Eunomia 2011 note that 62% of AD plants operate at mesophilic temperatures across Europe, implying around c.110 thermophilic plants.

Human health and environmental risks

Composting and anaerobic digestion are generally regarded as a sustainable alternative to landfill and incineration. However external effects associated with composting (covered and uncovered) and associated with AD are evaluated in Eunomia 2002:

- Composting involves some emission of CO_2, N_2O and VOCs, but this is offset by a reduction in pesticide/fertiliser production and use and leachate.

- AD also involves some emission of CO_2, N_2O and CH_4, VOCs, SO_x, NO_x (as well as potentially some chemical impurities), but this is again offset by a reduction in pesticide/fertiliser production and use. Anaerobic digestion is one of the most efficient biomass-to-energy routes, using c. 10% of the resources across the life cycle compared to conventional electricity generation (De Meester et al 2012, Massaro et al 2015).

No information was available to suggest these risks would be significantly higher or lower when the specific processes discussed above are used.

5.7 Conclusions on the most appropriate (combination of) risk management options

5.7.1 Justification of risk management at EU-level

Realistic worst case risk assessments have identified potential risks from the use of C/D as fertiliser arising from several contaminants. The following (groups of) substances have been prioritised for the RMOA (see Section 5.2):

- Heavy metals (Nickel (Ni), Lead (Pb), Copper (Cu), Zinc (Zn), Mercury (Hg));
- 17α-ethinylestradiol;
- PCBs (PCB28);
- Dioxins and furans (TCDD, PCDF);
- Nonylphenol; and
- PFAs (PFOA, PFOS);
- Cadmium and PAH16 substances (as a lower priority)[162].

For some substances, potential risks were identified, but they have not been prioritised for risk management for reasons summarised in Table 5.23.

Table 5.23 Substances not prioritised for risk management

Contaminant	Explanation
Bisphenol-A (BPA)	BPA in C/D can be considered a lower priority for further risk management (low contribution to background concentrations, available safe limits of human consumption not exceeded).
Di(2-ethylhexyl)phthalate (DEHP)	Further monitoring of the development of DEHP concentrations in C/D is required to judge the need for further risk management in the future.
Hexabromocyclododecane (HBCDD)	Following the expiry of the only REACH authorisation, any contribution to HBCDD concentrations in compost in digestate resulting from industrial release of HBCDD should be eliminated. Can therefore be considered a lower priority for further risk management.
PFHxA	Further monitoring of PFHxA concentrations in C/D is required to judge the need for further risk management in the future.

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[162] For these substances, the only main concern identified in the risk assessment was long-term gradual accumulation through repeated application. These substances are therefore also considered for risk management, but at a lower priority than the above.

Microplastics	Further monitoring of microplastics concentrations in C/D is required to judge the need for further risk management in the future.

Existing risk management lacks binding and coherent requirements for all types of C/D and all EU Member States (see Section 5.5.1). Moreover, the production of digestate as fertiliser is expected to increase significantly in the short to medium term. Existing risk management is therefore unlikely to adequately control the identified risks. Coherent rules across the EU could improve user confidence and help support a common market of C/D as fertiliser. Hence, further risk management on EU-level may be required.

5.7.2 Comparison of the assessed risk management options

The main regulatory risk management measures considered in this RMOA are the introduction of (further) concentration limits, restrictions on input materials, conditions of use, or the application of specific processes.

Table 5.24 lists the risk management measures judged most appropriate based on the assessment. It also demonstrates how, in combination, they address the risks identified from prioritised contaminants. Table 5.25 provides an overview of the advantages and disadvantages of the proposed measures, summarising the more detailed discussion from below and earlier sections.

The appropriateness and initial considerations on the potential scope for each measure are discussed in turn below. A summary of the expected socio-economic impacts of the proposed measure (based on the more detailed information provided in Section 5.6) is provided at the end of each measure’s section.

Table 5.24 Coverage of the prioritised contaminants by proposed combination of risk management options

Proposed risk management	Nickel (Ni)	Lead (Pb)	Copper (Cu)	Zinc (Zn)	Mercury (Hg)	17α-ethinylestradiol	PCBs (PCB28)	Dioxins and furans (TCDD, PCDF)	Nonylphenol	Perfluoroctanoic acid (PFOA)	Perfluoroctanesulfonic acid (PFOS)	Cadmium (Cd)	PAH16 (Benzo[a]pyrene, Chrysene, Benzo[a]anthracene, Benzo[b]fluoranthene, Indeno(1,2,3-cd)pyrene
Limit values based on calculated safe limits for application to agricultural land				x	x								
Limit values based on calculated safe limits for container growing	x		x	x					x				
Limit values based on existing limit values		x					(x)	(x)		(x)	(x)		x
Restriction on the use of sewage sludge C/D as a fertiliser			x	x	x	x		x		x	x		x
Restriction on the use of sewage sludge compost in container growing*			x	x	x	x		x		x	x		x
Restriction on the use of MBT and sewage sludge* digestate as a fertiliser except when using two-stage A/D	x	x	x	x								x	x

Proposed risk management	Nickel (Ni)	Lead (Pb)	Copper (Cu)	Zinc (Zn)	Mercury (Hg)	17α-ethinylestradiol	PCBs (PCB28)	Dioxins and furans (TCDD, PCDF)	Nonylphenol	Perfluoroctanoic acid (PFOA)	Perfluoroctanesulfonic acid (PFOS)	Cadmium (Cd)	PAH16 (Benzo[a]pyrene, Chrysene, Benzo[a]anthracene, Benzo[b]fluoranthene, Indeno(1,2,3-cd)pyrene
Restriction on the use of sewage sludge digestate as a fertiliser except when applying post-composting*							x						x

Notes:
*) Only relevant if sewage sludge C/D is not restricted for use as fertiliser in general
(x) Indicates that it is not certain that limit values should be set for these substances.

Table 5.25 Summary comparison of proposed risk management options

Proposed risk management	Main advantages	Main disadvantages
Option 1) **Concentration limits**	+ Directly limit pollutants to levels considered to pose no (or an ‘acceptable level’ of) risk. + Setting limit values only for pollutants where concentrations exceeding safe limits have been found minimises the regulatory burden (e.g. sampling costs). + Separate limit values for different use scenarios minimises the share of C/D restricted.	- Sampling costs. - Setting limit values only for pollutants where concentrations exceeding safe limits have been found does not ensure the control of risks from future increases in concentrations of other contaminants. - Separate limit values for different use scenarios are more complicated to enforce. - Main potential negative impacts: Reduced compost production; affected compost feedstocks and digestate have to be disposed of; increased synthetic fertiliser use.

Proposed risk management	Main advantages	Main disadvantages
Measure 1a) **Limit values based on calculated safe limits for application to agricultural land (zinc, mercury)**	+ Only a low share of C/D expected to be affected and potential negative impacts would be modest in scale.	
Measure 1b) **Limit values based on calculated safe limits for container growing (nickel, copper, zinc, nonylphenol)**	+ For copper and nonylphenol, only a low share of compost is expected to be affected and potential negative impacts would be modest in scale.	- For nickel and zinc a large share of compost used in container growing is expected to be affected, so the potential negative impacts could be significant for the container growing segment.
Measure 1c) **Limit values based on existing limit values (PCBs, PCDD/F, lead, PFAS, PAHs)**	+ Would ensure that the risk from these substances is limited EU-wide, while minimising the disruption to those markets where limit values are already in place. + Only a low share of C/D is expected to be affected and potential negative impacts would be modest in scale.	- It is not clear if existing limits are risk-based and if they would adequately control the risks. - Sampling costs, particularly for PCBs, PCDD/F and PFAS, may render the production/use of some C/D uneconomical, likely increasing the scale of the potential negative impacts.
Option 2) **Restriction on input materials**	+ Easier and less costly monitorability and enforceability compared to limit values (less comprehensive sampling). + Reinforced consumer confidence.	- Risk is not directly controlled (concentration of contaminants in input materials is subject to variation). - Some C/D that does not pose a risk may be restricted. - Not technology neutral (does not encourage innovation to enable use of restricted input materials). - Main potential negative impacts: Reduced compost production; affected compost feedstocks and digestate have to be disposed of; increased synthetic fertiliser use.
Measure 2a) **Restriction on the use of sewage sludge based C/D as a fertiliser**	+ Sewage sludge exhibits particularly high concentrations for most priority substances of concern, including several substances for which no calculated safe limits are derivable and concentration sampling is (potentially) particularly expensive. + Only a low share of C/D is expected to be affected and potential negative impacts would be modest in scale	- Sewage sludge could be applied directly to agricultural land instead of being digested first, unless coherent regulation on direct use of sewage sludge is implemented. - Further regulating the direct use of sewage sludge would increase the scale of impacts related to alternative waste management for sewage sludge.

Proposed risk management	Main advantages	Main disadvantages
Option 3) **Conditions of use**	+ Aims at reducing exposure, rather than banning certain composts/digestates or input materials. + No sampling required.	- Risk is not directly controlled (only reduced by eliminating uses with highest potential for exposure). - Potential difficulties with monitoring and ensuring compliance by consumers.
Measure 3a) **Restriction on the use of sewage sludge compost in container growing***	+ Addresses the risk associated with container growing, which is higher than application to agricultural land for most priority substances of concern (all except zinc and mercury). + Complementary to proposed limit values based on calculated safe limits (sewage sludge is linked to several substances for which no calculated safe limits are available). + Only a very low share of compost is expected to be affected and potential negative impacts would be very modest in scale.	- Main potential negative impacts if use on agricultural land is not feasible: Reduced compost production; sewage sludge has to be disposed of; increased synthetic fertiliser use.
Option 4) **Obligation to use specific processes**	+ Aims at reducing contamination, rather than banning certain composts/digestates or input materials.	- Effectiveness in reducing the risks is uncertain. - Not technology neutral (not supporting innovation and not leaving choice of most efficient process to operators).
Measure 4a) **Restriction on the use of MBT and sewage sludge* based digestate as a fertiliser except when using two-stage A/D**	+ Targeted at specific risks (contaminants reduced by this process are particularly linked to sewage sludge). + Associated additional costs are at least partly offset by operational benefits, so for a share of the affected operators there may be no negative net effects.	- A significant share of digestate is expected to be affected and potential negative impacts could be considerable in scale. - For a share of the affected operators, there will be a net cost. - Main potential negative impacts for operators for which the additional cost is not feasible: affected digestate (and MBT feedstocks/sewage sludge if replaced by alternatives) have to be disposed of; increased synthetic fertiliser use.
Measure 4b) **Restriction on the use of sewage sludge**	+ Targeted at specific risks (contaminants reduced by this process are particularly linked to sewage sludge).	- Associated with additional space, time and operational cost.

Proposed risk management	Main advantages	Main disadvantages
digestate as a fertiliser except when applying post-composting*	+ Only a low share of digestate is expected to be affected and potential negative impacts would be modest in scale.	- Main potential negative impacts for operators for which the additional cost is not feasible: affected digestate (and sewage sludge if replaced by alternatives) have to be disposed of; increased synthetic fertiliser use.

Notes:
Proposed risk management: Advantages and disadvantages associated for the main options are valid for all measures proposed under these options. The advantages and disadvantages associated with the specific measures proposed under each option are additional to those for the option in general or specify their expected magnitude for the specific measure.
*) Only relevant if sewage sludge C/D is not restricted for use as fertiliser in general.

Concentration limits

Concentration limits directly limit pollutants to levels considered to pose no (or an 'acceptable level' of) risk. These levels ('safe limits') have been calculated in the risk assessment where possible and appropriate (see Table 5.26). Note that where concentrations are already below existing safe limits, this implies no further risk management is required.

Safe limits have been calculated for the realistic worst case of two different use scenarios – container growing and application to agricultural land. Whether to apply consistent limit values for the same substances in both scenarios will depend on a judgement between the balance of risk and ease of enforcement/compliance. Setting different limit values for the different use scenarios would minimise the share of compost/digestate restricted.

In broad terms, Table 5.26 also shows the share of C/D currently exceeds calculated safe levels and therefore would be affected by setting concentration limits equal to the calculated safe limits. C/D producers would likely be able to reduce contaminant concentrations of some C/D to comply with the limit values. However, the proposed concentration limits for Nickel and Zinc in container growing would likely affect a large share of C/D.

Table 5.26 Safe limit values calculated in the risk assessment and likely share of compost and digestate currently exceeding them

Substance	Safe limit concentration in C/D for application to agricultural land	Safe limit concentration in compost for container growing[1]	Likely share of compost and digestate currently exceeding safe levels [2]	*For comparison: Limit values in the proposal for the revised Fertilising Products Regulation (FPR)*
Cadmium	[3]	[3]	n/a	*1.5 mg/kg dry weight*
Nickel	[3]	7.9 mg/kg dry weight	**Large for container growing:** Most reported median or mean concentrations exceed the safe level.	*50 mg/kg dry weight*
Copper	[3]	200 mg/kg dry weight	**Very low:** Only a few reported maximum concentrations exceed the safe level.	*300 mg/kg dry weight*
Zinc	600 mg/kg dry weight	70 mg/kg dry weight	**Very low for application to agricultural land:** Only a few reported maximum concentrations exceed the safe level. **Large for container growing:** Most reported median or mean concentrations exceed the safe level.	*800 mg/kg dry weight*
Mercury	0.2 mg/kg dry weight	[3]	**Low:** Most reported median or mean concentrations are below the safe level.	*1 mg/kg dry weight*
Nonylphenol	[3]	3.5 mg/kg dry weight [4]	**Low:** Most reported median or mean concentrations are below the safe level.	*None.*

Notes:
1) Note that there are some uncertainties associated with the container growing scenario used, as discussed in Section 5.5.2 and Appendix D, and so the estimated safe limits should be seen as preliminary only.
2) Likely share of compost and digestate currently exceeding safe levels is our judgement based on how many reported median, mean or average concentrations (data collected in Appendix C) exceed the calculated safe limits. A precise quantification of the scale is not

possible based on the available data. The qualitative indications (very low, low, large and very large) are meant to facilitate comparison between different limit values.
3) Safe limit would be higher than the current levels so this is not currently seen as a concern.
4) As per the definition of 'safe limit' earlier in this section, this refers only to the endpoint in question (for nonylphenol this is set out in Table 4.19). However, nonylphenol also has other adverse effects which can occur at lower concentrations.
Source FPR limit values: http://data.consilium.europa.eu/doc/document/ST-15103-2018-INIT/en/pdf

For PCBs, dioxins and furans, lead, PFAS and PAHs, any level is considered a risk and so safe limits cannot be defined in the risk assessment. However, existing limits (e.g. in national legislation) could inform the level of limit values. The most appropriate levels are discussed below:

- PCBs: Comparison of limit values is complicated by the fact that some are for PCB6 (three Member States + Norway, ranging between 0.1-1.2 mg/kg d.m.), some for PCB7 (five limits from four Member States, ranging between 0.15-0.8 mg/kg d.m.) and one for PCBs in general (POPs Regulation, not specifically for compost/digestate, 50 mg/kg d.m.). Given that stricter limit values could still be imposed in specific Member States due to the local conditions, it would seem more appropriate to adopt an EU-wide limit value at the higher end of the range of Member State limit values, to ensure this level of risk control is guaranteed consistently throughout the EU while minimising disruption. The highest limit value is for Norway (not an EU Member State), the next highest values are 0.8 mg/kg d.m. for PCB7. Most reported concentrations (as per Appendix C) are below this value.

- Dioxins and furans: The identified limit values for two Member States (Austria, Luxembourg) and Switzerland are all consistent, at 20 ng/kg d.m. for 17 polychlorinated dibenzo-p-dioxins/furans (PCDD/F) expressed in International Toxicity Equivalents. Germany has a limit value of 30 ng/kg d.m. for the sum of PCDD/F and dl-PCB, which appears roughly consistent with the abovementioned values for PCDD/F, while Wallonia's higher limit of 100 ng/kg d.m. for PCDD/F is higher. Most reported maximum PCDD/F concentrations (as per Appendix C) are below 20 ng/kg d.m.

- Lead: Three limit values have been identified between 100 and 150 mg/kg d.m. Given the extensive analysis in JRC (2014) and the proposed FPR, the FPR limit value of 120 mg/kg d.m., roughly in the middle of that range, appears appropriate. Most reported maximum concentrations (as per Appendix C) are below this value.

- PFAs: The identified limit values for three Member States (Austria, Denmark and Germany) are all consistent, at 100 µg/kg d.m. for the sum of PFOA and PFOS. Most reported maximum concentrations (as per Appendix C) are below this value.

- PAHs: Most limit values are for PAH16 (five Member States + Norway + the FPR proposal, ranging between 3-10 mg/kg d.m.), but one is for PAH11 (Denmark 3 mg/kg d.m.), and one Member State has limits for individual PAHs (France). Given the extensive analysis in JRC (2014) and the proposed FPR, the FPR limit value of 6 mg/kg d.m., roughly in the middle of the range of Member State limits, appears appropriate. Most reported concentrations (as per Appendix C) are below this value.

Setting limit values would ensure that the risk from these substances is limited EU-wide, while minimising the disruption to those markets where limit values are already in place. However, we do not know why the existing limit were set and what they were based on. Hence, it is not clear if existing limits are risk-based and if they would adequately control the risks. Furthermore, Section 5.5.2 has also shown that adding limit values for PCBs and PFAs can increase sampling costs significantly.

Of the substances prioritised for further risk management (as per Section 5.2), only for 17α-ethinylestradiol neither calculated safe limits nor existing limit values are available. Additional criteria would be needed to judge appropriateness of limit values for 17α-ethinylestradiol.

In conclusion, it seems appropriate to set limit values for nickel, copper, zinc, mercury and nonylphenol equal to safe limits calculated by the risk assessment. However, due to the large share of compost currently exceeding these levels for nickel and zinc for use in container growing, it is unclear if these specific limits would be proportionate. Additional limit values could be set for PCBs, PCDD/F, lead, PFAs and PAHs based on existing limit values, unless the risks from these substances can be addressed by other types of risk management or costs for sampling of PCBs, PCDD/F and PFAs are considered prohibitive.

Summary of expected socio-economic impacts of the proposed concentration limits	
Limit values based on calculated safe limits for application to agricultural land (zinc, mercury)	Only a low share of C/D currently exceeds the safe levels, so only a small quantity of C/D would be affected and all of the below impacts would be modest in scale. The highest zinc concentrations are found in C/D from MBT and sewage sludge; the highest mercury concentrations were in C/D from MBT, sewage sludge, green waste and biowaste. Regarding the affected compost: • Affected composting plants could replace the input materials with the highest concentrations of these contaminants (see above) with alternative feedstocks, subject to some uncertainty about economic feasibility. • If this is not feasible the affected compost would likely cease to be produced, leading to foregone revenue from compost sales. In addition, the compost would have to be replaced by alternative fertilisers. The most likely alternative, synthetic fertilisers, cannot fulfil compost's function of supplying organic matter and is associated with several additional environmental risks. • In both cases, the input materials previously used to produce the affected compost would then require alternative waste management, which would likely lead to additional environmental risks and contradict environmental policy objectives. Regarding the affected digestate: • The affected digestate may be used for alternative applications, but there is uncertainty about their technical feasibility. • If this is not feasible, biogas production (and thus digestate production) would likely still continue largely unchanged, because income from selling or using digestate is often secondary to AD operators. Hence, the affected digestate would have to be disposed of, which would likely lead to further waste management costs and additional environmental risks and could contradict environmental policy objectives. • In addition, the affected digestate would have to be replaced by alternative fertilisers. The most likely alternative, synthetic fertilisers, cannot fulfil digestate's function of supplying organic matter and is associated with several additional environmental risks. • Some AD operators may consider either changing the input materials used (as above for compost with the same implications of alternative waste management for the input materials) or employ a two-stage AD process (only addresses zinc). Both are subject to some uncertainty about economic feasibility. Additional costs are associated with a two-stage AD process, but at least partly offset by operational benefits.
Limit values based on calculated safe limits for container growing (nickel, copper, zinc, nonylphenol)	According to the market analysis, the vast majority of digestate produced in the EU is used directly as fertiliser in agriculture. Based on this, the risk assessment has assumed that only compost is used in container growing. Only a low share of compost currently exceeds the safe levels for copper and nonylphenol, so only a small quantity of compost would be affected and all of the impacts would be modest in scale. The highest copper concentrations are found in compost from MBT and sewage sludge; the highest nonylphenol concentrations were in compost from sewage sludge and green waste. However, for nickel and zinc a large share of compost used in container growing would be affected, so the impacts could be significant for the container growing segment. Note however that only up to 34% of compost is used in container growing, corresponding to in the order of 6 million tonnes of compost. The highest copper concentrations are found in compost from MBT, sewage sludge, green waste and biowaste; the highest zinc concentrations are found in compost from MBT and sewage sludge. The types of impacts expected would be the same as for the affected compost in the previous row.

Summary of expected socio-economic impacts of the proposed concentration limits	
Limit values based on existing limit values (PCBs, PCDD/F, lead, PFAS, PAHs)	Only a low share of C/D currently exceeds the safe levels, so only a small quantity of C/D would be affected and all of the below impacts would be modest in scale. The highest lead concentrations are found in C/D from MBT; the highest concentrations of PCDD/F, PFAS and PAHs are found in C/D from sewage sludge. For PCBs, no clear distinction of concentration levels between C/D from different input materials could be established. The types of impacts expected would be the same as for the affected C/D in the first row. However, there are two additional considerations: • Sampling costs, particularly for PCBs, PCDD/F and PFAS, may render the production of some composts and the use of some digestates in agriculture/soil improvement uneconomical. The affected C/D would have to be replaced by alternative fertilisers, subject to additional environmental risks. The input materials previously used to produce the affected compost, as well as the produced digestate, would have to be disposed of, subject to additional waste management costs and environmental risks. • Plants may consider employing certain processes to reduce concentrations of these contaminants in C/D such as post-composting of digestate (PCBs and PAHs reduction) and thermal treatment (PFAS extraction), subject to significant uncertainty about technical and economic feasibility.

Restrictions on input materials

The concentration of contaminants in input materials is subject to variation and so the risk cannot be directly controlled by restricting input materials. However, it is considered a potentially more workable alternative to checking concentration limits because it does not require sampling. It would therefore be appropriate to restrict those input materials that are the most significant sources of contaminants, which are judged of the greatest concern in the risk assessment, for which concentration sampling is prohibitively expensive, or where an appropriate concentration limit cannot be set:

- As discussed in Section 5.5.3, sewage sludge C/D exhibits generally higher or the maximum observed concentrations for most priority substances of concern. This includes several substances for which no calculated safe limits are available, and concentration sampling is (potentially) particularly expensive: 17α-ethinylestradiol, dioxins and furans, PFOA, PFOS and PAHs. Sewage sludge also accounts for a small share of C/D input materials and so a restriction would pose a relatively small disruption to the overall C/D market.
- Compost/digestate from biowaste, greenwaste and mechanical biological treatment (MBT) could only be associated with certainty to high concentrations of heavy metals and nonylphenol (as discussed in Section 5.5.3). For these contaminants, calculated safe limits (Ni, Cu, Zn, Hg, Cd) or existing limit values (Pb) to use as a basis for setting limit values are available, and sampling costs for these contaminants are also considered largely feasible (as discussed in Section 5.5.25.5.3). Therefore, it seems appropriate to address the risk from these contaminants with limit values (as discussed above), which means an additional restriction of MBT C/D might not be required to adequately control the risk. A ban on the use of MBT C/D could potentially have a large impact on the market because MBT accounts for a significant share (roughly a quarter) of C/D input materials. Note that it could still be appropriate to consider an obligation to use two-stage anaerobic digestion for MBT digestate, as is discussed further in the section on Specific processes below.
- Agricultural digestate (manure and energy crops) could not be associated with high concentrations of any priority substances of concern with certainty.

The above suggests sewage sludge based C/D poses the greatest risk, and prohibiting its use would seem to cause the least disruption to the market. In addition, a restriction on sewage sludge would also address other contaminants that can be found in sewage sludge but have not been investigated in this report. However, prohibiting the use of sewage sludge based C/D could reduce the incentive for improvements to treatment of sewage sludge at waste water treatment plants and/or prevent the use of what is expected to become a cleaner input material in the future due to these improvements. Moreover, such a restriction could lead to more sewage sludge being applied directly instead of digested first.

In conclusion, it seems appropriate to consider prohibiting the use as fertiliser of C/D made with sewage sludge, with an option to allow its use in the future given improvements to its treatment at waste water treatment plants. The direct application of sewage sludge to agricultural land would have to be restricted to be coherent with the restriction of sewage sludge C/D.

Summary of expected socio-economic impacts of the proposed restriction on input materials	
Restriction on the use of sewage sludge C/D as a fertiliser	Only a low share of C/D is currently produced from sewage sludge, so only a small quantity of C/D would be affected and all of the below impacts would be modest in scale. However, in order to avoid the unintended consequence that sewage sludge is applied directly to agricultural land instead of being digested first, coherent regulation would have to be applied to direct use of sewage sludge. This would in turn affect a large amount of sewage sludge and thus increase the scale of impacts related to alternative waste management for sewage sludge. Regarding the affected compost: • Affected composting plants could replace sewage sludge with alternative feedstocks, subject to some uncertainty about economic feasibility. • If this is not feasible the affected compost would likely cease to be produced, leading to foregone revenue from compost sales. In addition, the compost would have to be replaced by alternative fertilisers. The most likely alternative, synthetic fertilisers, cannot fulfil compost's function of supplying organic matter and is associated with several additional environmental risks. • In both cases, sewage sludge would then require alternative waste management, which would likely lead to additional environmental risks and could contradict environmental policy objectives. Regarding the affected digestate: • The affected digestate may be used for alternative applications (such as for algal cultures, construction materials, bioethanol production or as biopesticide), but there is uncertainty about their technical feasibility. • If this is not feasible, biogas production (and thus digestate production) would likely still continue largely unchanged, because income from selling or using digestate is often secondary to AD operators. Hence, the affected digestate would have to be disposed of, which would likely lead to further waste management costs and additional environmental risks and could contradict environmental policy objectives. • In addition, the affected digestate would have to be replaced by alternative fertilisers. The most likely alternative, synthetic fertilisers, cannot fulfil digestate's function of supplying organic matter and is associated with several additional environmental risks. • Some AD operators may consider replacing sewage sludge with alternative feedstocks. Sewage sludge would then require alternative waste management, which would likely lead to additional environmental risks and could contradict environmental policy objectives.

Conditions of use

For nickel, copper and nonylphenol, a potential concern (measured concentrations in C/D exceed safe limits) has only been identified for container growing but not for application to agricultural land. The risk associated with these substances could therefore be adequately controlled by prohibiting the use of compost in container growing (digestate does not appear to be currently used in container growing).

For lead, 17α-ethinylestradiol, HBCDD, PCBs, dioxins and furans and PFAs, safe limits could not be calculated, but exposures at the steady state are higher for the container growing scenario than for application onto agricultural land, and hence there is a higher risk associated with container growing. This risk could also be addressed by prohibiting the use of compost in container growing.

However, for substances for which limit values are considered appropriate (likely nickel, copper and nonylphenol, as well as potentially lead, PCBs, dioxins and furans and PFAs), prohibiting use in container growing would not be required, because the limit values already address the risk while minimising the amount of C/D prohibited.

To target other specific substances, conditions of use could be applied to compost from specific input materials. As discussed above, sewage sludge in particular is linked to several substances for which no calculated safe limits are available.

In conclusion, it appears appropriate to consider a restriction for container growing (if C/D made from sewage sludge is not restricted for use as fertiliser in general as discussed above).

Summary of expected socio-economic impacts of the proposed use conditions	
Restriction on the use of sewage sludge compost in container growing	According to the market analysis, the vast majority of digestate produced in the EU is used directly as fertiliser in agriculture. Based on this, the risk assessment has assumed that only compost is used in container growing. Only a low share of compost is currently produced from sewage sludge and only up to 34% of compost is used in container growing (probably an even smaller share of sewage sludge compost), so only a very small quantity of compost would be affected and all of the below impacts would be very modest in scale. Expected impacts: • If sewage sludge compost is only banned in container growing, it would likely be used in agriculture instead, subject to some uncertainty about economic feasibility due to the potential difference in market prices. • Alternatively, affected composting plants could replace sewage sludge with alternative feedstocks, subject to some uncertainty about economic feasibility. • If both of the above are not feasible, the affected compost would likely cease to be produced, leading to foregone revenue from compost sales. In addition, the compost would have to be replaced by alternative fertilisers. The most likely alternative, synthetic fertilisers, cannot fulfil compost's function of supplying organic matter and is associated with several additional environmental risks. • In the cases where sewage sludge is replaced by other input materials or the affected compost is no longer produced, sewage sludge would require alternative waste management. This would likely lead to additional waste management cost and environmental risks and could contradict environmental policy objectives.

Specific processes

An obligation to use specific processes does not seem recommendable where limit values are considered appropriate. This is because limit values directly control the concentrations of contaminants, while allowing operators to choose themselves through which processes or other means to achieve these concentrations. The concentration of contaminants achieved by applying specific processes depends on the removal efficiency and the concentration of the contaminants in the input materials, both of which depend on installation-specific conditions.

The most promising processes to reduce contaminants for which limit values have not been proposed above are:

- Two-stage anaerobic digestion can reduce cadmium, lead and PAH16 (as well as nickel, copper and zinc, for which limit values are recommended). Particularly high cadmium and lead concentrations have been reported in mechanical biological treatment (MBT) C/D and PAH16 in sewage sludge C/D.
- Post-composting of digestate can reduce PAH16 and PCB, which have been reported in particularly high concentrations in sewage sludge C/D.

Introducing a legal obligation to use specific processes is appropriate where a) it can be targeted at specific risks and b) ensure a high level of control of these risks.

The above processes could be prescribed when using input materials associated with high concentrations of specific contaminants, in order to target specific risks (a). Sewage sludge (two-stage anaerobic digestion and post composting) and MBT (only two-stage anaerobic digestion) have been identified as the most appropriate input materials to target the specific risks that can be addressed by these processes. Note that sewage sludge would only be relevant if C/D made from sewage sludge is not restricted for use as fertiliser in general, as discussed in the section on Restrictions on input materials above. Although a restriction of the use of MBT C/D as fertiliser in general might not be required (see section on Restrictions on input materials above), it could still be appropriate to consider an obligation to use two-stage anaerobic digestion for MBT digestate. That is because two-stage anaerobic digestion can reduce lead contamination and the proposed limit value for lead (see section on Concentration limits above) is not based on a calculated safe limit (i.e. it is not clear if it is risk based). Two-stage anaerobic digestion also reduces cadmium and MBT C/D is associated with relatively high concentrations of cadmium[163]. The disruption that this obligation would cause to the market would be somewhat smaller than the disruption caused by a restriction on MBT as an input material in general, because at least a part of MBT installations already use two-stage anaerobic digestion, or could start using it. This would be associated with a cost but also co-benefits in terms of higher overall energy recovery.

However, it should be noted that the precise contamination removal is uncertain for the assessed processes, so there is still some level of uncertainty regarding how well the risks are controlled (b).

In conclusion, an obligation to use two-stage anaerobic digestion could be appropriate for MBT digestate and sewage sludge digestate, and an obligation to apply post-composting could be appropriate for sewage sludge digestate (if C/D made from sewage sludge is not restricted for use as a fertiliser in general).

Summary of expected socio-economic impacts of the proposed obligatory processes	
Restriction on the use of MBT and sewage sludge digestate as a fertiliser except when using two-stage A/D	About a quarter of digestate is currently produced from the organic fraction of mixed municipal solid waste (MBT) and sewage sludge (most of this from MBT). Only a small share of plants (some 290[164] of at least over 17,000[165] plants in Europe) already apply two-stage AD (European Bioplastic 2015). Hence, a significant share of digestate would be affected and the below impacts could be considerable in scale. Expected impacts: • Upgrading to a two-stage AD process is associated with additional costs, which is at least partly offset by operational benefits. The net economic effect to operators has not been quantified and will likely vary on a case by case basis (it could be positive or negative). It is likely that for some operators, the upgrade will not be feasible. For these operators, the following impacts are expected, but as they only apply to a part of affected operators, these impacts would be smaller in scale. • The affected digestate may be used for alternative applications, but there is uncertainty about their technical feasibility. • If this is not feasible, biogas production (and thus digestate production) would likely still continue largely unchanged, because income from selling or using digestate is often secondary to AD operators. Hence, the affected digestate would have to be disposed of, which would likely lead to further waste management costs and additional environmental risks and could contradict environmental policy objectives. • In addition, the affected digestate would have to be replaced by alternative fertilisers. The most likely alternative, synthetic fertilisers, cannot fulfil digestate's function of supplying organic matter and is associated with several additional environmental risks.

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[163] Although not high enough for safe limits to be exceeded and hence no limit values for cadmium are proposed (see section on Concentration limits above. The only main concern identified for cadmium was long-term gradual accumulation.

[164] As of 2015, source: https://docs.european-bioplastics.org/publications/bp/EUBP_BP_Anaerobic_digestion.pdf

[165] As of 2014, source: http://european-biogas.eu/wp-content/uploads/2016/01/Graph-1-Biogas-plants.png

	• Some AD operators may consider replacing sewage sludge and the organic fraction of mixed municipal solid waste (MBT) with alternative feedstocks. Sewage sludge and the mixed municipal solid waste would then require alternative waste management, which would likely lead to additional environmental risks and could contradict environmental policy objectives.
Restriction on the use of sewage sludge digestate as a fertiliser except when applying post-composting	Only a low share of digestate is currently produced from sewage sludge and some (unquantified) share of AD plants is likely already operating post-composting, so only a very small quantity of digestate would be affected and all of the below impacts would be very modest in scale. Expected impacts: • The implementation of this process would be associated with additional space, time and operational cost. • It is likely that for some operators, the upgrade will not be feasible. For these operators, the same impacts as in the previous row would be expected, but as they only apply to a part of affected operators, these impacts would be even smaller in scale.

5.7.3 Legal options

Possible legal options to implement the proposed risk management measures are briefly discussed below:

- Article 42(4) of the proposal for the revised Fertilising Products Regulation (FPR)[166] gives the European Commission the authority to amend the annexes[167] in the light of new scientific evidence where a risk assessment shows this is necessary to ensure that EU fertilising products do not present a risk to human, animal, or plant health, to safety or to the environment. This gives the Commission the power to change limit values (except for Cadmium), add new limit values for additional contaminants, change allowed input materials and change process requirements for composting/digestion. However, the FPR only applies to CE-marked fertilisers. National fertilisers can still co-exist without following the FPR (European Commission 2018b).

- REACH restriction: This is a flexible risk management tool, allowing specific uses of substances to be banned or otherwise restricted. Depending on the scope and definitions applied, it therefore has the potential to be effective in addressing the risks to the environment. Compared to a restriction introduced through a dedicated legal instrument (ad-hoc legislation), it also has the potential to be implemented rapidly.

- Possible bespoke legislation: This is more time-consuming to implement and feasibility depends on a range of factors including judgement about the relative risk of contamination from C/D compared to other environmental concerns. However, bespoke legislation may be necessary if using existing legislation such as the FPR or REACH is not feasible.

- Waste Framework Directive: Article 6 (1) and (2) of the Waste Framework Directive (2008/98/EC) provides a procedure for defining criteria that wastes undergoing a recovery operation have to fulfil in order to cease to be waste and receive product status (end-of-waste criteria). According to Article 6(1), these criteria "shall include limit values for pollutants where necessary and shall take into account any possible adverse environmental effects". As discussed in JRC (2014), end-of-waste criteria could be developed for and applied to all C/D, or a sub-group of C/D (e.g. made from specific input materials). However, the results of JRC (2014) were in the end not used to define end-of-waste-criteria, but instead to inform provisions under the revised Fertilising Products Regulation. It is therefore uncertain if end-of-waste criteria are feasible.

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[166] http://data.consilium.europa.eu/doc/document/ST-15103-2018-INIT/en/pdf

[167] With the exception of cadmium limit values and the definitions, or other elements relating to scope, of product function categories.

- Other waste legislation: In addition, there are specific pieces of legislation regulating the use of specific waste streams that are also used as input materials for C/D.
  - For instance, the Sewage Sludge Directive 86/278/EEC seeks to encourage the use of sewage sludge in agriculture but also regulates the use of sewage sludge to prevent harmful effects on the environment and man by setting limit values for heavy metals. This does not currently apply to treated sewage sludge (such as C/D from sewage sludge). It could be further investigated whether the Directive could be revised to include limit values for treated sewage sludge and add limit values for additional contaminants.
  - The Urban Waste Water Treatment Directive encourages the re-use of sewage sludge “whenever appropriate”, while “minimising adverse effects on the environment”, however no targets or risk management measures are specified. It could be further investigated whether the Directive could be revised to include additional specifications on sewage sludge resulting from urban waste water treatment. The Directive is currently undergoing an evaluation, which might trigger revision of the Directive in the future.

Glossary

AD:	Anaerobic digestion.
BCF:	Bioconcentration. Accumulation of a chemical in or on an organism when the source of chemical is solely water.
BMDL10:	Benchmark dose level. Study endpoint that is associated with a 10% extra risk of adverse effect in the exposed test animals, as compared to the background levels of risk.
BPA:	Bisphenol-A.
C/D:	Compost and/or digestate.
Cd, Cu, Hg, Ni, Pb, Zn:	Chemical element symbols for the heavy metals cadmium, copper, mercury, nickel, lead and zinc.
DEHP:	Di(2-ethylhexyl)phthalates.
dw/dm:	dw - dry weight; dm – dry mass.
EBA:	European Biogas Association.
ECN:	European Compost Network.
ECN-QAS:	European Compost Network Quality Assurance Scheme for Compost and Digestate.
EQS:	Environmental Quality Standard in accordance with the Water Framework Directive (2000/60/EC).
ESR:	Council Regulation (EEC) No 793/93, also known as the Existing Substances Regulation (ESR). Repealed by the REACH Regulation (EC) No 1907/2006.
EUSES:	European Union System for the Evaluation of Substances (EUSES), a decision-support instrument to carry out rapid and efficient assessments of the general risks posed by chemical substances.
Fertiliser:	It should be noted that C/D, particularly compost, fulfil other functions than fertilisation, such as adding organic matter to the soil. However, for simplicity we refer to the main function as fertiliser throughout the report, except where the specific function is relevant for the analysis. Abbreviated fertilisers (N/P/K fertiliser) refer to synthetic fertilisers containing the following macronutrients: N – nitrogen, P – phosphorus, K – potassium.
FPR:	Fertilising Products Regulation (Proposal for a Regulation of the European Parliament and the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009).
HBCDD:	Hexabromocyclododecane.
Input materials:	Feedstocks used to produce compost or in anaerobic digestion (producing biogas and digestate).
Koc/Kow:	Koc: Soil Organic Carbon-Water Partitioning Coefficient. The ratio of the adsorbed organic analyte to the dissolved; Kow: Octanol-Water Partition Coefficient.

MBT: Mechanical Biological Treatment processing mixed waste, particularly mixed municipal solid waste.

MSW: Municipal solid waste.

PAH: Polycyclic aromatic hydrocarbons.
PAH2, PAH4, PAH16, etc. are indicators to measure PAHs. The most common is:
PAH16= sum of US EPA 16 priority listed polycyclic aromatic hydrocarbons.

PBT: Persistent, bioaccumulative, toxic.

PCB: Polychlorinated biphenyls.
PCB6, PCB7 etc. are indicators to measure PCBs. The most common are:
PCB6=sum of PCBs 28, 52, 101, 138, 153 and 180;
PCB7=sum of PCBs 28, 52, 101, 118, 138, 153 and 180; 2,4,4'-Trichlorobiphenyl (PCB28).

PCDD/F: Dioxins and furans. Sum of 17 polychlorinated dibenzo-p-dioxins/furans expressed in International Toxicity Equivalents.
Specific dioxins and furans: 2,3,7,8-Tetrachlorodibenzodioxin (TCDD), 2,3,4,7,8-Pentachlorodibenzofuran (PCDF).

PFAS: Per- and Polyfluoroalkyl Substances.
Specific PFAS: Perfluoroctanoic acid (PFOA), Perfluoroctanesulfonic acid (PFOS), Perfluorohexanoic acid (PFHxA).

POPs: Persistent Organic Pollutants.

RAC and SEAC:
ECHA's Committee for Socio-economic Analysis (SEAC) and Committee for Risk Assessment (RAC).

RCR, PEC, PNEC, DNEL: Risk characterisation ratios (RCRs) are derived by comparing exposure levels to suitable predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs). For the environmental end-points, this is the ratio of predicted environmental concentration (PEC) to PNEC. RCR=PEC/PNEC or Exposure/DNEL.

REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

RMOA: Risk management options analysis.

Safe limit: For the endpoints where conventional quantitative risk characterisation is appropriate, a limit below which adverse effects are not expected has been calculated. This is referred to as “safe limit” throughout the report. Note that this does not preclude possible other effects at lower concentrations, related to other endpoints for which quantitative risk characterisation was not possible.

Scenario I: Compost and digestate products, handling and application as soil amendment, including application of compost; whole digestate; crude dry fibre and all liquid products.

Scenario II: Compost used as a growing medium, e.g. for consumer (hobby) and professional growers.

SVHC: Substance of very high concern. Substance on the Candidate List for Authorisation under the REACH Regulation.

TEF/TEQ:	Toxic Equivalency Factors (TEFs) and Toxic Equivalent (TEQ) express the weighted concentration equivalent to the most toxic dioxin 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).
vPvB:	Very persistent, very bioaccumulative.

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WRAP (2016). *Digestate and Compost Use In Agriculture – Good Practice Guidance*. [Viewed 21 January 2019] Available at: http://www.wrap.org.uk/sites/files/wrap/Digestate_compost_good_practice_guide_reference_version.pdf

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Appendix A
Overview of market analysis data

This appendix presents the available data on the tonnages of compost (Table A.1) and digestate (Table A.2) for each EU Member State. The tables also explain how the total estimate of compost/digestate tonnage used in this study was derived from the various data sources. In addition, Table A.3 presents Member State market data specifically for digestate from separated bio-waste, agri-food industry and sewage sludge, for which no EU-level estimates of digestate quantity were available.

Table A.1 Compost market data by country

Country	**JRC 2014 (data for 2005-2009):** Tonnes of compost produced	**Eurostat material flow accounts 2014:** Tonnes of compost applied	**Data from consultation:** Tonnes of compost	**Data from literature review:** Tonnes of compost	**Estimate for this study:** Tonnes of compost (central estimate)	**Estimate for this study:** Tonnes of compost (range)	**Estimate for this study:** Explanation of the basis for the estimate
EU28	14,360,000	17,920,000	ECN response: 12,100,000-16,150,000 (excluding sewage sludge compost)		**17,300,000**	12,900,000-17,900,000	Central: Sum of country estimates; Range: Sum of ECN consultation response and estimate for sewage sludge compost (See Section 2.2.4, Eurostat data on sewage sludge disposed as 'compost and other applications'); All rounded to closest 100,000.
Germany	4,380,000	4,340,000	BDE response: 4,300,000	German Federal Environment Agency 2017: 3,900,000	**4,300,000**	4,300,000-4,380,000	BDE consultation response, Eurostat material flow accounts 2014 and JRC 2014 (all in close agreement)
United Kingdom	2,040,000	2,550,000		ECN country report 2017: 3,470,000	**2,800,000**	2,040,000-3,470,000	Central: Midpoint of range (rounded to closest 100,000) (note this is also close to Eurostat material flow accounts 2014); Range: JRC 2014 – ECN country report 2017.
France	2,490,000	2,540,000			**2,500,000**	2,490,000-2,540,000	Eurostat material flow accounts 2014 and JRC 2014 (both in close agreement) (central estimate rounded to closest 100,000).
Italy	1,000,000	2,430,000	CIC response: 1,900,000	ECN country report 2017: 1,760,000	**2,200,000**	1,900,000-2,430,000	Central: Midpoint of range (rounded to closest 100,000); Range: CIC consultation response - Eurostat material flow accounts 2014.

Country	**JRC 2014 (data for 2005-2009):** Tonnes of compost produced	**Eurostat material flow accounts 2014:** Tonnes of compost applied	**Data from consultation:** Tonnes of compost	**Data from literature review:** Tonnes of compost	**Estimate for this study:** Tonnes of compost (central estimate)	**Estimate for this study:** Tonnes of compost (range)	**Estimate for this study:** Explanation of the basis for the estimate
Netherlands	1,600,000	1,210,000			**1,400,000**	1,210,000-1,600,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Spain	610,000	1,450,000			**1,000,000**	610,000-1,450,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Poland	630,000	580,000			**600,000**	580,000-630,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Belgium	500,000	490,000		ECN country report 2017: 360,000 (only Flanders)	**500,000**	490,000-500,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Denmark	370,000	410,000			**400,000**	370,000-410,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Sweden	200,000	350,000			**300,000**	200,000-350,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.

Country	**JRC 2014 (data for 2005-2009):** Tonnes of compost produced	**Eurostat material flow accounts 2014:** Tonnes of compost applied	**Data from consultation:** Tonnes of compost	**Data from literature review:** Tonnes of compost	**Estimate for this study:** Tonnes of compost (central estimate)	**Estimate for this study:** Tonnes of compost (range)	**Estimate for this study:** Explanation of the basis for the estimate
Austria	0	0		Kompost- und Biogasverband Österreich: 580,000m^3	**300,000**		Estimated based on Kompost- und Biogasverband Österreich.[1)]
Romania	0	200,000			**200,000**	200,000-200,000	Eurostat material flow accounts 2014.
Finland	180,000	190,000			**200,000**	180,000-190,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Hungary	50,000	120,000		ECN country report 2017: 200,000 (excluding mechanical biological treatment of 550,000 t of MSW)	**200,000**	120,000-480,000	Central: ECN country report 2017 (excluding mechanical biological treatment); Range: Eurostat material flow accounts 2014 - ECN country report 2017 (including estimated 275,000 t of compost resulting from mechanical biological treatment of 550,000 t of MSW).[2)]
Estonia	0	210,000		ECN country report 2017: 39,000 (only biowaste and sewage sludge)	**100,000**	40,000-210,000	Central: Midpoint of range (rounded to closest 100,000); Range: ECN country report 2017 - Eurostat material flow accounts 2014.
Ireland	100,000	180,000			**100,000**	100,000-180,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.

Country	JRC 2014 (data for 2005-2009): Tonnes of compost produced	Eurostat material flow accounts 2014: Tonnes of compost applied	Data from consultation: Tonnes of compost	Data from literature review: Tonnes of compost	Estimate for this study: Tonnes of compost (central estimate)	Estimate for this study: Tonnes of compost (range)	Estimate for this study: Explanation of the basis for the estimate
Portugal	30,000	180,000			**100,000**	30,000-180,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Slovakia	30,000	170,000			**100,000**	30,000-170,000	Central: Midpoint of range (rounded to closest 100,000); Range: JRC 2014 - Eurostat material flow accounts 2014.
Greece	10,000	80,000			**<100,000**	10,000-80,000	JRC 2014, Eurostat material flow accounts 2014.
Slovenia	0	70,000			**<100,000**	Up to 70,000	JRC 2014, Eurostat material flow accounts 2014.
Lithuania	0	60,000			**<100,000**	Up to 60,000	JRC 2014, Eurostat material flow accounts 2014.
Czech Republic	80,000	50,000			**<100,000**	50,000-80,000	JRC 2014, Eurostat material flow accounts 2014.
Luxembourg	20,000	30,000			**<100,000**	20,000-30,000	JRC 2014, Eurostat material flow accounts 2014.
Bulgaria	0	30,000			**<100,000**	Up to 30,000	JRC 2014, Eurostat material flow accounts 2014.
Croatia	0	20,000			**<100,000**	Up to 20,000	JRC 2014, Eurostat material flow accounts 2014.

Country	**JRC 2014 (data for 2005-2009):** Tonnes of compost produced	**Eurostat material flow accounts 2014:** Tonnes of compost applied	**Data from consultation:** Tonnes of compost	**Data from literature review:** Tonnes of compost	**Estimate for this study:** Tonnes of compost (central estimate)	**Estimate for this study:** Tonnes of compost (range)	**Estimate for this study:** Explanation of the basis for the estimate
Cyprus	0	10,000			**<100,000**	Up to 10,000	JRC 2014, Eurostat material flow accounts 2014.
Latvia	0	0			**unknown**		
Malta	0	0			**unknown**		

Sources:

Wood 2018 based on:

JRC technical proposals on end-of-waste criteria for biodegradable waste subjected to biological treatment, 2014, available at: http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=6869;

Eurostat material flow accounts - domestic processed output [env_ac_mfadpo], compost 'supplied by the national economy and taken up by the natural environment' in 2014;

Consultation responses from ECN (European Compost Network), BDE (German Waste, Water and Raw Materials Management Industry Association), and CIC (Italian Compost Consortium);

ECN country reports, available at https://www.compostnetwork.info/publications/;

German Federal Environment Agency: Bioabfallkomposte und -gärreste in der Landwirtschaft. position // januar 2017. Available at: https://www.umweltbundesamt.de/sites/default/files/medien/377/publikationen/170131_uba_pos_bioabfall_bf.pdf;

Kompost- und Biogasverband Österreich: http://www.kompost-biogas.info/kompost/statistik-kompost/.

Notes:

1) Mass of compost produced in Austria was estimated from the 580,000m^3 volume as follows: The volume in m^3 was converted to litres by multiplying with 1,000. The volume in litres was then converted to weight in kg assuming an average density of the compost of 0.5kg/l (See for instance: https://www.hotbincomposting.com/blog/quick-composting-faqs.html or http://www.severnwaste.com/composting/greengrow/). The mass in kg was then converted to tonnes by multiplying with 1,000.

2) The mass of compost produced from mechanical biological treatment of 550,000 t of municipal solid waste (MSW) in Hungary was estimated using the assumption that the average weight of compost produced is about half the weight of the feedstocks used (this is roughly the ratio of compost weight to feedstock weight indicated by the figures in ECN's consultation response).

Table A.2 Digestate market data by country (all types of digestate)

Country	JRC 2014: Tonnes of digestate	Estimation based on 2016 biogas production[1)]: Tonnes of digestate (central estimate)	Estimation based on 2016 biogas production[1)]: Tonnes of digestate (range)	Data from consultation: Tonnes of digestate	Data from literature review: Tonnes of digestate	Estimate for this study: Tonnes of digestate (central estimate)	Estimate for this study: Tonnes of digestate (range)	Estimate for this study: Explanation of the basis for the estimate
EU28	56,000,000	118,180,000	35,750,000-1,312,800,000	EBA response: Ca. 120,000,000 (agricultural plants only); Ca. 55,000,000t organic fraction of mixed MSW treated in mechanical biological treatment plants	Digestate and REACH Position Paper 2013: 80,000,000	176,000,000		Sum of the following: • Agricultural digestate (EBA consultation response); • Mixed MSW digestate (estimation based on feedstock from mechanical biological treatment plants according to EBA consultation response);[2)] • Source separated biowaste, agro-food industry and sewage sludge digestate (several country-specific sources, see Table A.3 for more details). Rounded to closest 1 million tonnes. Note that this matches reasonably well with the sum of central estimates for the 28 Member States (170,100,000t).
Germany	36,000,000	57,630,000	17,430,000-640,190,000	EBA response: 60,000,000 (agricultural plants only)	French Environment and Energy Management Agency 2014: 86,680,000	87,000,000	60,000,000-96,000,000	Central: French Environment and Energy Management Agency 2014 (rounded to closest 100,000); Range: EBA consultation response (agricultural only) - JRC 2014 extrapolated from 2008 to 2016 based on increase in biogas production over this period[3)].

Country	**JRC 2014:** Tonnes of digestate	**Estimation based on 2016 biogas production**[1]**:** Tonnes of digestate (central estimate)	**Estimation based on 2016 biogas production**[1]**:** Tonnes of digestate (range)	**Data from consultation:** Tonnes of digestate	**Data from literature review:** Tonnes of digestate	**Estimate for this study:** Tonnes of digestate (central estimate)	**Estimate for this study:** Tonnes of digestate (range)	**Estimate for this study:** Explanation of the basis for the estimate
United Kingdom	124,000	18,520,000	5,600,000-205,690,000		WRAP 2015: 4,500,000	18,500,000	4,500,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: WRAP 2015 (note that it seems unlikely this covers all digestate in the UK given this is lower than the lower end of the range based on 2016 biogas production) - no data for upper end of range available[4].
Italy	83,100	13,350,000	4,040,000-148,290,000		Italian Biogas Association quoted in EBA 2015: Up to 30,000,000	30,000,000	13,400,000-30,000,000	Central: Italian Biogas Association quoted in EBA 2015; Range: Estimation based on 2016 biogas production - Italian Biogas Association quoted in EBA 2015.
France		5,410,000	1,640,000-60,110,000		Panorama du Gaz Renouvable 2016: 1,030,000t of feedstocks for biogas injected into the natural gas network	5,400,000	900,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: Estimation based on feedstock according to Panorama du Gaz Renouvable 2016[2] - no data for upper end of range available[4].
Czech Republic	80,000	4,280,000	1,290,000-47,530,000			4,300,000	500,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: JRC 2014 extrapolated from 2008 to 2016 based on increase in biogas production over this period[3] - no data for upper end of range available[4].

Country	JRC 2014: Tonnes of digestate	Estimation based on 2016 biogas production1): Tonnes of digestate (central estimate)	Estimation based on 2016 biogas production1): Tonnes of digestate (range)	Data from consultation: Tonnes of digestate	Data from literature review: Tonnes of digestate	Estimate for this study: Tonnes of digestate (central estimate)	Estimate for this study: Tonnes of digestate (range)	Estimate for this study: Explanation of the basis for the estimate
Netherlands		2,270,000	690,000-25,200,000		Dutch Central Bureau of Statistics 2012: 1,930,000; Groen Gas Forum 2014: 3,770,000t of feedstocks for biogas production	2,900,000	2,200,000-3,500,000	Central: Midpoint of range (rounded to closest 100,000); Range: Dutch Central Bureau of Statistics 2012 - Renewable gas route map 2014 (both extrapolated from 2011 and 2012 respectively to 2016 based on increase in biogas production over these periods3))
Austria		2,230,000	670,000-24,760,000		FABbiogas national report: Capacity of 860,000t of waste as feedstock for biogas production (actual use in 2006 was 410,000t)	2,200,000	900,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: Estimation based on feedstock according to FABbiogas national report2) - no data for upper end of range available4).
Poland		1,860,000	560,000-20,650,000		Global Methane 2014: 1,580,000t of feedstock for biogas production (agricultural only)	1,300,000	600,000-1,900,000	Central: Estimation based on feedstock according to Global Methane 2014 (agricultural only) 2); Range: Lower end of range to central estimate of the estimation based on 2016 biogas production (rounded to closest 100,000, note that the lower and central estimates were used because they are reasonably close to Global Methane 2012).

Country	**JRC 2014:** Tonnes of digestate	**Estimation based on 2016 biogas production[1]):** Tonnes of digestate (central estimate)	**Estimation based on 2016 biogas production[1]):** Tonnes of digestate (range)	**Data from consultation:** Tonnes of digestate	**Data from literature review:** Tonnes of digestate	**Estimate for this study:** Tonnes of digestate (central estimate)	**Estimate for this study:** Tonnes of digestate (range)	**Estimate for this study:** Explanation of the basis for the estimate
Spain	504,000	1,750,000	530,000-19,390,000		Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016: 400,000t of sewage sludge and municipal (bio) waste digested	1,800,000	300,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: Estimation based on feedstock according to Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016 (sewage sludge and municipal waste only)[2]) - no data for upper end of range available[4]).
Belgium	800,000	1,610,000	490,000-17,940,000		ECN country report: 1,300,000 (Flanders only)	1,600,000	1,300,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: ECN country report 2015 (Flanders only) - no data for upper end of range available[4]).
Denmark		1,560,000	470,000-17,280,000			1,600,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available[4]).
Sweden	389,000	1,240,000	370,000-13,720,000		French Environment and Energy Management Agency 2014: 7,220,000 (relating to 2010)	7,200,000	1,200,000-11,300,000	Central: French Environment and Energy Management Agency 2014; Range: Estimation based on 2016 biogas production (central estimate, rounded to closest 100,000) - French Environment and Energy Management Agency 2014 extrapolated from 2010 to 2016 based on increase in biogas production over this period[3]).
Slovakia		1,080,000	330,000-12,010,000			1,100,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.

Country	**JRC 2014:** Tonnes of digestate	**Estimation based on 2016 biogas production[1]:** Tonnes of digestate (central estimate)	**Estimation based on 2016 biogas production[1]:** Tonnes of digestate (range)	**Data from consultation:** Tonnes of digestate	**Data from literature review:** Tonnes of digestate	**Estimate for this study:** Tonnes of digestate (central estimate)	**Estimate for this study:** Tonnes of digestate (range)	**Estimate for this study:** Explanation of the basis for the estimate
Finland		800,000	240,000-8,870,000			800,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Greece		720,000	220,000-8,040,000			700,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Latvia		640,000	190,000-7,110,000			600,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Hungary		630,000	190,000-7,000,000		ECN country report: 350,000t of sewage sludge and agricultural waste or liquid manure and agricultural residues digested	600,000	300,000-?	Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: Estimation based on feedstock according to ECN country report[2] - no data for upper end of range available[4].
Portugal		570,000	170,000-6,350,000			600,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Bulgaria		430,000	130,000-4,740,000			400,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Ireland		400,000	120,000-4,450,000			400,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.

Country	**JRC 2014:** Tonnes of digestate	**Estimation based on 2016 biogas production[1]:** Tonnes of digestate (central estimate)	**Estimation based on 2016 biogas production[1]:** Tonnes of digestate (range)	**Data from consultation:** Tonnes of digestate	**Data from literature review:** Tonnes of digestate	**Estimate for this study:** Tonnes of digestate (central estimate)	**Estimate for this study:** Tonnes of digestate (range)	**Estimate for this study:** Explanation of the basis for the estimate
Croatia		330,000	100,000-3,690,000			300,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Lithuania		230,000	70,000-2,530,000			200,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Slovenia		210,000	70,000-2,390,000			200,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Luxembourg	177,000	140,000	40,000-1,570,000			100,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Romania		130,000	40,000-1,400,000			100,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Cyprus		80,000	30,000-930,000			100,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Estonia		80,000	20,000-850,000			100,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.
Malta		10,000	<10,000-150,000			<100,000		Central: Estimation based on 2016 biogas production (rounded to closest 100,000); Range: No data available.

Sources:

Wood 2018 based on:

JRC technical proposals on end-of-waste criteria for biodegradable waste subjected to biological treatment, 2014, available at: http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=6869;

Eurostat data on biogas production for 2016 (in: supply, transformation and consumption of renewable energies - annual data [nrg_107a]) and several sources to inform assumptions on estimating the resulting quantities of digestate – these are described on more detail in Section 2.2.4;

Consultation response from EBA (European Biogas Association);

Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016, available at http://www.mapama.gob.es/estadistica/pags/anuario/2016/AE16.pdf;

ECN country reports, available at https://www.compostnetwork.info/publications/;

Fachverband Biogas / EBA / BiPRO: Digestate and REACH – Position Paper, 2013, available at: http://european-biogas.eu/wp-content/uploads/files/2013/11/2013-11-28-Position-paper-digestate-and-REACH-EN-final.pdf;

French Environment and Energy Management Agency (ADEME): Benchmark des stratégies européennes des filières de production et de valorisation de biogaz et prospectives pour la filière française de méthanisation, 2014, available at https://www.actu-environnement.com/media/pdf/news-24244-benchmark-strategies-europ-biogaz.pdf;

WRAP: Organics recycling industry status report 2015, available at: http://www.wrap.org.uk/sites/files/wrap/asori%202015.pdf;

Italian Biogas Association quoted in EBA Digestate Factsheet, 2015, available at: http://european-biogas.eu/wp-content/uploads/2015/07/Digestate-paper-final-08072015.pdf;

Panorama du gaz renouvelable au 31 décembre 2016, available at: https://www.actu-environnement.com/media/pdf/news-28505-panorama-gaz-2016-SER-GRDF.pdf;

Dutch Central Bureau of Statistics (CBS): Co-vergisting van dierlijke mest 2006–2011, 2012, available at https://www.cbs.nl/-/media/imported/documents/2012/31/2012-co-vergisting-dierlijk-mest-2006-2011-art.pdf;

Groen Gas Forum: Routekaart hernieuwbaar gas, 2014, available at: https://www.rvo.nl/sites/default/files/2014/07/Routekaart%20Hernieuwbaar%20gas.pdf;

FABbiogas: Biogas production and biogas potentials from residues of the European Food and beverage industry – Austria – national situation, available at: http://www.fabbiogas.eu/fileadmin/user_upload/Download/National_Report_AUSTIRA_german.pdf;

Global Methane Initiative: The agricultural biogas plants in Poland, 2014, available at: https://www.globalmethane.org/documents/Poland-Ag-Biogas-Plants-April-2014.pdf.

Notes:

1) The quantity of digestate produced as a result of biogas production according to Eurostat data was estimated for each country based on a set of assumptions described on more detail in Section 2.2.4.

2) Where only the tonnage of feedstocks used for anaerobic digestion was available, the resulting amount of digestate was estimated as follows: The tonnage of feedstocks was multiplied with 0.84, the midpoint between the mass reductions from feedstock to digestate suggested by the EBA consultation response and WRAP 2012.

3) 2016 tonnages of digestate were extrapolated from older figures based on the assumption that digestate production increased at the same rate as biogas production in terms of energy (Eurostat: Supply, transformation and consumption of renewable energies - annual data [nrg_107a]). This implies the assumption that on average similar production techniques and feedstocks have been used which produce a similar amount of energy per weight of input material used. The extrapolation was calculated as follows: the old figure of digestate tonnage was divided by the biogas production in the same year and country, and then multiplied by the biogas production in 2016 in the same country.

4) The ranges reflect estimates that we consider to reflect likely minimum values or underestimates on the one end, and likely maximum values or overestimates on the other end. Central estimates reflect what we consider the most likely value. In some cases, no estimates above what we consider the most likely value (central estimate) were available, so there was no basis for an upper end of the range.

Table A.3 Separated biowaste, agri-food industry and sewage sludge digestate market data by country

Country	Source separated biowaste digestate		Agro-food industry digestate		Sewage sludge digestate		Sources
	Tonnes of digestate	**Tonnes of feedstock**	**Tonnes of digestate**	**Tonnes of feedstock**	**Tonnes of digestate**	**Tonnes of feedstock**	
Germany	3,600,000	4,280,000 (estimated)					German Federal Environment Agency (2017)
Italy	1,990,000 (estimated)	2,370,000	10,000	10,000 (estimated)	380,000 (estimated)	450,000	Agro-food: JRC 2014 Source separated biowaste, sewage sludge: World Biogas Association 2017
Denmark	10,000 (estimated)	10,000	240,000 (estimated)	280,000	30,000 (estimated)	40,000	JRC 2014
Belgium (Flanders only)	80,000 (estimated)	100,000					JRC 2014
United Kingdom	250,000 (estimated)	300,000			10,000 (estimated)	10,000	Sewage sludge: JRC 2014 Source separated biowaste: WRAP 2015
Netherlands	180,000 (estimated)	210,000	1,020,000 (estimated)	1,220,000	830,000 (estimated)	990,000	Groen Gas Forum 2014
France	260,000 (estimated)	310,000	100,000 (estimated)	120,000	360,000 (estimated)	430,000	Panorama du Gaz Renouvable 2016 Note: Covers only biogas injected into the natural gas network
Spain	210,000 (estimated)	250,000			90,000 (estimated)	110,000	Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016
Poland	230,000 (estimated)	270,000					Global Methane Initiative 2014
Sweden	210,000 (estimated)	240,000	330,000 (estimated)	390,000			French Environment and Energy Management Agency 2014
SUM	**7,020,000**	**8,340,000**	**1,690,000**	**2,010,000**	**1,700,000**	**2,020,000**	

Sources:

Wood 2018 based on:

German Federal Environment Agency: Bioabfallkomposte und -gärreste in der Landwirtschaft. position // januar 2017. available at: https://www.umweltbundesamt.de/sites/default/files/medien/377/publikationen/170131_uba_pos_bioabfall_bf.pdf;

World Biogas Association: Anaerobic Digestion Market Report Italy, 2017, available at: http://www.worldbiogasassociation.org/wp-content/uploads/2017/07/WBA-italy-4ppa4_v1.pdf;

WRAP: Organics recycling industry status report 2015, available at: http://www.wrap.org.uk/sites/files/wrap/asori%202015.pdf;

Groen Gas Forum: Routekaart hernieuwbaar gas, 2014, available at: https://www.rvo.nl/sites/default/files/2014/07/Routekaart%20Hernieuwbaar%20gas.pdf;

Panorama du gaz renouvelable au 31 décembre 2016, available at: https://www.actu-environnement.com/media/pdf/news-28505-panorama-gaz-2016-SER-GRDF.pdf;

Spanish Ministry of Agriculture, Fishing, Food and the Environment Statistical Year Book 2016, available at http://www.mapama.gob.es/estadistica/pags/anuario/2016/AE16.pdf;

Global Methane Initiative: The agricultural biogas plants in Poland, 2014, available at: https://www.globalmethane.org/documents/Poland-Ag-Biogas-Plants-April-2014.pdf;

French Environment and Energy Management Agency (ADEME): Benchmark des stratégies européennes des filières de production et de valorisation de biogaz et prospectives pour la filière française de méthanisation, 2014, available at https://www.actu-environnement.com/media/pdf/news-24244-benchmark-strategies-europ-biogaz.pdf.

Notes:

All figure marked with "(estimated)": Where only the tonnage of feedstocks used for anaerobic digestion was available, the resulting amount of digestate was estimated as follows: The tonnage of feedstocks was multiplied with 0.84, the midpoint between the mass reductions from feedstock to digestate suggested by the EBA consultation response and WRAP 2012 (http://www.wrap.org.uk/sites/files/wrap/Digestates%20from%20Anaerobic%20Digestion%20A%20review%20of%20enhancement%20techniques%20and%20novel%20digestate%20products_0.pdf). Vice versa, where only the tonnage of amount of digestate was available, the underlying amount of digestate was estimated by dividing the tonnage of digestate by 0.84.

Appendix B

Overview of further processing techniques for digestate

The use of digestate as fertiliser is sometimes hindered by practical and economic issues (large volumes of digestate, high transportation and storage costs), as well as environmental issues (nitrogen and phosphorus fertilisation limits in high nutrient areas) (Vaneeckhaute et al. 2018). Further processing of digestate allows concentration and recovery of the nutrients in digestate in order to be more easily stored, transported and/or applied were most needed.

The following digestate processing technologies have been identified and are discussed in this section:

- Separation of liquid and solid fractions;
- Digestate drying;
- Ammonia stripping;
- Phosphorous precipitation/Struvite crystallisation;
- Phosphorous (P) extraction;
- Micro filtration/Membrane filtration; and
- Microalgae production.

The choice of technology used to recover nutrients from digestate depends on the characteristics of waste input, and strongly affects the properties of fertiliser end-products. With the exception of separation, drying and ammonia stripping, the majority of these digestate treatment processes are still in the embryonic stages of development (According to EBA consultation response and Vaneeckhaute et al. 2018). This is largely due to high costs and is further hindered by problematic waste classification of digestate and its associated derivates. For example, in the European Union, all derivates of animal manure are normally classified as waste in fertiliser legislation, requiring further processing to make high quality end-products (Vaneeckhaute et al. 2018).

Separation of liquid and solid fractions

According to the EBA consultation response, this is a well-established process which creates two outputs that need to be handled separately. The drier fraction can then go on to be stored, while lowering the volume of liquid makes storage of the liquid fraction easier. This can then be pumped later. Mechanical methodologies for the separation process and their efficacy are summarised for instance in Lukehurst *et al.* 2010.

Digestate drying

Drying of digestate liquor and sludge is also an established processing technique according to the EBA consultation response. It reduces the handling and spreading of digestate, as well as allowing for easier storage. Furthermore, the dry end-product can be used as animal bedding as well as organic fertiliser and biomass for green energy[168]. However, according to the European Biogas Association, digestate drying is a questionable process due to the unnecessary wasting of heat. Furthermore, during the drying process, if there is no effective air scrubbing in place, ammonium gets released into the air (EBA 2013).

Following separation, thermal treatment (drying) can be used to remove water and further increase dry solids content. Digestate is dried to over 90% dry matter to facilitate long term storage. Drying typically occurs in two forms:

- Direct: hot air (300-600˚C) flows through the vessel containing digestate;

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[168] https://stronga.com/drying-material/drying-digestate/

- Indirect: digestate is separated from the source of heat by metal walls where heat is passed to digestate by conduction. Temperatures are typically lower than with direct systems e.g. using steam at 135-215°C or thermal oil at 200-250°C (NNFCC 2016).

Ammonia stripping

This method involves converting NH_4 from the waste stream in question to a gas. This gas is then transferred to a scrubber which recovers a concentrated solution of ammonium sulphate as an end-product. According to the EBA consultation response, ammonia stripping is used at waste water treatment facilities. According to Vaneeckhaute et al (2018), the implementation of this process to treat N-rich digestate and manure is gaining traction.

Phosphorous precipitation - Struvite crystallisation

The controlled precipitation of struvite from waste water could contribute to the reduction of phosphorous in effluent. Due to struvite's fertilising properties, it has potential to produce valuable fertiliser. A range of processes (i.e. stirred tank reactors, air agitated and fluidised bed reactors) have been assessed as possible means for this further processing. According to Corre *et al.* (2009), fluidised bed reactors are the most promising, with the potential to remove up to 70% phosphorous or more, while Vaneeckhaute *et al.* (2018) estimates this figure at 80-90%.[169] According to Vaneeckhaute *et al.* (2018), this process has been fully implemented for wastewater, sludge and manure treatment the uptake of this technology has not been widespread due to economic and legislative developments and the difficulty in guaranteeing a pure product.

Phosphorous (P) extraction

Several companies have designed processes to extract P from ashes from the combustion of bio wastes and materials including digestate (Vaneeckhaute et al. 2018). The ashes generally contain P, K, Al, Si compounds, as well as potentially heavy metals. The phosphorus is bound as $CaHPO_4$ and can then be sold on as a chemical mineral fertiliser substitute. In a lot of countries digestate is eligible for recycling as a soil conditioner and therefore not authorised to be converted into energy by combustion/pyrolysis according to environmental legislation (Vaneeckhaute et al. 2018).

Micro filtration/Membrane filtration

Microfiltration, (MF) ultrafiltration (UF), nanofiltration (NF) and reverse osmosis (RO) are forms of pressure-driven membrane filtration used in the treatment of wastewater. Thus far, they have not been established as a valuable option for digestate treatment and few commercial pilot studies have been installed to date – most are only on a short-term basis due to high upfront capital costs (Vaneeckhaute et al. 2018). RO has been implemented at full-scale for NH_3-stripping of liquid digestate in Denmark. In general, the application of this process for digestate treatment is not widespread due to uncertainty over costs - membrane clogging, and associated cleaning and replacement poses high energy and capital costs (Masse et al. 2007, Vaneeckhaute et al. 2018).

Microalgae production

According to Fenton & Ó hUallacháin (2012), digestate has the potential to be used as a substitute for inorganic fertiliser for the commercial production of algae. The harvested alga/macrophytes can be used as feedstock for biofuels, animal feed or as an organic fertiliser. However, it is predicted that the breakthrough of algae in the bio-based economy will take another 5–15 years, due to high costs compared to other types of biomass (Vaneeckhaute et al. 2018).

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[169] This process has been fully implemented for wastewater, sludge and manure treatment

Appendix C
Evaluation matrix

The evaluation matrix is attached as separate excel document. It includes:

- the evaluation sheet for all substances;
- a literature list;
- identified and evaluated information for each substance group;
- a sheet describing the evaluation steps 1 to 3; and
- the relevant substance list used for step 1.

Appendix D
Risk assessment supporting report

Executive Summary

Realistic worst case risk assessments have been carried out for selected priority chemicals that have been detected in composts and digestates in Europe in recent literature. The focus of the exposure assessments is the environment and humans exposed via food and drinking water. Exposures and risks for two local scale scenarios are characterised. These scenarios consider the use of composts and digestates as a fertiliser and soil conditions and use of composts as a growing media as follows:

I. Compost and digestate products, handling and application as soil amendment
  - *application of compost; whole digestate; crude dry fibre and all liquid products*
  - *use on both large and small-scales by farmers/growers and the general public*
  - *any application onto soil post-use following use in container growing.*

II. Compost used as a growing medium
  - *use by professional and general public (amateur) growers.*

The risk assessments combine an assessment of exposure with an analysis of hazard in order to determine the likelihood of negative impacts. Were possible the significance of the estimated exposures derived by modelling has been assessed by comparison with available measurements of soil and water quality and/or from estimated exposures arising from the industrial lifecycle where this has previously been assessed in an exposure assessment.

Where appropriate, estimated exposure levels are also compared with threshold levels associated with toxicity hazards. In the risk assessment of chemical substances, the hazard is normally determined based on the intrinsic properties of the substance. The risk is normally determined by the comparison of an acceptable level of hazard (i.e. a 'no effect concentration') to the exposure concentration, in order to derive a ratio of the exposure level to the no-effect level (a risk characterisation ratio (RCR)). This is valid determinant for the cases where a safe threshold can be established. For some substances (e.g. those which are SVHCs based on persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties, or those with a non-threshold toxicological effect) such a comparison is not appropriate. In these cases, the focus of the risk assessment is on understanding of how such substances of concern present in digestate and compost can migrate between the different environmental compartments, at what concentrations, and with what environmental burden. This information is useful in assessing if these concentrations can be reduced in the risk management option analysis and analysis of alternatives.

The priority substances and chemical families considered in the risk assessment are as follows:

- Heavy metals – represented by cadmium, nickel, lead, copper, zinc and mercury.
- Bisphenol-A.
- Phthalates – represented by di(2-ethylhexyl)phthalate (DEHP).
- Pharmaceuticals – represented by 17α-Ethinylestradiol (EE2).
- Hexabromocyclododecane (HBCDD).
- Dioxins, furans and dioxin-like PCBs – represented by 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD) and 2,3,4,7,8-pentachlorodibenzofuran (2,3,4,7,8-PCDF).
- Other PCB – represented by 2,4,4'-Trichlorobiphenyl (PCB-28).
- Nonylphenol isomers and ethoxylates – represented by nonylphenol.

- Polycyclic aromatic hydrocarbons (PAH) – represented by benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene and indeno[,2,3-cd]pyrene.
- Perfluoralkyl substances (PFAs) – represented by perfluoroctanesulfonic acid (PFOS) and undecafluorohexanoic acid (PFHxA).
- Physical impurities – represented by microplastics.

It is important to note that a relatively simplistic realistic worst-case approach has be used in the risk assessment in order to simplify the risk assessment process. The results of the risk assessment are therefore subject to a number of uncertainties:

- Assumptions made in defining the local exposure scenarios.
- Amounts of compost and digestate used.
- Concentrations of the substances within those composts and digestates.
- Uncertainties over the properties of the substances.

Of these a key uncertainty is the concentrations of the substances found within composts and digestates. The available data for many of the substances considered is limited, covering only a small number of samples from a small number of regions/countries. In addition, the concentrations found in compost and digestate is variable for some substances, with the range reported spanning several orders of magnitude. Further some of the reported concentrations in the literature may reflect past use of the substance and this may be an important consideration for substances where usage has declined (or discontinued) in recent years. The uncertainties associated with each substance have been considered as part of each risk assessment.

The main findings of the risk assessments are outlined below.

For substances where it was possible to estimated risk characterisation ratios, RCRs >1 (indicating a potential risk) were found at the local scale in the following cases.

- Nickel. The overall range of reported nickel concentrations in composts and digestates is typically <10 to 39 mg/kg dry wt. However, levels above this (up to 250 mg/kg dry wt. in compost and 40 mg/kg dry wt.) have been measured in some samples. A potential risk from use of composts for container growing was identified and a safe limit of 7.9 mg/kg dry wt. was estimated for this use. No risks were identified for use of compost and digestate on agricultural land from the typical concentrations found, but a potential risk was identified for this use when the maximum concentration measured in compost was considered. This risk would be controlled if the concentration of nickel in compost or digestate applied to agricultural land is 130 mg/kg dry wt. or lower; the majority of the measured data are below this value. The available data set of occurrences in composts and digestates covers only a limited number of countries. The nickel from compost and digestate is estimated to contribute up to around 20% of the total background nickel present in soil.
- Copper. The overall range of reported copper levels in compost and digestate is up to 980 mg/kg dry wt., but more typically the levels are around 50-60 mg/kg dry wt. A potential risk from use of composts for container growing was identified and a safe limit of 200 mg/kg dry wt. was estimated for this use. The available data set of occurrences in composts and digestates covers only a limited number of countries. Copper is an essential element. Therefore, accumulation through the food chain is not a relevant concept for copper and no quantitative assessment of secondary poisoning or man

exposed via the environment has been carried out. The copper from compost and digestate is estimated to contribute up to around twice the amount of the background level of copper present in soil.

- Zinc. The overall range of reported zinc levels in compost and digestate is 132 to 1098 mg/kg dry wt., but median values are typically around 200-280 mg/kg dry wt. A potential risk from use of composts and digestates on agricultural land and composts for container growing was identified. A safe limit of 600 mg/kg dry wt. was derived for application of compost and digestate to agricultural land, and a safe limit of 70 mg/kg dry wt. was estimated for use as compost. The available data set of occurrences in composts and digestates covers only a limited number of countries and there are also uncertainties over the risk assessment at the regional level. Zinc is an essential element. Therefore, accumulation through the food chain is not a relevant concept for zinc and no quantitative assessment of secondary poisoning or man exposed via the environment has been carried out. The input of zinc to agricultural soil from compost and digestate is relatively small (around 10% of the total) compared with other sources.
- Mercury. The overall range of reported mercury levels in compost and digestate <0.018 to 0.98 mg/kg dry wt. A safe limit of 0.2 mg/kg dry wt. was derived for application of compost and digestate to agricultural land. Transport over long-distances is a possibility. The available data set of occurrences in composts and digestates covers only a limited number of countries. The overall contribution from compost and digestate to the total concentration of mercury in agricultural soil is low.
- Nonylphenol. The overall range of reported nonylphenol levels in compost and digestate was <0.1 - 50 mg/kg dry wt.. A safe limit of 3.5 mg/kg dry wt. was derived for use of compost in container growing. The available data set of occurrences in composts and digestates covers only a limited number of countries. The estimated regional exposures arising from the application of compost and digestate are very low compared with natural background concentrations in fresh water and sediments based on data cited in the ESR RAR (2008). The annual average EQS for inland surface waters (Directive 2008/105/EC as amended (2013/39/EU)) is not predicted to be exceeded.

No risks (RCRs<1) were identified in the following cases.

- Cadmium. Many cadmium compounds have been identified as SVHCs under REACH based on their carcinogenicity and in some case their mutagenicity. However, threshold values have been established for cadmium exposure and these have been used in the risk assessment. The median range of reported cadmium concentrations in composts and digestates is approximately 0.2-0.8 mg/kg. No risks were identified at the limit value from the proposal for the revised Fertilising Products Regulation (FPR). The majority of the measured data are below this limit. However there is uncertainty over the safe threshold for dietary exposure. In addition, the data set of occurrence in composts and digestates covers only a limited number of countries. The contribution from compost and digestate to the total cadmium present in soil from all sources is relatively small.

Substances for which quantitative RCRs or safe limit concentrations could not be determined are listed below. For the following assessed substances, regional plus continental amounts exceeding ~10 tonnes were found at steady state.

- Lead. Lead compounds are non-threshold neurotoxic substances. The overall range of reported lead concentrations in composts and digestates is <2.5 to 230 mg/kg dry wt., but more typically <2.5 to 91 mg dry wt. The total steady-state mass predicted in the region + continent is estimates as 1.41E+06 tonnes resulting from compost and digestate use. A significant contribution from compost and digestate to the total background level of lead in soil is predicted.

- DEHP is an SVHC in REACH based on toxicity to reproduction and endocrine disrupting properties. The overall range of reported DEHP concentrations in composts and digestates is 0.6 to at least 140 mg/kg dry wt. (the upper limit value is reportedly an average). The total steady-state mass predicted in the region + continent is estimates as 1850 tonnes resulting from compost and digestate use.
- PAH are of concern in respect of CMR, PBT and vPvB properties; several are SVHC based on these properties. The overall range of reported concentrations in composts and digestates is <0.04 – 0.52 mg benzo[a]pyrene/kg dry wt., <0.04 – 0.61 mg chrysene/kg dry wt., <0.04 – 0.33 mg benz[a]anthracene/kg dry wt., 0.12-2.14 mg benzo[b]fluoranthene/kg dry wt., <0.04-2.32 mg indeno[1,2,3-cd]pyrene /kg dry wt., and <0.3 – 20.8 mg total PAH/kg. The total estimated steady-state mass predicted in the region + continent at steady state varies between ca 14 t (indeno[1,2,3-cd]pyrene) and ca 170 t (benzo[b]fluoranthene) resulting from compost and digestate use.

Introduction

This Appendix and its annex outlines the application scenarios assessed for compost and digestate products, which can be differentiated in a meaningful way and for which separate assessment scenarios are therefore useful. On this basis, the team has defined two local scenarios. This project has applied these scenarios in assessing several priority chemicals that have been detected in composts and digestates in Europe in recent literature. The section also sets out some of the inter-relationships between various key input parameters and outputs from the EUSES model.
The focus of the risk assessment in this project is the environment, and humans exposed via food and drinking water. The methods applied follow ECHA guidance[1], as far as possible. The assessment uses standard exposure models to estimate the distribution of chemical contaminants from the application of fertilisers on agricultural land, and as a result of similar uses such as in domestic or allotment gardening.

The focus is on composts and digestates applied to soil as a fertiliser and soil conditioner and those used as a growing medium. As agreed with the European Commission at the inception meeting, the assessment has used exposure scenarios developed for the known contexts of use of compost or digestate. The assessment also takes account of the use of different types of product by different types of user (i.e. domestic garden, consumer allotment garden, commercial agriculture).

The type of modelling usually applied for exposure estimation within risk assessment of chemicals is based on fugacity. This is the propensity for a substance, based on its physicochemical properties (such as the octanol-water partition coefficient and Henry's law constant), to move from one environmental medium (compartment) to another. In this, case the partitioning between interstitial water and organic carbon within the compost/digestate and soil matrix, along with the degradation potential, are important factors that affect the environmental fate and hence the modelled predicted environmental concentrations (PECs).

Risk assessment is an analysis of hazard and exposure to determine the likelihood of negative impacts. The significance of the estimated exposures derived by modelling is assessed by comparison with available measurements of soil and water quality and/or from estimated exposures arising from the industrial life cycle where this has previously been assessed in an exposure assessment[2].
Comparison with reliable measured data is a useful validation of the model method used. However, it is important to note that such survey data may be influenced by sources of the substances other than compost and digestate, for example many metals occur naturally in soil and processes such as atmospheric deposition onto crops may also be important for some substances. This context can be important for some cases. Likewise, in other cases, measured data may not be available for environmental concentrations influenced substantially by compost and digestate application.

Where appropriate, the assessment characterises risk, by comparing estimated exposure levels with threshold safe limit levels (associated with toxicity hazards) relevant in the EU. In the risk assessment of chemical substances, the hazard is normally determined based on the intrinsic properties of the substance. The risk is normally determined by the comparison of an acceptable level of hazard (i.e. a 'no effect concentration') to the exposure concentration, in order to derive a ratio of the exposure level to the no-effect level (a risk characterisation ratio). This is valid for the cases where a safe threshold (no adverse effect level) can be established. For some substances this is not appropriate (e.g. for

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[2] Extensive literature searching for exposures arising from industrial use is outside the scope of the present work.

substances which are SVHC based on PBT/vPvB or equivalent concern or those with a non-threshold toxicological effect such as various carcinogens). What is important in these cases, however, is understanding of how substances of concern that are present in digestate and compost can migrate between the different environmental compartments, at what concentrations, and with what environmental burden based on total load. This information is useful in assessing if these concentrations can be reduced in the risk management option analysis and analysis of alternatives.

The exposure assessment uses simple scenarios, focusing on the use of composts and digestates applied to soil as a fertiliser and soil conditioner, and additionally use of compost as a growing medium. The assessments cover the environment and humans exposed via the environment for a series of selected chemicals. The protection targets for assessment are the terrestrial environment, aquatic environment (surface water and groundwater) and humans exposed via the environment (particularly via diet and drinking water). Some exclusions from the scope, agreed during the inception phase of the present project, are noted (under a specific subheading) below; these have not been assessed further.

1. Scenario development

1.1 Models, tools and defaults

ECHA Guidance on information requirements and chemical safety assessment, Part R.16 (ECHA, 2016) defines the approach to assessing soil exposure to chemicals via the application of sewage sludge and related models. This is the basis of the risk assessment approach in the current project.

The methods outlined in ECHA Guidance R.16 are applied via the EUSES[3] tool (including spreadsheet versions). The team also consulted the sector-specific environmental assessment parameters published by industry groups European Crop Protection Agency[4] (ECPA) and Fertilizers Europe[5] (intended for use by REACH registrants).

The important variables for the risk assessment, and how these have been dealt with within the risk assessment scenarios in this project, are discussed in connection with each assessed substance and illustrated in subsections on 'Sensitivity to specific variables'. The Annex to this report presents further discussion of defaults assumed in the R.16 default scenario and how they influence the exposures estimated in this work.

1.2 Compost and digestate products and their applications

WRAP (2011a) reports that there are three main types of digestate commercially available (termed whole, liquid or liquor, and fibre), since digester plant operators may choose to separate the product for operational reasons. Whole digestate was reportedly the most commonly available type at the time of that report. The separated fibre fraction still retains moisture and is typically between 20% and 40% dry matter, while the liquid fraction is reportedly between 1% and 4% dry matter, although these proportions will vary depending upon the separation process or processes employed. Refer to the Annex Section 4.1 for further details of the characteristics of composts and digestates.

Whole digestate, digestate fibre, and compost can be assessed together using exposure scenarios defined in terms of mass as dry weight per hectare (ha) or as concentration in dry weight terms.

The raw material feedstocks from which composts and digestates are prepared can originate from a range of sources. The literature research indicates in many cases both the raw material types and preparation/treatment methods associated with each sample.
The occurrence of chemical contaminants in such products would typically arise from their presence in the raw materials prior to the composting or anaerobic digestion process. The conditions under which composting and anaerobic digestion processes take place could affect the chemistry of contaminant substances, for example: pH conditions; moisture levels; aerobic or anaerobic conditions; or thermal decomposition (composting and anaerobic digesters can reach temperatures of 60-70°C or higher (Saveyn and Eder, EC, 2014)). The literature research has focussed on substance concentrations found in C/D products after processing and ready for application, hence it is not necessary to adjust for these factors in the exposure assessment.

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[3] The European Union System for the Evaluation of Substances: https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances.

[4] http://www.ecpa.eu/pre-market-resources-for-industry/reach-registration-evaluation-authorisation-and-restriction-chemicals

[5] http://www.reachfertilizers.com/

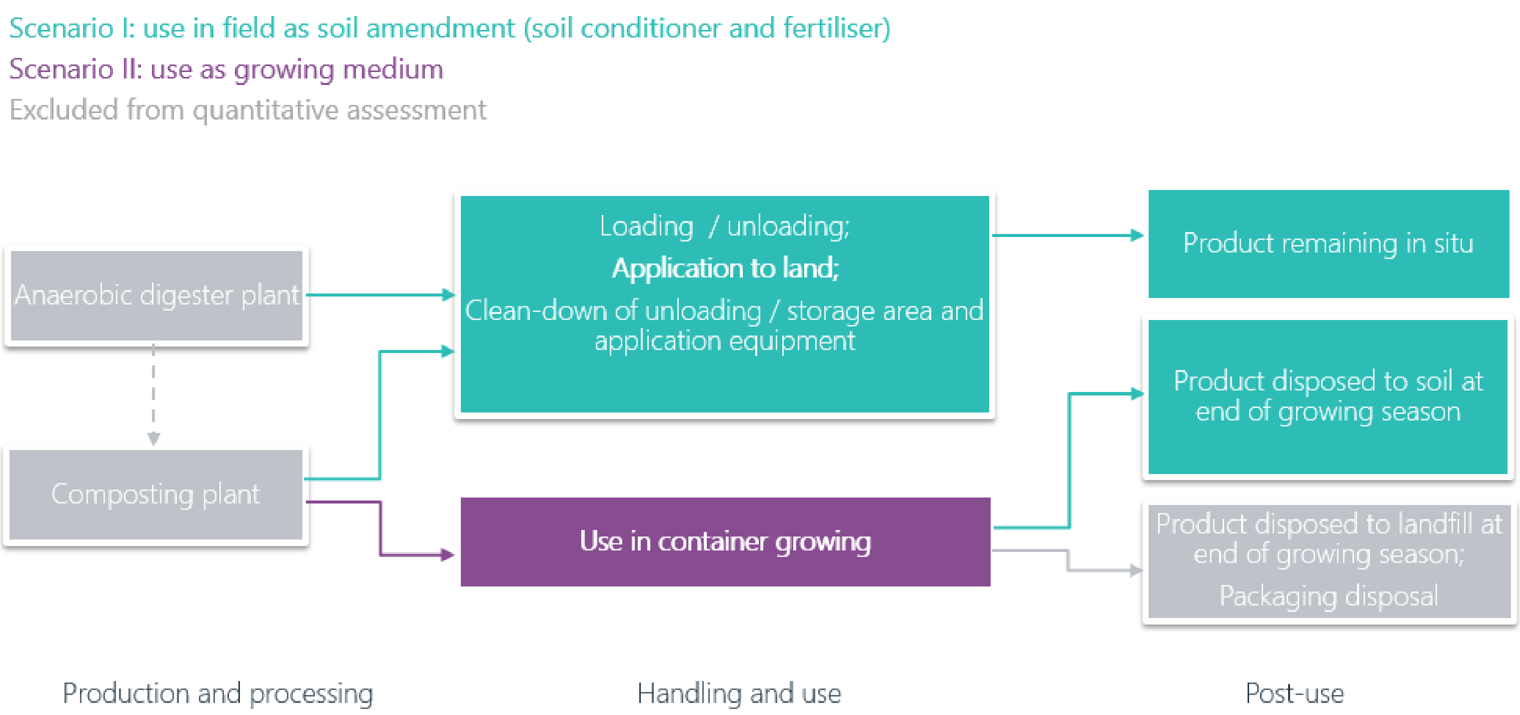
For some of the selected priority chemicals for assessment within the scope of this project, a standard environmental exposure assessment or risk assessment was conducted under the previous Existing Substances Regulation. Where these assessments exist they already cover a quantitative assessment of the same target organisms and populations, usually based on estimated releases from the industrial life cycle via wastewater treatment plant sludge. The present assessment expands on any such pre-existing assessment, by applying measured concentrations in the C/D.

The present assessment also offers the opportunity to refine aspects of the use scenario for compost or digestate in agriculture and related uses. This does not in any way undermine the standard approach defined in guidance part R.16 which is entirely fit for purpose.

1.3 The compost and digestate life cycle

The life cycle of digestates and composts in the agricultural context is illustrated overleaf.

Figure 1.1 Summary life cycle of composts and digestates



1.4 Defining exposure scenarios for quantitative exposure assessment

Given the limited amount of quantitative data that are available, the scenarios developed are relatively simple. However, it is important not to neglect releases e.g. from the handling and use of products by users alongside the main mode of use.

Two separate local scenarios are discussed in the following sections:

I. C/D products, handling and application as soil amendment
  - *application of compost; whole digestate; crude dry fibre and all liquid products*
  - *use on both large and small-scales by farmers/growers and the general public*
  - *any application onto soil post-use following use in container growing.*

II. Compost used as a growing medium
  - *use by professional and general public (amateur) growers.*

Agreed exclusions are outlined below.

The assessment made in this project focuses on the exposure resulting from application of contaminated C/D. Possible exposure from industrial point sources and wide-dispersive uses is not included in the modelling.

Exposure and risks for workers and consumers handling the compost/digestate product is outside the scope of this work, as is environmental exposure assessment for site location(s) where the compost/digestate product is processed and prepared prior to application.

A full environmental exposure assessment covering all contributing sources would normally take into account exposure via air, which could contribute to predicted environmental concentrations and dietary exposures at the background level, particularly from other environmental pathways such as the industrial life cycle of the same contaminant chemical. However as this exposure route is not considered relevant for application of C/D, direct releases to air are excluded.

The option to assess application of liquid digestate fertiliser by aerial spraying in a fully separate scenario was considered early in the project, but it was agreed with the client to merge the scenarios with no need to consider this separately. If applicable, any application by spraying is covered by Local Scenario I[6].

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[6] The user consultation suggests this is not a significant form of application, which called into question the relevance and realism of the scenario; the frequency of application is assumed to be the same as for use of other digestate forms, while the application area and degree of incorporation differ. The exposure is proportionate to loading rate, which is expected to be the same regardless of application method in view that the user will adapt the loading of digestate accordingly to deliver the desired amount of nutrients, whichever form of digestate fertiliser is chosen.

1.5 Scenario I: Compost and digestate products, handling and application as soil amendment: key assumptions and parameters

1.5.1 Nature of the products and mode of use

This scenario applies to both **composts and digestates**, which can be derived from a range of starting materials.

The main product types considered are:

- Compost
- Whole digestate
- Separated digestate fibre
- Liquid digestate

Whole digestate may be separated into dry fibre and aqueous liquor.

In simplistic terms, the application to soil of either compost or solid digestate is analogous to the application of sewage sludge as an essentially solid material directly to soil. The ECHA risk assessment framework assumes application of the sewage sludge at a standard rate once per year to either agricultural soil or grassland, with incorporation to a standard depth once applied to the soil. The yearly application is considered to occur for ten consecutive years. In the absence of specific information from the consultation and research phase, it is reasonable to consider that the ECHA scenario is applicable when compost, whole digestate or digestate fibre are used.

Liquid digestate is rich in organics and nutrients and may be used as a fertiliser separately from the solid. The aqueous concentration of contaminant chemicals in liquor will depend on the physical and chemical composition of the digestate (for example the content of particulates and fibres; dissolved and dispersed organic carbon and the contaminant chemical's solubility in water and affinity for organic carbon). Concentrations of substances in digestates are generally reported in terms of mg/kg dry weight of digestate solids. Furthermore, it is not fully clear whether reported concentrations in digestates relate to whole digestates or separated fibre portion. The reported values are also quite variable in some cases. In view of these contributing uncertainties it is not appropriate to develop complex scenarios given the data currently available. Annex 4.4 of this report describes the approach taken in the assessments.

In the event that liquid digestate is applied using spraying equipment, there is potential for overspray (spray drift) to occur with a resulting potential for direct discharge into surface water (for example into a stream or river bordering a field). It is acknowledged that consultation (particularly the response by EBA, 2018, presented in the (draft) final report and corroborated by WRAP, 2016) suggests that, of the application methods available, direct application (using equipment which minimises the possibility of volatile losses of the useful nitrogen compounds as well as managing odour), appears likely to account for the majority of liquid digestate use. Exposure of contaminant substances introduced via liquid products that are incorporated into soil by injection can be assessed using the same scenario as whole products and composts. This has an advantage of simplicity in that it does not require assumptions to be made over the fraction of the digestate that is applied in whole form or in liquid form or using specific application equipment.

Regardless of the application method or the form of the compost/digestate, the potential exists for handling losses which could pass to waste water or direct to surface water: arising from loading/unloading of the transportation container / on-site storage container; cleaning of on-site storage container and application equipment. Such releases will be small in absolute quantity compared to the application to land, but have the potential to enter watercourses directly. A small surface water release would also cover any incidental release to water during application (e.g. overspray, spillages, run-off). The absolute mass releases associated with each of these possible contributing scenarios is not known precisely and consultation in the scope of this project has not revealed definitive information. Therefore, a pragmatic approach has been taken. Specific Environmental Release categories (SPERCs) defined by sector groups relevant for agricultural scenarios, from ECPA and FEE, are defined with fraction release to water values of between 1.6 (FEE SPERC value is 1.57%-3.32% depending on crop type) and 2.8% (ECPA SPERC value is 2.8%), for release to water arising from overspray during application. Whilst the evidence suggests that application by spraying is not extensive, it is postulated that a release of this size should cover any loss from storage/handling/cleaning and/or any direct release from application (e.g. overspray, overspill, runoff during application) at the local site. Effectively the reasoning is that the releases from all these contributing sources combined will be similar to those from overspray where applicable. In the worst case this release could enter the surface water directly without passing through a wastewater treatment plant. All of the remainder of the substance (e.g. 100%-2.8%=97.2%) is applied to soil either as compost, whole digestate or liquid digestate.

1.5.2 Parameters associated with application

Growers apply compost, solid digestate or liquid digestate as a fertiliser with a relatively high nutrient content, with additional benefits as a soil improver. Using such products can be beneficial in pH stabilisation, aeration, increase of soil organic matter, and improving water retention.

The standard ECHA REACH guidance scenario (ECHA, 2016) assumes once-annual application of biosolid on agricultural land and grassland for ten consecutive years. Research has not revealed evidence to directly support or contradict this. In principle it appears that, provided any restrictions such as existing national specified limits are complied with (where applicable), European farmers may apply the products as needed.

To avoid loss of soluble nutrients over time, the guidance recommends applying the fertilisers shortly before planting, subject to specified grazing and harvest intervals which may apply. For example, WRAP (2016) presents a summary of the recommended timings of application for different grades of C/D in light of the context (the nature of the crops; no-graze periods for livestock grassland/forage; and no-harvest intervals for crops; and dependent on whether the compost or digestate is pasteurised to the applicable BSI standards). In case of application more than once-annually, in terms of the exposure assessment, the degree of degradation of a substance in soil since the preceding application could be affected by this. A simplistic approach within EUSES would be to model a larger single application to account for the total applied per year. While other exposure modelling tools (ECPA-LET, Steps 1-2 in FOCUS) allow for repeat application, EUSES was selected as the primary exposure modelling tool in this project in view of its models being fully aligned to the standard approaches defined in ECHA R.16 guidance and this was considered more important for the work than an alternative model that included the possibility to adapt for repeat application, particularly when definite evidence is lacking.

In principle, repeated applications of C/D could actually increase the soil horizon and hence slightly dilute the contaminants (ECN, 2015) in the long-term. The ECHA risk assessment framework assumes a 10-year application period in estimating the local concentrations, so in order to simplify the approach, the effects of such dilution do not require detailed adjustment.

1.5.3 Local Scenario I: defining the scenario in EUSES

The release values of specific substances due to the handling and application of C/D products as a soil amendment (local scenario I) derive from the concentrations in C/D reported in literature, using equations developed for the purpose of the present project. These values are key inputs in EUSES for the exposure model of local scenario I. The inputs used, and calculation method where applicable, are set out in Table 1.1 below.

The release to water in this scenario is the total amount of chemical entering a local surface watercourse per day based on a single tankerload (arising from spillages, use in field, and cleaning of equipment, and subsequent run-off passing directly into local water rather than being diverted to the wastewater treatment system). It is set as release to waste-water, but without subsequent waste-water treatment in a sewage-treatment plant. Different approaches were investigated early in the project to quantify the release to water. All are subject to uncertainties. The calculation approach described below is considered to be reasonably conservative as well as being a convenient way to use the features of EUSES to incorporate regional background for surface water in addition to this realistic worst case contribution coming from the immediate locality.

Table 1.1 Key parameters of EUSES set-up for Scenario I (local)

EUSES input Parameter	Value	Comment
Chemical properties (physicochemical, degradation, transport/distribution, PNECs (where defined)	Substance-specific	Values to be used are set according to existing regulatory assessments
Daily release rate to waste water (kg/d) (entered at the local releases screen)	Calculate based on 0.25 * 140 kg dry wt./d * *Concentration in dry sewage sludge* value (see below) in mg/kg dry wt. * 1E-06	The value of 0.25 in this equation comes from an assumption that the release to water is likely to occur over the course of a few days owing to rainfall and slow drainage of run-off. For example, runoff/drainage in the ECPA scenario is calculated over 4 days following the (final) application. The value of 140 kg/d is derived as 0.028 * 5 t (dw) (taken to be the approximate dry weight equivalent of a tanker load sized delivery of dry or slurry product). The value of 0.028 used in the equation above is the release of plant protection product to surface water during use assumed in ECPA SPERCs. The value of 1E-06 is a units correction factor to convert mg/d to kg/d
SimpleTreat settings	Set SimpleTreat to 'bypass STP' so that the release to waste water calculated above passes to local surface water	Conservative in respect of freshwater and associated food chains. Risks in WWTP microorganisms are outside the scope of the present work but would have been characterised in any pre-existing mainstream exposure assessment looking at industrial use.

EUSES input Parameter	Value	Comment
Concentration in dry sewage sludge (mg/kg dry wt.) (entered at the SimpleTreat outputs screen)	Concentration (**highest** reliable value) from literature for concentration in any compost or digestate product, used directly	Based on literature evidence for contaminant concentration of the assessed chemical Where useful to examine sensitivity to this variable, the assessment also uses an alternative concentration based on **mid-range** values (particularly where the worst-case assessment indicates concerns). Note that EUSES uses this value even though Simpletreat is set to 'Bypass STP'

Note: unless stated otherwise, standard defaults are assumed

1.6 Scenario II: Composts used as a growing medium, for professional or consumer use

1.6.1 Nature of the products and mode of use

This scenario applies specifically to **composts**, which can be derived from a range of starting materials. For composts used for professional or consumer use, compost may be used directly as a component of the growing medium. Saveyn and Eder (2014, quoting WRAP guidelines) indicate that such composts 'would normally be suitable for use as a growing medium constituent at a maximum rate of 33% by volume in combination with peat and/or other suitable low nutrient substrate(s) such as bark, processed wood, forestry coproducts or coir' and remark that higher rates usually affect plant growth negatively because of the compost's naturally high conductivity. The realistic worst case scenario therefore assumes use in a diluted form (33% w/w). However, in the worst case, a compost product could possibly be used as such as growing medium and it would be hard to control that, particularly in regard to use by the general population.

The subsequent intake into root crops and leaf crops for human exposure is modelled in EUSES by the usual methods as described in ECHA R.16 guidance (ECHA, 2016, Section A.16-3.3.9 Humans exposed indirectly via the environment). The sensitivity of the outcomes for Scenario II to possible losses from the system by leaching has been explored using a fugacity method, as discussed further in Section 2.2.

The scope of Scenario II covers use of compost in growing medium in container beds, bags, or pots; which may vary in the physical design, materials, porosity, size and management of the system. The substance introduced into the container system via contaminated compost can be expected to distribute according to its chemical properties between the growing medium solid phase (organic and inorganic constituents); interstitial water (soil pore-water) and air; be taken up into plants and other soil biota. Leaching of substances out of the system via drainage of interstitial water, as well as loss from the system by volatilisation could occur.

The purpose and intention of the local scenario II is to assess well managed container growing resulting in edible crops which are consumed by humans, under realistic worst case conditions. As such loss from these mechanisms are assumed to be negligible in the baseline assessments for local Scenario II.

1.6.2 Local Scenario II: defining the scenario in EUSES

For this use there would be no direct addition to soil in the course of use[7] and there is limited potential for leaching from soil into groundwater or surface water. However, the substances of interest could be present in the compost and be available for uptake into plants grown in that compost, with subsequent potential for human exposure if those plants are edible crops. In order to take this into account the assessment calculates the concentration of specific substances in compost in a mixed growing medium (local scenario II), used in EUSES in place of the concentration of the substance in agricultural soil. EUSES models the subsequent uptake into plants and the resulting human exposure. The release values derive directly from the concentrations in compost specifically, as reported in literature, using equations developed for the purpose of the present project. These values are then entered in EUSES as key inputs for the exposure model of local scenario II. The inputs used are set out in Table 1.2 below.

Table 1.2 Key parameters of EUSES set-up for Scenario II (local)

Parameter	Value	Comment
Chemical properties (physicochemical, degradation, transport/distribution, PNECs (where defined)	Substance-specific	Values to be used are set according to existing regulatory assessments
Daily release rate to waste water (kg/d) **(entered at the local releases screen)**	0	
SimpleTreat settings	n/a	Assuming no local releases to waste water
Concentration in agric. soil averaged over 30 / 180 days (mg/kg dry wt.) **(entered at the Local concentrations and depositions screen)**	Calculate based on 0.33 * Concentration (**highest** reliable value) from literature for concentration in compost specifically	Based on literature evidence for contaminant concentration of the assessed chemical 0.33 comes from the assumption that best practice would be to dilute the compost by mixing in a ratio of 1:2 with other media prior to use, and represents the realistic worst case, but it is noted this is difficult to enforce. In the worst case the compost could be used unmixed.
Concentration in grassland averaged over 180 days (mg/kg dry wt.)	0	The pasture grazing exposure route is not applicable for this scenario

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[7] It is noted that spent compost could be disposed of onto soil at the end of the growing season, but exposure in this circumstance would not exceed that from the general fertiliser and soil improver scenario.

1.7 Regional background exposure

1.7.1 Nature of the products and mode of use

The background exposure covers both **composts and digestates**, which can be derived from a range of starting materials, and both use by application to land and in container growing.
There are two objectives in making a regional releases estimate in this project: firstly, to take account of the background contribution to local exposure arising from the compost/digestate use at a regional level, making use of the quantitative data available for EU member states; secondly it allows the estimated exposure via the use of C/D to be quantified which can then be compared with existing regional background values which take into account other sources of the same substance (such as releases from industrial sites); this allows the C/D exposure to be understood in context.

The EUSES model uses a regional[8] concentration ($PEC_{regional}$) in water, sediment, soil and air, to represent the background concentration of the substance in a heavily industrialised area. These regional concentrations add to the predicted concentration from a local source (such as resulting from application of digestate to a field) to give the final local predicted environmental concentration (PEC_{local}).

The regional concentration is normally determined based on the consideration of the entire life-cycle of a substance and takes into account the release from all possible sources. Full determination of the regional concentration for all of the substances considered in this report is beyond the scope of the project.

A regional concentration from the use of digestate and/or compost alone has been generated by EUSES based on the knowledge of the total amount of digestate and/or compost containing the substance in the EU. The regional emissions and calculations are always averaged over 365 days. It is noted that this "added risk" method relates to the contribution to regional background due specifically to the long-term use of compost or digestate and disregarding other exposure pathways (such as industrial releases), at steady-state and will not take account of other sources of the contaminants.

The resulting regional PECs can be compared with existing regional background concentrations from existing risk assessment or risk evaluation reports where possible. This could include modelled values from prior EUSES-based assessments, and/or values based on measurements. Chemicals which are already under regulatory control may be in a phase of declining use in Europe since the time that the pre-existing risk assessment was conducted. The present-day accuracy of the reported European background concentrations will therefore vary from case to case.

1.7.2 Regional scale: defining the scenario in EUSES

The regional assessment assumes that 10% of the total C/D is applied in a region. This is conservative but consistent with the known amounts of C/D used in EU countries, taking into account the agricultural land use in those countries (refer to Section 6.5 in the Annex).

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[8] Within the ECHA (2016) approach the region is taken to be a typical densely populated and heavily industrialised area (size 200 km x 200 km with a population of 20 million inhabitants) in which 10% of the total EU industrial activity takes place.

Table 1.3 Key parameters of EUSES set-up for regional and continental exposure

Parameter	Value	Comment
Mass of substance in EU-28 in compost (kg/y) [1]	Calculated as EU total mass compost (t/y dw) * Concentration (**mean or median**) in compost (mg/kg dry wt.) * 1E-03	Value derived from available literature concentrations in compost products specifically
Mass of substance in EU-28 in digestate (kg/y) [1]	Calculated as EU total mass digestate (dw) * Concentration (**mean or median**) in digestate (mg/kg dry wt.)	Value derived from available literature concentrations in digestate products specifically
Total regional emission to surface water (kg/d) **(entered in Regional and continental total emissions screen)**	Calculated as 0.1 * 0.028 *(Mass of substance in EU-28 in compost + Mass of substance in EU-28 in digestate)/365	The value of 0.028 in this equation is the release of plant protection product to surface water during use assumed in ECPA SPERCs The value of 0.1 in this equation relates to the fraction of overall EU use in the main region. The value of 0.1 is the default in EU R.16 guidance and in EUSES for wide-dispersive uses and was found to be reasonably conservative based on EUROSTAT land use data[9]
Total regional emission to agricultural soil (kg/d) **(entered in Regional and continental total emissions screen)**	Calculated as 0.1 * 0.972 *(Mass of substance in EU-28 in compost + Mass of substance in EU-28 in digestate)/365	The value of 0.972 in this equation is calculated as 1-0.028 (see comment above) The value of 0.1 in this equation relates to the fraction of overall EU use in the main region. The value of 0.1 is the default in EU R.16 guidance and in EUSES for wide-dispersive uses and was found to be reasonably conservative based on EUROSTAT land use data
Total continental emission to surface water (kg/d) **(entered in Regional and continental total emissions screen)**	Calculated as 0.9 * 0.028 *(Mass of substance in EU-28 in compost + Mass of substance in EU-28 in digestate)/365	This relates to the EU continent excluding the main region (for the contributions within the main region, refer to the rows above) The value of 0.028 in this equation is the release of plant protection product to surface water during use assumed in ECPA SPERCs
Total continental emission to agricultural soil (kg/d)	Calculated as	This relates to the EU continent excluding the main region (for the

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[9] This is discussed further in Annex 6.5.

Parameter	Value	Comment
(entered in Regional and continental total emissions screen)	0.9 * 0.972 *(Mass of substance in EU-28 in compost + Mass of substance in EU-28 in digestate)/365	contributions within the main region, refer to the rows above) The value of 0.972 in this equation is calculated as 1-0.028 (see comment above)

Note: 1 - Calculated outside EUSES

2. Discussion of some specific topics

2.1 Approach to assessment of substances with non-threshold hazards and effects

Several of the assessed substances are persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); carcinogens, mutagens or toxic to reproduction (CMR); endocrine disrupting; and/or persistent organic pollutants (POPs). There may or may not be precedent for an effect threshold, but even where these exist a true quantitative risk characterisation ratio as such would not be considered meaningful in a REACH context. As discussed and agreed in the course of the project, it is not appropriate to quantify a risk characterisation ratio in these circumstances. Specifically, for any non-threshold hazard affecting a target population (i.e. humans via the environment, or environmental organisms), it is not feasible to derive or interpret a quantitative risk characterisation ratio that takes into account these hazardous properties, which are considered to be of greater significance than any other hazards to the same target populations, for which a PNEC or DNEL could be determined.

Therefore, for substances with a non-threshold environmental concern the following approach has been used:

- This report presents PECs.
- In case a PNEC had been developed in a prior regulatory assessment in the public domain, this is noted. EQS in the public domain are presented and predicted concentrations in water and in predators' diet (fish, earthworms) are compared with the applicable EQS limit values.
- RCRs are not derived.

For substances with a non-threshold human health concern the following approach has been used:

- Human local total daily intake levels, and predator exposure levels via diet, are presented.
- In case a DNEL, NOAEL, or tolerable daily intake had been developed in a prior regulatory assessment in the public domain, this is noted.
- RCRs are not derived.

The following information is presented (where sufficient information is available to allow calculation):

- Total amount of the substance that will be present in C/Ds – this is estimated using the concentration(s) in the compost/digestate(s) and the amount(s) of compost/digestate(s) generated.
- The estimated steady state masses and percentage distribution in the various environmental compartments. This has been estimated from the regional model within EUSES and represents the steady state distribution following continuous use of the compost/digestate[10].

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[10] Please note that the steady state predicted by the model are the amounts and distribution of the substance at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

2.2 Sources of uncertainty in the risk assessment and approach to evaluation of sensitivity

The key sources of uncertainty in the assessment are:

- Uncertainties in the assumptions made in defining the local exposure scenarios.
- Uncertainties in the amounts of C/D used.
- Uncertainties in the concentrations of the substances within those composts and digestates.
- Uncertainties over the properties of the substances.

Each of these contributing uncertainties is discussed below.

Uncertainties in the assumptions made in defining the local exposure scenarios

The specific parameters of the local assessments could vary from one location to another depending on the facilities, quantities and working practices.

In respect of local Scenario I, the general principles of application to agricultural and grass land with a small fraction passing direct to water has clear precedents and is a reasonable basis for a realistic worst case screening examination.

Furthermore, an assessment at the regional scale has also been made, which takes account of degradation and distribution processes.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching has been explored using a fugacity method, described below.

Both the physicochemical characteristics of the contaminant chemical, and also the design and management of the container growing system, affect the possible significance of volatilisation and leaching to lead to loss of substance from the container altogether and impact the estimate of local PEC for local Scenario II. The design and management aspect will vary from situation to situation. For example:

- If the container stands in a drip tray this would keep compost in contact and in equilibrium with any excess water that drains out of the compost; whereas if the container is free draining then any leached chemical would be lost from the system.
- A regime of watering heavily from above could lead to more water exchange throughout the system than if water is provided mainly from a tray below the container by absorption.
- If a surface mulch of organic matter, card or polythene is in place at the upper surface of the growing medium this could inhibit volatile losses to some extent.

The assessment of this sensitivity used a Microsoft Excel spreadsheet-based multi-media fugacity model based on equations established by Mackay (1991)[11]. This model approach has its own uncertainties, but it gives at least some insights. The soil matrix is treated as four phases: air, water,

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[11] Mackay 1991: Multimedia environmental models: The fugacity approach. Donald Mackay. Lewis Publishers, Michigan, USA. 1991

organic matter and mineral matter. The volume fractions and densities of the four phases, the soil area and depth and concentration of the chemical are specified. The chemical is assumed to be evenly distributed throughout the soil volume and the fugacity calculation is completed using the physicochemical property data of the chemical. This gives the equilibrium distribution of the chemical between the four phases.

It is to be expected that the water content of the system will vary as water is added and lost by volatilisation/transpiration by plants. As long as the water holding capacity is not exceeded, substances present will partition between phases, but remain within the system/container.

Leaching as such could occur when excess water is added to a system already at capacity. If excess clean water is then introduced to such a system, it could displace some or all of the system's interstitial water (along with any substance dissolved in it). Hence to assess the sensitivity of a substance to be leached out, an adjusted system composition is modelled to reflect a much higher water content than the EUSES standard soil, approaching or exceeding the water holding capacity. The adjusted 'high water content' composition is defined as 16% solids, 64% water and 20% air by volume (for comparison, a standard soil defined in ECHA R.16 guidance is 60% solids, 20% water and 20% air). The water holding capacity of the compost component of the solids is based on a range 3.5-4.4 g water/g dry matter for compost (El-Sayed G. Khater, 2015).

Hence substances which have more than a few % distributed to the interstitial water at equilibrium under these 'high water content' conditions are seen as sensitive to the approach to water management in Scenario II, for which PECs and indirect exposure of humans estimated in the 'baseline' assessments could be too high. This is noted case by case. For the majority of substances assessed as part of this project it was found that the proportion of substance in interstitial water in the system and hence sensitive to leaching is low (a few percent or less).

It is reasonable to expect that agricultural growers are likely to manage watering with some degree of care to maximise yields and quality, since water-logging can contribute to problems such as plant disease and rotting of root tissue. With regard to human exposure via fruit and vegetables, container growing with poor water management is less likely to produce good-quality edible produce.

Uncertainties in the model tools and scenarios

The substance-specific assessments are deliberately conservative and relatively broad, intended to give a (realistic) worst case.

The industry sector group ECPA has made available the ECPA-LET tool within which spreadsheet macros apply key elements from the STEPS 1-2 in FOCUS model for plant protection products. Some of the assumptions and parameters differ from ECHA standard models, for example, degradation is assumed when calculating local PECs in freshwater and sediment; the local water and sediment compartments have different dimensions than in EUSES; the methodology for PEC soil includes an adjustment for volatilisation removal which can be significant for substances of high vapour pressure; and the methodology for calculating local PECs for water and particularly for sediment differ from EUSES, resulting in quite different PEC values.

In general, the methodology of EUSES is more conservative and more adaptable and allows a self-contained scenario to be constructed. It is therefore appropriate to carry out all modelling within EUSES within the scope of the current study.

It is noted that a project is in progress to adapt EUSES. The models associated with aerial deposition and re-volatilisation from soil are potentially affected but the effect is unlikely to be significant for local

PECs for the types of substances assessed in this project, particularly given that the major exposure is direct application and incorporation into the soil surface.

Uncertainties in the amounts of compost and digestate used

The quantity of compost or digestate applied will be approximately proportional to the local concentration, when the concentration of contaminant chemical is constant. However, the amount of information on application rates is very limited. In addition, the range in magnitude of application rates is much narrower than either the range of chemical concentrations reported in the compost or digestate (which can vary by many orders of magnitude), or the variability in geographical extent to which application takes place (in terms of how representative the results are).

The models account for repeated exposure, based on a fundamental (and standard) assumption of ten years annual application to soil. In case application is more frequent than once annually, the models might under-estimate predicted exposure concentrations to some extent. This should not be significant for substances which tend to remain mainly in soil at steady state with slow degradation rates as the loss of the substance from soil predicted in the models between the yearly applications will be relatively small, allowing the increase in concentration from repeated applications (in this case 10) to be modelled.

Therefore, the uncertainties in the application rates are not considered further as part of this risk assessment. They can be expected to be small compared with the uncertainties in the concentrations of substances in the compost/digestate.

Uncertainties in the concentrations of the substances within those composts and digestates

For the substance concentration, a range of concentrations is usually available. The realistic worst case would be to take a representative high concentration (e.g. maximum value or a high percentile value) within that range and the 'baseline' assessment of each substance has used that approach. Where proposed FPR limit values are available (EU 2018) gives values for e.g. metals) these have also been considered in selecting the representative high concentration used in the baseline assessment, but the uncertainty analysis considers the overall range of concentrations available.
A secondary less-conservative assessment has been made in which lower concentrations from the reported range have been applied at both the local and regional scales. This is useful particularly where the reported range spans several orders of magnitude, so that the uncertainty can be better understood.

Hence, in general, exposures for each assessed substance have been estimated for two concentration scenarios, to provide information about sensitivity to the concentration inputs:

- A more conservative (baseline) assessment is derived using the representative maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- Where appropriate, a less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

It is important to note that the concentrations of substances in digestate/compost from the literature may reflect past use of the substance, particularly if the data are from several years ago. This may be an important consideration for the substances where usage has been in decline (or discontinued) in recent years.

Uncertainties over the properties of the substances.

Uncertainties over the properties of the substances (e.g. physicochemical properties, effects, biodegradation) had been expected to be outside of the scope of the current project because *de novo* assembly of data sets was not expected to be necessary. Such uncertainties were minimised as far as possible by utilising precedent data sets from existing regulatory risk assessments preferably made in EUSES (especially ESR risk assessment reports), reviews and evaluations (where available). However, in some cases literature data and predictions have been necessary. In such cases the sensitivity of predicted exposure concentrations to specific inputs has been explored.

3. Assessment of specific priority substances

3.1 Introduction and approach to assessment

The approach to assessing the priority substances and chemical families is summarised below. Sections 3.2 to 3.24 present and discuss the data, approach, and findings for each individual assessed substance.

Chemical category or family	Representative substances assessed	Comments
Heavy metals	Cadmium, Nickel, Lead, Copper, Zinc and Mercury	The assessment includes exposure and risk characterisation. Natural background and active accumulation mechanisms present a challenge. The assessments are in terms of total metal although in the environmental media it could be present in different forms. This is discussed as part of the individual assessments.
	Bisphenol A	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
Phthalates	DEHP	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
Pharmaceuticals	17α-Ethinylestradiol	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
	Hexabromocyclododecane	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
Dioxins, furans and dioxin-like PCBs	2,3,7,8-TCDD, 2,3,4,7,8-PCDF	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
Other PCB	PCB-28	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
Nonylphenol isomers and ethoxylates	Nonylphenol	The assessment includes exposure and risk characterisation.
PAH16	Benzo[a]pyrene, chrysene, benz[a]anthracene, benzo[b]fluoranthene, indeno[,2,3-cd]pyrene	Collectively the first two are termed PAH2 and the first four are termed PAH4. Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed and estimated human exposures are compared with the BMDL10.
PFAs	PFOA, PFHxA	Conventional quantitative risk characterisation is not appropriate, but exposures at the steady state are discussed
Physical impurities	Microplastics	The assessment includes a generic estimate only; fugacity modelling is not reliable

For the endpoints where conventional quantitative risk characterisation is appropriate, a limit below which adverse effects are not expected has been calculated. This is referred to as "safe limit" throughout the report. Note that this does not preclude possible other effects at lower concentrations, related to other endpoints for which quantitative risk characterisation was not possible.

3.2 Cadmium (Cd)

Background information and remarks

Cadmium metal (CAS 7740-43-9) has been subject to a comprehensive EU risk assessment (EC, 2007). Cadmium has been identified as a substance of very high concern (SVHC) under the EU REACH Regulation based on its carcinogenicity (it is classified as carcinogen category 1B) and based on its adverse effects on kidney and bone tissue after prolonged exposure (ECHA, 2013a). Three cadmium salts (cadmium carbonate, cadmium hydroxide and cadmium nitrate) are separately additionally listed as SVHCs based on their mutagenicity.

ECHA (2013a) noted that, in terms of exposure of the general public, food was the main intake route of cadmium in non-smokers and that deposition from air dominates the input of cadmium into soil. A Tolerable Weekly Intake (TWI) of 2.5 µg/kg bw has been derived in Europe for cadmium exposure via diet (EFSA, 2009 and 2012a), although ECHA (2013a) notes that there are some uncertainties over the actual "safe" level for cadmium exposure for humans.

Chemical properties and hazards data set

The relevant property data are summarised in Table 3.1 below. The data are taken mainly from EC (2007). Where information from other sources is included this is indicated in the Table.

The EU harmonised CLP classification for cadmium (non-pyrophoric) is: Acute Tox 2. – H330; Muta. 2 – H341; Carc. 1B – H350; Repr. 2 – H361fd; STOT RE 1 – H372; Aquatic Acute 1 – H400; Aquatic Chronic 1 – H410. PNECs and DNELs are available from existing published assessments. In addition, an EU TWI is also available for dietary exposure.

Table 3.1 Property information for cadmium (from EC (2007) unless otherwise indicated)

Property	Value	Comment
Molecular weight	112.41 g/mol	
Melting point	321°C	Value from ECHA (2013a)
Boiling point	765°C	
Vapour pressure	Negligible at 25°C	
Water solubility	2.3 mg/l at 20°C	Value from ECHA (2013a). Solubility varies with the salt. This should not affect the assessment as the Henry's law constant has been set to be very low.
log Kow	Not relevant for metals	
Henry's law constant	No data	Assumed to be very small.

Property	Value	Comment
Koc	Koc not relevant for metals Kp = 130,000 l/kg for suspended sediment Kp = 280 l/kg for soil	Kp values are measured solids-water partition coefficients and are used directly in the EUSES modelling.
BCF	BCF for fish is typically around 100 l/kg. Median BAF for earthworms is 1.4-19 kg/kg wet wt	See text for secondary poisoning and plant uptake
Biodegradability	Not applicable. Assumed to be not degradable.	
Half-life in air	Not relevant for metals	
PNECs	$PNEC_{water}$ = 0.19 µg/l $PNEC_{sediment}$ = 2.3 mg/kg dry wt $PNEC_{soil}$ = 1.15-2.3 mg/kg dry wt $PNEC_{oral}$ = 0.16 mg/kg food	The PNEC for soft water is 0.08 µg/l (for waters with hardness 2.7-40 mg $CaCO_3$/l and dissolved organic carbon (DOC) concentrations above 2 mg C/l). The annual average EQS[a] is dependent on water hardness and is in the range ≤0.08 to 0.25 µg/L. The maximum allowable concentration MAC-EQS is ≤0.45-1.5 µg/l. The lower value for the $PNEC_{soil}$ of 1.15 mg/kg dry wt is based on secondary poisoning (see text).
DNEL	TWI 2.5 µg/kg bw/week	EFSA Current Tolerable Weekly Intake TWI is 2.5 µg/kg bw (EFSA, 2009). EC (2007) defines a critical concentration in soil not causing excessive Cd exposure via the diet based on a critical intake of 47-37 µg/day. These were in the range 0.7-1.32 mg Cd/kg soil depending on the regional and the critical intake.
Other relevant data	Identified as a SVHC under Article 57(a) and Article 57(e) of the REACH Regulation	SVHC based on carcinogenicity and effects on kidney and bones (equivalent concern).

Note: a) Environmental Quality Standard (EQS) set under Directive 2008/105/EC (EU, 2008) as amended by Directive 2013/39/EU (EU, 2013).

The EUSES model uses the octanol-water partition coefficient (log Kow) in order to model the uptake into fish and earthworms for the assessment of secondary poisoning and to model the uptake from soil into the human food chain. This approach is not appropriate for metals such as cadmium as the log Kow value is not applicable to such metals and their inorganic salts. Instead, it is necessary to model the uptake into the food chain using appropriate accumulation factors, in many cases outside of the EUSES program. Table 3.1 shows the relevant accumulation factors.

Occurrence data set

Table 3.2 presents a summary of the reported concentrations of cadmium in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. Consultation and literature research suggests contamination rates of cadmium typically of up to around 0.8 mg/kg dry wt in digestate and compost. The proposed FPR limit value is 1.5 mg/kg dry wt (EU, 2018).

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. The exposure assessment uses the following realistic worst case scenario.

- A conservative but realistic worst case assessment is derived using the proposed FPR limit value in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background. The majority of the available measured data for cadmium in C/D are close to or below this limit value, and the limit value represents the likely upper limit of the concentrations in composts and digestates going forward.

It is relevant to note, however, that there are a limited number of reported occurrences of cadmium in C/D at higher concentrations than assumed in the assessment. The EC (2014) study reported one occurrence at 2.5 mg/kg dry wt. in digestate derived from biowaste and around 20% of the values in compost derived from mechanical biological treatment were >1.5 mg/kg dry wt., with a maximum reported of 2.75 mg/kg dry wt. The significance of this is assessed in the section on sensitivity to specific variables (see below).

Table 3.2 Reported occurrence of cadmium in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Composts - data availability		Most of data from one study in DE-Bavaria. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤1.3 mg/kg dry wt for compost from biowaste and green waste, ≤1.5 mg/kg dry wt. green waste compost, ≤1 mg/kg dry wt. for sewage sludge compost and ≤2.75 mg/kg dry wt. in mechanical biological treatment compost.
Compost - minimum concentration	0.032	Estimated as 1/10 of the lowest median or mean value
Compost - mid-range or average concentration	0.4	Most mean and median values are around this value
Compost - maximum concentration	1.5	Proposed FPR limit value is assumed in the main assessment. There are a limited number of reported occurrences above this value and these are considered further in the section on sensitivity to specific variables below.
Digestates - data availability		Most of data from one study in DE-Bavaria and one in Norway. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤2.5 mg/kg dry wt for digestate from biowaste and

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
		green waste and ≤0.4 mg/kg dry wt. in mechanical biological treatment digestate. Data for UK gives maximum of 0.003 kg/ha and with a limit value (PAS110; WRAP) of 0.036 kg/ha and commented that the quantities applied in digestates are very low and will have little effect on soil concentration.
Digestate - minimum concentration	0.02	Estimated as 1/10 of the lowest median or mean value
Digestate - mid-range or average concentration	0.45	Most mean and median values are around this value
Digestate - maximum concentration	1.5	Proposed FPR limit value is assumed in the main assessment. There are a limited number of reported occurrences above this value and these are considered further in the section on sensitivity to specific variables below.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.3 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	3528
Mass of substance in EU-28 in digestate (kg/year)	15876
Total regional emission to surface water (kg/day)	0.15
Total regional emission to soil (kg/day)	5.2
Total continental emission to surface water (kg/day)	1.3
Total continental emission to agricultural soil (kg/day)	47

Table 3.4 shows the reported regional background concentrations of cadmium, taking into account all sources of cadmium. The data are taken from EC (2007).

Table 3.4 Reported background concentrations of cadmium in the environment (from EC (2007))

$PEC_{regional}$	Value	Remarks
Air	0.55 ng/m^3	
Surface water	0.11 µg/l	
Sediment	2.66 mg/kg dry wt	Based on measured data (average of the 90th percentiles of surveys). Predicted value is 3.88 mg/kg wet wt.
Agricultural soil	0.363 mg/kg wet wt	
Soil pore water/ground water	No data	
Natural soil	0.322 mg/kg wet wt	

PEC$_{regional}$	**Value**	**Remarks**
Urban/industrial soil	0.322 mg/kg wet wt	
Other relevant data		

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of cadmium resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.5.

Table 3.5 Predicted exposures for cadmium arising from use of composts and digestates

	Scenario I	**Units**
PECagricultural soil	2.47E-02	[mg/kg dry wt.]
PECgrassland soil	9.79E-03	[mg/kg dry wt.]
PEC in groundwater	8.83E-05	[mg/l]
PECfreshwater	4.15E-06	[mg/l]
PECfreshwater-sediment	5.40E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	See text	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	3.06E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	See text	
Secondary poisoning – freshwater fish-eating birds and mammals	3.71E-04	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	6.19E-03	[mg.kg-1]

	Scenario II	**Units**
PECagricultural soil	4.95E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	See text	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	See text	
Secondary poisoning – worm-eating birds and mammals	4.16E-02	[mg.kg-1]

Table 3.6 presents the results of the quantitative risk characterisation along with the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use

application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.6 Quantitative risk characterisation conclusions for cadmium in compost and digestates

Scenario I	
RCR for local soil	1.08E-02
RCR for local freshwater	2.19E-02
RCR for local freshwater-sediment	2.35E-01
RCR for Humans via the environment: local total daily intake	0.019-0.035
RCR for fish-eating birds and mammals (fresh water)	2.32E-03
RCR for worm-eating birds and mammals	3.87E-02

Scenario II	
RCR for local soil	2.15E-01
RCR for Humans via the environment: local total daily intake	0.38-0.71
RCR for worm-eating birds and mammals	2.60E-01

Regional	
RCR for regional soil	2.49E-02
RCR for regional freshwater	1.72E-02
RCR for regional freshwater-sediment	3.69E-01

	Steady state mass	Units
Total steady-state mass (region + continent)	4.27E+03	[t]
Steady-state mass in regional freshwater (kg)	3.46E+01	[kg]
Steady-state mass in regional seawater (kg)	3.48E+00	[kg]
Steady-state mass in regional air (kg)	5.92E-10	[kg]
Steady-state mass in regional agricultural soil (kg)	4.13E+05	[kg]
Steady-state mass in regional natural soil (kg)	3.23E-03	[kg]
Steady-state mass in regional industrial soil (kg)	1.20E-03	[kg]
Steady-state mass in regional freshwater sediment (kg)	7.63E+03	[kg]
Steady-state mass in regional seawater sediment (kg)	4.11E+02	[kg]
Steady-state mass in continental freshwater (kg)	3.93E+02	[kg]

Steady-state mass in continental seawater (kg)	5.55E+03	[kg]
Steady-state mass in continental air (kg)	5.35E-09	[kg]
Steady-state mass in continental agricultural soil (kg)	3.72E+06	[kg]
Steady-state mass in continental natural soil (kg)	1.47E-02	[kg]
Steady-state mass in continental industrial soil (kg)	5.46E-03	[kg]
Steady-state mass in continental freshwater sediment (kg)	8.67E+04	[kg]
Steady-state mass in continental seawater sediment (kg)	3.28E+04	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)		
Steady-state mass fraction in regional freshwater (%)	5.44E-04	[%]
Steady-state mass fraction in regional seawater (%)	5.47E-05	[%]
Steady-state mass fraction in regional air (%)	9.29E-15	[%]
Steady-state mass fraction in regional agricultural soil (%)	6.49E+00	[%]
Steady-state mass fraction in regional natural soil (%)	5.08E-08	[%]
Steady-state mass fraction in regional industrial soil (%)	1.88E-08	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.20E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	6.46E-03	[%]
Steady-state mass in continental freshwater (kg)	6.18E-03	[%]
Steady-state mass in continental seawater (kg)	8.72E-02	[%]
Steady-state mass in continental air (kg)	8.40E-14	[%]
Steady-state mass in continental agricultural soil (kg)	5.84E+01	[%]
Steady-state mass in continental natural soil (kg)	2.32E-07	[%]
Steady-state mass in continental industrial soil (kg)	8.58E-08	[%]
Steady-state mass in continental freshwater sediment (kg)	1.36E+00	[%]
Steady-state mass in continental seawater sediment (kg)	5.15E-01	[%]

The RCRs for soil, water and sediment are all <1 in the realistic worst case assessment, indicating a low risk from the use of C/D containing cadmium at the levels currently identified.

For the assessment of secondary poisoning, the model for uptake into fish and earthworms uses the measured bioconcentration factor (BCF) of 100 l/kg for fish and the earthworm bioaccumulation factor (BAF) of 19 kg/kg wet weight as input data for EUSES (see Table 3.1). These values reflect the range of median values reported in EC (2007).

Using these factors, the RCRs are <1 for exposure scenario I for both the fish and earthworm food chains. Secondary poisoning via the fish food chain is not relevant for exposure scenario II. Exposure via the food chain for metals is complicated as the default methods in EUSES are not appropriate for metals. The modelling of the uptake of cadmium from soil into food was considered in EC (2007) and this used an approach whereby a critical concentration in soil that would not cause excessive cadmium exposure via the diet was determined. This critical concentration in soil was in the range 0.7-1.32 mg Cd/kg soil based on a critical intake of 37-47 µg/day. The realistic worst case, concentrations in agricultural soil predicted for cadmium from the use of C/D are below this critical concentration (0.0247 mg/kg dry weight for scenario I (RCR 0.019-0.035) and 0.495 mg/kg dry weight for scenario II (RCR 0.38-0.71), suggesting that the risk from exposure of man via crops would be low.

The current tolerable weekly intake (TWI) value for cadmium from diet is reported as 2.5 µg/kg bw. This figure is not directly comparable with the approach used in EC (2007). However for a typical adult body weight of 70 kg, the critical intake figure of 37-47 µg/day used in EC (2007) would be equivalent to a weekly intake of 3.7-4.7 µg/kg bw, which is similar to the EFSA (2012a) TWI.

The realistic worst case regional concentration in agricultural soil predicted for the use of C/D is 0.0422 mg/kg wet weight (0.0479 mg/kg dry weight). For comparison, EC (2007) gives the regional background concentration from all sources as 0.363 mg/kg wet weight in agricultural soil and 0.322 mg/kg wet weight in natural soil (see above). Therefore, the contribution from C/D to the total background cadmium present in soil from all sources is relatively small.
It is important to note that the realistic worst case exposure assessment has been based on the concentrations in composts and digestates given in Table 3.2. For cadmium the local concentrations were both based on the FPR limit values, as the majority of the available measured data for cadmium are close to or below this limit value. The mean and median concentrations actually measured in composts and digestates are around one third to one quarter of this limit value, and the resulting RCRs would be correspondingly lower if assessed based on the mean and median concentrations. However, it is important to note that there are a limited number of reported occurrences of cadmium in C/D at concentrations slightly above this limit value. The significance of these higher concentrations is assessed in the section on sensitivity to specific variables below.

Sensitivity to specific variables

The assessment above is based on a cadmium concentration in C/D of 1.5 mg/kg dry wt. As noted earlier there are a small number of data above this concentration, up to 2.75 mg/kg dry wt. in compost and 2.5 mg/kg dry wt. in digestate. The RCRs obtained If these highest concentrations are used in the worst case local scenario are shown in Table 3.7.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Table 3.7 Quantitative risk characterisation conclusions for cadmium in compost and digestates using the highest measured concentrations in compost and digestate

Scenario I	
RCR for local soil	1.97E-02
RCR for local freshwater	2.58E-02
RCR for local freshwater-sediment	2.77E-01
RCR for Humans via the environment: local total daily intake	see text
RCR for fish-eating birds and mammals (fresh water)	2.56E-03
RCR for worm-eating birds and mammals	4.77E-02

Scenario II	
RCR for local soil	3.95E-01
RCR for Humans via the environment: local total daily intake	see text
RCR for worm-eating birds and mammals	4.9E-01

For the exposure of humans via the food chain, the concentrations predicted in agricultural soil using the maximum concentrations are 0.045 mg/kg dry wt. for local scenario I and 0.91 mg/kg dry wt. for local scenario II. The predicted concentrations in agricultural soil are below the critical concentration of 0.7-1.32 mg/Cd/kg soil for scenario I (RCR 0.034-0.064) but are within this critical range for scenario II (RCR 0.69-1.3). Whether this presents an actual risk or not is highly uncertain as a) it assumes that the human's diet consists of crops grown entirely in compost containing the maximum recorded level of cadmium; the latter assumption is unlikely given that the majority of the measured cadmium concentrations in compost are below this maximum level, and b) that the consumption of such crops occurs daily by the same human; whilst this is not impossible it may not apply to a large population especially if consuming a balanced diet.

Summary of findings

Table 3.8 below presents the summary of key findings from the risk assessment of cadmium that has been made in this project. The findings are discussed further below the table.

Table 3.8 Summary of key findings for exposure of cadmium via use of compost and digestates

Key findings of the risk assessment of cadmium in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Median values approximately 0.2 to 0.8 mg/kg dry wt. The maximum values reported are 2.75 mg/kg dry wt. in compost and 2.5 mg/kg dry wt. in digestate.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). The highest concentrations reported

Key findings of the risk assessment of cadmium in contaminated composts and digestates	
	are in mechanical biological treatment compost and in digestate from biowaste and green waste. It is not possible to differentiate whether natural or anthropogenic in origin[12].
Safe limit concentration in compost and digestate	No risks identified at the proposed FPR limit value. The majority of the measured data are below this limit. The safe limit would be higher than the current levels so this is not currently seen as a concern.
Main concern(s) arising	Cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Toxicity to kidney and bone via dietary exposure. The European Food Safety Authority (EFSA) has identified that at least in the case of children, the tolerable weekly intake of cadmium via total diet, could be exceeded. Cadmium in compost and digest could contribute to this dietary exposure.
Uncertainties and their implications	Uncertainty over the safe threshold for dietary exposure. Small occurrence data set covering limited number of countries. The highest concentrations reported could present a risk to humans exposed via crops, however this significance of this is highly uncertain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	The contribution from C/D to the total cadmium present in soil from all sources is relatively small.

The realistic worst case analysis carried out indicates that the risks to the environment from the presence of cadmium in C/D are generally low. The contribution from C/D to the total cadmium present in soil from all sources is relatively small. For man exposed via the diet, the levels predicted are below the available toxicity threshold values. However, it should be noted that cadmium and its salts have been identified as SVHC based on mutagenicity and/or carcinogenicity and effects on kidney and bones and, according to ECHA (2013), there is some uncertainty over the safe threshold for dietary exposure. ECHA (2013) indicated that atmospheric deposition to soil was the major source of cadmium entering the diet and recommended that action should be taken at Community level to control and reduce cadmium pollution. Although the input of cadmium into soil, and hence the diet, from C/D appears to be small compared with other sources, C/D will contribute to the total dietary intake of cadmium.

At steady state, 67% of the total mass remains within the region + continent[13], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D. The realistic worst case mass of cadmium in the region + continent at steady state as a result of use of C/D is estimated to be around 4.27×10^6 kg assuming that all compost contains cadmium at the mid-

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[12] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

[13] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

range of the measured concentration. This steady-state mass amounts to approximately 220 times the mass released annually via application of composts and digestates[14].

3.3 Nickel (Ni)

Background information and remarks

Nickel metal (CAS 7440-02-0) has been subject to a comprehensive EU risk assessment (EC, 2008a).

Chemical properties and hazards data set

The relevant property data are summarised in Table 3.9 below. The data are taken mainly from EC (2008a). Where information from other sources is included this is indicated in the Table.
The EU harmonised CLP classification for nickel is: Skin Sens. 1 – H317; Carc. 2 – H351;
STOT RE 1 - H372. PNECs are available from existing published assessment. The exposure of man via the environment is assessed indirectly using the method in EC (2008a).

Table 3.9 Property information for nickel (from EC (2008a) unless otherwise indicated)

Property	Value	Comment
Molecular weight	58.7	
Melting point	1455°C	
Boiling point	2730°C	
Vapour pressure	Negligible	
Water solubility	Practically insoluble (metal) – 254 g/100 ml at 20°C	Solubility varies with the salt. This should not affect the assessment as the Henry's law constant has been set to be very low.
log Kow	Not relevant for metals	
Henry's law constant	Assumed to be very low	
Koc	Koc not relevant for metals Kp = 724 l/kg for soil Kp = 26303 l/kg for suspended sediment Kp = 7079 l/kg for sediment	Kp values are measured solids-water partition coefficients and are used directly in the EUSES modelling.
BCF	BCF for fish 270 l/kg BAF for earthworms 0.30 kg/kg dry wt BCF 0.07 kg/kg dry wt for root crops and above ground vegetables from soil.	BCF shows a negative relationship with exposure concentration - value was obtained with experiments at 1-2 µg/L. See text for secondary poisoning and plant uptake

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[14] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

Property	Value	Comment
Biodegradability	Not applicable. Assumed to be not degradable.	
Half-life in air	Not relevant	
PNECs	$PNEC_{water}$ = 2.74 µg/l dissolved nickel $PNEC_{sediment}$ = 47 mg/kg dry wt $PNEC_{soil}$ = 29.9 mg/kg dry wt. (reasonable worst case value) $PNEC_{soil}$ = 20.4 mg/kg dry wt. (added risk approach) $PNEC_{oral}$ = 0.73 mg/kg food (generic PNEC for mammals)	Directive 2008/105/EC[a] annual average EQS 4 µg/L (related to the bioavailable fraction) and maximum acceptable concentration 34 µg/l. PNEC for sediment is taken from ECHA (2012).
DNEL		In EC (2008a) man exposed via the environment is assessed via an internal dose – see text.
Other relevant data		

Note: a) Environmental Quality Standard (EQS) set under Directive 2008/105/EC (EU, 2008) as amended by Directive 2013/39/EU (EU, 2013).

The EUSES model uses the octanol-water partition coefficient (log Kow) in order to model the uptake into fish and earthworms for the assessment of secondary poisoning and to model the uptake from soil into the human food chain. This approach is not appropriate for metals such as nickel as the log Kow value is not applicable to such metals and their inorganic salts. Instead, it is necessary to model the uptake into the food chain using appropriate accumulation factors, in many cases outside of the EUSES program. Table 3.9 shows the relevant accumulation factors.

Occurrence data set

Table 3.10 presents a summary of the reported concentrations of nickel in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. Consultation and literature research suggest typical contamination rates of nickel in the range <10 to 31 mg/kg dry weight in digestate and up to around 39 mg/kg dry weight in compost.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposure has been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background. The proposed FPR limit value (EU, 2018) is slightly higher than the range of typically reported concentrations and is also taken into account in the generic exposure outcomes (see summary of findings below).
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

It is relevant to note that there are a limited number of reported concentrations higher than assumed in the conservative assessment above. The proposed FPR limit value is 50 mg/kg dry weight (EU, 2018).

EC (2014) reported that most samples were well below this limit (and consistent with the concentrations assumed in the conservative assessment) with the exception of 4 compost samples derived from biowaste, 1 compost sample derived from green waste, 1 compost sample derived from sewage sludge and 1 compost sample derived from mechanical biological treatment. The highest concentration reported was 250 mg/kg dry wt. for the compost derived from green waste. The highest concentration reported in digestate in the EC (2014) study was around 40 mg/kg dry weight in a sample derived from biowaste and green waste. The significance of this limited number of reported higher concentrations is considered in the section on sensitivity to specific variables (see below).

Table 3.10 Reported occurrence of nickel in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Composts - data availability		Most of data from one study in DE-Bavaria. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤160 mg/kg dry wt for compost from biowaste and green waste, ≤250 mg/kg dry wt. green waste compost, ≤70 mg/kg dry wt. for sewage sludge compost and ≤130 mg/kg dry wt. in mechanical biological treatment compost.
Compost - minimum concentration	1.2	No min value given - assumed to be 1/10 of the lowest median (12 mg/kg dry wt)
Compost - mid-range or average concentration	14.5	Approximate mid-point of range of medians
Compost - maximum concentration	38.5	Typical upper limit of the measured data. FPR limit value is 50 mg/kg dry wt. Only a limited number of data exceed this value and these are considered further in the section on sensitivity to specific variables below.
Digestates - data availability		Most data are from one study in DE-Bavaria and one in Norway. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤40 mg/kg dry wt for digestate from biowaste and green waste and ≤20 mg/kg dry wt. in mechanical biological treatment digestate. Data for UK gives maximum of 0.063 kg/ha and with a limit value (PAS110; WRAP) of 1.2 kg/ha and commented that the quantities applied in digestates are very low and will have little effect on soil concentration.
Digestate - minimum concentration	2.9	Lowest reported value
Digestate - mid-range or average concentration	13.5	Approximate mid-point of range of mean/median values
Digestate - maximum concentration	31.3	Typical upper limit of measured data. FPR limit value is 50 mg/kg dry wt. Only a limited number of data

	exceed this value and these are considered further in the section on sensitivity to specific variables below).

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.11 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	127,890
Mass of substance in EU-28 in digestate (kg/year)	476,280
Total regional emission to surface water (kg/day)	4.6
Total regional emission to soil (kg/day)	161
Total continental emission to surface water (kg/day)	42
Total continental emission to agricultural soil (kg/day)	1448

Table 3.12 shows the reported regional background concentrations of nickel, taking into account all sources of nickel. The data are taken from EC (2008a).

Table 3.12 Reported background concentrations of nickel in the environment

PECregional	Value	Remarks
Air	2.69 ng/m^3	Modelled.
Surface water	3.29 µg/L - dissolved	Modelled. 2.9 µg/L based on measurements.
Sediment	23.3 mg/kg dry wt	Modelled. 33.5 mg/kg dry wt based on measurements.
Agricultural soil	19 mg/kg dry wt.	Modelled. 26.2 mg/kg dry wt in agricultural soil and 35.8 mg/kg dry wt in grassland based on measurements.
Soil pore water/ground water	No data	
Natural soil	16.9 mg/kg dry wt.	Modelled. 27.8 mg/kg dry wt. in forest soil based on measurements.
Urban/industrial soil	17.6 mg/kg dry wt.	Modelled.
Other relevant data		None.

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of nickel resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.13.

Table 3.13 Predicted exposures for nickel arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	6.39E-01	[mg/kg dry wt.]
PECgrassland soil	2.54E-01	[mg/kg dry wt.]
PEC in groundwater	8.82E-04	[mg/l]
PECfreshwater	4.12E-04	[mg/l]
PECfreshwater-sediment	1.08E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	see text	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.52E-05	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Approximately 86% from crops - see text	
Secondary poisoning – freshwater fish-eating birds and mammals	1.05E-01	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	2.11E-01	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	1.27E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	see text	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Approximately 99% from crops - see text	
Secondary poisoning – worm-eating birds and mammals	7.53E-01	[mg.kg-1]

Table 3.14 presents the results of the quantitative risk characterisation along with the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.14 Quantitative risk characterisation conclusions for nickel in compost and digestates

	Scenario I
RCR for local soil	2.14E-02
RCR for local freshwater	1.50E-01
RCR for local freshwater-sediment	2.30E-01
RCR for Humans via the environment: local total daily intake	see text
RCR for fish-eating birds and mammals (fresh water)	1.43E-01

RCR for worm-eating birds and mammals	2.90E-01

Scenario II	
RCR for local soil	4.25E-01
RCR for Humans via the environment: local total daily intake	see text
RCR for worm-eating birds and mammals	1.03E+00

Regional	
RCR for regional soil	1.35E-01
RCR for regional freshwater	1.33E-01
RCR for regional freshwater-sediment	4.04E-01

Steady state mass		**Units**
Total steady-state mass (region + continent)	2.95E+05	[t]
Steady-state mass in regional freshwater (kg)	1.83E+03	[kg]
Steady-state mass in regional seawater (kg)	1.93E+02	[kg]
Steady-state mass in regional air (kg)	2.83E-24	[kg]
Steady-state mass in regional agricultural soil (kg)	2.92E+07	[kg]
Steady-state mass in regional natural soil (kg)	1.22E-07	[kg]
Steady-state mass in regional industrial soil (kg)	4.78E-08	[kg]
Steady-state mass in regional freshwater sediment (kg)	1.71E+05	[kg]
Steady-state mass in regional seawater sediment (kg)	6.61E+03	[kg]
Steady-state mass in continental freshwater (kg)	2.48E+04	[kg]
Steady-state mass in continental seawater (kg)	3.69E+05	[kg]
Steady-state mass in continental air (kg)	2.54E-23	[kg]
Steady-state mass in continental agricultural soil (kg)	2.62E+08	[kg]
Steady-state mass in continental natural soil (kg)	5.00E-07	[kg]
Steady-state mass in continental industrial soil (kg)	1.84E-07	[kg]
Steady-state mass in continental freshwater sediment (kg)	2.33E+06	[kg]
Steady-state mass in continental seawater sediment (kg)	6.30E+05	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)		
Steady-state mass fraction in regional freshwater (%)	4.77E-04	[%]
Steady-state mass fraction in regional seawater (%)	5.05E-05	[%]
Steady-state mass fraction in regional air (%)	7.40E-31	[%]
Steady-state mass fraction in regional agricultural soil (%)	7.62E+00	[%]
Steady-state mass fraction in regional natural soil (%)	3.19E-14	[%]
Steady-state mass fraction in regional industrial soil (%)	1.25E-14	[%]
Steady-state mass fraction in regional freshwater sediment (%)	4.47E-02	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.73E-03	[%]
Steady-state mass in continental freshwater (kg)	6.49E-03	[%]
Steady-state mass in continental seawater (kg)	9.64E-02	[%]
Steady-state mass in continental air (kg)	6.63E-30	[%]
Steady-state mass in continental agricultural soil (kg)	6.86E+01	[%]
Steady-state mass in continental natural soil (kg)	1.31E-13	[%]
Steady-state mass in continental industrial soil (kg)	4.82E-14	[%]
Steady-state mass in continental freshwater sediment (kg)	6.08E-01	[%]
Steady-state mass in continental seawater sediment (kg)	1.65E-01	[%]

The RCRs for soil, water and sediment are all <1 in the realistic worst case assessment, indicating a low risk from the use of C/D containing nickel at the levels currently present (this is also true if the proposed FPR limit concentration of 50 mg/kg dry weight (EU, 2018) is assumed). However, it is relevant to note that there are a limited number of reported occurrences of nickel in C/D at concentrations above this limit value. The significance of these higher concentrations is assessed in the section on sensitivity to specific variables below.
For secondary poisoning, the uptake into fish and earthworms has been modelled using the measured bioconcentration factor (CF) of 270 for fish and the bioaccumulation factor (BAF) of 0.30 mg/kg on a dry weight basis (equivalent to 0.048 mg/kg on a wet weight basis) as input data for EUSES. These values were the selected values reported in EC (2008a).

Using these factors, the RCRs are <1 for exposure scenario I for both the fish and earthworm food chains. Secondary poisoning via the fish food chain is not relevant for exposure scenario II. The RCR for the earthworm food chain for scenario II is >1 in the realistic worst case assessment.

The modelling of the uptake of nickel from soil into food for the man via the environment assessment was considered in EC (2008a). The uptake from soil into both root crops and above ground vegetables was modelled in EC (2008a) in terms of a concentration factor of 0.07 on a dry weight basis (the same factor was applicable for both root crops and leaf crops).

The realistic worst case concentrations in agricultural soil predicted for nickel from the use of C/D are 0.639 mg/kg dry weight for scenario I and 12.7 mg/kg dry weight for scenario II). Thus the concentrations in leaf crops and root crops can be estimated as 0.045 mg/kg dry weight for scenario I and 0.89 mg/kg dry weight for scenario I. EC (2008a) assumed an average moisture content of 11% for plants and so the wet weight concentrations in leaf and root crops can be estimated to be 0.040 mg/kg wet weight for scenario I and 0.79 mg/kg wet weight for scenario II.

For the risk characterisation for man exposed via the food chain, EC (2008a) considered the exposure and effects in terms of an internal dose. The internal dose from environmental exposure was estimated assuming an absorption factor of 50% for inhalation, 30% for drinking water, 5% for soil/dust and 5% for food. Using this approach the internal dose from environmental exposure can be estimated as 5.3×10^{-5} mg/kg bw/day for scenario I and 8.9×10^{-4} mg/kg bw/day for scenario II. Around 86-99% of these predicted doses is estimated to come from crops for these scenarios.

No DNEL was derived in EC (2008a). Instead the margin of safety (MOS) was estimated using a relevant toxicological threshold value, and the MOS was then compared with a reference MOS_{ref}. If the MOS calculated is $>\text{MOS}_{\text{ref}}$ then it can be concluded that the exposure represents a low risk. For man exposed via the environment, the relevant toxicological thresholds and MOS_{ref} used in EC (2008a), all based on absorbed dose, was 0.11 mg Ni/kg bw/day with a MOS_{ref} of 300 for repeated dose systemic toxicity, and 0.055 mg Ni/kg bw/day with a MOS_{ref} of 200-300 for developmental toxicity. The MOS calculated for scenario I using these threshold values is >1000 for scenario I (in terms of RCRs[15] this can be interpreted in terms of RCRs of 0.14-0.29) of but only 62 (based on developmental effects; equivalent RCR = 3.3-4.9) or 123 (based on repeated dose systemic toxicity; equivalent RCR = 2.4) for scenario II. This suggests a possible risk for scenario II. These conclusions would also apply at the proposed FPR limit value of 50 mg/kg dry wt.

When the less conservative scenario is considered (assuming the approximate mean or median concentration measured in C/D) the predicted internal dose for scenario II reduces from 8.9×10^{-4} mg/kg bw/day to 3.4×10^{-4} mg/kg bw/day. The MOS for the less conservative scenario is 326 (equivalent RCR of 0.92) for repeated dose systemic toxicity but 163 (equivalent RCR of 1.2-1.8) for developmental effects. Again this suggests a possible risk for scenario II when the typical levels of nickel present in C/D are considered.

For scenario II, the levels in soil, earthworms and crops are directly proportional to the level in compost. In order to give an adequate MOS (or a RCR <1) the maximum level of nickel present in compost would need to be around 7.9 mg/kg dry weight.

The realistic worst case regional concentration in agricultural soil predicted for the use of C/D is 3.57 mg/kg wet weight (4.05 mg/kg dry weight). For comparison, EC (2008a) gives the regional background concentration from all sources as 19 mg/kg dry weight in agricultural soil and 17 mg/kg dry weight in natural soil based on model calculations. Measured data are also reported in EC (2008a) and these show similar regional background concentrations around 26 mg/kg dry weight in agricultural soil and 36 mg/kg dry weight in grassland. Therefore, the nickel from C/D contributes up to around 20% of the total background nickel present in soil.

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[15] The RCR can be approximated by the ratio of the calculated MOS_{ref}/calculated MOS.

Sensitivity to specific variables

The assessment above is based on the typical range of nickel concentrations in C/D of up to 39 mg/kg dry wt. in compost and 31 mg/kg dry wt. in digestate. As noted earlier there are a small number of data above these concentrations, up to 250 mg/kg dry wt. in compost and 40 mg/kg dry wt. in digestate.

The RCRs obtained, if these highest concentrations are used in the worst case local scenario, are shown in Table 3.15.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Table 3.15 Quantitative risk characterisation conclusions for nickel in compost and digestates using the highest measured concentrations in compost and digestate

Scenario I	
RCR for local soil	0.14
RCR for local freshwater	2.45E-01
RCR for local freshwater-sediment	3.75E-01
RCR for Humans via the environment: local total daily intake	see text
RCR for fish-eating birds and mammals (fresh water)	1.69E-02
RCR for worm-eating birds and mammals	5.05E-01

Scenario II	
RCR for local soil	2.76
RCR for Humans via the environment: local total daily intake	see text
RCR for worm-eating birds and mammals	5.33

Using the same approach as above, the estimated exposure for humans via the environment would be as an internal dose of 3.4×10^{-4} mg/kg bw/day for scenario I and 5.8×10^{-3} mg/kg bw/day for scenario II. For scenario I, no unacceptable risks are identified using the highest concentration measured in compost for soil freshwater, sediment or secondary poisoning. The estimated human exposure via diet for this scenario results in an MOS of 323 (equivalent RCR 0.93) for repeated dose systemic toxicity but 161 ((equivalent RCR of 1.2-1.8) for developmental effects. This suggests a possible risk at the highest concentrations found. In order to control this risk the concentration of nickel in C/D would need to be limited to around 130 mg/kg dry wt. The majority of the measured data are below this value.

As before, for scenario II, the estimated exposures for humans via the environment and for secondary poisoning in a possible risk using the highest concentrations in compost. In addition, a possible risk to soil itself is indicated for scenario II. As before the maximum level of nickel in compost to give an adequate margin of safety is derived as 7.9 mg/kg (see previous section). The maximum concentrations in compost are well above this value.

Summary of findings

Table 3.16 below presents the summary of key findings from the risk assessment of nickel that has been made in this project. The findings are discussed further below the table.

Table 3.16 Summary of key findings for exposure of nickel via use of compost and digestates

Key findings of the risk assessment of nickel in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Typically <10 to 39 mg/kg dry wt.. The maximum values reported are 250 mg/kg dry wt. in compost and 40 mg/kg dry wt. in digestate.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). The highest overall concentrations have been reported in compost samples derived from biowaste, green waste, sewage sludge and mechanical biological treatment. It is not possible to differentiate whether natural or anthropogenic in origin[16].
Safe limit concentration in compost and digestate	7.9 mg/kg dry wt for compost for container growing. 130 mg/kg dry wt. for compost or digestate for application to agricultural land. The majority of measured data are below this value.
Main concern(s) arising	Human exposure through crops from use of compost in container growing. Secondary poisoning from use of compost in container growing. Cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Human toxicity based on mammalian developmental toxicity
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	The nickel from C/D contributes up to around 20% of the total background nickel present in soil.

The realistic worst case analysis carried out indicates a potential risk for secondary poisoning and human exposure through use of compost containing nickel for scenario II. No risks are identified for use of compost or digestate containing nickel in scenario I based on the typical range of concentrations and the proposed FPR limit value. However, there are a limited number of measured concentrations in nickel in compost above this limit value and these would indicate a potential risk to humans via diet if the concentration exceeds around 130 mg/kg dry wt. The majority of the available measured data are below this value.

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[16] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

In order to control the risks from scenario II the level of nickel present in compost would need to be around 7.9 mg/kg dry weight or below.

The contribution from C/D to the total nickel present in agricultural soil from all sources is relatively small. At steady state, 77% of the total mass remains within the region + continent[17], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D. The realistic worst case mass of nickel in the region + continent at steady state as a result of use of C/D is estimated to be around 2.95×10^8 kg assuming that all compost contains nickel at the mid-range of the reported measured levels. This steady-state mass amounts to approximately 490 times the mass released annually via application of composts and digestates[18].

3.4 Lead (Pb)

Background information and remarks

Lead metal (CAS No 7439-92-1) has been subject to a risk assessment (LDAI, 2008). The risk assessment was carried out voluntarily by the lead industry but underwent a detailed review procedure by the EU's Technical Committee on New and Existing Substances (TCNES, 2008a and 2008b). The risk assessment was also reviewed by the EU Scientific Committee on Health and Environmental Risks (SCHER, 2009a and 2009b).

Chemical properties and hazards data set

The relevant property data are summarised in Table 3.17 below. The data are taken mainly from LDAI (2008). Where information from other sources is included this is indicated in the Table.
The EU harmonised CLP classification for lead is: Lact. – H362; Repr. 1A – H360FD (CLP Inventory entry for lead powder with particle size <1mm, checked 11 October 2018).

Lead is a non-threshold neurotoxic substance and the risks to humans via the environment cannot be adequately addressed in a quantitative way (e.g. by derivation of DNELs) (ECHA, 2017a).

Table 3.17 Property information for lead (from LDAI (2008) unless otherwise indicated)

Property	Value	Comment
Molecular weight	207.2	
Melting point	326°C	
Boiling point	>600°C	
Vapour pressure	Negligible at 20°C	
Water solubility	185 mg/l at 20°C	Solubility varies with the salt. This should not affect the assessment as the

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[17] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[18] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

Property	Value	Comment
		Henry's law constant has been set to be very low.
log Kow	Not relevant for metals	
Henry's law constant	No data	Assumed to be very small
Koc	Koc not relevant for metals Kp = 295,121 l/kg for suspended sediment Kp = 154,882 l/kg for sediment Kp = 6,400 l/kg for soil	Kp values are measured solids-water partition coefficients and are used directly in the EUSES modelling. Kp suspended sediment 10th-90th percentile 50,119 -1,698,244 l/kg. Kp sediment 10th-90th percentile 35,481 - 707,946 l/kg. Kp soil 10th-90th percentile 600 - 43,000 l/kg.
BCF	BAF for fish 23 l/kg. BAF for earthworms 0.10 kg/kg	Fish BAF includes both bioconcentration (BCF) and biomagnification (BMF). In LDAI (2008) man exposed via the environment is assessed based on measured data in food (see text).
Biodegradability	Not applicable. Assumed to be not degradable.	
Half-life in air	Not relevant	
PNECs	$PNEC_{water}$ = 2.7 µg/l $PNEC_{sediment}$ = 174 mg/kg dry wt $PNEC_{soil}$ = 166 mg/kg dry wt. $PNEC_{oral}$ = 49 mg/kg food Critical concentration in soil for secondary poisoning = 491 mg/kg dry wt.	Directive 2008/105/EC[a] is annual average EQS of 1.2 µg/L (related to the bioavailable fraction) and maximum acceptable concentration of 14 µg/l.
DNEL	Non-threshold	Lead is a non-threshold neurotoxic substance and the risks to humans via the environment cannot be adequately addressed in a quantitative way (e.g. by derivation of DNELs) (ECHA, 2017a).
Other relevant data		

Note: a) Environmental Quality Standard (EQS) set under Directive 2008/105/EC (EU, 2008) as amended by Directive 2013/39/EU (EU, 2013).

The EUSES model uses the octanol-water partition coefficient (log Kow) in order to model the uptake into fish and earthworms for the assessment of secondary poisoning and to model the uptake from soil into the human food chain. This approach is not appropriate for metals such as lead as the log Kow value is not applicable to such metals and their inorganic salts. Instead, it is necessary to model the uptake into the food chain using appropriate accumulation factors, in many cases outside of the EUSES program. Table 3.17 shows the relevant accumulation factors.

Occurrence data set

Table 3.18 presents a summary of the reported concentrations of lead in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. Consultation and literature research suggest typical contamination rates of lead in the range <2.5 to 80 mg/kg dry weight in digestate and up to 90.8 mg/kg dry weight in compost. The proposed FPR limit value is 120 mg/kg dry weight (EU, 2018) and the vast majority of the reported data are below this value (see below).

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for one concentration scenario:

- A conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background. The proposed FPR limit value of 120 mg/kg dry weight (EU, 2018) is also taken into account in the generic exposure outcomes (see summary of findings below).

It is relevant to note that there are a limited number of reported concentrations higher than assumed in the conservative assessment above. EC (2014) reported that most samples of C/D showed lead levels below the proposed FPR limit value of 120 mg/kg dry wt. The one exception to this was compost from mechanical biological treatment in which lead was present at a maximum concentration of 230 mg/kg dry wt. and exceeded the 120 mg/kg dry wt. limit in four samples overall (approximately 30% of the mechanical biological treatment samples). For the other sources of compost considered in the study, most of the measured levels were <75 mg/kg dry wt. with one sample of compost derived from sewage sludge showing a level of 105 mg/kg dry wt. The levels of lead in digestate found in this study were generally lower than found in compost. The significance of this limited number of reported higher concentrations is considered in the section on sensitivity to specific variables (see below).

Table 3.18 Reported occurrence of lead in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Composts - data availability		Most of data from one study in DE-Bavaria. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤75 mg/kg dry wt for compost from biowaste and green waste, ≤70 mg/kg dry wt. green waste compost, ≤105 mg/kg dry wt. for sewage sludge compost and ≤230 mg/kg dry wt. in mechanical biological treatment compost.
Compost - minimum concentration	2.3	No minimum - assumed to be 1/10 of lowest median (23.3 mg/kg dry wt.).
Compost - mid-range or average concentration	33.8	Approximate mid-point of range of median values.
Compost - maximum concentration	90.8	Typical upper limit of the measured data. Only a very limited number of data exceed this value (see text). Proposed FPR limit value of 120 mg/kg dry wt. Only a limited number of data exceed this value and these are considered further in the section on sensitivity to specific variables below.

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
		Other limits reported in LFU (2016) are 75 mg/kg dry wt (quality assured Fachvereinigung Bayerischer Komposthersteller e.V. (FBK, 2015)), 45 mg/kg dry wt. (Quality assured EU Öko-V (2008)) and 100 mg/kg dry wt. and 150 mg/kg dry wt. (DüMV, 2012 and 2015).
Digestates - data availability		Most of data from one study in DE-Bavaria and one in Norway. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤55 mg/kg dry wt for digestate from biowaste and green waste and ≤55 mg/kg dry wt. in mechanical biological treatment digestate. Data for UK gives maximum of 0.018 kg/ha and with a limit value (PAS110; WRAP) of 4.8 kg/ha and commented that the quantities applied in digestates are very low and will have little effect on soil concentration.
Digestate - minimum concentration	<2.5	
Digestate - mid-range or average concentration	15.5	Approximate mid-point of range of median and mean values
Digestate - maximum concentration	79.7	Upper limit of the measured data. Proposed FPR limit value 120 mg/kg dry wt. Only a limited number of data exceed this value and these are considered further in the section on sensitivity to specific variables below. Other limits proposed in LFU (2016) are 75 mg/kg dry wt (quality assured Fachvereinigung Bayerischer Komposthersteller e.V. (FBK, 2015), 45 mg/kg dry wt. (Quality assured EU Öko-V (2008) and 100 mg/kg dry wt. and 150 mg/kg dry wt. (DüMV).

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.19 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	298,116
Mass of substance in EU-28 in digestate (kg/year)	546,840
Total regional emission to surface water (kg/day)	6.5
Total regional emission to soil (kg/day)	225
Total continental emission to surface water (kg/day)	58
Total continental emission to agricultural soil (kg/day)	2025

Table 3.20 shows the reported regional background concentrations of lead, taking into account all sources of lead. The data are taken from LDAI (2008).

Table 3.20 Reported background concentrations of lead in the environment

PECregional	Value	Remarks
Air	20 ng/m^3	Median ambient regional PEC for Europe based on measured data
Surface water	0.61 µg/l dissolved	Median ambient regional PEC for Europe based on measured data
Sediment	100.1 mg/kg dry wt	Median ambient regional PEC for Europe based on measured data
Agricultural soil	29.7 mg/kg dry wt	Median measured value in agricultural soils in Europe
Soil pore water/ground water	No data	
Natural soil	28.3 mg/kg dry wt	Modelled value
Urban/industrial soil		
Other relevant data		

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of lead resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.21.

Table 3.21 Predicted exposures for lead arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.51E+00	[mg/kg dry wt.]
PECgrassland soil	6.04E-01	[mg/kg dry wt.]
PEC in groundwater	2.36E-04	[mg/l]
PECfreshwater	8.54E-05	[mg/l]
PECfreshwater-sediment	2.52E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	see text	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	6.74E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	see text	
Secondary poisoning – freshwater fish-eating birds and mammals	1.63E-03	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	9.43E-01	[mg.kg-1]

	Scenario II	Units

PECagricultural soil	3.00E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	see text	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	see text	
Secondary poisoning – worm-eating birds and mammals	2.22E+00	[mg.kg-1]

Table 3.22 presents the results of the quantitative risk characterisation for water, soil and sediment, along with the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.22 Quantitative risk characterisation conclusions for lead in composts and digestates

Scenario I	
RCR for local soil	9.10E-03
RCR for local freshwater	7.12E-02
RCR for local freshwater-sediment	1.45E-01
RCR for Humans via the environment: local total daily intake	non-threshold
RCR for fish-eating birds and mammals (fresh water)	3.32E-05
RCR for worm-eating birds and mammals	1.93E-02

Scenario II	
RCR for local soil	1.81E-01
RCR for Humans via the environment: local total daily intake	non-threshold
RCR for worm-eating birds and mammals	4.53E-02

Regional	
RCR for regional soil	1.17E-01
RCR for regional freshwater	4.68E-02
RCR for regional freshwater-sediment	1.90E-01

	Steady state mass	Units
Total steady-state mass (region + continent)	1.41E+06	[t]
Steady-state mass in regional freshwater (kg)	1.10E+03	[kg]
Steady-state mass in regional seawater (kg)	1.06E+02	[kg]
Steady-state mass in regional air (kg)	3.09E-12	[kg]
Steady-state mass in regional agricultural soil (kg)	1.40E+08	[kg]

Steady-state mass in regional natural soil (kg)	1.22E-02	[kg]
Steady-state mass in regional industrial soil (kg)	4.52E-03	[kg]
Steady-state mass in regional freshwater sediment (kg)	2.98E+05	[kg]
Steady-state mass in regional seawater sediment (kg)	1.90E+04	[kg]
Steady-state mass in continental freshwater (kg)	1.20E+04	[kg]
Steady-state mass in continental seawater (kg)	1.61E+05	[kg]
Steady-state mass in continental air (kg)	2.79E-11	[kg]
Steady-state mass in continental agricultural soil (kg)	1.26E+09	[kg]
Steady-state mass in continental natural soil (kg)	5.56E-02	[kg]
Steady-state mass in continental industrial soil (kg)	2.06E-02	[kg]
Steady-state mass in continental freshwater sediment (kg)	3.27E+06	[kg]
Steady-state mass in continental seawater sediment (kg)	1.44E+06	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)		
Steady-state mass fraction in regional freshwater (%)	7.38E-05	[%]
Steady-state mass fraction in regional seawater (%)	7.16E-06	[%]
Steady-state mass fraction in regional air (%)	2.08E-19	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.45E+00	[%]
Steady-state mass fraction in regional natural soil (%)	8.22E-10	[%]
Steady-state mass fraction in regional industrial soil (%)	3.04E-10	[%]
Steady-state mass fraction in regional freshwater sediment (%)	2.01E-02	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.28E-03	[%]
Steady-state mass in continental freshwater (kg)	8.11E-04	[%]
Steady-state mass in continental seawater (kg)	1.08E-02	[%]
Steady-state mass in continental air (kg)	1.88E-18	[%]
Steady-state mass in continental agricultural soil (kg)	8.50E+01	[%]

Steady-state mass in continental natural soil (kg)	3.74E-09	[%]
Steady-state mass in continental industrial soil (kg)	1.39E-09	[%]
Steady-state mass in continental freshwater sediment (kg)	2.20E-01	[%]
Steady-state mass in continental seawater sediment (kg)	9.69E-02	[%]

The RCRs for soil, water and sediment are all <1 in the realistic worst case assessment, indicating a low risk from the use of C/D containing lead at the levels currently present (this is also true if the proposed FPR limit concentration of 120 mg/kg dry weight is assumed). However, it is relevant to note that there are a limited number of reported occurrences of lead in C/D at concentrations above this limit value. The significance of these higher concentrations is assessed in the section on sensitivity to specific variables below.

For secondary poisoning the uptake into fish and earthworms has been modelled using the measured bioaccumulation factor (BAF) of 23 for fish (this value takes into both bioconcentration and biomagnification) and the bioaccumulation factor (BAF) of 0.10 mg/kg on a dry weight basis (equivalent to 0.016 mg/kg on a wet weight basis) as input data for EUSES. These values were the selected values reported in the voluntary risk assessment report for lead (LDAI, 2008).
Using these factors, the RCRs are <1 for exposure scenario I for both the fish and earthworm food chains. Secondary poisoning via the fish food chain is not relevant for exposure scenario II. However, it is important to note that lead is a non-threshold neurotoxic substance in humans and so the relevance of the quantitative risk characterisation to other mammals can be questioned.

The exposure of man via the environment was estimated in LDAI (2008) using measured data on the concentrations of lead in food. This approach is not possible for the use of C/D containing lead and so no exposure calculations for man via the environment are carried out. In addition, lead is a non-threshold neurotoxic substance and the risks to humans via the environment cannot be adequately addressed in a quantitative way (ECHA, 2017a) and so no risk characterisation is carried out for man exposed via the environment.

The realistic worst case regional concentration in agricultural soil predicted for the use of C/D is 17.2 mg/kg wet weight (19.5 mg/kg dry weight). This is based on the mid-range lead concentration measured in C/D. For comparison, LDAI (2008) gives the regional background concentration from all sources as 29.7 mg/kg dry weight in agricultural soil (median measured value in agricultural soils in Europe). Therefore, the lead from C/D contributes up to around 66% of the total background lead present in soil based on the mid-range lead concentrations measured; the contribution would be higher if the highest concentrations or the proposed FPR limit value is assumed.

Sensitivity to specific variables

The assessment above is based on the typical range of lead concentrations in C/D of up to 90.8 mg/kg dry wt. in compost and 80 mg/kg dry wt. in digestate. As noted earlier there are a small number of data above these concentrations, up to 230 mg/kg dry wt. in compost.
The RCRs obtained if this highest concentration is used in the worst case local scenario are shown in Table 3.23.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under ‘high water content’ conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Table 3.23 Quantitative risk characterisation conclusions for lead in compost and digestates using the highest measured concentrations in compost and digestate

Scenario I	
RCR for local soil	2.31E-02
RCR for local freshwater	1.09E-01
RCR for local freshwater-sediment	2.22E-01
RCR for Humans via the environment: local total daily intake	non-threshold
RCR for fish-eating birds and mammals (fresh water)	4.38E-05
RCR for worm-eating birds and mammals	2.14E-02

Scenario II	
RCR for local soil	4.57E-01
RCR for Humans via the environment: local total daily intake	non-threshold
RCR for worm-eating birds and mammals	8.74E-2

Using the highest measured concentration in compost, the RCRs for soil, water and sediment are all <1 in the worst case assessment, confirming a low risk from the use of C/D containing lead at the levels currently present.

Summary of findings

Table 3.24 below presents the summary of key findings from the risk assessment of lead that has been made in this project. The findings are discussed further below the table.

Table 3.24 Summary of key findings for exposure of lead via use of compost and digestates

Key findings of the risk assessment of lead in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Typically <2.5 to 91 mg/kg dry wt.. The maximum concentration reported is 230 mg/kg dry wt.. in compost. The concentrations in digestate are generally lower than in compost.
Major raw material sources	The data suggests that the concentrations may be higher with biowaste and green waste, and solid and liquid biowaste as raw material sources than renewable raw materials and co-digestion as raw material sources. The highest concentration overall was found in compost derived from mechanical biological treatment. However, only very

Key findings of the risk assessment of lead in contaminated composts and digestates	
	limited data are available. It is not possible to differentiate whether natural or anthropogenic in origin[19].
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Non-threshold neurotoxic substance. Cumulative loads at steady state. Significant contribution from C/D to the total background level of lead in soil.
Effects associated with the main concern hazard(s)	Non-threshold neurotoxin.
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	-

The realistic worst case analysis carried out indicates RCRs <1 for soil, sediment, water and secondary poisoning based on the realistic worst case assumptions for both scenario I and scenario II. However, lead is a non-threshold neurotoxic substance and so it is not possible to carry out a quantitative risk characterisation for man exposed via the environment (refer to Section 2.1).

The contribution from C/D to the total background levels of lead present in soil from all sources is significant (estimated to be up to 66% based on the mid-range measured levels; this would be higher if the highest measured levels or the proposed FPR limit value is assumed).

At steady state, 95% of the total mass remains within the region + continent[20], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D. The realistic worst case mass of lead in the region + continent at steady state as a result of use of C/D is estimated to be more than 1 million tonnes assuming that all compost contains lead at the mid-range of the reported measured levels. This steady-state mass amounts to approximately 1,670 times the mass released annually via application of composts and digestates[21].

3.5 Copper (Cu)

Background information and remarks

Copper metal (CAS No 7440-50-8) has been subject to a comprehensive voluntary risk assessment ECI, 2008). The risk assessment was carried out voluntarily by the copper industry but underwent a detailed review procedure by the EU's Technical Committee on New and Existing Substances (TCNES, 2008c

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[19] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

[20] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[21] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

and 2008d). The risk assessment was also reviewed by the EU Scientific Committee on Health and Environmental Risks (SCHER, 2008 and 2009c).

Chemical properties and hazards data set

The relevant property data are summarised in Table 3.25 below. The data are taken mainly from ECI (2008). Where information from other sources is included this is indicated in the Table.
There is no EU harmonised CLP classification for copper. A proposal for a harmonised classification of copper (granulated) as Eye Irrit. 2 – H319 and Aquatic Chronic 2 – H411) has been submitted in relation to the Biocidal Products Regulation[22].

Table 3.25 Property information for copper (from ECI (2008) unless otherwise indicated)

Property	Value	Comment
Molecular weight	63.55 g/mole	
Melting point	1083°C	
Boiling point	2595°C	
Vapour pressure	Negligible at 20°C	
Water solubility	Practically insoluble to soluble	Solubility varies with the salt. This should not affect the assessment as the Henry's law constant has been set to be very low.
log Kow	Not relevant for metals	
Henry's law constant	Assumed to be very low	In the EUSES modelling the Henry's law constant was set to a value of 1E-10 Pa m^3 mol^{-1} as the substance is assumed to be non-volatile.
Koc	Koc not relevant for metals. Kp= 30,246 l/kg for suspended sediment Kp = 24,409 l/kg for sediment Kp = 2,120 l/kg for soil	Kp values are measured solids-water partition coefficients and are used directly in the EUSES modelling. The values given are the median values used in ECI (2008).
BCF	BCF not applicable owing to homeostasis	See text
Biodegradability	Not applicable. Assumed to be not degradable.	
Half-life in air	Not relevant	
PNECs	$PNEC_{water}$ = 7.8-27.2 µg/l $PNEC_{sediment}$ = 1741 mg/kg organic carbon (indicative value) $PNEC_{soil}$ = 73.1-172.8 mg/kg dry wt. $PNEC_{oral}$ – no value available	Values reported reflect different methods for derivation used in ECI (2008). The lowest values have been considered in the risk characterisation. The PNEC for sediment is considered an indicative value (SCHER, 2009c). The indicative PNEC of 1741 mg/kg organic carbon is equivalent to a PNEC for 174

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[22] https://www.echa.europa.eu/web/guest/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180748711

Property	Value	Comment
		mg/kg dry weight for a freshwater sediment normalised to 10% organic carbon (the default value assumed in EUSES for the local assessment). No $PNEC_{oral}$ was derived in ECI (2008). The no observed adverse effect level (NOAEL) was given as 255 mg/kg dry diet for mammals and 288 mg/kg dry diet for birds.
DNEL		See text
Other relevant data	Copper is an essential element	

The EUSES model uses the octanol-water partition coefficient (log Kow) in order to model the uptake into fish and earthworms for the assessment of secondary poisoning and to model the uptake from soil into the human food chain. This approach is not appropriate for metals such as copper as the log Kow is not applicable to such metals and their inorganic salts. Instead, it is necessary to model the uptake into the food chain using appropriate accumulation factors, in many cases outside of the EUSES program. The relevant accumulation factors for copper are discussed in the section on generic exposure outcomes below.

Occurrence data set

Table 3.26 presents a summary of the reported concentrations of copper in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. Consultation and literature research suggest contamination rates of copper up to 981 mg/kg dry weight in digestate and up to 350 mg/kg dry weight in compost. The highest concentrations measured in both C/D are above the proposed FPR limit of 200 mg/kg dry weight (EU, 2018). These maximum concentrations may be outlier values as the majority of the remaining measurements in both digestate and compost are <200 mg/kg dry weight (approximate mid-range values are 50 mg/kg dry wt. in compost and 61 mg/kg dry weight in digestate).

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. The assessment estimates exposures for the following realistic worst case scenario:

- A conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background. The proposed FPR limit value is below the maximum reported concentrations (see summary of findings below).

Table 3.26 Reported occurrence of copper in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Composts - data availability		Most of data from one study in DE-Bavaria. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤110 mg/kg dry wt. for compost from biowaste and green waste, ≤110 mg/kg dry wt. green waste compost, ≤350 mg/kg dry wt. for sewage sludge compost and

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
		≤210 mg/kg dry wt. in mechanical biological treatment compost.
Compost - minimum concentration	3.4	No minimum value given – assumed 1/10 of the lowest median (34.4 mg/kg dry wt.)
Compost - mid-range or average concentration	50	Approximate mid-point of median values.
Compost - maximum concentration	350	Proposed FPR limit value 200 mg/kg dry weight. The maximum reported value is above this limit.
Digestates - data availability		Most of data from one study in DE-Bavaria and one in Norway. A study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤325 mg/kg dry wt. for digestate from biowaste and green waste and ≤50 mg/kg dry wt. in mechanical biological treatment digestate. Data for UK gives maximum of 0.041 kg/ha and with a limit value (PAS110; WRAP) of 4.8 kg/ha and commented that the quantities applied in digestates are very low and will have little effect on soil concentration.
Digestate - minimum concentration	2.9	No clear minimum – assumed 1/10 of the lowest median (28.7 mg/kg dry wt.)
Digestate - mid-range or average concentration	61	Approximate mid-point of median/mean values
Digestate - maximum concentration	981.3	Highest value may be an outlier. The next highest value is 151 mg/kg dry wt. Proposed FPR limit value 200 mg/kg dry weight. The maximum value reported is above this limit.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.27 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	441,000
Mass of substance in EU-28 in digestate (kg/year)	2,152,080
Total regional emission to surface water (kg/day)	20
Total regional emission to soil (kg/day)	691
Total continental emission to surface water (kg/day)	179
Total continental emission to agricultural soil (kg/day)	6215

Table 3.28 presents the reported regional background concentrations of copper, taking into account all sources of copper. The data are taken from SCHER (2008).

Table 3.28 Reported background concentrations of copper in the environment

PECregional	Value	Remarks
Air	~10^{-4} ng/m^3	
Surface water	2.9 µg/l as dissolved Cu 4.5 µg/l as total Cu	Range of medians for individual countries 0.5-4.7 µg/l as dissolved Cu and 1.8-18.3 µg/l as total Cu
Sediment	67.5 mg Cu/kg dry wt.	Range of medians for individual countries: 45.8-88.3 mg/kg dry wt.
Agricultural soil	14.2 mg Cu/kg dry wt. (50th percentile value) - Agricultural soil 15.9 mg Cu/kg dry wt. (50th percentile value) - Grassland	90th percentile 31.2 mg/kg dry wt - agricultural soil, and 32.8 mg/kg dry wt. - grassland.
Soil pore water/ground water	No data	
Natural soil	Forest soil 10.7 mg Cu/kg dry wt. (50th percentile)	90th percentile 24.4 mg Cu/kg dry wt..
Urban/industrial soil		
Other relevant data	Surface water: median 0.88 µg/l as dissolved Cu Sediment: median 21 mg/kg dry wt. Soil: 12 mg/kg dry wt.	Natural background concentrations (concentrations resulting from predominantly natural sources).

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of copper resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.29.

Table 3.29 Predicted exposures for copper arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.73E+01	[mg/kg dry wt.]
PECgrassland soil	7.54E+00	[mg/kg dry wt.]
PEC in groundwater	8.18E-03	[mg/l]
PECfreshwater	2.46E-03	[mg/l]
PECfreshwater-sediment	7.44E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	No calculation possible – see text	[mg.kg-1.d-1]

Humans via the environment: daily dose via drinking water	2.34E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	No calculation possible – see text	
Secondary poisoning – freshwater fish-eating birds and mammals	No calculation possible – see text	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	No calculation possible – see text	[mg.kg-1]

	Scenario II	**Units**
PECagricultural soil	1.17E+02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	No calculation possible – see text	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	No calculation possible – see text	
Secondary poisoning – worm-eating birds and mammals	No calculation possible – see text	[mg.kg-1]

Table 3.30 presents the results of the quantitative risk characterisation for water, sediment and soil, along with the predicted steady state mass balance in the region and the continent.

Table 3.30 Quantitative risk characterisation conclusions for copper in compost and digestates

	Scenario I
RCR for local soil	2.37E-01
RCR for local freshwater	3.15E-01
RCR for local freshwater-sediment	4.27E-01
RCR for Humans via the environment: local total daily intake	No calculation possible – see text
RCR for fish-eating birds and mammals (fresh water)	No calculation possible – see text
RCR for worm-eating birds and mammals	No calculation possible – see text

	Scenario II
RCR for local soil	1.59E+00
RCR for Humans via the environment: local total daily intake	No calculation possible – see text
RCR for worm-eating birds and mammals	No calculation possible – see text

	Regional
RCR for regional soil	4.73E-01

RCR for regional freshwater	1.64E-01
RCR for regional freshwater-sediment	8.88E-01

	Steady state mass	Units
Total steady-state mass (region + continent)	2.50E+06	[t]
Steady-state mass in regional freshwater (kg)	6.69E+03	[kg]
Steady-state mass in regional seawater (kg)	7.11E+02	[kg]
Steady-state mass in regional air (kg)	2.36E+01	[kg]
Steady-state mass in regional agricultural soil (kg)	2.49E+08	[kg]
Steady-state mass in regional natural soil (kg)	8.29E+05	[kg]
Steady-state mass in regional industrial soil (kg)	3.07E+05	[kg]
Steady-state mass in regional freshwater sediment (kg)	6.95E+05	[kg]
Steady-state mass in regional seawater sediment (kg)	2.80E+04	[kg]
Steady-state mass in continental freshwater (kg)	8.81E+04	[kg]
Steady-state mass in continental seawater (kg)	1.91E+06	[kg]
Steady-state mass in continental air (kg)	3.78E+02	[kg]
Steady-state mass in continental agricultural soil (kg)	2.23E+09	[kg]
Steady-state mass in continental natural soil (kg)	6.71E+06	[kg]
Steady-state mass in continental industrial soil (kg)	2.48E+06	[kg]
Steady-state mass in continental freshwater sediment (kg)	9.16E+06	[kg]
Steady-state mass in continental seawater sediment (kg)	3.76E+06	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)		

Steady-state mass fraction in regional freshwater (%)	2.24E-04	[%]
Steady-state mass fraction in regional seawater (%)	2.38E-05	[%]
Steady-state mass fraction in regional air (%)	7.91E-07	[%]
Steady-state mass fraction in regional agricultural soil (%)	8.32E+00	[%]
Steady-state mass fraction in regional natural soil (%)	2.78E-02	[%]
Steady-state mass fraction in regional industrial soil (%)	1.03E-02	[%]
Steady-state mass fraction in regional freshwater sediment (%)	2.33E-02	[%]
Steady-state mass fraction in regional seawater sediment (%)	9.36E-04	[%]
Steady-state mass in continental freshwater (kg)	2.95E-03	[%]
Steady-state mass in continental seawater (kg)	6.40E-02	[%]
Steady-state mass in continental air (kg)	1.27E-05	[%]
Steady-state mass in continental agricultural soil (kg)	7.47E+01	[%]
Steady-state mass in continental natural soil (kg)	2.24E-01	[%]
Steady-state mass in continental industrial soil (kg)	8.31E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	3.07E-01	[%]
Steady-state mass in continental seawater sediment (kg)	1.26E-01	[%]

The RCRs for water and sediment are all <1 in the realistic worst case assessment, indicating a low risk from the use of C/D containing copper at the levels currently present. For soil, the RCRs based on the maximum reported concentrations of copper are <1 for scenario I but just over 1 (RCR 1.59) for scenario II. The calculation for scenario II is based on a copper content in the compost of 350 mg/kg dry weight. This value is above the proposed FPR limit value of 200 mg/kg dry weight, and the majority of the other measured data are below this limit value. It is therefore not clear if the value of 350 mg/kg is representative of current levels of copper in composts, or is an outlier value. If the maximum copper content in compost is assumed to be up to <200 mg/kg dry weight as a maximum, the RCR for soil for scenario II reduces to <0.9. Thus it can be concluded that at concentrations up to the proposed FPR limit value of 200 mg/kg would present a low risk to soil in this scenario.

Copper is an essential element and the levels within an organism are controlled by homeostasis. Therefore, accumulation through the food chain is not a relevant concept for copper and no assessment of secondary poisoning is carried out. This is in line with the approach used in ECI (2008). For the exposure of man via the environment, the uptake of copper from soil into plants is complicated as homeostasis reduces the concentrations at higher soil concentrations. Therefore, it is not possible to reliably quantify the exposure of man via the environment from the use of C/D.

The risk characterisation for man exposed via the environment carried out in ECI (2008) used measured data on the concentrations of copper in drinking water as a realistic worst case (leaching from copper pipes was considered to be the main source of dietary exposure from copper). No risks to man exposed via the environment were identified in ECI (2008) using this approach. Therefore, it is considered that dietary intake of copper from plants grown on compost- or digestate-amended soils would not contribute significantly to the risks from dietary copper.

The realistic worst case regional concentration in agricultural soil predicted for the use of C/D is 30.5 mg/kg wet weight (34.5 mg/kg dry weight). For comparison, ECI (2008) gives the regional background concentration from all sources as 14.2 mg/kg dry weight in agricultural soil and 15.9 mg/kg dry weight in grassland (both 50th percentile measured values). Therefore, the copper from C/D contributes up to around twice the amount of the background level of copper present in soil.

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.31 below presents the summary of key findings from the risk assessment of copper that has been made in this project. The findings are discussed further below the table.

Table 3.31 Summary of key findings for exposure of copper via use of compost and digestates

Key findings of the risk assessment of copper in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Up to 980 mg/kg dry wt. More typically 50-60 mg/kg dry wt.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). It is not possible to differentiate whether natural or anthropogenic in origin[23].
Safe limit concentration in compost and digestate	200 mg/kg dry weight for compost for container growing

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[23] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

Key findings of the risk assessment of copper in contaminated composts and digestates	
Main concern(s) arising	Soil organisms for compost for container growing. Cumulative loads at steady state.
Effects considered in the main concern hazard(s)	PNEC for soil organism is estimated statistically from a species sensitivity distribution of the available toxicity data for plants, soil invertebrates and soil microorganisms.
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Copper is an essential element. Therefore, accumulation through the food chain is not a relevant concept for copper and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out. The copper from C/D contributes up to around twice the amount of the background level of copper present in soil.

The realistic worst case analysis carried out indicates RCRs <1 for water, sediment and soil in scenario I for both C/D. However, the highest concentration measured in compost would lead to a RCR of 1.02 for soil for scenario II. The highest concentration measured in compost is above the proposed FPR limit value for copper (200 mg/kg dry wt), and therefore it is unclear if this concentration represents current typical levels in soil. Most of the other available measured data show that the concentration of copper measured in C/D is below this limit value, and the resulting RCR for soil in scenario II is <1 for copper concentrations in compost ≤200 mg/kg dry wt. Therefore, it can be concluded that if the C/D meets the proposed FPR limit value, the risk to water, sediment and soil would be low in both scenarios.

Copper is an essential element and the levels within an organism are controlled by homeostasis. Therefore, accumulation through the food chain is not a relevant concept for copper and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out. The contribution from C/D to the total background levels of copper present in soil from all sources is significant. At steady state, 84% of the total mass remains within the region + continent[24], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D. The realistic worst case mass of copper in the region + continent at steady state as a result of use of C/D is estimated to be around 2.5×10^9 kg assuming that all compost contains copper at the mid-range of the levels that have been measured. This steady-state mass amounts to 960 times the mass released annually via application of composts and digestates[25].

3.6 Zinc (Zn)

Background information and remarks

Zinc metal (7740-66-6) has been subject to a comprehensive EU risk assessment (EC, 2010a).

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[24] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[25] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

Chemical properties and hazards data set

The relevant property data are summarised in Table 3.32 below. The data are taken mainly from EC (2010). Where information from other sources is included this is indicated in the Table.
The EU harmonised CLP classification for zinc dust (pyrophoric) is: Pyr. Sol. 1 – H250; Water-react.1 - H260; Aquatic Acute 1 – H400; Aquatic Chronic 1 – H410.

Table 3.32 Property information for zinc (from EC (2010) unless otherwise indicated)

Property	Value	Comment
Molecular weight	65.38 g/mole	
Melting point	420°C	
Boiling point	908°C	
Vapour pressure	31 Pa at 450°C assumed to be negligible at 20°C	
Water solubility	Practically insoluble to soluble	Solubility varies with the salt. This should not affect the assessment as the Henry's law constant has been set to be very low.
log Kow	Not relevant for metals	
Henry's law constant	Assumed to be very low	
Koc	Koc not relevant for metals Kp = 110000 l/kg for suspended sediment Kp = 73000 l/kg for sediment Kp = 158 l/kg for soil	Kp values are measured solids-water partition coefficients and are used directly in the EUSES modelling.
BCF	BCF not applicable owing to homeostasis	See text
Biodegradability	Not applicable. Assumed to be not degradable.	
Half-life in air	Not relevant	
PNECs	$PNEC_{water}$ = 7.8 µg/l as dissolved zinc $PNEC_{sediment}$ = 49 mg/kg dry wt. $PNEC_{soil}$ = 26 mg/kg dry wt. PNECoral – no concern for secondary poisoning owing to zinc homeostasis	The PNECs refer to added zinc (i.e. zinc added above the background concentration). $PNEC_{water}$ for very soft water is 3.1 µg/l as dissolved zinc
DNEL		See text
Other relevant data	Zinc is an essential element	

The EUSES model uses the octanol-water partition coefficient (log Kow) in order to model the uptake into fish and earthworms for the assessment of secondary poisoning and to model the uptake from soil into the human food chain. This approach is not appropriate for metals such as zinc as the log Kow is not applicable to such metals and their inorganic salts. Instead, it is necessary to model the uptake into the food chain using appropriate accumulation factors, in many cases outside of the EUSES program. The relevant accumulation factors for zinc are discussed in the section on generic exposure outcomes below.

Occurrence data set

Table 3.33 presents a summary of the reported concentrations of zinc in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. Consultation and literature research suggest contamination rates of zinc up to 1098 mg/kg dry weight in digestate and 650 mg/kg dry weight in compost. The proposed FPR limit value is 600 mg/kg dry weight (EU, 2018). The highest values measured in C/D are above this limit value however most of the other measured data are below this limit. It is not clear if the value of 1098 mg/kg dry weight is representative of the current maximum level likely or is an outlier.
These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background. The proposed FPR limit value is lower than the maximum reported concentration in both digestate and compost (see summary of findings below).
- A less conservative assessment is derived separately using a minimum concentration used in estimating the regional background. This scenario is used to further define the regional background concentration.

Table 3.33 Reported occurrence of zinc in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Composts - data availability		Most of data from one study in DE-Bavaria. Another study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤250 mg/kg dry wt. for compost from biowaste and green waste, ≤200 mg/kg dry wt. green waste compost, ≤650 mg/kg dry wt. for sewage sludge compost and ≤500 mg/kg dry wt. in mechanical biological treatment compost.
Compost - minimum concentration	13.6	No minimum given – assumed 1/10 of the lowest median (136 mg/kg dry wt.)
Compost - mid-range or average concentration	197	Approximate mid-point of the range of medians
Compost - maximum concentration	650	Highest actual (non-limit) value reported. One sample is stated to be 1000 mg/kg but this looks to be an outlier. Proposed FPR limit value 600 mg/kg dry wt. Other limit values in Germany reported in LFU (2016) are 5000 mg/kg dry wt. (DüMV, 2012 and 2015), 200 mg/kg dry weight (quality assured Fachvereinigung Bayerischer Komposthersteller e.V (FBK, 2015)), and 200 mg/kg dry wt. (quality assured EU Öko-V (2008)).

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Digestates - data availability		
Digestate - minimum concentration	132	
Digestate - mid-range or average concentration	276	
Digestate - maximum concentration	1098	Proposed FPR limit value is 600 mg/kg dry wt. The highest reported concentration is above this value.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.34 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	1,737,540
Mass of substance in EU-28 in digestate (kg/year)	9,737,280
Total regional emission to surface water (kg/day)	88
Total regional emission to soil (kg/day)	3056
Total continental emission to surface water (kg/day)	792
Total continental emission to agricultural soil (kg/day)	27,501

The reported regional background concentrations of zinc, taking into account all sources of zinc, are shown in Table 3.35. The data are taken from EC (2010).

Table 3.35 Reported background concentrations of zinc in the environment

PECregional	Value	Remarks
Air	0.04 μg/m^3	Based on measured data. Natural background component is assumed to be negligible.
Surface water	6.7-8.8 μg/l	Based on monitoring data. Dissolved concentration. PNEC.
Sediment		Regional PEC was not defined for the added risk approach used in EC (2010)
Agricultural soil		Regional PEC was not defined for the added risk approach used in EC (2010)
Soil pore water/ground water	No data	
Natural soil	0.5 mg/kg wet wt.	Calculated PECadd value.
Urban/industrial soil		Regional PEC was not defined for the added risk approach used in EC (2010)

PECregional	Value	Remarks
Other relevant data	Surface water: 3-12 µg/l. Sediment: 140 mg/kg dry wt. (range 70-175 mg/kg dry wt.) Soil: Large variation in natural background in soil - 140 mg/kg dry wt. for Dutch reference soil Air: <1 µg/m^3.	Natural background concentrations (concentrations resulting from predominantly natural sources).

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of zinc resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.36.

Table 3.36 Predicted exposures for zinc arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.80E+01	[mg/kg dry wt.]
PECgrassland soil	7.06E+00	[mg/kg dry wt.]
PEC in groundwater	1.14E-01	[mg/l]
PECfreshwater	2.99E-03	[mg/l]
PECfreshwater-sediment	3.29E+02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	No calculation possible – see text	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	3.25E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	No calculation possible – see text	
Secondary poisoning – freshwater fish-eating birds and mammals	No calculation possible – see text	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	No calculation possible – see text	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	2.15E+02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	No calculation possible – see text	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	No calculation possible – see text	
Secondary poisoning – worm-eating birds and mammals	No calculation possible – see text	[mg.kg-1]

Table 3.37 presents the results of the quantitative risk characterisation along with the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.37 Quantitative risk characterisation conclusions for zinc in composts and digestates

Scenario I	
RCR for local soil	6.91E-01
RCR for local freshwater	3.83E-01
RCR for local freshwater-sediment	6.71E+00
RCR for Humans via the environment: local total daily intake	No calculation possible – see text
RCR for fish-eating birds and mammals (fresh water)	0.00E+00
RCR for worm-eating birds and mammals	0.00E+00

Scenario II	
RCR for local soil	8.25E+00
RCR for Humans via the environment: local total daily intake	No calculation possible – see text
RCR for worm-eating birds and mammals	0.00E+00

Regional	
RCR for regional soil	7.66E-01
RCR for regional freshwater	2.90E-01
RCR for regional freshwater-sediment	1.02E+01

	Steady state mass	Units
Total steady-state mass (region + continent)	1.51E+06	[t]
Steady-state mass in regional freshwater (kg)	2.16E+04	[kg]
Steady-state mass in regional seawater (kg)	2.19E+03	[kg]
Steady-state mass in regional air (kg)	4.68E-20	[kg]
Steady-state mass in regional agricultural soil (kg)	1.43E+08	[kg]
Steady-state mass in regional natural soil (kg)	1.54E-06	[kg]
Steady-state mass in regional industrial soil (kg)	5.70E-07	[kg]
Steady-state mass in regional freshwater sediment (kg)	4.48E+06	[kg]

Steady-state mass in regional seawater sediment (kg)	2.32E+05	[kg]
Steady-state mass in continental freshwater (kg)	2.48E+05	[kg]
Steady-state mass in continental seawater (kg)	3.53E+06	[kg]
Steady-state mass in continental air (kg)	4.24E-19	[kg]
Steady-state mass in continental agricultural soil (kg)	1.29E+09	[kg]
Steady-state mass in continental natural soil (kg)	7.02E-06	[kg]
Steady-state mass in continental industrial soil (kg)	2.60E-06	[kg]
Steady-state mass in continental freshwater sediment (kg)	5.14E+07	[kg]
Steady-state mass in continental seawater sediment (kg)	1.88E+07	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)		
Steady-state mass fraction in regional freshwater (%)	7.76E-04	[%]
Steady-state mass fraction in regional seawater (%)	7.86E-05	[%]
Steady-state mass fraction in regional air (%)	1.68E-27	[%]
Steady-state mass fraction in regional agricultural soil (%)	5.15E+00	[%]
Steady-state mass fraction in regional natural soil (%)	5.53E-14	[%]
Steady-state mass fraction in regional industrial soil (%)	2.05E-14	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.61E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	8.36E-03	[%]
Steady-state mass in continental freshwater (kg)	8.91E-03	[%]
Steady-state mass in continental seawater (kg)	1.27E-01	[%]
Steady-state mass in continental air (kg)	1.52E-26	[%]
Steady-state mass in continental agricultural soil (kg)	4.64E+01	[%]
Steady-state mass in continental natural soil (kg)	2.52E-13	[%]

Steady-state mass in continental industrial soil (kg)	9.35E-14 [%]
Steady-state mass in continental freshwater sediment (kg)	1.85E+00 [%]
Steady-state mass in continental seawater sediment (kg)	6.75E-01 [%]

The realistic worst case RCRs for water and soil for scenario I, indicating a low risk from the use of C/D for water and soil. However, the RCRs are >1 for sediment for scenario I and soil for scenario II. These are based on a maximum concentration in digestate of 1098 mg/kg dry weight and a maximum concentration in compost of 650 mg/kg dry wt. Further, the realistic worst case approach leads to a regional RCR of 10.2 for sediment when the approximately mid-range concentration in C/D is considered. When the regional RCRs are calculated using a more conservative scenario assuming that the concentration in C/D is at the minimum level reported the regional RCR is reduced to 4.2.

It is important to note that the regional RCRs have a high uncertainty associated with them. The calculations are steady-state calculations assuming a continuous input of zinc. The timescales involved before steady-state is reached (in the model) are large and may run and may be over hundreds if not thousands of years and are highly uncertain. The regional concentrations predicted also impact on the local RCRs as they act as the background concentration for the local concentrations. There is also some uncertainty resulting from the form of zinc at the regional level; this may not necessarily be bioavailable.

The potential uncertainties in the regional background for zinc were considered in EC (2010) and in that risk assessment the PNECs were all defined in terms of added zinc, that is freshly added zinc over that present in the background. This effectively ignores the regional background concentration and focuses more on the concentration resulting from the freshly added zinc over that of the background concentration. This is known as the "added risk approach".

When the added risk approach is used for the current scenarios, RCRs >1 are still obtained in the realistic worst case scenarios for sediment for scenario I and soil for scenario II. For scenario I this is based on the highest measured digestate concentration of 1098 mg/kg dry weight. This concentration is above the proposed FPR limit value of 600 mg/kg dry weight. When the concentration in digestate is ≤600 mg/kg dry weight the RCR for sediment for scenario I is ≤0.89. For scenario II the concentration in compost would need to be ≤70 mg/kg dry weight in order to achieve RCRs <1 for soil. For comparison, the approximate mid-range concentration measured in compost is higher than this limit (mid-range concentration around 197 mg/kg dry weight).

Zinc is an essential element and the levels within an organism are controlled by homeostasis. Therefore, accumulation through the food chain is not a relevant concept for zinc and no assessment of secondary poisoning is carried out. This is in line with the approach used in EC (2010).
The human health parts of the EU risk assessment for zinc (EC 2010) are not publicly available and so the approach taken in the EU risk assessment for man exposed via the environment is unclear.

Similar to copper, the uptake of zinc from soil into plants is complicated as homeostasis will tend to reduce the concentrations in plants at higher soil concentrations. Therefore, it is not possible to reliably quantify the exposure of man via the environment from the use of C/D.

The conclusions of the risk characterisation for man exposed via the environment carried out in EC (2010) reported no risk to man via the environment from exposure via the food chain from the industrial use of zinc, including from agricultural activities (e.g. the presence in fertiliers). Therefore, it is considered that dietary intake of zinc from plants grown on compost- or digestate-amended soils would not contribute significantly to the risks from dietary zinc.

The realistic worst case regional concentration in agricultural soil predicted for the use of C/D is 17.6 mg/kg wet weight (19.9 mg/kg dry weight). For comparison, EC (2010) gives the natural background concentration (e.g. the concentration resulting from natural sources alone) as up to 140 mg/kg dry weight, although it was noted that there was a large variation in this value. Therefore, the concentration in soil resulting from zinc from C/D is less than the natural background (around 14%), and this strengthens the above conclusion that C/D would not significantly contribute to the risks from dietary zinc.

EC (2010) also considers the input of zinc from soil from agricultural uses (including presence in fertilisers) and estimates that the total input to soil from all agricultural uses was around 17,000 tonnes/year (equivalent to an input of 0.124 kg zinc/ha across the EU). The amount of zinc input to soil from use in C/D is estimated to be around 1,700 tonnes/year assuming the mid-range concentration. Again, this suggests that the input of zinc to soil from C/D is relatively small (around 10%) compared with other sources.

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is 1.1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.38 below presents the summary of key findings from the risk assessment of zinc that has been made in this project. The findings are discussed further below the table.

Table 3.38 Summary of key findings for exposure of zinc via use of compost and digestates

Key findings of the risk assessment of zinc in contaminated composts and digestates	
Overall range of compost and digestate concentrations	132 to 1098 mg/kg dry wt. Median values typically around 200-280 mg/kg dry wt.
Major raw material sources	Only limited data are available. Concentrations broadly similar across different raw material sources (renewable raw materials, co-digestion, biowaste and green waste, and solid and liquid biowaste). It is not possible to differentiate whether natural or anthropogenic in origin[26].
Safe limit concentration in compost and digestate	600 mg/kg dry weight for application of compost or digestate to agricultural land. 70 mg/kg dry weight for compost used in container growing.

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[26] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

Key findings of the risk assessment of zinc in contaminated composts and digestates	
Main concern(s) arising	Sediment for scenario I, related to application of compost or digestate onto agricultural land. Soil for scenario II, related to compost use in container growing. High cumulative loads at steady state and high predicted regional RCRs in sediment.
Effects considered in the main concern hazard(s)	PNEC for sediment is derived from survival and growth data for benthic organisms. PNEC for soil is based on toxicity to soil microbial processes, plants and soil inverbrates derived from species sensitivity distributions.
Uncertainties and their implications	Small occurrence data set covering limited number of countries. Uncertainties over the risk at the regional level. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Zinc is an essential element. Therefore, accumulation through the food chain is not a relevant concept for zinc and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out. The input of zinc to agricultural soil from C/D is relatively small (around 10% of the total) compared with other sources.

The realistic worst case analysis carried out indicates RCRs <1 for water and soil for scenario I, indicating a low risk. However the realistic worst case analysis results in RCRs >1 for sediment for scenario I and soil for scenario II. RCRs >1 are also indicated for sediment at a regional level when calculated using the approximate mid-range concentration in C/D, however the regional risk assessment for zinc is highly uncertain.

When the added risk approach is used, RCRs for scenario I for sediment, water and soil are all <1 when the concentration in digestate or compost is limited to ≤600 mg/kg dry weight, which corresponds to the proposed limit value for FPR for zinc (EU, 2018). This shows that the proposed limit value would be sufficient to control the risks from this scenario. For scenario II (which relates to compost only), the concentration in compost would need to be limited to ≤70 mg/kg dry weight in order to achieve RCRs <1. This is below the proposed FPR limit value, and also lower than the approximate mid-range of the measured data.

Zinc is an essential element and the levels within an organism are controlled by homeostasis. Therefore, accumulation through the food chain is not a relevant concept for zinc and no quantitative assessment of secondary poisoning or man exposed via the environment is carried out.

The contribution from C/D to the total background levels, including other agricultural uses and natural sources, of zinc present in soil from all sources is small. The total EU input of zinc into agricultural soil from C/D (assuming the concentration present is around the mid-range level) estimated to be around 1,700 tonnes; this compares with an estimate of the total EU input of zinc into agricultural soil of 17,000 tonnes from all agricultural uses. The natural background of zinc in soil is also relatively high. At steady state, 54% of the total mass remains within the region + continent[27], suggesting that there is

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[27] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

some transfer over long distances following release via the handling and application of C/D[28]. The realistic worst case mass of zinc in the region + continent at steady state as a result of use of C/D is estimated to be around 1.51×10^9 kg assuming that all compost contains zinc at the mid-range of the levels that have been measured. This steady-state mass amounts to 130 times the mass released annually via application of composts and digestates[29].

3.7 Mercury (Hg)

Background information and remarks

Mercury (CAS 7439-97-6) has been subject to a number of international health and or environmental evaluations including those carried out by the World Health Organization under the International Programme on Chemical Safety (WHO, 1976, 1989a, 1990 and 1991), United Nations Environment Programme (UNEP, 2013) and evaluations of dietary intake undertaken by the European Food Safety Authority (EFSA, 2008a and 2012b). These evaluations have been used as the basis of the chemical properties and hazard data set for mercury.

In the environment, mercury can undergo biological methylation to form methyl-mercury compounds, which is a more bioaccumulative form of mercury. Therefore the properties of methyl-mercury compounds have also been considered in relation to the assessment of secondary poisoning and exposure of man via the environment.

The EU has adopted a Community Strategy on Mercury[30]. The strategy includes a comprehensive plan aimed at addressing mercury use and pollution. The European Union is also a signatory to the Minamata Convention on Mercury[31]. The Minamata Convention is a global treaty to protect human health and the environment from the adverse effects of mercury and entered into force on 16 August 2017.

Chemical properties and hazards data set

The relevant property data are summarised in Table 3.39 below. Based on global cycling (see below), assess the concentrations in water, soil, air and sediment in terms of elemental Hg but secondary poisoning and fish based on the appropriate log Kow and BCFs for dimethyl mercury.
The EU harmonised CLP classification for mercury is: Acute Tox. 2; STOT RE 1 – H372; Repr. 1B; Aquatic Acute 1 – H400; Aquatic Chronic 1 – H410.

Table 3.39 Property information for mercury

Property	Value	Comment
Molecular weight	200.59 g/mol - elemental 251.1 g/mol - methylmercury chloride	EFSA (2008a).

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[28] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[29] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

[30] Community Strategy Concerning Mercury. Communication from the Commission to the Council and the European Parliament. COM (2005) 20 final. http://ec.europa.eu/environment/chemicals/mercury/strategy_en.htm

[31] http://www.mercuryconvention.org/Countries/tabid/3428/Default.aspx

Property	Value	Comment
	230.7 g/mol - dimethyl mercury	
Melting point	-38.8°C – elemental	
Boiling point		
Vapour pressure	0.18 Pa at 20°C - elemental 1.76 Pa at 25°C - methylmercury chloride 8300 Pa at 25°C - dimethyl mercury	EFSA (2008a).
Water solubility	5.6×10^{-5} g/l at 25°C - elemental 5-6 g/l at 25°C - methylmercury chloride Practically insoluble - dimethyl mercury	EFSA (2008a). Dimethyl mercury is thermodynamically unstable in water below pH 5 and is spontaneously converted to methyl mercury.
log Kow	0.62 - elemental 0.41 - methylmercury chloride 2.28 - dimethyl mercury	EFSA (2008a).
Henry's law constant	729 Pa m^3/mol at 20°C - elemental 0.038 Pa m3/mol at 15°C and pH 5.2 - methylmercury chloride 646 Pa m3/mol at 25°C - dimethyl mercury"	
Koc	Kp = 6,300 l/kg for soil (same value assumed for sediment and suspended sediment)	Much of mercury in natural waters is strongly bound to sediment or organic material and is unavailable to organisms (WHO, 1989a). Kp values are measured solids-water partition coefficients and are used directly in the EUSES modelling. The Kp value is taken from the dissemination dossier for mercury available on the ECHA website.
BCF	BCF for fish ~8000 l/kg BMF 10 BAF plant leaves 0.002-0.03 BAF plant roots 0.05-0.12"	For methyl mercury. WHO (1990) gives bioaccumulation factors of 10,000-100,000 for fish including biomagnification. Plant BAFs are based on concentration in plant/concentration in soil, both on a dry weight basis.
Biodegradability	Assumed not be biodegradable	
Half-life in air	Assumed not to be degradable	
PNECs	Maximum allowable concentration MAC-EQS = 0.07 µg/l EQS for biota = 20 µg/kg wet weight.	No PNECs have been derived in EU Risk Assessment reports. Directive 2008/105/EC[a] sets maximum allowable concentration MAC-EQS 0.07 µg/l for surface water and an EQS for biota of 20 µg/kg wet weight (Directive 2008/105/EC as amended

Property	Value	Comment
		(2013/39/EU)). The EQS values are for mercury and its compounds. No published PNECs have been located for sediment or soil. WHO (1989a) summarises the available terrestrial toxicity data but indicates that the data are difficult to interpret and may not reflect the field situation. Therefore it is not currently possible to carry out a meaningful qualitative assessment for the soil and sediment compartment.
DNEL	TWI = 4 µg Hg/kg bw/week for inorganic mercury TWI = 1.3 µ Hg/kg bw/week for methyl mercury	EFSA Tolerable Weekly Intake (TWI) values (EFSA, 2012).
Other relevant data	Limit value for drinking water 1 µg/l (Council Directive 98/83/EC). Maximum levels (ML) in fish for mercury are 0.5 mg/kg wet wt or 1 mg/kg wet wt depending on species (Commission Regulation (EC) No 1881/2006 amended by Commission Regulation (EC) No 629/2008).	EFSA (2012)

Note: a) Environmental Quality Standard (EQS) set under Directive 2008/105/EC (EU, 2008) or proposed EQS (EC, 2012).

Occurrence data set

Table 3.40 presents a summary of the reported concentrations of mercury in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. Consultation and literature research suggest that contamination rates of mercury between <0.018 and 0.21 mg/kg dry weight to in digestate and 0.085 and 0.98 in compost. The proposed FPR limit value is 1 mg/kg dry weight (EU, 2018) and all of the measured data are below this value.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for the following realistic worst case concentration scenario:

- A conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background. The proposed FPR limit value is slightly higher than the maximum reported concentrations (see summary of findings below).

Table 3.40 Reported occurrence of mercury in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
Composts - data availability		One study from DE-Bavaria. Input material greenwaste or biowaste. Data may show a declining trend over the years 2000 to 2013/14 but cannot be certain owing to limited data.

Concentrations in composts/digestates	Value - units of mg/kg dry wt	Remarks
		Another study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finnland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values for concentration of ≤0.175 mg/kg dry wt for compost from biowaste and green waste, ≤0.19 mg/kg dry wt. green waste compost, ≤0.51 mg/kg dry wt. for sewage sludge compost and ≤0.60 mg/kg dry wt. in mechanical biological treatment compost.
Compost - minimum concentration	0.0085	Minimum values not given. The value used corresponds to the lowest median of 0.085. Have assumed the actual minimum is 1/10 of this value.
Compost - mid-range or average concentration	0.13	Approximate mid-point of the range of median values.
Compost - maximum concentration	0.98	Proposed FPR limit value 1 mg/kg dry wt. Highest measured value is just below this limit.
Digestates - data availability		Data from DE-Bavaria and Norway. Also another study from Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Italy, Luxembourg, Malta, Netherlands, Portugal, Sweden, UK, Switzerland gives upper limit values of ≤0.21 mg/kg dry wt. in digestate derived from biowaste and green waste and also from mechanical biological treatment.. Data for UK gives maximum of 0.002 kg/ha and with a limit value (PAS110; WRAP) of 0.024 kg/ha and commented that the quantities applied in digestates are very low.
Digestate - minimum concentration	<0.018	Lowest median value.
Digestate - mid-range or average concentration	0.095	Approximate mid-point of the range of median values.
Digestate - maximum concentration	0.21	Proposed FPR limit value 1 mg/kg dry wt.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.41 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	1147
Mass of substance in EU-28 in digestate (kg/year)	3352
Total regional emission to surface water (kg/day)	0.035
Total regional emission to soil (kg/day)	1.2
Total continental emission to surface water (kg/day)	0.31
Total continental emission to agricultural soil (kg/day)	10.8

The reported background concentrations of mercury, taking into account all sources of mercury, are shown in Table 3.42. The data are taken from a number of sources as indicated in the Table.

Table 3.42 Reported background concentrations of mercury in the environment

PECregional	Value	Remarks
Air	1.5-1.7 ng/m^3	Natural background level in Northern Hemisphere. EFSA (2012)
Surface water	1-20 ng/l <5 ng/l	Total background mercury in freshwater is 1-20 ng/l (EFSA, 2012). EFSA (2008) gives concentration in uncontaminated freshwater as <5 ng/l total mercury. EFSA (2012): methyl mercury can contribute up to 30% of the total mercury in freshwaters.
Sediment		Levels at uncontaminated sites similar to levels in soil. Contribution of methyl mercury to total mercury in sediments is about 1-1.5%. (EFSA, 2012; WHO, 1976)
Agricultural soil	0.02-0.4 mg/kg dry wt.	"Normal" range in agricultural soils from EFSA (2008a).
Soil pore water/ground water	No data	
Natural soil	0.02-0.625 mg/kg dry wt.	General background levels in soil (WHO, 1989a)
Urban/industrial soil		
Other relevant data		Global emissions to atmosphere in 2010 from human activities 1960 tonnes/year (range 1010-4070 tonnes/year). The EU 27 account for around 4.5% of this or around 87.5 tonnes/year (range 44.5-226 tonnes/year) (UNEP, 2013). Global emissions to air from natural degassing of earths' crust - 2,700-6,000 tonnes/year (WHO, 1990). Anthropogenic sources of mercury emission account for about 30% and re-emission and remobilization account for around 60% of the total amount of mercury entering the atmosphere each year (UNEP, 2013). Global cycling is mainly as inorganic forms but methylation is important for accumulation (WHO, 1990). Monomethyl mercury is predominant product of biological methylation at near neutral pH (WHO, 1989a).

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of mercury resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted realistic worst case environmental exposure concentrations are as summarised in Table 3.43.

Table 3.43 Predicted exposures for mercury arising from use of composts and digestates

	Scenario I	Units

PECagricultural soil	1.33E-02	[mg/kg dry wt.]
PECgrassland soil	4.40E-03	[mg/kg dry wt.]
PEC in groundwater	2.08E-06	[mg/l]
PECfreshwater	1.66E-06	[mg/l]
PECfreshwater-sediment	1.04E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	2.79E-05 (see text)	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	5.95E-08	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Fish 78%	
Secondary poisoning – freshwater fish-eating birds and mammals	6.98E-02	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	6.54E-04	[mg.kg-1]

	Scenario II	**Units**
PECagricultural soil	3.24E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	8.07E-06 (see text)	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Air 74.8%	
Secondary poisoning – worm-eating birds and mammals	1.47E-02	[mg.kg-1]

Table 3.44 presents the results of the quantitative risk characterisation along with the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.44 Quantitative risk characterisation conclusions for mercury in composts and digestates

Scenario I	
RCR for local soil	no estimate possible
RCR for local freshwater	2.37E-02
RCR for local freshwater-sediment	no estimate possible
RCR for Humans via the environment: local total daily intake	see text
RCR for fish-eating birds and mammals (fresh water)	3.49E+00
RCR for worm-eating birds and mammals	3.27E-02

Scenario II

RCR for local soil	no estimate possible
RCR for Humans via the environment: local total daily intake	see text
RCR for worm-eating birds and mammals	7.33E-01

Regional	
RCR for regional soil	no estimate possible
RCR for regional freshwater	1.28E-03
RCR for regional freshwater-sediment	no estimate possible

	Steady state mass	Units
Total steady-state mass (region + continent)	4.24E+02	[t]
Steady-state mass in regional freshwater (kg)	3.55E-01	[kg]
Steady-state mass in regional seawater (kg)	1.29E-01	[kg]
Steady-state mass in regional air (kg)	8.53E+02	[kg]
Steady-state mass in regional agricultural soil (kg)	9.86E+03	[kg]
Steady-state mass in regional natural soil (kg)	1.83E+02	[kg]
Steady-state mass in regional industrial soil (kg)	6.78E+01	[kg]
Steady-state mass in regional freshwater sediment (kg)	1.02E+01	[kg]
Steady-state mass in regional seawater sediment (kg)	1.17E+00	[kg]
Steady-state mass in continental freshwater (kg)	1.12E+01	[kg]
Steady-state mass in continental seawater (kg)	1.84E+04	[kg]
Steady-state mass in continental air (kg)	1.48E+05	[kg]
Steady-state mass in continental agricultural soil (kg)	2.16E+05	[kg]
Steady-state mass in continental natural soil (kg)	1.60E+04	[kg]
Steady-state mass in continental industrial soil (kg)	5.93E+03	[kg]
Steady-state mass in continental freshwater sediment (kg)	3.19E+02	[kg]
Steady-state mass in continental seawater sediment (kg)	8.38E+03	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)		
Steady-state mass fraction in regional freshwater (%)	2.45E-06	[%]

Steady-state mass fraction in regional seawater (%)	8.87E-07	[%]
Steady-state mass fraction in regional air (%)	5.89E-03	[%]
Steady-state mass fraction in regional agricultural soil (%)	6.81E-02	[%]
Steady-state mass fraction in regional natural soil (%)	1.26E-03	[%]
Steady-state mass fraction in regional industrial soil (%)	4.68E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	7.01E-05	[%]
Steady-state mass fraction in regional seawater sediment (%)	8.07E-06	[%]
Steady-state mass in continental freshwater (kg)	7.70E-05	[%]
Steady-state mass in continental seawater (kg)	1.27E-01	[%]
Steady-state mass in continental air (kg)	1.02E+00	[%]
Steady-state mass in continental agricultural soil (kg)	1.49E+00	[%]
Steady-state mass in continental natural soil (kg)	1.10E-01	[%]
Steady-state mass in continental industrial soil (kg)	4.09E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	2.20E-03	[%]
Steady-state mass in continental seawater sediment (kg)	5.79E-02	[%]

For surface water, the realistic worst case assessment results in RCRs <1 for both scenario I and scenario II suggesting the risk to surface water from use of C/D at current levels is low.

Unlike the other metals considered, the accumulative form of mercury is as methyl-mercury compounds, and appropriate log Kow values exist. For secondary poisoning the concentrations in fish have been estimated using an experimental BCF value of 8,000 l/kg (from WHO, 1989a) and a biomagnification factor of 10. The uptake into earthworms has been estimated using the default methods in EUSES.

Using these factors, the RCR is <1 for exposure scenario I for the earthworm food chains but is >1 for the fish food chain, indicating a potential risk. Secondary poisoning via the fish food chain is not relevant for exposure scenario II.

With the exception of fish (for which an experimental BCF value of 8000 l/kg has been used (WHO, 1989a), the uptake into the food chain has therefore been estimated using the default methods within EUSES. This gives the total daily intake for humans as 2.79×10^{-5} mg/kg bw/day for scenario I and 8.07×10^{-6} mg/kg bw/day for scenario II.

For comparison, accumulation factors from soil are available for mercury for plant leaves (0.002-0.03) and plant roots (0.05-0.12), both related to the concentration in plant/concentration in soil on a dry weight basis (WHO, 1990). The predicted concentrations in agricultural soil for scenario I and scenario II are respectively 0.0133 mg/kg dry weight and 0.324 mg/kg dry weight respectively. Therefore, the concentrations in leaf crops can be estimated to be approximately 2.7×10^{-5}-4.0×10^{-4} mg/kg dry weight for scenario I and 6.5×10^{-4}-9.7×10^{-3} mg/kg dry weight. Similarly, the concentrations in root crops can be estimated to be approximately 6.7×10^{-4}-1.6×10^{-3} mg/kg dry weight for scenario I and 0.016-0.039 mg/kg dry weight. Assuming that the leaf crops and root crops are approximately 11% water (as assumed earlier for nickel), and assuming the EUSES default daily intake rates of leaf crops and root crops, the daily human intake can be estimated to be approximately 3.7×10^{-6}-1.4×10^{-5} mg/kg bw/day (0.026-0.097 µg/kg bw/week) for scenario I and 8.9×10^{-5}-3.4×10^{-4} mg/kg bw/day (0.62-2.4 µg/kg bw/week) for scenario I using these data. These values are all below the EFSA Tolerable Weekly Intake (TWI) value for mercury (4 µg Hg/kg bw/week) but the top end of the range for scenario II (very much a worst case estimate) is slightly above the EFSA TWI for methyl mercury of 1.3 µg Hg/kg bw/week only if it is assumed that the crops from this source are eaten every day of the week, which is highly unlikely.

Overall, it is concluded that the use of C/D with the currently assessed levels of mercury are unlikely to lead to a risk to humans through the food chain, but may present a risk to fish-eating birds and mammals in scenario I. In order to control this risk, the maximum concentration of mercury in compost or digestate would need to be limited to ≤0.2 mg/kg dry weight. This value is below the proposed FPR limit value for mercury of 1 mg/kg dry weight (EU, 2018). The highest reported concentration of mercury in digestate is 0.21 mg/kg dry weight, which would lead to RCRs close to, but above 1 for secondary poisoning but the majority of data are below this concentration. The mid-range concentration reported in compost are <0.2 mg/kg dry weight, which would not lead to a risk based on these calculations, but the highest reported concentration in compost (0.98 mg/kg dry weight) would lead to RCRs >1 for secondary poisoning.

It is important to note that no quantitative risk characterisation for sediment or soil has been carried out as reliable PNECs have not been located for sediment or soil.

The regional concentration of mercury in agricultural soil calculated using the mid-range concentration for both C/D is 1.21×10^{-3} mg/kg wet weight (1.4×10^{-4} mg/kg dry weight). The "normal" range of mercury in agricultural soil is 0.02-0.4 mg/kg dry weight. Therefore the overall contribution from C/D to the total concentration of mercury in soil is low.

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.45 below presents the summary of key findings from the risk assessment of mercury that has been made in this project. The findings are discussed further below the table.

Table 3.45 Summary of key findings for exposure of mercury via use of compost and digestates

Key findings of the risk assessment of mercury in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.018-0.98 mg/kg dry wt.
Major raw material sources	The data suggests that the concentrations may be higher with biowaste and green waste, and solid and liquid biowaste as raw material sources than renewable raw

Key findings of the risk assessment of mercury in contaminated composts and digestates	
	materials and co-digestion as raw material sources. However, only very limited data are available. It is not possible to differentiate whether natural or anthropogenic in origin[32].
Safe limit concentration in compost and digestate	0.2 mg/kg dry wt for C/D applied to agricultural land
Main concern(s) arising	Secondary poisoning. Transfer over long distances.
Effects considered in the main concern hazard(s)	Concerns for secondary poisoning are based on the existing EQS for biota. The effects considered in deriving the EQS are not clear.
Uncertainties and their implications	No quantitative risk characterisation for sediment or soil has been carried out. Therefore the risks to these protection goals is unclear. Small occurrence data set covering limited number of countries. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	The overall contribution from C/D to the total concentration of mercury in agricultural soil is low. European Union is a signatory to the UN Minamata Convention on Mercury.

The realistic worst case analysis carried out indicates RCRs <1 for water for scenario I and scenario II, indicating a low risk. However the realistic worst case analysis results in RCRs >1 for secondary poisoning for scenario I. In order to control this risk, the maximum concentration of mercury in compost or digestate would need to be limited to ≤0.2 mg/kg dry weight. This value is below the proposed FPR limit value for mercury. The highest reported concentration of mercury in digestate is 0.17 mg/kg dry weight and the mid-range concentration reported in compost are <0.2 mg/kg dry weight, which would not lead to a risk based on these calculations, but the highest report concentration in compost (0.98 mg/kg dry weight) would lead to RCRs >1 for secondary poisoning.

The contribution from C/D to the total background levels of mercury present in agricultural soil from all sources is small. At steady state, ~3% of the total mass remains within the region + continent[33], suggesting that there is potential for transfer over long distances following release via the handling and application of C/D[34]. The realistic worst case mass of mercury in the region + continent at steady state as a result of use of C/D is estimated to be around 4.24×10^5 kg assuming that all compost contains mercury at the mid-range of the levels that have been measured. This steady-state mass amounts to 10 times the mass released annually via application of composts and digestates[35]. It is

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[32] The presence of heavy metals in compost/digestate could result from natural occurrence, industrial sources or a combination of both. Metals will generally be present (at relatively low levels) in most living matter and survive the processes associated with anaerobic digestion / composting.

[33] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[34] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[35] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) and natural sources, could lead to a different steady state picture.

important to note, however, that a significant proportion (~97%) of the steady-state mass of mercury is predicted to have transported out of the region and continent to more remote areas.

It should be noted that the European Union is a signatory to the UN Minamata Convention on Mercury. The Minamata Convention is a global treaty to protect human health and the environment from the adverse effects of mercury and entered into force on 16th August 2017. Among other things the Convention covers control measures on emissions to air and on releases to land and water, and disposal of mercury once it becomes waste; hence it could be anticipated that levels of mercury in raw materials for composts and digestates would consequently be reduced in future.

3.8 Bisphenol-A (BPA)

Background information and remarks

BPA (4,4'-isopropylidenediphenol, Bisphenol A, CAS 80-05-7), a plastics additive, has been subject to a comprehensive EU risk assessment (EC, 2010b).
The main source of uncertainty for the present exposure assessment is that the data set for reported occurrence in composts and digestates is small.

Chemical properties and hazards data set

The European Commission identifies BPA as an SVHC substance under the REACH Regulation on the basis of it being toxic for reproduction (Article 57c of REACH) and its endocrine disrupting properties in relation to both human health and the environment (Article 57f of REACH). There are restrictions under REACH (Annex XVII), and BPA is under evaluation in CoRAP.

Harmonised classification and labelling applies in the EU under CLP (Eye Dam. 1 - H318; Skin Sens. 1 - H317; STOT SE 3 - H335; Repr. 1B - H360F); some CLP notifiers also self-classify for the environment. PNECs and DNELs are available from existing published assessments.

The substance property data has been taken mainly from the EU risk assessment (EC, 2010b) risk assessment. Documentation relating to the Restriction has also been referred to. The key property information from EC (2010b) needed for the modelling is summarised in Table 3.46. Where information from other sources is included this is indicated in the Table.

Table 3.46 Property information for BPA (from EC (2010b) unless otherwise indicated)

Property	Value	Comment
Molecular weight	228.29 g/mol	
Melting point	155°C	
Boiling point	360°C	Decomposes.
Vapour pressure	5.3×10^{-9} kPa at 25°C	
Water solubility	300 mg/l at room temperature	
log K_{ow}	3.4	
Henry's law constant	4.03×10^{-6} Pa m^3/mol at 25°C	
K_{oc}	715 l/kg	

Property	Value	Comment
BCF	67 l/kg (fish) 7.9 kg/kg (earthworms)	Note: ECHA guidance part R16 recommends a value of 1 l/kg wet wt. as RHOearthworm. The assessment uses a value of 7.9 l/kg wet wt. in EUSES.
Biodegradability	Readily biodegradable fulfilling the 10-day window	
Half-life in air	0.2 day	
PNECs	$PNEC_{water}$ = 1.5 µg/l $PNEC_{sediment}$ = 63 µg/kg dry wt.t $PNEC_{soil}$ 3.7 mg/kg dry wt $PNEC_{oral}$ = 2.67 mg/kg food	The PNEC for water derived using species sensitivity distributions. Higher values are given in the REACH registration dossier for water and sediment: $PNEC_{water}$ = 0.018 mg/l, $PNEC_{sediment}$ = 1.2 mg/kg dry wt.t.
DNEL	$DNEL_{oral}$ for the general population = 0.004 mg/kg bw/day	Value reported is the t-TDI derived value (from EFSA (2015), also adopted by RAC (2015) and used in the REACH registration dossier) in respect of effects on mammary gland, reproductive, neurobehavioural, immune and metabolic systems.
Other relevant data	BPA is identified as a SVHC substance under the REACH Regulation on the basis of toxicity for reproduction (Article 57c of REACH) and its endocrine disrupting properties in relation to both human health and the environment (Article 57f of REACH).	

Occurrence data set

Table 3.47 presents a summary of the reported concentrations of bisphenol-A in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. It is notable that the data set for concentrations in composts and digestates is small, but the reason for this is unknown; it may be the case that this contaminant is not often found.

Table 3.47 Reported occurrence of bisphenol-A in composts and digestates (All values derived from Bayerisches Landesamt für Umwelt (BayLfU), 2016)

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		One range result only which is a range for a specific region (2015, Bavaria)
Compost - minimum concentration	0.01	Very few values reported and no limit value mentioned. The range given is <10-170 µg/kg TM.

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Compost - mid-range or average concentration	0.085	It is not possible to be sure if the range mentioned is representative. The mid-range value is therefore set as 0.5* the maximum value of the reported range.
Compost - maximum concentration	0.17	The maximum value of the reported range.
Digestates - data availability		Two range results only which are ranges and relate to a specific region (2015, Bavaria)
Digestate - minimum concentration	0.01	The ranges reported are <10-1000 µg/kg and <10-390 µg/kg TM.
Digestate - mid-range or average concentration	0.39	It is not possible to be sure if the range mentioned is representative. The mid-range value is set as the upper range limit from the two reported ranges.
Digestate - maximum concentration	1	The maximum value reported (upper limit of higher range)

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.48 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	750
Mass of substance in EU-28 in digestate (kg/year)	13,759
Total regional emission to surface water (kg/day)	0.11
Total regional emission to soil (kg/day)	3.9
Total continental emission to surface water (kg/day)	1.0
Total continental emission to agricultural soil (kg/day)	35

Consultation and literature research suggests contamination rates of BPA in the range <10-1000 µg/kg in digestate and <10-170 µg/kg in compost.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios. These scenarios are particularly useful to provide information about sensitivity in view that little evidence is available on concentrations:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.49 below summarises background exposure data compiled as part of the ESR risk assessment (EC, 2010b).

The EC (2010b) gives the following concentrations to represent the regional background ($PEC_{regional}$). Modelled values relate to the industrial use pattern as assessed at the time in 2010 using EUSES. It should be noted that these regional concentrations are likely to reflect the past use of BPA rather than the current use[36].

Table 3.49 Reported background concentrations of bisphenol-A in the environment

PECregional	Value	Remarks
Surface water	32 ng/l (modelled) 10 ng/l (median, measured) 42 ng/l (75%ile, measured)	PECregional modelled as part of the EU risk assessment (ESR, EC 2010b). Median value from the whole freshwater measured data set is reported as 10 ng/l, 75%ile value from the data set as 42 ng/l.
Sediment	0.52 µg/kg wet wt. (modelled) 10-20 µg/kg wet wt. (25-50 ng/g dwt) (mid-range measured)	PECregional modelled as part of the EU risk assessment (ESR, EC 2010). The RAR reports that "the highest of the 95%iles from the measured values are higher than calculated. The higher calculated values are similar to the middle of the range of measured levels, 10-20 µg/kg wet wt. (25-50 ng/g dwt)."
Agricultural soil	0.07 µg/kg wet wt. (modelled)	PECregional modelled as part of the EU risk assessment (ESR, EC 2010). No measured data reported.

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of bisphenol-A resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.50 below.

Table 3.50 Predicted exposures for bisphenol-A arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.20E-03	[mg/kg dry wt.]
PECgrassland soil	1.56E-04	[mg/kg dry wt.]
PEC in groundwater	2.72E-05	[mg/l]
PECfreshwater	2.28E-06	[mg/l]
PECfreshwater-sediment	1.71E-04	[mg/kg dry wt.]
Humans via the environment: local total daily intake	7.34E-06	[mg.kg-1.d-1]

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[36] BPA has since been added to the candidate list of substances of very high concern for authorisation. In addition, some uses of BPA are subject to restrictions under Annex XVII of REACH. This means that the use pattern of BPA may have changed markedly since the EC (2010) risk assessment was carried out.

	Scenario I		Units
Humans via the environment: daily dose via drinking water		7.78E-07	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 51.3%		
Secondary poisoning – freshwater fish-eating birds and mammals		9.39E-05	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals		1.21E-04	[mg.kg-1]

	Scenario II		Units
PECagricultural soil		5.61E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake		9.01E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 59.6%		
Secondary poisoning – worm-eating birds and mammals		1.63E-02	[mg.kg-1]

Table 3.51 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.51 Predicted background exposures for bisphenol-A at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	1.69E+00	[t]
Steady-state mass in regional freshwater (kg)	1.90E+00	[kg]
Steady-state mass in regional seawater (kg)	1.96E-01	[kg]
Steady-state mass in regional air (kg)	3.25E-09	[kg]
Steady-state mass in regional agricultural soil (kg)	1.65E+02	[kg]
Steady-state mass in regional natural soil (kg)	3.32E-05	[kg]
Steady-state mass in regional industrial soil (kg)	1.23E-05	[kg]
Steady-state mass in regional freshwater sediment (kg)	3.54E-01	[kg]

	Steady state mass	Units
Steady-state mass in regional seawater sediment (kg)	8.69E-03	[kg]
Steady-state mass in continental freshwater (kg)	2.22E+01	[kg]
Steady-state mass in continental seawater (kg)	1.00E+01	[kg]
Steady-state mass in continental air (kg)	2.98E-08	[kg]
Steady-state mass in continental agricultural soil (kg)	1.49E+03	[kg]
Steady-state mass in continental natural soil (kg)	1.54E-04	[kg]
Steady-state mass in continental industrial soil (kg)	5.70E-05	[kg]
Steady-state mass in continental freshwater sediment (kg)	4.13E+00	[kg]
Steady-state mass in continental seawater sediment (kg)	2.22E-02	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	9.98E+01	[%]
Steady-state mass fraction in regional freshwater (%)	1.12E-01	[%]
Steady-state mass fraction in regional seawater (%)	1.16E-02	[%]
Steady-state mass fraction in regional air (%)	1.92E-10	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.74E+00	[%]
Steady-state mass fraction in regional natural soil (%)	1.96E-06	[%]
Steady-state mass fraction in regional industrial soil (%)	7.24E-07	[%]
Steady-state mass fraction in regional freshwater sediment (%)	2.08E-02	[%]
Steady-state mass fraction in regional seawater sediment (%)	5.11E-04	[%]
Steady-state mass in continental freshwater (kg)	1.31E+00	[%]
Steady-state mass in continental seawater (kg)	5.91E-01	[%]
Steady-state mass in continental air (kg)	1.76E-09	[%]
Steady-state mass in continental agricultural soil (kg)	8.78E+01	[%]
Steady-state mass in continental natural soil (kg)	9.06E-06	[%]
Steady-state mass in continental industrial soil (kg)	3.35E-06	[%]
Steady-state mass in continental freshwater sediment (kg)	2.43E-01	[%]

	Steady state mass	Units
Steady-state mass in continental seawater sediment (kg)	1.31E-03	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is 3.7% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.52 below presents the summary of key findings from the risk assessment of bisphenol-A that has been made in this project. The findings are discussed further below the table.

Table 3.52 Summary of key findings for exposure of bisphenol-A via use of compost and digestates

Key findings of the risk assessment of bisphenol-A in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Very limited data, all for one specific sampled region (2015, Bavaria) <0.01 - 1 mg/kg dry wt.
Major raw material sources	renewable raw materials, or not stated
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Reprotoxin and endocrine disruptor (SVHC)
Effects considered in the main concern hazard(s)	SVHC (reproduction; endocrine disrupting in relation to both human health and the environment) DNELoral for the general population available in respect of effects on mammary gland, reproductive, neurobehavioural, immune and metabolic systems. PNECs are available derived using species sensitivity distributions. Quantitative risk characterisation has not been attempted in this study.
Uncertainties and their implications	Very limited data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low. In circumstances where a) the system is watered in excess of the water holding capacity of the growing medium and b) where the container design means that excess water will drain away and not remain in contact with the container/growing medium, then a small proportion of the substance could be lost from the system in the drained water.
Other remarks	None

Bisphenol A is an SVHC (toxic for reproduction with endocrine disrupting properties in respect of both the environment and human health) and in view of these hazardous properties, quantitative risk characterisation has not been attempted in this study. However, it is noted that the predicted local total daily intake for humans does not exceed the DNEL used by EFSA and RAC, and the PNECs adopted in the 2010 ESR risk assessment (EC, 2010b) are not exceeded. The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

The regional scale predicted environmental concentration (PEC) in agricultural soil arising from the application of C/D is well below the background concentration arising from the industrial life cycle, calculated in the ESR risk assessment.

At steady state, >99% of the total mass remains within the region + continent[37], of which the significant majority remains within soil. This suggests there is low mobility and little potential for transfer over long distances following release via the handling and application of C/D. The total mass in the region + continent at steady state is however relatively low, less than 2 t in total even when a conservative concentration in the compost/digestate is assumed. This steady-state mass amounts to a small fraction (~0.1) of the mass released annually via application of composts and digestates[38], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

3.9 Di(2-ethylhexyl)phthalate (DEHP)

Background information and remarks

DEHP (Bis(2-ethylhexyl) phthalate, CAS 117-81-7) has been used as a plastics additive with the potential for exposure from numerous industrial and wide-dispersed uses largely relating to plastics, articles and medical devices.

DEHP has been subject to a comprehensive EU risk assessment (EC, 2008b) and has been reviewed by the member state committee (ECHA, 2014a) in respect of equivalent concern based on endocrine disrupting properties. The substance property data used in this assessment has been taken mainly from those prior assessment documents.

Chemical properties and hazards data set

DEHP has been identified as an SVHC substance under the REACH Regulation on the basis of it being toxic for reproduction (Article 57c of REACH) and its endocrine disrupting properties in relation to both human health and the environment (Article 57f of REACH); requiring Authorisation (Annex XIV) under REACH, Restrictions in REACH (Annex XVII).

Harmonised classification and labelling applies in the EU under CLP (Repr. 1b – H360FD); some CLP notifiers also self-classify for the environment. PNECs and DNELs are available from existing published assessments.

The key property information from ECHA (2014a) or EC (2008b) needed for the modelling is summarised in Table 3.53. Where information from other sources is included this is indicated in the Table.

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[37] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[38] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Table 3.53 Property information for DEHP (from ECHA (2014a) unless otherwise indicated)

Property	Value	Comment
Molecular weight	390.6 g/mol	
Melting point	-50°C	
Boiling point	385°C	
Vapour pressure	3.4×10-5 Pa at 20°C	
Water solubility	3 µg/l at c.a. 20°C	
log Kow	7.5	A value of 7 (the maximum recommended) was used in the EUSES calculations carried out in EC (2008b).
Henry's law constant	4.43 Pa m3/mol at 20°C	
Koc	165,000 l/kg	
BCF	840 l/kg (fish) 2700 l/kg (invertebrates) 1 kg/kg (earthworms)	Note: ECHA guidance part R16 recommends a value of 1 l/kgwwt as RHOearthworm. Therefore a value of 1 l/kg wet wt. is used in EUSES.
Biodegradability	Readily biodegradable fulfilling the 10-day window; 50d half life in surface water at 12C; 300 d half life in soil at 12C	Half-life for mineralisation in soil estimated in EC (2008b) to be around 300 days at 10°C. For surface water the half-life was set to 50 days and for sediment the half-life was set to 3,000 days.
Half-life in air	1 day	
PNECs	PNECwater cannot be derived. PNECsediment >100 mg/kg dry wt.t PNECsoil >13 mg/kg dry wt PNECoral = 3.3 mg/kg food	The same values are given in the REACH registration dossier. An annual average EQS of 1.3 µg/l is applicable (Directive 2008/105/EC as amended (2013/39/EU)) for inland surface waters. No MAC EQS is defined.
DNEL	DNELoral for the general population = 0.048 mg/kg bw/day (ECHA/Danish EPA, 2016) DNELoral (internal dose) for the general population =0.034 mg/kg bw/day (RAC	No DNEL derived in EC (2008b). This value is taken from Table 6 of ECHA/Danish EPA (2016). The REACH registration dossier uses a value of 3.6 kg bw/d.
Other relevant data	Kplant-water = 1,940 m3/m3	

Occurrence data set

Table 3.54 presents a summary of the reported concentrations of DEHP in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.54 Reported occurrence of DEHP in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Data available for two locations (Finland, Kapanen et al 2013 and Germany, Bay LfU 2015).
Compost - minimum concentration	0.6	lowest value overall (bottom of a range reported for German composts)
Compost - mid-range or average concentration	16	Concentration reported in compost after 1 year, representing a conservative mid-range value.
Compost - maximum concentration	38	Highest value overall for composts (derived municipal sewage sludge after 3 months composting)
Digestates - data availability		Data available for several locations (Finland, Kapanen et al 2013, Germany, Bay LfU 2015, Norway, Govasmark et al 2011, and from EU data reported by Saveyn and Eder). The range of values covers about 2 orders of magnitude.
Digestate - minimum concentration	2	1.9 mg/kg dry wt. reported as bottom of range in two German digestates.
Digestate - mid-range or average concentration	40	An average has been calculated to be approximately 40 mg/kg dry wt., although several of the reported values are already stated to be averages.
Digestate - maximum concentration	140	140 is the highest mentioned figure overall, for a liquid digestate product in the Norway 2011 data set. This is actually reportedly an average value. A second value of 100 mg/kg is also available from the Finland 2013 data set. It is notable that regulatory limit values are applicable for BE (AGW du 14/06/2001 favorisant la valorisation de certains déchets (BE)), DK (Slambekendtgørelsen) and Norway (Forskrift om organisk gjødsel; Mattilsynet, 2005), 50 mg/kg dry wt. in each case. Both the Finland and Norway data sets include values in excess of 50 mg/kg dry wt..

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.55 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	141,120
Mass of substance in EU-28 in digestate (kg/year)	1,411,200
Total regional emission to surface water (kg/day)	12
Total regional emission to soil (kg/day)	413
Total continental emission to surface water (kg/day)	107
Total continental emission to agricultural soil (kg/day)	3,720

Consultation and literature research has indicated that DEHP has been detected in a range of composts and digestates. The reported concentrations typically lie in the range 1-100 mg/kg dry wt.

with the lowest value reported as a minimum being 0.6 mg/kg dry wt. (in a stabilised sterilised compost product), the highest 'average' reported value as 140.2 mg/kg dry wt. (in a digestate product derived from biowaste-food and garden waste by anaerobic digestion). The highest concentration reported in a compost product is 38 mg/kg dry wt. No reported information about liquid digestate fertiliser has been found. There is no evidence as to whether the composts containing DEHP are primarily for use as a soil amendment or as a growing medium.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.56 below summarises background exposure data compiled as part of existing major regulatory assessment (EC, 2008b). It should be noted that these regional concentrations are likely to reflect the past use of DEHP rather than the current use[39].

Table 3.56 Reported background concentrations of DEHP in the environment (EC, 2008b)

PECregional	Value	Remarks
Air	7.5×10-6	
Surface water	2.2 µg/l	
Sediment	33.7 mg/kg dry wt.t	
Agricultural soil	0.07 mg/kg dry wt.t	EC, 2008b modelled PEC (regional)
	ca. 0.1 - 3.4 mg/kg dry wt. depending on depth (agricultural soil amended with high amounts of sewage sludge over 25 years)	measured data (local)
Soil pore water/ground water	0.02 µg/l	
Natural soil	0.015 mg/kg dry wt.t	
Urban/industrial soil	3.2 mg/kg dry wt.t	
Other relevant data		

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[39] DEHP has since been identified as a substance of very concern (SVHC) under REACH and as a result it now requires authorisation before it is used. In addition, some uses of DEHP are subject to restrictions under Annex XVII of REACH. This means that the use pattern of DEHP may have changed markedly since the EC (2008b) risk assessment was carried out.

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of DEHP resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.57 below.

Table 3.57 Predicted exposures for DEHP arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	3.88E-01	[mg/kg dry wt.]
PECgrassland soil	1.28E-01	[mg/kg dry wt.]
PEC in groundwater	9.90E-05	[mg/l]
PECfreshwater	2.24E-04	[mg/l]
PECfreshwater-sediment	3.69E+00	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.85E-03	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.83E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 81.3%	
Secondary poisoning – freshwater fish-eating birds and mammals	1.05E-01	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.58E-02	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	1.25E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	5.76E-02	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.9%	
Secondary poisoning – worm-eating birds and mammals	5.64E-01	[mg.kg-1]

Regional background		Units
Regional PEC in surface water (total)	3.40E-05	[mg/l]
Regional PEC in air (total)	1.94E-07	[mg.m-3]
Regional PEC in agricultural soil (total)	2.13E-02	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	7.32E-06	[mg/l]
Regional PEC in natural soil (total)	3.53E-04	[mg/kg wet wt.]

Regional PEC in industrial soil (total)	3.53E-04	[mg/kg wet wt.]
Regional PEC in sediment (total)	1.93E-01	[mg/kg wet wt.]

Table 3.58 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.58 Predicted background exposures for DEHP at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	1.85E+03	[t]
Steady-state mass in regional freshwater (kg)	1.23E+02	[kg]
Steady-state mass in regional seawater (kg)	1.20E+01	[kg]
Steady-state mass in regional air (kg)	7.83E+00	[kg]
Steady-state mass in regional agricultural soil (kg)	1.74E+05	[kg]
Steady-state mass in regional natural soil (kg)	3.24E+02	[kg]
Steady-state mass in regional industrial soil (kg)	1.20E+02	[kg]
Steady-state mass in regional freshwater sediment (kg)	8.00E+03	[kg]
Steady-state mass in regional seawater sediment (kg)	2.64E+02	[kg]
Steady-state mass in continental freshwater (kg)	1.32E+03	[kg]
Steady-state mass in continental seawater (kg)	2.44E+03	[kg]
Steady-state mass in continental air (kg)	1.55E+02	[kg]
Steady-state mass in continental agricultural soil (kg)	1.57E+06	[kg]
Steady-state mass in continental natural soil (kg)	3.25E+03	[kg]
Steady-state mass in continental industrial soil (kg)	1.20E+03	[kg]
Steady-state mass in continental freshwater sediment (kg)	8.62E+04	[kg]
Steady-state mass in continental seawater sediment (kg)	2.68E+03	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	9.98E+01	[%]

Steady-state mass fraction in regional freshwater (%)	6.63E-03	[%]
Steady-state mass fraction in regional seawater (%)	6.49E-04	[%]
Steady-state mass fraction in regional air (%)	4.23E-04	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.40E+00	[%]
Steady-state mass fraction in regional natural soil (%)	1.75E-02	[%]
Steady-state mass fraction in regional industrial soil (%)	6.50E-03	[%]
Steady-state mass fraction in regional freshwater sediment (%)	4.32E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.43E-02	[%]
Steady-state mass in continental freshwater (kg)	7.15E-02	[%]
Steady-state mass in continental seawater (kg)	1.32E-01	[%]
Steady-state mass in continental air (kg)	8.40E-03	[%]
Steady-state mass in continental agricultural soil (kg)	8.47E+01	[%]
Steady-state mass in continental natural soil (kg)	1.76E-01	[%]
Steady-state mass in continental industrial soil (kg)	6.51E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	4.66E+00	[%]
Steady-state mass in continental seawater sediment (kg)	1.45E-01	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.59 below presents the summary of key findings from the risk assessment of DEHP that has been made in this project. The findings are discussed further below the table.

Table 3.59 Summary of key findings for exposure of DEHP via use of compost and digestates

Key findings of the risk assessment of DEHP in contaminated composts and digestates	
Overall range of compost and digestate concentrations	0.6-140 mg/kg dry wt. (or higher; the upper limit value is reportedly an average)

Key findings of the risk assessment of DEHP in contaminated composts and digestates	
Major raw material sources	High concentrations associated with digestates prepared from biowaste-food and garden waste (Norway), and municipal sewage sludge from wastewater treatment plants (Finland)
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Humans via dietary exposure (container growing); High cumulative loads at steady state; Absolute concentrations in compost/digestate exceeding existing local limit values / guide values Local PEC in freshwater (local scenario I) exceeds annual average EQS (Directive 2008/105/EC as amended (2013/39/EU)) (though regional background PEC does not)
Effects considered in the main concern hazard(s)	SVHC (toxic for reproduction, endocrine disrupting in relation to both human health and environment). Basis of the EQS (AA-QS) is not stated in the Directive but is understood to relate to secondary poisoning of predators[40].
Uncertainties and their implications	Concentrations in composts and digestates have high variability – local PECs would similarly be variable and could be still higher than modelled here. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Measured concentration in sludge-amended soil support the local estimated concentration.

The highest reported occurrence values in digestate exceed a national limit value of 50 mg/kg digestate d.w. applicable (or relevant as a guide value) in several European countries. This in itself indicates a potential issue. These high occurrence concentrations were reported in digestates prepared from biowaste-food and garden waste (Norway), and municipal sewage sludge from wastewater treatment plants (Finland).

As an SVHC (toxic for reproduction with endocrine disrupting properties for environment and human health), risk characterisation has not been quantified. However, it is noted that the local total daily intake for humans associated with local scenario II slightly exceed the DNELoral for general population defined by ECHA/Danish EPA (2016). Additionally, the predicted exposures in soil in local scenario II are approaching the PNEC value defined by EC (2008b).

The estimated regional exposures in agricultural soils and grassland arising from the application of C/D are below the estimated background PECs derived from the EC (2008b) ESR risk assessment based on the industrial life cycle. The estimated local exposures in agricultural soils from Scenario I is within the range measured for a sludge-fertilised agricultural soil.

The highest contribution to human exposure via the environment arising from the use of C/D in either scenario is mainly associated with dietary consumption of root vegetables.

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[40] EQS Substance Data Sheet (2005) available online at https://circabc.europa.eu/sd/a/337d62ba-6a8f-49ce-9c0e-591bb248e560/12_DEHP_EQS_Final%20Data%20Sheet.pdf

At steady state, >99% of the total mass remains within the region + continent[41], with the vast majority of substance remaining in the agricultural soil. This suggests there is low potential for transfer over long distances following release via the handling and application of C/D.

The total mass in the region + continent at steady state is very high (>1000 t) based on the more conservative interpretation of the available concentration data, and still significant (90 t) even when releases are based on a less conservative, relatively low concentration of DEHP in compost/digestate. This steady-state mass amounts to 1.2 times the mass released annually via application of composts and digestates[42], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

3.10 17α-Ethinylestradiol

Background information and remarks

17α-Ethinylestradiol (EC no 200-342-2, CAS no 57-63-6) is a human pharmaceutical used for its estrogenic properties. It was nominated as a priority substance under the WFD 2000/60/EC and at present is on a water quality 'watch list'. A precedent regulatory risk assessment for the environment was conducted by RIVM (2011).

Chemical properties and hazards data set

The chemical property inputs used in the present assessment are based on those applied by RIVM (2011) in its environmental risk assessment. This assessment did not include secondary poisoning or humans via the environment. Table 3.60 below summarises the data used, as used in RIVM, 2011 risk assessment unless otherwise stated in the table.

Table 3.60 Property information for 17α-ethinylestradiol

Property	Value	Remarks
Molecular weight	296.4	HSDB data set citing Lide, D.R. CRC Handbook of Chemistry and Physics 88TH Edition 2007-2008. CRC Press, Taylor & Francis, Boca Raton, FL 2007, p.3-234
Melting point	142-146 °C. May also exist in a polymorphic modification with mp 180-186 °C	HSDB data set citing Lewis, R.J. Sr.; Hawley's Condensed Chemical Dictionary 15th Edition. John Wiley & Sons, Inc. New York, NY 2007., p. 515
Boiling point		
Vapour pressure	2.6E-07 Pa at 25C used by RIVM (2011 risk assessment of 18 pharmaceuticals); no source stated; thought to be equivalent to the EPI value. 1.9X10-9 mm Hg at 25 °C	the HSDB value is estimated and is equivalent to 2.53E-07 Pa

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[41] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[42] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Property	Value	Remarks
Water solubility	11.3 mg/l used by RIVM (2011) - citing an EPI experimental database match.	11.3 mg/l at 27°C used in EUSES
	Insoluble in water. (PIM, IPCS, 1997, Section 3.3.3)	
	In double-distilled water, 4.83 mg/L	HSDB data set citing Tabak HH et al; Dev Ind Microbiol 22: 497-519 (1981)
	In water, 11.3 mg/L at 27 °C	HSDB data set citing Yalkowsky, S.H., He, Yan., Handbook of Aqueous Solubility Data: An Extensive Compilation of Aqueous Solubility Data for Organic Compounds Extracted from the AQUASOL dATAbASE. CRC Press LLC, Boca Raton, FL. 2003., p. 1158
log Kow	3.67 (same value used by RIVM in the 2011 risk assessment)	The same value appears in the HSDB data set citing Hansch, C., Leo, A., D. Hoekman. Exploring QSAR - Hydrophobic, Electronic, and Steric Constants. Washington, DC: American Chemical Society., 1995., p. 168
Henry's law constant	7.94X10-12 atm-cu m/mol at 25 °C (est)	HSDB data set citing US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Jan, 2010. Available from, as of Feb 9, 2011: http://www.epa.gov/oppt/exposure/pubs/episuitedl.htm
Koc	A value of 4768 was used by RIVM (source not stated). A QSAR estimated value of 510 is available from SRC EPIWIIN.	The origin of this value is unclear however due to the precedent regulatory use, this value was used in EUSES.
BCF	An estimated BCF of 110 was calculated in fish for ethinylestradiol(SRC); EUSES derives a value of 263 from the log Kow.	
Biodegradability	Ethinylestradiol has been classified as not readily biodegradable using a sewage treatment plant study based in Stockholm, Sweden.	HSDB data set citing Carlsson C et al; Sci Total Environ 364: 67-87 (2006)
	Biodegradation rates of 1.62 and 148/day of 500 ng/L ethinylestrogen were reported using batch tests using mixed liquor from an activated sludge wastewater treatment plant operating at a 3-day solids retention time and a membrane bioreactor.	HSDB data set citing Gaulke LS et al; Environ Sci Technol 43: 7111-7116 (2009)
Half-life in air	Ethinylestradiol absorbs light at wavelengths 281 nm, and therefore may be susceptible to direct photolysis by sunlight. AOP prediction is 125.04E-12 cm3/mol.s.	HSDB data set

Property	Value	Remarks
Threshold hazard values if available	**Value**	**Remarks**
PNECaquatic (freshwater)	No PNEC is available.	No EQS is set.
PNECsediment (freshwater)		
PNECsoil		
PNECoral predator	No PNEC is available	No biota EQS is set.
DNEL general population oral		
Other relevant data	The pharmaceutical dosage (in combined medicines) is between 20 µg to 2 mg/d for different indications (IPCS 1997 and Laurenson et al, 2014)); if a bodyweight of 60 kg is assumed for the patient this is equivalent to between 0.33 µg/kg bw/d to 33 µg/kg bw/d.	**Endocrine disruptor**

Occurrence data set

Table 3.61 presents a summary of the reported concentrations of 17α-ethinylestradiol in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.61 Reported occurrence of 17α-ethinylestradiol in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Only two entries are available (which are ranges, but the scope is uncertain).
Compost - minimum concentration	0.0332	This is the lower of the two minimum values from the two range results.
Compost - mid-range or average concentration	0.08	Average of the reported min and max range values
Compost - maximum concentration	0.119	
Digestates - data availability		Only one entry is available (which is a range, but the scope is uncertain).
Digestate - minimum concentration	0.00824	The bottom of the range is actually <LOD, which is 8.24 µg/kg. This is taken as the minimum value.
Digestate - mid-range or average concentration	0.1449	In view of the small amount of data, the mid-range value is set as 0.3x the top limit of the range.
Digestate - maximum concentration	0.483	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.62 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	706
Mass of substance in EU-28 in digestate (kg/year)	5112
Total regional emission to surface water (kg/day)	0.045
Total regional emission to soil (kg/day)	1.5
Total continental emission to surface water (kg/day)	0.40
Total continental emission to agricultural soil (kg/day)	14

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

A full literature search for the latest background data has not been attempted and no pre-existing regulatory compilation of measured exposure data is known. PECs derived in the RIVM assessment and in a US published assessment are summarised in Table 3.63 below.

Table 3.63 Reported concentrations of 17α-ethinylestradiol in the environment (RIVM, 2011)

PECregional	Value	Remarks
Surface water	4.65E-07 mg/l	Local PEC calculated by RIVM assessment using the EMA method
	1E-07 mg/l	99%ile PEC calculated by GREAT-ER (USA) (Laurenson et al, 2014)

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of 17α-ethinylestradiol resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.64 below.

Table 3.64 Predicted exposures for 17α-ethinylestradiol arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.36E-03	[mg/kg dry wt.]
PECgrassland soil	4.57E-04	[mg/kg dry wt.]

PEC in groundwater		1.20E-05	[mg/l]
PECfreshwater		1.47E-06	[mg/l]
PECfreshwater-sediment		7.05E-04	[mg/kg dry wt.]
Humans via the environment: local total daily intake		4.69E-06	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water		3.44E-07	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 62.9%		
Secondary poisoning – freshwater fish-eating birds and mammals		2.76E-04	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals		3.88E-04	[mg.kg-1]

	Scenario II		**Units**
PECagricultural soil		3.93E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake		1.27E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 79.3%		
Secondary poisoning – worm-eating birds and mammals		1.23E-02	[mg.kg-1]

	Regional background		**Units**
Regional PEC in surface water (total)		6.34E-07	[mg/l]
Regional PEC in air (total)		2.17E-15	[mg.m-3]
Regional PEC in agricultural soil (total)		8.10E-05	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils		9.61E-07	[mg/l]
Regional PEC in natural soil (total)		3.21E-10	[mg/kg wet wt.]
Regional PEC in industrial soil (total)		3.21E-10	[mg/kg wet wt.]
Regional PEC in sediment (total)		1.16E-04	[mg/kg wet wt.]

Table 3.65 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.65 Predicted background exposures for 17α-ethinylestradiol at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	7.39E+00	[t]
Steady-state mass in regional freshwater (kg)	2.28E+00	[kg]
Steady-state mass in regional seawater (kg)	2.50E-01	[kg]
Steady-state mass in regional air (kg)	8.76E-08	[kg]
Steady-state mass in regional agricultural soil (kg)	6.61E+02	[kg]
Steady-state mass in regional natural soil (kg)	2.95E-04	[kg]
Steady-state mass in regional industrial soil (kg)	1.09E-04	[kg]
Steady-state mass in regional freshwater sediment (kg)	4.80E+00	[kg]
Steady-state mass in regional seawater sediment (kg)	1.37E-01	[kg]
Steady-state mass in continental freshwater (kg)	4.58E+01	[kg]
Steady-state mass in continental seawater (kg)	6.12E+02	[kg]
Steady-state mass in continental air (kg)	9.51E-07	[kg]
Steady-state mass in continental agricultural soil (kg)	5.95E+03	[kg]
Steady-state mass in continental natural soil (kg)	1.62E-03	[kg]
Steady-state mass in continental industrial soil (kg)	5.99E-04	[kg]
Steady-state mass in continental freshwater sediment (kg)	9.63E+01	[kg]
Steady-state mass in continental seawater sediment (kg)	1.68E+01	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	6.40E+00	[%]

	Steady state mass fraction	Units
Steady-state mass fraction in regional freshwater (%)	1.98E-03	[%]
Steady-state mass fraction in regional seawater (%)	2.16E-04	[%]
Steady-state mass fraction in regional air (%)	7.59E-11	[%]
Steady-state mass fraction in regional agricultural soil (%)	5.73E-01	[%]
Steady-state mass fraction in regional natural soil (%)	2.56E-07	[%]
Steady-state mass fraction in regional industrial soil (%)	9.47E-08	[%]
Steady-state mass fraction in regional freshwater sediment (%)	4.16E-03	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.19E-04	[%]
Steady-state mass in continental freshwater (kg)	3.97E-02	[%]
Steady-state mass in continental seawater (kg)	5.31E-01	[%]
Steady-state mass in continental air (kg)	8.24E-10	[%]
Steady-state mass in continental agricultural soil (kg)	5.15E+00	[%]
Steady-state mass in continental natural soil (kg)	1.40E-06	[%]
Steady-state mass in continental industrial soil (kg)	5.19E-07	[%]
Steady-state mass in continental freshwater sediment (kg)	8.35E-02	[%]
Steady-state mass in continental seawater sediment (kg)	1.45E-02	[%]

Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- BCF in fish (value 110 l/kg ± 1 log unit)
- Koc (range QSAR value 510 to RIVM 4768 (source uncertain)
- Kow (value 3.67 ± 1 log unit)
- Water solubility (value 11.3 mg/l ± 1 log unit)
- Vapour pressure (value 2.6E-07 Pa ± 1 log unit)

The impact of varying each property within the specified range or within a suitable uncertainty range was explored independently. Refer to Figure 3.1-Figure 3.5, which illustrate the impact on relevant predicted exposure concentrations.

Figure 3.1 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the Koc input value: fresh water sediment

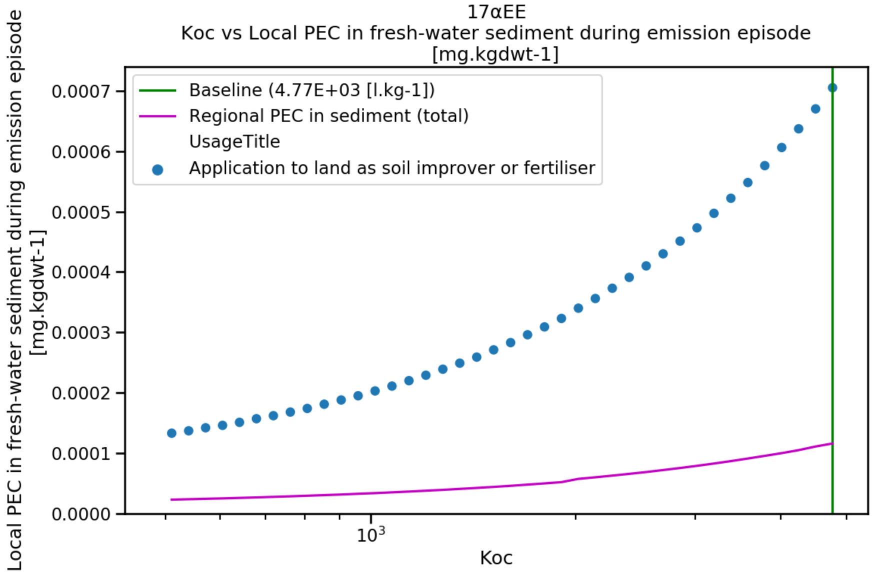


Figure 3.2 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the Koc input value: diet of worm-eating birds and mammals

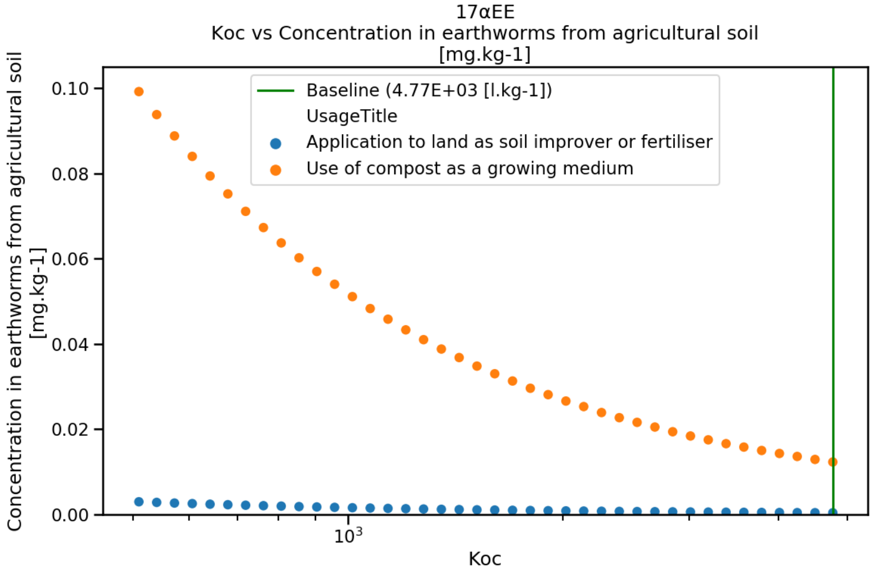


Figure 3.3 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the log Kow input value: diet of worm-eating birds and mammals

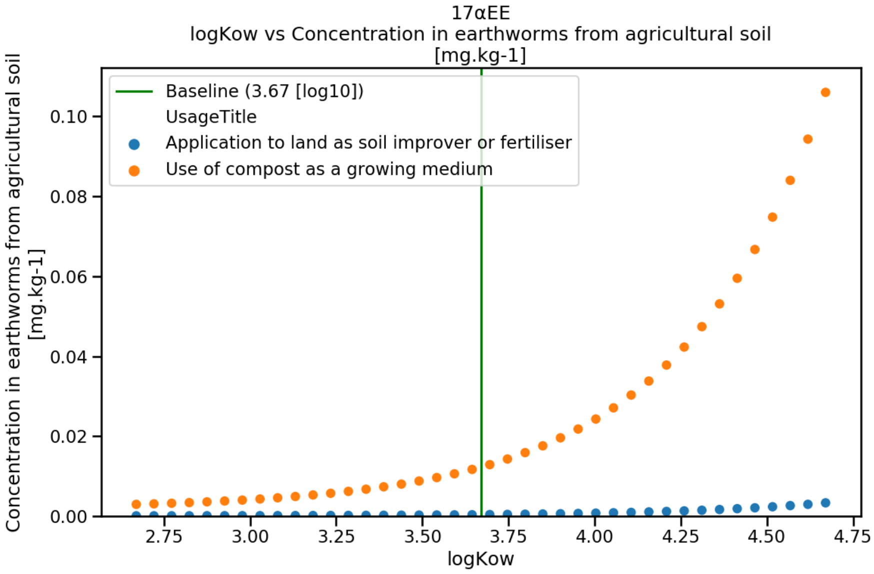


Figure 3.4 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the Koc input value: total daily intake of humans

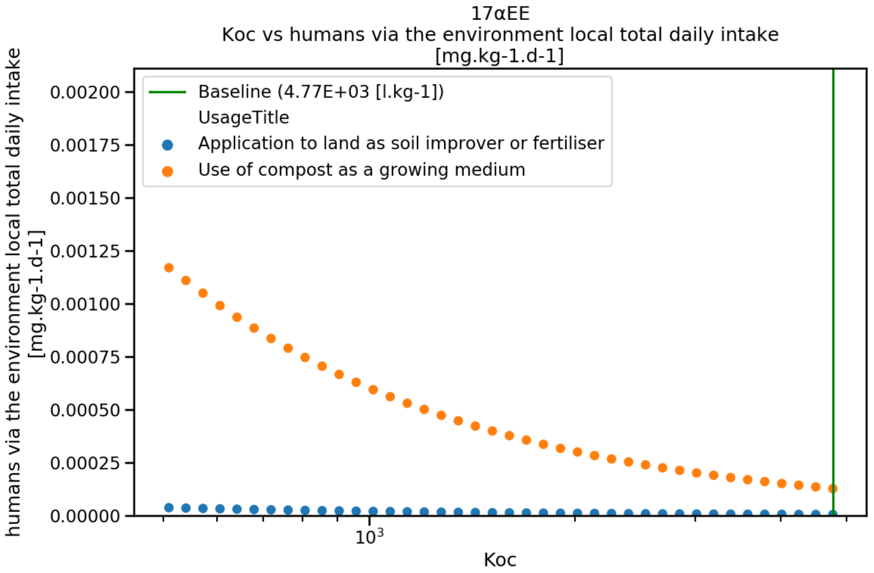
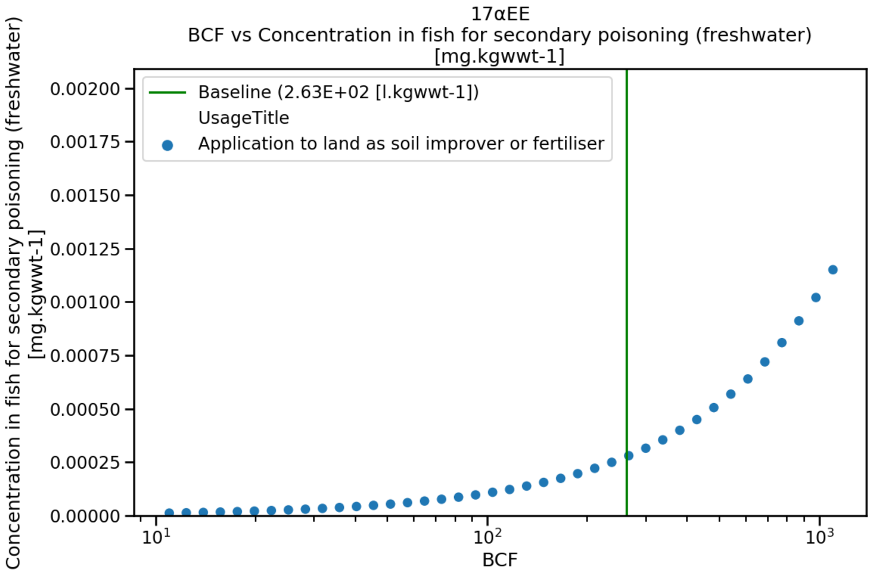


Figure 3.5 Sensitivity of selected outputs in the assessment of 17α-ethinylestradiol to the BCF input value: diet of fish-eating birds and mammals



It can be concluded that:

- At the Koc value used in the baseline assessment, the PNECsediment arising from the application to land scenario has been estimated conservatively.
- The secondary poisoning exposure of worm-eating birds and mammals and local total daily intake, arising from use in the container growing scenario, could have been significantly higher than estimated in the baseline assessment, if the lower value of Koc is accurate, and/or within a reasonable uncertainty range around the literature log Kow value.
- The secondary poisoning exposure of fish-eating birds and mammals (local scenario I) could be up to 5x higher within a reasonable uncertainty range around the BCF value, which is estimated in the absence of data.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.66 below presents the summary of key findings from the risk assessment of 17α-ethinylestradiol that has been made in this project. The findings are discussed further below the table.

Table 3.66 Summary of key findings for exposure of 17α-ethinylestradiol via use of compost and digestates

Key findings of the risk assessment of 17α-ethinylestradiol in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<LOD – 0.483 mg/kg dry wt.
Major raw material sources	WWTP sewage sludges
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Endocrine disruptor with unclear safe limit thresholds. Modelling suggests a possibility of transfer over long distances.
Effects considered in the main concern hazard(s)	No quantitative hazard threshold available.
Uncertainties and their implications	Very limited data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model., Some uncertainties in chemical property data values which could be significant for predicted exposures. Threshold values for the environment (EQS) are not established. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	None

In view that the substance is an endocrine disruptor with unclear safe limit thresholds, risk characterisation has not been quantified in this assessment.

Both the BCF and Koc values used in the exposure assessment are associated with some uncertainty. The sensitivity to these as uncertainty sources has been checked and the local predator exposure (secondary poisoning) could be higher than estimated here.

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables. The upper limit of possible exposure from use of C/D in the baseline assessment is only approximately a factor of less than three times lower than the lower limit of the pharmaceutical dose range in combined medicines; the sensitivity assessment indicates that exposures could be higher within the uncertainty range of the BCF and Koc values.

At steady state, only around 6% of the total mass remains within the region + continent[43], suggesting there may be relatively high mobility and potential for transfer over long distances following release via the handling and application of C/D[44]. Global scale modelling within EUSES suggests that at the steady state, the majority of the substance would be found in global tropic waters, (53%), moderate waters (24%) and arctic waters (16%). In view of the pharmaceutical use, it is noted that the absolute exposure of aquatic environments arising from the use of C/D containing 17α-ethinylestradiol is likely to be small compared to the exposure of receiving waters from municipal wastewater treatment plants.

The total mass in the region + continent at steady state is low (approximately 7 t total) even when the exposure model assumes relatively conservative concentrations in the compost/digestate. This steady-

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[43] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[44] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

state mass amounts to 1.3 times the mass released annually via application of composts and digestates[45].

3.11 Hexabromocyclododecane (HBCDD)

Background information and remarks

HBCDD has been used as a flame retardant. HBCDD exists in several isomeric forms having CAS numbers 3194-55-6, 24637-99-4, 134237-52-8, 134237-50-6, 134237-51-7.

HBCDD has been subject to a comprehensive EU risk assessment (EC, 2008c) and the substance property data has been taken mainly from that risk assessment. HBCDD occurs in several different isomeric forms. The assessment has been made for the representative isomer with CAS 25637-99-4.

As HBCDD is a PBT and POP, quantitative risk characterisation ratios have not been derived.

Chemical properties and hazards data set

SVHC (PBT) requiring Authorisation (Annex XIV) under REACH; POP

Harmonised classification and labelling applies in the EU under CLP (Repr. 2 - H361; lact. – H362), all CLP notifiers also self-classify for the environment. PNECs and DNELs are available from existing published assessments.

The key property information from EC (2008c) needed for the modelling is summarised in Table 3.67. Where information from other sources is included this is indicated in the Table.

Table 3.67 Property information for HBCDD (from EC (2008c) unless otherwise indicated)

Property	Value	Comment
Molecular weight	641.7 g/mol	
Melting point	172-184°C	
Boiling point	>190°C	Decomposes.
Vapour pressure	6.3×10^{-5} Pa at 21°C	
Water solubility	66 µg/l at 20°C	
log K_{ow}	5.62	
Henry's law constant	0.75 Pa m^3/mol at 20-21°C	
K_{oc}	4.57×10^4 l/kg	log Koc = 4.66
BCF	18,100 l/kg (fish) 6 kg/kg (earthworms)	Note: ECHA guidance part R16 recommends a value of 1 l/kgwwt as

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[45] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Property	Value	Comment
		RHOearthworm. Therefore the assessment uses a value of 6 l/kg wet wt. in EUSES.
Biodegradability	Not readily biodegradable	EC (2008c) gives the degradation half-life in soil as 119 days and the degradation half-life in aerobic and anaerobic sediment as 2.6-124 days and 19-190 days respectively (all data refer to 12°C).
Half-life in air	51 hours	
PNECs	As a PBT and POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here. However, it is noted that PNECs have previously been defined (EC, 2008c) $PNEC_{water}$ = 0.31 µg/l $PNEC_{sediment}$ = 0.86 mg/kg dry wt.t $PNEC_{soil}$ = 5.9 mg/kg dry wt $PNEC_{oral}$ = 5 mg/kg food	The REACH registration dossier gives higher values for sediment, soil and secondary poisoning: $PNEC_{sediment}$ = 10 mg/kg dry wt.t $PNEC_{soil}$ = 12.8 mg/kg dry wt.t. $PNEC_{oral}$ = 222 mg/kg food an annual average EQS of 0.0016 µg/l and MAC EQS of 0.5 µg/l are applicable for inland surface waters (Directive 2008/105/EC as amended (2013/39/EU) an EQS for biota of 167 µg/kg wet weight is applicable (Directive 2008/105/EC as amended (2013/39/EU)
DNEL	As a PBT and POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.	No DNEL derived in EC (2008c). Value taken from the REACH registration dossier. $DNEL_{oral}$ for the general population = 0.102 mg/kg bw/day
Other relevant data	n/a	

The European Commission identifies HBCDD as a SVHC substance under the REACH Regulation on the basis of it being PBT (Article 57d of REACH). In addition, HBCDD has also been identified as a POP under the Stockholm Convention (United Nations Environment Program (UNEP), 2010).

Occurrence data set

Table 3.68 presents a summary of the reported concentrations of HBCDD in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report. The data availability is limited and the associated uncertainty is explored in the Sensitivity to specific variables section.

Table 3.68 Reported occurrence of HBCDD in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Only one result (a reported range) is available for HBCDD in composts.
Compost - minimum concentration	0.00014	

Compost - mid-range or average concentration	3	Mid-range value is the average of the range.
Compost - maximum concentration	6.1	
Digestates - data availability		Only two results (reported ranges) are available for HBCDD in composts.
Digestate - minimum concentration	0.00001	
Digestate - mid-range or average concentration	0.53	Mid-range value is the average of the two ranges.
Digestate - maximum concentration	2.1	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.69 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	26,460
Mass of substance in EU-28 in digestate (kg/year)	18,698
Total regional emission to surface water (kg/day)	0.35
Total regional emission to soil (kg/day)	12
Total continental emission to surface water (kg/day)	3.1
Total continental emission to agricultural soil (kg/day)	108

Consultation and literature evidence demonstrates that HBCDD is present in composts and digestates at concentrations of between <0.01 – 6100 µg/kg dry wt.. Reported levels in digestates are <0.01 to 2100 µg/kg dry wt. but only a few values are available. There is no evidence as to whether the composts containing HBCDD are primarily for use as a soil amendment or as a growing medium.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.70 below summarises the background exposure levels estimated as part of the ESR risk assessment (EC, 2008c).

In light of its status as a POP, there is an international commitment to restrict its use; under REACH an authorisation applies which is due to expire; hence significant decline in use is to be expected going forward and the predicted environmental concentrations from use of C/D should be considered in this context. These restrictions should eliminate new inputs, but there is significant "stock" remaining in products with potential for environmental release.

The EC ESR risk assessment (2008c) gives the following concentrations to represent the regional background ($PEC_{regional}$). It should be noted that these regional concentrations are likely to reflect the past use of HBCDD, rather than the current use, which should be lower[46].

Table 3.70 Reported background concentrations of HBCDD in the environment

PECregional	Value	Remarks
Air	0.025 ng/m3	
Surface water	0.028 µg/l	
Sediment	85 µg/kg dry wt.t	ESR RAR (EC, 2008c) reported that available measured data are comparable
Agricultural soil	0.23 mg/kg dry wt.t	ESR RAR (EC, 2008c) reported only local-scale measured data available
Soil pore water/ground water		
Natural soil	0.00066 mg/kg dry wt.t	
Urban/industrial soil	0.00066 mg/kg dry wt.t	
Other relevant data		

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of HBCDD resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.71 below.

Table 3.71 Predicted exposures for HBCDD arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.06E-02	[mg/kg dry wt.]
PECgrassland soil	2.82E-03	[mg/kg dry wt.]
PEC in groundwater	7.77E-06	[mg/l]
PECfreshwater	1.14E-05	[mg/l]
PECfreshwater-sediment	5.20E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	4.72E-04	[mg.kg-1.d-1]

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[46] HBCDD has since been identified as a substance of very concern (SVHC) under REACH and as a result it now requires authorisation before it is used. This means that the use pattern of HBCDD may have changed markedly since the EC (2008c) risk assessment was carried out.

Humans via the environment: daily dose via drinking water	2.22E-07	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Fish 71.7%	
Secondary poisoning – freshwater fish-eating birds and mammals	1.16E+00	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	3.54E-04	[mg.kg-1]

	Scenario II	**Units**
PECagricultural soil	2.01E+00	[mg/kg dry wt.]
Humans via the environment: local total daily intake	3.77E-02	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.8%	
Secondary poisoning – worm-eating birds and mammals	9.62E-02	[mg.kg-1]

	Regional background	**Units**
Regional PEC in surface water (total)	1.51E-06	[mg/l]
Regional PEC in air (total)	2.19E-09	[mg.m-3]
Regional PEC in agricultural soil (total)	2.50E-04	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	3.11E-07	[mg/l]
Regional PEC in natural soil (total)	4.79E-07	[mg/kg wet wt.]
Regional PEC in industrial soil (total)	4.79E-07	[mg/kg wet wt.]
Regional PEC in sediment (total)	1.12E-03	[mg/kg wet wt.]

Table 3.72 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.72 Predicted background exposures for HBCDD at steady state arising from use of composts and digestates

	Steady state mass	**Units**
Total steady-state mass (region + continent)	2.15E+01	[t]
Steady-state mass in regional freshwater (kg)	5.43E+00	[kg]
Steady-state mass in regional seawater (kg)	5.79E-01	[kg]
Steady-state mass in regional air (kg)	8.83E-02	[kg]

Steady state mass		Units
Steady-state mass in regional agricultural soil (kg)	2.04E+03	[kg]
Steady-state mass in regional natural soil (kg)	4.40E-01	[kg]
Steady-state mass in regional industrial soil (kg)	1.63E-01	[kg]
Steady-state mass in regional freshwater sediment (kg)	4.65E+01	[kg]
Steady-state mass in regional seawater sediment (kg)	7.28E-01	[kg]
Steady-state mass in continental freshwater (kg)	6.46E+01	[kg]
Steady-state mass in continental seawater (kg)	3.14E+02	[kg]
Steady-state mass in continental air (kg)	2.63E+00	[kg]
Steady-state mass in continental agricultural soil (kg)	1.84E+04	[kg]
Steady-state mass in continental natural soil (kg)	6.62E+00	[kg]
Steady-state mass in continental industrial soil (kg)	2.45E+00	[kg]
Steady-state mass in continental freshwater sediment (kg)	5.54E+02	[kg]
Steady-state mass in continental seawater sediment (kg)	1.97E+01	[kg]

Steady state mass fraction		Units
Total steady-state mass fraction (region + content)	6.73E+01	[%]
Steady-state mass fraction in regional freshwater (%)	1.70E-02	[%]
Steady-state mass fraction in regional seawater (%)	1.82E-03	[%]
Steady-state mass fraction in regional air (%)	2.77E-04	[%]
Steady-state mass fraction in regional agricultural soil (%)	6.41E+00	[%]
Steady-state mass fraction in regional natural soil (%)	1.38E-03	[%]
Steady-state mass fraction in regional industrial soil (%)	5.11E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.46E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	2.28E-03	[%]
Steady-state mass in continental freshwater (kg)	2.02E-01	[%]
Steady-state mass in continental seawater (kg)	9.85E-01	[%]
Steady-state mass in continental air (kg)	8.24E-03	[%]

Steady-state mass in continental agricultural soil (kg)	5.77E+01	[%]
Steady-state mass in continental natural soil (kg)	2.07E-02	[%]
Steady-state mass in continental industrial soil (kg)	7.68E-03	[%]
Steady-state mass in continental freshwater sediment (kg)	1.74E+00	[%]
Steady-state mass in continental seawater sediment (kg)	6.19E-02	[%]

Sensitivity to specific variables

The main source of uncertainty in the assessment of this substance is:

- wide range in the reported concentration levels of the substance in C/D.

The impact of varying the releases within the specified range was explored. Refer to Table 3.73 below, which illustrates the impact on relevant predicted exposure concentrations. The inputs used in the 'more conservative' and 'less conservative' assessments are explained in the Occurrence data set section.

Table 3.73 Sensitivity of selected outputs in the assessment of HBCDD to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (general case)	Units
PECagricultural soil – local scenario I	1.06E-02	5.19E-03	[mg/kg dry wt.]
PECagricultural soil – local scenario II	2.01E+00	9.90E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake – local scenario I	4.72E-04	2.12E-04	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	3.77E-02	1.85E-02	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	2.15E+01	7.56E-04	[t]
Total steady-state mass fraction (region + continent)	6.73E+01	6.72E+01	[%]
Regional PEC in surface water (total)	1.51E-06	5.32E-11	[mg/l]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	1.16E+00	4.45E-01	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals – local scenario I	3.54E-04	1.67E-04	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	9.62E-02	4.74E-02	[mg.kg-1]

It can be concluded that:

- At the local scale, the variability in HBCDD in composts and digestates is not particularly significant as the predicted exposure concentrations of HBCDD in important compartments are within a factor of 2-3. This is mainly a consequence of how close the mid range concentrations in compost/digestate are compared to the maximum values, due to the small number of data points.
- At the regional scale, the difference between the two scenarios is much more significant for HBCDD.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.74 below presents the summary of key findings from the risk assessment of HBCDD that has been made in this project. The findings are discussed further below the table.

Table 3.74 Summary of key findings for exposure of HBCDD via use of compost and digestates

Key findings of the risk assessment of HBCDD in contaminated composts and digestates	
Overall range of compost and digestate concentrations	Very few reported values <1E-05 – 6.1 mg/kg dry wt.
Major raw material sources	The type of input material is not mentioned for the higher concentration compost/digestates. Digestate produced from renewable raw materials had lower concentration of HBCDD.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP/PBT Fresh water PEC exceeds the annual average EQS for inland surface water at both the local (scenario I) and regional scales (the MAC EQS is not exceeded); predator exposure via diet (local scenario I) exceeds the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	POP; SVHC (PBT); basis of EQS is not stated in the Directive but a background document suggests both the biota and freshwater EQS relate to effects in birds[47].
Uncertainties and their implications	Very limited data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	

As a POP and PBT SVHC under REACH, it is in itself a potentially important finding that HBCDD has been detected in freshly-produced composts and digestates in recent years. The raw material waste streams could be investigated further. It is noted though that very few of the literature has identified

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[47] EQS dossier available online at

HBCDD. The same factors mean that the very small data set size for occurrence is not necessarily a cause of concern in respect of uncertainty in the risk assessment.

The estimated regional scale exposures arising from the application of C/D are well below the anthropogenic background concentrations modelled in the ESR risk assessment (EC 2008c, which were reported to compare well with measured concentrations).

The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

At steady state, ca. 67% of the total mass remains within the region + continent[48], suggesting that there is limited redistribution following release via the handling and application of C/D. Much of the remainder is modelled to distribute to global tropic (13.5%) and global moderate (12%) waters. The total mass in the region + continent at steady state is approximately 20 t. When a comparable scenario is assessed using a lower level release based on the range of occurrence data, the total mass at steady state is much lower at <1 kg. This steady-state mass amounts to 0.48 times the mass released annually via application of composts and digestates[49], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

3.12 2,3,7,8-Tetrachlorodibenzodioxin (TCDD) (representative of Dioxins, Furans and Dioxin-like PCBs chemical family)

Dioxins and related compounds are persistent organochlorine compounds generated during incineration and as a by-product of certain industrial processes. This group covers numerous poly-chlorinated chemical structures; theoretically there are 75 polychlorinated dibenzo-p-dioxin (PCDD) and 135 polychlorinated dibenzofuran (PCDF) congeners, and 12 'dioxin-like polychlorinated biphenyls' (dl-PCBs). One representative PCDD and one PCDF have been selected for detailed assessment of this chemical family.

Toxicity in this group is assessed based on Toxic Equivalency Factors (TEFs) and Toxic Equivalent (TEQ) expressing the weighted concentration equivalent to the most toxic dioxin 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).

Background information and remarks

2,3,7,8-TCDD (CAS 1746-01-6, EC 217-122-7) is assessed as a representative substance of the Dioxins, Furans and Dioxin-like PCBs chemical family. This is the most toxic of the dioxins and is relatively data-rich providing a strong basis for the risk assessment.

Chemical properties and hazards data set

As a POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here. Table 3.75 summarises the property data, which is derived from WHO IPCS (1989b) EHC monograph 88 unless otherwise stated in the table.

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[48] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[49] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Table 3.75 Property information for 2,3,7,8-TCDD

Property	Value	Remarks
Molecular weight	321.9	
Melting point	305-306	
Boiling point		
Vapour pressure	low (no values) MPBPVP experimental database value: 1.5E-9 mmHg at 25C = 2E-07 Pa subcooled liquid VP 0.000118 Pa at 25C (no ref) - this was the value used in EUSES.	
Water solubility	2E-7 g/l; 12.5-19.2 ng/litre	A value of 15 ng/l was used in EUSES based on this.
log Kow	6.64	
Henry's law constant	HENRYWIN bond method 3.53E-6 atm.m3/mol; 5E-005 atm-m3/mole (Henry experimental database), which is equivalent to 5.07 Pa.m3/mol	5.07 Pa.m3/mol used in EUSES
Koc	highly adsorbed to sediments and biota. Matsumura et al. (1983) suggested that more than 90% of the 2,3,7,8-tetraCDD in an aquatic medium could be present in the adsorbed state. KOCWIN - Experimental Log Koc: 6.5 (database)	
BCF	Catfish; whole body: 28d BCF=4875 No earthworm data available. Snail BCFs in range ca. 3000-5500	
Biodegradability	not at all biodegradable. Slow abiotic degradation, probably photodegradation, but very long half lives >10y in all compartments	Abiotic reactivity: slow in soil (half-life of TCDD of about 10-12 years, for soil)
Half-life in air	Photochemical degradation possible - TCDD adsorbed on silica gel undergoes 'rapid' photo-chemical degradation AOPWIN prediction for 1746-01-6: reaction rate constant 0.753E-12 cm3/molecule-sec (equivalent to half life 21.3d)	

PNECs are not definable, however it is noted that an EQS of 0.0065 µg/kg TEQ is applicable for biota (Directive 2008/105/EC as amended (2013/39/EU)) as the sum of PCDD + PCDF + PCB-DL.

Occurrence data set

Table 3.76 presents a summary of the reported concentrations of PCDD/PCDF in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.76 Reported occurrence of PCDD/PCDF in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		42 individual result rows pertaining to total PCDD/F, several are replicates in terms of location and/or year. Many results are presented as I-TEQ. Very wide variation in values, from pg/kg to µg/kg. Three of the (sets of) values are reporting on a range of data, as ranges/median.
Compost - minimum concentration	7.00E-09	Lowest value of all is 7 pg/kg
Compost - mid-range or average concentration	0.0013	Average calculated from all reported figures is 1.3E-03 mg/kg. the median is 1.8E-05 mg/kg.
Compost - maximum concentration	0.012	The highest value of all is 12 µg/kg (2014 in a sewage sludge compost, this is the maximum reported value across a range from different countries). Result is in terms of I-TEQ for 17 PCDD/PCDF.
Digestates - data availability		14 individual result rows pertaining to total PCDD/F, several are replicates in terms of location and/or year. Many results are presented as I-TEQ. All in the ng/kg to µg/kg range. Eight of the (sets of) values are reporting on a range of data, as ranges/median or mean.
Digestate - minimum concentration	7.00E-08	Lowest value of all is 0.07-1.1 ng I-TEQ/kg TM (Bavaria, 2015)
Digestate - mid-range or average concentration	1.10E-03	Average calculated from all reported figures is 1.1E-03 mg/kg. the median is 3.1E-06 mg/kg
Digestate - maximum concentration	0.0145	The highest value of all is 14.5 µg/kg (2014 in a biowaste/green waste manure energy crop digestate; this is the maximum reported value across a range from different countries). Result is in terms of I-TEQ for 17 PCDD/PCDF.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.77 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	11
Mass of substance in EU-28 in digestate (kg/year)	39
Total regional emission to surface water (kg/day)	0.00039
Total regional emission to soil (kg/day)	0.013
Total continental emission to surface water (kg/day)	0.0035
Total continental emission to agricultural soil (kg/day)	0.12

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

A full literature search for the latest background data has not been attempted but European exposure data compiled by WHO are summarised in Table 3.78 below. In light of its status as a POP, there is an international commitment to restrict its use, and hence significant decline in use is to be expected going forward and the context of predicted environmental concentrations should be considered in this context.

Table 3.78 Reported background concentrations of PCDD/PCDF in various foodstuffs (Western Europe) (WHO, 2002)

Food category	Value (weighted mean / derived median; units of pg/g whole food)
Dairy	0.06/0.04
Eggs	0.07/0.03
Fish	0.37/0.11
Meat	0.09/0.01
Vegetable products	0.003/0.002

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of 2,3,7,8-TCDD resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.79 below.

Table 3.79 Predicted exposures for 2,3,7,8-TCDD arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	2.40E-04	[mg/kg dry wt.]
PECgrassland soil	9.57E-05	[mg/kg dry wt.]
PEC in groundwater	3.75E-09	[mg/l]
PECfreshwater	4.83E-09	[mg/l]
PECfreshwater-sediment	1.55E-03	[mg/kg dry wt.]
Humans via the environment: local total daily intake	7.75E-07	[mg.kg-1.d-1]

Humans via the environment: daily dose via drinking water	1.07E-10	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 77.2%	
Secondary poisoning – freshwater fish-eating birds and mammals	2.58E-05	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.90E-04	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	3.96E-03	[mg/kg dry wt.]
Humans via the environment: local total daily intake	9.98E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 98.8%	
Secondary poisoning – worm-eating birds and mammals	1.72E-03	[mg.kg-1]

Table 3.80 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.80 Predicted background exposures for 2,3,7,8-TCDD at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	1.59E+01	[t]
Steady-state mass in regional freshwater (kg)	9.52E-03	[kg]
Steady-state mass in regional seawater (kg)	8.80E-04	[kg]
Steady-state mass in regional air (kg)	1.31E-02	[kg]
Steady-state mass in regional agricultural soil (kg)	1.58E+03	[kg]
Steady-state mass in regional natural soil (kg)	1.32E-01	[kg]
Steady-state mass in regional industrial soil (kg)	4.90E-02	[kg]
Steady-state mass in regional freshwater sediment (kg)	2.62E+00	[kg]
Steady-state mass in regional seawater sediment (kg)	1.62E-01	[kg]
Steady-state mass in continental freshwater (kg)	1.01E-01	[kg]
Steady-state mass in continental seawater (kg)	5.73E-01	[kg]
Steady-state mass in continental air (kg)	9.11E-01	[kg]

Steady-state mass in continental agricultural soil (kg)	1.43E+04	[kg]
Steady-state mass in continental natural soil (kg)	4.66E+00	[kg]
Steady-state mass in continental industrial soil (kg)	1.73E+00	[kg]
Steady-state mass in continental freshwater sediment (kg)	2.78E+01	[kg]
Steady-state mass in continental seawater sediment (kg)	5.27E+00	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)	9.91E+01	[%]
Steady-state mass fraction in regional freshwater (%)	5.95E-05	[%]
Steady-state mass fraction in regional seawater (%)	5.50E-06	[%]
Steady-state mass fraction in regional air (%)	8.16E-05	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.87E+00	[%]
Steady-state mass fraction in regional natural soil (%)	8.26E-04	[%]
Steady-state mass fraction in regional industrial soil (%)	3.06E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.64E-02	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.01E-03	[%]
Steady-state mass in continental freshwater (kg)	6.31E-04	[%]
Steady-state mass in continental seawater (kg)	3.58E-03	[%]
Steady-state mass in continental air (kg)	5.69E-03	[%]
Steady-state mass in continental agricultural soil (kg)	8.90E+01	[%]
Steady-state mass in continental natural soil (kg)	2.91E-02	[%]
Steady-state mass in continental industrial soil (kg)	1.08E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	1.74E-01	[%]
Steady-state mass in continental seawater sediment (kg)	3.29E-02	[%]

Sensitivity to specific variables

The main source of uncertainty in the assessment of this substance is:

- wide range in the reported concentration levels of the substance in C/D

The impact of varying the releases within the specified range was explored. Refer to Table 3.81 below, which illustrates the impact on relevant predicted exposure concentrations. The inputs used in the 'more conservative' and 'less conservative' assessments are explained in the Occurrence data set section.

Table 3.81 Sensitivity of selected outputs in the assessment of 2,3,7,8-TCDD to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (general case)	Units
PECagricultural soil – local scenario I	2.40E-04	2.15E-05	[mg/kg dry wt.]
PECagricultural soil – local scenario II	3.96E-03	4.29E-04	[mg/kg dry wt.]
Humans via the environment: local total daily intake – local scenario I	7.75E-07	5.87E-08	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	9.98E-06	1.07E-06	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	1.59E+01	8.00E-04	[t]
Total steady-state mass fraction (region + continent)	9.91E+01	9.91E+01	[%]
Regional PEC in surface water (total)	2.65E-09	1.33E-13	[mg/l]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	2.58E-05	1.91E-06	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals – local scenario I	1.90E-04	8.89E-06	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	1.72E-03	1.77E-04	[mg.kg-1]

It can be concluded that:

- At the local scale, the predicted exposure concentrations of 2,3,7,8-TCDD in important compartments differ by a factor of around x10-20.
- At the regional scale, the difference between the two scenarios is much more significant for 2,3,7,8-TCDD at around 4 orders of magnitude.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.82 below presents the summary of key findings from the risk assessment of 2,3,7,8-TCDD that has been made in this project. The findings are discussed further below the table.

Table 3.82 Summary of key findings for exposure of 2,3,7,8-TCDD via use of compost and digestates

Key findings of the risk assessment of 2,3,7,8-TCDD in contaminated composts and digestates	
Overall range of compost and digestate concentrations	7E-09 – 0.0145 mg/kg dry wt. (total PCDD/PCDF)
Major raw material sources	Highest values are reported for sewage sludge composts and biowaste/green waste manure energy crop digestate
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP/PBT; significant cumulative loads at steady state; absolute concentrations exceeding previously published measured concentrations in foods; absolute concentrations in compost/digestate exceeding existing local limit values / guide values (but not exceeding EC Regulation 1195/2006); predator exposure via diet (local scenarios I and II) exceed the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	POP; basis of EQS is not stated in the Directive and is unclear
Uncertainties and their implications	Very variable data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	

As POPs, it is noteworthy that PCDD/PCDF and PCBs have been detected in freshly-produced composts and digestates at several different locations in recent years. Their presence may result from atmospheric deposition of emissions from combustion or municipal solid waste incineration rather than originating from the raw material waste streams. This could be investigated further if needed.

The highest reported concentrations in composts and digestates already appear to exceed the national limit value for several member states, although still within the 15 µg/kg limit referenced from Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 (POPs Regulation). These high occurrence concentrations arise from composts and digestates from a range of raw materials and processing types.

The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with (dietary consumption of root vegetables). The estimated exposures arising from the application of C/D are high compared with reported mean/median levels of PCDD/PCDF in foodstuffs including vegetables, in Western Europe as summarised by WHO (2002). This is the case even when lower concentrations were assumed in the exposure model (for example, the 'low concentration' exposure assessment for 2,3,7,8-TCDD results in concentrations of 1E-05 mg/kg and 2E-04 mg/kg in root tissue of plants arising from application to land (local scenario I) and container growing (local scenario II) respectively. However the WHO summary reports a weighted mean of 0.003 pg PCDD/PCDF/g whole food (equivalent to 3E-9 mg/kg) for vegetable products.

At steady state, >99% of the total mass remains within the region + continent[50], suggesting that there is relatively low potential for transfer over long distances following release via the handling and application of C/D. The total mass in the region + continent at steady state is 16t which is significant but not particularly high. This steady-state mass amounts to 320 times the mass released annually via application of composts and digestates[51]. When a comparable scenario is assessed using a lower level release, the steady state mass is very low (below 1 kg).

3.13 2,3,4,7,8-Pentachlorodibenzofuran (PCDF) (representative of Dioxins, Furans and Dioxin-like PCBs chemical family)

Background information and remarks

2,3,4,7,8-Pentachlorodibenzofuran (PCDF) (CAS 57117-31-4, no EC number) is an example of a furan structure in this chemical family.

Chemical properties and hazards data set

As a POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.

Despite consulting several sources, no single robust pre-existing regulatory assessment data set covering the core physical chemistry required by EUSES was identified. The data are drawn from literature sources as reported by common databases. Koc and BCF are estimated values. The sensitivity of the assessment to variation around the key input physicochemical properties has been investigated.

Table 3.83 Property information for 2,3,4,7,8-PCDF

Property	Value	Remarks
Molecular weight	340.42	
Melting point	196	EPI Suite Experimental Database
Boiling point		
Vapour pressure	3.51E-07 Pa at 25C	Rordorf BF (1989), cited by EPI Suite experimental database
Water solubility	0.000235 at 23C	Friesen KJ et al (1990), cited by EPI Suite experimental database
log Kow	6.92	Sijm DTHM et al; Chemosphere 19: 263-6 (1989) cited in EPI experimental database and Pubchem chemical profile

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[50] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[51] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Property	Value	Remarks
Henry's law constant	1.16 Pa.m3/mol (est)	No measured data found. This is the Bond method value estimated by EPI Suite
Koc	Koc Estimate from MC) (SRC QSAR): Estimated Koc: 2.33e+005 L/kg	EUSES derives Koc 5.08E+05 l/kg from Kow (predominantly hydrophobics).
BCF		
Biodegradability	no biodegradation half-life defined	
Half-life in air	OH reaction rate constant: 0.1147E-12 cm3.molecule-1.s-1 (est)	AOPWIN reaction rate

PNECs are not definable, however it is noted that an EQS of 0.0065 µg/kg TEQ is applicable for biota (Directive 2008/105/EC as amended (2013/39/EU)) as the sum of PCDD + PCDF + PCB-DL.

Occurrence data set

A summary of the reported concentrations of PCDD/PCDF in composts and digestates is presented in Table 3.76 in the previous section, and is not repeated here.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

A full literature search for the latest background data has not been attempted but European exposure data compiled by WHO are summarised in Table 3.78 in the previous section and are not repeated here. In light of its status as a POP, there is an international commitment to restrict its use, and hence significant decline in use is to be expected going forward and the context of predicted environmental concentrations should be considered in this context.

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of 2,3,4,7,8-PCDF resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.84 below.

Table 3.84 Predicted exposures for 2,3,4,7,8-PCDF arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	3.14E-04	[mg/kg dry wt.]

PECgrassland soil	1.69E-04	[mg/kg dry wt.]
PEC in groundwater	3.09E-08	[mg/l]
PECfreshwater	2.21E-08	[mg/l]
PECfreshwater-sediment	1.12E-03	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.08E-05	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	8.83E-10	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 84%	
Secondary poisoning – freshwater fish-eating birds and mammals	6.89E-03	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	4.05E-03	[mg.kg-1]

	Scenario II	**Units**
PECagricultural soil	4.03E-03	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.17E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.5%	
Secondary poisoning – worm-eating birds and mammals	2.06E-02	[mg.kg-1]

fferent steady state balance.

Table 3.85 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.85 Predicted background exposures for 2,3,4,7,8-PCDF at steady state arising from use of composts and digestates

	Steady state mass	**Units**
Total steady-state mass (region + continent)	4.88E+01	[t]
Steady-state mass in regional freshwater (kg)	5.04E-02	[kg]
Steady-state mass in regional seawater (kg)	5.70E-03	[kg]
Steady-state mass in regional air (kg)	6.19E-03	[kg]
Steady-state mass in regional agricultural soil (kg)	4.27E+03	[kg]
Steady-state mass in regional natural soil (kg)	5.97E+01	[kg]

Steady-state mass in regional industrial soil (kg)	2.21E+01	[kg]
Steady-state mass in regional freshwater sediment (kg)	7.07E+00	[kg]
Steady-state mass in regional seawater sediment (kg)	3.32E-01	[kg]
Steady-state mass in continental freshwater (kg)	7.07E-01	[kg]
Steady-state mass in continental seawater (kg)	8.15E+01	[kg]
Steady-state mass in continental air (kg)	2.21E-01	[kg]
Steady-state mass in continental agricultural soil (kg)	4.25E+04	[kg]
Steady-state mass in continental natural soil (kg)	1.08E+03	[kg]
Steady-state mass in continental industrial soil (kg)	3.99E+02	[kg]
Steady-state mass in continental freshwater sediment (kg)	9.91E+01	[kg]
Steady-state mass in continental seawater sediment (kg)	2.38E+02	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)	5.87E+01	[%]
Steady-state mass fraction in regional freshwater (%)	6.06E-05	[%]
Steady-state mass fraction in regional seawater (%)	6.85E-06	[%]
Steady-state mass fraction in regional air (%)	7.45E-06	[%]
Steady-state mass fraction in regional agricultural soil (%)	5.14E+00	[%]
Steady-state mass fraction in regional natural soil (%)	7.19E-02	[%]
Steady-state mass fraction in regional industrial soil (%)	2.66E-02	[%]
Steady-state mass fraction in regional freshwater sediment (%)	8.50E-03	[%]
Steady-state mass fraction in regional seawater sediment (%)	4.00E-04	[%]
Steady-state mass in continental freshwater (kg)	8.50E-04	[%]
Steady-state mass in continental seawater (kg)	9.80E-02	[%]
Steady-state mass in continental air (kg)	2.66E-04	[%]
Steady-state mass in continental agricultural soil (kg)	5.12E+01	[%]
Steady-state mass in continental natural soil (kg)	1.30E+00	[%]

Steady-state mass in continental industrial soil (kg)	4.80E-01 [%]
Steady-state mass in continental freshwater sediment (kg)	1.19E-01 [%]
Steady-state mass in continental seawater sediment (kg)	2.86E-01 [%]

Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- Log Kow (value 6.92 ± 1 log unit)
- Water solubility (value 2.35E-04 mg/l ± 1 log unit)
- Vapour pressure (value 3.51E-07 ± 1 log unit)
- Wide range in the reported concentration levels of the substance in C/D

The impact of varying each property within a suitable uncertainty range around the selected (baseline) value was explored independently. Refer to Figure 3.6 to Figure 3.10 and Table 3.86 below, which illustrate the impact on relevant predicted exposure concentrations.

In respect of the concentration in the compost/digestate, the impact of varying the releases within the specified range was explored. In respect of the variable concentrations/releases, the inputs used in the 'more conservative' and 'less conservative' assessments are explained in the Occurrence data set section.

Figure 3.6 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the vapour pressure input value: diet of fish-eating birds and mammals

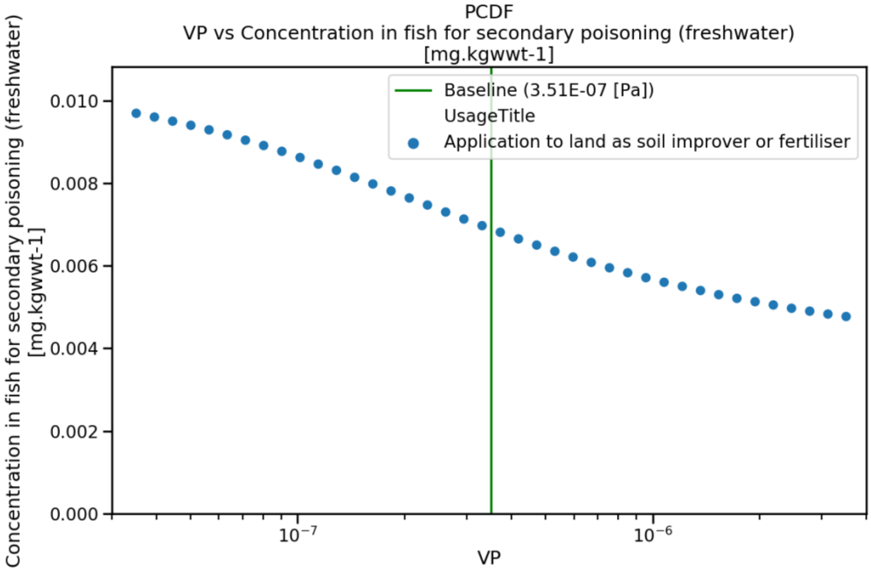

Figure 3.7 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the vapour pressure input value: diet of worm-eating birds and mammals

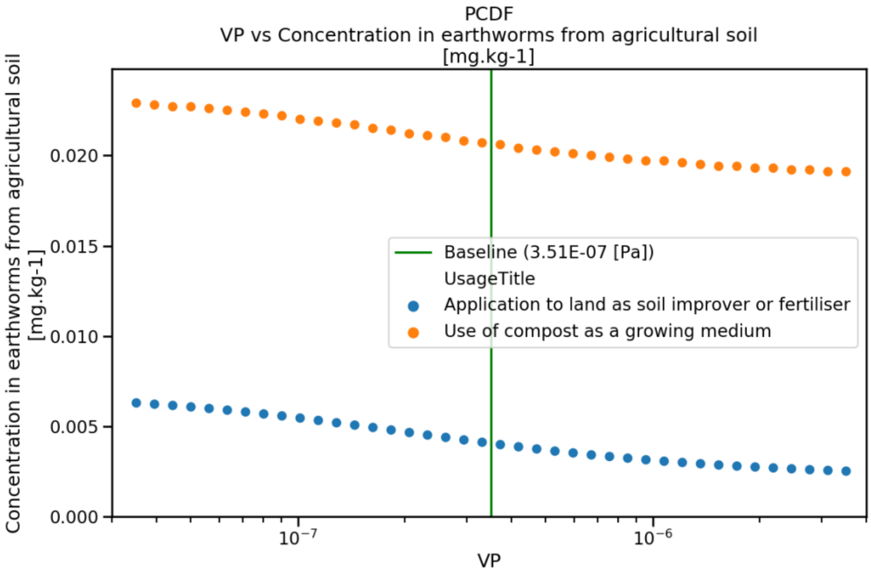

Figure 3.8 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the log Kow input value: fresh-water sediment

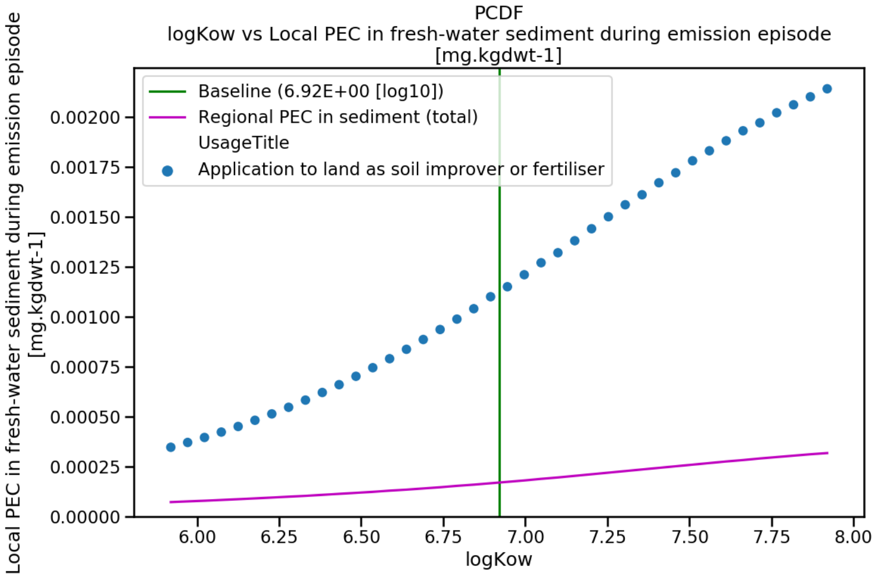

Figure 3.9 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the log Kow input value: diet of fish-eating birds and mammals

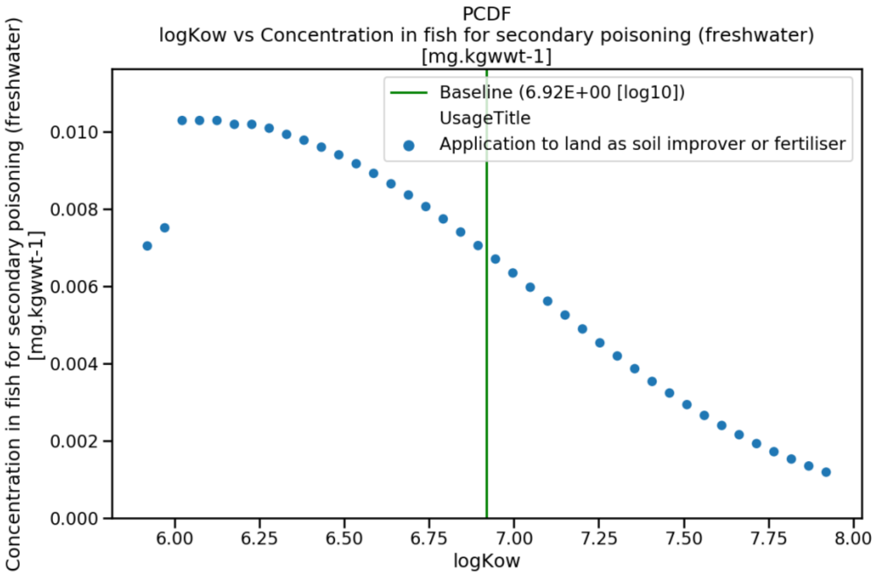

Figure 3.10 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the log Kow input value: diet of worm-eating birds and mammals

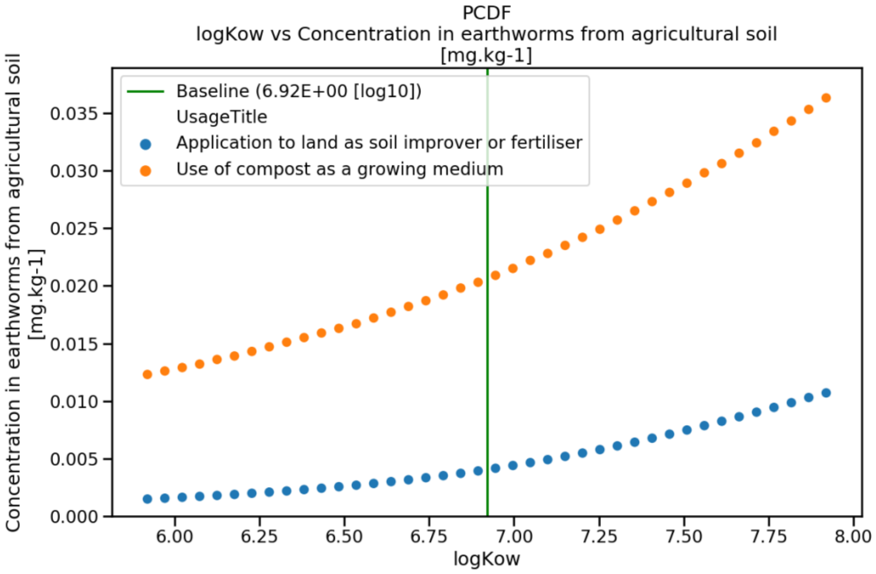

Table 3.86 Sensitivity of selected outputs in the assessment of 2,3,4,7,8-PCDF to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (general case)	Units
PECagricultural soil – local scenario I	3.14E-04	2.15E-05	[mg/kg dry wt.]
PECagricultural soil – local scenario II	4.03E-03	4.29E-04	[mg/kg dry wt.]

	More conservative (realistic worst case)	Less conservative (general case)	Units
Humans via the environment: local total daily intake – local scenario I	1.08E-05	7.22E-07	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	1.17E-04	1.24E-05	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	4.88E+01	2.46E-03	[t]
Total steady-state mass fraction (region + continent)	5.87E+01	5.87E+01	[%]
Regional PEC in surface water (total)	1.40E-08	7.05E-13	[mg/l]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	6.89E-03	2.98E-04	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals – local scenario I	4.05E-03	9.61E-05	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	2.06E-02	1.91E-03	[mg.kg-1]

It can be concluded that:

- At the water solubility value used in the baseline assessment, all PECs have been estimated conservatively. Within the uncertainty range, some PECs could be higher, but some could be lower.
- The secondary poisoning exposure of worm-eating birds and mammals, and of fish-eating birds and mammals could have been significantly higher (up to 2x) than estimated in the baseline assessment, at lower Kow values and VP value within a reasonable uncertainty range around the literature values.
- The local total daily intake via both exposure scenarios could have been significantly higher (up to 2x) than estimated in the baseline assessment, at lower Kow values within a reasonable uncertainty range around the literature log Kow value.
- The secondary poisoning exposure of fish-eating birds and mammals (local scenario I), and sediment PECs, could be up to 2x higher at lower Kow values within a reasonable uncertainty range.
- At the local scale, the predicted exposure concentrations of 2,3,4,7,8-PCDF in important compartments differ by a factor of around x10-20.
- At the regional scale, the difference between the two scenarios is much more significant for 2,3,4,7,8-PCDF at more than 4 orders of magnitude.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.87 below presents the summary of key findings from the risk assessment of 2,3,4,7,8-PCDF that has been made in this project. The findings are discussed further below the table.

Table 3.87 Summary of key findings for exposure of 2,3,4,7,8-PCDF via use of compost and digestates

Key findings of the risk assessment of 2,3,4,7,8-PCDF in contaminated composts and digestates	
Overall range of compost and digestate concentrations	7E-09 – 0.0145 mg/kg dry wt. (total PCDD/PCDF)
Major raw material sources	Highest values are reported for sewage sludge composts and biowaste/green waste manure energy crop digestate
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP/PBT; significant cumulative loads at steady state; absolute concentrations exceeding previously published measured concentrations in foods; absolute concentrations in compost/digestate exceeding existing local limit values / guide values (but not exceeding EC Regulation 1195/2006); predator exposure via diet (local scenarios I and II) exceed the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU))
Effects considered in the main concern hazard(s)	POP; basis of EQS is not stated in the Directive and is unclear.
Uncertainties and their implications	Very variable data set of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Variability in some important physicochemical input property data could be significant for PECs. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	

The findings and conclusions for 2,3,4,7,8-PCDF are to some extent in line with those set out for 2,3,7,8-TCDD in the previous section. However unlike for 2,3,7,8-TCDD, the models indicate that at steady state, ca. 59% of the total mass of 2,3,4,7,8-PCDF remains within the region + continent[52], suggesting that there is some potential for transfer over long distances following release via the handling and application of C/D[53]. The total mass in the region + continent at steady state is 49 t. When a comparable scenario is assessed using a lower level concentration in C/D within the reported range, the steady state mass is much lower at ca. 3 kg. This steady-state mass amounts to 970 times the mass released annually via application of composts and digestates[54].

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[52] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[53] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[54] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use

The differences may be attributable to the apparent higher water solubility and lower Koc for 2,3,4,7,8-PCDF compared to 2,3,7,8-TCDD. The sensitivity of the assessment to possible uncertainty around the physicochemical input data confirm that the aquatic compartment and predator food chains especially may be affected by the uncertainty.

3.14 2,4,4'-Trichlorobiphenyl (PCB-28) (representative of PCBs chemical family)

Background information and remarks

2,4,4'-Trichlorobiphenyl (EC 230-293-2, CAS 7012-37-5) is a trichlorinated PCB congener. The group of polychlorinated biphenyls (PCBs) is one of the original twelve POPs covered by the Stockholm Convention. A sub-category of PCBs (tetra- and higher chlorinated structures) are referred to as 'dioxin-like' PCBs. Although PCB-28 does not meet this definition for a 'dioxin-like PCB', it is relevant that the PCBs used were as mixtures rather than pure substances. The detection of any such substance in C/D is therefore indicative for the wider group of PCB including 'dioxin-like' PCBs. Exposure of PCB-28 has been modelled as a representative marker substance for the group, and resulting exposures have been compared to applicable thresholds for dioxin-like PCBs.

Chemical properties and hazards data set

As a POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here. Table 3.88 summarises the property data, which is literature data referenced from WHO (1993) IPCS EHC monograph unless otherwise stated in the table.

Table 3.88 Property information for PCB-28

Property	Value	Remarks
Molecular weight	257.54 g/mol	
Melting point	57-58C	
Boiling point	206-207	
Vapour pressure	0.026 Pa at 25C	
Water solubility	0.27 mg/l at 25C 0.067-0.312	
log Kow	4.38-5.81. Hansch & Leo: 5.62	The value from Hansch and Leo was used in EUSES.
Henry's law constant		
Koc	3.53 - 5.80	log values
BCF	4.32-5.62	fish. Log values

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application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Property	Value	Remarks
Biodegradability	limited, slow biodegradability is possible for some congeners, reliable data not readily available. No half-life entered in EUSES.	
Half-life in air	AOP rate constant: 1.1856E-12 cm3/molecule-sec	Variable data available on fraction sorbed to airborne particulates. 0.00058 Junge-Pankow Mackay average. 0.000999 Koa method. The sorbed fraction may be resistant to atmospheric oxidation.

PNECs are not definable, however it is noted that an EQS of 0.0065 µg/kg TEQ is applicable for biota (Directive 2008/105/EC as amended (2013/39/EU)) as the sum of PCDD + PCDF + PCB-DL.

Occurrence data set

Table 3.89 presents a summary of the reported concentrations of PCB-28 in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.89 Reported occurrence of PCB-28 in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		23 data points, of which several are ranges or represent an external data set. Quite a lot of variability with values in the ng/kg, µg/kg and up to mg/kg order. No consistency between specific PCB, PCB vs DL-PCB, or total across all PCB or dioxin/furan/dioxin-like-PCB
Compost - minimum concentration	0.004	Lowest reported value for PCB7 is for green waste compost in BE (Flanders) cited in Saveyn and Eder
Compost - mid-range or average concentration	0.03	The median value of 27.3 µg/kg dry wt. from Saveyn and Eder seems to be reasonably representative of this very variable dataset.
Compost - maximum concentration	0.2	100 µg/kg d.m. 90-percentile levels (PCBs specifically). A limit value of 200 µg/kg d.m. is mentioned by Saveyn and Eder. Several entries report values approx 100 µg/kg d.m. A report of 4.4. - 10 mg PCBs/kg in compost made from low grade waste wood may be an outlier[55]
Digestates - data availability	0	18 data points, of which several are ranges or represent an external data set. Quite a lot of variability with values in the fractions of ng/kg, µg/kg and up to several mg/kg order. No consistency between specific PCB, PCB vs DL-PCB, or total across all PCB or dioxin/furan/dioxin-like-PCB
Digestate - minimum concentration	0.001	Lowest reported value for PCB7 is for bio-waste and green waste manure energy crops digestate (this value is the lower limit of the range for several EEA countries) from Saveyn and Eder, 2014.

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[55] Very high PCB levels indicate that ill-defined or contaminated input materials have a detrimental effect on compost quality

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Digestate - mid-range or average concentration	0.03	The median value of 27.3 µg/kg dry wt. from Saveyn and Eder seems to be reasonably representative of this very variable dataset.
Digestate - maximum concentration	1.2	The reported values in Norway are far higher than the other values in the set. highest value of all is ~9 mg PCB6/kg dry wt. which is mentioned as an average. A limit of 1.2 mg PCB6/kg dry wt. mentioned as being applicable in Norway.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.90 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	265
Mass of substance in EU-28 in digestate (kg/year)	1058
Total regional emission to surface water (kg/day)	0.010
Total regional emission to soil (kg/day)	0.35
Total continental emission to surface water (kg/day)	0.91
Total continental emission to agricultural soil (kg/day)	3.2

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.91 below summarises some relevant background exposure data previously presented by WHO (2002). In light of the status of the PCB family as a POP, there is an international commitment to restrict the use of PCBs, and hence significant decline in use is to be expected going forward and the context of predicted environmental concentrations should be considered in this context.

Table 3.91 Reported background concentrations of coplanar PCBs in various foodstuffs (Western Europe) (WHO, 2002)

Food category	Value (weighted mean / derived median; units of pg/g whole food)
Dairy	0.08/0.07
Eggs	0.07/0.06
Fish	2.55/0.90

Meat	0.41/0.08
Vegetable products	0.04/LOD

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of PCB-28 resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.92 below.

Table 3.92 Predicted exposures for PCB-28 arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.96E-02	[mg/kg dry wt.]
PECgrassland soil	7.72E-03	[mg/kg dry wt.]
PEC in groundwater	2.12E-05	[mg/l]
PECfreshwater	2.10E-06	[mg/l]
PECfreshwater-sediment	9.73E-03	[mg/kg dry wt.]
Humans via the environment: local total daily intake	6.87E-04	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	6.07E-07	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 52.9%	
Secondary poisoning – freshwater fish-eating birds and mammals	1.05E+00	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	5.79E-02	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	6.60E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.24E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 98.2%	
Secondary poisoning – worm-eating birds and mammals	1.73E-01	[mg.kg-1]

Table 3.93 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.93 Predicted background exposures for PCB-28 at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	2.72E+02	[t]
Steady-state mass in regional freshwater (kg)	5.91E-01	[kg]
Steady-state mass in regional seawater (kg)	5.77E-02	[kg]
Steady-state mass in regional air (kg)	2.83E-01	[kg]
Steady-state mass in regional agricultural soil (kg)	2.70E+04	[kg]
Steady-state mass in regional natural soil (kg)	3.62E+00	[kg]
Steady-state mass in regional industrial soil (kg)	1.34E+00	[kg]
Steady-state mass in regional freshwater sediment (kg)	1.16E+01	[kg]
Steady-state mass in regional seawater sediment (kg)	3.45E-01	[kg]
Steady-state mass in continental freshwater (kg)	6.27E+00	[kg]
Steady-state mass in continental seawater (kg)	1.74E+02	[kg]
Steady-state mass in continental air (kg)	1.71E+01	[kg]
Steady-state mass in continental agricultural soil (kg)	2.44E+05	[kg]
Steady-state mass in continental natural soil (kg)	1.10E+02	[kg]
Steady-state mass in continental industrial soil (kg)	4.08E+01	[kg]
Steady-state mass in continental freshwater sediment (kg)	1.23E+02	[kg]
Steady-state mass in continental seawater sediment (kg)	5.19E+01	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	9.71E+01	[%]
Steady-state mass fraction in regional freshwater (%)	2.11E-04	[%]
Steady-state mass fraction in regional seawater (%)	2.07E-05	[%]
Steady-state mass fraction in regional air (%)	1.01E-04	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.67E+00	[%]
Steady-state mass fraction in regional natural soil (%)	1.30E-03	[%]
Steady-state mass fraction in regional industrial soil (%)	4.80E-04	[%]

Steady-state mass fraction in regional freshwater sediment (%)	4.14E-03	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.23E-04	[%]
Steady-state mass in continental freshwater (kg)	2.24E-03	[%]
Steady-state mass in continental seawater (kg)	6.23E-02	[%]
Steady-state mass in continental air (kg)	6.12E-03	[%]
Steady-state mass in continental agricultural soil (kg)	8.72E+01	[%]
Steady-state mass in continental natural soil (kg)	3.95E-02	[%]
Steady-state mass in continental industrial soil (kg)	1.46E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	4.40E-02	[%]
Steady-state mass in continental seawater sediment (kg)	1.86E-02	[%]

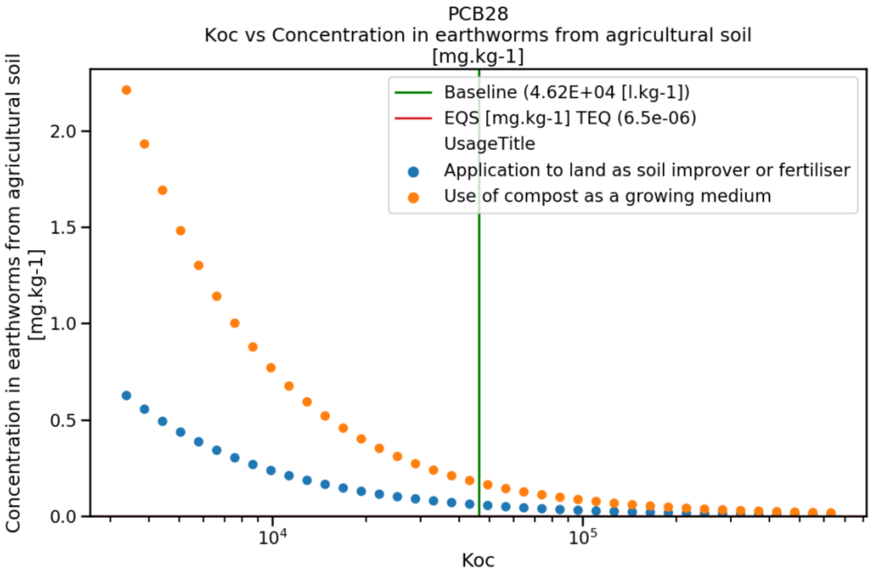
Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- BCF in fish (literature data range 2E+04 to 4E+05 l/kg)
- Koc (literature data range 3.4E+03 to 6.3E+05 l/kg)
- log Kow (literature data range 4.4 to 5.9)

The impact of varying each property within the specified range around a selected baseline value from within the range was explored independently. Refer to Figure 3.11 to Figure 3.15, which illustrate the impact on relevant predicted exposure concentrations.

Figure 3.11 Sensitivity of selected outputs in the assessment of PCB-28 to the Koc input value: diet of worm-eating birds and mammals



Note: the red line representing the EQS cannot be seen on this graph due to it overlapping the x-axis on this scale.

Figure 3.12 Sensitivity of selected outputs in the assessment of PCB-28 to the Koc input value: total daily intake for humans

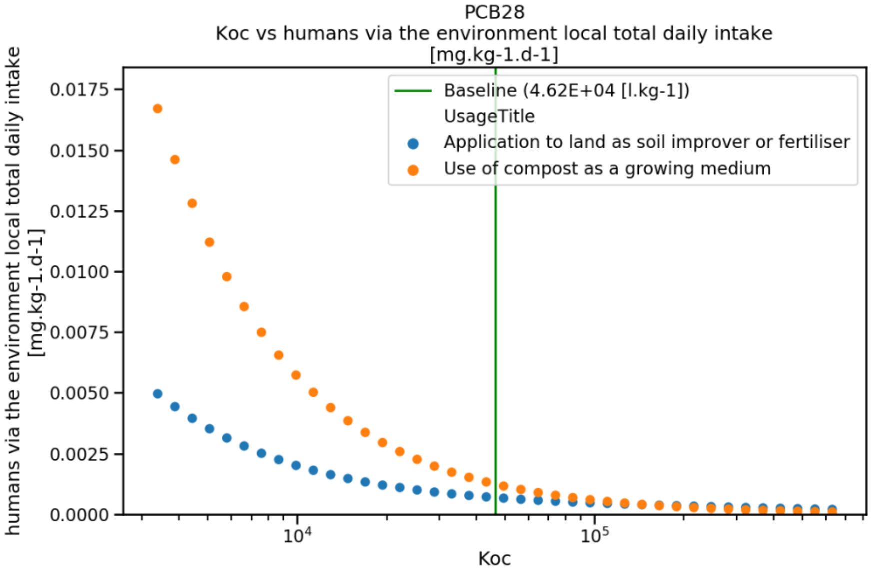
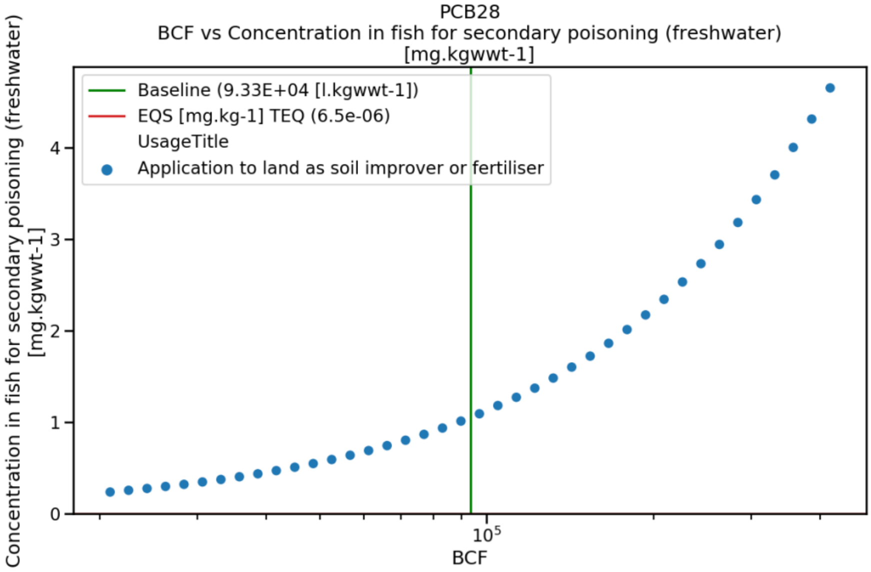


Figure 3.13 Sensitivity of selected outputs in the assessment of PCB-28 to the BCF input value: diet of fish-eating birds and mammals



Note: the red line representing the EQS cannot be seen on this graph due to it overlapping the x-axis on this scale.

Figure 3.14 Sensitivity of selected outputs in the assessment of PCB-28 to the log Kow input value: total daily intake for humans

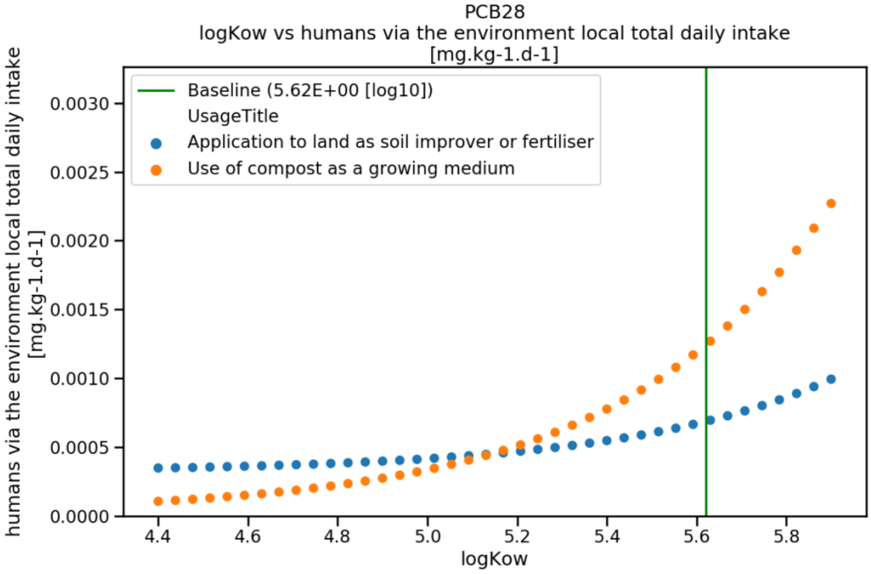
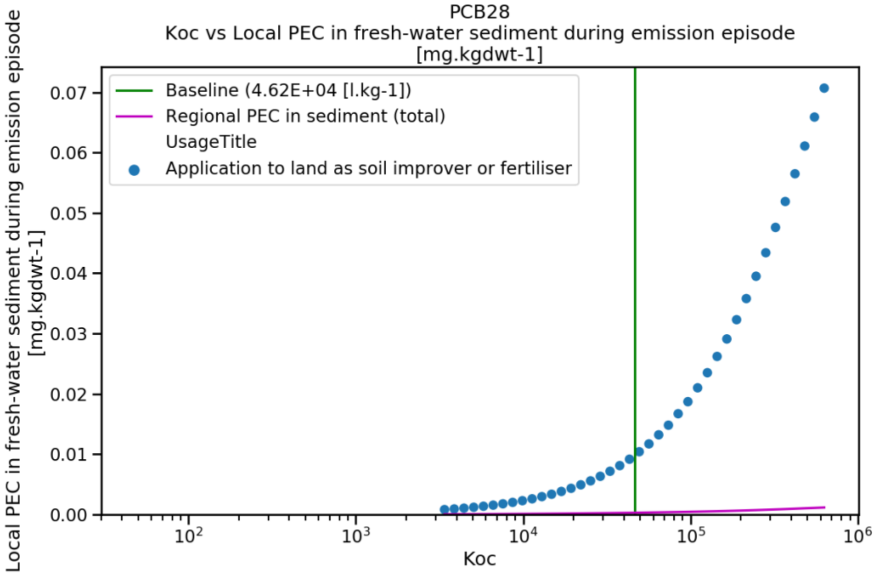


Figure 3.15 Sensitivity of selected outputs in the assessment of PCB-28 to the Koc input value: fresh-water sediment



It can be concluded that:

- The variation in Koc input value is of particular significance for human dietary intake levels, sediment biota, and also predator exposure via diet (earthworms). In respect of predator exposure the modelled concentrations in prey exceed the EQS for biota at all values of Koc so the uncertainty does not affect the assessment conclusions.
- Within the literature data range of log Kow, there is an impact on the local total daily intake for humans; a relatively conservative value has been used but in the realistic worst case exposures could be up to 2x higher than modelled here.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.94 below presents the summary of key findings from the risk assessment of PCB-28 that has been made in this project. The findings are discussed further below the table.

Table 3.94 Summary of key findings for exposure of PCB28 via use of compost and digestates

Key findings of the risk assessment of PCB28 in contaminated composts and digestates	
Overall range of compost and digestate concentrations	0.001 – 1.2 mg/kg dry wt. (higher values up to 9-10 mg PCB6/kg dry wt. appear to be exceptional)
Major raw material sources	Concentrations above ca. 0.1 µg PCBs/kg dry wt. are reported for digestates derived from biowaste-food and garden waste, biowaste and green waste compost, sewage sludge compost,

Key findings of the risk assessment of PCB28 in contaminated composts and digestates	
	C/Ds from source separation and compost made from low-grade waste wood.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of POP; significant cumulative loads at steady state; absolute concentrations exceeding previously published measured concentrations in foods; absolute concentrations in compost/digestate exceeding existing local limit values / guide values (but not exceeding EC Regulation 1195/2006); predator exposure via diet (local scenarios I and II) exceed the EQS for biota (Directive 2008/105/EC as amended (2013/39/EU))
Effects considered in the main concern hazard(s)	POP; basis of EQS is not stated in the Directive and is unclear.
Uncertainties and their implications	Range of concentrations in composts / digestates means release amounts could be under- or over-estimated in this model. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	

As POPs, it noteworthy that PCBs have been detected in freshly-produced composts and digestates at several different locations in recent years. Their presence may result from atmospheric deposition of emissions from combustion or municipal solid waste incineration rather than originating from the raw material waste streams. This could be investigated further if needed.

The highest reported concentrations especially in digestates in Norway (reported by Govasmark et al., 2011) appear to significantly exceed the national limit value for PCBs in that region (Forskrift om organisk gjødsel; Mattilsynet, 2005; 1.2 mg/kg DM). These high occurrence concentrations seem to mainly relate to digestates prepared from biowastes food and garden wastes.

The highest contribution(s) to human exposure via the environment arising from the application of C/D is mainly associated with (dietary consumption of root vegetables). The estimated exposures arising from the application of C/D are high compared with reported mean/median levels of PCBs in foodstuffs including vegetables, in Western Europe as summarised by WHO (2002). This is the case even when lower concentrations were assumed in the exposure model (for example, the 'low concentration' exposure assessment for PCB-28 results in concentrations of 2E-03 mg/kg and 0.03 mg/kg in root tissue of plants arising from application to land (local scenario I) and container growing (local scenario II) respectively. However, the WHO summary reports a weighted mean of 0.04 pg PCBs/g whole food (equivalent to 4E-08 mg/kg) for vegetable products.

At steady state, 97% of the total mass remains within the region + continent[56], suggesting that there is relatively low potential transfer over long distances following release via the handling and application of C/D. The total mass in the region + continent at steady state is very high at 270 t. Even when a comparable scenario is assessed using a lower level release, ca. 15 t is modelled to remain within the

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[56] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

region + continent at steady state. This steady-state mass amounts to 200 times the mass released annually via application of composts and digestates[57].

The consulted sources of property data show there is variation in some input properties. The sensitivity of the conclusions to this uncertainty has been investigated and it is noted that variation in the value of Koc and BCF particularly across the range given could be significant in respect of the predicted exposure concentrations in freshwater sediment, worm-eating predators via the food chain, and humans exposed via the environment. This is an important source of uncertainty in the exposure assessment.

3.15 Nonylphenol (representative of Nonylphenol and Nonylphenol Ethoxylates chemical family)

Background information and remarks

4-Nonylphenol (branched), CAS 84852-15-3, EC 284-325-5 has been subject to an EU regulatory risk assessment under ESR (EC, 2002) which concluded a need for risk reduction measures for several uses to protect the aquatic and soil compartments and predators via the food chain; a need for further information was indicated for humans via the environment.

A restriction proposal to control environmental risks has been proposed (supported by a detailed background document, ECHA, 2014b). According to the harmonised classification and labelling approved by the European Union, this substance causes severe skin burns and eye damage, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is harmful if swallowed and is suspected of damaging fertility and the unborn child. EQS are applicable under the WFD. There is evidence of estrogenic effects, and so the available threshold concentrations for humans by indirect exposure are doubtful and quantitative risk characterisation for humans has not been attempted.

Chemical properties and hazards data set

The chemical data set is as cited in the ESR risk assessment (EC 2002) or RAC/SEAC background document (2014b) prepared in support of the restriction proposal, unless otherwise stated. In accordance with the ESR risk assessment approach, the exposure assessment in this project is made for nonylphenol, to represent any other forms which might generate nonylphenol as a by-product.

Table 3.95 Property information for nonylphenol

Property	Value	Remarks
Molecular weight	220.34 g/mole	
Melting point	-8˚C	
Boiling point	The boiling range has been quoted as 290-302°C (Hüls, 1994); 287-306°C, with decomposition (Industrial Chemicals, 1975); 293-297°C (Merck Index, 1989); and 295°C (ICI, 1995). Other values include 295°C (Dutch Institute for the Working Environment, 1991) and 310°C (Kirk-	

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[57] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

	Othmer, 1993). The actual boiling/decomposition range will depend on the purity and origin of the material and the values quoted here can be considered representative of the commercially available material	
Vapour pressure	Approximately 0.3 Pa at 25°C	
Water solubility	Although no data have been found to show the solubility variation of a particular brand of nonylphenol with pH, the solubility is likely to be influenced by this factor. At environmental pHs, it is thought that nonylphenol would be present mainly in the undissociated form (pKa of 10; see Section 1.3.13). A water solubility of 6 mg/l at 20°C will be used for environmental modelling purposes.	
log Kow	Two values are used in the 2014 assessment: 4.48 and 5.4.	The higher value is more conservative and is used in the baseline assessment as a conservative approach.
Henry's law constant	11.02 Pa.m3.mol-1.	
Koc	Koc values derived from both alternative values of log Kow were examined in the RAC/SEAC background document. This assessment also considers the sensitivity of the outcomes to this variation.	
BCF	It is clear from the available data that nonylphenol bioconcentrates to a significant extent in aquatic species, with BCFs (on a fresh weight basis) of up to 1,300 in fish. However, this value may overestimate the BCF; more reliable values with a mean of 741 have been measured, which are of a similar order of magnitude. Bioconcentration factors of around 2,000-3,000 have been measured in mussels. The BCF calculated from the log Kow of 4.48, using the TGD equation, is 1,280, which agrees well with the measured values. The calculated value of 1,280 will be used in the risk assessment.	
Biodegradability	A large set of half-lives are summarised (see ECHA, 2014b for further details). Nonylphenol is not persistent in freshwater or estuarine sediment, since t1/2 <120 d. In EUSES, a half-life of 99d at 25°C has been entered. Nonylphenol is not persistent in soil, since t1/2 <120 d. In EUSES, a half-life of 40 d at 25°C has been entered.	Based upon the available biodegradation data, nonylphenol is inherently biodegradable, and so the rate constant for biodegradation in a WWTP is taken as 0.1 h^{-1} for modelling of the removal during wastewater treatment at plants producing or processing nonylphenol itself. Half-lives for biodegradation in soil of 300 days and surface water of 150 days have been estimated. (ESR RAR EC 2002, Page 75)
Half-life in air	Nonylphenol released to the atmosphere is likely to be degraded by reaction with hydroxyl radicals, with a half-life of around 0.3 days.	

Threshold hazard values if available	Value	Remarks
PNECaquatic (freshwater)	PNECwater of 0.39 µg/l - page 163 (RAC/SEAC background document). A very similar value of 0.3 µg/l is defined for the annual average EQS in inland surface waters; MAC EQS of 2.0 µg/l (Directive 2008/105/EC as amended (2013/39/EU))	
PNECsediment (freshwater)	4.62 mg NP/kg dry wt.	RAC/SEAC background document (ECHA, 2014b)
PNECsoil	1.2 mg NP/kg dry wt..	RAC/SEAC background document (based on enchytraeid reproductive effects). This updates the PNECsoil of 0.3 mg/kg wet wt used in the original ESR RAR stating it the data is now considered unreliable.
PNECoral predator	PNECoral is 10 mg/kg food	RAC/SEAC background document p69 (based on mammalian reproductive effects) concurs with ESR RAR EC 2002, Page 134
DNEL general population oral		not discussed in the 2013 restriction proposal which focuses on environment only.
Other relevant data		

Occurrence data set

Table 3.96 presents a summary of the reported concentrations of nonylphenol and its ethoxylates in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.96 Reported occurrence of nonylphenol in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		6 data points of which 1 is a range (Bavaria), two others are highest and second-highest from same data set (across several member states), and 3 are different samples from the same study (Finland)
Compost - minimum concentration	0.1	Actually reported as a limit value, <100 µg/kg TM (Bavaria, 2015)
Compost - mid-range or average concentration	10.4	The average across all reported measured values is approx 12 mg/kg (approx 7 if the high value of 47 is excluded). This is close to the value of 10.4 cited by Saveyn and Eder so this value is used.
Compost - maximum concentration	47	Highest single reported value is 47 mg/kg dry wt. (FI); a second value of 26 mg/kg is available for a different sample from the same location and a value of 10.4 mg/kg is reported as the maximum for green composts from several different member states. In view of the small data set the highest reported value is used as the max.

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Digestates - data availability		5 data points of which two are ranges from the same data set (Bavaria), and 3 are different samples from the same study (Finland)
Digestate - minimum concentration	0.1	Actually reported as a limit value, <100 µg/kg TM (Bavaria, 2015)
Digestate - mid-range or average concentration	2	Excluding the high value below, the range is aprox <0.1 - 2.0 mg/kg. The average across all values including the high of 50 mg/kg is 8.0. Selecting a value of 2.0 mg/kg is close to the upper end of the range for both locations with measurements, excluding the highest single value.
Digestate - maximum concentration	50	Highest reported value is 50 mg/kg dry wt. (FI) whereas the highest mentioned limit 'guide' value is 25 mg/kg dry wt. (AGW). In view of the small data set the highest reported value is used as the max.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.97 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	91,728
Mass of substance in EU-28 in digestate (kg/year)	70,560
Total regional emission to surface water (kg/day)	1.2
Total regional emission to soil (kg/day)	43
Total continental emission to surface water (kg/day)	11
Total continental emission to agricultural soil (kg/day)	389

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.98 below summarises background exposure data compiled as part of the ESR risk assessment (EC 2002).

Table 3.98 Reported background concentrations of nonylphenol in the environment

PECregional	Value	Remarks
Air		

Surface water	0.60 µg/l	PECs based on direct emissions and NPE breakdowns
Sediment	103 µg/kg	table 3.18 ESR RAR EC 2002, page 136
Agricultural soil		
Soil pore water/ground water		
Natural soil		
Urban/industrial soil		
Other relevant data		**see also table 3.18 ESR RAR EC 2002, page 136**

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of nonylphenol resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.99 below.

Table 3.99 Predicted exposures for nonylphenol arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	8.38E-02	[mg/kg dry wt.]
PECgrassland soil	2.11E-02	[mg/kg dry wt.]
PEC in groundwater	9.16E-05	[mg/l]
PECfreshwater	8.63E-05	[mg/l]
PECfreshwater-sediment	2.58E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.15E-03	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.62E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root crops 84%	
Secondary poisoning – freshwater fish-eating birds and mammals	5.69E-02	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.29E-01	[mg.kg-1]

	Scenario II	Units

PECagricultural soil	1.55E+01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	2.75E-01	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 100%	
Secondary poisoning – worm-eating birds and mammals	3.59E+01	[mg.kg-1]

	Regional background	Units
Regional PEC in surface water (total)	2.66E-06	[mg/l]
Regional PEC in air (total)	1.87E-08	[mg.m-3]
Regional PEC in agricultural soil (total)	8.25E-04	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	1.57E-06	[mg/l]
Regional PEC in natural soil (total)	7.96E-07	[mg/kg wet wt.]
Regional PEC in industrial soil (total)	7.96E-07	[mg/kg wet wt.]
Regional PEC in sediment (total)	2.95E-03	[mg/kg wet wt.]

Table 3.100 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.100 Predicted background exposures for nonylphenol at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	6.93E+01	[t]
Steady-state mass in regional freshwater (kg)	9.56	[kg]
Steady-state mass in regional seawater (kg)	0.97	[kg]
Steady-state mass in regional air (kg)	0.756	[kg]
Steady-state mass in regional agricultural soil (kg)	6.73E+03	[kg]
Steady-state mass in regional natural soil (kg)	0.731	[kg]

Steady-state mass in regional industrial soil (kg)	0.271	[kg]
Steady-state mass in regional freshwater sediment (kg)	122	[kg]
Steady-state mass in regional seawater sediment (kg)	3.19	[kg]
Steady-state mass in continental freshwater (kg)	98.3	[kg]
Steady-state mass in continental seawater (kg)	381	[kg]
Steady-state mass in continental air (kg)	10.9	[kg]
Steady-state mass in continental agricultural soil (kg)	6.06E+04	[kg]
Steady-state mass in continental natural soil (kg)	5.33	[kg]
Steady-state mass in continental industrial soil (kg)	1.98	[kg]
Steady-state mass in continental freshwater sediment (kg)	1.25E+03	[kg]
Steady-state mass in continental seawater sediment (kg)	62.5	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	9.44E+01	[%]
Steady-state mass fraction in regional freshwater (%)	0.013	[%]
Steady-state mass fraction in regional seawater (%)	1.32E-03	[%]
Steady-state mass fraction in regional air (%)	1.03E-03	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.18	[%]
Steady-state mass fraction in regional natural soil (%)	9.97E-04	[%]
Steady-state mass fraction in regional industrial soil (%)	3.69E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	0.166	[%]
Steady-state mass fraction in regional seawater sediment (%)	4.34E-03	[%]

Steady-state mass in continental freshwater (kg)	0.134	[%]
Steady-state mass in continental seawater (kg)	0.519	[%]
Steady-state mass in continental air (kg)	0.0149	[%]
Steady-state mass in continental agricultural soil (kg)	82.6	[%]
Steady-state mass in continental natural soil (kg)	7.27E-03	[%]
Steady-state mass in continental industrial soil (kg)	2.69E-03	[%]
Steady-state mass in continental freshwater sediment (kg)	1.71	[%]
Steady-state mass in continental seawater sediment (kg)	0.0853	[%]

Table 3.101 Quantitative risk characterisation conclusions for nonylphenol in composts and digestates

Scenario I	
RCR for local soil	6.99E-02
RCR for local freshwater	2.21E-01
RCR for local freshwater-sediment	5.57E-02
RCR for Humans via the environment: local total daily intake	
RCR for fish-eating birds and mammals (fresh water)	5.69E-03
RCR for worm-eating birds and mammals	1.29E-02

Scenario II	
RCR for local soil	1.29E+01
RCR for Humans via the environment: local total daily intake	
RCR for worm-eating birds and mammals	3.59E+00

Regional	
RCR for regional soil	7.79E-04
RCR for regional freshwater	6.51E-03
RCR for regional freshwater-sediment	2.93E-03

It can be seen that local exposure concentrations for terrestrial organisms and secondary poisoning (in worm-eating birds and mammals) arising from the container growing scenario (local scenario II) exceed the PNECs for these organisms. It is noted however that the container growing scenario is likely to be limited to exposure during a single growing season and in a container which may not be in contact with soil. It could be that the food chain envisaged by the model would not be fully established on this time scale. Regional RCRs and RCRs for the aquatic compartment including sediments do not indicate unacceptable risks, although it is noted that the local PEC in fresh water arising from local scenario I (application on land) is approaching 1.

For scenario II, the levels in soil, earthworms and crops are directly proportional to the level in compost. In order to give an adequate MOS for terrestrial organisms and secondary poisoning (or a RCR <1) the maximum level of nonylphenol present in compost would need to be around 3.5 mg/kg dry weight.

Sensitivity to specific variables

The main sources of uncertainty in the assessment of this substance are:

- Kow (reliable values within range 4.4 to 5.5)
- Wide range in the reported concentration levels of the substance in C/D

The impact of varying these parameters within the specified range around the baseline value was explored. Refer to Figure 3.16 to Figure 3.17, and to Table 3.102 below, which illustrate the impact on relevant predicted exposure concentrations. The inputs used in the 'more conservative' and 'less conservative' assessments are explained in the Occurrence data set section.

Figure 3.16 Sensitivity of selected outputs in the assessment of nonylphenol to the log Kow input value: freshwater sediment

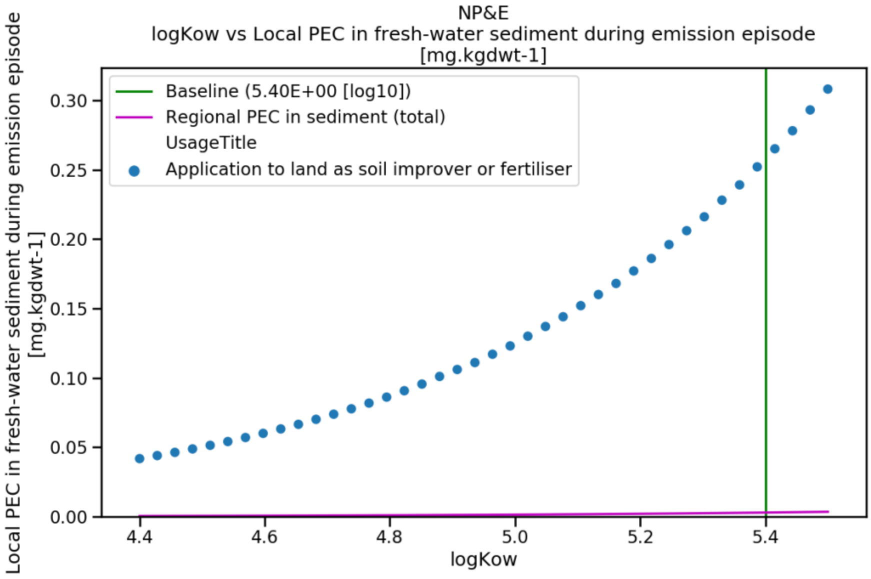

Figure 3.17 Sensitivity of selected outputs in the assessment of nonylphenol to the log Kow input value: diet of worm-eating birds and mammals

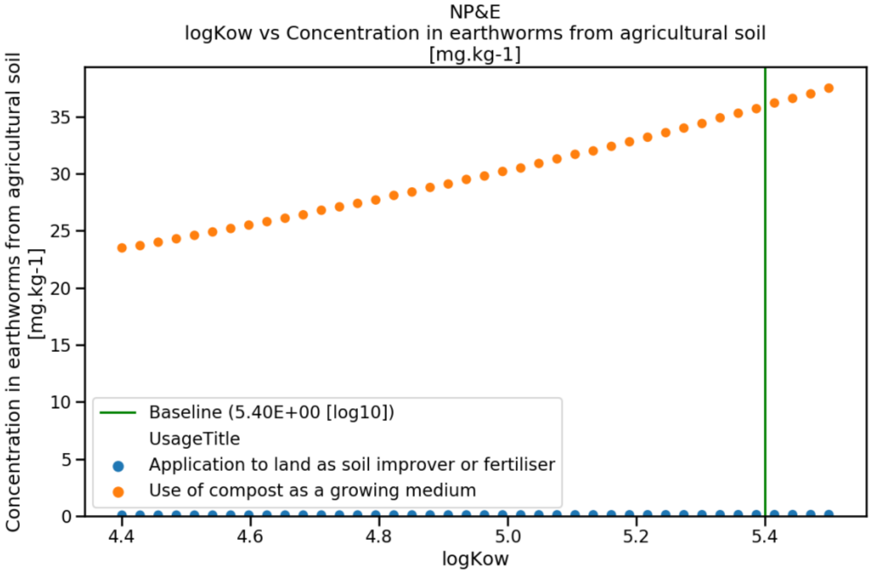

Table 3.102 Sensitivity of selected outputs in the assessment of nonylphenol to the concentrations reported in composts and digestates

	More conservative (realistic worst case)	Less conservative (3.5 mg/kg dry wt.t case)	Units
PECagricultural soil – local scenario I	8.38E-02	5.87E-03	[mg/kg dry wt.]
PECagricultural soil – local scenario II	1.55E+01	1.16E+00	[mg/kg dry wt.]
Humans via the environment: local total daily intake – local scenario I	1.15E-03	8.58E-05	[mg.kg-1.d-1]
Humans via the environment: local total daily intake – local scenario II	2.75E-01	2.05E-02	[mg.kg-1.d-1]
Total steady-state mass (region + continent)	6.93E+01	6.59E+01	[t]
Total steady-state mass fraction (region + continent)	9.44E+01	9.44E+01	[%]
Regional PEC in surface water (total)	2.66E-06	2.53E-06	[mg/l]
Secondary poisoning – freshwater fish-eating birds and mammals – local scenario I	5.69E-02	6.84E-03	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals – local scenario I	1.29E-01	1.09E-02	[mg.kg-1]
Secondary poisoning – worm-eating birds and mammals – local scenario II	3.59E+01	2.68E+00	[mg.kg-1]

It can be concluded that:

- If the lower log Kow value is correct then sediment PEC (local scenario I), secondary poisoning of worm-eating birds and mammals (local scenario II), and total local daily intake for humans could be lower than modelled. The baseline assessment is reasonably conservative.
- At the local scale, limiting the concentration of nonylphenol in composts and digestates to a maximum of 3.5 mg/kg dry wt.t could be expected to reduce the predicted exposure concentrations of nonylphenol in important compartments by a factor of more than 10 compared to the realistic worst case, sufficient to manage risks.
- At the regional scale at steady state, the difference between the two scenarios is not very significant for nonylphenol.

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.103 below presents the summary of key findings from the risk assessment of nonylphenol that has been made in this project. The findings are discussed further below the table.

Table 3.103 Summary of key findings for exposure of nonylphenol via use of compost and digestates

Key findings of the risk assessment of nonylphenol in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.1 - 50 mg/kg dry wt.
Major raw material sources	Concentrations of ca. 10 mg/kg and above reported for green waste compost and municipal sewage sludge-derived products
Safe limit concentration in compost and digestate	3.5 mg/kg dry wt for compost for container growing
Main concern(s) arising	Soil organisms and worm-eating predators exposed via the food chain, both for compost for container growing. Significant cumulative loads at steady state. Source of exposure of humans via diet to endocrine disrupting substance.
Effects considered in the main concern hazard(s)	Soil PNEC based on enchytraeid reproductive effects. Predator PNECoral based on mammalian reproductive effects.
Uncertainties and their implications	Two alternative log Kows are available and some protection targets are affected by the variation within the indicated range. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	It is noted that the container growing scenario is likely to be limited to exposure during a single growing season and in a

Key findings of the risk assessment of nonylphenol in contaminated composts and digestates	
	container which may not be in contact with soil. It could be that the food chain envisaged by the model would not be fully established on this time scale.

The highest reported concentrations in C/D already appear to exceed the national limit value for digestates (AGW du 14/06/2001 favorisant la valorisation de certains déchets (BE), guide value of 25 mg/kg dry wt. applicable in Belgium; Slambekendtgørelsen value 10 mg/kg dry wt. applicable in Denmark). The high occurrence concentrations were found in digestates prepared from municipal sewage sludge (Finland, Kapanen et al., 2013) although several other similar digestates and composted sludges reported lower values (even from the same literature source).

To the extent that risk characterisation has been possible, unacceptable risks are indicated for the container growing scenario (local scenario II), specifically in respect of the local soil and secondary poisoning (in worm-eating birds and mammals) protection targets (RCRs of ca. 13 and 3.6 respectively). While risk characterisation for humans exposed via the environment has not been quantified, it is noted that the predicted local total daily intake associated with either mode of use (application on land or container growing), modelled to be in the range ca. 2E-03 – 0.3 mg/kg bw/d, is comparable with the daily human intake for local exposures associated with the various industrial use scenarios modelled in the ESR RAR (EC, 2002). Exposure of humans via the environment is significantly dominated by consumption of root crops.

The estimated regional exposures arising from the application of C/D are very low compared with natural background concentrations in fresh water and sediments based on data cited in the ESR RAR (EC, 2002). The annual average EQS for inland surface waters (Directive 2008/105/EC as amended (2013/39/EU)) is not predicted to be exceeded.

It is notable that, at steady state, approximately 94% of the total mass remains within the region + continent[58], with the majority remaining within agricultural soil. This suggests there is relatively low transfer over long distances following release via the handling and application of C/D.

The total mass in the region + continent at steady state is 69 t, when relatively conservative assumptions are made in regard to the concentration of nonylphenol in the compost/digestate. This steady-state mass amounts to 0.4 times the mass released annually via application of composts and digestates[59], suggesting that long-term gradual accumulation is not anticipated from exposure via this source.

The value of log Kow has been identified in the RAC/SEAC assessment (ECHA, 2014b) as a key uncertainty, with possible impacts on various other parameters derived from it (particularly bioconcentration factor for earthworms and organic carbon adsorption coefficient Koc). In terms of the present assessment, it is noted that the two different values available for log Kow would indicate a relatively small difference in the predicted exposure concentrations in sediment (scenario I), although the PNEC is still not exceeded; and in the local total daily intake for humans via the environment. This

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[58] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[59] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

is therefore not considered to be an important source of uncertainty in the exposure assessment for these protection targets.

3.16 Benzo[a]pyrene (representative of PAH16 chemical family)

PAH are generated as by-products of combustion or pyrolysis of organic matter and hence almost always occur as mixtures. The PAH selected for substance-specific assessment are substances of higher molecular mass. There are precedents for assessing subgroups of PAH in regulatory contexts, and for use of certain PAH substances and small groups of PAHs as reference markers for the wider chemical family, to simplify analytical monitoring.

Background information and remarks

Benzo[a]pyrene (CAS 50-32-8, EU 200-028-5) is also known as benzo[def]chrysene. According to the harmonised classification and labelling under CLP, this substance may cause genetic defects, may cause cancer, may damage fertility and may damage the unborn child, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.
It is an SVHC included in the candidate list for authorisation based on CMR, PBT and vPvB properties. Some uses are restricted under annex XVII of REACH.

PAHs are frequently addressed as a group and benzo[a]pyrene is frequently used as a marker compound. Being among the most toxic of the PAH, it has particular significance as a reference compound. for example, EQS (annual average, biota levels) are only defined for benzo[a]pyrene as a marker for the group of priority PAH.

Chemical properties and hazards data set

As a CMR and SVHC, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.

Table 3.104 below summarises the relevant property data. The data are mainly taken from the ESR RAR for coal tar pitch high-temperature (EC 2008d); where information from other sources is included this is indicated in the Table.

Table 3.104 Property information for benzo[a]pyrene

Property	Value	Remarks
Molecular weight	252.32	
Melting point	175C 178.1	ESR RAR for CTPHT (2008d) - table 1.3 EHC 202 (1998)
Boiling point	496	
Vapour pressure	7.3E-7 Pa	EHC 202 (WHO, 1998) citing Murray JJ et al 1974)
Water solubility	1.54 µg/l (column method; temperature not stated) 3.8 µg/l at 25c	ESR RAR for CTPHT (2008d) EHC 202 (WHO, 1998)

Property	Value	Remarks
log Kow	6.13 (slow stirring method, temperature not stated) 6.5	ESR RAR for CTPHT (2008d) EHC 202 (WHO, 1998)
Henry's law constant	0.034 Pa.m3/mol (gas stripping method) (20 °C) EHC states H = 3.4E-05 kPa at 20C (unusual units for H - should it be kPa/m3/mol?) EPI exp-db match: 0.0463Pam3/mol at 25C, Ten Hulscher, TEM et al 1992, which seems to correspond well	ESR RAR for CTPHT (2008d) EHC 202 (WHO, 1998)
Koc	log Koc 5.92 (Karickhoff, 1979) applied in ESR RAR of CTPHT (2008) logKoc values: 6.66 (LSC), Eadie et al. (1990) 6.26 (Average on sediments) Kayal & Connell (1990) 8.3 (Specified particulate) Broman et al. (1990) 4.0 (Predicted to be dissolved) Broman et al. (1990)	Karickhoff value selected for use in EUSES, other values taken from EHC202 (WHO, 1998) table 25
BCF	values available for numerous types of organisms. SVHC support document gives key BCFs for fish as 377 (13°C) and 608 (23°C) which is assumed to be definitive. BCFs of benzo[a]pyrene in fish: ca. 3 - 4900 depending on species, duration, concentration, and method for calculating BCF, but may not all be reliable data.	ESR RAR for CTPHT (2008d) EHC 202 (WHO, 1998)
Biodegradability	Mean half-lives: 1700h in water, 17000h in soil and 55000h in sediment (temperatures not stated; assumed to be 25C) In a study with sandy loams, forest soil, and roadside soil partially loaded with sewage sludge from a municipal treatment plant, the following half-lives (in days) were found: 120-258 for benzo [a]pyrene (Wild & Jones, 1993). 3.5 × 10-5 h-1 19 800 h (Estimated rate constant in soil and water) (Ryan & Cohen (1986)	ESR RAR for CTPHT (2008d) EHC 202 (WHO, 1998) 708d used for soil in the EUSES run. Many values also presented in table 29 encompassing a wide range.
Half-life in air	AOP predicts rate constant 50E-12 cm3/molecule.sec, equivalent to just a few hours. However the EHC monograph cites Mackay (definitive author on environmental fate and fugacity) who proposes mean 170h and range 100-300 h in air for benzo[a]pyrene. This may be based on transport and distribution phenomena rather than degradation. it is cited under Transformation however.	

Threshold hazard values if available	Value	Remarks
PNECaquatic (freshwater)	Annual average EQS 1.7E-04 µg/l and MAC EQS 0.27 µg/l (for inland surface water) (Directive 2008/105/EC as amended (2013/39/EU)) 0.022 µg/l (PNEC in ESR RAR for CTPHT)	AA for inland surface water and other surface water in EQS directive 2008 was 0.05 µg/l. MAC for inland surface water and other surface water in EQS directive 2008 (L348/84) was 0.1 µg/l.

Property	Value	Remarks
		UV exposure has been shown to enhance long-term toxicity.
PNECsediment (freshwater)	1.83 mg/kg dry wt. (EQPM - from ESR RAR CTPHT)	
PNECsoil	0.053 mg/kg dry wt. (measured) (ESR RAR CTPHT)	
PNECoral predator	5 µg/kg applicable (Directive 2008/105/EC as amended (2013/39/EU))	A lower EQS for biota (fish) was proposed (COM 2011)
DNEL general population oral	BMDL10 = 0.07 mg/kg b.w. per day	EFSA scientific opinion (2008b) (derived from 2-year carcinogenicity study on coal tar mixtures by Culp et al. (1998)) (this value is derived using the multi-stage model).
Other relevant data		Benzo[a]pyrene is CMR and SVHC with harmonised C&L for very toxic for the environment. According to the harmonised classification and labelling approved by the European Union, this substance may cause genetic defects, may cause cancer, may damage fertility and may damage the unborn child, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.

Occurrence data set

Table 3.105 presents a summary of the reported concentrations of benzo[a]pyrene and other PAH in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

No substance-specific data for benzo[a]pyrene were reported in digestates although a small number of measured values in composts are available. This represents an uncertainty in the exposure assessment; in the absence of data it has been assumed that measurements in composts (particularly composts derived from sewage sludge) would be reasonably representative of digestates.

Table 3.105 Reported occurrence of benzo[a]pyrene in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Very few data specifically for the named structure: 4 values available for benzo[a]pyrene specifically: two separate values sampled at two sites. all state compost although two are from sewage sludge. The data set of generic PAH (PAH11 / PAH16 / PAH general / 4-ring PAH) is much larger with values available for a wide range of member states and several different sampling years. Many reported values are already ranges / averages.
Compost - minimum concentration	0.04	Lowest value for B[a]P specifically is actually <0.04 mg/kg. The value is taken as such.

Compost - mid-range or average concentration	0.172	Average of all available figures for B(a)P as such is 0.172 mg/kg dry wt.. Average across all reported values for PAH [4-ring] is about 2.9 mg/kg dry wt..
Compost - maximum concentration	1.5	NF U44-051 and NF U44-095 (Benzo[a]pyrene specific) proposes 1.5 mg/kg dm limit. For the PAH family, a relevant high percentile value of approx 6 mg/kg dry wt. is reasonable (consistent with FPR limit).
Digestates - data availability		Using the same values as above.
Digestate - minimum concentration	0.04	
Digestate - mid-range or average concentration	0.172	Based on average for Benzo[a]pyrene (in composts). Note: Average across all reported values for PAH [4-ring] is about 1.9 mg/kg dry wt..
Digestate - maximum concentration	1.5	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.106 Estimated regional and continental release amounts

Parameter	**Value**
Mass of substance in EU-28 in compost (kg/year)	13,230
Mass of substance in EU-28 in digestate (kg/year)	52,920
Total regional emission to surface water (kg/day)	0.51
Total regional emission to soil (kg/day)	18
Total continental emission to surface water (kg/day)	4.6
Total continental emission to agricultural soil (kg/day)	159

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Background exposure data previously presented by WHO (2002) are summarised below and in Table 3.107 - Table 3.108.

Table 3.107 Reported background concentrations of benzo[a]pyrene in the environment

PECregional	**Value**	**Remarks**

Agricultural soil	In soil of background and rural areas: 15 µg/kg dry weight (Norway) (depth, 0-10 cm) 6-12 µg/kg dry weight (Norway) 13/22 µg/kg dry weight (Wales, United Kingdom) (depth, 5 cm) ND-4.0 µg/kg dry weight Green Mountain (depth, 0-5 cm), USA	EHC 202 (WHO 1998)

The EHC monograph (WHO IPCS, 1998) summarised levels of various PAH in vegetables (table 53 of that document). Concentrations in tomatoes and fruits and cereals are reported separately in the EHC monograph (WHO IPCS, 1998). Table 3.108 overleaf summarises the values and ranges considered most relevant to the present assessment.

The monograph (WHO IPCS, 1998) also reports some specific facts relating to vegetable concentrations relative to concentrations in the soil in which the vegetables were grown, of direct relevance to the present assessment, as follows:

> *The benzo[a]pyrene levels in potatoes in eastern Germany were 0.2-400 µg/kg. The highest concentrations were detected in the peel of potatoes grown in soil containing 400 µg/kg benzo [a]pyrene, ...*
>
> *High concentrations of PAH were detected in lettuce grown close to a highway; the levels of individual PAH decreased with distance from the road. Washing the vegetables reduced their content of high-molecular-mass PAH but not of phenanthrene (Larsson & Sahlberg, 1982). In another study, the profiles of PAH in lettuce were similar to those in ambient air, indicating that deposition of airborne particles was the main source of contamination (Wickström et al., 1986).*
>
> *PAH concentrations were determined in fenugreek, spinach beet, spinach, amaranthus, cabbage, onion, lettuce, radish, tomato, and wheat grown on soil that had been treated with sewage sludge. The levels of individual PAH in lettuce leaves (Table 53) were one to two orders of magnitude lower than those in the sewage sludge and the soil on which the lettuce was grown (Lenin, 1994).*
>
> *The PAH levels in carrots and beans grown near a German coking plant were below 0.5 µg/kg wet weight. The levels of fluoranthene were 1.6- 1.7 µg/kg and those of pyrene 1.0-1.1 µg/kg. Vegetables with large, rough leaf surfaces, such as spinach and lettuce, had PAH levels that were 10 times higher, perhaps due to deposition from ambient air (Crössmann & Wüstemann, 1992).*

Table 3.108 Reported background concentrations of a range of PAH in vegetables

	Concentrations in root crops (µg/kg) [1]	Concentrations in leaf crops (µg/kg) [2]	Concentrations in fruits (µg/kg) [3]	Concentrations in cereal products (µg/kg) [4]
Benzo[a]pyrene		ND – 6.2	0.2-0.5	0.3/0.4

Notes:
1 - Potatoes, Netherlands (see table 53 of the EHC monograph (WHO IPCS, 1998) for further details)
2 – Kale, lettuce, cabbage from a range of studies in different countries (see table 53 of the EHC monograph (WHO IPCS, 1998) for further details)
3 – Tomatoes and/or fresh fruit (see table 54 of the EHC monograph (WHO IPCS, 1998) for further details))
4 - Oats, Finland (see table 55 of the EHC monograph (WHO IPCS, 1998) for further details; numerous data for a range of cereal-derived products from EU and north America are also reported in Table 55)

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of benzo[a]pyrene resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.109 below.

Table 3.109 Predicted exposures for benzo[a]pyrene arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	1.50E-02	[mg/kg dry wt.]
PECgrassland soil	5.86E-03	[mg/kg dry wt.]
PEC in groundwater	8.81E-07	[mg/l]
PECfreshwater	1.89E-06	[mg/l]
PECfreshwater-sediment	1.58E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	4.78E-05	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.52E-08	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 96.2%	
Secondary poisoning – freshwater fish-eating birds and mammals	4.94E-04	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.05E-02	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	4.95E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.55E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.9%	
Secondary poisoning – worm-eating birds and mammals	2.42E-01	[mg.kg-1]

	Regional background	Units
Regional PEC in surface water (total)	1.64E-06	[mg/l]
Regional PEC in air (total)	4.11E-10	[mg.m-3]

Regional PEC in agricultural soil (total)	6.22E-03	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	4.24E-07	[mg/l]
Regional PEC in natural soil (total)	5.97E-06	[mg/kg wet wt.]
Regional PEC in industrial soil (total)	5.97E-06	[mg/kg wet wt.]
Regional PEC in sediment (total)	2.52E-02	[mg/kg wet wt.]

Table 3.110 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.110 Predicted background exposures for benzo[a]pyrene at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	5.22E+02	[t]
Steady-state mass in regional freshwater (kg)	5.89E+00	[kg]
Steady-state mass in regional seawater (kg)	6.01E-01	[kg]
Steady-state mass in regional air (kg)	1.66E-02	[kg]
Steady-state mass in regional agricultural soil (kg)	5.08E+04	[kg]
Steady-state mass in regional natural soil (kg)	5.48E+00	[kg]
Steady-state mass in regional industrial soil (kg)	2.03E+00	[kg]
Steady-state mass in regional freshwater sediment (kg)	1.04E+03	[kg]
Steady-state mass in regional seawater sediment (kg)	4.68E+01	[kg]
Steady-state mass in continental freshwater (kg)	6.50E+01	[kg]
Steady-state mass in continental seawater (kg)	2.20E+02	[kg]
Steady-state mass in continental air (kg)	4.58E-01	[kg]
Steady-state mass in continental agricultural soil (kg)	4.57E+05	[kg]

Steady-state mass in continental natural soil (kg)	7.64E+01	[kg]
Steady-state mass in continental industrial soil (kg)	2.83E+01	[kg]
Steady-state mass in continental freshwater sediment (kg)	1.15E+04	[kg]
Steady-state mass in continental seawater sediment (kg)	8.59E+02	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)	9.84E+01	[%]
Steady-state mass fraction in regional freshwater (%)	1.11E-03	[%]
Steady-state mass fraction in regional seawater (%)	1.13E-04	[%]
Steady-state mass fraction in regional air (%)	3.13E-06	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.57E+00	[%]
Steady-state mass fraction in regional natural soil (%)	1.03E-03	[%]
Steady-state mass fraction in regional industrial soil (%)	3.83E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.97E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	8.83E-03	[%]
Steady-state mass in continental freshwater (kg)	1.22E-02	[%]
Steady-state mass in continental seawater (kg)	4.15E-02	[%]
Steady-state mass in continental air (kg)	8.63E-05	[%]
Steady-state mass in continental agricultural soil (kg)	8.62E+01	[%]
Steady-state mass in continental natural soil (kg)	1.44E-02	[%]
Steady-state mass in continental industrial soil (kg)	5.33E-03	[%]
Steady-state mass in continental freshwater sediment (kg)	2.17E+00	[%]

Steady-state mass in continental seawater sediment (kg)	1.62E-01	[%]

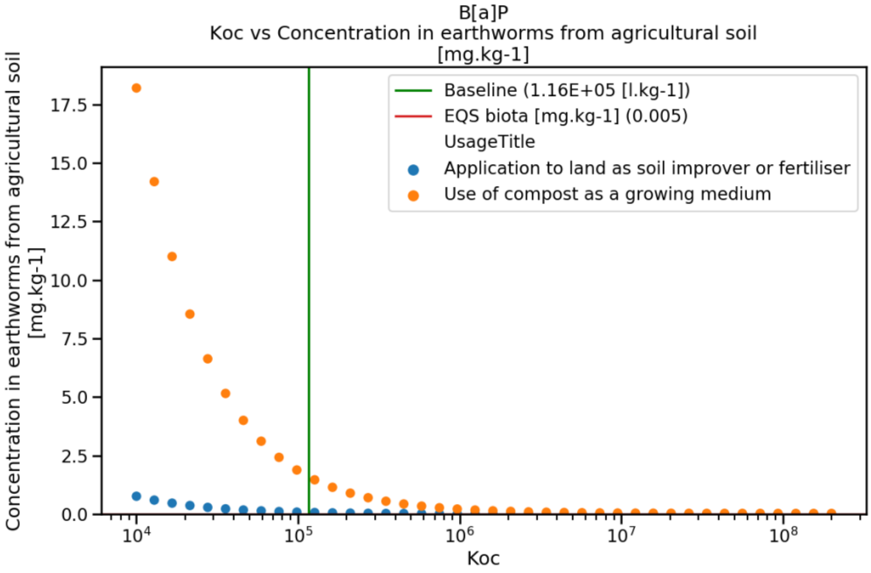
Sensitivity to specific variables

The main source of uncertainty in the assessment of this substance is the value of Koc. Several values covering an extremely wide range have been reported (log Koc 6.66 (LSC), Eadie et al. (1990); 6.26 (Average on sediments), Kayal & Connell (1990); 8.3 (Specified particulate), Broman et al. (1990), 4.0 (Predicted to be dissolved), Broman et al. (1990). The assessment in this project follows the approach used in the ESR RAR for coal tar pitch high temperature (log Koc 5.92, Karickhoff, 1979) but it is of interest to see how the variation across this range affects PECs resulting from these release scenarios:

- log Koc (range 4 to 8 as log values).

The impact of varying this property within the specified range around the baseline value was explored. Refer to Figure 3.18 to Figure 3.21, which illustrate the impact on relevant predicted exposure concentrations.

Figure 3.18 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: diet of worm-eating birds and mammals



Note: the red line representing the EQS cannot be seen on this graph due to it overlapping the x-axis on this scale.

Figure 3.19 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: diet of fish-eating birds and mammals

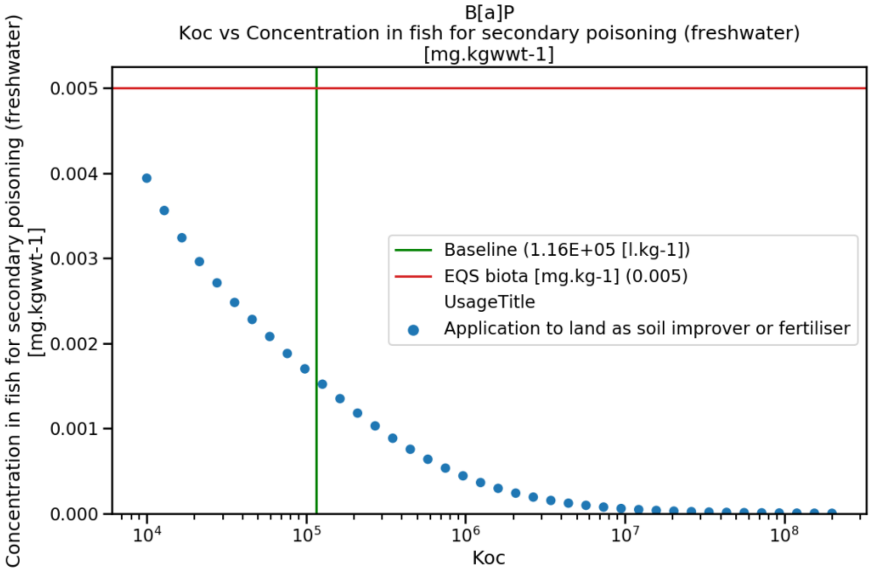
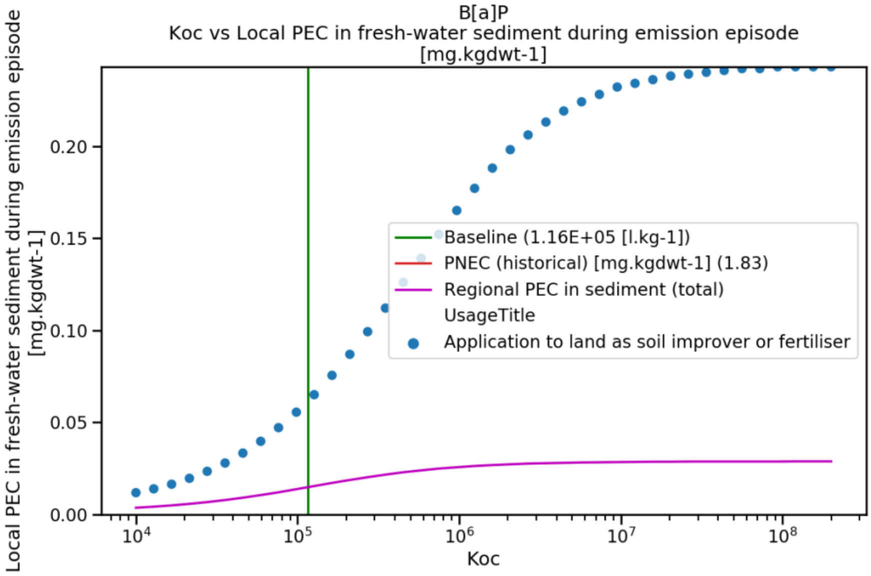
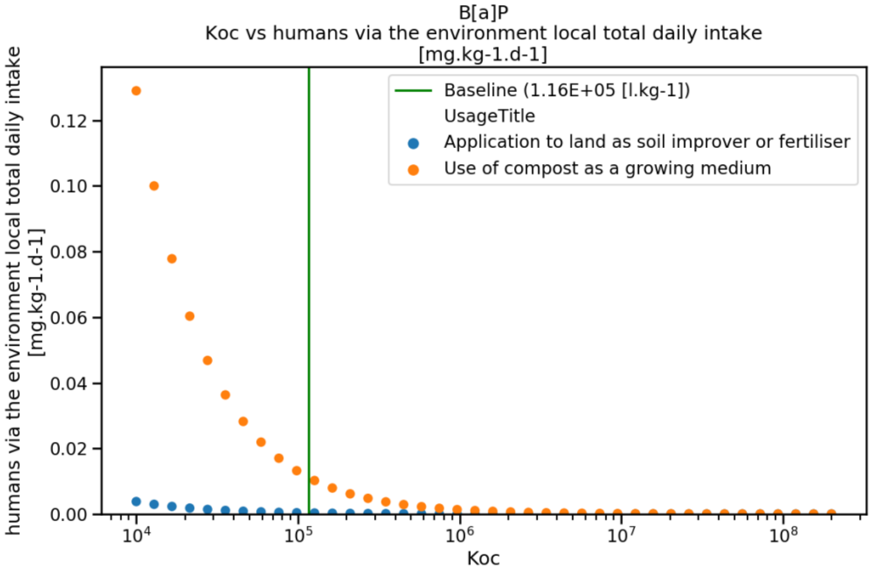


Figure 3.20 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: freshwater sediment



Note: the red line representing the PNEC cannot be seen on this graph due to it exceeding the maximum value of the y-axis on this scale.

Figure 3.21 Sensitivity of selected outputs in the assessment of benzo[a]pyrene to the Koc input value: human daily intake



It can be concluded that:

- Secondary poisoning exposure of fish-eating birds and mammals (local scenario I) could vary significantly with the value of Koc within the literature range and could be up to 4x higher than in the baseline assessment made here. However, exposure of worm-eating birds and mammals resulting from application of composts and digestates in either local scenario is in any case much higher and exceeds the existing EQS for biota.
- The local total daily intake via both exposure scenarios could have been significantly higher (up to 10x) than estimated in the baseline assessment, at lower Koc values within the literature range.
- The PEC in sediment from the application on land scenario could be significantly higher (up to 2x) than estimated in the baseline assessment, at higher Koc values within the literature range. Even the highest concentrations are however still well below the historical PNEC for sediment organisms (as applied in the ESR RAR for CTPHT, though a quantified PNEC may no longer be appropriate given the hazards of the substance).

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.111 below presents the summary of key findings from the risk assessment of benzo[a]pyrene that has been made in this project. The findings are discussed further below the table.

Table 3.111 Summary of key findings for exposure of benzo[a]pyrene via use of compost and digestates

Key findings of the risk assessment of benzo[a]pyrene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04 – 0.52 mg benzo[a]pyrene/kg dry wt., <0.3 – 20.8 mg PAH/kg
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, C/D from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state; PEC in surface water (at regional scale and local scenario I) exceeds the annual average EQS for benzo[a]pyrene as a marker for total PAH (EU, 2013); predator exposure via diet (local scenarios I and II) exceed the EQS for biota benzo[a]pyrene as a marker for total PAH (Directive 2008/105/EC as amended (2013/39/EU)).
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for benzo[a]pyrene specifically means that the exposure levels may be under- or over-estimated by the present assessment; exposures of humans via diet, predators via the food chain, sediment organisms could be sensitive to variability in Koc value. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

While risk characterisation has not been quantified, it is noted that the predicted exposures in fresh water arising from the application of composts/digestates on soil (local scenario I) exceed the safe limit (annual average inland surface water EQS for benzo[a]pyrene as a marker for total PAH set under Directive 2008/105/EC (EU, 2008) as amended by Directive 2013/39/EU (EU, 2013)) (the MAC EQS applicable for benzo[a]pyrene specifically is not exceeded).

It is noted that predator exposure via diet (earthworms) (local scenarios I and II) exceed the EQS for biota benzo[a]pyrene as a marker for total PAH (Directive 2008/105/EC as amended (2013/39/EU)) although this biota EQS normally relates to crustaceans and molluscs.

It is noted that the human exposures to PAH arising from the application of composts/digestates on soil do not exceed the BMDL10 value either in terms of benzo[a]pyrene alone, total for PAH2 or total for PAH4.

The estimated regional concentrations in vegetables arising from the application of C/D are comparable with the background concentrations reported by WHO in the EHC monograph. Local predicted concentrations of all assessed PAH in root crops are notably higher than the background levels presented in Table 3.108 but predicted regional concentrations are close to the reported measured concentrations. Predicted local concentrations of the assessed PAH in leaf crops are generally similar or lower than the reported levels.

The highest contributions to human exposure of PAH via the environment arising from the application of C/D is mainly associated with dietary consumption of fish (associated with local scenario I, application on land) and dietary consumption of root vegetables (local scenario II, container growing).

At steady state, between 96-99% of the total mass of each assessed PAH remains within the region + continent[60], suggesting that there is relatively low transfer over long distances following release via the handling and application of C/D.

The total mass in the region + continent at steady state varies between ca 14 t (indeno[1,2,3-cd]pyrene) and ca 170 t (benzo[b]fluoranthene). The reported concentrations in composts and digestates does not cover a large range meaning that when a comparable scenario is assessed using lower concentrations in the C/D within the reported range, the steady state masses are not significantly lower. For all five of the assessed PAHs, the steady-state mass amounts to approximately 8 times the mass released annually via application of composts and digestates[61].

The variability in input properties has been considered. It is noted that variation in the Koc value of benzo[a]pyrene could suggest that the exposures of humans via diet, predators via the food chain, sediment organisms could be sensitive to the uncertainty in this value.

3.17 Chrysene (representative of PAH16 chemical family)

Background information and remarks

Chrysene (CAS 218-01-9, 1719-03-5, EC 205-923-4) together with benzo[a]pyrene, are sometimes known as 'PAH2'.

According to the harmonised classification and labelling under CLP, this substance may cause cancer, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and is suspected of causing genetic defects.

It is an SVHC included in the candidate list for authorisation based on carcinogenic, PBT and vPvB properties. Some uses are restricted under annex XVII of REACH.

Chemical properties and hazards data set

As a SVHC, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.

Table 3.112 Property information for chrysene (from MSC SVHC support document unless otherwise stated)

Property	Value	Remarks
Molecular weight	228.29	

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[60] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[61] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Melting point	255.5	
Boiling point	448	
Vapour pressure	in range 8.4 x 10-7 Pa at 25°C (effusion method) 1.7 x10-4Pa at 20°C (supercooled liquid PL)	
Water solubility	in range 1.0 µg L-1 - 3.3 µg L-1	
log Kow	5.73 at 25C	
Henry's law constant		Value generated in EUSES from water solubility and vapour pressure.
Koc	log Koc 5.60 (Karickhoff, 1979) applied in ESR RAR of CTPHT (EC, 2008d)	Estimated in EUSES from log Kow. SVHC support document confirms correlation with log Kow.
BCF	Bioaccumulation potential of chrysene likely differs between species due to the organism's ability to metabolise PAHs (biotransformation). It is likely that chrysene is metabolised in fish using enzymes belonging to the Cytochrome P450 enzymes (Cyt P450) resulting in low BCF values. Molluscs might also have the ability to metabolise PAHs to some extent. However, BAF data give a clear concern for bioaccumulation in molluscs. Among crustaceans an experimental BCF value above 5000 (Newsted & Giesy, 1987) has been reported for Daphnia magna and a high BAF value has been obtained for a crab species from a field sample (Takeuchi et al., 2009 cited in Verbruggen and van Herwijnen, 2011a). No evidence for transformation processes of PAHs in algae and oligochaeta exist. Thus, chyrsene has a high bioaccumulation potential at lower trophic levels, which could contribute to a constant high exposure of chyrsene to predators for which the effects are unpredictable due to the absence of sufficient data. Trophic magnification factors (TMFs) <1 have been observed but these cannot refute the evidence of high bioaccumulation potential in lower trophic levels as TMFs reflect the average magnification along the food web trophic levels. Furthermore, a high BAF value has been reported for a benthic fish species feeding largely on invertebrates, amounting to 21,700 L/kgww (Takeuchi et al., 2009 cited in Verbruggen and van Herwijnen, 2011)	
Biodegradability	Mean half-lives: 1700h in water, 17000h in soil and 55000h in sediment (temperatures not stated; assumed to be 25°C) (half-lives as used in the CTPHT ESR risk assessment of chrysene, and also in the present assessment). The predicted half-lives range between 42 and 125 days for water degradation and half-lives higher than 1250 days for sediment. Wild and Jones (1993) reported a dissipation half-live for CHR of 106 to 313 days in a laboratory soil microcosm study. For assessing the persistence of CHR, half-lives obtained under realistic conditions, such as field conditions, are given higher weight. Under field conditions Wild et al. (1991) demonstrated a half-life of more than 8.1 years in soil for CHR. (summary from the SVHC MSC support document for chrysene)	

Half-life in air	half-lives in the range 1.3 to 100h in air with particles (WHO IPCS EHC 202)	100h used in the assessment

Threshold hazard values if available	Value	Remarks
PNECaquatic (freshwater)	0.07 µg/l (ESR RAR CTPHT)	Reliable data available but as this substance meets vPvB criteria for PNECs are not suitable. Also the substance is PBT (T met by carcinogenicity rather than ecotoxicity).
PNECsediment (freshwater)	2.79 mg/kgdw (by equilibrium partitioning) (ESR RAR CTPHT)	
PNECsoil	0.55 mg/kgdw (EQPM - ESR RAR CTPHT)	
PNECoral predator		
DNEL general population oral	BMDL10 = 0.17 mg/kg bw/d for PAH2 BMDL10 = 0.34 mg/kg bw/d for PAH4	Carcinogenic 1B: DNEL not definable
Other relevant data		

Occurrence data set

Table 3.113 presents a summary of the reported concentrations of chrysene and other PAH in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

No substance-specific data for chrysene were reported in digestates although a small number of measured values in composts are available. This represents an uncertainty in the exposure assessment; in the absence of data it has been assumed that measurements in composts (particularly composts derived from sewage sludge) would be reasonably representative of digestates.

Table 3.113 Reported occurrence of chrysene in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Only 2 compost data are available for Chrysene itself, for the same member state coming from the same study, <0.04-0.61 mg/kg d.m, 2017 Poland.
Compost - minimum concentration	0.04	The lower limit value is taken as such for the purpose of a minimum exposure background assessment, but is actually reported as a less-than limit value.
Compost - mid-range or average concentration	0.325	Mean of the range.
Compost - maximum concentration	0.61	

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Digestates - data availability		Using the same values as above, in the absence of specific data for digestate. The compost values are sewage sludge compost so in principle should also be representative of digestate.
Digestate - minimum concentration	0.04	
Digestate - mid-range or average concentration	0.325	
Digestate - maximum concentration	0.61	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.114 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	2867
Mass of substance in EU-28 in digestate (kg/year)	11,466
Total regional emission to surface water (kg/day)	0.11
Total regional emission to soil (kg/day)	3.8
Total continental emission to surface water (kg/day)	0.99
Total continental emission to agricultural soil (kg/day)	35

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.115 below summarises background exposure data previously presented by WHO (2002).

Table 3.115 Reported background concentrations of chrysene in vegetables

	Concentrations in root crops (µg/kg) [1]	Concentrations in leaf crops (µg/kg) [2]	Concentrations in fruits (µg/kg) [3]
Chrysene	0.8	2.4-62	0.5

Notes:

1 - Potatoes, Netherlands (de Vos et al., 1990)

2 – Kale, lettuce, cabbage from a range of studies in different countries (Kale, Netherlands (Vaessen et al., 1984); Lettuce, Finland (Wickstrom et al., 1986) Lettuce, Germany, from an industrial area (Ministry of Environment, 1994); Lettuce, Sweden, concentration in µg/kg fresh weight (Larsson & Sahlberg, 1982); Lettuce and cabbage, United Kingdom, concentration in µg/kg fresh weight (McGill et al., 1982); Lettuce, India (Lenin, 1994))

3 – Tomatoes, Netherlands (Vaessen et al., 1984) (table 53) and/or fresh fruit, Netherlands (de Vos et al., 1990) (table 54)

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of chrysene resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.116 below.

Table 3.116 Predicted exposures for chrysene arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	6.10E-03	[mg/kg dry wt.]
PECgrassland soil	2.38E-03	[mg/kg dry wt.]
PEC in groundwater	7.47E-07	[mg/l]
PECfreshwater	9.55E-07	[mg/l]
PECfreshwater-sediment	3.80E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	3.96E-05	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.13E-08	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Fish 58.6%	
Secondary poisoning – freshwater fish-eating birds and mammals	9.19E-02	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	3.05E-03	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	2.01E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	5.58E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 98.7%	
Secondary poisoning – worm-eating birds and mammals	8.28E-02	[mg.kg-1]

	Regional background	Units
Regional PEC in surface water (total)	4.61E-07	[mg/l]
Regional PEC in air (total)	2.98E-10	[mg.m-3]

Regional PEC in agricultural soil (total)	1.34E-03	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	1.91E-07	[mg/l]
Regional PEC in natural soil (total)	2.92E-06	[mg/kg wet wt.]
Regional PEC in industrial soil (total)	2.92E-06	[mg/kg wet wt.]
Regional PEC in sediment (total)	4.74E-03	[mg/kg wet wt.]

Table 3.117 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.117 Predicted background exposures for chrysene at steady state arising from use of composts and digestates

Steady state mass		Units
Total steady-state mass (region + continent)	1.13E+02	[t]
Steady-state mass in regional freshwater (kg)	1.66E+00	[kg]
Steady-state mass in regional seawater (kg)	1.74E-01	[kg]
Steady-state mass in regional air (kg)	1.20E-02	[kg]
Steady-state mass in regional agricultural soil (kg)	1.10E+04	[kg]
Steady-state mass in regional natural soil (kg)	2.68E+00	[kg]
Steady-state mass in regional industrial soil (kg)	9.94E-01	[kg]
Steady-state mass in regional freshwater sediment (kg)	1.96E+02	[kg]
Steady-state mass in regional seawater sediment (kg)	7.57E+00	[kg]
Steady-state mass in continental freshwater (kg)	1.94E+01	[kg]
Steady-state mass in continental seawater (kg)	8.97E+01	[kg]
Steady-state mass in continental air (kg)	3.35E-01	[kg]
Steady-state mass in continental agricultural soil (kg)	9.87E+04	[kg]

Steady-state mass in continental natural soil (kg)	3.77E+01	[kg]
Steady-state mass in continental industrial soil (kg)	1.40E+01	[kg]
Steady-state mass in continental freshwater sediment (kg)	2.30E+03	[kg]
Steady-state mass in continental seawater sediment (kg)	1.95E+02	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)	9.63E+01	
Steady-state mass fraction in regional freshwater (%)	1.42E-03	[%]
Steady-state mass fraction in regional seawater (%)	1.49E-04	[%]
Steady-state mass fraction in regional air (%)	1.03E-05	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.39E+00	[%]
Steady-state mass fraction in regional natural soil (%)	2.30E-03	[%]
Steady-state mass fraction in regional industrial soil (%)	8.51E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.68E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	6.48E-03	[%]
Steady-state mass in continental freshwater (kg)	1.66E-02	[%]
Steady-state mass in continental seawater (kg)	7.68E-02	[%]
Steady-state mass in continental air (kg)	2.87E-04	[%]
Steady-state mass in continental agricultural soil (kg)	8.45E+01	[%]
Steady-state mass in continental natural soil (kg)	3.23E-02	[%]
Steady-state mass in continental industrial soil (kg)	1.20E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	1.97E+00	[%]

Steady-state mass in continental seawater sediment (kg)	1.67E-01	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.118 below presents the summary of key findings from the risk assessment of chrysene that has been made in this project.

Table 3.118 Summary of key findings for exposure of chrysene via use of compost and digestates

Key findings of the risk assessment of chrysene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04 – 0.61 mg chrysene/kg dry wt., <0.3 – 20.8 mg PAH/kg
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, compost and digestate from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for chrysene specifically means that the exposure levels may be under- or over-estimated by the present assessment; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 3.16.

3.18 Benz[a]anthracene (representative of PAH16 chemical family)

Background information and remarks

Benz[a]anthracene (CAS 56-55-3, 1718-53-2, EC 200-280-6), together with benzo[a]pyrene, chrysene and benzo[b]fluoranthene, are sometimes known as 'PAH4'.

According to the harmonised classification and labelling under CLP, this substance may cause cancer, is very toxic to aquatic life and is very toxic to aquatic life with long lasting effects.

It is an SVHC included in the candidate list for authorisation based on carcinogenic, PBT and vPvB properties. Some uses are restricted under annex XVII of REACH.

Chemical properties and hazards data set

As an SVHC, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here. Table 3.119 summarises the chemical property data, as cited by ECHA, 2017c unless otherwise stated in the table.

Table 3.119 Property information for benz[a]anthracene

Property	Value	Remarks
Molecular weight	228.29	
Melting point	160.5	
Boiling point	438	
Vapour pressure	6.67 x 10-7 Pa at 20°C (effusion method) to 1.47 x10-5 Pa at 25°C (effusion method).	6.67E-07 value used in EUSES.
Water solubility	0.00837 mg/l at 25C to 0.0168 mg/l at 25C.	0.00837 mg/l used in EUSES.
log Kow	5.91	
Henry's law constant		Value generated in EUSES from water solubility and vapour pressure.
Koc	log Koc 5.70 (Karickhoff, 1979) applied in ESR RAR of CTPHT (2008d)	Estimated in EUSES from log Kow. SVHC support document confirms correlation with log Kow.
BCF	265 (fish); 5000 (crustaceans); 12000 (BAF, fish)	Bioaccumulation potential of BaA differs between the species due to the organism's ability to metabolise PAHs (biotransformation). BaA can be transformed in fish using enzymes belonging to the Cytochrome P450 enzymes (Cyt P450) and other mechanism. A reliable BCF of **265** for fish is derived from a laboratory study (De Maagd etal., 1998). Nevertheless, Verbruggen and van Herwijnen (2011) pointed out that laboratory BCF values might underestimate BAF in field. Molluscs might also have the ability to metabolise PAHs to some extent. However, BAF data give a clear concern for bioaccumulation in molluscs. Among crustaceans an experimental BCF value above **5000** (Newsted & Giesy, 1987) has been reported for Daphnia magna and a high BAF value has been obtained for a crab species from a field sample (Takeuchi et al., 2009 cited in Verbruggen and van Herwijnen, 2011).

Property	Value	Remarks
		No evidence for transformation processes of PAHs in algae and oligochaeta exist. Thus, BaA has a high bioaccumulation potential at lower trophic levels, which could contribute to a constant high exposure of BaA to predators for which the effects are unpredictable due to the absence of sufficient data. TMFs <1 have been observed but these cannot refute the evidence of high bioaccumulation potential in lower trophic levels as TMFs reflect the average magnification along the food web trophic levels. Furthermore, a high BAF value has been reported for a benthic fish species feeding largely on invertebrates, amounting to **12,000** L/kgww (Takeuchi et al., 2009 cited in Verbruggen and van Herwijnen, 2011).
Biodegradability	Mean half-lives: 1700h in water, 17000h in soil and 55000h in sediment (temperatures not stated; assumed to be 25C) The half-lives predicted by Mackay et al. (1992) indicate that BaA persists in sediment with half-lives higher than 250 days. For water degradation, Mackay et al. (1992) predicted long elimination half-lives between 42 and **125 days.** However, considering the chemical structure of BaA that consists of four aromatic rings, standard tests for biodegradation in water may reveal that BaA is biodegradable under aerobic conditions (EC, 2008). Biodegradation studies in laboratory soil microcosms show dissipation half-lives up to **313 days** (Wild and Jones, 1993). Biodegradation studies on soil done by Wild et al. (1991) revealed a half-life of BaA of more than 8.1 years under field conditions. Hence, BaA biodegrades very slowly in sediments and soils. This conclusion was also drawn in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).	
Half-life in air	While half-lives for direct photolysis of PAHs are in the range of hours (Vu Duc & Huynh, 1991, cited in The Netherlands, 2008), it was demonstrated by EC (2001) (cited in The Netherlands (2008)), that particle surface-adsorbed BaA does have representative lifetimes between 15min and 3.3days under natural conditions.	Photolysis of PAHs at the atmosphere was assessed in the EU risk assessment report (EC, 2008d) as following: Photolysis in the troposphere results in the formation of reactive hydroxyl and nitrate (NO3) radicals and ozone (O3), which reacts as oxidizing agent with organic compounds, like PAHs. These radical and ozone reactions comprise mainly degradation of gas-phase PAHs (Calvert et al., 2002). Particle-associated PAHs are expected to degrade in air predominantly via direct photolysis by light with a wavelength < 290 nm (Kamens et al., 1988), although reaction with ozone will also occur (Peters and Seifert, 1980; Grosjean et al., 1983; Pitts et al., 1986;Coutant et al., 1988). As stated earlier, BaA is mainly particle associated. The degradation rate of PAHs, and therefore of BaA, depends on the type of particle to which they are bound (Behymer & Hites, 1988, cited in The Netherlands, 2008). While half-lives for direct photolysis of PAHs are in the range of hours (Vu

Property	Value	Remarks
		Duc & Huynh, 1991, cited in The Netherlands, 2008), it was demonstrated by EC (2001)(cited in The Netherlands (2008)), that particle surface-adsorbed BaA does have representative lifetimes between 15min and 3.3 days under natural conditions. According to the Annex XV Transitional Dossier for CTPHT (The Netherlands, 2008), the photolysis of PAHs is as follows: A two layer model has been proposed for the behaviour of naturally occurring PAH on airborne particulate matter, in which photo oxidation takes place in the outer layer, and much slower, 'dark' oxidation takes place in the inner layer (Valerio et al., 1987). This model is in line with the results of Kamens et al. (1991), who reported that PAH on highly loaded particles degrade more slowly than those on particles with low loads. As PAH occur mainly on particulate matter with a high carbon content, their degradation in the atmosphere is slower than that of PAH in the vapour phase under laboratory conditions or adsorbed on synthetic material."

Threshold hazard values if available	Value	Remarks
PNECaquatic (freshwater)	0.012 µg/l (ESR RAR CTPHT)	Photo-toxic effects in shallow aquatic environments. Reliable data available but as this substance meets PBT criteria for PNECs are not suitable.
PNECsediment (freshwater)	0.6 mg/kgdw (by EQPM - ESR RAR CTPHT)	
PNECsoil	0.079 mg/kg dry wt. (measured) (ESR RAR CTPHT)	
PNECoral predator		
DNEL general population oral	BMDL10 = 0.34 mg/kg bw/d for PAH4	Carcinogenic 1B: DNEL not definable.
Other relevant data		Some members of the group are PBT/vPvB therefore it is not possible to not make a quantitative assessment of environmental risk.

Occurrence data set

No substance-specific data for benz[a]anthracene were reported in digestates although a small number of measured values in composts are available. This represents an uncertainty in the exposure assessment; in the absence of data it has been assumed that measurements in composts (particularly composts derived from sewage sludge) would be reasonably representative of digestates. Table 3.120 presents a summary of the reported concentrations of benz[a]anthracene and other PAH in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

No substance-specific data for benz[a]anthracene were reported in digestates although a small number of measured values in composts are available. This represents an uncertainty in the exposure assessment; in the absence of data it has been assumed that measurements in composts (particularly composts derived from sewage sludge) would be reasonably representative of digestates.

Table 3.120 Reported occurrence of benz[a]anthracene in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Very few data specifically for the named structure: 2 values available for benz[a]anthracene specifically: two separate composts sampled at the same site; both state compost although made from sewage sludge. The data set of generic PAH (PAH11 / PAH16 / PAH general / 4-ring PAH) is much larger with values available for a wide range of member states and several different sampling years. Many reported values are already ranges / averages. Concentrations reported are relatively consistent (overall range <0.04 - 20.8 mg/kg dry wt. in composts).
Compost - minimum concentration	0.04	
Compost - mid-range or average concentration	0.168	Average of all available figures for B(a)A as such is 0.17 mg/kg dry wt.. Average across all reported values for PAH [4-ring] is about 2.9 mg/kg dry wt..
Compost - maximum concentration	0.33	0.33 mg/kg (2017 Poland; sewage sludge compost prepared by vermicomposting). For the PAH family, a relevant high percentile value of approx., 6 mg/kg dry wt. is reasonable (consistent with FPR limit).
Digestates - data availability		Using the same values as above unless where noted.
Digestate - minimum concentration	0.04	
Digestate - mid-range or average concentration	0.168	No digestate data for B[a]A as such. Average across all reported values for PAH [4-ring] is about 1.9 mg/kg dry wt..
Digestate - maximum concentration	0.33	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.121 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	1482
Mass of substance in EU-28 in digestate (kg/year)	5927
Total regional emission to surface water (kg/day)	0.057
Total regional emission to soil (kg/day)	2.0
Total continental emission to surface water (kg/day)	0.51
Total continental emission to agricultural soil (kg/day)	18

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.122 below summarises background exposure data previously presented by WHO (2002).

Table 3.122 Reported background concentrations of benz[a]anthracene in vegetables

	Concentrations in root crops (µg/kg) [1]	**Concentrations in leaf crops (µg/kg)** [2]	**Concentrations in fruits (µg/kg)** [3]	**Concentrations in cereal products (µg/kg)** [4]
Benz[a]anthracene	0.4	0.05 - 15	0.3	<0.1/0.2

Notes:
1 - Potatoes, Netherlands (see table 53 of the EHC monograph (WHO IPCS, 1998) for further details)
2 – Kale, lettuce, cabbage from a range of studies in different countries (see table 53 of the EHC monograph (WHO IPCS, 1998) for further details)
3 – Tomatoes and/or fresh fruit (see table 54 of the EHC monograph (WHO IPCS, 1998) for further details))
4 - Oats, Finland (see table 55 of the EHC monograph (WHO IPCS, 1998) for further details; numerous data for a range of cereal-derived products from EU and north America are also reported in Table 55)

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of benz[a]anthracene resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.123 below.

Table 3.123 Predicted exposures for benz[a]anthracene arising from use of composts and digestates

	Scenario I	**Units**
PECagricultural soil	3.31E-03	[mg/kg dry wt.]
PECgrassland soil	1.29E-03	[mg/kg dry wt.]
PEC in groundwater	3.21E-07	[mg/l]
PECfreshwater	4.62E-07	[mg/l]
PECfreshwater-sediment	2.31E-02	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.07E-05	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	9.18E-09	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 97.3%	

Secondary poisoning – freshwater fish-eating birds and mammals	3.54E-03	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.93E-03	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	1.09E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	3.51E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.9%	
Secondary poisoning – worm-eating birds and mammals	5.29E-02	[mg.kg-1]

	Regional background	Units
Regional PEC in surface water (total)	2.31E-07	[mg/l]
Regional PEC in air (total)	1.50E-11	[mg.m-3]
Regional PEC in agricultural soil (total)	6.97E-04	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	7.88E-08	[mg/l]
Regional PEC in natural soil (total)	2.37E-07	[mg/kg wet wt.]
Regional PEC in industrial soil (total)	2.37E-07	[mg/kg wet wt.]
Regional PEC in sediment (total)	2.78E-03	[mg/kg wet wt.]

Table 3.124 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.124 Predicted background exposures for benz[a]anthracene at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	5.85E+01	[t]
Steady-state mass in regional freshwater (kg)	8.32E-01	[kg]
Steady-state mass in regional seawater (kg)	8.70E-02	[kg]
Steady-state mass in regional air (kg)	6.08E-04	[kg]

Steady-state mass in regional agricultural soil (kg)	5.69E+03	[kg]
Steady-state mass in regional natural soil (kg)	2.18E-01	[kg]
Steady-state mass in regional industrial soil (kg)	8.07E-02	[kg]
Steady-state mass in regional freshwater sediment (kg)	1.15E+02	[kg]
Steady-state mass in regional seawater sediment (kg)	4.73E+00	[kg]
Steady-state mass in continental freshwater (kg)	9.66E+00	[kg]
Steady-state mass in continental seawater (kg)	3.23E+01	[kg]
Steady-state mass in continental air (kg)	1.51E-02	[kg]
Steady-state mass in continental agricultural soil (kg)	5.12E+04	[kg]
Steady-state mass in continental natural soil (kg)	2.74E+00	[kg]
Steady-state mass in continental industrial soil (kg)	1.01E+00	[kg]
Steady-state mass in continental freshwater sediment (kg)	1.33E+03	[kg]
Steady-state mass in continental seawater sediment (kg)	8.78E+01	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	9.73E+01	[%]
Steady-state mass fraction in regional freshwater (%)	1.38E-03	[%]
Steady-state mass fraction in regional seawater (%)	1.45E-04	[%]
Steady-state mass fraction in regional air (%)	1.01E-06	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.46E+00	[%]
Steady-state mass fraction in regional natural soil (%)	3.62E-04	[%]
Steady-state mass fraction in regional industrial soil (%)	1.34E-04	[%]

Steady-state mass fraction in regional freshwater sediment (%)	1.91E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	7.87E-03	[%]
Steady-state mass in continental freshwater (kg)	1.61E-02	[%]
Steady-state mass in continental seawater (kg)	5.37E-02	[%]
Steady-state mass in continental air (kg)	2.51E-05	[%]
Steady-state mass in continental agricultural soil (kg)	8.52E+01	[%]
Steady-state mass in continental natural soil (kg)	4.55E-03	[%]
Steady-state mass in continental industrial soil (kg)	1.69E-03	[%]
Steady-state mass in continental freshwater sediment (kg)	2.22E+00	[%]
Steady-state mass in continental seawater sediment (kg)	1.46E-01	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.125 below presents the summary of key findings from the risk assessment of benz[a]anthracene that has been made in this project.

Table 3.125 Summary of key findings for exposure of benz[a]anthracene via use of compost and digestates

Key findings of the risk assessment of benz[a]anthracene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04 – 0.33 mg benz[a]anthracene/kg dry wt., <0.3 – 20.8 mg PAH/kg
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, compost and digestate from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).

Key findings of the risk assessment of benz[a]anthracene in contaminated composts and digestates	
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for benz[a]anthracene specifically means that the exposure levels may be under- or over-estimated by the present assessment, particularly for digestate for which no values were found; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 3.16.

3.19 Benzo[b]fluoranthene (representative of PAH16 chemical family)

Background information and remarks

Benzo[b]fluoranthene (CAS 205-99-2, EC 205-911-9) is also known as Benzo[e]acephenanthrylene. According to the harmonised classification and labelling under CLP, this substance may cause cancer, is very toxic to aquatic life and is very toxic to aquatic life with long lasting effects. Some uses of this substance are restricted under Annex XVII of REACH.

It is useful to make a quantitative assessment of this substance in view of the possibility of food contamination. The EFSA scientific opinion (2008b) references benzo[b]fluoranthene, benzo[a]pyrene, chrysene and benz[a]anthracene together as 'PAH4', and states that PAH4 and PAH8 are the most suitable indicators of PAHs in food, with PAH8 (a larger group of 8 marker PAH) not providing much added value compared to PAH4.

Chemical properties and hazards data set

In view of the hazards, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.

Table 3.126 below summarises the relevant property data. The data are mainly taken from the WHO EHC 202 monograph (WHO, 1998); where information from other sources is included this is indicated in the Table.

Table 3.126 Property information for benzo[b]fluoranthene

Property	Value	Remarks
Molecular weight	252.32	

Melting point	168	SRC EPI experimental literature database (unreferenced)
Boiling point		
Vapour pressure	6.67E-05Pa at 25C (Coover MP and Sims R, 1987)	SRC EPI experimental literature database
Water solubility	0.0015 mg/l (Yalkowsky and Dannenfelser 1992)	
log Kow	5.78 (Wang et al 1986)	SRC EPI experimental literature database
Henry's law constant	0.0666 Pa.m3/mol - 25C (Ten Hulscher, TEM et al, 1992)	
Koc		
BCF		
Biodegradability	In a study with sandy loams, forest soil, and roadside soil partially loaded with sewage sludge from a municipal treatment plant, the following half-lives (in days) were found: 113-282 for benzo[b]fluoranthene (Wild & Jones, 1993).	
Half-life in air	18.5540 E-12 cm3/molecule-sec (AOP estimate) - note: Fraction sorbed to airborne particulates (phi): 0.0902 (Junge-Pankow, Mackay avg) 0.306 (Koa method) Note: the sorbed fraction may be resistant to atmospheric oxidation	

Threshold hazard values if available	Value	Remarks
PNECaquatic (freshwater)	MAC EQS of 0.017 µg/l applies (Directive 2008/105/EC as amended (2013/39/EU))	
PNECsediment (freshwater)		
PNECsoil		
PNECoral predator		
DNEL general population oral	BMDL10 = 0.34 mg/kg bw/d	EFSA scientific opinion (2008b) (derived from 2-year carcinogenicity study on coal tar mixtures by Culp et al. (1998)) (this value is derived using the multi-stage model).
Other relevant data		Some members of the group are PBT/vPvB therefore it is not possible to make a quantitative assessment of environmental risk

Occurrence data set

Table 3.127 presents a summary of the reported concentrations of benzo[b]fluoranthene in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

No substance-specific data for benzo[b]fluoranthene were reported in digestates although a small number of measured values in composts are available. This represents an uncertainty in the exposure assessment; in the absence of data it has been assumed that measurements in composts (particularly composts derived from sewage sludge) would be reasonably representative of digestates.

Table 3.127 Reported occurrence of benzo[b]fluoranthene in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Only compost data are available for B[b]F itself, in a relatively narrow range. The values for Benzo[b]fluoranthene as such are <0.48-0.80 mg/kg d.m. 2017 Poland / 0.12 mg/kg 2012 France / 0.22 mg/kg 2012 France / 0.35-2.14 mg/kg d.m. 2017 Poland.
Compost - minimum concentration	0.12	
Compost - mid-range or average concentration	0.48	(median)
Compost - maximum concentration	2.14	Note, Saveyn and Eder report NF U44-051 and NF U44-095 2.5 mg/kg d.m.(France).
Digestates - data availability		In the absence of specific data on digestates, the values reported in composts are applied in the exposure assessment.
Digestate - minimum concentration	0.12	
Digestate - mid-range or average concentration	0.48	
Digestate - maximum concentration	2.14	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.128 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	4234
Mass of substance in EU-28 in digestate (kg/year)	16,934
Total regional emission to surface water (kg/day)	0.16
Total regional emission to soil (kg/day)	5.6
Total continental emission to surface water (kg/day)	1.5
Total continental emission to agricultural soil (kg/day)	51

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.129 and Table 3.130 below summarise background exposure data previously presented by EFSA (2008b) and by WHO (2002).

Table 3.129 Reported background concentrations of benzo[b]fluoranthene in the environment

PECregional	Value	Remarks
Agricultural soil	Polycyclic aromatic hydrocarbon concentrations (µg/kg dry weight) in soil of background and rural areas - Benzo[b]fluoranthene: 14/25 - Wales, United Kingdom (depth, 5 cm) (Jones et al., 1987).	
Other relevant data	Polycyclic aromatic hydrocarbon concentrations (µg/kg fresh weight) in meat and meat products - Benzo[b]fluoranthene: 0.04 - 92.3 in a range of product types (EHC monograph). Polycyclic aromatic hydrocarbon concentrations (µg/kg) found in fish and marine foods - Benzo[b+k]fluoranthenes: NC - 24.3 Polycyclic aromatic hydrocarbon concentrations (µg/kg) in vegetables - Benzo[b]fluoranthene:	EFSA report states that based on the currently available data relating to occurrence and toxicity, the CONTAM Panel concluded that PAH4 (which includes benzo[b]fluoranthene) and PAH8 are the most suitable indicators of PAHs in food, with PAH8 not providing much added value compared to PAH4.

Table 3.130 Reported background concentrations of benzo[b]fluoranthene in vegetables

	Concentrations in leaf crops (µg/kg) *
Benzo[a]fluoranthene	0.08-2.6

Notes:
* – Kale, lettuce, cabbage from a range of studies in different countries (see table 53 of the EHC monograph (WHO IPCS, 1998) for further details)

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of benzo[b]fluoranthene resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.131 below.

Table 3.131 Predicted exposures for benzo[b]fluoranthene arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	2.14E-02	[mg/kg dry wt.]
PECgrassland soil	8.36E-03	[mg/kg dry wt.]
PEC in groundwater	1.26E-06	[mg/l]
PECfreshwater	1.90E-06	[mg/l]
PECfreshwater-sediment	1.58E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.78E-04	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	3.59E-08	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Fish 63.4%	
Secondary poisoning – freshwater fish-eating birds and mammals	3.84E-01	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.09E-02	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	7.06E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	2.18E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.3%	
Secondary poisoning – worm-eating birds and mammals	3.34E-01	[mg.kg-1]

	Regional background	Units
Regional PEC in surface water (total)	5.24E-07	[mg/l]
Regional PEC in air (total)	4.93E-10	[mg.m-3]
Regional PEC in agricultural soil (total)	1.98E-03	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	1.35E-07	[mg/l]
Regional PEC in natural soil (total)	5.52E-06	[mg/kg wet wt.]

Regional PEC in industrial soil (total)	5.52E-06	[mg/kg wet wt.]
Regional PEC in sediment (total)	8.01E-03	[mg/kg wet wt.]

ifferent steady state balance.

Table 3.132 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.132 Predicted background exposures for benzo[b]fluoranthene at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	1.66E+02	[t]
Steady-state mass in regional freshwater (kg)	1.89E+00	[kg]
Steady-state mass in regional seawater (kg)	1.92E-01	[kg]
Steady-state mass in regional air (kg)	1.99E-02	[kg]
Steady-state mass in regional agricultural soil (kg)	1.62E+04	[kg]
Steady-state mass in regional natural soil (kg)	5.07E+00	[kg]
Steady-state mass in regional industrial soil (kg)	1.88E+00	[kg]
Steady-state mass in regional freshwater sediment (kg)	3.32E+02	[kg]
Steady-state mass in regional seawater sediment (kg)	1.50E+01	[kg]
Steady-state mass in continental freshwater (kg)	2.08E+01	[kg]
Steady-state mass in continental seawater (kg)	8.64E+01	[kg]
Steady-state mass in continental air (kg)	3.82E-01	[kg]
Steady-state mass in continental agricultural soil (kg)	1.45E+05	[kg]
Steady-state mass in continental natural soil (kg)	4.90E+01	[kg]
Steady-state mass in continental industrial soil (kg)	1.82E+01	[kg]

Steady-state mass in continental freshwater sediment (kg)	3.66E+03	[kg]
Steady-state mass in continental seawater sediment (kg)	3.36E+02	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	9.80E+01 [%]	
Steady-state mass fraction in regional freshwater (%)	1.11E-03	[%]
Steady-state mass fraction in regional seawater (%)	1.13E-04	[%]
Steady-state mass fraction in regional air (%)	1.18E-05	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.53E+00	[%]
Steady-state mass fraction in regional natural soil (%)	2.99E-03	[%]
Steady-state mass fraction in regional industrial soil (%)	1.11E-03	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.96E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	8.83E-03	[%]
Steady-state mass in continental freshwater (kg)	1.23E-02	[%]
Steady-state mass in continental seawater (kg)	5.09E-02	[%]
Steady-state mass in continental air (kg)	2.25E-04	[%]
Steady-state mass in continental agricultural soil (kg)	8.58E+01	[%]
Steady-state mass in continental natural soil (kg)	2.89E-02	[%]
Steady-state mass in continental industrial soil (kg)	1.07E-02	[%]
Steady-state mass in continental freshwater sediment (kg)	2.16E+00	[%]
Steady-state mass in continental seawater sediment (kg)	1.98E-01	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.133 below presents the summary of key findings from the risk assessment of benzo[b]fluoranthene that has been made in this project.

Table 3.133 Summary of key findings for exposure of benzo[b]fluoranthene via use of compost and digestates

Key findings of the risk assessment of benzo[b]fluoranthene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	0.12-2.14 mg benzo[b]fluoranthene/kg dry wt., <0.3 – 20.8 mg PAH/kg.
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, compost and digestate from source separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for benzo[b]fluoranthene specifically means that the exposure levels may be under- or over-estimated by the present assessment, especially for digestate where no values were found; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 3.16.

3.20 Indeno[1,2,3-cd]pyrene (representative of PAH16 chemical family)

Background information and remarks

Indeno[1,2,3-cd]pyrene (CAS 193-39-5, EC 205-893-2) is among the eight carcinogenic and genotoxic PAHs (with benzo[a]pyrene, benz[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, chrysene, dibenz[a,h]anthracene) that were measured in the coal tar mixtures in carcinogenicity studies (Culp et al., 1998) referenced by the EFSA CONTAM panel (PAH8). It is of higher molecular weight than the PAH with slightly different chemical properties which is associated with slightly different distribution properties and so offers an alternative perspective in terms of exposures and distribution via this exposure pathway.

Chemical properties and hazards data set

Table 3.134 summarises the available chemical property data. The data are mainly taken from the ESR RAR for coal tar pitch high-temperature (EC 2008d); where information from other sources is included this is indicated in the Table.

Table 3.134 Property information for indeno[1,2,3-cd]pyrene

Property	Value	Remarks
Molecular weight	276.3	From CTPHT PBT assessment (ECB 2008)
Melting point	163.6	As above
Boiling point	536	As above
Vapour pressure	1.7 x 10-8 Pa at 25C (estimated by EPIWIN)	ESR RAR for CTPHT (EC, 2008d)
Water solubility	For indeno[1,2,3-cd]pyrene no data were available, a default value of 0.1 µg/L was used	As above
log Kow	6.58 (estimated by ClogP)	As above
Henry's law constant	0.046 Pa.m3/mol (calculated by EUSES from input data values)	ESR RAR for CTPHT (EC, 2008d)
Koc	log Koc = 6.37	Karickhoff et al. (1979) (cited by ESR RAR for CTPHT)
BCF		
Biodegradability	Mean half-lives: 1700h in water, 17000h in soil and 55000h in sediment (temperatures not stated; assumed to be 25C)	ESR RAR for CTPHT uses mean half-lives by Mackay et al. (1992).
Half-life in air		

Threshold hazard values if available	Value	Remarks

PNECaquatic (freshwater)	0.0027 µg/l (ESR RAR for CTPHT)	PAHs can be toxic via different mode of actions, such as non-polar narcosis and phototoxicity. The last is caused by the ability of PAHs to absorb ultraviolet A (UVA) radiation (320–400 nm), ultraviolet B (UVB) radiation (290–320 nm), and in some instances, visible light (400–700 nm). This toxicity may occur through two mechanisms: photosensitization, and photomodification. Photosensitization generally leads to the production of singlet oxygen, a reactive oxygen species that is highly damaging to biological material. Photomodification of PAHs, usually via oxidation, results in the formation of new compounds and can occur under environmentally relevant levels of actinic radiation (Lampi et al., 2005). The phototoxic effects can be observed after a short period of exposure, which explains why for PAHs like anthracene, fluoranthene and pyrene, where photoxicity is most evident, the acute toxicity values are even lower than the chronic toxicity values. (ESR RAR for CTPHT).
PNECsediment (freshwater)	0.63 mg/kgdw (EQPM - from ESR RAR CTPHT)	
PNECsoil	0.13 mg/kgdw (EQPM - from ESR RAR CTPHT)	
PNECoral predator		
DNEL general population oral		
Other relevant data		Some members of the group are PBT/vPvB therefore it is not possible to make a quantitative assessment of environmental risk.

Occurrence data set

Table 3.135 presents a summary of the reported concentrations of indeno[1,2,3-cd]pyrene and other PAH in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

No substance-specific data for indeno[1,2,3-cd]pyrene were reported in digestates although a small number of measured values in composts are available. This represents an uncertainty in the exposure assessment; in the absence of data it has been assumed that measurements in composts (particularly composts derived from sewage sludge) would be reasonably representative of digestates.

Table 3.135 Reported occurrence of indeno[1,2,3-cd]pyrene in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Only 2 compost data are available for Indeno[1,2,3-cd]pyrene itself / 6-ring PAH, for the same member state coming from the same study. <0.04-2.32 mg/kg d.m. 2017 Poland.
Compost - minimum concentration	0.04	The lower limit value is taken as such for the purpose of a minimum exposure background assessment, but is actually reported as a less-than limit value.

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Compost - mid-range or average concentration	1.18	Mean of the range.
Compost - maximum concentration	2.32	
Digestates - data availability		Using the same values as above, in the absence of specific data for digestate. The compost values are sewage sludge compost so in principle should also be representative of digestate.
Digestate - minimum concentration	0.04	
Digestate - mid-range or average concentration	1.18	
Digestate - maximum concentration	2.32	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.136 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	10,408
Mass of substance in EU-28 in digestate (kg/year)	41,630
Total regional emission to surface water (kg/day)	0.40
Total regional emission to soil (kg/day)	14
Total continental emission to surface water (kg/day)	3.6
Total continental emission to agricultural soil (kg/day)	125

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.137 below summarises background exposure data previously presented by EFSA (2008b) and WHO (2002).

Table 3.137 Reported background concentrations of indeno[1,2,3-cd]pyrene in the environment

PECregional	Value	Remarks
Air		

Surface water		
Sediment		
Agricultural soil	Polycyclic aromatic hydrocarbon concentrations (µg/kg dry weight) in soil of background and rural areas - indeno[1,2,3-cd]pyrene: 0.5-4.0 - Green Mountain, USA (depth, 0-5 cm) (Sullivan & Mix, 1985).	EHC 202 (WHO 1998).
Soil pore water/ground water		
Natural soil		
Urban/industrial soil		
Other relevant data		EFSA report states Based on the currently available data relating to occurrence and toxicity, the CONTAM Panel concluded that PAH4 and PAH8 (which includes indeno[1,2,3-cd]pyrene) are the most suitable indicators of PAHs in food, with PAH8 not providing much added value compared to PAH4.

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of indeno[1,2,3-cd]pyrene resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.138 below.

Table 3.138 Predicted exposures for indeno[1,2,3-cd]pyrene arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	2.32E-02	[mg/kg dry wt.]
PECgrassland soil	9.06E-03	[mg/kg dry wt.]
PEC in groundwater	4.83E-07	[mg/l]
PECfreshwater	1.12E-06	[mg/l]
PECfreshwater-sediment	2.62E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.52E-04	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	1.38E-08	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Fish 54.1%	

Secondary poisoning – freshwater fish-eating birds and mammals	2.99E-01	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	1.36E-02	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	7.66E-01	[mg/kg dry wt.]
Humans via the environment: local total daily intake	2.30E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.3%	
Secondary poisoning – worm-eating birds and mammals	3.72E-01	[mg.kg-1]

	Regional background	Units
Regional PEC in surface water (total)	1.01E-06	[mg/l]
Regional PEC in air (total)	4.31E-11	[mg.m-3]
Regional PEC in agricultural soil (total)	4.90E-03	[mg/kg wet wt.]
Regional PEC in pore water of agricultural soils	1.18E-07	[mg/l]
Regional PEC in natural soil (total)	6.83E-07	[mg/kg wet wt.]
Regional PEC in industrial soil (total)	6.83E-07	[mg/kg wet wt.]
Regional PEC in sediment (total)	2.16E-02	[mg/kg wet wt.]

Table 3.139 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.139 Predicted background exposures for indeno[1,2,3-cd]pyrene at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	4.11E+02	[t]
Steady-state mass in regional freshwater (kg)	3.62E+00	[kg]
Steady-state mass in regional seawater (kg)	3.51E-01	[kg]

Steady-state mass in regional air (kg)	1.74E-03	[kg]
Steady-state mass in regional agricultural soil (kg)	4.00E+04	[kg]
Steady-state mass in regional natural soil (kg)	6.27E-01	[kg]
Steady-state mass in regional industrial soil (kg)	2.32E-01	[kg]
Steady-state mass in regional freshwater sediment (kg)	8.93E+02	[kg]
Steady-state mass in regional seawater sediment (kg)	4.93E+01	[kg]
Steady-state mass in continental freshwater (kg)	3.84E+01	[kg]
Steady-state mass in continental seawater (kg)	9.53E+01	[kg]
Steady-state mass in continental air (kg)	4.43E-02	[kg]
Steady-state mass in continental agricultural soil (kg)	3.60E+05	[kg]
Steady-state mass in continental natural soil (kg)	8.06E+00	[kg]
Steady-state mass in continental industrial soil (kg)	2.99E+00	[kg]
Steady-state mass in continental freshwater sediment (kg)	9.46E+03	[kg]
Steady-state mass in continental seawater sediment (kg)	6.69E+02	[kg]

	Steady state mass fraction	**Units**
Total steady-state mass fraction (region + continent)	9.92E+01	[%]
Steady-state mass fraction in regional freshwater (%)	8.75E-04	[%]
Steady-state mass fraction in regional seawater (%)	8.46E-05	[%]
Steady-state mass fraction in regional air (%)	4.20E-07	[%]
Steady-state mass fraction in regional agricultural soil (%)	9.65E+00	[%]
Steady-state mass fraction in regional natural soil (%)	1.51E-04	[%]

Steady-state mass fraction in regional industrial soil (%)	5.60E-05	[%]
Steady-state mass fraction in regional freshwater sediment (%)	2.15E-01	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.19E-02	[%]
Steady-state mass in continental freshwater (kg)	9.27E-03	[%]
Steady-state mass in continental seawater (kg)	2.30E-02	[%]
Steady-state mass in continental air (kg)	1.07E-05	[%]
Steady-state mass in continental agricultural soil (kg)	8.68E+01	[%]
Steady-state mass in continental natural soil (kg)	1.95E-03	[%]
Steady-state mass in continental industrial soil (kg)	7.21E-04	[%]
Steady-state mass in continental freshwater sediment (kg)	2.28E+00	[%]
Steady-state mass in continental seawater sediment (kg)	1.62E-01	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.140 below presents the summary of key findings from the risk assessment of indeno[1,2,3-cd]pyrene that has been made in this project.

Table 3.140 Summary of key findings for exposure of indeno[1,2,3-cd]pyrene via use of compost and digestates

Key findings of the risk assessment of indeno[1,2,3-cd]pyrene in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<0.04-2.32 mg indeno[1,2,3-cd]pyrene /kg dry wt. , <0.3 – 20.8 mg PAH/kg.
Major raw material sources	PAHs reported above ca. 3 mg/kg in sewage sludge (composted and non-composted), bio-waste and green waste compost, compost and digestate from source

Key findings of the risk assessment of indeno[1,2,3-cd]pyrene in contaminated composts and digestates	
	separation, digestate derived from manure/slurry, and digestate derived from renewable raw materials.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	High cumulative loads at steady state.
Effects considered in the main concern hazard(s)	Basis of the EQS is not stated in the Directive but is understood to relate to human health via consumption of fishery products. Human BMDL10 based on carcinogenicity.
Uncertainties and their implications	Small occurrence data set for indeno[1,2,3-cd]pyrene specifically means that the exposure levels may be under- or over-estimated by the present assessment, particularly for digestate for which no values were found; exposures of humans via diet, predators via the food chain. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	Local human exposure via diet does not exceed the BMDL10.

The assessment findings for all assessed PAH are discussed in the equivalent section in Section 3.16.

3.21 Perfluoroctanoic acid (PFOA) (representative of PFAs chemical family)

Background information and remarks

PFOA (Perfluorooctanoic acid, CAS No. 335-67-1, EC 206-397-9) has been used industrially, for example as a surface modifier compound / surfactant in a range of applications, though it has not been registered in REACH.
Perfluorooctanoic acid[62] (PFOA), its salts and PFOA-related compounds have been proposed as persistent organic pollutants (POPs) for inclusion in Annex A, B and/or C to the Stockholm Convention (UNEP, 2015) and there is also a REACH restriction.

It is an SVHC (Toxic for reproduction (Article 57c) PBT (Article 57d)), CMR, PBT.
Harmonised classification and labelling applies in the EU under CLP (Acute Tox. 4 - H302; Eye Dam. 1 - H318; Acute Tox. 4 - H332; Carc. 2 - H351; Lact. - H362; STOT RE 1 - H372 (liver); Repr. 1B - H360D); some CLP notifiers also self-classify for the environment.

Chemical properties and hazards data set

The relevant property data summarised in Table 3.155 below (taken from UNEP, 2016). Where information from other sources is included this is indicated in the Table.

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[62] Also known as pentadecafluorooctanoic acid.

Table 3.141 Property information for PFOA (from UNEP (2016) unless otherwise indicated)

Property	Value	Comment
Molecular weight	414.07 g/mol	
Melting point	44-56.5°C	
Boiling point	188°C	
Vapour pressure	4.2 Pa at 25°C	
Water solubility	9,500 mg/l at 25°C	This value is high but it is noted that this substance is surface active which affects it properties in water.
log Kow	not measurable	According to UNEP (2016) the log Kow is not measurable. ECHA (2013b) gives a calculated log Kow of 2.69 at pH 7 and 25°C but indicates that there is a large uncertainty over the log Kow.
Henry's law constant	0.18 Pa m3/mol (at 25°C)	No data in UNEP (2016). Value estimated from the water solubility and vapour pressure.
Koc	115 l/kg	From Danish EPA (2015). Value given as log Koc = 2.06. This value is relatively low but as a surfactant, adsorption to surfaces could be relatively high.
BCF	1.8-8.0 l/kg in aquatic organisms no data for earthworms	Values taken from ECHA (2013b).
Biodegradability	Extremely persistent in all environmental compartments	
Half-life in air	130 day	
PNECs	As a PBT and proposed POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.	No PNECs derived in UNEP (2016) or ECHA (2013b or 2014c). Ecotoxicity data for ammonium perfluorooctanoate taken from OECD (2008).
DNEL	As a PBT and POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here. The existence of the following proposed safe levels is however noted TDI = 1.5 µg/kg bw/day (EFSA, 2008) TDI = 0.1 µg/kg bw/day (Danish EPA, 2015)	No DNEL derived in UNEP (2016) or ECHA (2013b). ECHA (2017) only defines DNEL for general population in terms of the internal dose which is not directly comparable. The tolerable daily intake (TDI) has been determined to be 1.5 µg/kg bw/day (EFSA, 2008). A lower TDI of 0.1 µg/kg bw/day has been determined by Danish EPA (2015).
Other relevant data	Trophic magnification factors (TMFs): TMF 0.3-0.58 aquatic piscivorous food webs TMF 1.1-13 in air-breathing mammals	Values taken from ECHA (2013b).

Note: a) PFO is the conjugate base of PFOA. The dissociation constant given in UNEP (2016) is 1.5-2.8 with another value given as <1.6. Under most environmental conditions UNEP (2016) indicates that the substance will be present as the PFO anion.

PFOA has been identified as an SVHC substance under the REACH Regulation on the basis of it being toxic for reproduction (Article 57c of REACH) and its PBT properties (Article 57d of REACH).

Occurrence data set

Table 3.142 presents a summary of the reported concentrations of PFOA (PFT (PFOA+PFOS), or PFOA specifically) in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.142 Reported occurrence of PFOA in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Both the highest and lowest reported values are for perfluorinated surfactants (not differentiating specific substances). The majority of values are cited by Saveyn and Eder and refer to composts and digestates prepared by different treatment methods.
Compost - minimum concentration	0.0018	Many values are less-than limit values. The value used is the lower range of one of the few reported quantitative values available.
Compost - mid-range or average concentration	0.025	Many values are less-than limit values. The value used is the upper range of one of the few reported quantitative values available.
Compost - maximum concentration	0.165	≤ 165 µg/kg d.m. (note - actually a less-than limit value) is the highest mentioned limit value and is for a sewage sludge compost. There are regulatory limit or guide values of 0.1 mg/kg in all cases for: Austria, Germany, Denmark (Österreichische Düngemittelverordnung, Deutsche Düngemittelverordnung, Slambekendtgørelsen)
Digestates - data availability		Very few digestate specific concentrations are reported. Almost all of the reported concentration values are less-than limit values. The larger data set for composts has been taken into account.
Digestate - minimum concentration	0.0018	Many values are less-than limit values. The value used is the lower range of one of the few reported quantitative values available.
Digestate - mid-range or average concentration	0.025	Many values are less-than limit values. The value used is the upper range of one of the few reported quantitative values available.
Digestate - maximum concentration	0.045	≤ 45 µg/kg d.m. (note - actually a less-than limit value) is the highest mentioned limit value and is for a bio-waste & green waste manure energy crops digestate.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.143 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	221
Mass of substance in EU-28 in digestate (kg/year)	882
Total regional emission to surface water (kg/day)	0.0085
Total regional emission to soil (kg/day)	0.29
Total continental emission to surface water (kg/day)	0.076
Total continental emission to agricultural soil (kg/day)	2.6

Perfluorinated chemicals including PFOS and PFOA have been detected in composts and digestates; many of the values (including both the highest and lowest reported levels) refer to the sum of pefluorinated surfactants and are not substance-specific. The majority of the quoted concentrations found are presented as less-than limit concentrations (i.e. <x mg/kg) which may reflect the limit of detection of the analytical method used. For the purpose of the present assessment these values have been interpreted as equal to the limit concentration stated, but it is recognised that the true content of PFOA could be below this.

The highest non-limit concentration is 24.6 µg/kg dry wt. (it is not specified whether this value is for compost(s) or digestate(s) so it is assumed to apply for both); the highest concentration is ≤165 µg/kg dry wt. in green waste compost, and this is the value used in the assessment for scenarios I and II. It is noted that the concentration of ≤165 µg/kg dry wt. could actually exceed the regulatory limit values of 0.1 mg/kg d.m. for perfluorinated compounds, defined by Österreichische Düngemittelverordnung and Slambekendtgørelsen. The highest concentration in digestate is ≤45 µg/kg dry wt. in bio-waste & green waste manure energy crops digestate and this value is used in calculating the contribution to regional exposure arising from use of digestate. There is no evidence as to whether the composts containing PFOA are primarily for use as a soil amendment or as a growing medium.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.144 below summarises background exposure data previously presented by ECHA (2014c). The current regional background level of PFOA is not well established although ECHA (2014c) summarises some literature findings. In light of its status as a proposed POP, there is an international commitment to restrict its use, and hence significant decline in use is to be expected going forward and the context of predicted environmental concentrations should be considered in this context.

Table 3.144 Reported background concentrations of PFOA in the environment

PECregional	Value	Remarks
Air		

Surface water	Very variable	Table A.B.4-6 in ECHA (2014c) documents results of 9 studies covering a range of European fresh waters with values in the range <0.0005 ng/l to 33,900 ng/l. The majority are below ≤100 ng/l but there are several above this value (occasional high concentrations are not representative of background).
Sediment		
Agricultural soil / Natural soil / Urban/industrial soil	Up to 50 ng/g dwt	
Soil pore water/ground water	Very variable; mainly up to 84 ng/l	
Other relevant data		

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of PFOA resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.145 below.

Table 3.145 Predicted exposures for PFOA arising from use of composts and digestates

	Scenario I		Units
PECagricultural soil		7.36E-04	[mg/kg dry wt.]
PECgrassland soil		1.50E-04	[mg/kg dry wt.]
PEC in groundwater		2.76E-04	[mg/l]
PECfreshwater		1.73E-06	[mg/l]
PECfreshwater-sediment		2.61E-05	[mg/kg dry wt.]
Humans via the environment: local total daily intake		1.83E-05	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water		7.89E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 51.2%		
Secondary poisoning – freshwater fish-eating birds and mammals		1.27E-05	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals		9.09E-04	[mg.kg-1]

	Scenario II		Units
PECagricultural soil		5.45E-02	[mg/kg dry wt.]

Humans via the environment: local total daily intake		8.39E-04	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 90.4%		
Secondary poisoning – worm-eating birds and mammals		7.14E-02	[mg.kg-1]

Table 3.146 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.146 Predicted background exposures for PFOA at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	4.82E+00	[t]
Steady-state mass in regional freshwater (kg)	5.19E+00	[kg]
Steady-state mass in regional seawater (kg)	5.71E-01	[kg]
Steady-state mass in regional air (kg)	9.93E-02	[kg]
Steady-state mass in regional agricultural soil (kg)	1.57E+02	[kg]
Steady-state mass in regional natural soil (kg)	2.22E-01	[kg]
Steady-state mass in regional industrial soil (kg)	8.22E-02	[kg]
Steady-state mass in regional freshwater sediment (kg)	2.02E-01	[kg]
Steady-state mass in regional seawater sediment (kg)	6.43E-03	[kg]
Steady-state mass in continental freshwater (kg)	1.18E+02	[kg]
Steady-state mass in continental seawater (kg)	3.07E+03	[kg]
Steady-state mass in continental air (kg)	5.14E+00	[kg]
Steady-state mass in continental agricultural soil (kg)	1.45E+03	[kg]
Steady-state mass in continental natural soil (kg)	5.80E+00	[kg]
Steady-state mass in continental industrial soil (kg)	2.15E+00	[kg]
Steady-state mass in continental freshwater sediment (kg)	4.59E+00	[kg]
Steady-state mass in continental seawater sediment (kg)	1.73E+00	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	8.78E-01	[%]
Steady-state mass fraction in regional freshwater (%)	9.46E-04	[%]
Steady-state mass fraction in regional seawater (%)	1.04E-04	[%]
Steady-state mass fraction in regional air (%)	1.81E-05	[%]
Steady-state mass fraction in regional agricultural soil (%)	2.87E-02	[%]
Steady-state mass fraction in regional natural soil (%)	4.04E-05	[%]
Steady-state mass fraction in regional industrial soil (%)	1.50E-05	[%]
Steady-state mass fraction in regional freshwater sediment (%)	3.68E-05	[%]
Steady-state mass fraction in regional seawater sediment (%)	1.17E-06	[%]
Steady-state mass in continental freshwater (kg)	2.15E-02	[%]
Steady-state mass in continental seawater (kg)	5.59E-01	[%]
Steady-state mass in continental air (kg)	9.38E-04	[%]
Steady-state mass in continental agricultural soil (kg)	2.64E-01	[%]
Steady-state mass in continental natural soil (kg)	1.06E-03	[%]
Steady-state mass in continental industrial soil (kg)	3.92E-04	[%]
Steady-state mass in continental freshwater sediment (kg)	8.37E-04	[%]
Steady-state mass in continental seawater sediment (kg)	3.15E-04	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is 18% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be potentially significant.

Summary of findings

Table 3.147 below presents the summary of key findings from the risk assessment of PFOA that has been made in this project. The findings are discussed further below the table.

Table 3.147 Summary of key findings for exposure of PFOA via use of compost and digestates

Key findings of the risk assessment of PFOA in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<2E-03 - ≤0.165 mg/kg dry wt.
Major raw material sources	PFOA/PFOS measured above ca 0.01 mg/kg in compost and digestate from source separation, bio-waste & green waste compost, green waste compost, sewage sludge compost, "mechanical biological treatment compost", bio-waste & green waste manure energy crops digestate, "mechanical biological treatment digestate".
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of a POP; Humans exposed via the environment (especially via diet and drinking water); possible transfer over long distances.
Effects considered in the main concern hazard(s)	Proposed POP; human TDI based on mammalian liver toxicity.
Uncertainties and their implications	Small occurrence data sets for PFOA specifically, and almost all stated values are less-than limit values. Sensitivity of exposures to variations in water management in the local container growing scenario is potentially significant. In circumstances where a) the system is watered in excess of the water holding capacity of the growing medium and b) where the container design means that excess water will drain away and not remain in contact with the container/growing medium, then a significant proportion of the substance could be lost from the system in the drained water.
Other remarks	

As a proposed POP, it is in itself a potentially important finding that PFOA or other PFAs have been detected in freshly-produced composts and digestates at several different locations in recent years. The raw material waste streams could be investigated further. However, the reported concentrations in composts and digestates do not exceed the national limit values according to the data collected in this project.

While risk characterisation has not been quantified, it is noted that the predicted exposures of humans in the form of local total daily intake associated with local exposure when used for container growing could exceed the safe limit (TDI) based on the value derived by Danish EPA (2015).
The estimated regional-scale predicted environmental concentrations in surface water, ground water and agricultural soil arising from the application of C/D are within the range of the literature concentrations presented in this section compared with natural background concentrations based on ECHA (2014c).

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables; exposure via drinking water is also high for local scenario I (application on land).

At steady state, <1% of the total mass remains within the region + continent[63], suggesting that there is high potential for transfer over long distances following release via the handling and application of C/D[64]. The majority of the substance is modelled to be present in global tropic waters (56%) at steady state followed by moderate waters (26%) and arctic waters (17%). The total mass in the region + continent at steady state is <10 t in the baseline scenario. This steady-state mass amounts to 4.4 times the mass released annually via application of composts and digestates[65].

3.22 Perfluoroctanesulfonic acid (PFOS) (representative of PFAs chemical family)

Background information and remarks

PFOS and its salts are among the more recently adopted 'new' POPs. PFOS is both intentionally produced and also is an unintended degradation product of related anthropogenic chemicals. Various applications have been relevant in the international chemicals industry.

Chemical properties and hazards data set

The relevant property data summarised in Table 3.148 below (taken from the UNEP POP risk profile (2011) and Environment Agency EUSES risk assessment (2004)). Where information from other sources is included this is indicated in the Table.

Table 3.148 Property information for PFOS (from the UNEP POP risk profile (2011) unless otherwise indicated)

Property	Value	Comment
Molecular weight	538	all data is from the UNEP POP risk profile unless otherwise stated
Melting point	>400°C	
Boiling point	not measurable	
Vapour pressure	3.31E-04 Pa (temperature not stated, assumed to be ambient)	
Water solubility	519 mg/L (20 ± 0,5°C); 680 mg/L (24 - 25°C).	519 mg/l value used in EUSES
log Kow	Cannot be determined	A surrogate value of 4.88 is used in EUSES to support the humans via environment assessment (EA, 2004 risk assessment)

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[63] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[64] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[65] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Property	Value	Comment
Henry's law constant	3.09 x 10-9 atm m3/mol pure water	Equivalent to 3.1E-04 Pa.m3/mol, EUSES derives a very similar value; reported value from risk profile entered in EUSES.
Koc	Measured Kd values in l/kg from OECD 106 study (mean from adsorption and desorption phases): 12.8-35.1 in different soil types, mean 27 l/kg; 8.7 in river sediment; 1028 in WWTP sludge. These Kds have been used in EUSES.	From EA environmental risk assessment (2004)
BCF	BCF values around 3000 from fish studies (whole-fish kinetic bioconcentration factor (BCFK)) 2796 in *L. macrochirus* (OECD 305, 3M, 2002); BCF in liver and plasma 2900 and 3100 respectively (estimated, Martin et al, 2003). BMF values are variable and are high especially in top predators; range 22 - ~4000 for several predator species types mainly referring to marine food chain and levels in specific tissues (refer to the report for further details). A trophic magnification factor (TMF) of 5.9 was calculated for PFOS based on a pelagic food web including: one invertebrate species, Mysis; two forage fish species, rainbow smelt and alewife; and a top predator fish species, lake trout. A diet-weighted bioaccumulation factor of approximately 3 was determined for the trout (Martin et al., (2004b). Note: EA 2004 used BMF1, BMF2 = 2. BCF earthworm: 60.5 l/kg wet wt. (derived in EA 2004 risk assessment).	The diet weighted bioaccumulation factor has been entered in EUSES as the BMF for fish, and a nominal value of 100 has been entered for predators
Biodegradability	t1/2 >41 years (hydrolysis); >3.7 years (photodegradation in water); no aerobic or anaerobic biodegradability.	
Half-life in air	114d (estimated)	
PNECs	An annual average EQS of 6.5E-04 µg/l and MAC EQS of 36 µg/l are established for inland surface waters; an EQS of 9.1 mg/kg for biota is applicable (Directive 2008/105/EC as amended (2013/39/EU)).	
DNEL	As a PBT and POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here. The existence of the following proposed safe levels is however noted	The tolerable daily intake (TDI) has been determined to be 150 ng/kg bw/day (EFSA, 2008). A lower TDI of 0.03 µg/kg bw/day has been determined by Danish EPA (2015).

Property	Value	Comment
	TDI = 0.15 µg/kg bw/day (EFSA, 2008) TDI = 0.03 µg/kg bw/day (Danish EPA, 2015).	
Other relevant data		

Occurrence data set

Table 3.156 presents a summary of the reported concentrations of PFOS (PFT (PFOA+PFOS), or PFOS specifically) in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.149 Reported occurrence of PFOS in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Both the highest and lowest reported values are for perfluorinated surfactants (not differentiating specific substances). The majority of values are cited by Saveyn and Eder and refer to composts and digestates prepared by different treatment methods.
Compost - minimum concentration	0.0018	Many values are less-than limit values. The value used is the lower range of one of the few reported quantitative values available.
Compost - mid-range or average concentration	0.025	Many values are less-than limit values. The value used is the upper range of one of the few reported quantitative values available.
Compost - maximum concentration	0.165	≤ 165 µg/kg d.m. (note - actually a less-than limit value) is the highest mentioned limit value and is for a sewage sludge compost. There are regulatory limit or guide values of 0.1 mg/kg in all cases for: Austria, Germany, Denmark (Österreichische Düngemittelverordnung, Deutsche Düngemittelverordnung, Slambekendtgørelsen).
Digestates - data availability		Very few digestate specific concentrations are reported. Almost all of the reported concentration values are less-than limit values. The larger data set for composts has been taken into account.
Digestate - minimum concentration	0.0018	Many values are less-than limit values. The value used is the lower range of one of the few reported quantitative values available.
Digestate - mid-range or average concentration	0.025	Many values are less-than limit values. The value used is the upper range of one of the few reported quantitative values available.
Digestate - maximum concentration	0.045	≤ 45 µg/kg d.m. (note - actually a less-than limit value) is the highest mentioned limit value and is for a bio-waste & green waste manure energy crops digestate.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.150 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	221
Mass of substance in EU-28 in digestate (kg/year)	882
Total regional emission to surface water (kg/day)	0.0085
Total regional emission to soil (kg/day)	0.29
Total continental emission to surface water (kg/day)	0.076
Total continental emission to agricultural soil (kg/day)	2.6

Perfluorinated chemicals including PFOS and PFOA have been detected in composts and digestates; many of the values (including both the highest and lowest reported levels) refer to the sum of pefluorinated surfactants and are not substance-specific. The majority of the quoted concentrations found are presented as less-than limit concentrations (i.e. <*x* mg/kg) which may reflect the limit of detection of the analytical method used. For the purpose of the present assessment these values have been interpreted as equal to the limit concentration stated, but it is recognised that the true content of PFOS could be below this.

The highest non-limit concentration is 24.6 µg/kg dry wt. (it is not specified whether this value is for compost(s) or digestate(s) so it is assumed to apply for both); the highest concentration for composts is ≤165 µg/kg dry wt. (in green waste compost), and this is the value used in the assessment for scenarios I and II; the highest concentration in digestate is also a limit value but potentially lower, at ≤45 µg/kg dry wt.. It is noted that the concentration of ≤165 µg/kg dry wt. could actually exceed the regulatory limit values of 0.1 mg/kg d.m. for perfluorinated compounds, defined by Österreichische Düngemittelverordnung and Slambekendtgørelsen. The highest concentration in digestate of ≤45 µg/kg dry wt. is for bio-waste & green waste manure energy crops digestate and this value is used in calculating the contribution to regional exposure arising from use of digestate. There is no evidence as to whether the composts containing PFOA are primarily for use as a soil amendment or as a growing medium.

These values have been applied in estimating the exposure concentrations for this substance arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.151 below summarises background exposure data previously presented by the Environment Agency (2004). In light of its status as a POP, there is an international commitment to restrict its use, and hence significant continuing decline in use is to be expected going forward and the context of predicted environmental concentrations should be considered in this context.

Table 3.151 Reported background concentrations of PFOS in the environment

PECregional	Value	Remarks
Air		
Surface water	ND - 0.138 ppb (urban, USA)	quoted in EA (2004)
Sediment		
Agricultural soil / Natural soil / Urban/industrial soil		
Soil pore water/ground water	4 – 110 µg/l	quoted in EA (2004)
Other relevant data		

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of PFOS resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.152 below.

Table 3.152 Predicted exposures for PFOS arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	2.49E-03	[mg/kg dry wt.]
PECgrassland soil	9.02E-04	[mg/kg dry wt.]
PEC in groundwater	9.15E-05	[mg/l]
PECfreshwater	2.71E-06	[mg/l]
PECfreshwater-sediment	3.34E-05	[mg/kg dry wt.]
Humans via the environment: local total daily intake	3.28E-04	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.62E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 94.7%	
Secondary poisoning – freshwater fish-eating birds and mammals	2.31E-02	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	2.96E-03	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	5.45E-02	[mg/kg dry wt.]

Humans via the environment: local total daily intake	6.85E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root Crops 99.4%	
Secondary poisoning – worm-eating birds and mammals	5.73E-02	[mg.kg-1]

Table 3.153 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.153 Predicted background exposures for PFOS at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	2.81E+01	[t]
Steady-state mass in regional freshwater (kg)	8.75E+00	[kg]
Steady-state mass in regional seawater (kg)	9.55E-01	[kg]
Steady-state mass in regional air (kg)	5.81E-05	[kg]
Steady-state mass in regional agricultural soil (kg)	2.47E+03	[kg]
Steady-state mass in regional natural soil (kg)	9.69E-01	[kg]
Steady-state mass in regional industrial soil (kg)	3.59E-01	[kg]
Steady-state mass in regional freshwater sediment (kg)	4.39E-01	[kg]
Steady-state mass in regional seawater sediment (kg)	1.46E-02	[kg]
Steady-state mass in continental freshwater (kg)	2.39E+02	[kg]
Steady-state mass in continental seawater (kg)	3.28E+03	[kg]
Steady-state mass in continental air (kg)	5.81E-04	[kg]
Steady-state mass in continental agricultural soil (kg)	2.21E+04	[kg]
Steady-state mass in continental natural soil (kg)	4.89E+00	[kg]
Steady-state mass in continental industrial soil (kg)	1.81E+00	[kg]
Steady-state mass in continental freshwater sediment (kg)	1.20E+01	[kg]
Steady-state mass in continental seawater sediment (kg)	2.50E+00	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	4.59E+00	[%]
Steady-state mass fraction in regional freshwater (%)	1.43E-03	[%]
Steady-state mass fraction in regional seawater (%)	1.56E-04	[%]
Steady-state mass fraction in regional air (%)	9.49E-09	[%]
Steady-state mass fraction in regional agricultural soil (%)	4.03E-01	[%]
Steady-state mass fraction in regional natural soil (%)	1.58E-04	[%]
Steady-state mass fraction in regional industrial soil (%)	5.86E-05	[%]
Steady-state mass fraction in regional freshwater sediment (%)	7.17E-05	[%]
Steady-state mass fraction in regional seawater sediment (%)	2.38E-06	[%]
Steady-state mass in continental freshwater (kg)	3.89E-02	[%]
Steady-state mass in continental seawater (kg)	5.35E-01	[%]
Steady-state mass in continental air (kg)	9.48E-08	[%]
Steady-state mass in continental agricultural soil (kg)	3.61E+00	[%]
Steady-state mass in continental natural soil (kg)	7.99E-04	[%]
Steady-state mass in continental industrial soil (kg)	2.96E-04	[%]
Steady-state mass in continental freshwater sediment (kg)	1.96E-03	[%]
Steady-state mass in continental seawater sediment (kg)	4.09E-04	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under 'high water content' conditions, and hence sensitive to leaching, is ≤1% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.154 below presents the summary of key findings from the risk assessment of PFOS that has been made in this project. The findings are discussed further below the table.

Table 3.154 Summary of key findings for exposure of PFOS via use of compost and digestates

Key findings of the risk assessment of PFOS in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<2E-03 - ≤0.165 mg/kg dry wt..
Major raw material sources	PFOA/PFOS measured above ca 0.01 mg/kg in compost and digestate from source separation, bio-waste & green waste compost, green waste compost, sewage sludge compost, "mechanical biological treatment compost", bio-waste & green waste manure energy crops digestate, "mechanical biological treatment digestate".
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of a POP; Humans exposed via the environment (especially via diet and drinking water); possible transfer over long distances. Highest reported concentrations are limit values, but could exceed the guidance level of 100 µg/kg dry wt.. Local and regional PECs exceed the annual average EQS.
Effects considered in the main concern hazard(s)	POP; human TDI based on mammalian liver toxicity; Basis of the EQS is not stated in the Directive but is understood to relate to accumulation in fish.
Uncertainties and their implications	Almost all stated values are less-than limit values. Sensitivity of exposures to variations in water management in the local container growing scenario is low.
Other remarks	

As a POP, it is in itself a potentially important finding that PFOS has been detected in freshly-produced composts and digestates at several different locations in recent years. The raw material waste streams could be investigated further. The highest among the reported concentrations in composts and digestates exceed the national limit values according to the data collected in this project.

While risk characterisation has not been quantified, it is noted that the predicted exposures of humans in the form of local total daily intake associated with both types of use could exceed the safe limit (TDI) based on the values derived by EFSA (2008) and Danish EPA (2015).

The estimated regional-scale predicted environmental concentrations in surface water, ground water and agricultural soil arising from the application of C/D appear to be low compared to the measured background concentrations quoted by EA (2004).

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

At steady state, 5% of the total mass remains within the region + continent[66], suggesting that there is high potential for transfer over long distances following release via the handling and application of C/D[67]. The majority of the substance is modelled to be present in global tropic waters (54%) at steady state followed by moderate waters (25%) and arctic waters (16%). The total mass in the region + continent at steady state is 28 t in the baseline scenario. This steady-state mass amounts to 25 times the mass released annually via application of composts and digestates[68].

3.23 PFHxA (representative of PFAs chemical family)

Background information and remarks

Undecafluorohexanoic acid / ammonium undecafluorohexanoate have at the time of writing very recently been proposed for listing as SVHC on the basis of equivalent concern for the environment and human health based on numerous justifying factors.

Chemical properties and hazards data set

The relevant property data summarised in Table 3.155 below (taken from ECHA, 2018). Where information from other sources is included this is indicated in the Table.

Table 3.155 Property information for PFHxA (from ECHA, 2018 unless otherwise indicated)

Property	Value	Comment
Molecular weight	314.05 g/mol	
Melting point	12-14 °C	Huang, Bing Nan, 1987
Boiling point	157 °C	Savu PM (Kirk Othmer)
Vapour pressure	263.93 Pa	Estimated value (EPIWIN)
Water solubility	15.7 g/l (ambient temperature)	Zhao et al, 2014
log Kow	4.06	Estimated value (COSMOtherm)
Henry's law constant	5.279 Pa * m^3/mol	Derived from VP and WS
Koc	log Koc = 3.0	Vierke, 2014
BCF	A comparative analysis of a homologues series of C7-C14 PFCAs and lipophilic organohalogens in an Arctic Marine Food Web by Kelly et al. ((Kelly et	

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[66] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[67] The possibility or not for transfer over long distance is largely an inherent property of the substances themselves, but it is interesting if this is expressed even when the pathway into the environment is so dominated by incorporation into soil.

[68] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

Property	Value	Comment
	al., 2009) shows an efficient respiratory elimination in water-respiring organisms due to high water throughput and high water solubility of PFCAs but very slow elimination and biomagnification in air-breathing animals of PFCAs.	
Biodegradability	Extremely persistent in all environmental compartments.	
Half-life in air	Photolytic degradation half life of 20.57 days.	
PNECs	As a proposed SVHC and proposed POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.	
DNEL	As a proposed SVHC and POP, the reliability of any threshold no-effect value is highly uncertain. Risk characterisation has not been attempted here.	
Other relevant data		

Note: a) PFHx is the conjugate base of PFHxA. The dissociation constant given in UNEP (2016) is 1.5-2.8 with another value given as <1.6. Under most environmental conditions UNEP (2016) indicates that the substance will be present as the PFHx anion.

PFHxA has been proposed as a SVHC substance under the REACH Regulation on the basis of a large number of equivalent concern factors.

Occurrence data set

Concentrations of PFHxA as such were not found in the data gathering phase of the project, however A summary of the reported concentrations of PFOS, PFOA, PFNA, or PFT (PFOA+PFOS), in composts and digestates is presented in Table 3.156. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.156 Reported occurrence of PFHxA in composts and digestates

Concentrations in composts/digestates	Value - units of mg/kg dry wt.	Remarks
Composts - data availability		Both the highest and lowest reported values are for perfluorinated surfactants (not differentiating specific substances). The majority of values are cited by Saveyn and Eder and refer to composts and digestates prepared by different treatment methods.
Compost - minimum concentration	0.0018	Many values are less-than limit values. The value used is the lower range of one of the few reported quantitative values available.

Compost - mid-range or average concentration	0.025	Many values are less-than limit values. The value used is the upper range of one of the few reported quantitative values available.
Compost - maximum concentration	0.165	≤ 165 µg/kg d.m. (note - actually a less-than limit value) is the highest mentioned limit value and is for a sewage sludge compost. There are regulatory limit or guide values of 0.1 mg/kg in all cases for: Austria, Germany, Denmark (Österreichische Düngemittelverordnung, Deutsche Düngemittelverordnung, Slambekendtgørelsen).
Digestates - data availability		Very few digestate specific concentrations are reported. Almost all of the reported concentration values are less-than limit values. The larger data set for composts has been taken into account.
Digestate - minimum concentration	0.0018	Many values are less-than limit values. The value used is the lower range of one of the few reported quantitative values available.
Digestate - mid-range or average concentration	0.025	Many values are less-than limit values. The value used is the upper range of one of the few reported quantitative values available.
Digestate - maximum concentration	0.045	≤ 45 µg/kg d.m. (note - actually a less-than limit value) is the highest mentioned limit value and is for a bio-waste & green waste manure energy crops digestate.

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.157 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (kg/year)	221
Mass of substance in EU-28 in digestate (kg/year)	882
Total regional emission to surface water (kg/day)	0.0085
Total regional emission to soil (kg/day)	0.29
Total continental emission to surface water (kg/day)	0.076
Total continental emission to agricultural soil (kg/day)	2.6

Table 3.158 Reported background concentrations of PFHxA in the environment (as cited in ECHA, 2018)

PECregional	Value	Remarks
Air		
Surface water	<0.63 – 31.4 ng/l in European freshwaters	

Sediment	<50 – 1600 pg/kg in European sediments
Agricultural soil / Natural soil / Urban/industrial soil	0.00043 - 2761 µg/kg dry wt.t in European soils
Soil pore water/ground water	
Other relevant data	

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of PFHxA resulting from the use scenarios defined in Section 1 , using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.159 below.

Table 3.159 Predicted exposures for PFHxA arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	2.13E-03	[mg/kg dry wt.]
PECgrassland soil	6.61E-04	[mg/kg dry wt.]
PEC in groundwater	1.04E-04	[mg/l]
PECfreshwater	6.64E-07	[mg/l]
PECfreshwater-sediment	6.88E-05	[mg/kg dry wt.]
Humans via the environment: local total daily intake	6.24E-05	[mg.kg-1.d-1]
Humans via the environment: daily dose via drinking water	2.98E-06	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root crops 95.1%	
Secondary poisoning – freshwater fish-eating birds and mammals	4.16E-06	[mg/kg wet wt.]
Secondary poisoning – worm-eating birds and mammals	7.11E-03	[mg.kg-1]

	Scenario II	Units
PECagricultural soil	0.0545	[mg/kg dry wt.]
Humans via the environment: local total daily intake	1.54E-03	[mg.kg-1.d-1]
Humans via the environment: dominant exposure source and fraction	Root crops 99.9%	
Secondary poisoning – worm-eating birds and mammals	0.171	[mg.kg-1]

Table 3.160 presents the predicted steady state mass balance in the region and continent. Please note that the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the C/D use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state balance.

Table 3.160 Predicted background exposures for PFHxA at steady state arising from use of composts and digestates

	Steady state mass	Units
Total steady-state mass (region + continent)	1.25E+01	[t]
Steady-state mass in regional freshwater (kg)	1.35	[kg]
Steady-state mass in regional seawater (kg)	0.138	[kg]
Steady-state mass in regional air (kg)	0.182	[kg]
Steady-state mass in regional agricultural soil (kg)	1.21E+03	[kg]
Steady-state mass in regional natural soil (kg)	0.114	[kg]
Steady-state mass in regional industrial soil (kg)	0.042	[kg]
Steady-state mass in regional freshwater sediment (kg)	0.496	[kg]
Steady-state mass in regional seawater sediment (kg)	0.0128	[kg]
Steady-state mass in continental freshwater (kg)	15.4	[kg]
Steady-state mass in continental seawater (kg)	396	[kg]
Steady-state mass in continental air (kg)	10.9	[kg]
Steady-state mass in continental agricultural soil (kg)	1.09E+04	[kg]
Steady-state mass in continental natural soil (kg)	3.43	[kg]
Steady-state mass in continental industrial soil (kg)	1.27	[kg]
Steady-state mass in continental freshwater sediment (kg)	5.64	[kg]
Steady-state mass in continental seawater sediment (kg)	1.84	[kg]

	Steady state mass fraction	Units
Total steady-state mass fraction (region + continent)	31.7	[%]
Steady-state mass fraction in regional freshwater (%)	3.43E-03	[%]

Steady-state mass fraction in regional seawater (%)	3.49E-04	[%]
Steady-state mass fraction in regional air (%)	4.60E-04	[%]
Steady-state mass fraction in regional agricultural soil (%)	3.05	[%]
Steady-state mass fraction in regional natural soil (%)	2.87E-04	[%]
Steady-state mass fraction in regional industrial soil (%)	1.06E-04	[%]
Steady-state mass fraction in regional freshwater sediment (%)	1.25E-03	[%]
Steady-state mass fraction in regional seawater sediment (%)	3.24E-05	[%]
Steady-state mass in continental freshwater (kg)	0.039	[%]
Steady-state mass in continental seawater (kg)	1	[%]
Steady-state mass in continental air (kg)	0.0275	[%]
Steady-state mass in continental agricultural soil (kg)	27.5	[%]
Steady-state mass in continental natural soil (kg)	8.67E-03	[%]
Steady-state mass in continental industrial soil (kg)	3.21E-03	[%]
Steady-state mass in continental freshwater sediment (kg)	0.0143	[%]
Steady-state mass in continental seawater sediment (kg)	4.66E-03	[%]

Sensitivity to specific variables

In respect of local Scenario II, the sensitivity of the outcomes to possible losses from the system by leaching and drainage of excess water has been explored using a fugacity method. For this substance the proportion of substance in the system distributed to the interstitial water at equilibrium under ‘high water content’ conditions, and hence sensitive to leaching, is 2.7% of the substance present in the system. Hence, the sensitivity of the exposure scenario to such variations in water management is considered to be low.

Summary of findings

Table 3.161 below presents the summary of key findings from the risk assessment of PFHxA that has been made in this project. The findings are discussed further below the table.

Table 3.161 Summary of key findings for exposure of PFHxA via use of compost and digestates

Key findings of the risk assessment of PFHxA in contaminated composts and digestates	
Overall range of compost and digestate concentrations	<2E-03 - ≤0.165 mg/kg dry wt..

Key findings of the risk assessment of PFHxA in contaminated composts and digestates	
Major raw material sources	PFOA/PFOS measured above ca 0.01 mg/kg in compost and digestate from source separation, bio-waste & green waste compost, green waste compost, sewage sludge compost, "mechanical biological treatment compost", bio-waste & green waste manure energy crops digestate, "mechanical biological treatment digestate".
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	Source of exposure of a proposed SVHC; Humans exposed via the environment (especially via diet and drinking water); possible transfer over long distances.
Effects considered in the main concern hazard(s)	Proposed SVHC under the REACH Regulation on the basis of a large number of equivalent concern factors.
Uncertainties and their implications	No data available for PFHxA specifically, and almost all stated values are less-than limit values. Sensitivity of exposures to variations in water management in the local container growing scenario is low. In circumstances where a) the system is watered in excess of the water holding capacity of the growing medium and b) where the container design means that excess water will drain away and not remain in contact with the container/growing medium, then a small proportion of the substance could be lost from the system in the drained water.
Other remarks	

The estimated regional-scale predicted environmental concentrations in surface water, ground water and agricultural soil arising from the application of C/D are close to the range of the literature concentrations presented in the Occurrence data set section based on ECHA (2018).

The highest contributions to human exposure via the environment arising from the application of C/D is mainly associated with dietary consumption of root vegetables.

At steady state, 31.7% of the total mass remains within the region + continent[69], suggesting that there is some potential for transfer over long distances following release via the handling and application of C/D. A significant proportion of the substance is modelled to be present in global tropic waters (29%) at steady state. The total mass in the region + continent at steady state is 12.5 t in the baseline scenario. This steady-state mass amounts to 11 times the mass released annually via application of composts and digestates[70].

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[69] This refers to the regional and continental spatial scales in the EUSES model. Refer to Section 1.7 and the Annex for further information.

[70] Please note this is not to be interpreted as how much time elapses to reach steady state; the steady state predicted by the model are the amounts and distribution at the regional and continental scale arising from the compost and digestate use application pathway only. Adding in the release of the same substances via other pathways (air and waste water) could lead to a different steady state picture.

3.24 Microplastics

Background information and remarks

Microplastics are of concern and a specific restriction may be proposed in future. The European Commission (2017) has made an assessment of environmental exposure and risks arising from microplastics and the approach taken in the present assessment is intended to be fully consistent with that work. In addition to issues of microplastic toxicity, the presence of physical impurities including plastics and other particulates and small objects can cause issues in respect of clogging or damage of spreading equipment; quality of produce is affected by assimilation of particles.

Fugacity modelling, food chain uptake and risk characterisation are not amenable to conventional assessment. A key uncertainty is around accumulation and food chain exposure. The values derived by EUSES may be misleading. The previous Commission study uses a qualitative assessment approach, and a similar approach is used here.

Chemical properties and hazards data set

A limited exposure assessment has been made using EUSES based on generic characteristics and using particle count in place of concentration. Generic chemical property characteristics are applied to define the physicochemical and environmental fate descriptors used by the models. Table 3.162 summarises the values used which are based on the previous assessment (EC, 2017). In line with the preceding assessment, different polymer types do not require separate assessment; the particle size range is acceptable to assess as a group. Furthermore, no attempt has been made to model exposure of hazardous contaminants present within (or absorbed to) plastic microparticles.

Table 3.162 Property information for microplastics

Property	Value	Remarks
Molecular weight	10000 g/mol	These properties essentially assume that the microplastics will behave as non-soluble, non-volatile and non-degradable substances that will associate with the solid phase within the waste water treatment plant.
Melting point	150°C	
Boiling point	>500°C	
Vapour pressure	1E-10 Pa at 25°C	
Water solubility	1E-10 mg/l at 25°C	
log Kow	15	
Henry's law constant	1E-10 Pa.m3/mol at 25C	
Koc	>1E+8	
BCF	BCF 0.036 l/fish and up to 1 g/l fish in standard OECD 305 tests. This would suggest a result of 36 l/kg wet wt. (although not explicitly derived in commission report); human exposure would	

Property	Value	Remarks
	be predominantly via consumption of shellfish	
Biodegradability	Not biodegradable	In the EC (2017) assessment approach, a removal fraction of 0.025 d-1 for surface water and 2.74×10-4 d-1 for sediment were assumed (based on the residence times of these compartments)
Half-life in air	Not defined	

Occurrence data set

Table 3.163 presents a summary of the reported concentrations of microplastics in composts and digestates. This is based on the survey of the available literature collected in Task 2 of the project and reported in the main project report.

Table 3.163 Reported occurrence of microplastic particles (MPP) in composts and digestates

Concentrations in composts/digestates	Value - units of particles/kg dry wt.	Remarks
Composts - data availability		30 separate records of which 18 are based on particle count rather than w/w and are for different specific polymer types in compost from the same site and 10 others are ranges rather than individual values. The values in terms of total MPP/kg dry wt. are relatively consistent.
Compost - minimum concentration	20	
Compost - mid-range or average concentration	38	An average of the values available
Compost - maximum concentration	70	
Digestates - data availability		23 separate records of which 20 are based on particle count rather than w/w and are for different specific polymer types in compost from the same site and the other 3 are ranges rather than individual values.
Digestate - minimum concentration	14	
Digestate - mid-range or average concentration	94	An average of the values available
Digestate - maximum concentration	146	

These concentrations in compost and in digestate equate to the following release amounts at the regional and continental scale.

Table 3.164 Estimated regional and continental release amounts

Parameter	Value
Mass of substance in EU-28 in compost (particles/year)	335,160

Mass of substance in EU-28 in digestate (particles/year)	3,316,320
Total regional emission to surface water (particles/day)	28
Total regional emission to soil (particles/day)	762
Total continental emission to surface water (particles/day)	252
Total continental emission to agricultural soil (particles/day)	8752

These values have been applied in estimating the exposure concentrations for microplastics arising from use of composts and digestates. Exposures have been estimated for two concentration scenarios:

- A more conservative assessment is derived using the maximum reported concentrations in estimating the local releases from the two scenarios, with a mid-range concentration used in estimating the regional background.
- A less conservative assessment is derived separately using the mid-range reported concentrations in estimating the local releases from the two scenarios, with a minimum concentration used in estimating the regional background.

Table 3.165 below summarises background exposure data previously presented by the European Commission (2017).

Table 3.165 Reported background concentrations of microplastics in the environment

PECregional	Value	Remarks
Air		
Surface water	0.774-1.3 particles/l (modelled regional PECs)	Only marine water results were found in the literature search, which has not been repeated.
Sediment	0.6 to 50.1 microplastics per gram of dry river sediment (measured)	Particle size range 55 - 115 µm; Scheldt river (Belgium; citing Van Cauwenberghe, 2015.).
Agricultural soil	15000-20000 particles/kg dry wt. (modelled regional PECs)	
Soil pore water/ground water		
Natural soil	9500-10300 particles/kg dry wt. (modelled regional PECs)	At the time no soil values were found in the literature search, which has not been repeated.
Urban/industrial soil		
Other relevant data		General remark: Numerous concentration data reported in EC(2017) (pages 57-59) but almost all are marine.

Generic exposure scenario outcomes

The assessment has estimated local and background exposures of microplastic particles resulting from the use scenarios defined in Section 1, using the chemical property data and concentration in composts and digestates in the previous sections as inputs. The predicted environmental exposure concentrations are as summarised in Table 3.166 below.

Table 3.166 Predicted exposures for microplastics arising from use of composts and digestates

	Scenario I	Units
PECagricultural soil	3.00E+00	[particles/kg dry wt.]
PECgrassland soil	1.54E+00	[particles/kg dry wt.]
PEC in groundwater	8.43E-11	[particles/l]
PECfreshwater	4.74E-10	[particles/l]
PECfreshwater-sediment	8.44E+01	[particles/kg dry wt.]

	Scenario II	Units
PECagricultural soil	2.37E+01	[particles/kg dry wt.]

Summary of findings

Table 3.167 below presents the summary of key findings from the risk assessment of microplastics that has been made in this project. The findings are discussed further below the table.

In considering these findings readers should note that EUSES is not designed to model distribution of particulates which severely restricts the use in this project. Findings are indicative only.

Table 3.167 Summary of key findings for exposure of microplastics via use of compost and digestates

Key findings of the risk assessment of microplastics in contaminated composts and digestates	
Overall range of compost and digestate concentrations	14 – 146 particles/kg dry wt.
Major raw material sources	All reported data relate to composts and digestates prepared from household biowaste combined with green clippings and some energy crops.
Safe limit concentration in compost and digestate	Not applicable (risk characterisation ratio not definable).
Main concern(s) arising	A potentially important source of microplastic exposure of the environment via wastewater treatment plant sludge (with possible consequent human exposure to microplastics via the environment)
Effects considered in the main concern hazard(s)	No quantitative assessment of hazard was applied in this assessment.
Uncertainties and their implications	Quantitative exposure of humans and predators via the food chain cannot be reliably modelled using the present methods. Steady state exposures are not reliable and not presented. Wastewater treatment digestate could potentially contain higher concentrations of particles; data were not found in this project. Sensitivity of exposures to variations in water management in the local container growing scenario can not be modelled.

Key findings of the risk assessment of microplastics in contaminated composts and digestates	
Other remarks	Other sources of microplastics release appear to be much higher than exposure via composts and digestates, although use of digestate obtained from sewage sludge could be an important source of microplastics for the soil.

The exposures of soil and sediment arising from the application of C/D estimated in the present model are very low compared with the PECs modelled in the recent risk assessment of exposures arising from a range of industrial and consumer uses (EC, 2017). However the assessment does not cover the possible release of microfibres released by washing of textiles. While exposure of man via the environment arising from the use of compost and digestate is not important compared to other sources, the occurrence data used in this assessment is largely based on household biowaste-derived products rather than WWTP digestates. ECHA[71] (2018) reports that sewage sludge could be an important source of emissions of microplastics to the soil.

Exposure of humans via root and leaf crops in the diet is possible, however (similarly to the EC 2017 exposure assessment), the washing of vegetables and peeling of root vegetables would be expected to limit levels of human consumption.

Cattle could ingest contaminated soil adhering to the grass, and therefore the exposure of cattle is related to the concentration in soil, however (in line with EC, 2017) the assessment assumes that this remains within gut contents and passes through the cattle without entering into meat or milk. This indicates that human exposure via these foodstuffs is negligible.

The occurrence data found in this project suggest use of composts and digestates contributes an overall total release of 3650 billion microplastic particles per year in the region plus continent, however it is not feasible using EUSES to model the multimedia fate, distribution and flux of particles following release.

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[71] ECHA press release, Intentionally added microplastics likely to accumulate in terrestrial and freshwater environments, ECHA/PR/18/15, 22 November 2018.

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4. Annex: Supporting information on approach to scenario modelling in EUSES

4.1 EUSES parameters relating to biosolid spreading

Predicted environmental concentrations in soil rely on numerous inputs. The key inputs used for the modelling and risk assessment are outlined in the ECHA risk assessment framework defined in ECHA guidance (2016).

The normal parameters or operation of the following have been applied as defined in ECHA (2016) with no adaptation.

- Characteristics of the receiving compartments (soils, receiving water) including organic matter content.
- Assumptions concerning soil rain water infiltration, soil erosion rates, or temperature.
- Models which calculate leaching and accumulation in drinking water, bioaccumulation in soil-dwelling organisms or their food chains, animal grazing and feedstuffs, human foodstuffs and air.
- The predicted environmental concentration (PEC) is calculated based on one (1) application of the compost / digestate matrix annually and this is not easily accessible to modify within EUSES, although other tools can be applied if modification is necessary (e.g. the ECPA LET model[72]).
- Characteristics of the applied product – organic carbon (OC) content. This parameter is available for adaptation by the user; however testing demonstrates this does not significantly affect the PECsoil.
- Application rate (kg/ha) of the applied product.
- Mixing depth of the target matrix is accessible to modify for grassland; although not for agricultural soil. The mixing depth of agricultural soil is set by default to 20 cm in EUSES.

Table 4.1 presents a comparison of the main parameters for soil within EUSES, including data for C/Ds where available.

Not all of these parameters are significant variables in the calculation of PECs. They are discussed here because they offer useful context and validation of consistency with the default EUSES scenarios and methods. Please refer to the further discussion in Sections 4.2 and 4.3.

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[72] Local Environmental Tool: http://www.ecpa.eu/pre-market-resources-for-industry/reach-registration-evaluation-authorisation-and-restriction-chemicals. This model is broadly in line with the ECHA (2016) approach but allows more than one application per year to be considered. The model does not, however, consider exposure of humans via the food chain.

Table 4.1 Main modelling parameters used in the EUSES model, and the available data for compost and digestate

Parameter	EUSES baseline scenario (STP sludge applied to agricultural soil)	EUSES baseline scenario (STP sludge applied to grassland soil)	Whole digestate	Liquid digestate (liquor)	Compost
General context of use	Fertiliser (commercial agriculture)	Fertiliser (commercial grazing)	Fertiliser (agriculture and grazing)	Liquid fertiliser	Fertiliser (agriculture and grazing); horticulture and hobby gardening; component of growing media
Product composition					
- **Dry matter content**			The dry matter content of a crude digestate may vary between ca. 2% to more than 20% depending on the source (DEFRA, 2010)	Five digestate types had a dry matter content of 1.9 – 4.56% in the separated liquor (WRAP, 2011b)	The dry matter content is reported as 60% of fresh weight (WRAP, 2016)
- **Organic carbon content**	0.30 kg/kg (primary settled sludge) 0.37 kg/kg (activated sludge and effluent sludge)	0.30 kg/kg (primary settled sludge) 0.37 kg/kg (activated sludge and effluent sludge)	The organic matter content of the dry matter in the fibre was 81.7% OM (WRAP, 2011b), equivalent to approximately 0.48 kg/kg[73]	The organic matter content of the dry matter of the liquor was 69.6% OM (WRAP, 2011b), equivalent to approximately 0.41 kg/kg.	38.2% OC as dry matter, equivalent to 0.38 kg/kg
- **Water content**			ca. 70 – 96% (DEFRA, 2010, WRAP 2016)	ca. 25 – 98% (DEFRA, 2010)	Ca. 40% (WRAP, 2016)
- **Bulk Density**	1500 kg/dry weight/m^3 (suspended and settled sludge in primary settler) 1300 kg dry weight/m^3 (suspended and settled sludge in solids/liquid separator)	1500 kg/dry weight/m^3 (suspended and settled sludge in primary settler) 1300 kg dry weight/m^3 (suspended and settled sludge in solids/liquid separator)			

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[73] A conversion factor of approximately 59% organic carbon present in organic matter is taken from ECHA Guidance part R16 (2016).

Parameter	EUSES baseline scenario (STP sludge applied to agricultural soil)	EUSES baseline scenario (STP sludge applied to grassland soil)	Whole digestate	Liquid digestate (liquor)	Compost
Application and mixing					
- **Rate (single application)** - ***note: 1 hectare (ha) = 10,000 m2***	0.5 kg/m^2 dry weight	0.1 kg/m^2 dry weight	5 kg/m^2 wet weight 34 m^3/ha for a food waste-derived digestate; 57 m^3/ha for a manure-derived digestate[74] (WRAP, 2011a)	30 m^3/ha (DEFRA 2010)	
- **Quantity per year** - ***note: 1 hectare (ha) = 10,000 m2***	5000 kg/ha/year dry weight	1000 kg/ha/year dry weight	Variable dependent on crop-available nitrogen content of product (and other mineral nutrients)	Variable dependent on crop-available nitrogen content of product (and other mineral nutrients)	Variable dependent on crop-available nitrogen content of product (and other mineral nutrients) 3000 (pasture); 15000 (arable) kg/ha/year dry weight (maximum indicated by existing restrictions (Saveyn and Eder (2014)
- **Application method**	Spreading as either wet or dried sludge	Spreading as either wet or dried sludge	Whole slurry or separated dry fibre; applied via a range of spreader equipment; there can be issues of odour nuisance hence broadcast spreading is not recommended (WRAP 2011b).	Injection, trailing hose or trailing shoe (WRAP, 2016) Limited evidence for irrigator spray application (only possible very-low-solid separated liquor products) (WRAP 2011a)	
- **Product homogeneity**	At the local scale, assumed to be an even application at the concentration calculated.	At the local scale, assumed to be an even application at the concentration calculated			
- **Mixing depth**	0.2 m	0.1 m	0.1 m assumed in WRAP (2017) assessment of risk from		

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[74] it is noted that cattle manure slurries have considerably lower nitrogen (and particularly readily available nitrogen) than other forms of digestate, and so could require higher application rates to achieve the equivalent delivery of this key fertilising element.

Parameter	EUSES baseline scenario (STP sludge applied to agricultural soil)	EUSES baseline scenario (STP sludge applied to grassland soil)	Whole digestate	Liquid digestate (liquor)	Compost
			microbiological infectious agents		
- **Frequency**	1/y	1/y			

4.2 Establishing the sensitivity context: Application rates

In whatever form it is applied to the soil, the application rate in terms of the loading rate of the toxic substance is a key variable in the exposure calculations. The application rate of the substance is derived from the amount of compost or digestate containing the substance that is applied to soil and the concentration of the substance within the compost or digestate.

The EUSES model calculates the concentration in both agricultural soil and grassland at the local level. The calculations assume that there is one application of sludge per year for ten consecutive years, and the concentration calculated is estimated as an average over 30 or 180 days (agricultural soil) or 180 days (grassland) following the last application. The calculation takes into account removal processes (such as biodegradation and volatilisation) and also leaching into groundwater. The 30-day average in agricultural soil is used for the assessment of exposure of soil-dwelling organisms and humans via the environment for root crops and leaf crops, whereas the 180-day average in agricultural soil is used to assess the indirect exposure of humans via the environment through consumption of meat and milk[75]. The assessment of secondary poisoning of predators via earthworms in the food chain is assessed based on the 180-day average concentration in agricultural soil[76].

For substances that are lost from soil only slowly, the 30-day and 180-day average values are generally very similar.

It is important to note that the EUSES model also includes atmospheric inputs of pollutants into soil. For the current project such inputs have been ignored as the focus is on the concentration resulting from application of digestate or sludge. Thus, the atmospheric releases of the substance have been set to zero.

Figure 4.1 overleaf illustrates the results of an illustrative model for soil, for a hypothetical substance with the following properties. A similar linear relationship would apply for any substance, when only the concentration in sludge is being varied.

Molecular weight	250 g/mole
Vapour pressure	10 Pa at 25°C
Water solubility	100 mg/l at 25°C
Log K_{ow}	4
Biodegradability	Not biodegradable

These show that the concentrations predicted in soil are linear and proportional to the concentration in sludge. A similar trend is also evident in the predicted groundwater concentration. As these concentrations are used within EUSES as the starting point of calculation for other protection targets, such as secondary poisoning and exposure of humans via the environment, it would be expected that the predicted concentrations for these would also increase linearly as the concentration in sludge increases.

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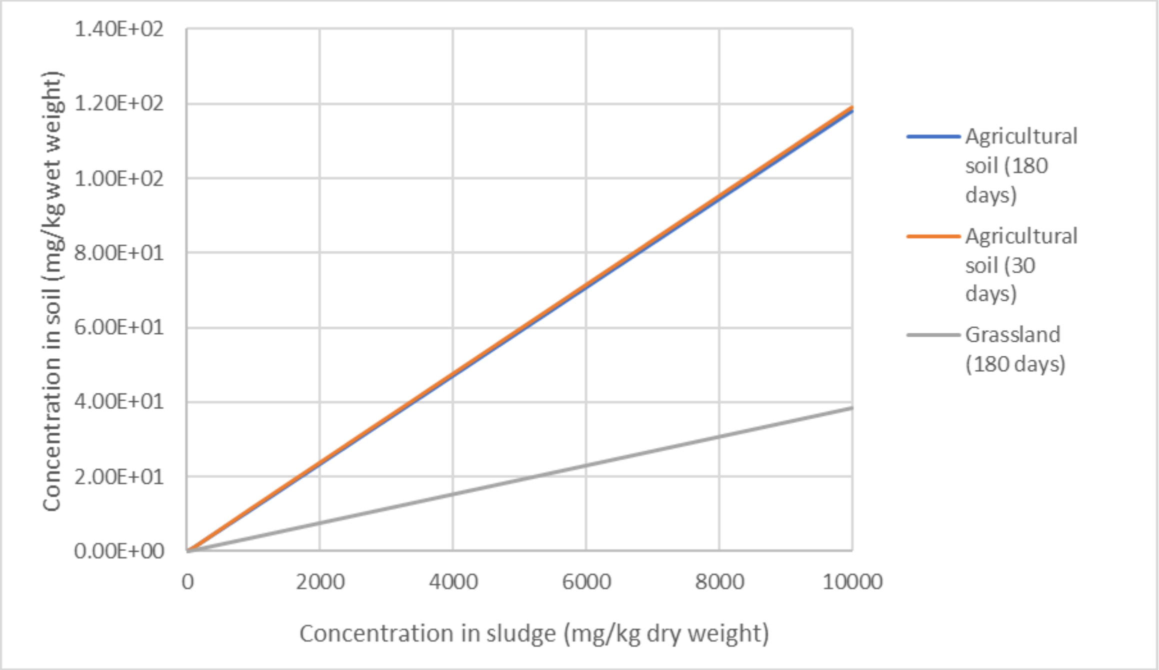
[75] The calculation is based on cattle grazing on the grassland.

[76] The secondary poisoning calculation in EUSES assumes that 50% of the exposure comes from local sources and 50% of the exposure comes from regional sources in order to take into account that predators feeding on earthworms may feed over a relatively wide area.

Figure 4.1 Trends in the predicted concentration in soil and groundwater with increasing concentration in sludge



Note: the two lines for agricultural soil predicted concentrations are almost directly overlaid.

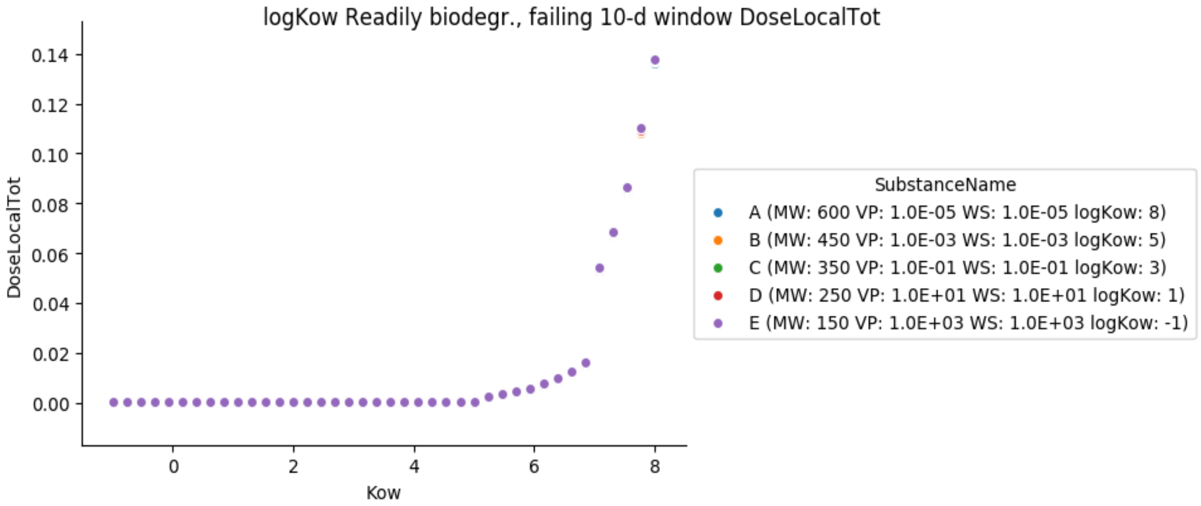
4.3 Establishing the sensitivity context: chemical properties

Following on from the analysis carried out in Section 4.2, a more detailed investigation of different input parameters (including assumed sludge concentration and sludge application rate) on the concentrations predicted by EUSES has been undertaken using a set of hypothetical substances with different chemical properties. This type of modelling is useful for identifying the sensitivity of the methodology to the various assumptions made and how this may vary from substance to substance within the ranges of chemical properties investigated.

Effect of properties of the assessed chemical

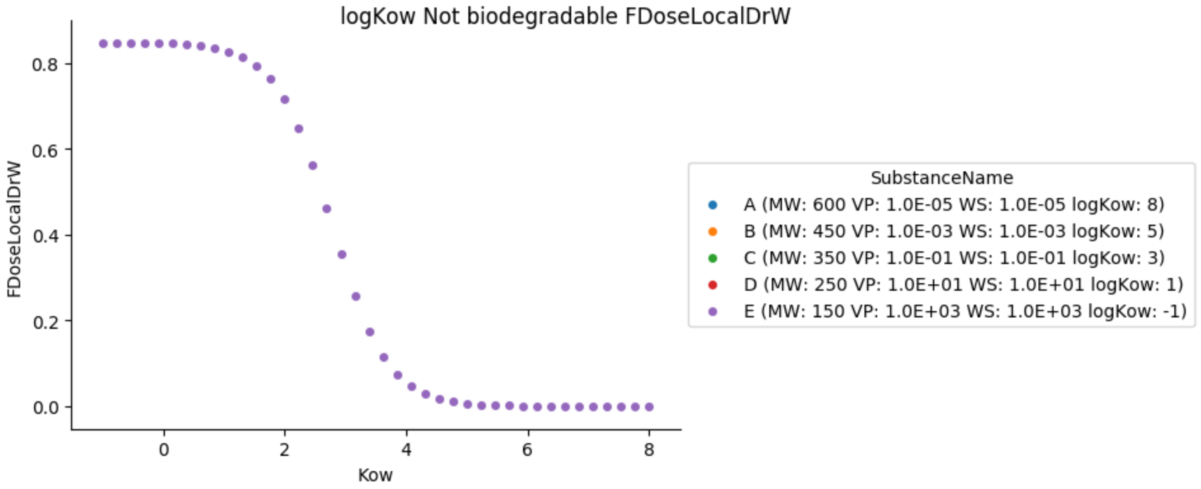
The following figures illustrate how variation in specific chemical properties can influence the exposure of target organisms or populations of interest in this project. These simply reflect how the EUSES algorithms work, and are presented for illustration only.

Figure 4.2 Effect of varying log Kow on human local total daily intake



Note: the markers representing the different combinations of physicochemical properties cannot be seen on this graph due to being directly overlaid.

Figure 4.3 Effect of varying log Kow on fraction of human local total daily intake derived from drinking water



Note: the markers representing the different combinations of physicochemical properties cannot be seen on this graph due to being directly overlaid.

Figure 4.4 Effect of varying water solubility on concentration in drinking water

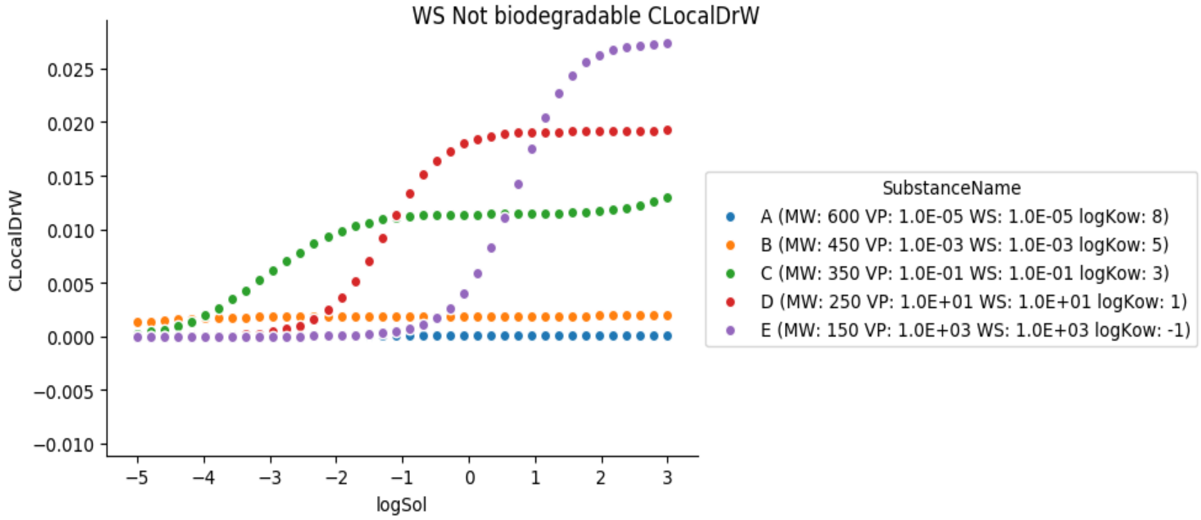
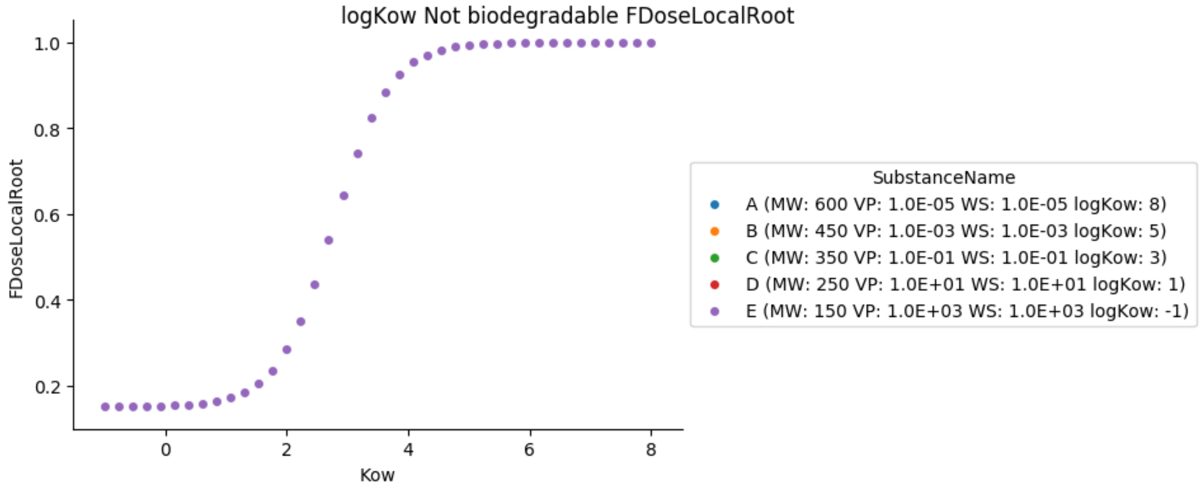


Figure 4.5 Effect of varying log Kow on fraction of human local total daily intake derived from consumption of root crops



Note: the markers representing the different combinations of physicochemical properties cannot be seen on this graph due to being directly overlaid.

Figure 4.6 Effect of varying water solubility on predicted concentration in agricultural soil

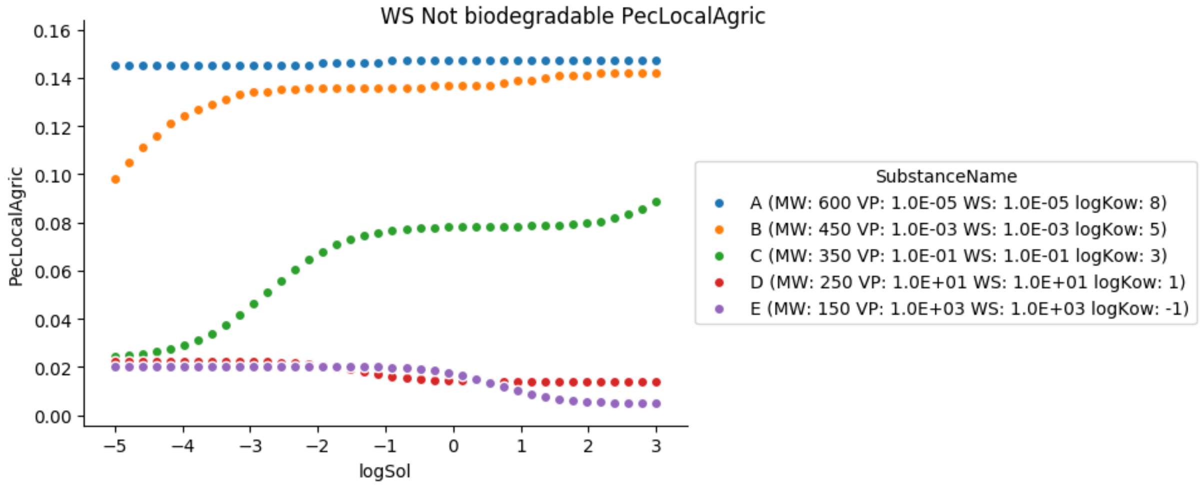


Figure 4.7 Effect of varying log Kow on predicted concentration in agricultural soil

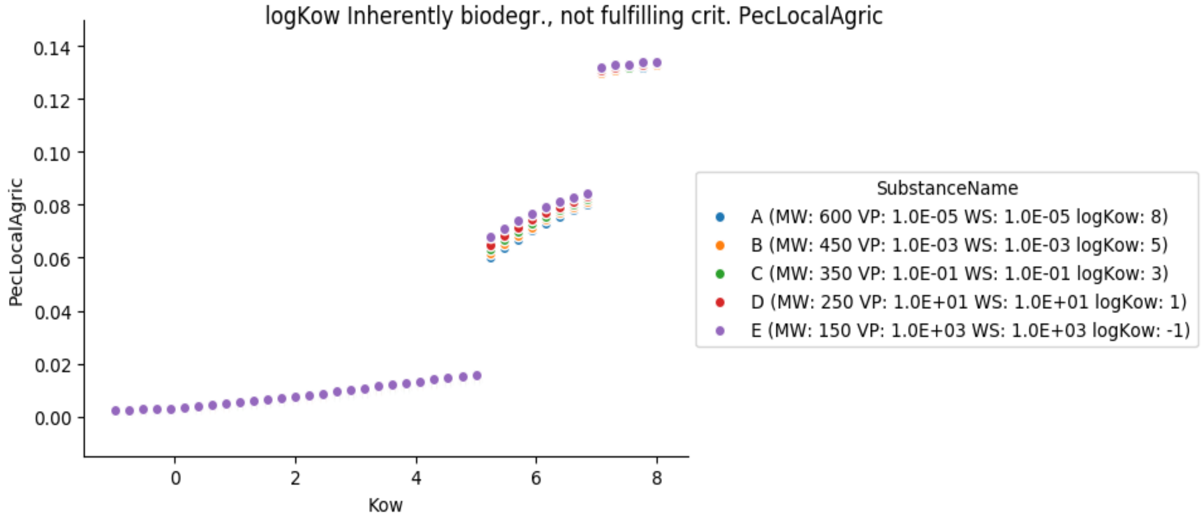
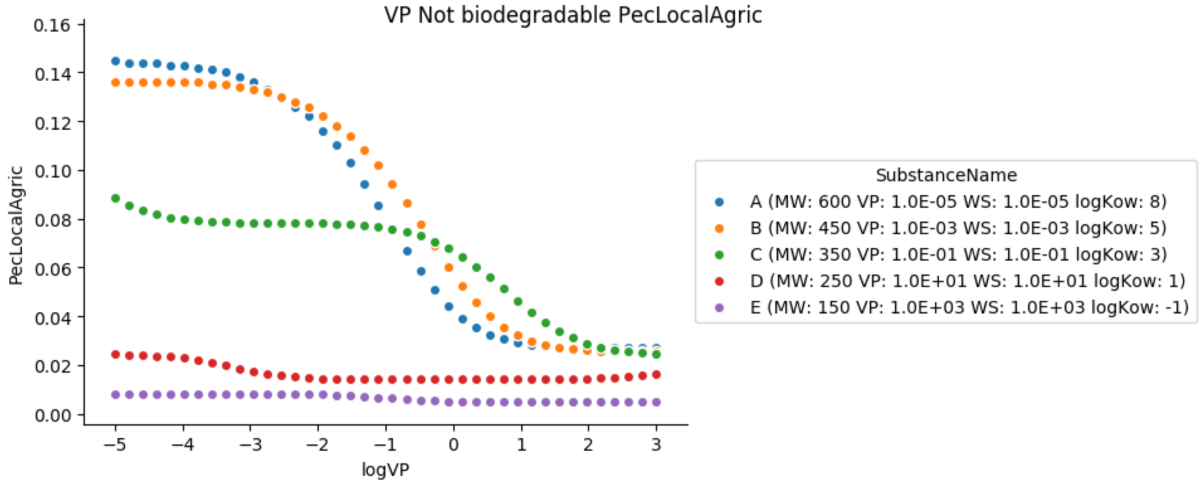


Figure 4.8 Effect of varying vapour pressure on predicted concentration in agricultural soil

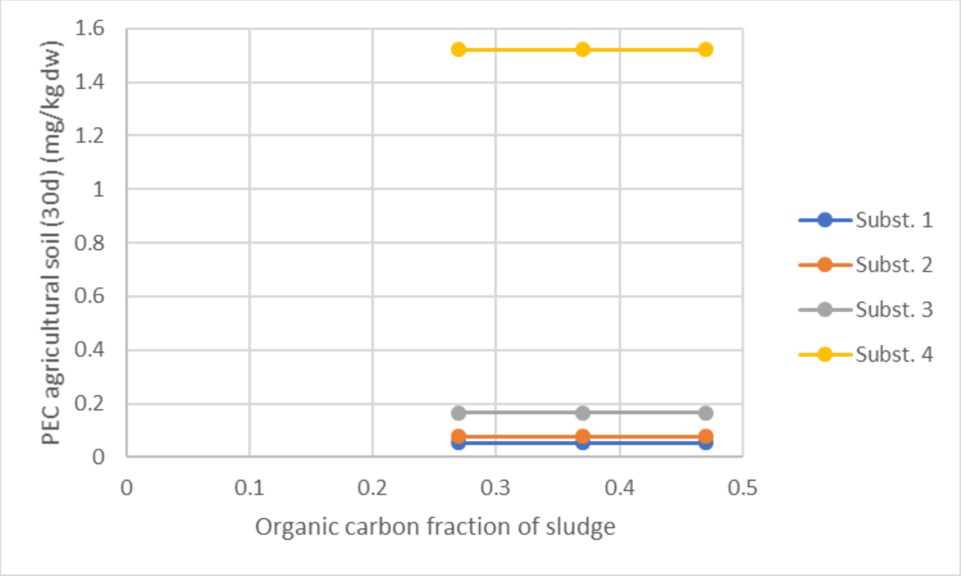


Effect of assumed sludge properties on the predicted concentration in soil

As part of the assessment, the effect of varying different characteristics of sludge (as a proxy for compost or digestate) in the EUSES model is illustrated and discussed in this section.

The effect of **organic carbon fraction** in sewage sludge on the predicted concentration in agricultural soil was investigated for four hypothetical chemicals with different physicochemical and degradability properties. In each run the concentration of the substance in dry sludge was kept constant but the organic content fraction of the sewage sludge was varied within the range 0.27 to 0.47 (based on the EUSES default of 0.37 ± 0.1). The results of this analysis are summarised in Figure 4.9.

Figure 4.9 Effect of assumed organic carbon content of sludge on the predicted concentration in agricultural soil (averaged over 30 days) for a series of hypothetical chemicals



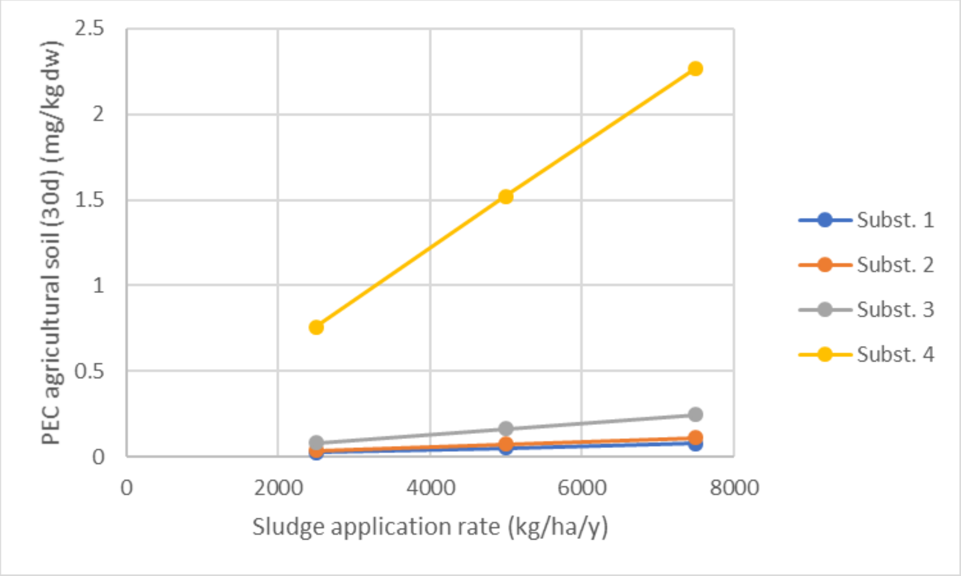
The results show that the predicted concentration in agricultural soil is **not dependent** upon the assumed organic carbon content of the sewage sludge over the range of chemical properties studied. The reason for this is that, within the EUSES model (and the ECHA (2016) risk assessment approach) the organic carbon content of the sewage sludge is only used to estimate the partitioning behaviour/removal of a substance in the sewage treatment plant. This is not needed for the current project as the assessment is based on the known concentration in the digestate or compost which is directly applied to soil. This means that in the assessments made in this project, any differences in organic carbon contents between different digestates does not require further investigation or adjustments and can effectively be ignored.

It is possible that application to soil of different digestates with high organic carbon contents may increase the organic carbon content of the soil. However, the approach outlined in ECHA (2016) assumes a standard organic carbon content of 2% for agricultural soil (including those to which sewage sludge is applied) and this standard organic carbon content in the risk assessment methodology is used in this project.

The modelling results also show that the concentration in soil is dependent upon the chemical properties. This is because, once applied to the soil, the substance partitions between the various phases of the soil (water, solids and air) based on its physicochemical properties and undergoes removal processes such as biodegradation; these are different for different substances.

The effect of the assumed **sludge application rate** on the predicted concentration in agricultural soil was investigated for the same four hypothetical chemicals. In this case the concentration of the substance in sludge was kept constant but the sludge application rate was varied within the range 2,500 to 7,500 kg/ha/year (based on the EUSES default of 5,000 kg/ha/year ± 50%). The results of the modelling are illustrated in Figure 4.10. These simulations showed that, across the range of chemical properties investigated, the concentration in agricultural soil increased linearly in proportion to the increasing sludge application rate. This shows the potential importance of application rates of compost and digestate products in the exposure assessment. It should be noted that the assessments presented in Sections 3.2 to 3.24 used default application rates in the absence of specific evidence.

Figure 4.10 Effect of assumed sludge application rate on the predicted concentration in agricultural soil (averaged over 30 days) for a series of hypothetical chemicals



The effect of different **sludge concentrations** on the predicted concentration in agricultural soil, grassland, drinking water (derived from ground water) and the estimated total daily human intake was explored. The purpose of this was to investigate how the human exposure may vary with different chemical properties.

All of the most important concentrations derived in the risk assessment in this project (concentrations in soil, drinking water/groundwater and total human intake) increase linearly with increasing concentration in the sludge for a range of illustrative substance properties, when exposure is via sludge application at the local scale only. The human intake figures for these simulations were dominated by intake through drinking water and through root crops. The proportion of the total intake coming from each of these two sources varied with the substance properties and was predominantly through drinking water for the substances with the lower log Kow values considered (log Kow -1 and 1) and, as the log Kow increased the proportion from drinking water decreased and the proportion from root crops increased such that the human intake was predominantly through root crops for the higher log Kow values considered (log Kow 5 and 8). The variation in sludge concentration had no effect on the proportion of human intake arising from the different routes (root crops and drinking water).

The proportion of local total daily intake from other dietary sources varied to a lesser extent. These EUSES simulations do not consider the possibility of entry into surface water from run-off or overspray (see Annex Section 4.4). These may subsequently lead to exposure of fish and this may also become important for the total human intake for some substances that have a high potential for bioaccumulation.

It is also important to note that these EUSES simulations only consider direct addition of the substance to soil through sludge (as a proxy for digestate and compost) at the local scale, and do not take into account a) the background concentration of the substance that might be present in the soil and b) inputs of the substance into soil other than through sludge (see Annex Section 4.4). Background concentrations could be important in terms of absolute concentrations i.e. to interpret available monitoring data for specific substances, and also to understand the predicted concentrations arising from this exposure method in the wider context of exposure of the European environment to the same substances.

Overall, the results of this modelling indicate that the following are the most important parameters for the estimation of the PECs for the risk assessment:

- Substance properties (log K_{ow}, vapour pressure, water solubility, biodegradability).
- Concentration in compost/digestate.
- Compost/digestate application rate.

4.4 Defining exposure scenarios for quantitative risk assessment

Based on the analysis carried out above, the following exposure scenarios are considered appropriate for assessing the risks of substances present in digestates or compost.

Scenario I: Solid digestates (and compost where it is applied to agricultural land) applied as a soil amendment (soil improver or fertiliser)

Default application rate:	5000 kg/ha to agricultural land 1,000 kg/ha to grassland
Default mixing depth of soil:	20 cm agricultural soil 10 cm grassland

These values can be modified as appropriate based on the specific information available. The application rates and the mixing depth in grassland can be modified easily in EUSES. The mixing depth in agricultural soil cannot be modified directly but a "workaround" for this would be to adjust the application rate so it matches the required depth using the approach outlined below.

$$Adjusted\ application\ rate = \frac{Actual\ application\ rate \times 20}{Depth}$$

where *Depth* = required mixing depth of the soil (cm).
Adjusted application rate = equivalent application rate (kg/ha) for a 20 cm mixing depth to be used in EUSES.
Actual application rate = actual application rate (kg/ha) applied to the soil of the required mixing depth.

It should be noted that the EUSES model does not include processes such as run-off into surface water or input into surface water as a result of soil erosion.

Liquid digestates and spray application

With liquor and slurry products the solids and organic matter content varies; above-ground spraying may or may not be applicable depending on the product and the user. If digestate liquor is sprayed, there is a possibility of overspray into water sources.

It is reasonable to expect that the products available will lie on a spectrum in terms of solids content and composition, but that only the most liquid products will be candidates for spray application due to the equipment requirements (excess solids and fibres could cause a malfunction). The dry matter tolerance for irrigator application of such products is up to 3% (WRAP, 2011a).

For context, reference has been made to approaches applied by models other than EUSES: Parameters associated with the fraction of overspray (spray drift) and the local environment of a field and nearby watercourse have been defined in an existing stand-alone model designed for exposure assessment of co-formulants used in crop protection products in the REACH context. The ECPA Guidance on REACH chemical safety assessment for co-formulants used in crop protection products (ECPA, 2015) contains values for these parameters, which are in turn based on the 'Steps 1-2 in FOCUS' model (FOCUS, 2003).

For overspray, ECPA (2015) gives spray-drift values in the range 0 (for direct incorporation) to 33.2% (for aerial application). The liquid digestates are not likely to be applied in the same way as crop protection products (fine spray) and so the potential for spray-drift for liquid digestates would be expected to be much lower than the crop protection products. Therefore, it is proposed to use a standard maximum value of 2.8% (F = 0.028) for liquid digestates, which is the same as the values given in ECPA (2015) for spray application to bare soil/pre-emergent use, as a realistic worst case.

The ECPA model (2015) covers exposure of watercourses via run-off, erosion and drainage and has been used to calculate the PEClocal for water and sediment. The FOCUS calculations assume a standardised water body scenario with 30 cm water depth overlying sediment of 5 cm depth. The sediment is assumed to have a density of 0.8 g/cm^3 and an organic carbon content of 5%. The water body is assumed to have an area equivalent to one tenth of the field from which it receives run-off or drainage water (a field:water ratio of 10). The ECPA model (2015) allows for greater evaporation from soil than EUSES and therefore predicts much lower PECs for substances with vapour pressure higher than 0.001 Pa.

It is also of interest to consider the area of land being treated per event (per day). In Europe, farm holding sizes vary considerably with just over half (50.7%) of utilised agricultural land being farmed by the largest farms (100 ha or more) in 2010 (Eurostat, 2014). In terms of the number of holdings, the largest size range is 0-2 ha (46.9%) and 69.3% of all holdings are less than 5 ha. ECPA (2015) assumes treatment of a 1 ha field with a 0.1 ha (1000 m^2) water body with a volume of 300,000 litres to model the local scenario. As the field area and water volume are relative, the variable size of fields for treatment is not expected to be a significant factor for local PEC in the present assessment.

4.5 Regional and continental distribution of cropland and grassland

The concept of the 'main region' in exposure assessment in line with the ECHA R.16 guidance refers to a semi-industrialised area notionally comprising 10% of the size of the EU, "represented by a typical densely-populated EU-area located in Western Europe (~ 20 million inhabitants, 200 · 200 km^2)."
Eurostat data (2015[77]) provides useful reference information on land usage in the EU member states as shown in Table 4.2. While the highest agricultural land use is in France, France is considerably larger than one single region by both population and surface area definitions, and there is no need to modify the standard assumption of 10% distribution of substance in the main region, which is appropriately conservative.

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[77] available online at http://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Land_cover,_2015.png

Table 4.2 EU member state land usage data (cropland and grassland)

Member State	Total area (km2)	Cropland (%)	Cropland (km^2)	Fraction of EU total cropland	Grassland (%)	Grassland (km^2)	Fraction of EU total grassland	Cropland + Grassland	Fraction of EU total (cropland+grass-land)	Nominal number of EU regions (total area / 40,000 km^2)	Popul-ation (millions)	Equivalent number of EU regions based on average popul-ation (total popul-ation / 20M)
	4.37E+06	**22.20**	**9.70E+05**	**1.00**	**20.70**	**9.04E+05**	**1.00**	**1.87E+06**	**1.00**	**109.23**	**508.45**	**25.42**
Belgium	3.07E+04	28.50	8.74E+03	0.01	31.00	9.51E+03	0.01	1.82E+04	0.01	0.77	11.26	0.56
Bulgaria	1.11E+05	29.20	3.24E+04	0.03	18.80	2.09E+04	0.02	5.33E+04	0.03	2.77	7.20	0.36
Czech Republic	7.89E+04	32.00	2.52E+04	0.03	22.30	1.76E+04	0.02	4.28E+04	0.02	1.97	10.54	0.53
Denmark	4.32E+04	50.60	2.18E+04	0.02	17.50	7.55E+03	0.01	2.94E+04	0.02	1.08	5.66	0.28
Germany	3.58E+05	32.30	1.16E+05	0.12	21.90	7.85E+04	0.09	1.94E+05	0.10	8.96	81.20	4.06
Estonia	4.53E+04	13.50	6.12E+03	0.01	15.90	7.21E+03	0.01	1.33E+04	0.01	1.13	1.31	0.07
Ireland	7.06E+04	5.80	4.09E+03	0.00	56.30	3.97E+04	0.04	4.38E+04	0.02	1.77	4.63	0.23
Greece	1.32E+05	15.30	2.02E+04	0.02	19.40	2.56E+04	0.03	4.58E+04	0.02	3.30	10.86	0.54
Spain	4.99E+05	21.30	1.06E+05	0.11	19.00	9.47E+04	0.10	2.01E+05	0.11	12.46	46.45	2.32

Member State	Total area (km2)	Cropland (%)	Cropland (km^2)	Fraction of EU total cropland	Grassland (%)	Grassland (km^2)	Fraction of EU total grassland	Cropland + Grassland	Fraction of EU total (cropland+grass-land)	Nominal number of EU regions (total area / 40,000 km^2)	Popul-ation (millions)	Equivalent number of EU regions based on average popul-ation (total popul-ation / 20M)
France	5.49E+05	28.90	1.59E+05	**0.16**	26.70	1.47E+05	**0.16**	3.05E+05	**0.16**	**13.73**	66.42	**3.32**
Croatia	5.65E+04	16.70	9.44E+03	0.01	19.10	1.08E+04	0.01	2.02E+04	0.01	1.41	4.23	0.21
Italy	3.01E+05	25.10	7.56E+04	0.08	21.70	6.54E+04	0.07	1.41E+05	0.08	7.53	60.80	3.04
Cyprus	9.25E+03	19.40	1.79E+03	0.00	13.20	1.22E+03	0.00	3.02E+03	0.00	0.23	0.85	0.04
Latvia	6.55E+04	14.30	9.37E+03	0.01	22.50	1.47E+04	0.02	2.41E+04	0.01	1.64	1.99	0.10
Lithuania	6.54E+04	29.40	1.92E+04	0.02	24.90	1.63E+04	0.02	3.55E+04	0.02	1.64	2.92	0.15
Luxembourg	2.60E+03	23.30	6.05E+02	0.00	28.90	7.50E+02	0.00	1.35E+03	0.00	0.06	0.56	0.03
Hungary	9.30E+04	43.70	4.06E+04	0.04	19.90	1.85E+04	0.02	5.92E+04	0.03	2.33	9.86	0.49
Malta	3.15E+02	26.30	8.28E+01	0.00	23.40	7.37E+01	0.00	1.57E+02	0.00	0.01	0.43	0.02
Netherlands	3.78E+04	24.20	9.15E+03	0.01	36.30	1.37E+04	0.02	2.29E+04	0.01	0.95	16.90	0.85
Austria	8.39E+04	15.30	1.28E+04	0.01	24.70	2.07E+04	0.02	3.36E+04	0.02	2.10	8.58	0.43

Member State	Total area (km2)	Cropland (%)	Cropland (km^2)	Fraction of EU total cropland	Grassland (%)	Grassland (km^2)	Fraction of EU total grassland	Cropland + Grassland	Fraction of EU total (cropland+grass-land)	Nominal number of EU regions (total area / 40,000 km^2)	Popul-ation (millions)	Equivalent number of EU regions based on average popul-ation (total popul-ation / 20M)
Poland	3.14E+05	33.20	1.04E+05	0.11	22.60	7.09E+04	0.08	1.75E+05	0.09	7.85	38.01	1.90
Portugal	8.88E+04	11.70	1.04E+04	0.01	23.60	2.10E+04	0.02	3.14E+04	0.02	2.22	10.37	0.52
Romania	2.39E+05	32.20	7.70E+04	0.08	27.10	6.48E+04	0.07	1.42E+05	0.08	5.98	19.87	0.99
Slovenia	2.03E+04	9.50	1.93E+03	0.00	21.70	4.40E+03	0.00	6.33E+03	0.00	0.51	2.06	0.10
Slovakia	4.90E+04	26.60	1.30E+04	0.01	19.50	9.56E+03	0.01	2.26E+04	0.01	1.23	5.42	0.27
Finland	3.38E+05	5.90	1.99E+04	0.02	4.40	1.49E+04	0.02	3.48E+04	0.02	8.44	5.47	0.27
Sweden	4.50E+05	4.20	1.89E+04	0.02	5.40	2.43E+04	0.03	4.32E+04	0.02	11.25	9.75	0.49
United Kingdom	2.48E+05	19.70	4.88E+04	0.05	36.20	8.97E+04	0.10	1.38E+05	0.07	6.19	64.88	3.24