Evidence

Review of human health and environmental risks associated with land application of mechanical - biological treatment outputs (Revision 1)

Report: SC030144/R5

Better regulation programme

Evidence Directorate

The Environment Agency is the leading public body protecting and improving the environment in England and Wales.

It's our job to make sure that air, land and water are looked after by everyone in today's society, so that tomorrow's generations inherit a cleaner, healthier world.

Our work includes tackling flooding and pollution incidents, reducing industry's impacts on the environment, cleaning up rivers, coastal waters and contaminated land, and improving wildlife habitats.

This report is the result of research commissioned and funded by the Environment Agency.

Published by:
Environment Agency, Rio House, Waterside Drive, Aztec West, Almondsbury, Bristol, BS32 4UD
Tel: 01454 624400 Fax: 01454 624409
www.environment-agency.gov.uk

ISBN: 978-1-84911-160-7

Author(s):
Graham Merrington, Mark Crane and Bob Barnes

Dissemination Status:
Released to all regions
Publicly available

Keywords:
MBT, MHT, compost, metals, organic micropollutants, risk assessment

Research Contractor:
wca environment, Brunel House, Volunteer Way, Faringdon, Oxon, SL7 7YR.

Environment Agency's Project Manager:
Bob Barnes, Evidence Directorate

Project Number:
SC030144

Product Code:
SCHO1209BRQE-E-P

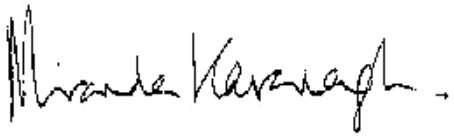
Evidence at the Environment Agency

Evidence underpins the work of the Environment Agency. It provides an up-to-date understanding of the world about us, helps us to develop tools and techniques to monitor and manage our environment as efficiently and effectively as possible. It also helps us to understand how the environment is changing and to identify what the future pressures may be.

The work of the Environment Agency's Evidence Directorate is a key ingredient in the partnership between research, policy and operations that enables the Environment Agency to protect and restore our environment.

The Research & Innovation programme focuses on four main areas of activity:

- **Setting the agenda**, by informing our evidence-based policies, advisory and regulatory roles;
- **Maintaining scientific credibility**, by ensuring that our programmes and projects are fit for purpose and executed according to international standards;
- **Carrying out research**, either by contracting it out to research organisations and consultancies or by doing it ourselves;
- **Delivering information, advice, tools and techniques**, by making appropriate products available to our policy and operations staff.



Miranda Kavanagh

Director of Evidence

Executive summary

This is a revision to a previous Environment Agency Technical Report (2009a) that assessed the potential human health and environmental risks from chemicals following the use of mechanical biological treatment (MBT) outputs (CLO) on land. Revisions in the current version of the report arise from recommendations in that original report which were primarily targeted at reducing uncertainties in the generic screening assessment.

These recommendations included:

- undertaking a monitoring programming of the chemical quality of CLO in order to provide a more robust estimate of exposure concentration distributions – this enables reliable use of a high percentile of the frequency distribution of the data (such as the 90th percentile) which is common practice in generic risk assessments;

- derivation of environmental limit values (predicted no effect concentrations; PNECs) for triclosan, perfluorooctane sulphonates (PFOS), polycyclic aromatic hydrocarbons (PAHs) and several phthalates to provide toxicity thresholds against which risks from exposure concentrations could be assessed.

This revision of the risk assessment is based on new exposure data from duplicate samples taken over a five month period at four plants in England. Plants sampled undertook either MBT or mechanical heat treatment (MHT) processes. Groups from the chemical industry have collaborated in the project and provided new data to facilitate the derivation of PNECs.

Limit values for the UK and other jurisdictions have been used to assess potential chemical risks to human and environmental health.

As with the original risk assessment, risks are identified for several metals and organic micropollutants when CLO is used undiluted.

When the outputs are used in more realistic scenarios, and are limited by nitrogen or a tonnage application rate, environmental risks are identified for cadmium, chromium and zinc when worst case ambient background concentrations of these elements are included in the calculations. No human health risks are identified for the scenarios for metals.

Environmental and human health risks are identified for benzo-a-pyrene in the rate-limited scenarios when ambient background concentrations are included. No other organic chemicals considered here present potential risks, although it was not possible to assess human health risks for PFOS or triclosan as no there were no existing limit values for these chemicals.

Contents

List of Tables

1 Introduction

1.1 Revision structure

The purpose of this revised report is to reassess the potential human and environmental health risk associated with the application of compost-like output (CLO) from mechanical-biological treatment (MBT) and mechanical heat treatment (MHT) plants to land. This risk has been characterised previously in an Environment Agency report; this reassessment incorporates several recommendations made in the previous report in order to reduce levels of uncertainty in the generic risk screening.

The previous report recommended:

- that the number of samples of CLO taken from MBT plants should be increased and that sampling should take place over a longer period in order to provide a robust basis for the estimation of chemical exposure concentrations;
- for priority chemicals (i.e. perfluorooctane sulphonates (PFOS), polycyclic aromatic hydrocarbons (PAHs), triclosan and several phthalates) that limit values should be derived where previously none existed and existing limit values should be revised where new data are available;
- closer collaboration with manufacturers and commercial downstream users of the priority chemicals in order to access recent and relevant ecotoxicity data;
- a revision of the human health and environmental risks associated with land application of CLO, using the new exposure and effects data.

In following the recommendations of this earlier work, this revision provides clarity to policy makers and stakeholders on the potential chemical risks from the use of CLO on agricultural land.

This introductory section discusses the revisions made in this report since the original Environment Agency report (2009a). A sister report, in which several other recommendations from the original report have been addressed, is also available (Environment Agency, 2009b).

Chapter 2 provides summary statistics for selected physicochemical determinands from a five-month sampling programme of four MBT/mechanical heat treatment (MHT) plants in England which produce CLOs or similar material. The methodology and results of the estimation of exposure concentrations are given in this chapter.

Chapter 3 presents the revised risk assessment, incorporating the new exposure and effects data. The formulation of risks and the exposure scenarios used in the assessment are the same as those used in the original report (Environment Agency, 2009a).

Chapter 4 offers some brief conclusions from this screening risk assessment and highlights some areas of remaining uncertainty.

This report also provides five annexes (Annexes A–E). Four of these annexes supply and justify the predicted no effect concentrations (PNECs) for the priority chemicals identified in the original report. The fifth annex provides and justifies the limit values used in this report for the assessment of environmental and human health risks.

1.2 Revisions since the first report

The key revisions within the risk assessment section of this report are related to updated estimates of exposure concentrations for priority chemicals and changes in the derivation of limit values used to assess potential environmental risks associated with these priority chemicals.

In the first report (Environment Agency, 2009a), the outputs from three MBT plants were analysed, using samples from a single sampling session. However, it is well established that the organic outputs from MBT can be physically and chemically heterogeneous (Environment Agency, 2007a). Therefore, to gain a greater insight into this heterogeneity and provide a more robust basis from which to estimate exposure concentrations when CLOs are applied to agricultural land, this revision is based on a more thorough monitoring and sampling programme.

For this report, four plants in England were sampled on at least five separate occasions over a five month period. It was originally envisaged that annual averages (i.e. the mean of 12 monthly samples) or similar could be calculated for each plant. This approach is similar to the way in which water quality is monitored to assess compliance with Environmental Quality Standards (EQS). However, financial constraints on the project meant that instead of using annual averages, the revised exposure estimates are based on duplicate samples taken each month over a five month period. Nevertheless, this is a major improvement over the previous sample data.

In addition to MBT, an MHT plant was included within this sampling exercise. Mechanical heat treatment (MHT), as the name suggests, includes a heating step such as autoclaving either before or after mechanical separation. The resulting material still requires an effective biological stabilisation stage to reduce the biodegradability to produce a final CLO.

Along with the re-evaluation of exposure concentrations, it was also necessary to derive environmental limit values for several chemicals which had been identified as priorities for further investigation by the Environment Agency's previous studies on biowastes (e.g. Environment Agency, 2007a). In the original report (Environment Agency 2009a) it was not possible to assess the potential environmental risks posed by triclosan, perfluorinated alkyl substances, several phthalates and PAHs because reliable limit values were not available. Annexes A to D provide more detail on how limits for these substances have now been derived, although it should be stressed that for some chemicals and some exposure routes the uncertainty due to a paucity of data is still significant.

For human health, the withdrawal and subsequent revision of the soil guideline values (SGVs) means that, as of July 2009, only eight chemicals currently have limit values. Therefore, the majority of chemicals in this report have been assessed using values from alternative jurisdictions (e.g. The Netherlands).

2 Results

The results outlined in this chapter are presented in full in Chapter 2 of the Environment Agency's report *Assessment of MBT input and output quality* (Environment Agency, 2009b). The data were collected from four plants in England over a five month period between December 2008 and April 2009. Duplicate samples of the CLO were taken on each sampling date. The plants took part in this study on the understanding that the results of the sampling and analysis would not be attributed to individual operations and that anonymity is maintained. Hence the data are referred to below as from Site 1, Site 2, Site 3 and Site 4 (S1–S4).

The list of determinands measured and the laboratory details are all provided in the separate report (Environment Agency, 2009b).

The following section describes the process by which the exposure concentrations of several priority chemicals, previously identified by the Environment Agency (2009a) and Partl and Cornander (2006), are estimated for subsequent use in the exposure scenarios and risk assessment in Section 3.

2.1 Estimation of exposure concentrations for the CLO

Previous monitoring exercises of the physical, chemical and biological quality of CLO have shown a high degree of intra-plant variability for some determinands (Environment Agency, 2007a; Zmora-Nahum *et al.,* 2007; Environment Agency, 2009a and b). This variability makes it difficult to estimate representative concentrations in the CLO for use in exposure scenarios.

It is common risk assessment practice to use a parameter such as a 'reasonable worst case percentile' (e.g. 90th percentile) to represent the temporal distribution of exposure values (EC, 2003). This is appropriate if the frequency distribution can reasonably be inferred from measurement or theory.

However, we may not know or be able to predict the distributions of some chemicals in CLO and therefore estimates of 90th percentiles may not be a valid method on which to base exposure concentrations. We therefore took the results from our monthly analyses of outputs to determine whether a defensible statistical distribution could be fitted to the data.

We were unable to justifiably fit a distribution due to the significant variability in the concentration of some determinands and the relatively limited number of samples (fewer than 15), especially as many values were below the limits of detection. Instead, data was logged and the percentile function in Excel was used, which ranks the logged data. This simplistic approach was deemed to be fit for purpose because the data set was limited, the approach is relatively insensitive to samples with values at the limits of detection and because this is a non-distributional method (i.e. does not rely upon the fit of a curve).

The calculated 10th and 90th percentile concentrations of priority physical and chemical determinands from the CLO are shown in Table 2.1 to Table 2.3. These data will be used to assess the potential chemical risks from the use of CLO in Chapter 3. The chemicals analysed here were selected based on their identification as priority substances in previous projects. The full list of chemical determinands and their concentrations in CLO are given in Environment Agency (2009b).

Table 2.1 The 10th and 90th percentiles of metals, pH and organic carbon in CLOs from four sites sampled on five separate occasions (n < 10).

		S1		S2		S3		S4	
Substance	**Units**	**10th%**	**90th%**	**10th%**	**90th%**	**10th%**	**90th%**	**10th%**	**90th%**
pH		8.00	8.25	7.51	8.67	6.16	7.26	5.40	7.60
OC	%	9.15	18.51	17.37	21.74	14.42	23.54	24.61	41.03
Cd	mg kg^{-1}	1.48	2.22	1.10	5.24	0.43	1.47	0.48	0.79
Cr	mg kg^{-1}	38.15	107.27	18.52	28.64	26.90	34.46	48.16	87.54
Cu	mg kg^{-1}	257.72	643.45	262.27	423.52	94.53	323.16	42.56	80.39
Ni	mg kg^{-1}	36.72	52.72	34.34	53.56	30.46	59.47	38.35	58.55
Pb	mg kg^{-1}	437.17	776.23	229.63	390.29	199.13	842.42	68.84	139.24
Zn	mg kg^{-1}	531.97	1700.60	580.17	947.06	390.89	691.26	188.90	250.77

Table 2.2 The 10th and 90th percentiles of selected organic chemicals in CLOs from four sites sampled on five separate occasions (n < 10).

		S1		S2		S3		S4	
Substance	**Units**	**10th%**	**90th%**	**10th%**	**90th%**	**10th%**	**90th%**	**10th%**	**90th%**
Sum of all PCDD/Fs	ITEQ in ng kg^{-1}	7.04	25.84	-	-	-	-	-	-
Hydrocarbons – Total extractable	mg kg^{-1}	1881	8897	3.49	4804.91	9.30	4764.87	5.97	7552
PFOS (µg/kg)	µg kg^{-1}	0.13	7.02	0.0001	4.67	0.0001	3.89	0.0001	15.12
BaP (µg/kg)	µg kg^{-1}	0.0001	238.67	0.0001	437.54	0.0001	234.16	0.0001	191.21
Fluoranthene	ug kg^{-1}	228.65	1780.2	597.6	1500.0	0.0001	1128.50	254.27	1364.05
Butylbenzylphthalate	mg kg^{-1}	-	-	-	-	0.21	5.04	6.26	12.00
Dibutylphthalate	mg kg^{-1}	-	-	0.0001	0.72	1.48	6.73	8.12	18.67
DEHP	mg kg^{-1}	0.78	37.43	9.17	26.00	19.98	47.08	56.52	170.30
Triclosan	mg kg^{-1}	0.0001	3.86	0.0001	5.87	0.43	7.55	0.0001	6.18

Table 2.3 The 10th and 90th percentiles of physical contaminants in CLOs from four sites sampled on five separate occasions (n < 10).

		S1		S2		S3		S4	
Substance	**Units**	**10th%**	**90th%**	**10th%**	**90th%**	**10th%**	**90th%**	**10th%**	**90th%**
Plastic >2 mm	% of total sample (W/W)	0.25	21.94	0.54	2.81	0.40	4.63	0.42	3.64
Glass >2 mm	% of total sample (W/W)	0.54	14.00	3.99	7.94	4.59	12.69	0.78	4.59
Metal >2 mm	% of total sample (W/W)	0.0001	0.63	0.0001	0.59	0.0001	0.16	0.004	1.13

One of the exposure scenarios given in Section 3 is based on the mean application of total nitrogen (N) present within the CLO. The total N values for each of the sites are given in Table 2.4.

Table 2.4 Mean (and standard deviation) of total nitrogen content of CLO from four sites sampled on five separate occasions (n <10).

		S1	S2	S3	S4
Substance	**Units**	**Mean**	**Mean**	**Mean**	**Mean**
Total N	Kg/t DW	17.4 (σ=5.4)	21.0 (σ=0.6)	20.2 (σ=3.0)	13.3 (σ=2.5)
Total N[1]	Kg/t FW	25.2	29.3	24.0	21.9

Note: [1] Calculated using dry matter figures given in Environment Agency (2009b).

3 Revised risk assessment

This section assesses potential environmental and human health risks from the application of CLO to agricultural land under a range of exposure scenarios. It considers the same uses and scenarios as those detailed in Section 5 of the original report (Environment Agency, 2009a).

3.1 Problem formulation

The original report described two distinct uses for the application of CLO to land. Regeneration, remediation and amenities use in which the outputs would be used undiluted as a soil-forming material. The second was for agriculture, where it would be applied in a similar way to sewage sludge.

Two separate calculations were made in the original report to establish the potential exposure concentrations of chemicals in the agricultural use of CLO. The first approach followed work previously commissioned on the assessment of risks of CLO to land; the second method was similar to that used in the recent EU Risk Assessments for New and Existing Chemicals (EC, 2003). Were CLO to be used in agriculture it would be important to take account of the existing concentration of chemicals in the soil. Like other regulatory regimes involving the application of organic waste to soil (DoE, 1986; WRAP, 2007), it would therefore be necessary to assess the levels of chemicals present in the receiving soil prior to application. The final exposure calculations for the application of CLO to agricultural land were based on the sum of the concentration of chemicals added in the CLO application and their concentration in the existing soil.

Table 3.1 gives the 90th percentile concentrations of selected chemicals, derived from soils data from England and Wales. The 90th percentiles are used to represent reasonable worst case ambient background concentrations for the characterisation of risks (EC, 2003). For a number of the organic micropollutants (such as triclosan, PFOS and phthalates), data for soils in England and Wales were not readily available.

Table 3.1 Reasonable worst case physico-chemical properties from the National Soil Inventory (Zhao *et al.,* 2007) and the Environment Agency (2007b).

Parameter	90^{th} percentile values
Cd	1.4
Cr	64
Cu	37
Ni	42
Pb	131
Zn	147
BaP (µg kg^{-1})*	348
Fluoranthene (µg kg^{-1})*	568
PCDD/F (ng kg^{-1} I-TEQ)*	36

Notes: * Data for rural soils for England and Wales.
Units are mg kg^{-1} unless otherwise stated.

As in the first report (Environment Agency, 2009a), the reasonable worst case scenarios for environmental risks assessed here are those related to direct ecotoxicity of the contaminants to organisms living in or on the natural or manufactured topsoil.

Ecotoxicities include phytotoxicity and adverse effects on soil-dwelling vertebrates and invertebrates.

The key exposure pathways (see Table 3.2) are generally through:

- direct soil ingestion (Scenarios 1);
- contact with pore water (Scenario 4);
- the consumption of contaminated food items (secondary poisoning; (Scenarios 2 and 3).

Other risk scenarios for the environment include exposure to contaminants and nutrients in surface and ground waters via leaching or runoff from CLO. These scenarios (Scenarios 5 and 6) may also be relevant for situations in which significant volumes of CLO material were stored in the open (i.e. unbound). The receptors under these final two scenarios could be human health (via drinking and recreational waters) and aquatic flora and fauna. Importantly, the final receptors may also greatly depend on users of CLO following good agricultural practice (Defra, 2002; 2007), which we have assumed to be the case in Table 3.2.

Table 3.2 Reasonable worst case exposure scenarios for the application of CLO to land.

Scenario number	Reasonable worst case scenario	Receptor
1	Child accidentally ingesting soil in a domestic garden or recreational area	Human health
2	Humans consuming produce grown in domestic setting, including allotments and horticulture. In addition to Scenario 1	Human health
3	Humans or livestock consuming produce grown in agricultural setting	Human health
4	Organisms living in or on land receiving CLO	Flora and fauna
5	Leaching/runoff of contaminants from CLO into surface and groundwaters	Human health, aquatic flora and fauna, groundwater, surface water
6	Leaching/runoff of nutrients from a natural or manufactured topsoil into surface and groundwaters	Aquatic flora and fauna, groundwater, surface water

The list of scenarios in Table 3.2 is not exhaustive, but includes situations believed to be the most sensitive to exposure from CLO micropollutants. These scenarios have been used in other risk assessments and quality protocols involving the application of waste to land (WRAP, 2007). If the assessment of these scenarios identifies low risks then other less sensitive scenarios will clearly also present lower risks to the environment and human health.

3.2 Risk evaluation – environment

As in the first report (Environment Agency 2009a), the potential risks associated with the application of CLO to land are characterised by calculating the ratio of the measured or predicted environmental concentration of a chemical to its predicted no

effect concentration (PEC/PNEC). This is the risk characterisation ratio (RCR). If the ratio is equal to or greater than unity then a potential risk has been identified with that chemical; use of CLO is in question and the specific scenario requires further investigation.

3.2.1 Limit values

Sludge limit values (DoE, 1986) and values from EU risk assessments (Environment Agency, 2008) are used here for the assessment of environmental risks associated with the metals in CLO when they are applied to land. These limits values are given in Annex E. With EU limit values, the 10th percentile of the pH and organic matter (OM) in the CLO have been used in the assessment for Scenario 4 to best represent the reasonable worst case conditions (Environment Agency, 2009a).

3.2.2 Metals

For metals exposure, Scenarios 5 and 6 represent relatively low risk in the UK if good practice is followed; therefore, these are not considered further in this assessment.

Table 3.3 shows RCRs for the regeneration, remediation and landscaping use of CLO for Scenario 4. Table 3.3 clearly shows that that the CLO from all four sites present potential risks for at least two metals (i.e. RCR> 1 when maximum concentrations or 90th percentiles are used with either sludge limits or EU PNECs).

Mirroring the initial CLO risk assessment (Environment Agency, 2009a), a greater number of potential risks are identified when the calculations use the EU limits for metals and account for bioavailability (for Cu, Ni and Zn), compared to using the existing sludge limits.

Some of the greatest RCR values are identified for the outputs from S1. However, all sites have potential risks identified for Zn using both sets of limit values. The CLO from S4 shows the fewest risks associated with metals in Scenario 4 (where CLO are used ‘undiluted’).

The use of undiluted CLO for regeneration and remediation presents several potential environmental risks associated with metals. However, as the first report has already identified, the use of outputs in this way is not thought to be wholly realistic and assessment of risk must be undertaken on a site-specific basis.

Table 3.4 also gives RCRs for the use of CLO on agricultural land for application limited by 250 kg ha^{-1} N. The exposure concentrations have been calculated to account for ambient background concentrations in the soils to which the outputs are applied. As with the original risk assessment, risks have been identified using the EU limits, especially for Zn, Cd and Cr. No potential risks are identified when using the sludge limits.

Table 3.5 shows RCRs for the use of CLO on agricultural land where the application rate is limited to 5 t ha^{-1} yr^{-1} with an incorporation depth of 10 cm (i.e. worst-case conditions). Potential risks were identified for Cd, Cr and Zn using the EU limits. As with the N-limited exposures given in Table 3.4, no potential risks are identified for the use CLO from these plants if the existing sludge limits are used.

3.2.3 Organic micropollutants

The limit values used to evaluate environmental risks from organic micropollutants from the application of CLO to land are given in Annex E. These limits are from published sources, including EU risk assessments and Environment Canada. In addition, limit values for several chemicals have been specifically derived for this project (Annexes A, B, C and D). The derivation process followed is the same as that used in European risk assessments undertaken to fulfil the requirements of the Existing Substance Regulations (793/93/EEC) and REACH (EC1907/2006). Previously reviewed and accepted data from European risk assessments and any national risk assessments have been accepted without re-evaluation.

No suitable limit values have been identified for total petroleum hydrocarbons (TPH). Limit values for TPH fractions have been cited in RIVM (2001) and derived *de novo* by the Environment Agency (2007c). However, both of these sources state that the reliability of the limit values is low.

Only those limit values in Annex E have been used in the assessment of potential risks.

Table 3.6 gives the RCRs for environmental risks (Scenario 4, 5 and 6) for priority organic micropollutants when CLO are used 'undiluted' for regeneration, reclamation or landscaping. This table shows several potential environmental risks associated with the use of CLO in this way. All sites had risks for benzo-a-pyrene, fluoranthene, triclosan and at least one of the phthalates. The RCR for triclosan for CLO from all four sites was greater than 2. The RCR for dibutylphthalate for CLO from S3 and S4 was greater than 20. The highly elevated RCRs for these two substances suggest these are high priority substances for further investigation (EC, 2003). A risk was also identified for dioxins and furans at S1, the only site where these substances were present at detectable levels in CLO.

The RCRs for the nitrogen limited application of CLO to land for Scenarios 4, 5 and 6 are shown in Table 3.7. The exposure concentrations calculated for these uses have, where possible, taken account of the ambient background concentrations of organic micropollutants present in the soil. As in the first report (Environment Agency, 2009b), potential risks have been identified for benzo-a-pyrene from the CLO from all sites. No risks were identified for triclosan.

Table 3.8 shows RCRs for organic micropollutants for the application of CLO to agricultural land limited to 5 t ha^{-1}. This table also identifies potential risks for benzo-a-pyrene for all CLO for this use.

Table 3.3 Exposure concentrations and risk characterisation ratios for environmental risks (Scenario 4) for metals from CLO (units mg kg^{-1} unless otherwise stated) used for regeneration, reclamation and landscaping.

Parameter	Site 1			Site 2			Site 3			Site 4		
		RCR (no units)			RCR (no units)			RCR (no units)			RCR (no units)	
	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits#
pH	8.00	-	-	7.51	-	-	6.2	-	-	5.4	-	-
SOC (%)	9.51	-	-	17.37	-	-	14	-	-	25	-	-
Cd	2.22	0.73	1.93	5.2	1.73	4.5	1.5	0.5	1.30	0.79	0.26	0.69
Cr	107	0.27	5.07	29	0.07	1.4	34	0.09	1.61	88	0.22	4.17
Cu	643	3.22	11	424	2.12	6.7	323	2.39	2.34	80	1.00	0.46
Ni	53	0.48	2.60	54	0.49	2.7	59	0.79	0.76	59	1.18	0.59
Pb	776	2.59	4.6	390	1.30	2.3	842	2.81	5.0	139	0.46	0.83
Zn	1701	5.67	20	947	3.16	12	691	3.46	7.6	251	1.26	2.78

Notes: * Sludge limits are from DoE (1986).
EU limits are from EU risk assessments (The Netherlands, 2004; ECI, 2007; LDAI, 2007; Denmark, 2007; Belgium, 2007) and the Environment Agency (2008).

Table 3.4 Exposure concentrations and risk characterisation ratios for environmental risks (Scenario 4) for metals from the application to agricultural land (limited by 250 kg ha^{-1} N) of CLO (units mg kg^{-1} unless otherwise stated).

Parameter	Site 1			Site 2			Site 3			Site 4		
		RCR (no units)			RCR (no units)			RCR (no units)			RCR (no units)	
	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits#
pH	8.00	-	-	7.51	-	-	6.2	-	-	5.4	-	-
SOC (%)	9.51	-	-	17.37	-	-	14	-	-	25	-	-
Cd	1.403	0.47	1.22	1.406	0.47	1.22	1.402	0.47	1.22	1.401	0.47	1.22
Cr	64.14	0.16	3.04	64.03	0.16	3.03	64.06	0.16	3.04	64.12	0.16	3.04
Cu	37.86	0.19	0.37	37.51	0.19	0.25	37.55	0.28	0.27	37.11	0.46	0.21
Ni	42.07	0.38	0.63	42.07	0.38	0.39	42.10	0.56	0.60	42.08	0.84	0.42
Pb	132.0	0.44	0.79	131.47	0.44	0.78	132.45	0.44	0.79	131.19	0.44	0.78
Zn	149.0	0.50	1.65	148.14	0.49	1.64	148.19	0.74	1.64	147.34	0.74	1.63

Notes: * Sludge limits are from DoE (1986).
EU limits are from EU risk assessments (The Netherlands, 2004; ECI, 2007; LDAI, 2007; Denmark, 2007; Belgium, 2007) and the Environment Agency (2008).

Table 3.5 Exposure concentrations and risk characterisation ratios for environmental risks (Scenario 4) for metals from the application to agricultural land (limited to 5 t ha^{-1}) of CLO (units mg kg^{-1} unless otherwise stated) with a 10 cm depth of incorporation.

Parameter	Site 1			Site 2			Site 3			Site 4		
		RCR (no units)			RCR (no units)			RCR (no units)			RCR (no units)	
	10th or 90th percentile value	Sludge limits*	EU limits#	10th or 90th percentile value	Sludge limits*	EU limits	10th or 90th percentile value	Sludge limits*	EU limits	10th or 90th percentile value	Sludge limits*	EU limits
pH	8.00	-	-	7.51	-	-	6.2	-	-	5.4	-	-
SOC (%)	9.51	-	-	17.37	-	-	14	-	-	25	-	-
Cd	1.406	0.47	1.22	1.415	0.47	1.22	1.408	0.47	1.22	1.402	0.47	1.22
Cr	64.31	0.16	3.05	64.09	0.16	3.04	64.10	0.16	3.04	64.26	0.16	3.05
Cu	38.89	0.19	0.38	38.25	0.19	0.26	37.95	0.28	0.27	37.24	0.47	0.21
Ni	42.16	0.38	0.63	42.16	0.38	0.40	42.17	0.56	0.61	42.17	0.84	0.42
Pb	133.28	0.44	0.79	132.15	0.44	0.79	133.48	0.44	0.80	131.41	0.44	0.78
Zn	152.01	0.51	1.68	149.79	0.50	1.66	149.03	0.75	1.65	147.74	0.74	1.63

Notes: * Sludge limits are from DoE (1986).
EU limits are from EU risk assessments (The Netherlands, 2004; ECI, 2007; LDAI, 2007; Denmark, 2007; Belgium, 2007) and the Environment Agency (2008).

Table 3.6 Exposure concentrations and risk characterisation ratios for environmental risks (Scenarios 4, 5 and 6) for organic micropollutants from the use of CLO (units mg kg^{-1} unless otherwise stated) for regeneration, reclamation and landscaping.

Parameter	Site 1		Site 2		Site 3		Site 4	
	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)
Sum of all PCDD/Fs*	25.84	6.46	-	-	-	-	-	-
Hydrocarbons – Total extractable	8897	-	4804.91	-	4764.87	-	7552	-
PFOS (µg/kg)	7.02	(0.23)	4.67	(0.16)	3.89	(0.13)	15.12	(0.50)
BaP (µg/kg)	238.67	4.50	437.54	8.25	234.16	4.42	191.21	3.61
Fluoranthene (µg/kg)	1780.2	1.19	1500.0	1.00	1128.50	0.75	1364.05	0.91
Butylbenzylphthalate	-	-	-	-	5.04	3.63	12.00	8.63
Dibutylphthalate	-	-	0.72	2.57	6.73	24.03	18.67	66.7
DEHP	37.43	2.87	26.00	2.00	47.08	3.62	170.30	13.10
Triclosan	3.86	2.70	5.87	4.10	7.55	5.28	6.18	4.32

Notes: * Values as ITEQ in ng kg^{-1}.

Table 3.7 Exposure concentrations and risk characterisation ratios for environmental risks (Scenario 4, 5 and 6) for organic micropollutants from the application to agricultural land (limited by 250 kg ha^{-1} N) of CLO (units mg kg^{-1} unless otherwise stated).

Parameter	Site 1		Site 2		Site 3		Site 4	
	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)
Sum of all PCDD/Fs*	36.03	9.01	-	-	-	-	-	-
Hydrocarbons – Total extractable	11.93	-	5.78	-	8.19	-	10.26	-
PFOS (µg/kg)	0.009	(0.0003)	0.006	(0.0002)	0.007	(0.0002)	0.021	(0.0007)
BaP (µg/kg)	348.32	6.57	348.53	6.57	348.42	6.57	348.26	6.57
Fluoranthene (µg/kg)	570.39	0.38	569.81	0.38	569.94	0.38	569.85	0.38
Butylbenzylphthalate	-	-	-	-	0.009	0.0065	0.016	0.012
Dibutylphthalate	-	-	0.0009	0.0030	0.012	0.043	0.025	0.089
DEHP	0.050	0.004	0.031	0.0022	0.081	0.0062	0.231	0.018
Triclosan	0.005	0.003	0.007	0.005	0.013	0.009	0.008	0.006

Notes: * Values as ITEQ in ng kg^{-1}.

Table 3.8 Exposure concentrations and risk characterisation ratios for environmental risks (Scenario 4, 5 and 6) for organic micropollutants from the application to agricultural land (limited to 5 t ha^{-1}) of CLO (units mg kg^{-1} unless otherwise stated) with a 10 cm depth of incorporation.

Parameter	Site 1		Site 2		Site 3		Site 4	
	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)	10th or 90th percentile value	RCR (2˚ poisoning)
Sum of all PCDD/Fs*	36.08	9.02	-	-	-	-	-	-
Hydrocarbons – Total extractable	26.17	-	14.13	-	14.01		22.21	
PFOS (µg/kg)	0.021	(0.0007)	0.013	(0.0004)	0.011	(0.0004)	0.044	(0.0015)
BaP (µg/kg)	348.71	6.58	349.29	6.59	348.69	6.58	348.56	6.58
Fluoranthene (µg/kg)	573.24	0.38	572.41	0.38	571.32	0.38	572.01	0.38
Butylbenzylphthalate	-	-	-	-	0.015	0.011	0.04	0.029
Dibutylphthalate	-	-	0.002	0.0071	0.020	0.071	0.055	0.196
DEHP	0.110	0.008	0.076	0.0058	0.14	0.011	0.51	0.039
Triclosan	0.011	0.008	0.017	0.012	0.022	0.015	0.018	0.013

Notes: * Values as ITEQ in ng kg^{-1}.

3.3 Risk evaluation – human health

In the UK, few limit values have been derived for human exposure to soil contaminants. Therefore, it was necessary for this assessment to use values derived by other jurisdictions in order to screen the contaminants detected in CLO. There are currently eight published UK soil guideline values (SGVs)[1], but the direct relevance of these values in an assessment of potential exposure from agricultural applications of CLO is limited. Nevertheless, the available SGVs are used in this report as 'triggers' for further assessment. This report also uses other derived values in addition to the SGVs to evaluate human health risks, specifically the serious risk concentrations (SRCs) derived in The Netherlands (RIVM 2001). SRCs were also used in the original report (Environment Agency, 2009a).

3.3.1 Metals

Table 3.9 lists the exposure concentrations and resulting RCRs for Scenarios 1, 2 and 3 arising from the application of CLO as soil-forming material ('undiluted' CLO). Pb is identified as a potential risk for this use of CLO from sites S1 and S3. However, the RCR values for Pb from CLO from these sites are only just greater than unity; it is likely that further refinement of the assessment would show that Pb poses a negligible risk.

When applications of CLO to land are restricted by N or to a tonnage (5 t ha^{-1}), there are no potential human health risks associated with the metals (Table 3.10 and Table 3.11).

3.3.2 Organic micropollutants

Several priority organic chemicals have been identified from previous assessments as potentially being of risk to human health and the environment. For three of these chemicals – total extractable hydrocarbons, PFOS and triclosan – it has not been possible within this project to identify reliable screening thresholds to assess potential human health risks. There are no SGVs for the organic micropollutants considered in this subsection.

Table 3.12 gives the estimated exposure concentrations and RCRs for human health risks from the use of CLO for regeneration and reclamation. Potential risks are identified for benzo-a-pyrene in the CLO from S2 and for DEHP in the output from S4. No other potential risks were identified.

Table 3.13 and Table 3.14 give the estimated exposure concentrations and RCRs from the N-limited and tonnage-restricted uses of CLO to agricultural land. As in the first report, both uses have potential risks for benzo-a-pyrene for which ambient background concentrations have been included in the exposure estimate (and have an overriding influence). The RCRs for benzo-a-pyrene are relatively low for all outputs (<2) and could well be reduced using site specific ambient background concentrations were to be considered. Risks are not identified for any of the other chemicals.

[1] http://www.environment-agency.gov.uk/research/planning/33734.aspx

Table 3.9 Exposure concentrations and risk characterisation ratios for human health risks (Scenario 1, 2 and 3) for metals from the use of CLO (units mg kg^{-1} unless otherwise stated) for regeneration, reclamation and landscaping.

Parameter	Site 1			Site 2			Site 3			Site 4		
		RCR (no units)			RCR (no units)			RCR (no units)			RCR (no units)	
	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits
pH	8.00	-	-	7.51	-	-	6.2	-	-	5.4	-	-
SOC (%)	9.51	-	-	17.37	-	-	14	-	-	25	-	-
Cd	2.22	0.22	-	5.2	0.52	-	1.5	0.15	-	0.79	0.08	-
Cr**	107	-	0.039	29	-	0.011	34	-	0.012	88	-	0.032
Cu	643	-	0.075	424	-	0.049	323	-	0.038	80	-	0.009
Ni	53	0.23	-	54	0.23	-	59	0.26	-	59	0.26	-
Pb	776	-	1.25	390	-	0.63	842	-	1.35	139	-	0.22
Zn	1701	-	0.037	947	-	0.021	691	-	0.015	251	-	0.005

Notes: * SGVs for residential with private gardens.
** Assessed as Cr III, the likely species in such an organic rich media (McGrath, 1995).

Table 3.10 Exposure concentrations and risk characterisation ratios for human health risks (Scenario 1, 2 and 3) for metals from the application to agricultural land (limited by 250 kg ha^{-1} N) of CLO (units mg kg^{-1} unless otherwise stated).

Parameter	Site 1			Site 2			Site 3			Site 4		
		RCR (no units)			RCR (no units)			RCR (no units)			RCR (no units)	
	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits
pH	8.00	-	-	7.51	-	-	6.2	-	-	5.4	-	-
SOC (%)	9.51	-	-	17.37	-	-	14	-	-	25	-	-
Cd	1.403	0.140	-	1.406	0.140	-	1.402	0.140	-	1.401	0.140	-
Cr**	64.14	-	0.023	64.03	-	0.023	64.06	-	0.023	64.12	-	0.023
Cu	37.86	-	0.004	37.51	-	0.004	37.55	-	0.004	37.11	-	0.004
Ni	42.07	0.18	-	42.07	0.18	-	42.10	0.18	-	42.08	0.18	-
Pb	132.0	-	0.212	131.47	-	0.211	132.45	-	0.213	131.19	-	0.211
Zn	149.0	-	0.003	148.14	-	0.003	148.19	-	0.003	147.34	-	0.003

Notes: * SGVs for residential with private gardens.
** Assessed as Cr III, the likely species in such an organic rich media (McGrath, 1995).

Table 3.11 Exposure concentrations and risk characterisation ratios for human health risks (Scenario 1, 2 and 3) for metals from the application to agricultural land (limited to 5 t ha^{-1}) of CLO (units mg kg^{-1} unless otherwise stated).

Parameter	Site 1			Site 2			Site 3			Site 4		
		RCR (no units)			RCR (no units)			RCR (no units)			RCR (no units)	
	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits	10th or 90th percentile value	SGVs*	Other limits
pH	8.00	-	-	7.51	-	-	6.2	-	-	5.4	-	-
SOC (%)	9.51	-	-	17.37	-	-	14	-	-	25	-	-
Cd	1.406	0.140	-	1.415	0.142	-	1.408	0.141	-	1.402	0.140	-
Cr**	64.31	-	0.023	64.09	-	0.023	64.10	-	0.023	64.26	-	0.023
Cu	38.89	-	0.014	38.25	-	0.004	37.95	-	0.004	37.24	-	0.004
Ni	42.16	0.18	-	42.16	0.18	-	42.17	0.18	-	42.17	0.18	-
Pb	133.28	-	0.214	132.15	-	0.212	133.48	-	0.213	131.41	-	0.211
Zn	152.01	-	0.003	149.79	-	0.003	149.03	-	0.003	147.74	-	0.003

Notes: * SGVs for residential with private gardens.
** Assessed as Cr III, the likely species in such an organic rich media (McGrath, 1995).

Table 3.12 Exposure concentrations and risk characterisation ratios for human health risks (Scenario 1, 2 and 3) for organic micropollutants from the use of CLO (mg kg^{-1} unless otherwise stated) for regeneration, reclamation and landscaping.

Parameter	Site 1		Site 2		Site 3		Site 4	
	10th or 90th percentile value	RCR (no units)	10th or 90th percentile value	RCR (no units)	10th or 90th percentile value	RCR (no units)	10th or 90th percentile value	RCR (no units)
Sum of all PCDD/Fs*	25.84	0.071	-	-	-	-	-	-
Hydrocarbons – Total extractable	8897	-	4804.91	-	4764.87	-	7552	-
PFOS (µg/kg)	7.02	-	4.67	-	3.89	-	15.12	-
BaP (µg/kg)	238.67	0.852	437.54	1.563	234.16	0.836	191.21	0.004
Fluoranthene (µg/kg)	1780.2	0.059	1500.0	0.050	1128.50	0.037	1364.05	0.045
Butylbenzylphthalate	-	-	-	-	5.04	0.00002	12.00	0.00004
Dibutylphthalate	-	-	0.72	0.00003	6.73	0.0003	18.67	0.0008
DEHP	37.43	0.622	26.00	0.433	47.08	0.78	170.30	2.83
Triclosan	3.86	-	5.87	-	7.55	-	6.18	-

Note: * Values as ITEQ in ng kg^{-1}.

Table 3.13 Exposure concentrations and risk characterisation ratios for human health risks (Scenario 1, 2 and 3) for organic micropollutants from the application to agricultural land (limited by 250 kg ha-1 N) of CLO (mg kg-1 unless otherwise stated).

Parameter	Site 1		Site 2		Site 3		Site 4	
	10th or 90th percentile value	RCR (no units)	10th or 90th percentile value	RCR (no units)	10th or 90th percentile value	RCR (no units)	10th or 90th percentile value	RCR (no units)
Sum of all PCDD/Fs*	36.03	0.100	-	-	-	-	-	-
Hydrocarbons – Total extractable	11.93	-	5.78	-	8.19	-	10.26	-
PFOS (µg/kg)	0.009	-	0.006	-	0.007	-	0.021	-
BaP (µg/kg)	348.32	1.244	348.53	1.244	348.42	1.244	348.26	1.244
Fluoranthene (µg/kg)	570.39	0.019	569.81	0.019	569.94	0.019	569.85	0.019
Butylbenzylphthalate	-	-	-	-	0.009	<0.00001	0.016	<0.00001
Dibutylphthalate	-	-	0.0009	<0.00001	0.012	<0.00001	0.025	<0.00001
DEHP	0.050	0.0008	0.031	0.0005	0.081	0.0014	0.231	0.0039
Triclosan	0.005	-	0.007	-	0.013	-	0.008	-

Note: * Values as ITEQ in ng kg^{-1}.

Table 3.14 Exposure concentrations and risk characterisation ratios for human health risks (Scenario 1, 2 and 3) for organic micropollutants from the application to agricultural land (limited to 5 t ha^{-1}) of CLO (units mg kg^{-1} unless otherwise stated) with a 10 cm depth of incorporation.

Parameter	Site 1		Site 2		Site 3		Site 4	
	10th or 90th percentile value	RCR No units	10th or 90th percentile value	RCR No units	10th or 90th percentile value	RCR No units	10th or 90th percentile value	RCR No units
Sum of all PCDD/Fs*	36.08	0.100	-	-	-	-	-	-
Hydrocarbons – Total extractable	26.17	-	14.13	-	14.01	-	22.21	-
PFOS (µg/kg)	0.021	-	0.013	-	0.011	-	0.044	-
BaP (µg/kg)	348.71	1.25	349.29	1.25	348.69	1.25	348.56	1.24
Fluoranthene (µg/kg)	573.24	0.019	572.41	0.019	571.32	0.019	572.01	0.019
Butylbenzylphthalate	-	-	-	-	0.015	<0.00001	0.04	<0.00001
Dibutylphthalate	-	-	0.002	<0.00001	0.020	<0.00001	0.055	<0.00001
DEHP	0.110	0.0018	0.076	0.0013	0.14	0.0023	0.51	0.0085
Triclosan	0.011	-	0.017	-	0.022	-	0.018	-

Note: * Values as ITEQ in ng kg^{-1}.

3.4 Assumptions and refinements

The lack of data on ambient background concentrations in soils for some organic micropollutants introduces a significant uncertainty into the calculation of exposure concentrations, particularly for triclosan, the phthalates and PFOS.

The first report argued that the use of 90th percentiles of ambient background concentrations is overly conservative, yet in a screening assessment such as this it represents the ‘reasonable worst case’. Nevertheless, the overriding effect of these background concentrations on the identified risks suggests a need for further refinement. A local assessment of soils likely to receive CLO would provide more relevant exposure data and would clearly reduce uncertainty and the need for generic assumptions.

In addition, for organic micropollutants, no account has been taken of the organic carbon content of soil to which CLO is applied. A normalisation step could be performed, as the availability of most non-ionic organic micropollutants is strongly determined by the soil organic matter fraction. This step was not taken in this assessment due to the use of limit values from multiple sources. The RCRs and the overall assessment given here are very much ‘worst case’ for the organic micropollutants.

4 Conclusions

This is a revision to an original Environment Agency Technical Report (2009a) which assesses human health and environmental risks associated with the application to land of outputs from mechanical-biological treatment (MBT) processes. This report presents a revision to the generic risk assessment process to include new data on exposure and effects for several priority chemicals. This revisions leads to the following conclusions:

i. **More samples taken over a longer period of time reduces uncertainty.**
This revised risk assessment is based on a chemical analysis of CLO from four MBT/MHT plants. Compared with the original report, this current project took more samples from each plant over a longer time period. This provided an opportunity to use a high percentile of the frequency distribution of data to estimate exposure concentrations. This is a precautionary approach routinely taken in screening risk assessments. Nevertheless, for some of the determinands, significantly greater numbers of samples are needed before the measured exposure concentration can be deemed reliably 'representative' for the CLO (Environment Agency, 2009b).

ii. **Undiluted CLO present potential environmental and human health risks from metals and priority organic micropollutants.**
When used as soil-forming material (e.g. for reclamation, regeneration and landscaping) several metals and the priority organic chemicals DEHP, PFOS, benzo-a-pyrene and triclosan present potential risks to the environment and human health. This conclusion was also made by the original report (Environment Agency, 2009a).

iii. **If CLO were applied to agricultural land at rates limited by nitrogen, environmental risks could arise for Cd, Cr and Zn, accounting for the existing concentrations of these metals in the receiving soil**.
There are no potential risks from metals identified for human health. Similar patterns of risk were noted when exposure concentrations were calculated using the 5 t ha^{-1} yr^{-1} application rate. The identification of environmental risks was significantly influenced by the use of generic ambient background metal concentrations.

iv. **The 90th percentile levels of plastics at all sites were relatively high, especially for site S1.**

v. **The development of ecological limit values for PFOS, triclosan, PAHs and some of the priority phthalates in CLO has significantly reduced the uncertainty associated with the assessment of risks from these chemicals.**

vi. **Benzo-a-pyrene remains a potential environmental and human health risk for all the exposure scenarios.**

vii. **Significant uncertainty remains when assessing potential human health risks.**
There are very few established soil guideline values (SGVs) and their use in the context of land application is also questionable. This report relies heavily on limits from other jurisdictions. There is a need for a policy decision from the Environment Agency on the preferred choice of provisional human health limit values when UK values are not available. If acceptable sources of information on tolerable daily intakes (TDIs) for chemical substances can be agreed, it would be possible to develop exposure scenarios for comparison with these TDIs and to perform a risk assessment for all substances found in the CLOs.

viii. **Site specific refinements to the assessment would reduce uncertainties and limit the use of assumptions in the calculations.**
Calculations of exposure concentrations and the subsequent effects assessment

and risk characterisation would be greatly improved with more readily available site specific information. The ambient background concentrations of chemicals used in the loading scenarios have an overriding influence on the identification and characterisation of potential environmental risks.

5 References

DoE, 1986. Code of practice for agriculture use of sewage sludge. DoE Publications.

DEFRA, 2002. Guidelines for farmers in NVZs – England. Department for Environment, Food and Rural Affairs, Defra Publications, London (PB5505).

DEFRA, 2007. Draft code of good agricultural practice to protect water, soil and air quality. Department for Environment, Food and Rural Affairs, London.

EC, 2003. Technical Guidance Document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment of existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. European Commission, Joint Research Centre, EUR 20418 EN.

ENVIRONMENT AGENCY, 2007a. Biowaste materials: Quality and sustainability for land recycling. PO30129085, Environment Agency, Bristol.

ENVIRONMENT AGENCY, 2007b. UK Soil and herbage pollutant survey. Report SCHO0307. Environment Agency, Bristol.

ENVIRONMENT AGENCY, 2007c. Draft derivation of soil screening values for priority contaminants total petroleum hydrocarbons. Unpublished report. Environment Agency, Bristol.

ENVIRONMENT AGENCY, 2008. Guidance on the use of soil screening values for assessing ecological risks. SC070009/SR. Environment Agency, Bristol.

ENVIRONMENT AGENCY, 2009a. A review of human health and environmental risks associated with the land application of mechanical-biological treatment outputs. SC030144/SR. Environment Agency, Bristol.

ENVIRONMENT AGENCY, 2009b. Assessment of MBT input and output quality. SC030144/SR. Environment Agency, Bristol. In Press.

ENVIRONMENT AGENCY, 2009c. Soil Guideline Values (http://www.environment-agency.gov.uk/research/planning/64015.aspx) Accessed 25/6/2009.

MCGRATH, S. P., 1995. Chromium and Nickel. Chapter in: Heavy metals in soils, Ed. BJ Alloway. 2nd Edition. Blackie Academic and Professional. London. pp152–178.

RIVM, 2001. Technical evaluation of the intervention values for soil/sediment and groundwater. RIVM report 711701 023, RIVM, Bilthoven, The Netherlands.

THE NETHERLANDS, 2008. European Union risk assessment report on coal-tar pitch, high temperature. Prepared by The Netherlands, RIVM on behalf of the European Union. Draft of April 2008.

WRAP, 2007. Quality Protocol: Compost. Waste and Resources Action Programme and the Environment Agency, Banbury, Oxon.

ZHAO, F. J., MCGRATH, S. P. AND MERRINGTON, G., 2007. Estimates of ambient background concentrations of trace metals in soils for risk assessment. Environmental Pollution, 148, 221–229.

ZMORA-NAHUM, S., HADAR, Y., CHEN, Y., 2007. Physicochemical properties of commercial composts varying in their source materials and country of origin. Soil Biology & Biochemistry 39:1263–1276.

6 Abbreviations and definitions

AF	assessment factor
BaP	benzo-a-pyrene
CLO	compost-like outputs
DEHP	Diethylhexyl phthalate
EC_x	effect concentration for x% of the tested population
ED_x	effect dose for x% of the tested population
ERA	environmental risk assessment
EqP	equilibrium partitioning
European TGD	Technical Guidance Document
HC_x	hazardous concentration for x% of the species
LC_x	lethal concentration for x% of the tested population
LOEC	lowest observed effect concentration
MBT	mechanical biological treatment
MHT	mechanical heat treatment
NOEC	no observed effect concentration
OM	organic matter
PAH	polycyclic aromatic hydrocarbons
PCDD/F	polychlorinated dibenzodioxin and dibenzofuran
PEC	predicted environmental concentration
PFOS	Perfluorooctanesulphonate
PNEC	predicted no effect concentration
RCR	risk characterisation ratio
SGV	soil guideline value
SOC	soil organic carbon
SRC	serious risk concentrations
SSV	soil screening value
TPH	total petroleum hydrocarbons
TDI	tolerable daily intake

Annex A. Derivation of terrestrial predicted no effect concentrations (PNECs) for perfluoroctanesulphonate (PFOS)

A.1 Summary

This annex describes the derivation of Predicted No Effect Concentrations (PNECs) for **perfluorooctanesulphonate (PFOS)**.

The $PNEC_{soil}$ for PFOS is 0.29 mg kg^{-1}. The $PNEC_{soil}$ to protect against secondary poisoning is 26.3 μg kg^{-1}, which was extrapolated from a $PNEC_{secondary\ poisoning}$ of 0.067 mg kg^{-1} (wet weight in food). In accordance with usual practice and to ensure protection against ecological risk in the terrestrial environment, the recommended PNEC for PFOS is **26.3 μg kg^{-1} wet soil (29.9. μg kg^{-1} dry soil).** This value is derived by an assessment factor approach based on toxicity data for PFOS in soil, followed by an extrapolation procedure to derive a soil concentration from the prey concentration. The overall uncertainty associated with the final PNEC is high. The $PNEC_{secondary\ poisoning}$ itself is associated with low uncertainty, because it was based on chronic toxicity data for 11 endpoints. However, the procedure to extrapolate from the $PNEC_{secondary\ poisoning}$ to a soil concentration resulted in quite a wide concentration range (5.9 – 100 μg kg^{-1} wwt). Despite this, even the highest value in this range is more stringent than the $PNEC_{soil}$ for direct toxicity (Table A1.).

Table A1 Overview of the data used in the assessment.

Substance name		
Perflourooctanesulphonate (PFOS)		
CAS nr		
2795-39-3 (for potassium salt)		
Summary of acceptable data (number of data and range in mg kg^{-1})		
Group		
Terrestrial – plants	6 NOECs/EC10s (15.6 – 62.5 mg kg^{-1})	
Terrestrial – invertebrates	1 LC50 (373 mg kg^{-1})	
Terrestrial – microorganisms	None	
Terrestrial - avian	2 NOECs (5 – 10 mg kg^{-1}) 2 LC50s (212 – 603 mg kg^{-1})	
Terrestrial – mammalian	11 NOAELs (0.025 – 1.6 mg kg^{-1} bw d^{-1})	
Derivation of PNEC		
	$PNEC_{soil}$	**$PNEC_{oral}$ (secondary poisoning)**
PNEC derivation method	AF approach	AF approach
Critical toxicity data	27.79 mg kg^{-1} for plants (normalised to standard 3.4% organic matter content)	0.1 mg kg^{-1} bw d^{-1} (equivalent to 2 mg kg^{-1} in food) for rats
Assessment Factor	100	30
PNEC(mg kg^{-1} wwt)	0.28 mg kg^{-1}	0.067 mg kg^{-1} (prey concentration) 5.9 – 100 μg kg^{-1} (extrapolated soil concentration range 26.3 μg kg^{-1} (extrapolated mean soil concentration)
$PNEC_{soil, sec. pois}$ (μg kg^{-1} dwt)		6.6 – 114 μg kg^{-1} (extrapolated soil concentration range 29.9 μg kg^{-1} (extrapolated mean soil concentration)
Uncertainty	Medium	High. Extrapolation from $PNEC_{secondary\ poisoning}$ to a soil concentration introduces considerable uncertainty.

A.2 Introduction

Perfluorooctanesulphonate (PFOS) concentrations have been detected in surface water (up to 0.183 μg l^{-1}) and sediments (up to 53.1 ug kg^{-1} dry weight) downstream of production facilities, as well as in wastewater treatment works effluent (0.041 – 5.29 μg l^{-1}) and sewage sludge (0.2 – 3120 ug kg^{-1} dry weight) at a number of urban centres in a United States survey (cited in Environment Agency 2004). In recent surveys of UK groundwaters and surface waters, concentrations in the range of <0.1 to 6.3 μg l^{-1} and <0.1 to 14.5 μg l^{-1} have been found. The surface water concentrations were detected at 8% of the sites sampled, suggesting that any current inputs are intermittent, at low concentrations or localised (Environment Agency 2007).

In samples of Mechanical Biological Treatment / mechanical heat treatment Compost-like outputs (CLO) taken during the course of this and previous projects (Environment Agency 2008) concentrations in the range of <0.1 to >8.4 μg kg^{-1} have been detected. Various other perfluorinated compounds have also been detected in the samples (perfluorobutane sulphonic acid, perfluoro hexanoic acid, perfluoro heptanoic acid, perfluoro octanoic acid, perfluoro nonanoic acid, perfluoro decanoic acid, perfluoro undecanoic acid, perfluoro dodecanoic acid and perfluoro hexane sulphonate), but PFOS was consistently present at the highest concentrations amongst the perfluorinated compounds and also presents the greatest concern

toxicologically. For these reasons, this section on the evaluation of effects data for the derivation of a PNEC focuses on PFOS, and does not extend to other related perfluorinated compounds.

A.3 PNEC derivation

The major chemical and physical properties of PFOS are summarized in Table A2.

Table A2 Physical and chemical properties of PFOS potassium salt.

Property	Value
CAS	2795-39-3
molecular weight	538
physical state	White powder
melting point	>400°C
boiling point	Not calculable
vapour pressure	3.31×10^{-4} Pa @20°C
Henry's constant	3.19×10^{-4} Pa m^3 $mole^{-1}$ – from vapour pressure/solubility ratio
log Kow	Not possible to measure -1.08 (calculated in OECD 2002) 4.13 (calculated in Brooke et al. 2004)
water solubility	519 mg L^{-1} @20°C
Acid dissociation constant (pKA)	-3.27 (calculated)

Taken from Brooke et al. (2004) unless otherwise indicated.

Ecotoxicity data collation followed a tiered approach. First, terrestrial toxicity data were collated from the Environment Agency's Environmental Risk Evaluation Report (RER) for PFOS (Brooke et al. 2004). Further data were sought from the open literature from 2004 onwards (last date of literature search in the RER) using the following resources:

- Published literature data were obtained from searches on Web of Science[1] and ScienceDirect®[2]
- USEPA Ecotox database[3]

Each database was searched initially with two sets of keywords: i) terms for PFOS and, ii) terrestrial and mammalian/avian search terms. The abstracts of articles were then screened for potentially relevant articles. Full details of search terms can be found in Table A3.

The source data in Brooke et al. (2004) were assumed to be quality assured and were not assessed further in this report. In addition, due to resource and time constraints, effects data from the open literature were extracted and compiled from the abstracts, and only evaluated further if they were more sensitive than the data used to derive PNECs in Brooke et al. (2004).

[1] http://www.isiwebofknowledge.com
[2] http://www.sciencedirect.com/
[3] http://cfpub.epa.gov/ecotox/

Table A3 Search terms used for literature searching.

Chemical keywords	**Perfluorooctanesulphonate, perfluorooctanesulfonate, PFOS**
Terrestrial ecotoxicity keywords	terrestrial or soil or earthworm or plant or agriculture or sludge or waste or biowaste or compost or biosolid or land or *Eisenia* or collembola or *Folsomia* or enchytraeid or *Enchytraeus* or mite or *Hypoaspis* or seedling emergence or seedling or vegetative vigour or worm or springtail or vigor
Secondary poisoning keywords	Mammal* or avian or bird or rat or mouse or mice or dog or monkey or mallard or bobwhite or quail

Ecotoxicity data for the terrestrial environment are *very* limited. Only one earthworm and one plant study were available at the time the Environment Agency's RER was produced. These are summarised in Table A4. No further relevant studies were found from searches of the open literature.

Table A4 Terrestrial ecotoxicity data cited in Brooke et al. (2004).

Species	Common name	Study duration	Endpoint	Concentration (mg kg^{-1})	Substrate	Chemical anaysis	Method	Reference
Eisenia fetida	Earthworm	14 day	LC50	373	Artificial soil	Y[1]	Based on OECD 207	3M (2003) cited in Brooke et al. (2004)
Eisenia fetida	Earthworm	14 day	NOEC	77	Artificial soil	Y[1]	Based on OECD 207	3M (2003) cited in Brooke et al. (2004)
Allium cepa and *Lolium perenne*[2]	Onion and ryegrass	21 day	$NOEC_{emergence}$	62.5	Soil	Y[5]	Based on OECD 208	Brignole et al. (2003)
Allium cepa and *Lycopersicon esculentum*[2]	Onion and tomato	21 day	$NOEC_{survival}$	15.6	Soil	Y[5]	Based on OECD 208	Brignole et al. (2003)
Lactuca sativa[2]	Lettuce	21 day	$NOEC_{shoot\ height}$	<3.91[3]	Soil	Y[5]	Based on OECD 208	Brignole et al. (2003)
Lactuca sativa[2]	Lettuce	21 day	$NOEC_{shoot\ weight}$	<3.91[4]	Soil	Y[5]	Based on OECD 208	Brignole et al. (2003)

[1] Measured on days 0 and 14 and found to be within 80% of nominal.
[2] Seven plant species were included in the study; only the lowest NOECs for each endpoint are reported here
[3] 23% reduced compared to control. [4] 35% reduced compared to control.
[5] Concentrations measured on day 9 were within 70% of nominal. Concentrations also measured on day 21, but results considered to be artefacts due to irrigation and sampling methods used. Concentrations are reported as nominal.

Very limited effects data are available for the terrestrial compartment. Toxicity data are available for two trophic levels: producers (plant study) and consumers (earthworm study). When data are available for a producer, consumer and/or a decomposer, the $PNEC_{soil}$ is calculated using assessment factors.

One short term test is available for earthworms, with a 14 day LC50 of 373 mg kg^{-1} dwt. Applying a safety factor of 1000 to this value results in a $PNEC_{soil}$ of 0.373 mg kg-^{1} (or 373 µg kg^{-1}).

The plant study can be considered as a long-term study. According to the TGD an assessment factor of 100 would therefore be appropriate.

The most sensitive data point is the LOEC of <3.91 mg kg^{-1} for shoot height and weight in lettuce. Lettuce shoot weight was reduced by 35% and shoot height by 25% of controls. According to the TGD, a NOEC should be derived from a LOEC prior to PNEC derivation. If the LOEC is ≥ 20% effect and a distinct effect relationship exists, then the EC10 is calculated or extrapolated and regarded as the NOEC.

EC10s of 7.3 mg kg^{-1} (95% confidence interval: 0.01-5016.3) and 15.6 mg kg^{-1} (95% CI: 5.5-44.1) were calculated for shoot height and shoot weight, respectively, using the US EPA's TRAP software and a logistic model with exposure concentrations logged. The LOEC value reported in the study is lower than the EC10 derived, which is due to the different statistical derivation methods of the two values. It is possible to have a NOEL or LOEC value higher than the EC10 value (Hoekstra and van Ewijk 1993). Given the poor 95% confidence intervals for the shoot height EC10, the shoot weight EC10 of 15.6 mg kg^{-1} will be used for PNEC derivation.

The organic matter content of the soil used in this study was 2.1%. Following the normalization step to a standard organic matter content of 3.4%, as recommended in the TGD, results in an EC10 of 25.26 mg kg^{-1}. A further adjustment to derive a dry weight concentration based on a soil moisture content of 15% results in an EC10 of 27.79 mg kg^{-1} dry weight. Since data are only available for two trophic levels, an assessment factor of 100 is justified. This results in a PNEC of 0.28 mg kg^{-1}.

Triggers for the assessment of **secondary poisoning** in the TGD include a log Kow ≥ 3 or if a substance is known to have a potential to accumulate in living organisms. The surface active properties of PFOS do not allow direct measurements of log Kow. In a preliminary study reported by 3M an inseparable emulsion was formed (Brooke et al. 2004). The log Kow can, however, be calculated by various methods, which result in estimated log Kows ranging from –1.08 to 4.13 (Table A2). Given that some estimates fall in the range ≥ 3 and the fact that PFOS has been detected in various mammalian species, derivation of a PNEC for secondary poisoning of predators is justified.

Mammalian toxicity

The mammalian data in Brooke et al. (2004) were extracted from the OECD hazard assessment for PFOS (OECD 2002). The data are summarised in Table A5. Additional data extracted from abstracts of studies found in the open literature are also summarised in Table A5. Due to time and resource constraints, it was agreed that only studies with more sensitive endpoints should be evaluated further. However, none of the new data were more sensitive. They do, however, support the choice of NOEC for PNEC derivation in Brooke et al. (2004).

The lowest NOAEC is 0.5 ppm, for liver effects in male rats in a two year study (OECD 2002, cited in Brooke et al. 2004). Following a consultation on the draft evaluation report, the reviewers suggested that the NOAEC of 0.5 ppm for liver effects was an over-conservative choice of endpoint. One alternative they proposed was the 2 ppm LOAEC from the same study. The UK Committee on Toxicology, in their statement on PFOS, considered that the NOAEL for non-neoplastic liver pathology in this study to be 2 ppm, i.e. a mean achieved dose of 0.16 – 0.14 mg kg^{-1} bw^{-1} day^{-1} for males and females, respectively. This was based on the

consideration that the low incidence of liver hypertrophy (3/17 and 1/9 in males and females, respectively, at 2 ppm, compared with 0/11 and 0/25 for males and females in the control group) associated with a lack of any effect on liver weight at this dose did not represent an adverse effect.

Four further relevant chronic studies are available in the open literature since 2004 (Table A5). Three of these studies report NOAELs in the range of 0.1 to 0.4 mg kg^{-1} bw d^{-1}. A NOAEL of 0.1 mg kg^{-1} bw d^{-1} for overall parental effects was reported in a two generation study in rats (Luebker et al. 2005a), whilst a NOAEL of 0.4 mg kg^{-1} bw d^{-1} was found for decreased gestational length in a rat developmental study (Luebker et al. 2005b). In mice, a NOAEL of 0.1 mg kg^{-1} bw d^{-1} was found for suppressed immune activity (Kell et al. 2008). These studies lend weight to the reviewers' recommendation of the alternative NOAEL of 0.1 mg kg^{-1} bw d^{-1} (equivalent to a NOEC of 2 mg kg^{-1}).

Avian toxicity

The avian data cited in Brooke et al. (2004) are summarised in Table A5 together with two additional studies found in the open literature published since 2004. The study by Newsted et al. (2007) appears to be the 3M data cited Brooke et al. (2004), which has now been published.

None of the new data are more sensitive than the data reported in the risk evaluation report. However, the lowest NOAEC is <10 mg kg^{-1} (diet) for a reduction in offspring survival found in a 21-day dietary exposure of bobwhite quail (3M 2005, cited in Brooke et al. 2004; Newsted et al. 2007). The risk evaluation report uses the LOAEC of 10 mg kg^{-1} (diet) to derive the PNEC. According to the TGD, a NOEC should be derived from a LOEC prior to the PNEC derivation step. If the LOEC is >10 % and <20% effect, then a NOEC can be derived by dividing the LOEC by two. The reduction in offspring survival as a percentage of eggs placed for incubation was 15% less in the 10 mg kg^{-1} exposure group than the control (Newsted et al. 2007). Therefore, a NOEC of 5 mg kg^{-1} can be derived for this study.

Table A5 Mammalian and avian toxicity data.

Study type	Organism	Effect	NOAEL (mg kg^{-1} bw d^{-1})	LOAEL (mg kg^{-1} bw d^{-1})	NOEC (mg kg^{-1} diet)	LOEC (mg kg^{-1} diet)	LC50 or LD50	Reference
Mammals								
Two year carcinogenicity	Rat	Liver effects	0.025*		0.5	2		cited in 1
7 week toxicity	Monkey	Lethality	0.1	0.4				cited in 1
Two generation toxicity	Rat	Pup weight reduction in 2nd generation	0.1	0.4				cited in 1
Developmental toxicity	Mouse	Neonatal lethality	1	10				2
28 day dietary toxicity	Rat	Body weight reduction			-	50		3
28 day dietary toxicity	Rat	Body weight /liver increase	< 0.14	0.14	<2	2		3
Two generation toxicity	Rat	Repro outcome F0	1.6	-				4
Two generation toxicity	Rat	Overall parental effects	0.1	-				4
Two generation toxicity	Rat	Overall offspring effects	0.4	-				4
Developmental toxicity	Rat	Decreased gestation length	0.4	0.8				5
Developmental toxicity	Rat	Decreased offspring viability	1.2	1.6				5
Developmental toxicity	Mouse	Suppressed immune function	0.1	1				6
Avian								
5 day acute toxicity	Mallard	Lethality					603 mg kg^{-1} diet	cited in 1
5 day acute toxicity	Quail	Lethality					212 mg kg^{-1} diet	cited in 1
21 week dietary reproduction	Mallard	Spermatogenesis		10	<10 (5**)	10		cited in 1
21 week dietary reproduction	Quail	Decreased survivorship of offspring		10	<10 (5**)	10		cited in 1
21 week dietary reproduction	Mallard	Lethality			10	50		7
21 week dietary reproduction	Quail	Decreased survivorship of offspring		10	<10 (5**)	10		7
5 day acute	Mallard	Lethality			141		150 mg kg^{-1} bw d^{-1}	8
5 day acute	Quail	Lethality			70.3		61 mg kg^{-1} bw d^{-1}	8

Note: Data from references 2 – 9 were extracted from abstracts

* Derived using conversion factors in TGD for comparison with other NOAELs
**Derived from the LOEL
1 Brooke et al. 2004
2 Yahia et al. 2008
3 Lefebvre et al. 2008
4 Luebker et al. 2005a
5 Luebker et al. 2005b
6 Keil et al. 2008
7 Newsted et al. 2007
8 Newstead et al. 2006

Derivation of $PNEC_{oral}$ for secondary poisoning

The lowest mammalian NOAEC is 0.5 ppm, for liver effects in male rats from a chronic study. Applying a safety factor of 30 is appropriate for chronic studies, resulting in a PNEC of 0.0167 mg kg^{-1} in food. Following consultation on the draft evaluation report, the reviewers suggested that the NOAEC of 0.5 ppm for liver effects was an over-conservative choice of endpoint. The alternatives proposed were the 2 ppm LOAEC from the same study, or a NOAEL of 0.1 mg kg^{-1} bw d^{-1} from the two generation study in rats. NOAELs of 0.1 to 0.4 mg kg^{-1} bw d^{-1} have also been reported in further studies with rats (Luebker et al. 2005a, 2005b). Applying a conversion factor of 20 provided in the TGD to derive a concentration in food for the NOAEL of 0.1 mg kg^{-1} bw d^{-1} results in a NOEC of 2 mg kg^{-1}, which is equivalent to the LOAEC of the first study.

Applying a safety factor of 30 for chronic studies to the NOEC of 2 mg kg^{-1} results in a PNEC of 0.067 mg kg^{-1} (or 67 µg kg^{-1}).

The lowest avian NOEC is 5 mg kg^{-1}, derived from a LOEC of 10 mg kg^{-1} (see section 3.2.3.2) for reduction in offspring survival in a chronic study with bobwhite quail. Applying a safety factor of 30 for chronic avian studies to the NOEC of 5 mg kg^{-1} results in a PNEC of 0.167 mg kg^{-1} (or 167 µg kg^{-1}).

The mammalian PNEC is the lower of the two PNECs, and should be taken forward for use in risk assessment.

Conversion of $PNEC_{oral}$ to a $PNEC_{soil}$ for secondary poisoning

It is necessary to derive a soil concentration which can be considered as being protective against secondary poisoning so that soil concentrations, rather than the concentrations in prey organisms, can be used to assess potential risks to terrestrial predators. The concentration in worms (which are assumed to be the principal food source of terrestrial predators) can be estimated from a soil concentration according to current risk assessment guidance (ECHA 2008). It is therefore possible, in principle, to work backwards from a critical concentration in worms (the $PNEC_{oral}$ for predators) to derive a critical soil concentration below which risks due to secondary poisoning in terrestrial food chains would not be anticipated.

The concentration of a substance in worms can be calculated according to Equation R.16-78 from EC (2003). This requires information on the concentration of the substance in both soil and soil pore water. However, the soil pore water concentration is calculated from the soil concentration and the $K_{soil:water}$ value (a partition coefficient for partitioning of the substance between soil solids and soil pore water). It follows, therefore, that the soil concentration is required to calculate the soil pore water concentration before it is possible to back calculate from a critical concentration in worms to the critical soil concentration.

In order to resolve this problem the critical soil concentration is derived by an iterative process of modifying the input soil concentration until the predicted concentration in worms is equal to the $PNEC_{oral}$ (the critical concentration in worms). The resulting soil concentration is the critical soil concentration for secondary poisoning of terrestrial predators ($PNEC_{soil,\ sec.\ pois.}$).

The derived concentrations are subject to uncertainties about both the bioaccumulation of the substance and its partitioning between soil and soil pore water. It is important for these uncertainties to be taken into account so that the critical soil concentration for secondary poisoning can be compared against critical soil concentrations for other endpoints, such as direct effects on terrestrial ecosystems.

A BCF value for worms can be estimated from data reported from a toxicity study, by estimating the reported exposure concentrations in terms of the pore water concentration. The BCF values form the original report are derived on a total soil basis rather than on a soil pore water basis. Soil pore water concentrations can be calculated from $K_{soil:water}$ values according to Equation A1.

$$K_{soil:water} = C_{total} / C_{spw} \quad \text{(Eqn A1)}$$

Adsorption and desorption coefficients for the partitioning of PFOS in three different types of soils have been reported (Environment Agency 2004), and information about the range of possible partition coefficients can be estimated from this information. This results in $K_{soil:water}$ values of between 10.73 and 48.1 l kg^{-1}, with a mean value of 27.9 l kg^{-1}. These $K_{soil:water}$ values can then be used to estimate a reasonable range of soil pore water concentrations to which the worms were exposed. This results in a range of worm BCF values between 27.2 and 122, with a mean value of 68.0.

Calculation of critical total soil PFOS concentrations for secondary poisoning, taking into account the uncertainty in the partitioning behaviour of the substance results in a range of concentrations between **5.8** and **100 μg kg^{-1} (wwt)**, with a mean value of **26.3 μg kg^{-1} (wwt).** This is equivalent to 6.6 to 114 μg kg^{-1} dry weight, with a mean value of **29.9 μg kg^{-1} (dwt).**

An alternative approach to derive a BCF can be taken which considers all of the BCF data together and derives a BCF on the basis of a potential relationship with exposure concentrations. This approach has not been used for PNEC derivation, but is included here for comparison given the uncertainties in the partitioning and uptake behaviour of PFOS.

Bioconcentration factors for four species have been reported (Environment Agency 2004) for a range of exposure concentrations. There are 12 BCF values in total covering a range of exposure concentrations between 0.002 and 79 mg l^{-1}. There is a statistically significant relationship between the $\log_{10}$(BCF) and the $\log_{10}$(exposure concentration) ($p < 0.001$), with lower BCF values observed for higher exposure concentrations (see Figure A1). BCF values can therefore be estimated for different exposure concentrations using the derived relationship (Equation A2).

$$\text{Log}_{10}\text{BCF} = -0.889(\log_{10}\text{Exposure (mg l}^{-1})) + 1.333 \quad \text{(Eqn A2)}$$

The $K_{soil:water}$ values derived above can then be used to estimate a reasonable range of soil pore water concentrations which may result from the predicted critical total soil concentration. The resulting soil pore water concentrations range from 0.7 to 10.9 μg l^{-1}, with a mean value of 2.8 μg l^{-1}. The estimated soil pore water concentrations derived above can then be used to estimate a range of possible BCF values from equation A1 (and applying the upper and lower 95% confidence intervals about the relationship to estimate the range of BCF values).

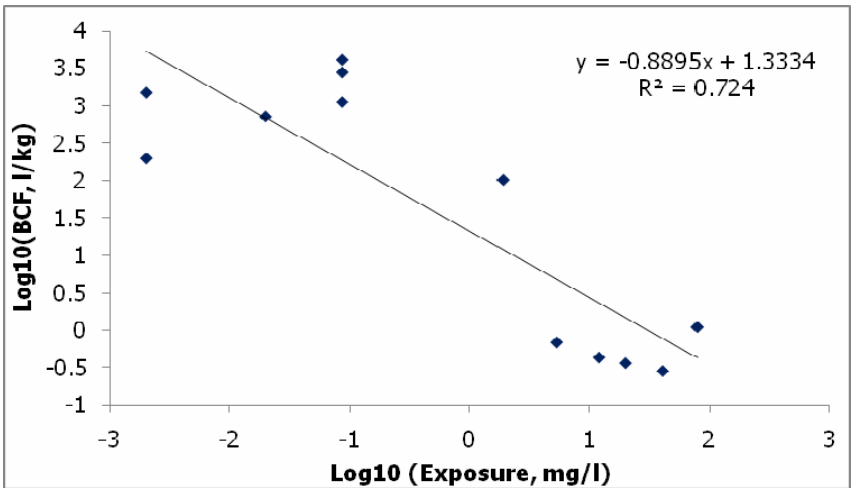


Figure A1. Relationship between exposure concentration and BCF for PFOS.

The above procedure results in BCF values of between 5.0 and 89 l kg^{-1}, with a mean value of 21.3 l kg^{-1}. The resulting critical soil concentrations for secondary poisoning of terrestrial predators range from 0.034 to 0.117 mg kg^{-1} wet weight (34 to 117 µg kg^{-1}), with an average value of 0.077 mg kg^{-1} wet weight (77.5 µg kg^{-1}). Using the conversion factor provided in the TGD (1.13) for wet to dry weight conversion this results in a concentration range of 0.038 to 0.132 mg kg^{-1} (38 – 132 µg kg^{-1}) and an average value of 0.087 mg kg^{-1} (87 µg kg^{-1}) dry weight. These calculations assume a $PNEC_{oral}$ value of 0.067 mg kg^{-1} (67 µg kg^{-1}) for predators.

Given the uncertainties surrounding both the partitioning and uptake of PFOS we recommend that $PNEC_{soil,\ sec.\ pois}$ values are considered as provisional, and preference is given to the analysis of prey samples (e.g. worms) where possible.

A.4 References

Brignole AJ, Porch JR, Krueger HO, van Hoven RL. 2003. PFOS: A toxicity test to determine the effects of the test substance on seedling emergence of seven species of plants. Final Report submitted to 3M by Wildlife International Ltd, Maryland USA.

Brooke D, Footitt A, Nwaogu TA. 2004. Environmental risk evaluation report: perfluorooctanesulphonate (PFOS). Environment Agency report.

EC, 2003 Technical Guidance Document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment of existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. European Commission, Joint Research Centre, EUR 20418 EN.

Environment Agency. 2004 Investigation of PFOS and other perfluorchemicals in groundwater and surface water in England and Wales. Product code GEHO0807BNAN-E-E.

Environment Agency. 2008. A review of human health and environmental risks associated with the land application of mechanical-biological treatment outputs. Science report SC030144.

Hoekstra JA, Van Ewijk PH. 1993. Alternatives for the no-observed-effect level. Environmental Toxicology and Chemistry 12:187-194.

Keil DE, Mehlmann T, Butterworth L, Peden-Adams MM. 2008. Gestational exposure to perfluorooctane sulfonate suppresses immune function in B6C3F1 mice. Toxicological Sciences 103:77-85.

Lefebvre DE, Curran I, Armstrong C, Coady L, Parenteau M, Liston V, Barker M, Aziz S, Rutherford K, Bellon-Gagnon P, Shenton J, Mehta R, Bondy G. 2008. Immunomodulatory effects of dietary potassium perfluorooctane sulfonate (PFOS) exposure in adult Sprague-Dawley Rats. Journal of Toxicology and Environmental Health – Part A-Current Issues 71:1516-1525.

Luebker DJ, Case MT, York RG, Moore JA, Hansen KJ, Butenhoff JL. 2005a. Two-generation reproduction and cross-foster studies of perfluorooctanesulfonate (PFOS) in rats. Toxicology 215:126-148.

Luebker DJ, York RG, Hansen KJ, Moore JA, Butenhoff JL. 2005b. Neonatal mortality from in utero exposure to perfluorooctanesulfonate (PFOS) in Sprague-Dawley rats: Dose-response, and biochemical and pharamacokinetic parameters. Toxicology 215:149-169.

Newsted JL, Beach SA, Gallagher SP, Giesy JP. 2006. Pharmacokinetics and acute lethality of perfluorooctanesulfonate (PFOS) to juvenile mallard and northern bobwhite. Archives of Environmental Contamination and Toxicology 50:411-420.

Newsted JL, Coady KK, Beach SA, Butenhoff JL, Gallagher S, Giesy JP. 2007. Effects of perfluorooctane sulfonate on mallard and northern bobwhite quail exposed chronically via the diet. Environmental Toxicology and Pharmacology 23:1-9.

OECD 2002. Hazard assessment of perfluorooctane sulfonate (PFOS) and its salts. ENV/JM/RD(2002)17/FINAL.

Yanai J, Dotan S, Goz R, Pinkas A, Seidler FJ, Slotkin TA, Zimmerman F. 2008. Exposure of developing chicks to perfluorooctanoic acid induces defects in prehatch and early posthatch development. Journal of Toxicology and Environmental Health – Part A-Current Issues 71:131-133.

Annex B. Derivation of terrestrial predicted no effect concentrations (PNECs) for polycyclic aromatic hydrocarbons (PAHs)

B.1 Summary

This annex briefly describes the derivation of predicted no effect concentrations (PNECs) for the 16 PAHs, namely:

- acenaphthene;
- acenaphthylene;
- anthracene;
- benzo(a)anthracene;
- benzo(a)pyrene;
- benzo(b)fluoranthene;
- benzo(k)fluoranthene;
- benzo(ghi)perylene;
- chrysene;
- dibenzo(a,h)anthracene;
- fluoranthene;
- fluorene;
- indeno(1,2,3-cd)pyrene;
- naphthalene;
- phenanthrene;
- pyrene.

A draft European Union risk assessment report (RAR) is available for coal tar pitch, high temperature (CTPHT). The focus of the RAR is on the 16 polycyclic aromatic hydrocarbons (PAHs) listed above. The EU RAR is the most recent authoritative evaluation of PAHs available, and the PNECs derived in the RAR evaluation are presented in Table B1 (The Netherlands, 2009).

Table B1 Overview of 16 PAH PNECs.

Substance	CAS nr	PNEC soil (mg kg^{-1} dw)	Assessment factor
Naphthalene	91-20-3	1.0	10
Acenaphthene	208-96-8	0.038	50
Acenaphthylene	91-20-3	0.29	100
Fluorene	86-73-7	1.0	10
Anthracene	120-12-7	0.13	50
Phenanthrene	85-01-8	1.8	10
Fluoranthene	206-44-0	1.5	10
Pyrene	129-00-0	1.0	10
Benzo(a)anthracene	56-55-3	0.079	10
Chrysene	218-01-9	0.55	EqP
Benzo(a)pyrene	50-32-8	0.053	10
Benzo(b)fluoranthene	205-99-2	0.28	EqP
Benzo(k)fluoranthene	207-08-9	0.27	EqP
Benzo(ghi)perylene	191-24-2	0.17	EqP
Dibenzo(a,h)anthracene	53-70-3	0.054	EqP
Indeno(1,2,3-cd)pyrene	193-39-5	0.13	EqP

Note: EqP: Equilibrium partitioning. No effects were seen up to the highest concentration in the few available ecotoxicity tests for these substances. The EU RAR used equilibrium partitioning to derive PNECs in these cases.

B.2 Introduction

The application of organic materials from non-agricultural sources to land can provide a range of agronomic benefits, including macronutrients such as nitrogen and phosphorus. However, these benefits must be balanced against the potential risks of any chemical contaminants also present within the applied material. This annex describes the derivation of terrestrial PNECs for 16 PAHs.

During the course of this and previous projects, individual PAH concentrations in the range of 6.8 to more than 520 µg kg^{-1} have been detected in samples of CLO (Environment Agency, 2008). The highest levels for individual PAHs were for fluoranthene and phenanthrene, as is usually the case for environmental solids.

A summary of the current state of information on the concentrations of PAHs in temperate top soils on a global scale is given by Wilcke (2000, cited in The Netherlands, 2009). Agricultural top soils on average contain 200 (median) and 350 (mean) µg kg^{-1} for the sum of the 16 PAHs. In forest soil the concentrations are somewhat higher with a mean and median around 900 and 400 µg kg^{-1}. The recent soil and herbage survey undertaken by the Environment Agency (2007) contains a comprehensive review of PAH concentrations in soils across the UK in both rural and urban areas.

Table B2 Physical and chemical properties of 16 selected PAHs.

Substance	**CAS No.**	Molecular **formula**	Molecular weight **(g mol^{-1})**	Melting point **(°C)**	Boiling point **(°C)**	Water solubility **(µg l^{-1})***	Log K_{ow}	Vapour pressure **(Pa at 25 °C)**	Density **(kg l^{-1})**	Henry's constant **(Pa m^3/mol at 25 °C)**
Naphthalene	91-20-3	$C_{10}H_8$	128.2	81	217.9[c]	31900[a]	3.34[c]	11.2[g]	1.154	50[l]
Acenaphthene	208-96-8	$C_{12}H_8$	154.2	96	278	3910[b]	4.00[e]	3.3 x 10^{-1}[h]	0.899	14.3[l]
Acenaphthylene	91-20-3	$C_{12}H_{10}$	150.2	92	279	16100[b]	3.62[f]	4.8 x 10^{-1}[i]	1.024	11.5[l]
Fluorene	86-73-7	$C_{13}H_{10}$	166.2	115-116	295[e]	1800[a]	4.22[e]	8.3 x 10^{-2}[i]	1.203	8.5[l]
Anthracene	120-12-7	$C_{14}H_{10}$	178.2	216.4	342[e]	47[a]	4.68[d]	9.4 x 10^{-4}[i]	1.283	4.3[l]
Phenanthrene	85-01-8	$C_{14}H_{10}$	178.2	100.5	340	974[a]	4.57[d]	2.6 x 10^{-2}[i]	0.980	3.7[l]
Fluoranthene	206-44-0	$C_{16}H_{10}$	202.3	108.8	375	200[a]	5.20[d]	1.2 x 10^{-3}[h]	1.252	1.1[o]
Pyrene	129-00-0	$C_{16}H_{10}$	202.3	156	360	125[a]	4.98[e]	1.0 x 10^{-3}[i]	1.271	1.4[n]
Benzo(a)anthracene	56-55-3	$C_{18}H_{12}$	228.3	160.7	435	10.2[a]	5.91[d]	7.6 x 10^{-6}[i]	1.226	0.81[p]
Chrysene	218-01-9	$C_{18}H_{12}$	228.3	253.8	448	1.65[a]	5.81[d]	5.7 x 10^{-7}[j]	1.274	0.079[q]
Benzo(a)pyrene	50-32-8	$C_{20}H_{12}$	252.3	175	496	1.54[a]	6.13[d]	7.3 x 10^{-7}[j]	1.35	0.034[o](20 °C)
Benzo(b)fluoranthene	205-99-2	$C_{20}H_{12}$	252.3	168.3	481	1.28[a]	6.12[f]	3.3 x 10^{-6}[k]	-	0.051[o](20°C)
Benzo(k)fluoranthene	207-08-9	$C_{20}H_{12}$	252.3	217	480	0.93[a]	6.11[d]	1.3 x 10^{-7}[k]	-	0.043[o](20°C)
Benzo(ghi)perylene	191-24-2	$C_{22}H_{12}$	276.3	277	545[i]	0.14[a]	6.22[d]	1.4 x 10^{-8}[j]	1.329	0.027[o](20°C)
Dibenzo(a,h)anthracene	53-70-3	$C_{22}H_{14}$	278.4	266.6	524	0.82[b]	6.50[e]	3.7 x 10^{-10}[j]	1.282	1.3.10^{-4}[q]
Indeno(1,2,3-cd)pyrene	193-39-5	$C_{22}H_{12}$	276.3	163.6	536	0.1*	6.58[f]	1.7 x 10^{-8}[k]	-	0.046[q]

The data presented in the table were taken form Mackay *et al*. (1992), cited in EC (2009). The selected values for water solubility were preferably based on generated column methods (*a*) and, if absent, on shake-flask (*b*) using geometric means (* for indeno(1,2,3-cd)pyrene no data were available, a default value of 0.1 µg l^{-1} was used). The selected values for log Kow were preferably based on slow-stirring/generator column (*c*) or slow-stirring methods (*d*) using average values. If absent the log Kow values were based on the shake-flask method (*e*), or in absence of data calculated using the ClogP model (*f*). The selected values for vapour pressure were based on manometry/gas saturation (*g*), gas saturation (*h*), gas saturation/effusion (*i*), effusion method (*j*) using geometric means or estimated using EPIWIN (*k*). The selected values for Henry's constant were based on batch/gas stripping/wetted-wall column (*l*), batch stripping/wetted-wall column (*m*), batch/gas stripping (*n*), gas stripping (*o*), batch column (*p*) using geometric means or, when no data were available, constants were calculated using EUSES 2.0 (*q*).

B.3 PNEC derivation

A draft European Union risk assessment report (RAR) is available for coal tar pitch, high temperature (CTPHT). The focus of the RAR is on polycyclic aromatic hydrocarbons (PAHs) only, since this was the main reason CTPHT was placed on a priority list for risk assessment (The Netherlands, 2009). The RAR is restricted to an assessment of the 16 EPA homocyclic PAHs, since sufficient effect and exposure data were only available for this group.

The EU RAR is the most recent authoritative evaluation of PAHs available, and evaluates the available terrestrial toxicity data for the derivation of terrestrial PNECs according to the TGD. For this reason only the PNECs, the critical data from which they were derived, and the derivation method are summarised in this annex. Details of all the effects data evaluated are not repeated in this annex, and the reader is referred to the EU RAR.

The PNECs derived in the draft EU RAR (2009) are summarised in Table B3, together with the critical endpoint and assessment factor (AF) used.

Table B3 Summary of terrestrial PNECs for 16 PAHs.

Compound	PNEC soil (mg kg^{-1} dw)	AF	Species	Critical endpoint
Naphthalene	1.0	10	*Folsomia candida*	NOEC reproduction
Anthracene	0.13	50	*Folsomia fimetaria*	EC_{10} reproduction
Phenanthrene	1.8	10	*Folsomia fimetaria*	EC_{10} reproduction
Fluoranthene	1.5	10	Nitrification	EC_{10} nitrification
Pyrene	1.0	10	*Folsomia candida*	NOEC reproduction
Fluorene	1.0	10	*Folsomia fimetaria*	EC_{10} reproduction
Acenaphthylene	0.29	100	*Folsomia fimetaria*	EC_{10} reproduction
Acenaphthene	0.038	50	*Lactuca sativa*	NOEC germination and shoot growth
Chrysene	0.55	EqP		No effects seen in three species tested
Benzo(a)anthracene	0.079	10	*Oniscus asellus*	EC_{10} growth
Benzo(b)fluoranthene	0.28	EqP		No effect seen in one species tested
Benzo(ghi)perylene	0.17	EqP		No effect seen in one species tested
Benzo(k)fluoranthene	0.27	EqP		No effect seen in two species tested
Benzo(a)pyrene[1]	0.053	10	*Porcellio scaber*	EC_{10} growth efficiency
Dibenzo(a,h)anthracene	0.054	EqP		No effect seen in one species tested
Indeno(123-cd)pyrene	0.13	EqP		No effect seen in one species tested

Notes: [1] See Section 2.4 of this annex for more information on benzo(a)pyrene.

For some PAHs – chrysene, benzo(b)fluoranthene, benzo(ghi)perylene, benzo(k)fluoranthene, dibenzo(a,h)anthracene and indeno(123-cd)pyrene – no effects were seen up to the highest exposure concentration in ecotoxicity tests. In these cases the EU RAR calculated the PNECs by equilibrium partitioning (EqP) by using the following equation:

$$PNEC_{soil} = \frac{K_{soil\text{-}water}}{RHO_{soil}} \bullet PNEC_{water} \bullet 1000$$

where:

RHO soil = the bulk of wet soil (1700 kg m^{-3})

$K_{soil\text{-}water}$ = partitioning coefficients for each of the affected PAHs:

Chrysene:	1.19 x104
Benzo(b)fluoranthene:	2.44 x104
Benzo(k)fluoranthene:	2.38 x104
Benzo(ghi)perylene:	3.06 x104
Dibenzo(a,h)anthracene:	5.85 x104
Indeno(1,2,3-cd)pyrene:	7.02 x104

There is evidence to suggest that the equilibrium partitioning method is insufficiently reliable for deriving PNECs, so the Environment Agency does not recommend its use for this purpose (Environment Agency, 2008). However, in the absence of relevant data, it can be regarded as an estimate for screening purposes. The TGD recommends that tests with soil organisms should be considered as an essential requirement for a refined effects assessment if the PEC/PNEC ratio (RCR) calculated using the equilibrium partitioning method is greater than one.

B.4 EU RAR PNEC and soil screening value for benzo(a)pyrene

The Environment Agency derived a soil screening value of 0.15 mg kg^{-1} dw. This was calculated by applying a safety factor of 10 to a NOEC of 1.47 mg kg^{-1} (normalised to 2% organic carbon content) for reproduction in the earthworm *Eisenia fetida* (Environment Agency, 2005).

The EU RAR derived a PNEC of 0.053 mg kg $^{-1}$ dw. This was calculated by applying a safety factor 10 to an EC_{10} of 0.53 mg kg^{-1} dw (normalised to 2% organic carbon content) for growth efficiency in the isopod *Porcellio scaber* (EU, 2009). This study was not included in the data review of the Environment Agency soil screening value report. The EU RAR is a more recent review of the available data, and the isopod study is a more sensitive endpoint than the earthworm endpoint. For these reasons, it is recommended that the EU RAR PNEC for benzo(a)pyrene be used. This is also in line with Environment Agency policy to directly adopt EU RAR PNECs.

B.5 Derivation of PNEC for secondary poisoning of predators

The TGD triggers an assessment for secondary poisoning when a substance has a log Kow ≥ 3 or if it is known to have a potential to accumulate in living organisms. The log Kows of all 16 PAHs are ≥ 3, so the trigger for the derivation of a PNEC for secondary poisoning of predators is met. However, according to the draft RAR, insufficient toxicity data are available for the derivation of a $PNEC_{oral}$. Therefore, this remains an

uncertainty in any assessment of potential terrestrial risks where monitoring data have established the presence of PAHs.

B.6 References

ENVIRONMENT AGENCY, 2005. Proposed soil screening value for benzo(a)pyrene. R&D report P6-020/5.

ENVIRONMENT AGENCY, 2007. UK Soil and herbage pollutant survey. Report SCHO0307, Environment Agency, Bristol.

ENVIRONMENT AGENCY, 2008. Guidance on the use of soil screening values for assessing ecological risks. Science report SC070009/SR.

THE NETHERLANDS, 2009. European Union Risk Assessment Report on coal-tar pitch, high temperature. Prepared by The Netherlands, RIVM on behalf of the European Union. R323_0711_ENV.

Annex C. Derivation of terrestrial predicted no effect concentrations (PNECs) for butylbenzylphthalate, dibutylphthalate and diethylhexylphthalate

C.1 Summary

This annex considers the derivation of predicted no effect concentrations (PNECs) for a range of phthalate esters, specifically butylbenzyl phthalate, dibutyl phthalate and diethylhexyl phthalate.

Due to limitations of time and resources only key studies have been considered. Current Environment Agency guidance is that where PNECs have already been derived as part of the European Union's programme of risk assessments for "Existing Substances" (793/93/EEC) these should be used as *de facto* limit values for the assessment of potential ecological risk. However, a review by Oehlmann *et al*. (2008) has cast doubt on the findings of some recent assessments for phthalates. The recent consultation from the Environment Agency (http://www.environment-agency.gov.uk /static/documents/Research/ssv_2149429.pdf) also clearly states that no PNEC will be recommended for a substance where there are no reliable terrestrial data or where there is significant remaining uncertainty surrounding the PNEC (usually due to the use an assessment factor of 50 or more).

The PNEC for butylbenzyl phthalate is 1.39 mg kg^{-1} wet soil. This value is derived using the equilibrium partitioning methodology and the aquatic PNEC of 7.5 µg l^{-1} derived from a NOEC from a chronic test on mysid shrimps. Terrestrial toxicity data for butylbenzyl phthalate is limited to a single acute worm test which produced an unbounded result (no effects at the highest test concentration) and from which no ecotoxicity summary statistic could be determined. The overall uncertainty associated with the final PNEC is high because it is based on chronic toxicity data from aquatic and not terrestrial species.

The PNEC for dibutyl phthalate is 0.28 mg kg^{-1} dry soil. This value is derived by an assessment factor approach based on toxicity data for di-butyl phthalate in soil. The overall uncertainty associated with the final PNEC is medium because it is based on chronic toxicity data for two endpoints from two trophic levels, and the value is at or close to the level of detection in soils for commercial laboratories.

The PNEC for diethylhexyl phthalate is greater than 13 mg kg^{-1} dry soil. This value is derived by an assessment factor approach based on toxicity data for diethylhexyl phthalate in soil. The overall uncertainty associated with the final PNEC is medium because it is based on chronic toxicity data for four endpoints from three trophic levels, but all the tests produced unbounded results and therefore the NOECs are the highest test concentrations tested as no effects were seen in any of the tests.

Dr. Marie-Amélie Paul of the European Council for Plasticisers and Intermediates was invited to participate in this brief consideration of the derivation of terrestrial PNECs for

a number of phthalates for the Environment Agency. However, she declined to take part in this work and stated that it was the "intention of the DEHP consortium …..to review all the available data on the health and environmental impact of DEHP and on the levels of exposure of humans and the environment. This review will include the EU Risk Assessment Report but will not be limited to it". This effectively means that industry generated data was not made available for the PNEC derivation process described here. A summary of the data used in the assessment is presented in Table C1a to Table C1c.

Table C1a Overview of the data used in the assessment: butylbenzyl phthalate.

Substance name		
Butylbenzyl phthalate*		
CAS No.		
85-68-7		
Summary of acceptable data (number of data and range in mg kg^{-1})		
Group		
Terrestrial – plants	None	
Terrestrial – invertebrates	1 acute test, not possible to derive LC_{50} as all organisms survived highest concentration.	
Terrestrial – microorganisms	None	
Terrestrial – avian	None	
Terrestrial – mammalian	>10 NOAEL (50–1000 mg kg^{-1} bw d^{-1})	
Derivation of PNEC		
	$PNEC_{soil}$	$PNEC_{oral}$ (secondary poisoning)
PNEC derivation method	Equilibrium Partitioning Methodology	AF approach
Critical toxicity data	0.075 mg kg^{-1} for aquatic invertebrates	50 mg kg^{-1} bw $d^{-1}$for developmental effects in rats
AF	100	30
PNEC(mg kg^{-1})	1.39 mg kg^{-1}	33 mg kg^{-1} (prey concentration)
Uncertainty	High	Medium

Note: * Data sourced from Norway (2007)

Table C1b Overview of the data used in the assessment: dibutyl phthalate.

Substance name		
Dibutyl phthalate[#]		
CAS No.		
84-74-2		
Summary of acceptable data (number of data and range in mg kg^{-1})		
Group		
Terrestrial – plants	1 NOEC (200 mg kg^{-1})	
Terrestrial – invertebrates	2 EC_{10}s (0.5–14 mg kg^{-1})	
Terrestrial – microorganisms	None	
Terrestrial – avian	None	
Terrestrial – mammalian	>12 NOAELs and LOAELs (52–600 mg kg^{-1} bw d^{-1})	
Derivation of PNEC		
	$PNEC_{soil}$	$PNEC_{oral}$ (secondary poisoning)
PNEC derivation method	AF approach	AF approach using a LOAEL
Critical toxicity data	14 mg kg^{-1} for collembolan reproduction	52 mg kg^{-1} bw d^{-1} oral LOAEL for rats
AF	50	0.5
PNEC(mg kg^{-1})	0.28 mg kg^{-1}	104 mg kg^{-1} (prey concentration)
Uncertainty	Medium	High, due to the use of a LOAEL for laboratory-based mammals.
Comments		

Note: [#] Data sourced from The Netherlands (2004) and Jensen *et al*. (2001)

Table C1c Overview of the data used in the assessment: diethylhexyl phthalate.

Substance name		
Diethylhexyl phthalate[$]		
CAS No.		
117-81-7		
Summary of acceptable data (number of data and range in mg kg^{-1})		
Group		
Terrestrial – plants	1 NOEC (> 130 mg kg^{-1})	
Terrestrial – invertebrates	2 NOECs (>1000 to >5000 mg kg^{-1})	
Terrestrial – microorganisms	1 NOEC (>300 mg kg^{-1})	
Terrestrial – avian	1 NOEC (1700 mg kg^{-1})	
Terrestrial – mammalian	> 10 NOAELs (4.8–50 mg kg^{-1} bw d^{-1})	
Derivation of PNEC		
	$PNEC_{soil}$	$PNEC_{oral}$ (secondary poisoning)
PNEC derivation method	AF approach	AF approach
Critical toxicity data	130 mg kg^{-1} for seedling emergence	4.8 mg kg^{-1} bw d^{-1} (equivalent to 100 mg kg^{-1} in food) for rats
AF	10	10
PNEC(mg kg^{-1})	13 mg kg^{-1}	3.3 mg kg^{-1} (prey concentration)
Uncertainty	Medium	High

Note: [$] Data sourced from Sweden (2008) and Jensen *et al*. (2001)

C.2 Introduction

Phthalate esters are used as plasticisers to soften synthetic polymers and they may constitute up to 50 per cent by weight of PVC plastics. Due to the high levels of use (the estimated global production of phthalates is 2.7 million tonnes) and continuous release to the environment, phthalates are routinely found in the terrestrial ecosystem (Oehlmann *et al.,* 2008). Phthalates are also regularly found in sewage sludge, waste waters and sediments of lowland streams.

Butylbenzyl phthalate (BBP) is used almost exclusively for indoor applications as plasticisers in sealants and adhesives and as an additive to vinyl flooring. The maximum concentration of BBP found in sediments was 120 mg kg^{-1} off the west coast of Sweden, but the greatest concentration recorded in sewage sludge from studies across Europe and the US was 3.5 mg kg^{-1}. Concentrations of BBP in CLO from the UK are similar to those recorded in sewage sludges (Environment Agency, 2009). Soil concentrations of BBP tend to be significantly lower than those observed in sludges and CLO (Norway, 2007).

Dibutyl phthalate, like the other phthalates considered in this annex, is a chemical produced in high volumes and is routinely found in the environment. Around three quarters of all dibutyl phthalate is used as plasticisers in resins and polymers and the remaining uses include printing inks, adhesives and cosmetics (Oelhmann *et al.,* 2008). Sewage sludges can contain relatively high concentrations of dibutyl phthalate of up to

25 mg kg^{-1}, but generally the range is between 0–5 mg kg^{-1}. Concentrations of up to 7.5 mg kg^{-1} have been measured in UK CLO (Environment Agency, 2009).

Diethylhexyl phthalate (DEHP) is used as a plasticiser in polymers, such as PVC. It represents 51 per cent of the total EU phthalate market use as plasticisers and is produced in the greatest volume (595,000 tonnes per annum; Oehlmann *et al.,* 2008). Concentrations in sewage sludge and soil are relatively low at between 1–3 mg kg^{-1} (Kinney *et al.,* 2008). Concentrations of over 200 mg kg^{-1} have been found in CLO (Environment Agency, 2009).

It has been widely reported that phthalates with shorter ester chains (such as butylbenzyl and dibutyl phthalates) can be readily degraded and mineralised, especially when compared to longer chain phthalates (such as diethylhexyl phthalate) which are much less susceptible to degradation. Furthermore, the rates of degradation of all the phthalates are significantly slower under anaerobic conditions; relatively high concentrations of phthalates and their metabolites have been shown to inhibit biodegradation significantly (Lang *et al.,* 2008).

C.3 PNEC derivation

The major chemical and physical properties of phthalate esters are summarised in Table C2.

Table C2 Physical and chemical properties of phthalate esters considered in this annex.

Property	Value
Butylbenzyl phthalate	
CAS	85-68-7
Molecular weight	312.35
Physical state	Clear oily liquid with a slight characteristic odour
Melting point	<−35°C
Boiling point	370°C
Vapour pressure	0.00112 Pa at 20°C
Henry's constant (calculated)	0.176 Pa m^3 mol^{-1}
Log Kow	4.84
Water solubility	2.8 mg l^{-1}
Dibutyl phthalate	
CAS	84-74-2
Molecular weight	278.3
Physical state	Oily liquid
Melting point	−69°C
Boiling point	340°C
Vapour pressure	9.7 ± 3.3 x10^{-5} hPa at 25°C
Henry's constant (calculated)	0.27 Pa m^3 $mole^{-1}$
Log Kow	4.57
Water solubility	10 mg l^{-1} at 20°C
Diethylhexyl phthalate (DEHP)	
CAS	117-81-7
molecular weight	390.6
physical state	Colourless oily liquid
melting point	−50°C
boiling point	385°C at 1013 Pa
vapour pressure	3.4 x10^{-5} Pa at 20°C
Henry's constant	4.43 x10^{-5} Pa m^3 $mole^{-1}$
log Kow	7.50
water solubility	0.003 mg l^{-1} at 20°C

Terrestrial toxicity data were collated from the relevant EU risk assessments, where they were available. Further data were then sought from the open literature from the date of the last official literature search in the EU risk assessments (2003, 1994 and 2005 for butylbenzyl phthalate, dibutyl phthalate and di-ethylhexyl phthalate, respectively) to the present date using two resources, namely:

- published literature data obtained from searches on Web of Science and ScienceDirect®;
- the USEPA Ecotox database.

Each database was searched initially with two sets of keywords: i) the substance name and, ii) terrestrial and soil related search terms. The abstracts of articles were then screened for potentially relevant articles. Full details of search terms can be found in Table C3. Relevancy was judged in terms of the adequacy, reliability and relevancy of the paper to terrestrial ecotoxicity for use in derivation of a PNEC for the chemical under consideration (EC, 2003).

Further additional searches were made of the OECD, USEPA, RIVM and KEMI sites using the generic search term 'phthalate' or the full substance name. The first 30 hits were briefly reviewed in each case, but no additional relevant information was found.

The source data in the EU risk assessment reports (RARs) were assumed to be quality assured and were not assessed further in this report. In addition, due to resource and time constraints, effects data from the open literature were extracted and compiled from the abstracts; they were only evaluated further if they were more sensitive than the data used to derive PNECs in the previous risk assessments.

Table C3 Search terms used for literature searching.

Chemical	Substance name AND	Number of hits	Number relevant and reviewed
Butylbenzyl phthalate	Terrestrial or soil or earthworm or plant or agriculture or sludge or waste or biowaste or compost or biosolid or land	12	0
Dibutyl phthalate		61	1
Diethylhexyl phthalate (DEHP)		71	0

Ecotoxicity data for the terrestrial environment are summarised in Table C4a to Table C4c. Several further relevant studies were found from searches of the open literature and have been added to the data from the European RARs.

For butylbenzyl phthalate no useable effects data are available for the terrestrial compartment. One short term test is available for earthworms, with an unbound 14-day LC_{50}. Nevertheless, the EU RAR for butylbenzyl phthalate still considered that this study was valid as no effects were observed at the highest test dose of 1000 mg kg^{-1}. The EU TGD (EC, 2003) recommends using the equilibrium partitioning method to estimate a $PNEC_{soil}$ when only one terrestrial study is available. This method is described in detail in Appendix 2 of Environment Agency (2008) and effectively uses the aquatic PNEC to estimate the terrestrial PNEC using the soil/water partition coefficient. This leads to an estimated $PNEC_{soil}$ for butylbenzyl phthalate of 1.39 mg kg^{-1} wwt. This method involves several significant assumptions; it provides, at best, a very coarse screen when compared with measured environmental concentrations of butylbenzyl phthalate.

Toxicity data are available for dibutyl phthalate from two trophic levels: producers (plant study) and consumers (collembolan study). When data are available for a producer, consumer and/or a decomposer, the $PNEC_{soil}$ is calculated using assessment factors. Of the two collembolan studies, the reproduction endpoint will be used because the quality of the cuticle growth endpoint has been questioned by the authors due to significant variability in the controls (Jensen *et al.,* 2001). The study by Jensen *et al.* was undertaken after the completion of the last literature review in the EU RAR. Therefore, the most sensitive data point is the EC_{10} of 14 mg kg^{-1} for collembolan reproduction. Only two chronic studies from two trophic levels are available and

according to the TGD an assessment factor of 50 would therefore be appropriate. This results in a PNEC for dibutyl phthalate of 0.28 mg kg^{-1}.

Ecotoxicity data for DEHP are available for three trophic levels and when data are available for a producer, consumer and/or a decomposer, the $PNEC_{soil}$ is calculated using assessment factors. All of the NOECs listed in Table C4c are unbounded, i.e. the highest test concentration did not produce a significant effect in the test organisms. Nevertheless, these studies are still valid and the most sensitive data point is the NOEC of >130 mg kg^{-1} for seedling emergence. Applying an assessment factor of 10 to the NOEC of >130 mg kg^{-1} results in a PNEC of >13 mg kg^{-1}.

The TGD triggers an assessment for secondary poisoning when a substances has a log Kow ≥ 3 or if it is known to have a potential to accumulate in living organisms. All of the phthalates considered here trigger an assessment of secondary poisoning.

Table C4a Terrestrial ecotoxicity data for butylbenzyl phthalate.

Species	Common name	Study duration	Endpoint	Concentration (mg kg^{-1})	Substrate	Chemical anaysis	Method	Reference
Eisenia foetida	Earthworm	14 day	LC_{50}	None determined, 100% survival of organisms	Artificial soil	Yes	Based on OECD 207	Norway (2007)

Table C4b Terrestrial ecotoxicity data for dibutyl phthalate.

Species	Common name	Study duration	Endpoint	Concentration (mg kg^{-1})	Substrate	Chemical anaysis	Method	Reference
Zea mays	Maize	21 days	NOEC	200	Sandy soil	Unknown	Unknown	Shea *et al*. (1982) cited in The Netherlands (2004)
Folsomia fimetaria	Collembolan	21 days	EC_{10} Reproduction	14	Sandy soil	Yes	Based on ISO 11267:1999	Jensen *et al*. (2001)
Folsomia fimetaria	Collembolan	7 day	EC_{10} Number of cuticles	0.5	Sandy soil	Yes	Based on ISO 11267:1999	Jensen *et al*. (2001)

Table C4c Terrestrial ecotoxicity data for diethylhexyl phthalate (DEHP).

Species	Common name	Study duration	Endpoint	Concentration (mg kg^{-1})	Substrate	Chemical anaysis	Method	Reference
Triticum aestivum	Wheat	18 days	NOEC, seedling emergence	>130	Sandy soil	Nominal	Based on OECD 208	Diefenbach *et al*. (1998) cited in Sweden (2008)
Lepidium sativum	Garden cress							
Brassica alba	White mustard							
Eisenia foetida	Earthworm	14 days	NOEC	> 1000	Artificial soil	Unknown	Unknown	Diefenbach *et al*. (1998) cited in Sweden (2008)
Folsomia fimetaria	Collembolan	21 days	NOEC Reproduction Development	>5000 >1000	Sandy soil	Yes	Based on ISO 11267:1999	Jensen *et al*. (2001)
	Microbial function	120 days	NOEC Respiration Nitrification Nitrogen mineralisation	> 300	Soil	Unknown	Unknown	Kirchmann *et al*. (1991) cited in Sweden (2008)

Mammalian toxicity

The mammalian data from the EU RAR for butylbenzyl phthalate is relatively limited and no higher organism studies were available, aside from studies on laboratory-based mammals. The lowest NOAEL reported is for 50 mg kg^{-1} bw d^{-1} from a rat reproduction study looking at reduced anogenital distance (Tyl *et al.,* 2004, cited in Norway, 2007). No additional studies were found since the completion of the risk assessment.

The lowest LOAEL reported in the EU risk assessment for dibutyl phthalate is 52 mg kg^{-1} bw d^{-1}, for reproductive effects in male rats in a two generation study (Wine *et al.,* 1997, cited in The Netherlands, 2004). No additional studies were found since the completion of the risk assessment.

Several studies are available on the ecotoxicty of DEHP on mice and rats, although only three studies can be considered robust. Of these three, a study with male rats that noted irreversible testicular damage when exposure was *in utero* and during suckling gave the lowest NOAEL of 4.8 mg kg^{-1} bw d^{-1} at a food concentration of 100 mg DEHP kg^{-1} (Wolfe *et al.,* 2003, cited in Sweden, 2008).

Avian toxicity

There are no avian toxicity data for butyl benzyl phthalate or dibutyl phthalate.

There are several studies on the ecotoxicity of DEHP on birds, but all show minor effects at relatively high concentrations and only one is suitable for the derivation of a PNEC. This study looked at egg production and effects on lipid metabolism in white leghorn hens exposed to DEHP through consumption of contaminated feed over a 28-day period. A LOEC of 10,000 mg kg^{-1} was calculated from this study, giving an initial NOEC of 5000 mg kg^{-1} which can be lowered to 1700 mg kg^{-1} through consideration of the calorific value of the feed as discussed in Appendix VII of the TGD (Wood and Bitman, 1980, cited in Sweden, 2008).

Table C5 The most sensitive mammalian toxicity data.

Study type	Organism	Effect	NOAEL (mg kg^{-1} bw d^{-1})	LOAEL (mg kg^{-1} bw d^{-1})	NOEC (mg kg^{-1} diet)	LOEC (mg kg^{-1} diet)	LC_{50}	Reference
Butylbenzyl phthalate								
Multi-generation study	Rat	Reproduction, reduced anogenital distance	50					Cited in Norway (2007)
Dibutyl phthalate								
Two generation study	Rat	Reproduction, embryotoxicity		52				Cited in The Netherlands (2004)
Diethylhexyl phthalate								
Multi-generation study	Rat	Reproduction, testicular atrophy	4.8					Wolfe *et al*. (2003) cited in Sweden (2008).

Derivation of $PNEC_{oral}$ for secondary poisoning

The $PNEC_{oral}$ for butylbenzyl phthalate was derived using the NOAEL for rat reproduction of 50 mg kg^{-1} bw d^{-1} with a conversion factor of 20 and an assessment factor of 30, giving a value of 33 mg kg^{-1} in food (Norway, 2007).

No data were available for the effects of dibutyl phthalate on higher organisms aside from laboratory-based animals. Therefore, the lowest oral LOAEL of 52 mg kg^{-1} bw d^{-1} was used with a conversion factor of 20 and an assessment factor of 10 for NOAELs - the TGD does not have assessment factors for LOAELs (The Netherlands, 2004). This gives a $PNEC_{oral}$ of 104 mg kg^{-1} in food.

The $PNEC_{oral}$ for DEHP was derived using the NOAEL of 4.9 mg kg^{-1} bw d^{-1} from the multi-generation rat study. An assessment factor of 3 is applied to the oral exposure concentration of 100 mg DEHP kg^{-1} and then an assessment factor of 10, according to the methodology set out in the TGD. This results in a $PNEC_{oral}$ of 3.3 mg kg^{-1} in food.

C.4 References

EC (EUROPEAN COMMISSION), 2003. Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the placing of biocidal products on the market. Ispra. Italy.

JENSEN, J., VAN LANGEVELDE, J., PRITZL, G. AND HENNING, P., 2001. Effects of di(2-ethylhexyl) phthalate and dibutyl phthalate on the collembolan *Folsomia fimetaria*. Environmental Science and Technology 20:1085–1091.

KINNEY, C. A., FURLONG, E. T., KOPLIN, D. W., BURHARDT, M. R., ZAUGG, S. D., WERNER, S. L., BOSSIO, J. P. AND BENOTTI, M. J., 2008. Bioaccumulation of pharmaceuticals and other anthropogenic waste indicators in earthworms from agricultural soil amended with biosolid or swine manure. Environment Science and Technology 42:1863–1870.

LANG, D. W., ZHANG, T., FANG, H. H. P. AND HE, J., 2008. Phthalates biodegradation in the environment. Applied Microbiology and Biotechnology 80:183–198.

NORWAY, 2007. European Union Risk Assessment Report on benzyl butyl phthalate prepared by Norway, Norwegian Pollution Control Authority on behalf of the European Union (http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/benzylbutylphthalatereport318.pdf).

OEHLMANN, J., OETKEN, M. AND SCHULTE-OEHLMANN, U., 2008. A critical evaluation of the environmental risk assessments for plasticizers in the freshwater environment in Europe, with special emphasis on bisphenol A and endocrine disruption. Environmental Research,108:140–149.

SWEDEN, 2008. European Union Risk Assessment Report on bis(di-thylhexyl) phthalate (DEHP) prepared by Sweden, Swedish Chemicals Agency on behalf of the European Union (http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dehpreport042.pdf).

THE NETHERLANDS, 2004. European Union Risk Assessment Report on dibutyl phthalate (with Addendum) prepared by The Netherlands, RIVM on behalf of the European Union (http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dibutylphthalatereport003.pdf).

Annex D. Derivation of terrestrial predicted no effect concentrations (PNECs) for triclosan

D.1 Summary

This annex describes the derivation of Predicted No Effect Concentrations (PNECs) for triclosan.

The $PNEC_{soil}$ for triclosan is 1.43 mg kg^{-1} dry soil. This value is derived by an assessment factor approach based on ecotoxicity data for triclosan in soil. The $PNEC_{soil}$ to protect against secondary poisoning is 188 mg kg^{-1} dry soil, which was extrapolated from a $PNEC_{secondary\ poisoning}$ of 20 mg kg^{-1}. In accordance with usual practice and to ensure protection against ecological risk in the terrestrial environment from triclosan, the recommended PNEC for triclosan is 1.43 mg kg^{-1} dry soil. The overall uncertainty associated with the final PNEC is moderate because it is based on chronic toxicity data for 23 endpoints. A summary of the data used in the assessment is presented in Table D1.

Table D1 Overview of the data used in the assessment.

Substance name		
Triclosan		
CAS nr		
3380-34-5		
Summary of acceptable data (number of data and range in mg kg^{-1})		
Group		
Terrestrial - plants	19 NOECs (0.065 – 750 mg kg^{-1})	
Terrestrial - invertebrates	1 LC50 (>1026 mg kg^{-1})	
Terrestrial – microorganisms (soil processes)	4 NOECs (1 - >100 mg kg^{-1})	
Terrestrial - avian	1 LC50 (>5000 mg kg^{-1}) 2 LD50s (862 - >2150 mg kg^{-1} bw)	
Terrestrial - mammalian	11 NOECs (6.5 - >125 mg kg^{-1} bw d^{-1})	
Derivation of PNEC		
	$PNEC_{soil}$	**$PNEC_{oral}$ (secondary poisoning)**
PNEC derivation method	AF approach	AF approach
Critical toxicity data	14.29 mg kg^{-1} for plants (normalised to standard 2% organic carbon content)	30 mg kg^{-1} bw d^{-1} (equivalent to 600 mg kg^{-1} in food) for baboons
AF	10	30
PNEC(mg kg^{-1})	1.43 mg kg^{-1}	20 mg kg^{-1} (prey concentration wt weight) 188 mg kg^{-1} (extrapolated soil concentration)
Uncertainty	Moderate. Based on data for three trophic levels.	High. Extrapolation from $PNEC_{secondary\ poisoning}$ to a soil concentration introduces uncertainty.

D.2 Introduction

The application of organic materials from non-agricultural sources to land can provide a range of agronomic benefits, including macronutrients such as nitrogen and phosphorus. However, these benefits must be balanced against the potential risks of any chemical contaminants also present within the applied material. This annex describes the derivation of terrestrial Predicted No Effect Concentrations for triclosan.

Triclosan concentrations in the range of 0.09 – 28.2 mg kg^{-1} (dry wt) have been reported in sewage sludges (NICNAS 2008, Ying and Kookana 2007). During the course of this and previous projects triclosan concentrations in the range of <0.2 to 18 mg kg^{-1} have been detected in samples of mechanical biological treatment (MBT) outputs (Environment Agency 2008).

D.3 PNEC Derivation

The major chemical and physical properties of triclosan are summarized in Table D2.

Table D2 Physical and chemical properties of triclosan.

Property	Value
CAS	3380-34-5
molecular weight	289.54
physical state	off-white crystalline powder
melting point	54 – 57.3°C
boiling point	280 – 29°C (HSDB)
vapour pressure	4 x 10^{-4} at 20°C
Henry's law constant	5 x 10^{-9} atm/m^3 mole (estimated)
log Kow	4.8
water solubility	10 mg L^{-1}
Acid dissociation constant (pKA)	7.9 (NICNAS 2008) 8.14 at 20°C (cited in Reiss et al. 2009)

Taken from NICNAS (2008) unless otherwise stated

Terrestrial toxicity data were collated from the Australian Government's Department of Health and Ageing NICNAS Priority Existing Chemical Assessment report (NICNAS 2008). Further data were sought from the open literature from 2006 onwards (last date of literature search in NICNAS report) using the following resources:

- Published literature data were obtained from searches on Web of Science[1] and ScienceDirect®[2]
- USEPA Ecotox database[3]

Each database was searched initially with two sets of keywords: i) terms for triclosan and, ii) terrestrial and mammalian/avian search terms. The abstracts of articles were

[1] http://www.isiwebofknowledge.com
[2] http://www.sciencedirect.com/
[3] http://cfpub.epa.gov/ecotox/

then screened for potentially relevant articles. Full details of search terms can be found in Table D3.

The source data in NICNAS (2008) were assumed to be quality assured and were not assessed further in this report.

Table D3 Search terms used for literature searching.

Chemical keywords	Triclosan or Irgasan or 5-chloro-2-{2,4-dichlorophenoxy]-phenol
Terrestrial ecotoxicity keywords	Terrestrial or soil or earthworm or plant or agriculture or sludge or waste or biowaste or compost or biosolid or land or *Eisenia* or collembola or *Folsomia* or enchytraeid or *Enchytraeus* or mite or *Hypoaspis* or seedling emergence or seedling or vegetative vigour or worm or springtail or vigor
Secondary poisoning keywords	Mammal or avian or bird or rat or mouse or mice or dog or monkey or mallard or bobwhite or quail

Terrestrial toxicity data

Ecotoxicity data for the terrestrial environment are limited to one earthworm and four plant studies, the latter covering several plant species. Data on the effects of triclosan on soil processes are available from two studies. These are summarised in Table D4.

Table D4 Terrestrial ecotoxicity data.

Species	Common name	Study duration	Endpoint	Concentration (mg kg^{-1})	Substrate	Chemical anaysis	Method	Reference
Invertebrates								
Eisenia foetida	Earthworm	14 day	NOEC/LC50	>1026	Artificial soil	N	OECD 207	RCC 1990
Plants								
Cucumis sativus	Cucumber	21 day	$NOEC_{shoot\ length}$	0.096 (0.065)[1]	Sand	Y[1]	US FDA 1990	Springborn Laboratories 1992
Zea mays	Corn	21 day	NOEC[2]	> 0.93	Sand	Y[1]	US FDA 1990	Springborn Laboratories 1992
Lolium perenne	Ryegrass	21 day	$NOEC_{root\ weight}$	0.28 (0.162)[1]	Sand	Y[1]	US FDA 1990	Springborn Laboratories 1992
Glycine max	Soybean	21 day	NOEC[2]	> 0.93 (0.61)[1]	Sand	Y[1]	US FDA 1990	Springborn Laboratories 1992
Lycopersicon esculentum	Tomato	21 day	$NOEC_{root\ and\ shoot\ weight}$	0.28 (0.162)[1]	Sand	Y[1]	US FDA 1990	Springborn Laboratories 1992
Triticum aestivum	Wheat	21 day	$NOEC_{shootweight}$	0.280 (0.162)[1]	Sand	Y[1]	US FDA 1990	Springborn Laboratories 1992
Cucumis sativus	Cucumber	28 day	NOEC	>1 (>0.446)[3]	Sandy loam	Y[3]	US FDA 1990	ABC Laboratories 1997
Oryza sativa	Rice	20 day	$NOEC_{shootheight}$ $NOEC_{root\ length}$ $EC10_{root\ length*}$	70 1 14.29	Silt loam soil	N	Modified from OECD 208	Liu et al. 2009
Cucumis sativus	Cucumber	20 day	$NOEC_{shootheight}$ $NOEC_{root\ length}$ $EC10_{root\ length*}$	10 10 34.15	Silt loam soil	N	Modified from OECD 208	Liu et al. 2009
Cucumis sativus	Cucumber	14 day	$NOEC_{phytotoxicity}$	500	Top soil	Y	OECD 208	Büche et al. 2009[4]
Glycine max	Soybean	14 day	$NOEC_{phytotoxicity}$	500	Top soil	Y	OECD 208	Büche et al. 2009[4]
Solanum lycopersicon	Tomato	14 day	$NOEC_{phytotoxicity}$ $NOEC_{ermergence}$	250 250	Top soil	Y	OECD 208	Büche et al. 2009[4]
Raphanus sativus	Radish	14 day	$NOEC_{phytotoxicity}$	250	Top soil	Y	OECD 208	Büche et al. 2009[4]
Vicia sativa	Vetch	14 day	$NOEC_{phytotoxicity}$ $NOEC_{ermergence}$	500 500	Top soil	Y	OECD 208	Büche et al. 2009[4]
Lolium perenne	Ryegrass	14 day	$NOEC_{phytotoxicity}$ $NOEC_{ermergence}$	100 100	Top soil	Y	OECD 208	Büche et al. 2009[4]

Species	Common name	Study duration	Endpoint	Concentration (mg kg^{-1})	Substrate	Chemical anaysis	Method	Reference
Triticum aestivum	Wheat	14 day	$NOEC_{phytotoxicity}$ $NOEC_{length}$ $NOEC_{ermergence}$	750 250 250	Top soil	Y	OECD 208	Büche et al. 2009[4]
Zea mays	Corn	14 day	$NOEC_{phytotoxicity}$	500	Top soil	Y	OECD 208	Büche et al. 2009[4]
Lactuca sativa	Lettuce	14 day	$NOEC_{ermergence}$ $NOEC_{weight}$ $NOEC_{phytotoxicity}$	500 50 100	Top soil	Y	OECD 208	Büche et al. 2009[4]
Pisum sativa	Pea	14 day	$NOEC_{phytotoxicity}$ $NOEC_{ermergence}$	500 750	Top soil	Y	OECD 208	Büche et al. 2009[4]
Soil processes								
Microbial respiration		28 day	NOEC	>2	Sandy loam	N	OECD 217	Völkel 2007a
Nitrification of lucerne meal		28 day	NOEC	>2	Sandy loam	N	OECD 216	Völkel 2007b
Microbial respiration		28 day	NOEC NOEC	10 >100	Clay soil Sandy loam	N	OECD 217 with modifications	Waller and Kookana 2009
Substrate induced nitrification		28 day	NOEC EC10* NOEC	10 31.2 1	Clay soil Sandy loam	N	OECD 216 with modifications	Waller and Kookana 2009

* Derived from data provided in publications.
[1] Concentrations measured on days 0 and 21. On day 21 there was significant loss of triclosan. Time weighted averages provided in brackets.
[2] No effect found on any parameter at concentration range tested.
[3] Concentrations measured on days 0, 14, 21 and 28. There was significant loss of triclosan over the duration of the experiment. On day 28 test concentration in 1000 µg kg^{-1} was 20% (191 µg kg^{-1}) of initial concentration, 60% (392 µg kg^{-1}) was lost by day 14. Time weighted average provided in brackets.
[4] Only NOECs determined within the concentration range tested are summarised from this study. Endpoints for NOECs expressed as > values (i.e. no effect at highest concentration range tested) have been omitted from the table.

Limited effects data are available for the terrestrial compartment. Toxicity data are reported for three trophic levels: producers (plants), consumers (earthworm) and soil processes (respiration and nitrification). When data are available for a producer, consumer and/or a decomposer, the $PNEC_{soil}$ is calculated using assessment factors.

Invertebrate data are limited to one short-term test for earthworms, with a 14 day LC50 of >1026 mg kg^{-1} dwt. No mortality was observed in the controls or the highest concentration tested. Four studies covering 11 plant species report NOECs in the range of 0.065 – 750 mg kg^{-1}). The plant studies can be considered as long-term studies. Two studies report NOECs of >2 - >100 mg kg^{-1} and 1 – 10 mg kg^{-1} for soil respiration and nitrification, respectively.

The most sensitive plant data point is the 21 day NOEC of 0.065 mg kg^{-1} for shoot length in cucumber (Springborn 1992). This study was conducted using quartz sand as a substrate (0.14% organic matter content), and it is therefore of lower relevance for risk assessment and PNEC derivation. Nonetheless for comparative purposes, conversion of the organic matter content to a standard content of 3.4% results in NOEC of 1.58 mg kg^{-1}.

The next most sensitive plant data points are the 21 day NOECs for wheat shoot weight and rye grass root weight (both 0.162 mg kg^{-1}) from the same study using a quartz sand substrate, which are therefore also of lower relevance for risk assessment and PNEC derivation (Springborn 1992).

The most sensitive plant data point from a study using a more appropriate substrate (silt loam soil) is the 20 day NOEC of 1 mg kg^{-1} for root length in rice, using a modified OECD test guideline 208 method (Liu et al. 2009). The concentrations of triclosan in the test soils were not analytically verified in this study. In another study using homogenised top soil, triclosan test concentrations were found to be relatively consistent and stable over 21 days (Büche et al. 2009). In two other studies using quartz sand and sandy loam substrates, respectively, triclosan concentrations could not be maintained over the study duration (Springborn 1992, ABC 1997). The substantial losses reported in these studies cause concern for studies reporting nominal concentrations. However, analytical verification of test concentrations is not a requirement in internationally accepted test guidelines for terrestrial tests (e.g. OECD 208, 216, 217). Therefore, this study cannot be rejected and can be used for PNEC derivation.

There are a number of deviations in the Liu et al. study from recommendations made in OECD test guideline 208. However, they are not of a nature that would result in the rejection of the study. Rather, they would lead to a Klimisch reliability score of 2: “reliable with restrictions”, i.e. a study which was not performed in accordance with an internationally accepted guideline, but which is nevertheless well documented and scientifically acceptable. One of the deviations was a fewer number of replicates, but a larger than recommended number of test concentrations. OECD 208 does state that if a larger number of test concentrations are used, the number of replicates may be reduced. If a NOEC is to be estimated, more replicates may be needed to obtain the desired statistical power. Liu et al. (2009) used seven concentrations (OECD recommends five for dose-response determination of an ECx). Therefore, the lower replication is justified and the test design is better suited for the determination of an EC10, which can be used as alternative to a NOEC to determine a PNEC (EC 2003).

Liu et al. (2009) do not report confidence intervals for their EC10 of 27 mg kg^{-1}. Re-analysis of the data provided in their paper resulted in an EC10 of 10.4 mg kg^{-1} (3.7-17.2 mg kg^{-1} 95% CI), using piecewise linear regression. The organic carbon content of the soil used in Liu et al.’s study was 1.82%. The final organic carbon content in the test vessels would have been 1.65% (addition of 10g of quartz sand to 100g of test

soil). Conversion to a standard organic carbon content of 2%, as recommended in the TGD, results in an EC10 of 12.6 mg kg^{-1}. Further adjustment to derive a dry weight concentration based on a soil moisture content of 20% results in an EC10 of 14.3 mg kg^{-1}.

The next most sensitive plant data point is the 20 day NOEC of 10 mg kg^{-1} for root length and shoot height in cucumber from the same study (Liu et al. 2009). Re-analysis of the data provided in the paper resulted in an EC10 of 24.86 mg kg^{-1} (16.17 – 38.24 mg kg^{-1} 95% CI). Conversion to a standard organic carbon content of 2% results in an EC10 of 30.13 mg kg^{-1}. Further adjustment to derive a dry weight concentration based on the soil moisture content results in an EC10 of 34.15 mg kg^{-1}. The EC10 of 14.29 mg kg^{-1} for rice root length is of the same order of magnitude as the EC10 for cucumber root length and shoot height.

The most sensitive data point available from decomposition studies is a 28 day NOEC of 1 mg kg^{-1} for substrate induced nitrification in a sandy loam soil and a NOEC of 10 mg kg^{-1} in a clay soil (Waller and Kookana 2009). Deviations in this study from recommendations made in OECD guideline 216 are of a nature that lead to a Klimsch score of 2: “reliable with restrictions” for the clay soil experiments. The sandy loam experiment was scored as 3: “unreliable”. Analysis of the raw data obtained from Waller and Kookana (2009) demonstrated a control variability greater than 15% in the sandy loam experiments, so this part of the study does not meet the validity criteria of OECD guidelines 216. The control variability of the clay soil experiment did meet the validity criteria (<15%). Clear effects on soil processes were found at concentrations of 50 mg kg^{-1} and greater. Therefore the NOEC in this study is 10 mg kg^{-1}. An EC10 of 28.9 mg kg^{-1} (15.5 – 42.4 mg kg^{-1} 95% CI) was derived from the raw data provided by the authors. Conversion of the organic carbon content of the clay soil (1.85%) to a standard organic carbon content of 2% results in a NOEC of 31.2 mg kg^{-1}. This is higher than the EC10 of 14.29 mg kg^{-1} for rice root length, which should be taken forward for PNEC derivation (see above).

An assessment factor of 10 has been applied, since the data from plants and microbial processes are likely more sensitive than earthworms. Therefore, they would be protective of this third trophic level.

Applying an assessment factor of 10 to the most sensitive EC10 of 14.29 mg kg^{-1} results in a **PNEC of 1.43 mg kg^{-1}**.

Triggers for the assessment of secondary poisoning in the TGD include a log Kow ≥ 3 or if a substance is known to have a potential to accumulate in living organisms. The log Kow of triclosan is 4.8, so the trigger for the derivation of a PNEC for secondary poisoning of predators is met.

Mammalian toxicity

Mammalian toxicity data were reviewed for the Australian chemical assessment report (NICNAS 2008). (Sub-)chronic data from studies with an oral or dietary exposure route were available for mouse, rat, hamster, rabbit, dog and baboon. Details of all studies are not included here and the reader is referred to the NICNAS assessment. Only data deemed reliable by NICNAS and with exposures of greater than 28 days are summarized in Table D5.

Table D5 Mammalian toxicity data.

Study type	Organism	Effect	NOAEL (mg kg^{-1} bw d^{-1})	Reference
28 day dietary	Mouse	Liver effects, haematology & clinical chemistry parameters	6.5 (M) 8.3 (F)	1
13 week dietary	Mouse	Liver weight, haematology & depression in total cholesterol	<25	2
42 day dietary	Rat	Liver effects	108	3
13 week dietary	Rat	Liver histopathology	65 (M) 82 (F)	4
2 year carcinogenicity	Rat	Clinical chemistry, haematology, liver histopathology	40(M) 56 (F)	5
13 week dietary	Hamster	Urinalysis & blood in urine	77 (M) 75 (F)	6
90-95 week carcinogenicity	Hamster	Systemic toxicity	75	7
90 day dietary	Rabbit	No treatment related effects	>125	8
90 day dietary	Dog	No treatment related effects	>25	9
90 day oral (gelatine capsules)	Dog	Clinical signs of toxicity, liver damage	<25	10
1 year oral (gelatine capsules)	Baboon	Clinical signs of toxicity (e.g. vomiting, failure to eat, diarrhoea)	30	11

1 Ciba-Geigy Limited (1987), cited in NICNAS (2008)
2 Trutter (1993), cited in NICNAS (2008)
3 Persohn & Molitor (1993), cited in NICNAS (2008)
4 Litton Bionetics Inc. (1983), cited in NICNAS (2008)
5 Ciba-Geigy Limited (1986), cited in NICNAS (2008)
6 Schmid et al. (1994) and Persohn (1994), cited in NICNAS (2008)
7 Huntingdon Life Sciences (1999), cited in NICNAS (2008)
8 Leuschner (1970a), cited in NICNAS (2008)
9 Leuschner et al. (1970b), cited in NICNAS (2008)
10 Paterson (1967), cited in NICNAS (2008)
11 Ciba-Geigy (1975), cited in NICNAS (2008)

Avian toxicity

The avian data cited in NICNAS (2008) are summarised in Table D6. No further studies were found in the open literature published since 2006.

Two acute oral studies (single dose) were available for mallard duck and bobwhite quail. The LD50s were >2150 mg bw kg^{-1} and 862 mg bw kg^{-1}, respectively. Only one 5-day dietary toxicity study was available for bobwhite quail. The LC50 was >5000 ppm, with a corresponding NOEC of 1250 ppm. The data indicate low oral and dietary acute toxicity.

No chronic avian toxicity studies were available.

Table D6 Avian toxicity data cited in NICNAS (2008).

Species	Common name	Study type	Endpoint	Concentration	Reference
Anas platyrhynchos	Mallard	14d acute oral (single dose)	LD50	>2150 mg kg^{-1} bw	1
Anas platyrhynchos	Mallard	14d acute oral (single dose)	NOEL	2150 mg kg^{-1} bw	1
Colinus virginianus	Bobwhite quail	14d acute oral (single dose)	LD50	862 mg kg^{-1} bw	2
Colinus virginianus	Bobwhite quail	14d acute oral (single dose)	NOEL	<147 mg kg^{-1} bw	2
Colinus virginianus	Bobwhite quail	5d dietary	LC50	>5000 ppm	3
Colinus virginianus	Bobwhite quail	5d dietary	NOEC	1250 ppm	3

1 Bio-Life Associates Ltd (1993a), cited in NICNAS (2008)
2 Bio-Life Associates Ltd (1993b), cited in NICNAS (2008)
3 Bio-Life Associates Ltd (1993c), cited in NICNAS (2008)

D.4 Derivation of PNEC for secondary poisoning of predators

The following evaluation is based on the summaries provided in the NICNAS toxicity evaluation of triclosan (2008). The original studies were not consulted.

Mammalian $PNEC_{oral}$

The lowest mammalian NOEALs are 6.5 and 8.3 mg kg^{-1} d^{-1} for male and female mice, respectively, from a 28 day dietary exposure study (Ciba-Geigy Limited 1987, cited in NICNAS 2008). Two dose levels were tested and the effects found at the higher dose level (males: 136 mg kg^{-1} d^{-1} and females: 169 mg kg^{-1} d^{-1}) consisted of an increase in relative liver weight (66% to 76%), microscopic changes such as hypertrophy and cell necrosis of hepatocytes along with clinical chemistry changes reflective of liver damage, slight decreases in red blood cell parameters and increases in platelets. NICNAS (2008) report that this was a well conducted study. However, current OECD guidelines for 28 day repeat dose tests in rodents recommend that at least three dose levels should be included, and dose intervals with large intervals (e.g. more than a factor of 10) are discouraged. In addition, the TGD places preference on longer-term studies. For these reasons, this study was not chosen as the critical study for PNEC derivation.

The next lowest mammalian NOAEL is <25 mg kg^{-1} d^{-1} for mice from a 13 week (90 day) dietary exposure study (Trutter 1993, cited in NICNAS 2008). A LOAEL of 25 mg kg^{-1} d^{-1} (the lowest concentration tested) was identified based on dose related trends in several haematology parameters, a dose-related increase in relative liver weight and statistically significant depression in total cholesterol. The dose related increase in absolute and relative liver weight was only statistically significant from 75 mg kg^{-1} d^{-1} (ranging from 23% to 205%). The increased liver weight was accompanied by dose related centrilobular hypertrophy and hepatocellular hypertrophy in males from 75 mg kg^{-1} d^{-1}, and in females from 200 mg kg^{-1} d^{-1}. Necrosis started at 200 mg kg^{-1} d^{-1} in males, males being more sensitive (necrosis observed in a single male at 75 mg kg^{-1} d^{-}

[1], whereas this only occurred in females from 350 mg kg^{-1} d^{-1}). None of the effects seen at 25 mg kg^{-1} d^{-1} are considered of high demographic relevance. However, the liver effects observed from 75 mg kg^{-1} d^{-1} were fairly significant and a NOAEL of 25 mg kg^{-1} d^{-1} for liver effects will be taken forward as supporting information.

An unbounded NOEAL of <25 mg kg^{-1} d^{-1} is also reported in a 91 day oral study with dogs (Paterson 1967, cited in NICNAS 2008). NICNAS (2008) describes this as a briefly reported study and, from the details given, it does not appear to be well-conducted. Three dogs were exposed per sex (current OECD guidelines recommend a minimum of four dogs), limited haematology, clinical chemistry, urinalysis investigations and histopathological examination were undertaken, and body weight changes were not determined. The effects seen at 25 mg kg^{-1} d^{-1} included diarrhoea, vomiting, haematology and clinical chemistry results suggestive of liver dysfunction, and liver damage in and mortality of one female (the summary does not state whether this was the same female dog). In a further 90 day oral study with dogs (Leuschner et al. 1970) no treatment related effects were seen in mortality, body weight gain, haematology, clinical chemistry, urinalysis, organ weights or histology up to and including the highest dose of 25 mg kg^{-1} d^{-1}. The study undertaken by Paterson (1967) was not chosen as the critical study for PNEC derivation, since it does not appear to be well conducted, and no effects were found in a second study on dogs by Leuschner et al. (1970). Since the NOAEL of >25 mg kg^{-1} d^{-1} generated in this second study is unbounded, it is also not suitable for PNEC derivation.

The next lowest NOAEL is 30 mg kg^{-1} d^{-1} for baboons from a one year repeat dose toxicity study (Ciba-Geigy 1975, cited in NICNAS 2008). Triclosan was administered in gelatine capsules to seven baboons per sex per group at dose levels of 0, 30, 100 or 300 mg kg^{-1} d^{-1}. At 100 mg kg^{-1} d^{-1} clinical signs of toxicity, such as increased incidence of diarrhoea, and vomiting, together with lower incidence of food intake were observed. From 30 mg kg^{-1} d^{-1} an increase in absolute brain weight in the absence of treatment related histopathological changes was found. The US EPA (2008) used the NOAEL of 30 mg kg^{-1} d^{-1} in baboons to establish an acute and chronic reference dose value for human health risk assessment. This NOAEL will be used to derive the mammalian $PNEC_{oral}$.

For the assessment of secondary poisoning, results given as a dose need to be expressed as a concentration in food (NOEC). The TGD provides a conversion factor of 20 for *Macaca sp.* Baboons belong to the genus *Papio* for which no conversion factors are provided in the TGD. However, the assessment factors used in the PNEC derivation account for interspecies variation, lab-to-field extrapolation and acute/subchronic to chronic extrapolation. Applying the conversion factor of 20 to the NOEAL of 30 mg kg^{-1} d^{-1} results in a NOEC of 600 mg kg_{food}^{-1}.

The baboon study was a one year repeat dose toxicity study, so a chronic assessment factor of 30 is justified. Application of this assessment factor to the NOEC of 600 mg kg_{food}^{-1} results in a $PNEC_{oral}$ of 20 mg kg_{food}^{-1}.

Avian $PNEC_{oral}$

According to the TGD, acute lethal doses (LD50s) are not acceptable for extrapolation to chronic toxicity, as these are not dietary studies. However, acute effect concentrations (e.g. OECD 205) for birds are acceptable for extrapolation. Therefore the only avian study suitable for PNEC derivation is the 5 day dietary study with bobwhite quail. This study reports an LC50 >5000 mg kg^{-1}. As the LC50 is a “greater than” value, the true LC50 is unknown, and should not be used for PNEC derivation.

Since no avian $PNEC_{oral}$ could be derived for comparative purposes, the mammalian $PNEC_{oral}$ will be taken forward for use in risk assessment.

Conversion of PNECoral to a PNECsoil for secondary poisoning

It is necessary to derive a soil concentration which can be considered as being protective against secondary poisoning so that soil concentrations, rather than the concentrations in prey organisms, can be used to assess potential risks to terrestrial predators. The concentration in worms (which are assumed to be the principal food source of terrestrial predators) can be estimated from a soil concentration according to current risk assessment guidance (ECHA 2008). It is therefore possible, in principle, to work backwards from a critical concentration in worms (the $PNEC_{oral}$ for predators) to derive a critical soil concentration below which risks due to secondary poisoning in terrestrial food chains would not be anticipated.

The concentration of a substance in worms can be calculated according to Equation R.16-78 (EC 2003). This requires information on the concentration of the substance in both soil and soil pore water. However, the soil pore water concentration is calculated from the soil concentration and the $K_{soil:water}$ value (a partition coefficient for partitioning of the substance between soil solids and soil pore water). It follows, therefore, that the soil concentration is required to calculate the soil pore water concentration before it is possible to back calculate from a critical concentration in worms to the critical soil concentration.

In order to resolve this problem the critical soil concentration is derived by an iterative process of modifying the input soil concentration until the predicted concentration in worms is equal to the $PNEC_{oral}$ (the critical concentration in worms). The resulting soil concentration is the critical soil concentration for secondary poisoning of terrestrial predators ($PNEC_{soil, sec. pois.}$).

The derived concentrations are subject to uncertainties about both the bioaccumulation of the substance and its partitioning between soil and soil porewater. It is important for these uncertainties to be taken into account so that the critical soil concentration for secondary poisoning can be compared against critical soil concentrations for other endpoints, such as direct effects on terrestrial ecosystems.

A bioaccumulation factor of 27 for earthworms was used in the equation (Kinney et al. 2008; a wet weight BAF of 6.35 was calculated from the worm and soil concentrations using a conversion factor of 0.206 to convert earthworm dry weight to wet weight, and the TGD conversion factor of 1.13 for soils). **The resulting critical soil concentration for secondary poisoning of terrestrial predators is 188 mg kg^{-1} dry weight**. These calculations assume a $PNEC_{oral}$ value of 20 mg kg^{-1} for predators.

D.5 References

BÜCHE C, FORT DJ, NAVARRO LT, PETER R, HAUK A, INAUEN J. 2009. Effects of triclosan on seedling emergence and growth. SETAC poster presented at SETAC Gothenburg, Sweden, June 1st to 4th, 2009.

EC, 2003 Technical Guidance Document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment of existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. European Commission, Joint Research Centre, EUR 20418 EN.

ENVIRONMENT AGENCY. 2008. A review of human health and environmental risks associated with the land application of mechanical-biological treatment outputs. Science report SC030144.

KINNEY CA, FURLONG ET, KOLPIN DW, BURKHARDT MR, ZAUGG SD, WERNER SL, BOSSIO JP, BENOTTI MJ. 2008. Bioaccumulation of pharmaceuticals and other anthropogenic waste indicators in earthworms from agricultural soil amended with biosolid or swine manure. Environmental Science and Technology 42:1863-1870.

LIU F, YING GG, YANG LH, ZHOU QX. 2009. Terrestrial ecotoxicological effects of the antimicrobial agent triclosan. Ecotoxicology and Environmental Safety 72:86-92.

NICNAS. 2008. Triclosan. Draft priority chemicals assessment report. Australian Government Department of Health and Ageing, Canberra, ACT.

RCC. 1990. Acute toxicity (LC50) of FAT 80'023 Q to earthworms. Study report number 262956.

SPRINGBORN LABORATORIES. 1992. Determination of effects on seedling growth of six pant species. Study report number 90-12-3574.

VÖLKEL 2007a. The effects of triclosan on soil respiration. Study number A88312.

VÖLKEL. 2007b. The effects of triclosan on soil nitrification. Study number A89954.

WALLER NJ, KOOKANA RS. 2009. Effect of triclosan on microbial activity in Australian soils. Environmental Toxicology and Chemistry 28:65-70.

YING GG, KOOKANA RS. 2007. Triclosan in wastewaters and biosolids from Australian wastewater treatment plants. Environment International 33:199-205.

Annex E. Limit values used in the risk assessment

Table E1 Limits used to evaluate environment risks.

	For Environmental Risk (in mg kg^{-1} unless otherwise stated)			
	Soil pH			
	5.0<5.5	5.5<6.0	6.0<7.0	>7.0
Zn	200	200	200	300
Cu	80	100	135	200
Ni′	50	60	75	110
Cd	3	3	3	3
Pb	300	300	300	300
Hg	1	1	1	1
Cr	400	400	400	400
Mo	4	4	4	4
Se	3	3	3	3
As	50	50	50	50
Fl	500	500	500	500

Limits for total metal concentrations in sludge-amended soils (mg kg^{-1} dw) Sludge (Use in Agriculture) Regulations (1989) and the Sewage Sludge Code of Practice (1986).

Table E2 Proposed soil screening values for ecological risk assessment (Environment Agency, 2008).

Substance	**Proposed SSV (mg kg^{-1})**	**Basis for derivation**
Cadmium	0.9-2.3	SSD for soil ecotoxicity data and secondary poisoning data◊, plus assessment factor of 1-2 on the HC5
Chromium	21.1	SSD approach and an assessment factor of 1
Copper	57.8*	SSD approach and an assessment factor of 1
Lead	167.9	SSD approach and an assessment factor of 2
Nickel	21.0*	SSD approach and an assessment factor of 2
Zinc	116.1*	SSD approach with terrestrial toxicity data and an assessment factor of 2

Notes: * These are SSVs for a soil of pH 6.5, organic matter of 2% and clay content of 10%.
◊ Based on renal thresholds of terrestrial mammals.

Table E3 Soil quality guidelines from other jurisdictions.

	For environmental risk (in mg kg^{-1} unless otherwise stated)	
	Agricultural land	**Residential and parkland**
PCDD/F (ng kg^{-1} I-TEQ)	4	4

Note: Source: http://www.ec.gc.ca/ceqg-rcqe/English/Pdf/GAAG_DioxinFuranSoil_e.pdf

Table E4 PNEC for the various PAHs for soil organisms (The Netherlands, 2008).

Compound	**PNEC soil (mg kg^{-1} $_{dw}$)**
Fluoranthene	1.5
Benzo(a)pyrene	0.053

Note: Secondary poisoning has not been addressed due to the limitations of the data.

Table E5 PNEC for priority chemicals as derived in this project (see previous Annexes) .

Chemical	**$PNEC_{soil}$**	**$PNEC_{oral}$ (secondary poisoning)**
Perfluoroctanesulphonate (PFOS)	0.29 mg kg^{-1}*	0.03 mg kg^{-1} dry soil
Butylbenzyl phthalate	1.39 mg kg^{-1}	33 mg kg^{-1} (prey concentration)
Dibutyl phthalate	0.28 mg kg^{-1}	104 mg kg^{-1} (prey concentration)
Diethylhexyl phthalate	>13 mg kg^{-1}	3.3 mg kg^{-1} (prey concentration)
Triclosan	1.43 mg kg^{-1}	188 mg kg^{-1} dry soil*

Note: * Likely to be considered too uncertain according to Environment Agency guidance (Environment Agency, 2008).

Table E6 Limits used to evaluate human health risks.

Substance	Limit value
Soil guideline values for human health risk (mg kg^{-1} unless otherwise stated)[#]	
Cd	10*
Ni	230*
Dutch Serious Risk Concentrations (RIVM, 2001)	
Cu	8,600
Cr	III – 2760 VI – 78
Pb	622
Zn	46,100
BaP	280
Fluoranthene	30300
Butylbenzylphthalate	294,000
Dibutylphthalate	22,600
DEHP	60
PCDD/F (ng kg^{-1})	360
Triclosan**	-
PFOS**	-

Notes:
* This value is based on a comparison of oral, dermal and inhalation exposure with the TDI and is for an allotment with a sandy loam soil or 6% organic matter (Environment Agency, 2009c).
** No human health limits currently available.

Would you like to find out more about us, or about your environment?

Then call us on

08708 506 506* (Mon-Fri 8-6)

email

enquiries@environment-agency.gov.uk

or visit our website

www.environment-agency.gov.uk

incident hotline 0800 80 70 60 (24hrs)
floodline 0845 988 1188

* Approximate call costs: 8p plus 6p per minute (standard landline).
Please note charges will vary across telephone providers

Environment first: This publication is printed on recycled paper.