Schedule B7
Appendix A3

PCBs and PBDE flame retardants

Contents

PCBs & PBDEs flame retardants

1 PCBs

1.1 General

The following relates to the assessment of non-dioxin-like PCBs only. The assessment of dioxins and dioxin-like PCBs needs to be conducted on a site-specific basis.

Polychlorinated biphenyls (PCBs) are a group of synthetic organic compounds comprising two benzene rings joined together with between one and ten chlorine atoms attached. There are 209 possible PCB variants (congeners); however, PCBs are typically found as a complex mixture in commercial products and in the environment (WHO 1993).

Several comprehensive reviews of PCBs in the environment and toxicity to humans are available and should be consulted for more detailed information not presented in this summary (ATSDR 2000; WHO 1993, 2003; EPHC 2003). The following provides a summary of the key aspects of PCBs that are relevant to the derivation of a soil HIL.

PCBs are typically in the form of an oily liquid or solid and are colourless to light yellow. Some PCB congeners may also exist as a vapour in air. They are odourless and tasteless. PCBs do not burn easily and have good insulating properties. They are both chemically and thermally stable. PCBs are relatively insoluble in water with the solubility decreasing with increasing chlorine content (ATSDR 2000).

Commercial PCB mixtures are also known by their trade names such as Aroclor (United States), Phenochlor (France), Clophen (Germany), Kanechlor (Japan), Fechlor (Italy) and Sovol (USSR). Information on the toxicity and behaviour of a number of commercial PCB mixtures, Aroclors, are available, with Aroclor 1254 most commonly used as an indicator for the assessment of PCB mixtures. WHO (2003) provides a review of the most common commercial Aroclor mixtures with respect to the composition and toxicity of congeners present and the various mixtures of indicator congeners (that differ from that of Aroclor 1254) may need to be considered on a site-specific basis.

Due to the thermal and chemical stability of PCBs, they are widely used as coolants and lubricants in transformers, capacitors and other electrical equipment (ATSDR 2000). In Australia, PCBs were also used in the manufacture of plastics, adhesives, paints and varnishes and were found in consumer products such as pesticides, fluorescent lighting and carbonless copy paper. PCBs were used in Australia between the 1930s and 1970s when the importation of PCBs was banned.

1.2 Previous HIL

The derivation of the previous HIL (HIL A = 10 mg/kg) for PCBs is presented by Di Marco and Buckett (1993) and NEPC (1999). In summary, the HIL was derived on the basis of the following:

- Background intakes from air, water and food were estimated to be 5.4 ng/kg/day for a child and 4.4 ng/kg/day for an adult, estimated to be approximately 5% of the adopted provisional tolerable daily intake (PTDI) (derived PTDI of 0.0001 mg/kg/day for Aroclor 1016).
- Due to the lack of published data for PCBs, the lowest threshold value derived for Aroclors 1016 and 1248 were considered. A PTDI of 0.0001 mg/kg/day was derived for Aroclor 1016 based on a no-observed-adverse-effect level (NOAEL) of 0.0125 mg/kg/day and a safety factor of 100.

- Intakes derived from ingestion (assuming 30% bioavailability), inhalation of dust (assuming 50% bioavailability) and dermal absorption (10% absorption) were considered in the derivation of the soil HIL of 10 mg/kg.

1.3 Significance of exposure pathways

Oral bioavailability

Bioavailability of PCBs in soil appears to be important due to their high affinity for soil particles and organic matter. Bioavailability was considered in the derivation of the current HIL (Di Marco & Buckett 1993) with 30% assumed for oral intakes and 50% assumed for inhalation. The basis for this assumption is not available and no more detailed reviewed of PCB bioavailability (oral or inhalation) in soil is available.

Insufficient data is available to adequately define the bioavailability of PCBs in the range of contaminated sites that may need to be considered in Australia. On this basis, a default approach of assuming 100% oral bioavailability has been adopted in the derivation of a HIL. It is noted that a site-specific assessment of bioavailability can be undertaken where required.

Dermal absorption

The US EPA (2004) recommends a dermal absorption value of 0.14 (14%) for PCB Aroclors 1254/1242 and other PCBs based on a study by Wester et al. (1993). A range of dermal absorption values are presented by ATSDR (2000). Review of these studies suggests that while the data is limited the value recommended by US EPA (2004) is adequately representative.

Inhalation of dust

PCBs are not considered sufficiently volatile to be of significance and inhalation exposures associated with particulates outdoors and indoors are expected to be of less significance than ingestion of soil. While likely to be negligible, potential inhalation exposures associated with dust have been considered in the HIL derived.

Plant uptake

PCBs accumulate in terrestrial vegetation by the following possible mechanisms: (1) uptake from soil through the roots, (2) dry deposition on aerial parts (particle-bound or gaseous), and (3) wet deposition on aerial parts (particle-bound or solute). Where PCB vapour is present, the potential for plant uptake is high. Where PCBs are sorbed to soil and organic matter, the potential for plant uptake is reduced; however, it remains of potential significance (CCME 1999). The uptake of PCBs (in soil) into edible fruit and vegetable crops has been the subject of a number of studies with a range of bioaccumulation factors derived for different crops (ATSDR 2000), with adsorption onto root surfaces most significant compared with translocation within the root or upper portions of the plant (CCME 1999). On this basis, the potential for the uptake of PCBs into home-grown produce has been considered in the derivation of HIL A.

This has been undertaken on the basis of the equations presented in Appendix B with the following parameters and plant uptake factors estimated:

Parameter	Value	Reference/Comment
Parameters		
Koc	131000 (cm^3/g)	RAIS (2010) for Aroclor 1254
log Kow	6.79	RAIS (2010) for Aroclor 1254
Diffusivity in water	$6.75x10^{-6}$ (cm^2/s)	RAIS (2010) for Aroclor 1221
Calculated plant uptake factors (mg/kg produce fresh weight per mg/kg soil)		
Green vegetables	0.00026	calculated
Root vegetables	0.0038	calculated
Tuber vegetables	0.079	calculated
Tree fruit	0.00096	calculated

Intakes from other sources – background

Background intakes (5.4 ng/kg/day for a child) were estimated by Di Marco and Buckett (1993) in the derivation of the previous HIL. Review of information available from FSANZ (2003) indicates that PCBs remain undetected in Australian and New Zealand food supplies, consistent with that identified by Di Marco and Buckett (1993). Hence, intakes from food are considered negligible.

Intakes estimated by the WHO (2003) are 0.3-3 ng/kg/day from air (including data derived from close to stack emissions from industrial/hazardous waste sources) and less than 0.2 ng/kg/day, from water. These values are similar to those noted above. Air concentrations reported by WHO (2003) from areas away from significant sources ranged from 0.002 to 0.95 ng/m^3 with PCBs in air noted to be slowly declining since the early 1980s. Based on these concentrations, intakes of PCBs in air away from significant sources is approximately 0.3 ng/kg/day (the lower end of the range reported by the WHO). Intakes estimated by RIVM (2001) are dominated by food (particularly where seafood dominates the diet) where the total intake is estimated to be 10 ng/kg/day. More recent review of intakes of PCBs by RIVM (2003) from food suggests that median lifelong intakes are estimated to be 5.6 ng/kg/day, similar to those estimated by Di Marco and Buckett (1993).

If the intakes estimated by the WHO (2003) for air (away from significant sources) and water are considered relevant to current background intakes in Australia (where intakes from food are negligible), these comprise approximately 0.5 ng/kg/day, approximately 2.5% of the recommended oral TRV. These intakes are considered negligible.

1.4 Identification of toxicity reference values

Classification

The International Agency for Research on Cancer (IARC 1987) has classified PCBs as Group 2A: probably carcinogenic to humans. This evaluation is based on limited evidence in humans (occupational studies) and sufficient evidence in experimental animals where some PCBs (particularly those with greater than 50% chlorination) produced liver neoplasms in mice and rats after oral administration.

It is noted that the US EPA has classified PCBs as Group B2: probably human carcinogen.

Review of available values/information

PCBs have been associated with carcinogenic effects (in particular, hepatocarcinogenic effects have been seen in animals for PCBs with higher levels of chlorination); however, the mode of action is of prime importance for determining the most appropriate dose-response approach to adopt for establishing a HIL. Review by WHO (2003) notes that the results of *in vitro* and *in vivo* genotoxicity studies on PCB mixtures are generally negative and suggest that PCB mixtures do not pose a direct genotoxic threat to humans. Although the mechanistic basis of the hepatocarcinogenicity of PCB mixtures in rodents is not clearly understood, it apparently is not due to genotoxicity. This is consistent with that provided by ATSDR (2000) and RIVM (2001).

On the basis of the available information, it is considered appropriate that a threshold dose-response approach be adopted for PCBs. The following are available from Level 1 Australian and international sources:

Source	Value	Basis/Comments
Australian		
ADWG	No evaluation available	
OCS (2008)	No evaluation available	
International		
WHO (2003)	TDI = 0.00002 mg/kg/day	Derived on the basis of a lowest-observed-adverse-effect level (LOAEL) of 0.005 mg/kg/day for Aroclor 1254 associated with immunological effects in a 23-month study in monkeys and an uncertainty factor of 300. The WHO considers this tolerable daily intake (TDI) relevant to mixtures of PCBs.
WHO DWG	No evaluation available	
RIVM (2001)	TDI = 0.00001 mg/kg/day TC = 0.0005 mg/m^3	TDI based on a LOAEL of 0.005 mg/kg/day for Aroclor 1254 associated with immunological effects in a 23-month study in monkeys and an uncertainty factor of 270 (approx. 300). An additional factor of 2 has been applied that relates the TDI derived from Aroclor 1254 to that relevant to PCB mixtures, where the seven indicator PCBs are present in Aroclor 1254 between 40 and 50%. Hence the assessment of mixtures has been undertaking by assuming 50% of the TDI for Aroclor 1254. TC is based on a LOAEC (adjusted) of 0.3 mg/m^3 for Aroclor 1254 associated with marginal effects in experimental animals and an uncertainty factor of 300. The additional 50% factor noted above is also applied to the Aroclor TC.
ATSDR (2000)	Oral MRL = 0.00002 mg/kg/day	Chronic oral MRL based on the same study as considered by RIVM and WHO (2003), with no additional adjustment for PCB mixtures. No inhalation MRL has been derived.
US EPA (IRIS, 2010)	RfD = 0.00002 mg/kg/day	US EPA reference dose (RfD) (last reviewed in 1994) derived on the same basis as that presented by ATSDR and WHO (2003). The US EPA also presents a non-threshold oral slope factor for PCBs which is not considered relevant in this assessment.

All the currently available oral threshold values for PCBs, based on Aroclor 1254, are derived from the same study with the only difference being the application of an additional factor by RIVM (2001) to address PCB mixtures. The WHO (2003) considers that the available TDI for Aroclor 1254 is adequate to address PCB mixtures with no further adjustment. Hence, the value derived by WHO (2003), also derived by ATSDR and US EPA, is recommended for use in the derivation of a soil HIL.

Few inhalation-specific studies are available, with RIVM deriving an inhalation specific value based on limited data. No dermal or inhalation specific studies or data are available. As the data is limited and does not suggest the toxicity of PCBs is significantly different via inhalation, the oral TDI is recommended for the assessment of all pathways of exposure.

Recommendation

On the basis of the discussion above, the following toxicity reference values (TRVs) have been adopted for PCBs in the derivation of HILs:

Recommendation for PCBs
Oral TRV = 0.00002 mg/kg/day (WHO 2003) for all pathways of exposure
Dermal absorption factor = 0.14 (or 14%) (US EPA 2004)
Intakes allowable from soil (as % of TRV) = 100%.

1.5 Calculated HILs

On the basis of the above, the following HILs have been derived for PCBs:

HIL scenario	HIL (mg/kg)	Percentage contribution from exposure pathways			
		Ingestion of soil/dust	Ingestion of home-grown produce	Dermal absorption of soil/dust	Inhalation (dust)
Residential A	1	20%	48%	32%	<1%
Residential B	2	13%	--	87%	<1%
Recreational C	1.5	24%	--	76%	<1%
Commercial D	8	9%	--	91%	<1%

-- Pathway not included in derivation of HIL

1.6 References for PCBs

ATSDR 2000, *Toxicological profile for polychlorinated biphenyls*, Agency for Toxic Substances and Disease Registry.

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2 Polybrominated diphenyl ether flame retardants (Br1 to Br9)

2.1 General

Polybrominated diphenyl ethers (PBDE) are a group of compounds manufactured for their flame retardant properties. They consist of a two phenyl groups bound to a single oxygen atom with the hydrogen atoms on the phenyl groups substituted with between one and ten bromine atoms. The group consists of 209 structurally similar compounds or 'congeners' which differ in the number and location of substituted bromine. The internationally accepted numbering system for PBDE congeners is the acronym 'BDE' followed by a number from one to 209 (NICNAS 2007).

Several comprehensive reviews of PBDEs in the environment and toxicity to humans are available and should be consulted for more detailed information not presented in this summary (ATSDR 2004; NICNAS 2007; UNEP 2009). The following provides a summary of the key aspects of these compounds that are relevant to the derivation of a soil HIL.

The literature to date indicates that the toxicity and environmental fate of PBDEs with a lower number of substituted bromine atoms (penta-BDE to hexa-BDE) is different to higher brominated BDEs (deca-BDE or BDE-209). Lower brominated BDE have been demonstrated to be more toxic in animal studies, have a higher bioavailability and are more readily transported in the environment. As a result, the ATSDR has recommended separating deca-BDE from 'lower brominated BDEs' (ATSDR 2004). For the purpose of this assessment, 'lower brominated BDEs are considered to be BDEs containing between one and nine substituted bromines and it is these lower brominated BDEs for which HILs have been derived.

Further studies regarding the toxicity and environmental fate of lower brominated BDEs may result in this grouping being revised to a smaller proportion of significant congeners in future reviews.

PBDE are manufactured compounds, which have been widely used in industrial, and consumer applications. A review of the compounds conducted by scientific and regulatory bodies have culminated in tetra- and penta-BDEs (components of technical penta-BDE) and hexa- and hepta-BDEs (components in technical octa-BDE) being listed as a persistent organic pollutants (POP) under the Stockholm Convention in May 2009 (UNEP 2009). All production and use of these compounds have subsequently been banned with the exception of recycling activities (UNEP 2009). PBDEs are not manufactured in Australia but were historically imported and used until 2005 (NICNAS 2007). Importation of products pre-treated with PBDEs is expected to decrease following the recent ban. Technical penta-BDE was mainly used in polyurethane foams (such as in furnishings) whereas technical octa-BDE and deca-BDE were mainly used in hard plastics (such as for electrical equipment) (NICNAS 2007). The articles treated with PBDEs usually have long lives and as such, articles containing PBDEs are still expected to be in use (NICNAS 2007).

Deca-BDE was declared a priority existing chemical in Australia and is currently being assessed as to its environment and human health risks (NICNAS 2007).

2.2 Previous HIL

No previous HIL is available for lower BDEs (NEPC 1999).

2.3 Significance of exposure pathways

Oral bioavailability

Insufficient data is available to adequately define the bioavailability of lower BDEs; hence, a default approach of assuming 100% oral bioavailability has been adopted in the derivation of a HIL. It is noted that a site-specific assessment of bioavailability can be undertaken where required.

Dermal absorption

Insufficient data is available on the dermal absorption of lower BDEs from soil. Hence the default values of 0.1 (10%) suggested by US EPA (2004) for semi-volatile organic compounds has been adopted in the derivation of HILs.

It is noted that the EU (2004) estimated a dermal absorption value of 1% as a maximum for deca-BDE based on assumptions associated with the lipophillic nature of the compound and analogies to PCB. However, it is also noted in this review that dermal absorption may also be associated with accumulation in the stratum corneum which may behave as a storage site resulting in a low systemic release over time.

Inhalation of dust

Lower BDEs are not considered sufficiently volatile to be of significance and inhalation exposures associated with dust particulates outdoors and indoors are expected to be of less significance than ingestion of soil. While likely to be negligible, potential inhalation exposures associated with dust have been considered in the HIL derived.

Plant uptake

Limited data is available on the potential for lower BDEs to be taken up by plants from soil into edible fruit and vegetable crops. ATSDT notes that PBDEs will be strongly adsorbed to soil; hence, PBDEs present in soil-pore water will bind to soil organic matter. Because PBDEs adsorb strongly to soil, they will have very low mobility and leaching of PBDEs from soil to groundwater will be insignificant.

Review of plant uptake of deca-PBDE (BDE-209) into plants from soil by Huang et al. (2010) suggests that deca-BDE is taken up and translocated within the plants assessed (ryegrass, alfalfa, pumpkin, squash, maize and radish). Nineteen lower brominated (di- to nona-) PBDEs were detected in the soil and plant samples and five hydroxylated congeners were detected in the plant samples, indicating debromination and hydroxylation of BDE-209 in the soil−plant system. Evidence of a relatively higher proportion of penta- through di-BDE congeners in plant tissues than in the soil indicates that there is further debromination of PBDEs within plants or low brominated PBDEs are more readily taken up by plants.

On the basis of the available information, the potential for the uptake of lower BDEs into home-grown produce has been considered in the derivation of HIL A.

This has been undertaken on the basis of the equations presented in Appendix B, with the following parameters and plant uptake factors estimated:

Parameter	Value	Reference/Comment
Parameters		
Koc	1698000 (cm^3/g)	Refer to note below*
log Kow	6.84	RAIS (2010) for pentaBDE (BDE-99)
Diffusivity in water	$5.32x10^{-6}$ (cm^2/s)	Estimated as per Guan et al, 2009
Calculated plant uptake factors (mg/kg produce fresh weight per mg/kg soil)		
Green vegetables	0.00026	calculated
Root vegetables	0.0038	calculated
Tuber vegetables	0.079	calculated
Tree fruit	0.00096	calculated

* The estimation of potential plant uptake of BDE is sensitive to the value of Koc adopted. The data would normally be derived from RAIS (2010) for consistency; however, the data provided is only for penta-BDE with data from no other lower BDEs presented for comparison. Data presented in ATSDR (2001) suggests log Koc ranges from 2.89-5.1 for penta-BDE and from 5.92-6.22 for octa-BDE. Review by Guan et al. (2009) provides log Koc values for the lower BDEs (BDE-28 to BDE-208) that range from 5.73 to 6.49. Due to the range of values provided for the lower BDEs, the average of values presented by Guan et al (2009), log Koc = 6.23 has been adopted.

Intakes from other sources – background

Background intakes were evaluated by NICNAS (2007) on the basis of PBDE levels in blood rather than as an intake. The presence of PBDEs in blood lipids indicates exposure by the general population; however, the data does not determine the major source of exposure. Data available from FSANZ (2007) suggests that dietary sources are likely to be low; therefore, house dust may be the major source; however, there is little correlation between exposure levels and house construction/contents. FSANZ notes a review in the US where dietary exposures did not explain the current body burden and exposures to hose dust were estimated to account for 82% of the total intake. Based on information presented in the available reviews, the following can be noted with respect to background intakes of PBDEs:

- A range of dietary intakes have been determined by FSANZ (2007) for all age groups. Estimated 95th percentile dietary intakes from FSANZ (2007) for a child aged 2-5 years ranged from 7 ng/kg/day (lower bound) to 389 ng/kg/day (upper bound). These intakes are consistent with data reported from other countries including Canada and the US and corresponded with a margin of exposure (MOE) of 300 or greater where a threshold of 0.1 mg/kg/day was considered. The MOE was greater for all other age groups considered in the study.
- PBDE in dust reported in indoor air in Australian buildings (Toms et al. 2006) ranged from 0.5 to 179 pg/m^3 for homes and 15 to 487 pg/m^3 for offices. Dust concentrations ranged from 87 ng/g to 3070 ng/g. PBCEs were detected in 9 out of 10 surface wipe samples. No estimation of intake associated with measured levels in air and dust were presented. The study size was limited and showed dust levels similar to or lower than those conducted overseas in Canada and the US.
- Upper bound total intakes of PBDEs from all sources (ambient and indoor air, dietary and dust) in Canada (Health Canada 2006) have been estimated to be approximately 0.95 µg/kg/day for children aged 0.5 to 4 years. Higher intakes (2.6 µg/kg/day) are noted for breastfed infants. Recent review of total intakes from food, dust and air of PBDEs in the US (Schecter et al. 2008) range from 1.2 ng/kg/day for adults to 307 ng/kg/day for infants.
- Based on the Australian data noted above, intakes by young children may range from 0.007 to 0.5 µg/kg/day. The higher values is half that estimated by Health Canada (2006), both of which exceed the recommended oral TRV.

- On the basis of the above, total intakes (and those reported from Australia) vary and may comprise a significant proportion of the recommended threshold value. Hence, consideration of 80% of the recommended TRV as background intakes is considered appropriate.

2.4 Identification of toxicity reference values

Classification

The International Agency for Research on Cancer (IARC 1999) has classified technical deca-BDE as Group 3: not classifiable. No classification is available for other BDEs.

It is noted that the US EPA has a classification for deca-BDE where it is classified as Group C: possible human carcinogen. The US EPA has classified technical penta-BDE and technical octa-BDE as Group D: not classifiable.

Review of available values/information

Review of PBDEs, in particular, penta-BDE and octa-BDE by NICNAS (2007) indicated there is insufficient information of the carcinogenic potential of these PBDEs and that the overall conclusion relating to penta-BDE is that it is not genotoxic. Further review of octa-BDE, PBDE mixtures and penta-BDE (JECFA 2006) suggest that PBDE mixtures and individual congeners are not genotoxic. On the basis of the available information, it is considered appropriate that a threshold dose-response approach be adopted for PBDEs. The following are available for the lower BDEs from Level 1 Australian and international sources:

Source	Value	Basis/Comments
Australian		
ADWG (NHMRC 2004)	No evaluation available	
OCS (2008)	No evaluation available	
NICNAS (2007)	No ADI/TDI established	Based on review of PBDEs and available studies the highest toxicity was associated with penta-BDE associated with neurodevelopmental effects in pups and dams where the LOAELs were 0.8 mg/kg/day in pups and 0.06 mg/kg/day in dams.
FSANZ (2007)	No ADI/TDI established	Review of dietary intakes considered a MOE approach where a threshold value of 0.1 mg/kg/day was considered based on review by JECFA.
International		
JECFA (2006)	No ADI/TDI established	Due to the complexity of PBDEs and the lack of adequate data a provisional maximum tolerable daily intake or provisional tolerable weekly intake has not been derived for PBDEs. Limited data suggests that for more toxic PBDE congeners adverse effects would be unlikely to occur in rodents at doses less than approximately 0.1 mg/kg/day.
WHO DWG	No evaluation available	
Health Canada (2006)	No ADI/TDI established	A threshold value of 0.8 mg/kg/day was identified for penta-BDE based on neurobehavioural effects in neonatal mice, considered the critical effects and appropriate for undertaking a MOE approach to the assessment of risk.
ATSDR (2004)	No chronic duration MRLs derived	No chronic duration MRLs have been derived for lower brominated BDEs due to insufficient data. An intermediate duration oral MRL of 0.007 mg/kg/day has been derived on the basis of a LOAEL of 2 mg/kg/day associated with liver effects in rats exposed to penta-BDE. An intermediate duration inhalation MRL of 0.006 mg/m^3 has been derived based on a NOAEL of 1.1 mg/m^3 for thyroid effects in rats exposed to commercial octa-BDE mixture.

Source	Value	Basis/Comments
US EPA (IRIS 2010)	RfD = 0.0001 mg/kg/day for penta-BDE (BDE-99)	RfD established (in 2008) for BDE-99 (penta-BDE) on the basis of a benchmark dose approach and a $BMDL_{1SD}$ of 0.29 mg/kg/day associated with neurobehavioral effects in mice and an uncertainty factor of 3000.
	RfD = 0.002 mg/kg/day for penta-BDE	Penta-BDE RfD established (in 1986) on the basis of a NOAEL of 1.77 mg/kg/day associated with liver effects in rats and an uncertainty factor of 1000. This evaluation is still available however the review in 2008 considered a specific penta-BDE congener and more sensitive end-point.
	RfD = 0.0004 mg/kg/day for hexa-BDE (BDE-153)	Hexa-BDE RfD established (in 2008) for BDE-153 on the basis of a NOAEL of 0.45 mg/kg/day associated with neurobehavioral effects in mice and an uncertainty factor of 3000.
	RfD = 0.0001 mg/kg/day for tetra-BDE (BDE-47)	Tetra-BDE RfD established (in 2008) for BDE-47 on the basis of a benchmark dose approach and a $BMDL_{1SD}$ of 0.35 mg/kg/day associated with neurobehavioral effects in mice and an uncertainty factor of 3000.
	RfD = 0.003 mg/kg/day for octa-BDE	Octa-BDE RfD (established in 1986) for octa-BDE based on a NOAEL of 2.51 mg/kg/day associated with liver effects in rats and an uncertainty factor of 1000.

Limited quantitative data is available for the characterisation of chronic exposures to lower BDEs. The more recent evaluations by the US EPA (IRIS) for individual congeners BDE-99, BDE-153 and BDE-47 have considered threshold values (BMDLs or NOAELs) that are consistent with those identified in reviews by NICNAS (2007), JECFA (2006) and Health Canada (2006) that are associated with the more sensitive end-point of neurobehavioral/developmental effects. These end-points are more sensitive than those considered by ATSDR in the derivation of intermediate duration MRLs and considered in older reviews by the US EPA for penta-BDE and octa-BDE. The uncertainty factor applied by the US EPA to the individual congeners considered, 3000, includes an additional 10 fold factor to address database deficiencies.

There is no evaluation of a chronic threshold value that would be applicable to all lower BDEs as a group, hence application of the US EPA values requires an assumption that the congeners studied are an appropriate indicator for total lower BDEs. This is likely to be conservative; however, no more detailed evaluations are available. The individual congener studies by the US EPA are noted by NICNAS (2007) to be those within commercial penta-BDE that are of most importance in biomonitoring and environmental sampling.

The lower RfD of 0.0001 mg/kg/day derived by the US EPA for BDE-99 and BDE-47, similar to that derived for BDE-153, is recommended for use in the derivation of a soil HIL for lower BDEs. As noted in most other reviews, the available database is poor and limited with respect to identification of a threshold associated with chronic exposures to the group of congeners. Hence, the use of this threshold TRV required further review and update in the future and when further studies are undertaken.

No dermal or inhalation specific chronic studies or data are available. For the presence of lower BDEs in soil, it is considered appropriate to consider use of the available threshold value for all pathways of exposures.

Recommendation

On the basis of the discussion above the following TRVs have been adopted for lower BDEs in the derivation of HILs:

Recommendation for lower BDEs

Oral TRV = 0.0001 mg/kg/day (US EPA [IRIS 2010] for BDE-99 and BDE-47) for all pathways of exposure

Dermal absorption factor = 0.1 (or 10%) (US EPA 2004)

Intakes allowable from soil (as % of TRV) = 20%

2.5 Calculated HILs

On the basis of the above, the following HILs have been derived for lower BDEs:

HIL scenario	HIL (mg/kg)	Percentage contribution from exposure pathways			
		Ingestion of soil/dust	Ingestion of home-grown produce	Dermal absorption of soil/dust	Inhalation (dust)
Residential A	1	42%	9	49%	<1%
Residential B	2 (2.2)	18%	--	82%	<1%
Recreational C	2 (1.9)	30%	--	69%	<1%
Commercial D	10	12%	--	88%	<1%

-- Pathway not included in derivation of HIL

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3 Shortened forms

ADI	Acceptable daily intake
ADWG	Australian Drinking Water Guidelines
ANZECC	Australia and New Zealand Environment and Conservation Council
ATDS	Australian Total Diet Survey
ATSDR	Agency for Toxic Substances and Disease Registry
BMD	Benchmark dose
BTEX	Benzene, toluene, ethylbenzene and total xylenes
CCME	Canadian Council of Ministers of the Environment
CICAD	Concise International Chemicals Assessment Document
CNS	Central nervous system
EHC	Environmental health criteria
EPA	Environment Protection Authority
FSANZ	Food Standards Australia New Zealand
HEC	Human equivalent concentration
HED	Human equivalent dose
HIL	Health investigation level
HSDB	Hazardous Substances Data Bank
HSL	Health screening level
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	WHO/FAO Joint Meeting on Pesticide Residues
LOAEL	Lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
MF	Modifying factor
MOA	Mode (or mechanism) of action
NEPC	National Environment Protection Council
NEPM	National Environment Protection Measure
NHMRC	National Health and Medical Research Council
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
NSW DECC	New South Wales Department of Environment and Climate Change
OCS	Office of Chemical Safety
PAH	Polycyclic aromatic hydrocarbon
PTDI	Provisional tolerable daily intake
PTWI	Provisional tolerable weekly intake
RAIS	Risk Assessment Information System
RfC	Reference concentration
RfD	Reference dose
SF	Slope factor
TC	Tolerable concentration
TCE	Trichloroethene
TDI	Tolerable daily intake
TPH	Total petroleum hydrocarbons

TPHCWG	Total Petroleum Hydrocarbon Criteria Working Group
UF	Uncertainty factor
UR	Unit risk
USEPA	United States Environmental Protection Agency
VC	Vinyl chloride
VOC	Volatile organic compound
WHO	World Health Organisation
WHO DWG	World Health Organisation Guidelines for Drinking Water