OSWER 9200.3-54

REVIEW OF INTERNATIONAL SOIL LEVELS FOR DIOXIN

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December 28, 2009

EXECUTIVE SUMMARY

A number of foreign nations have evaluated the toxicity of dioxin and have established concentration values in soil that are intended to provide protection to humans who may be exposed under residential or commercial/industrial land uses. Two types of soil levels have been established:

- Screening Levels are generally interpreted as concentrations below which health concern is minimal and no further investigations or evaluations are needed.

- Action Levels are generally interpreted as concentrations above which concern is likely to exist and where some sort of response action is likely to be needed.

Because dioxin is a carcinogen, the method used to derive screening levels or action levels depends on the assumed mode of action of dioxin. The World Health Organization (WHO) has evaluated the available data for dioxin, and has determined that cancer effects of dioxin are caused by a non-linear threshold mode of action. Consequently, human health will be protected from both cancer and non-cancer effects if the average daily ingested dose of dioxin does not exceed the Tolerable Daily Dose (TDI).

In 1990, the WHO estimated the TDI to be 10 pg/kg-day. In 1998, the WHO revised this estimate and identified a range of 1-4 pg/kg-day, with 1 pg/kg-day being the goal. In 2001, this range was re-evaluated using several new studies, and a range of 2-2.3 pg/kg-day was identified. Nearly all foreign nations have followed the approach recommended by the WHO for evaluating dioxin toxicity, and have selected TDI levels in the 1-10 pg/kg-day range. Each of these TDI values or ranges is a suitable candidate for consideration in EPA's determination of soil PRG levels, with preference for the most recent values.

The method for deriving a soil level from a TDI depends upon which soil exposure pathways are considered (ingestion, inhalation, dermal), and on the exposure parameters for each pathway. In some cases, other factors may also be considered. **Table ES-1** lists soil screening levels and action levels that were located for foreign nations, indicating the TDI values that were considered, and the exposure pathways that were included. As shown, screening levels range from 1 to 250 ppt, with most values of about 10 ppt. Residential action levels range from 10 to 1,500 ppt, with most values in the 100 to 1,000 ppt range. Commercial/industrial action levels range from 100 to 18,000 ppt, with most values in the 1,000 to 10,000 ppt range. Unfortunately, based on the information presently located, the detailed basis for the derivation of these soil levels is not clear except for the Netherlands.

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LIST OF ABBREVIATIONS AND ACRONYMS

BMD	Benchmark Dose
COT	Committee on the Toxicity of Chemicals in Food
EC	European Commission
ECEH	European Centre for Environmental Health Safety
IPCS	International Programme on Chemical
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
oSF	Oral Slope Factor
OSWER	Office of Solid Waste and Emergency Response
PBPK	Physiologically-based pharmacokinetic
PCDD	Polychlorinated dibenzodioxins
PCDF	Polychlorinated dibenzofurans
RfD	Reference Dose
SCF	Scientific Committee on Food
TCDD	2,3,7,8-tetrachloro-p-dibenzodioxin
TDI	Tolerable daily intake
TEQ	TCDD Equivalents
USEPA	United States Environmental Protection Agency
WHO	World Health Organization

REVIEW OF INTERNATIONAL SOIL LEVELS FOR DIOXIN

1.0 OVERVIEW

Regulatory agencies in many nations have sought to identify a default concentration of dioxin (2,3,7,8-TCDD) and related polychorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDFs) in soil that does not pose an unacceptable health risk to humans. These values are generally expressed in terms of TCDD-equivalent (TEQ) concentrations, which include the contributions from all of the relevant PCDD and PCDF congeners.

In general, one or both of two types of soil level have been established:

- Screening Levels are generally interpreted as concentrations below which health concern is minimal and no further investigations or evaluations are needed.

- Action Levels are generally interpreted as concentrations above which concern is likely to exist and where some sort of response action is likely to be needed.

The purpose of this report is to review the methods that have been used by other countries to derive screening levels and/or action levels for dioxin in soil, and to characterize the values that have been established.

2.0 BASIC STRATEGIES FOR DERIVING SOIL LEVELS

Review of the approaches used by various nations for deriving soil levels for dioxin have identified three basic strategies. These are discussed below.

2.1 Linear Non-Threshold Cancer Risk Model

Dioxin is a carcinogen. If the risk of cancer from dioxin is assumed to be linear in the low-dose range and to have no threshold, then the basic equation for calculating the soil level that corresponds to some specified acceptable "target cancer risk" is as follows:

$$Cancer\ Soil\ Level\ (pg/g) = \frac{Target\ Cancer\ Risk}{Soil\ Intake\ Rate\ (g/kg-d) \cdot Slope\ Factor(pg/kg-d)^{-1}}$$

As seen, the soil level for cancer depends on the slope factor, the intake rate of soil, and the target cancer risk. The slope factor is usually derived by fitting the linearized multistage model to an appropriate set of cancer exposure-response data (animal data), while intake rate is based

on default assumptions about residential or worker exposure to soil. Target cancer risk is a risk management choice, and is typically in the 1E-04 to 1E-06 range.

Because dioxin also causes non-cancer as well as cancer effects, it is also appropriate to calculate a soil level that will protect against non-cancer effects, as follows:

$$Non-Cancer\ Soil\ Level\ (pg/g) = \frac{Threshold\ Dose\ (pg/kg-day)}{Soil\ Intake\ Rate\ (g/kg-day)}$$

As seen, the soil level for non-cancer effects depends only on the ratio of the threshold dose (an intake level that does not cause any adverse effects) to the soil intake rate.

Given the cancer and non-cancer soil levels, the lower of the two is generally selected to ensure protection against both types of effect.

2.2 Non-Linear Threshold Cancer Risk Model

If the cancer effects of dioxin are assumed to occur via a non-linear threshold mode of action, then exposures that are below the threshold for non-cancer effects are assumed to be safe for both cancer and non-cancer effects. In this case, the soil level is calculated using the non-cancer equation described above:

$$Soil\ Level\ (pg/g) = \frac{Threshold\ Dose\ (pg/kg-day)}{Soil\ Intake\ Rate\ (g/kg-day)}$$

The threshold dose is usually referred to as a Reference Dose (RfD) in the United States, and as a Tolerable Daily Intake (TDI) in Europe and Asia. These two terms are conceptually equivalent and both describe the total amount of dioxin/TEQ that may be ingested per day that will not result in an adverse health effect.

The value of the TDI or RfD can be derived in several ways, including:

- Direct observation of no-effect dose levels in reliable studies
- Benchmark dose (BMD) modeling of reliable non-cancer dose-response data
- Calculations from a tissue-based no-effect level, using an appropriate physiologically based pharmacokinetic (PBPK) model

2.3 Exceedence of "Background"

If it is assumed that any excess exposure to dioxin is undesirable because of its high potency for both non-cancer and cancer effects, then the soil level may be set equal to the "background" level of dioxin in soil. This approach does not require any data on toxicity or exposure, but does

require robust data on the distribution of concentration values in soils that are considered to be "background". Because dioxin can be released from a variety of sources (ATSDR 1998), soil "background" levels may vary as a function of location and setting (rural, industrial, urban, pristine, etc.).

3.0 SEARCH OBJECTIVES AND METHODS

3.1 Search Objectives

The goal of this search effort was to identify soil action levels for dioxin that have been adopted by various nations. In addition, the primary objective was to document the underlying basis of these soil levels (e.g., toxicity value, derivation approach, exposure parameters) with regard to the following criteria. The resulting objective was to identify international soil levels based on the most recent, sound science and evaluate the levels based on the following criteria:

- Nature of peer review
- Transparency/reproducibility & public availability
- Scientific basis

These criteria are consistent with those recommended for Tier 3 human health toxicity value sources indicated in USEPA Office of Solid Waste and Emergency Response (OSWER) Directive 9285.7-53, *Human Health Toxicity Values in Superfund Risk Assessments* (USEPA 2003).

3.2 Search Methods

Searches for information on international soil levels for dioxin were primarily performed using web-based search engines. These searches were initially quite broad in scope in an attempt to locate any publicly-available information on dioxin (or TEQ) toxicity assessments and/or soil levels. These initial searches did not target specific soil level types (e.g., residential/commercial, screening/action level), and did not attempt to target specific nations or regions. Information on dioxin soil levels for European nations was initially located in two key summary reports:

- Carlon, C. (ed.). 2007. *Derivation Methods of Soil Screening Values in Europe. A Review and Evaluation of National Procedures Towards Harmonization*. European Commission, Joint Research Centre, Ispra, EUR 22805-EN, 306 pp. http://www.nicole.org/news/downloads/EUR22805-EN%20(3)_27_AUG.pdf

- AEA Technology. 1999. *Summary Report: Compilation of EU Dioxin Exposure and Health Data. Task 1 - Member State Legislation and Programmes.* Produced for European Commission DG Environment, UK Department of the Environment Transport and the Regions. October. http://ec.europa.eu/environment/dioxin/download.htm

When potentially relevant dioxin information was located for a particular nation, a more focused search of specific agency websites and peer-reviewed literature was performed to identify and gather the underlying documents providing the detailed information on the basis and derivation of the specified soil levels.

4.0 RESULTS

4.1 Nations that Use the Linear No-Threshold Risk Model

Only one foreign nation (Germany) evaluated the cancer effects of dioxin assuming a linear no-threshold mode of action. Based on information reported in Carlon (2007), both oral exposure and inhalation exposure are considered, and both cancer and non-cancer effects are evaluated. Two types of values are identified:

- "Trigger levels" are concentrations in soil that warrant further investigation to determine if the concentration of the contaminant in soil is hazardous.

- "Action levels" are concentrations in soil that, as a rule, indicate that a hazard is present that must be addressed. Further investigation is usually not necessary.

Equations for calculating "Trigger Levels" utilized by Germany are as follows:

Effect	Pathway	Equation
Cancer	Oral	$TL = D_{tb} \cdot f_{rc} \cdot 8.75 / IR$
	Inhalation	$TL = D_{tb} \cdot f_{rc} \cdot 8.75 / (IR \cdot AF)$
Non-Cancer	Oral	$TL = D_{tb} \cdot (f_{rc} - 0.8) / IR$
	Inhalation	$TL = D_{tb} \cdot f_{rc} / (IR \cdot AF)$

where:

TL = Trigger Level in soil (pg/g)
D_{tb} = Tolerable body dose (pk/kg-day)
f_{rc} = risk connecting factor
8.75 = ratio of averaging time to assumed exposure duration for cancer (70 yrs/8 yrs)
0.8 = fraction of total daily dioxin intake that is derived from the diet
IR = average daily soil intake (g/kg-day)
AF = accumulation factor of dioxin in dust

Default values employed by Germany in the computation of Trigger Levels for dioxin for residential land use are as follows (Carlon 2007):

Parameter	Cancer		Non-cancer	
	Oral	Inhal	Oral	Inhal
D_{tc} (pg/kg-day)	6.7E-02	6.0E-02	1.0	--
f_{rc}	5	5	3.2	--
IR (g/kg-day)	1.65E-02	4.1E-05	1.65E-02	--
AF	--	10	--	--

Note that the soil ingestion rate (16.5 mg/kg-day) used by Germany is substantially higher than the default value used by the United States Environmental Protection Agency (USEPA) (3.81 mg/kg-day). Likewise, the soil inhalation rate used by Germany (4.1E-02 mg/kg-day) is also higher than the USEPA default (2.3E-04 mg/kg-day), although the air pathway remains minor in both cases. Also note that the exposure duration for cancer effects (8 years) is much shorter than assumed by USEPA (30 years), and that for non-cancer effects, only 20% of the allowable daily intake is allocated to soil.

For cancer effects, the oral slope factor (oSF) utilized by Germany may be calculated as follows:

$$oSF = \text{Target Risk} / D_{tc} = 1E\text{-}05 / 6.7E\text{-}02 = 1.5E\text{-}04 \text{ (pg/kg-day)}^{-1}$$

This is the same value utilized by the United States.

Based on the inputs provided above, the derived soil Trigger Levels for dioxin are as shown below:

Effect	Toxicity Value	Target Risk	Trigger Level (pg/g)		
			Oral	Inhal.	Combined
Cancer	1.5E-04 (pg/kg-day)$^{-1}$	1E-05	178	6400	173
Non-cancer	1.0 pg/kg-day	HQ = 1	145	--	145

As seen, the Trigger Level for cancer effects (1E-05) is 173 ppt, and the Trigger Level for non-cancer effects is 145 ppt. Presuming that the lower of the two values is selected as the final value, the final soil Trigger Level for dioxin would be 145 ppt. However, no information was located on the selected Trigger Level for dioxin in the literature.

As noted above, Germany utilizes an approach in which both a Trigger Level and an Action Level are identified. The residential Action Level for dioxin selected by Germany is 1,000 ppt. No information was located on the process used by Germany to derive the selected soil Action Level.

4.2 Nations that Use the Non-Linear Threshold Risk Model

4.2.1 TDI Values

Most foreign nations for which information was located follow the approach in which the cancer effects of dioxin are believed to be mediated by a non-linear threshold mode of action. This approach has been developed mainly by the World Health Organization (WHO) and several other international health groups. **Table 1** provides a summary of TDI values that have been derived by WHO and others. These are discussed in greater detail below.

WHO 1990

In 1990, the World Health Organization (WHO) Regional Office for Europe organized several expert consultations and working groups to perform a toxicological evaluation for TCDD (WHO 1991, 1992). It was concluded that TCDD was carcinogenic in animals, acting as a non-genotoxic promoter-carcinogen. Therefore, the consultation decided to establish a TDI based on general toxicological effects. The no-effect dose was estimated to be about 1,000 pg/kg-day in various laboratory animals, which was adjusted to an equivalent human dose of 100 pg/kg-day using toxicokinetic data. After applying an uncertainty factor of 10 to account for insufficient data on reproductive effects in humans, a TDI of 10 pg/kg-day was recommended.

WHO 1998

In 1998, the WHO European Centre for Environmental Health (WHO-ECEH) and International Programme on Chemical Safety (IPCS) performed a re-assessment of the available information on the toxicity of dioxin (WHO 1998), and reached the following key conclusions:

- the cancer effects of dioxin are mediated by a non-genotoxic mode of action that is mediated via a receptor binding mechanism. Consequently, cancer risk has a threshold, and exposures that do not cause non-cancer effects will not increase cancer risk.
- the most sensitive non-cancer effects caused by dioxin included developmental and reproductive effects in rats and monkeys.
- the most reliable metric of exposure for use in risk evaluation is tissue burden rather than ingested dose.

Based on these key conclusions, WHO (1998) estimated the TDI (pg/kg-day) for lifetime exposure in a series of 3 steps, as follows:

Step 1: Identify the tissue burden effect level for the most sensitive (and relevant) adverse responses. Based on studies in rats and monkeys, the WHO estimated that the lowest observed adverse effect level (LOAEL) tissue burdens ranged from 28-73 ng/kg (28,000-73,000 pg/kg).

Step 2: Given the tissue burden range, calculate the TDI that would yield this tissue burden range. The WHO computed the TDI using a simple steady-state pharmacokinetic model of the following form:

$$TDI\ (pg/kg\text{-}d) = Tissue\ Burden\ (pg/kg) \cdot [1-\exp(-\ln(2)/t_{1/2})] / f$$

where:

$t_{1/2}$ = half-time of dioxin in the body (days)
f = fraction of an ingested dose that is absorbed

WHO utilized a half-time of 7.5 years (2,738 days), and an assumed fractional absorption of 0.5 (50%). Based on this, the TDI was estimated to range from 14-37 pg/kg-day.

Step 3: Adjust the TDI to account for uncertainties. A factor of 10 was applied to address the following uncertainties: a) the use of a range of LOAELs instead of a no-effect level, b) the possible differences in susceptibility between humans and experimental animals, c) the potential differences in susceptibilities within the human population, and d) differences in half-lives of elimination for the compounds of a complex TEQ mixture. After application of the uncertainty factor, the TDI (rounded) was estimated to range from 1-4 pg/kg-day.

The WHO (1998) consultation stressed that the upper range of the TDI of 4 pg/kg-day should be considered a maximal tolerable intake on a provisional basis and that the ultimate goal is to reduce human intake levels to below 1 pg/kg bw-day.

EC-SCF and JECFA 2001

In 2001, the European Commission Scientific Committee on Food (EC-SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) incorporated several new studies published since the 1998 WHO re-assessment and estimated the TDI to be 2.0-2.3 pg/kg-day, respectively, using an approach similar to the one described above[1].

Table 1a summarizes the TDI values recommended by these various international organizations.

TDI Values Selected by Various Nations

Table 2 provides a summary of the information that was located for nations that follow the TDI approach for evaluating dioxin toxicity. As indicated, a majority of nations have chosen to adopt TDI values recommended by WHO. This includes:

[1] EC-SCF recommended a tolerable weekly intake (TWI) of 14 pg/kg, while JECFA recommended a tolerable monthly intake (TMI) of 70 pg/kg. These values correspond to TDI values of 2.0 to 2.3 pg/kg-day.

WHO (1990) TDI = 10 pg/kg-day	WHO (1998) TDI = 1-4 pg/kg-day	JECFA (2001) TDI = 2.3 pg/kg-day
▪ Austria ▪ Italy	▪ France ▪ Germany ▪ Netherlands ▪ New Zealand[2]	▪ Australia ▪ Canada

However, several nations (see **Table 1b**) have performed their own re-assessment of the available toxicity data for dioxin to derive a TDI, rather than adopting TDI values derived by others. Japan derived a TDI of 4 pg/kg-day, which is equivalent to the maximum TDI established by WHO (1998). For the United Kingdom, the Government's independent advisory Committee on the Toxicity of Chemicals in Food (COT) recommended a TDI of 2 pg/kg-day, which is equivalent to the TDI identified by EC-SCF (2001). In August 2000, several countries (Denmark, Finland, Sweden) considered revising the Nordic Council TDI value of 5 pg/kg-day to a value of 4 pg/kg-day in accord with WHO (1998), but it was determined that no change was appropriate (Johansson and Hanberg 2000).

4.2.2 Derivation of Soil Levels

As noted above, given a TDI, the soil level is computed as follows:

$$Soil\ Level\ (pg/g) = \frac{TDI\ (pg/kg-day)}{Soil\ Intake\ Rate\ (g/kg-day)}$$

The soil intake rate may be computed in a number of different ways, depending on which exposure pathways are considered (ingestion, dermal contact, inhalation of particulates, and/or ingestion of crops or livestock that have been impacted by soil). The general form of the equation is:

$$Soil\ Level = \frac{TDI}{\sum (k_i \cdot IR_i)}$$

where:

TDI = Tolerable daily intake
k_i = Ratio of dioxin concentration in medium "i" to concentration in soil
IR_i = Intake rate of medium "i"

[2] New Zealand has recently adopted the WHO 1998 TDI values; however, the soil action levels identified utilize WHO 1990 TDI values.

For example, if only the soil ingestion pathway is considered, the basic equation is:

$$Soil\ Level\ (pg/kg) = \frac{TDI}{IR_s}$$

where:

TDI = Tolerable daily intake (pg/kg-day)
IR_s = Average soil intake rate (g/kg-day)

If dermal contact, inhalation exposure and intake of foods (e.g., garden vegetables) grown in contaminated soil are considered, the equation is:

$$Soil\ Level\ (pg/kg) = \frac{TDI}{IR_s + IR_d + k_{air} \cdot IR_{PM10} + k_{veg} \cdot IR_{gv}}$$

where:

IR_d = Intake rate of soil from dermal exposure (g/kg-day)
k_{air} = Concentration in air (pg/m^3) divided by concentration in soil (pg/g)
IR_{PM10} = Intake rate of air (m^3/kg-day)
k_{veg} = Concentration in vegetable (pg/g) divided by concentration in soil (pg/g)
IR_{gv} = Intake rate of garden vegetables (g/kg-day)

Note that inhalation exposure from PM10 particles usually contributes only a small dose compared to oral exposure (typically <1%). Consequently, whether the inhalation pathway is included or not generally has little influence on the result.

Soil Levels Identified by Various Nations

Not all nations that utilize the TDI approach have derived soil levels. **Table 2** provides the detailed information for all soil levels located for various nations. This table includes a variety of different soil levels and nomenclature in describing these levels. As described above, the various soil levels reported by the nations were stratified into two broad categories – screening levels and action levels. Screening levels are soil values below which no further investigation is likely to be needed. Usually these screening values are not land use specific, but are applied to all land use types. Action levels are soil values above which cleanup actions are warranted. These values are often effects-based (i.e., derived from a TDI) and land use specific. The most common land use types are residential and commercial/industrial, although some nations also derive action levels for agricultural and recreational land uses.

Table 3 summarizes the screening levels and action levels for residential and commercial/ industrial soils that have been derived. **Figure 1** presents these soil levels in a graphical format. As shown, screening levels (Panel A) range from 1 to 250 ppt, with most values of about 10 ppt.

Residential action levels (Panel B) range from 10 to 1,500 ppt, with most values in the 100 to 1,000 ppt range. Commercial/industrial action levels (Panel C) range from 100 to 18,000 ppt, with most values in the 1,000 to 10,000 ppt range.

Figure 2 presents the soil action levels for residential (Panel A) and commercial/industrial (Panel B) grouped by the selected TDI. As shown, there is a wide range of soil levels within each TDI value (e.g., residential action levels range from 100 to 1,000 ppt for a TDI of 1 pg/kg-day). This suggests that the primary reason for the differences in the derived soil levels is due to differences in the exposure parameters utilized.

Unfortunately, the basis of these soil levels is not always clear. Carlon (2007) sought to determine the methods that had been used by each nation to establish the soil levels, and concluded that, in most cases, the basis of the soil levels was not well documented. Even in cases where documentation is available, derived soil values are not always reproducible. Therefore, it is suspected that most soil values reflect risk management decisions that are not based solely on risk-based exposure-response models.

4.3 Nations that Use the Exceedence of Background Approach

Two nations (Canada and Czech Republic) were identified in which the soil screening level is stated to be based on background levels of dioxin. For Canada, the soil screening level identified as the average background level is 4 ppt, and this value is intended to apply to all land use types (i.e., agricultural, residential, commercial, industrial). For the Czech Republic, there are two soil screening levels identified: 1 ppt, which was identified as the 95th percentile of background, and 100 ppt, which is a value selected between background and the "limit of pollution". Most nations, including the United States (USEPA 2007), report background concentrations within range of 1-10 ppt.

5.0 EVALUATION

In order for the USEPA to consider a human health toxicity value (TDI, slope factor) for use in risk calculations or in the derivation of a soil level, it must meet the criteria of a Tier 3 value established by USEPA OSWER Directive 9285.7-53 (USEPA 2003). As noted above, these criteria are as follows:

- Nature of peer review – in accord with USEPA (2003), "draft assessments are not appropriate for use until they have been through peer review, the peer review comments have been addressed in a revised draft, and the revised draft is publicly available".

- Transparency/reproducibility and public availability – in accord with USEPA (2003), values should be "available to the public, and…transparent about the methods and

processes used to develop the values". In addition to being transparent, values should be reproducible (i.e., able to be derived based on the provided information).

- Scientific basis – in accord with USEPA (2003), values should be "based on similar methods and procedures" as USEPA guidance (e.g., cancer risk assessment guidelines, soil screening guidance).

Table 4 presents a matrix of the evaluation criteria for the TDI values (top panel) and soil action levels (bottom panel) currently utilized by various nations. In general, most of the TDI values derived by the WHO and other international health groups have been peer reviewed, are transparent/reproducible and publically available, and are based on science that is consistent with current USEPA guidance procedures (assuming that a threshold mode of action is accepted). Thus, all of these TDI values would rank as appropriate for use as Tier 3 human health toxicity values. TDI values developed by various nations (e.g., Japan), do not meet all of the specified criteria in full.

For the soil action levels (**Table 4**, lower panel), with the exception the Netherlands, no nations provided sufficient detail to document the underlying basis of the adopted soil values and no information was located on the peer review process associated with the adopted values. For the Netherlands, soil levels were derived using an exposure model called CSOIL. Detailed information on this model and the underlying exposure parameters and assumptions are documented in the *Technical Evaluation of the Intervention Values for Soil/Sediment and Groundwater* (RIVM 2001). The derived soil values are subject to review by the Netherland Technical Soil Protection Committee and Health Council.

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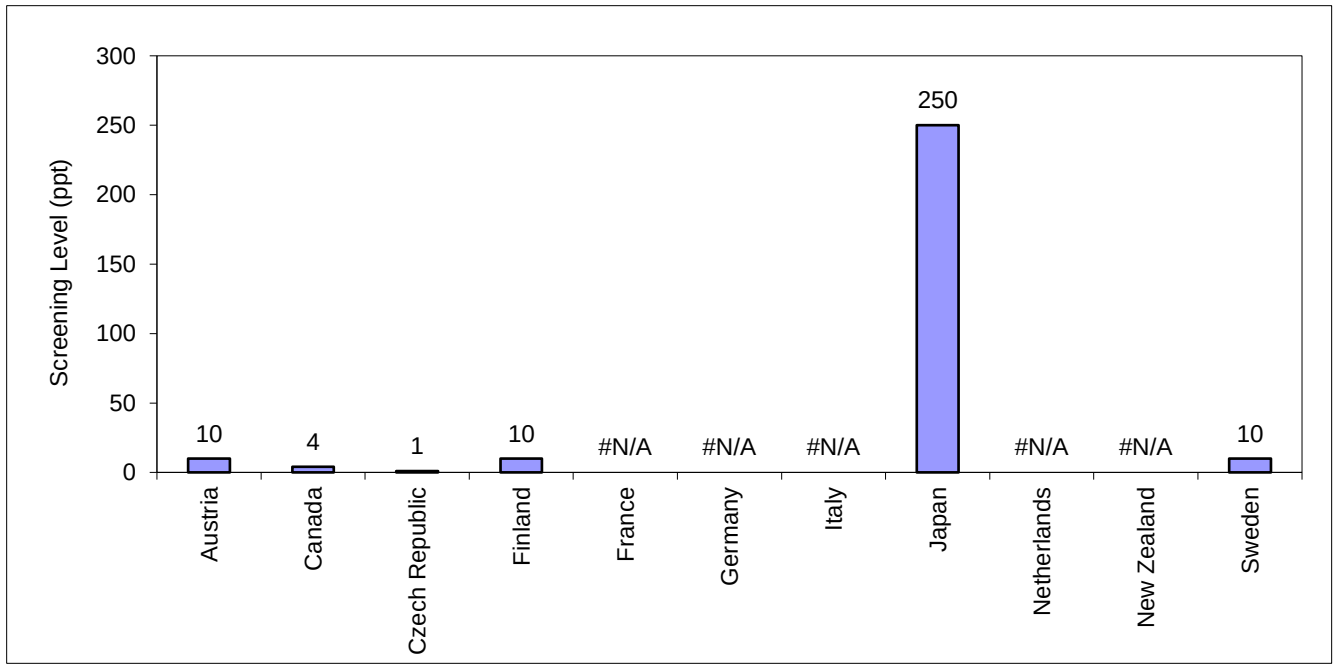
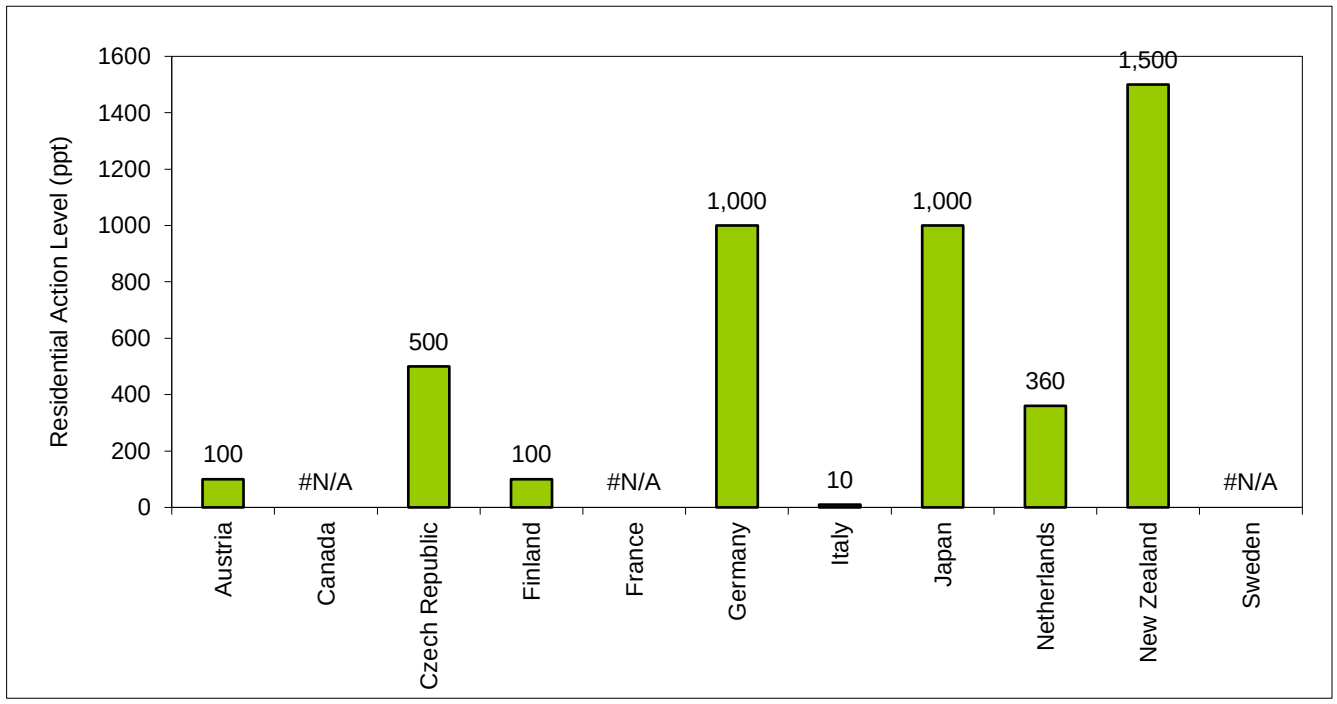
Figure 1. International Screening Level and Action Levels

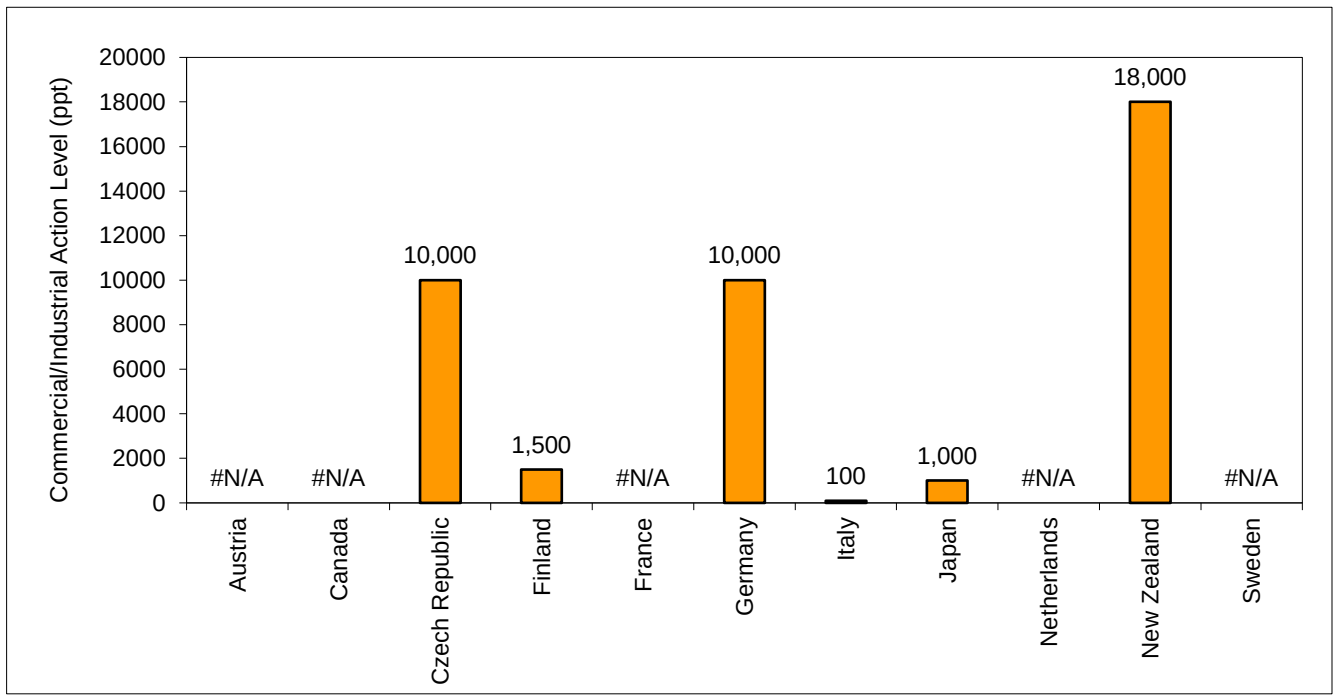
Panel A: Screening Levels



Panel B: Residential Action Levels



Panel C: Commercial/Industrial Action Levels

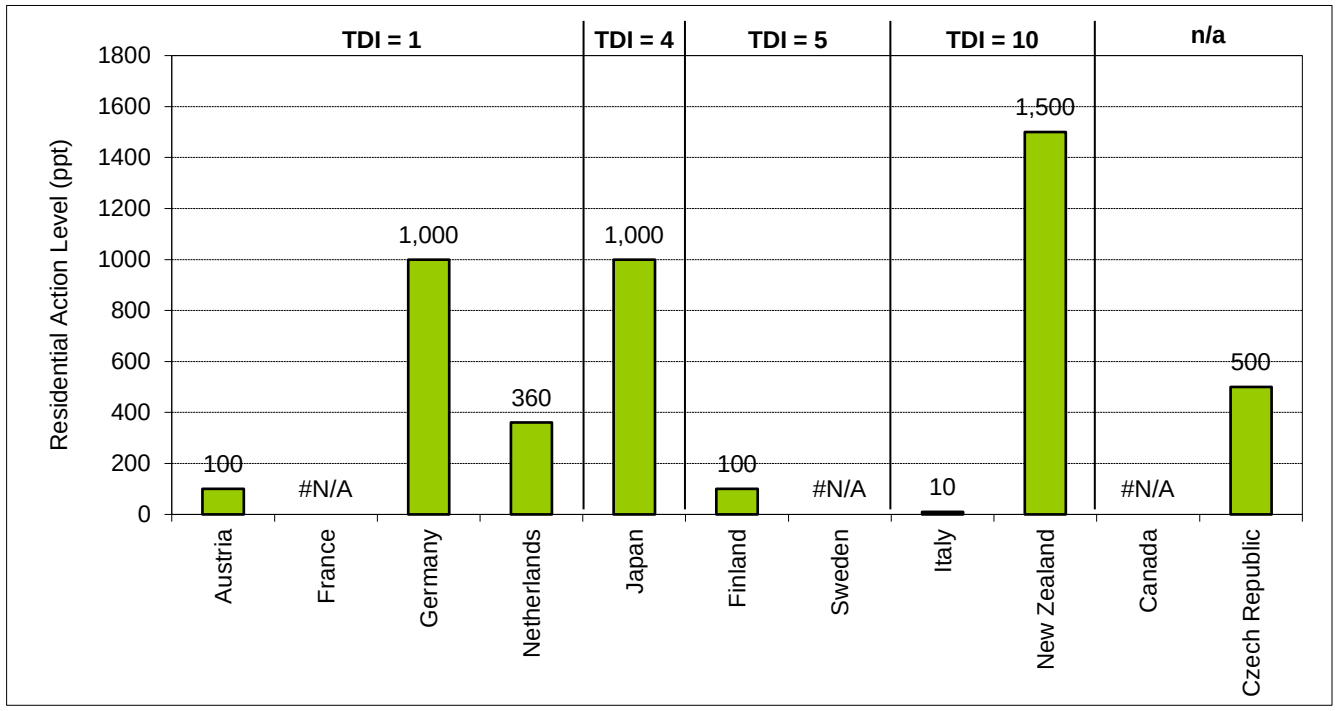


#N/A = not available

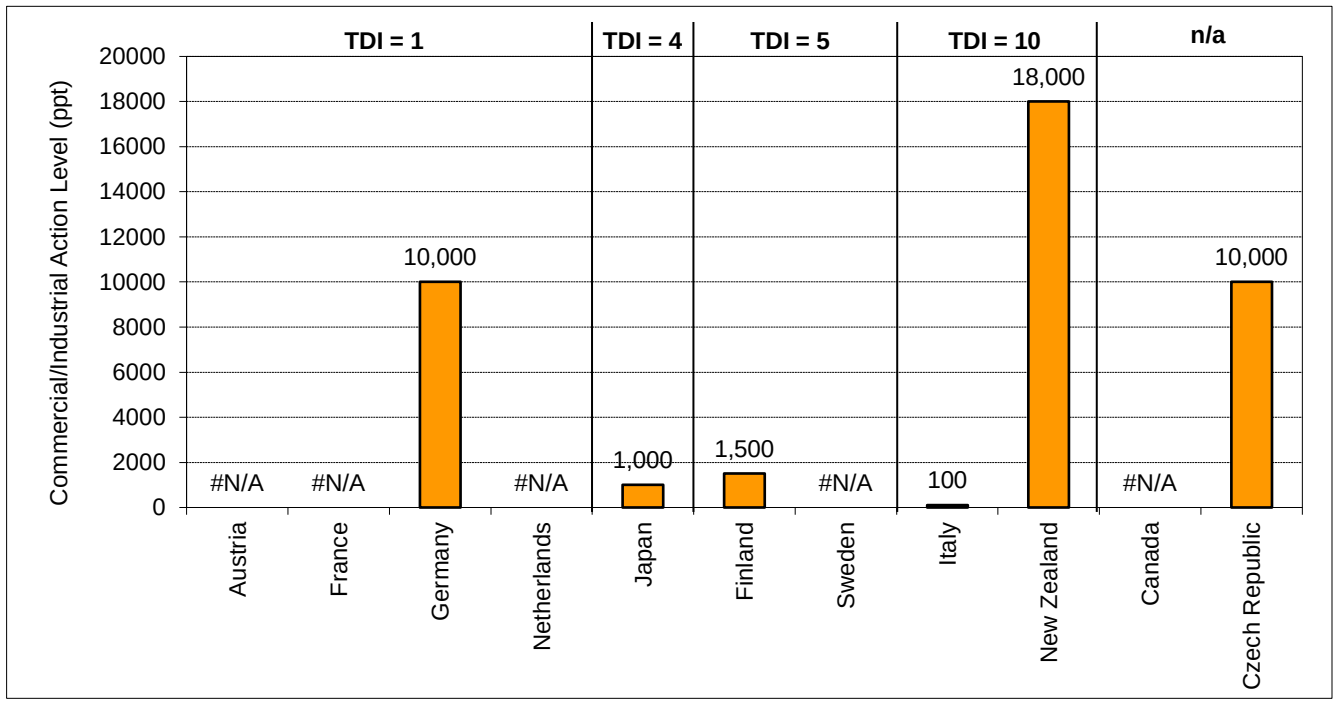
dioxinsoillevels-international.xls

Figure 2. International Action Levels Stratified by Adopted TDI

Panel A: Residential Action Levels



Panel B: Commercial/Industrial Action Levels



#N/A = not available

Table 1a. Tolerable Daily Intake (TDI) Values Developed by International Organizations

International Organization	Date	TDI (RfD)			Tissue Burden Used to Dereive TDI (RfD)					Information Source(s)	Nature of Peer Review	Transparency/ Reproducibilty- Public Availability	Scientific Basis	Incorporation of Most Recent Science	Notes
		Value	Parameter [see note A]	Basis	Tissue Value	Basis	Uncertainty Factor (UF)	Half-time in body ($t_{1/2}$)	Absorption Fraction (f)						
World Health Organization (WHO)	1990	10 pg/kg/d	Maximum TDI	Noncancer effects in humans (based on animal studies)	--	no effect level of 100 pg/kg/d (equivalent dose in humans) for non-cancer effects in various laboratory animals	10	--	--	Ref [27] ***More detailed information on TDI derivation may be available in Ref [28]*	Based on consensus of many different national and international experts. Consultation was attended by 20 experts from 11 countries, one representative from the Netherlands government, 3 observers and 5 staff from the Regional Office and WHO headquarters.	Documents available online	Studies of liver toxicity and reproductive and immunotoxicology in the various laboratory animal species identified a no-effect level of 1000 pg/kg-day. Pharmacokinetic data indicated that this was equivalent to a dose of 100 pg/kg-day in humans. Because of the inadequate data based on reproductive effects in humans, an uncertainty factor of 10 was employed by the Consultation and therefore a TDI of 10 pg/kg-day was recommended.	Based on available toxicological literature and studies available at the time of the consultation (1990).	
World Health Organization European Centre for Environmental Health (WHO-ECEH) & International Programme on Chemical Safety (IPCS)	May 1998	1-4 pg/kg/d (reported as TEQ) 4 pg/kg/d 1 pg/kg/d	Provisional TDI for lifetime exposure Maximum TDI Target TDI	Noncancer effects in humans (based on animal studies)	28-73 ng/kg bw (maternal body burden)	range of LOAELs across multiple studies for developmental and reproductive effects in rats and monkeys	10	7.5 years	50%	Ref [18]	Based on consensus of many different national and international experts. The WHO-ECEH coordinated a comprehensive programme in collaboration with IPCS. Consultation attended by 40 experts from Australia, Belgium, Canada, Denmark, Finland, Germany, Italy, Japan, The Netherlands, New Zealand, Spain, Sweden, United Kingdom, and USA and by staff from UNEP, IARC, IPCS and WHO-ECEH.	Document available online Procedure for selection of tissue burden and calculation of TDI is transparent and reproducible	The LOAELs for the most sensitive adverse responses (noncancer effects) reported in experimental animals were associated with maternal body burdens of 28-73 ng/kg bw, from which a range of estimated long-term human daily intakes of 14-37 pg/kg/d was calculated (see Table 4). An uncertainty factor of 10 was applied to account for: a) the use of a range of LOAELs instead of a NOAEL, b) the possible susceptibility differences between humans and experimental animals, c) the potential differences in susceptibilities within the human population, and d) differences in half-lives of elimination for the compounds of a complex TEQ mixture. Based on this, a final TDI, expressed as a range of 1-4 TEQ pg/kg bw (rounded figures) was established for dioxins and dioxin-like compounds.	Based on available toxicological literature and studies available at the time of the consultation (1998).	
European Commission Scientific Committee on Food (EC-SCF)	30-May-01	14 pg/kg/d 2 pg/kg/d	TWI (TDI equiv.)	Noncancer effects in humans (based on animal studies)	40 ng/kg bw (maternal body burden)	LOAEL for reproductive effects in Wistar rats *(Faqi et al., 1998)*	9.6	7.5 years (see notes)	50% (see notes)	Ref [19]	The SCF took cognisance of comments received from the Swedish National Food Administration (2001), the Norwegian Food Control Authority (2001) and from some members of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission.	Document available online Procedure for selection of tissue burden and calculation of TDI is generally transparent and reproducible (see notes)	An estimated human daily intake (EHDI) of 20 pg/kg bw/day was calculated from the estimated steady state TCDD body burden in the rat dams at the LOEL of 40 ng/kg bw. Application of a 9.6-fold safety factor to the EHDI yielded a TDI of 2 pg/kg bw/day. Due to the long half-lives of TCDD and related compounds in the human body, this figure was converted to a TWI of 14 pg/kg bw.	The EC-SCF based their updated risk assessment on the LOEL for reproductive toxicity in male offspring of pregnant rats from the study by Faqi et al (1998), rather than the rat and monkey studies used by the WHO (1998).	$t_{1/2}$ & f not specified explicitly in Ref [19], but confirmed based on calculation of the TDI from the specified tissue burden.
Joint FAO/WHO Expert Committee on Food Additives (JECFA)	2002	70 pg/kg/d 2.3 pg/kg/d	Provisional TMI (TDI equiv.)	Noncancer effects in humans (based on animal studies)	NOAEL: 16-22 ng/kg bw LOAEL: 28-42 ng/kg bw (range of total body burdens as estimated by two different models)	NOAEL for reproductive effects in Holzman rats *(Ohsako et al., 2001)* LOAEL for reproductive effects in Wistar rats *(Faqi et al., 1998)*	NOAEL: 3 LOAEL: 9.6	7.6 years	50%	Ref [21]	Based on consensus of many different national and international experts.	Document available online Procedure for selection of tissue burden and calculation of TDI is transparent and reproducible	JECFA derived estimated human monthly intakes (EHMIs) of 237 and 330 pg TEF/kg bw, using the linear and nonlinear models, respectively, from the study by Ohsako et al (2001). The corresponding EHMI values derived from the study by Faqi et al (1998) were 423 and 630 pg TEF/kg bw. A safety factor of 3.2 was applied to the EHMIs associated with the NOEL identified by Ohsako et al (2001). JECFA considered that use of the LOEL from by Faqi et al (1998) warranted an additional safety factor of 3, leading to an overall safety factor of (3 x 3.2) = 9.6. The four resulting provisional tolerable monthly intake (PTMI) values ranged from 44 to 103 pg/kg bw/month. JECFA took the mid-point of the range (70 pg TEF/kg bw/month) as the chosen PTMI for PCDDs, PCDFs and coplanar compounds.	JECFA chose the LOEL established in the study of Faqi et al (1998) and the NOEL provided by the study of Ohsako et al (2001). Two different models were used to estimate the equivalent maternal body burden with long-term dosing: a model that assumed a linear relationship between maternal and foetal body burden, and a nonlinear model.	

Notes:

[A] Maximum TDI - Maximum Tolerable Daily Intake; life-time exposure and occasional short-term excursions above this level would have no health consequences provided that the averaged intake over long periods is not exceeded.
Target TDI - Target Tolerable Daily Intake; the ultimate goal is to reduce human intake levels below this level.
TWI - Tolerable Weekly Intake; similar to maximum TDI, but expressed on a weekly basis. TDI equivalent is calculated as TWI / 7 days.
TMI - Tolerable Monthly Intake; similar to maximum TDI, but expressed on a monthly basis. TDI equivalent is calculated as TMI / 30 days.

TDI is equivalent to a non-cancer Reference Dose (RfD)

Table 1b. Tolerable Daily Intake (TDI) Values Developed by Specific Nations

Nation -- Agency	Date	TDI (RfD)			Tissue Burden Used to Dereive TDI (RfD)					Information Source(s)	Nature of Peer Review	Transparency/ Reproducibilty- Public Availability	Scientific Basis	Incorporation of Most Recent Science	Notes
		Value	Parameter [see note A]	Basis	Tissue Value	Basis	Uncertainty Factor (UF)	Half-time in body ($t_{1/2}$)	Absorption Fraction (f)						
Japan -- Environment Agency of Japan	June 1999	4 pg/kg/d (reported as TEQ, includes PCBs)	Lifetime TDI	Noncancer effects in humans (based on animal studies)	86 ng/kg bw	LOAEL (lowest body burden value just below or above that at which effects are manifested across multiple studies)	10	7.5 years	50%	Ref [17]	The Environment Agency and the Ministry of Health and Welfare have established expert committees (the Dioxin Risk Assessment Subcommittee, Environmental Health Committee, Central Environment Council; the Living Environment Council; and the Special Dioxin Health Effects Evaluation Committee, Food Sanitation Investigation Council) and it was decided at a joint consultation earlier this year that the TDI should be re-evaluated in Japan. On 30 March 1999, a Cabinet Meeting adopted the “Basic Guidelines of Japan for the Promotion of the Measures Against Dioxins” which required a review of the TDI	Document available online Procedure for selection of tissue burden and calculation of TDI is transparent and reproducible	TDI (meaning the daily dose of 2,3,7,8-TCDD which is assumed to have no adverse effects on human health if taken constantly over a lifetime), which shall be a guideline for measures against dioxins taken by the national government and local governments, shall not exceed 4 pg/kg bw. Established based upon effects due to exposure during the fetal period which is the most sensitive period. Manifestation of effects such as carcinogenicity would only occur as a result of higher exposure than the established TDI. TDI value is determined by extrapolating results of animal tests for humans, multiplied by a factor of 0.1 for taking account of uncertainty.	A level of approximately 86 ng/kg is the lowest body burden value just below or above that at which effects are manifested and is used as the basis for estimating TDI. This body burden corresponds to a human daily intake of 43.6 pg TEQ/kg/day, to which an an uncertainty factor of 10 was applied. The resulting TDI is 4 pg/kg/d (rounded).	Ref [17] : *"This report discusses the TDI of dioxins and related compounds by analyzing and assessing the discussions of the 1998 WHO Consultation and contributing new information."* *"...this paper utilizes newly calculated values instead of the noted [WHO] body burden values."* *"...memorandum accepts the conclusions of the WHO Consultation..."*
Nordic Council	2000	5 pg/kg/d	TDI	no information located	no information located					[Ref 23]	Recommendation of "Nordic expert group" (details on this group not located)	Summary document vailable in public journal Available documents do not provide the underlying basis for the derivation of the selected TDI	no information located	no information located	
United Kingdom -- Food Standards Agency, Committee on Toxicity of Chemicals in Food (COT)	2001	2 pg/kg/d	TDI	Noncancer effects in humans (based on animal studies)	33 ng/kg bw (maternal body burden)	LOAEL for reproductive effects in Wistar rats *(Faqi et al., 1998)*	9.6	7.5 years	50%	Ref [29]	No information located	Document available online Procedure for selection of tissue burden and calculation of TDI is transparent and reproducible	The calculated total steady-state maternal body burden arising from the subcutaneous dosing protocol at the LOAEL from Faqi et al. is approximately 30 ng/kg bw, which would be about 33 ng/kg bw after allowing for the TCDD intake from food. The resulting tolerable daily intake for humans is 1.7 pg/kg bw/day (rounded to 2).	Evaluation included a review of the risk assessments of dioxins carried out by the WHO, the SCF, and the USEPA. Because the correct mathematical model cannot be determined based on goodness of fit, and because the regressions are determined largely by body burdens higher than those relevant for derivation of a tolerable intake, we decided to adopt a simpler method of correction using the ratios calculated directly from the lowest doses in each of the studies by Hurst et al.	

TDI is equivalent to a non-cancer Reference Dose (RfD)

Table 2. International Data on Dioxin Levels in Soil

Note: Shaded soil values represent a "residential action level"

Nation	Agency	Soil Level (ppt TCDD/TEQ)							Soil Exposure Parameters					TDI (RfD)				Information Source(s)	Nature of Peer Review	Transparency/ Reproducibility- Public Availability	Notes
		Value	Land Use	Interpretation/ Application	Derivation Approach	Date	Regulatory Status	Enforcement	Pathways considered	Soil Intake Rate	Body weight	Exposure Freq. & Dur.	RBA	Value	Parameter [see note A]	Basis	Date				
Australia	National Health and Medical Research Council (NHMRC)	not specified							not applicable					2.3 pg/kg/d	Maximum TDI	Adopted the TDI recommended by JECFA (2001)	2002	As provided in Ref [22]	not appliable (no soil levels identified)	TDI value is available online	
Austria	Federal Environment Agency Austria, Contaminated Sites Department	10	not specified; assumed to be all land uses	trigger value for further investigation	Uncertain; identified by expert working group	-- (per document dated 2007]	guideline	Ref [25] *...soil screening values are hardly recognized due to missing legal backup...*	Ref [25]: *"The soil screening values used for risk assessment of contaminated sites have not been calculated along specific exposure scenarios or the use of models but have been identified by an expert working group established at the Austrian Standards Institute (ON)...a simplified and conservative conceptual approach referring to oral uptake by children is assumed."*					10 pg/kg/d (reported as TCDD)	Maximum TDI Target TDI	Appears to have adopted the maximum TDI from WHO (1990) and target TDI from WHO (1998)	-- (per document dated 1999]	Soil conc: As provided in Ref [25] TDI: As provided in Ref [1] ***Cited soil conc derivation source [26]*	No information located	information only available in secondary reports; primary reports not available	Soil intervention values are applicable to uses for which a direct hazard from oral intake of contaminated topsoil (0-10 cm) cannot be excluded (e.g. residential areas, sport fields, playgrounds). By purpose, no soil screening values for industrial areas have been included.
		100	residential (see notes)	intervention value; no description of the proper interpretation of "intervention value" was located																	
		--	industrial (see notes)																		
Canada	Canadian Council of Ministers of the Environment (CCME)	4	all (agricultural, residential/ parkland, commercial, and industrial)	soil quality guideline (SoQG); if exceeded, further investigation is needed to determine whether or not there is a negative impact	Soil Big Level	Mar-05	guideline (can be used by governments on a voluntary basis to set guidelines and clean-up targets)	No information located	not applicable					2.3 pg/kg/d	Maximum TDI	Adopted the TDI recommended by JECFA (2001)	Sep-05	Soil conc: Ref [2] TDI: Ref [20]	No information located	CSoQG and derivation protocol are available online.	Developed in accord with Ref [3]. The Soil Quality Guidelines Task Group develops, approves and publishes national soil quality guidelines for the protection of environmental and human health. The National Guidelines and Standards Office of Environment Canada acts as the technical secretariat for the task group, providing technical coordination and delivery of new and revised soil quality guidelines. This guideline was determined from the average background soil concentration in Canada because exposure to higher levels is not recommended. Health Canada is doing a comprehensive reassessment of the risks posed by dioxins (per publication dated Sept 2005).
Czech Republic	Czech Ministry of the Interior	1	not specified; assumed to be all land uses	upper level for natural big (set equal to 95th percentile of big dataset)	Soil Big Level	1994?	guideline?	Ref [25]: *"no human health screening values are directly specified in the legislation...legal force is rather low..."*	Details not available Ref [25]: *"The methodology for the calculation of values is not available."*					not specified			--	As provided in Ref [25] ***Soil derivation source: Ref [30]*	No information located	information only available in secondary reports; primary reports not available	
		100		value btwn big & limit of pollution																	
		500	residential	limit value; maximum accessible values that are statistically derived, not effects-based	Basis is not documented																
		1,000	recreational																		
		10,000	industrial																		
Denmark	not specified	not specified							not applicable					5 pg/kg/d (reported as N-TEQ)	Maximum TDI	Adopted the TDI recommended by Nordic Council	-- (per document dated 1999]	As provided in Ref [1] and Ref [25]	not appliable (no soil levels identified)	information only available in secondary reports	
Finland	Ministry of the Environment, Department for Environmental Protection	10	not specified; assumed to be all land uses	threshold trigger value; if value is exceeded, a site-specific assessment of contamination and remediation needs has to be carried out	Unknown	1994?	guideline *Ref [25]: "...values were originally meant to be advisory only and not to act straightforwardly as remediation targets."*	No information located	Details not available					5 pg/kg/d (reported as N-TEQ)	Maximum TDI	Adopted the TDI recommended by Nordic Council	-- (per document dated 1999]	Soil conc & derivation: As provided in Ref [25] (based on RIVM approach) TDI: As provided in Ref [1]	No information located	information only available in secondary reports; primary reports not available	The threshold value for soil has been set to a concentration level, in which risks to humans and ecosystems can be considered negligible. Additionally, certain socio-economic values were taken into account in defining the threshold values. The software Risc-Human version 3.1. was used to derive SSLs for the land uses considered; only the CSOIL model included in the software was applied. Specific model inputs are not specified.
		100	residential	lower limit guideline; if value is exceeded, soil is considered as contaminated and risk reduction measures are required	Uncertain; likely based on TDI approach, but this cannot be documented				1, soil ingestion; 2, inhalation (indoors and outdoors) of particulates; 3, dermal exposure (indoors and outdoors); 4, consumption of homegrown vegetables.	not specified	not specified	child>adult ED = 70 yrs	1								
		1,500	industrial	upper limit guideline; if value is exceeded, soil is considered as contaminated and risk reduction measures are required						not specified	not specified	adult only ED = 40 yrs	1								
France	Conseil Supérieur d'Hygiène Publique of France	500	not specified	VDSS: "soil source definition value"; is not intended to define a pollution source in a site characterization	Uncertain; likely based on TDI approach, but this cannot be documented	-- (per document dated 2007]	guideline? Ref [25]: *"VDSS and VCI should not be used outside the tsoring system of the ESR ("simplified risk assessment")."*	Ref [25]: *"...no significance outside the ranking process of the ESR."*	(set equal to 1/2 the VCI for sensitive use)					1 pg/kg/d (reported as I-TEQ)	Target TDI	Appears to have adopted the target TDI from WHO (1998)	-- (per document dated 1999]	Soil conc: As provided in Ref [25] TDI: As provided in Ref [1]	No information located	information only available in secondary reports; primary reports not available	
		1,000	sensitive use (playground, garden, ...)	VCI: "impact statement value"; based on German regulatory values; not intended to be screening values or remediation goals					1, soil and dust ingestion; 2, ingestion of home-grown produce (residential only); 3, dermal exposure to soil and dust. *Page 116 in Ref [25] provides detailed parameters for all pathways*	child: 150 mg/d adult: 50 mg/d	not specified	EDchild: 6 yrs EDadult: 24 yrs	not specified								
		10,000	non-sensitive use (industrial and commercial use, offices,...)								not specified	ED: 40 yrs	not specified								
Germany	German Federal Environmental Agency (Umweltbundes amt) & Joint Working Group of the Federal and Lander Ministers of the Environment	5	agricultural	long-term goal for use (see notes)	Basis is not documented	July 1999	guideline?	No information located	Details not available					1 pg/kg/d 0.2 pg/kg/d	TDI(total) TDI(soil)	Adopted the target TDI from WHO (1998)	Oct 2002	Soil Conc provided in Ref [1], Ref [4], and Ref [25] TDI provided in Ref [24] ***Cited soil conc derivation source: Ref [5]*	No information located	Soil concentrations available online; derivation basis for specified soil concentrations is only available in secondary source	More recent documents summarizing soil concentration levels (e.g., Ref [25]) only include the reported action levels. Action values pursuant to Article 8 (1) second sentence No. 2 of the Federal Soil Protection Act for the direct intake of dioxins/furanes at playgrounds, in residential areas, parks and recreational facilities, and pics of land used for industrial and commercial purposes (in ng/kg dry matter, fine soil).
		40		cultivation of certain foodstuffs					Details not available												
		100	playgrounds	risk-based action levels for protection of human exposures, if exceeded, usually leads to remedial action	Includes both non-cancer TDI and cancer SF approaches		regulation (Article 8 (1) second sentence No. 2 of the Federal Soil Protection Act)	No information located	Details for the derivation of the action level are unclear (see Attachment 1)												
		1,000	residential, parks/recreation																		
		10,000	industrial, commercial																		
Italy	National Toxicology Commission (CCTN)	10	residential/ public use	threshold limit values for the protection of human health; if exceeded, site is considered to be polluted and remedial action must be performed; are intended to be both intervention values and remediation targets	Uncertain; likely based on TDI approach, but this cannot be documented	-- (per document dated 2007]	regulation (Article 17 of Law No. 22/97, Italian Ministerial Decree No. 471/1999)	No information located Ref [25]: *"future regulations concerning soil pollution and soil clean-up are in preparation"*	Details not available Ref [25]: *"...multiple exposure scenarios (inhalation, ingestion, skin contact)...applying the ASTM PS104-98 'RBCA, Risk – Based Corrective Action' procedures"*					10 pg/kg/d (reported as I-TEQ, excluding PCBs)	Maximum TDI	Appears to have adopted the maximum TDI from WHO (1990)	-- (per document dated 1999]	Soil Conc: As provided in Ref [25] TDI: As provided in Ref [1] ***Possible soil conc derivation source: Ref [31]*	No information located	information only available in secondary reports; primary reports not available	Ref [25]: *"Soil values have been criticized both scientifically and practically...because they lack flexibility and do not take sufficient account of regional and local specificities."*
		100	commercial/ industrial use																		
Japan	Environment Agency of Japan	250	not specified; assumed to be all land uses	"survey index"; if exceeded, testing required	Basis is not documented	2009	guideline?	No information located	Details not available					4 pg/kg/d (reported as TEQ, includes PCBs)	Lifetime TDI	Noncancer effects in humans (based on animal studies) See Table 1 for details	June 1999	Ref [6], [7], [8], [9] TDI derivation details provided in: Ref [17]	No information located	Soil concentrations and TDI value available online; derivation basis for specified soil concentrations is not provided.	Ref [17]: *"...This report discusses the TDI of dioxins and related compounds by analyzing and assessing the discussions of the 1998 WHO Consultation and contributing new information."* *"...this paper utilizes newly calculated values instead of the noted [WHO] body burden values."* *"...memorandum accepts the conclusions of the WHO Consultation..."*
		1,000	not specified; assumed to be all land uses	"quality standard" for human health; if exceeded, remediation is needed	Uncertain; likely based on TDI approach, but this cannot be documented				Details not available												
Netherlands	National Institute for Public Health and the Environment (RIVM)	360	residential	intervention value (IV) for the protection of human exposures; if exceeded, soil is deemed "seriously contaminated" and remediation will be necessary (urgency of remediation to be determined)	TDI Approach	Feb-01	regulation? (Dutch Soil Protection Act in 2007)	No information located	1, ingestion of soil/dust; 2, inhalation of indoor air; 3, ingestion of contaminated crops. *Table 3.11 & 3.13 in Ref [12] provide detailed parameters for all pathways*	child: 100 mg/d adult: 50 mg/d	not specified	EDchild: 6 yrs EDadult: 64 yrs	1	4 pg/kg/d 1 pg/kg/d	Maximum TDI Target TDI	Adopted the recommended TDIs from WHO (1998)	Feb-01	Soil conc and TDI provided in Ref [12]	The derived SRCs will be reviewed by the Technical Soil Protection Committee (TCB) and (partly) by the Health Council of the Netherlands (Gezondheidsraad).	Soil derivation source document available online	In deriving the Serious Risk Concentrations for human exposures (SRChuman) for soil, sediment and groundwater, the human-toxicological Maximal Permissible Risk (MPR) level was used in combination with the CSOIL exposure model (exposure to contaminated soil). MPR reliability score = high.
New Zealand	Ministry for the Environment (MfE) and the Ministry of Health (MoH)	10	agricultural	interim soil acceptance criteria, to be used as a general indication of acceptable concentrations of dioxins in soil	TDI Approach (based on WHO 1990)	Jun-05	draft guideline (see notes)	No information located	Details not available					Soil Level Derivation: 10 pg/kg/d 8 pg/kg/d (reported as TEQ) Updated: 1 pg/kg/d	Maximum Oral TDI(total) TDI(soil) IMMI	Adopted the TDI from WHO (1990) Adopted the Target TDI from WHO (1998)	Jun-05	*Ref* [13] ***Soil conc derivation and TDI source info is unpublished: Ref [24]*	No information located	Soil concentrations and TDI values available online; derivation basis for specified soil concentrations is not available.	Interim Soil Acceptance Criteria are based on site-specific values developed for dioxins and furans at the Waipa Processing Complex, as part of the "Pentachlorophenol Risk Assessment Pilot Study" (NTG, 1992). Levels were calculated using a TDI of 10 pg/kg/d (WHO 1990). Care should be exercised when applying the above values to other sites, given they were developed for specific scenarios at a particular site. Since the derivation of these values, the Organochlorines Technical Advisory Committee (OTAG) has chosen to adopt the target TDI of 1 pg/kg/d (WHO 1998). This value was adjusted to represent an "interim monthly maximum intake (IMMI)".
		1,500	residential						Details not available												
		18,000	industrial, unpaved						Details not available												
		90,000 - ∞	industrial, paved						(lower bound: industrial, unpaved * 5 [assumed protection factor]) (upper bound: assumes ongoing paving integrity or capping)												
		21,000	maintenance						Details not available												
Sweden	Swedish Environmental Protection Agency	10	sensitive land use (residential)	Non-binding guidance values when revising land use for a contaminated area	Uncertain; likely based on TDI approach, but this cannot be documented	1996	guideline	No information located	Details not available					5 pg/kg/d (reported as TEQ, including PCBs)	Maximum TDI	Adopted the TDI recommended by Nordic Council	-- (per document dated 1999]	As provided in Ref [1], Ref [10], and Ref [25] ***Cited soil conc derivation source: Ref [15] & Ref [32]* ***TDI source?: Ref [23]*	Draft versions of the soil level derivation model spreadsheet (SEPA, 2005a) and risk assessment guidance (SEPA, 2005b) are currently under review.	information only available in secondary reports; primary reports not available	Soil values are derived assuming multi-media exposures and adjusted to account for bkg (90th percentile of bkg).
		250	non-sensitive land use (commercial/ industrial)						Details not available												
United Kingdom	Environmental Agency; Department for Environment, Food and Rural Affairs (Defra)	in development (see notes)							not applicable					2 pg/kg/d 0.4 pg/kg/d	TDI(total) TDI(soil)	Adopted the TDI recommended by COT (2001) TDI for soil specified in Ref [16]	March 2003	Ref [16]	not appliable (no soil levels identified)	Documents are available online	Defra reviewed evaluations by numerous Expert Committees. There was general consensus that the critical effects include immunological, developmental and reproductive effects, and that cancer effects are mediated via receptor-based non-genotoxic mechanism, so protection against non-cancer effects is also protective for cancer. Exposure is best characterized using a tissue-burden based dose metric, and a NOAEL-LOAEL approach with uncertainty factors is appropriate for estimating a Tolerable Daily Intake (TDI). Almost all estimates of TDI are about 2 pg/kg/day (total). Most of this comes from the diet. Allowing 20% of total to come from soil yields TDI(soil) = 0.4 pg/kg/day. Final step needed is to estimate PRG (soil guideline value = SGV) from TDI. Defra uses a Contaminated Land Exposure Assessment (CLEA) software program to do this. Using standard USEPA exposure methods, the PRG would be estimated as follows: PRG = TDI / (IR/BW * RBA) Assuming IR = 0.1 g/day for a 70 kg person, the PRG for soil would be in the range of 300-3000 ppt, depending on assumed RBA for dioxin in soil.

Countries where no information was located on dioxin soil levels and/or TDI (per Ref [1], Ref [25]): Belgium, Greece, Ireland, Lithuania, Poland, Portugal, Slovakia, Spain (in development per Ref [1])

Notes:

[A] Maximum TDI - Maximum Tolerable Daily Intake; life-time exposure and occasional short-term excursions above this level would have no health consequences provided that the averaged intake over long periods is not exceeded.
Target TDI - Target Tolerable Daily Intake; the ultimate goal is to reduce human intake levels below this level.
TWI - Tolerable Weekly Intake; similar to maximum TDI, but expressed on a weekly basis. TDI equivalent is calculated as TWI / 7 days.
TMI - Tolerable Monthly Intake; similar to maximum TDI, but expressed on a monthly basis. TDI equivalent is calculated as TMI / 30 days.

TDI is equivalent to a non-cancer Reference Dose (RfD)

Table 3. Summary of International Soil Levels for Dioxin

Nation	Agency	Screening Level (ppt TCDD/TEQ)	Action Level (ppt TCDD/TEQ)		Soil Action Level Derivation Approach	Exposure Pathways Considered	TDI (RfD) (pg/kg-d)	Date	Regulatory Status
			Residential	Commercial/ Industrial					
Austria	Federal Environment Agency Austria; Contaminated Sites Department	**10**	**100**	**--**	[9]	n/a	1 - 10	-- [2]	guideline
Canada	Canadian Council of Ministers of the Environment (CCME)	**4**	**--**	**--**	[11]	n/a	n/a	Mar-05	guideline
Czech Republic	Czech Ministry of the Interior	**1 - 100**	**500**	**10,000**	Basis is not documented [12]	n/a	--	1994?	guideline?
Finland	Ministry of the Environment, Department for Environmental Protection	**10**	**100**	**1,500**	TDI Approach [1]	Ing. (soil and plant), Inhal., Dermal	5	1994?	guideline
France	Conseil Supérieur d'Hygiène Publique of France	[8]			TDI Approach [1]	Ing. (soil and plant), Dermal	1	-- [2]	guideline?
Germany	German Federal Environmental Agency (Umweltbundesamt) & Joint Working Group of the Federal and Lander Ministers of the Environment	**--**	**1,000**	**10,000**	TDI and oSF Approach	Ing. (soil only), Inhal.	1 [4]	July 1999	regulation
Italy	National Toxicology Commission (CCTN)	**--**	**10**	**100**	TDI Approach [1]	n/a	10	-- [2]	regulation [3]
Japan	Environment Agency of Japan	**250**	**1,000** [7]		TDI Approach [1]	n/a	4	2009	guideline?
Netherlands	National Institute for Public Health and the Environment (RIVM)	**--**	**360**	**--**	TDI Approach	Ing. (soil and plant), Inhal.	1 - 4	Feb-01	regulation?
New Zealand	Ministry for the Environment (MfE) and the Ministry of Health (MoH)	**--**	**1,500** [10]	**18,000** [6,10]	TDI Approach	n/a	10 [5]	Jun-05	draft guideline
Sweden	Swedish Environmental Protection Agency	**10 - 250**	**--**	**--**	TDI Approach [1]	n/a	5	1996	guideline

See Table 2 for detailed information on soil levels and derivation approach

[1] Uncertain; likely based on TDI approach, but this cannot be documented

[2] Soil levels provided in a document dated 2007.

[3] Soil values have been criticized both scientifically and practically, because they lack flexibility and do not take sufficient account of regional and local specificities. Future regulations concerning soil pollution and soil clean-up are in preparation.

[4] Uses an adjusted TDI of 0.2 pg/kg/d (to account from fraction of TDI attributable to soil).

[5] Uses an adjusted TDI of 8 pg/kg/d (to account from fraction of TDI attributable to contaminated soil). Since the derivation of these soil levels, New Zealand has adopted target TDI of 1 pg/kg-d.

[6] Applicable to unpaved areas.

[7] Reported action levels are applicable to all land uses.

[8] Derived soil values are not intended to be screening values or remediation goals and should not be used outside of the simplified risk assessment scoring system.

[9] Uncertain; identified by expert working group.

[10] Site-specific values are used as interim soil acceptance criteria; use care when applying values to other sites.

[11] No action levels specified; screening level is based on a background soil approach.

[12] Screening levels are based on a background soil approach.

TDI = Tolerable Daily Intake; equivalent to a non-cancer Reference Dose (RfD)

Table 4. Evaluation of TDI Values and Soil Action Levels

TDI Values

	Nature of peer review	Transparency/ Reproducability & Public Availability	Scientific basis	Incorporation of new science
WHO 1990	●	●	●	
WHO 1998	●	●	●	
EC-SCF 2001	●	●	●	
JECFA 2001	●	●	●	
Japan 1999	❍	●	●	
Nordic Council 2000	X	X	X	
UK, COT 2001	X	●	●	

Soil Action Levels

	Nature of peer review	Transparency/ Reproducability & Public Availability	Scientific basis	Incorporation of new science
Austria	X	X	X	
Czech Republic	X	X	X	
Finland	X	❍	❍	
Germany	X	❍	●	
Italy	X	X	X	
Japan	X	X	X	
Netherlands	❍	●	●	
New Zealand	X	X	X	

Legend:

●	meets evaluation criteria in full
❍	meets evaluation criteria in part
X	does not meet evaluation criteria or no information was located

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ATTACHMENT 1 DERIVATION DETAILS FOR THE COMPUTATION OF GERMANY TRIGGER LEVELS

Nation	Agency	Land Use	Soil Exposure Parameters used in Trigger Level Calculation							Estimated Trigger Level (ppt)**	Specified Action Level (ppt)
			Pathways considered	Intake Rate	Body weight	Exposure Freq. & Dur.	RBA	Target risk or hazard	Daily Intake Rate (mg/kg-d)		
Germany	German Federal Environmental Agency (Umweltbundesamt) & Joint Working Group of the Federal and Lander Ministers of the Environment	playgrounds	1. ingestion of soil; 2. inhalation of soil particles.	ing: 500 mg/d inh: 0.625 m^3/hr	10 kg	EF=240 d/yr ET=2 hr/d ED=8 yrs	not specified	HQ=1 Risk=1E-05	ing: 33 inhal: 0.082	~73	100
		residential		(residential: set equal to 1/2 playground daily intake rates)					ing: 16.5 inhal: 0.041	~145	1,000
		parks/recreation		(parks/recreation: set equal to 1/5 playground daily intake rates)					ing: 6.6 inhal: 0.016	~364	1,000
		industrial, commercial	1. inhalation of soil particles	not specified	not specified	EF=225 d/yr ET=8 hr/d	not specified	HQ=1 Risk=1E-05	inhal: --	--	10,000

**only incorporates soil ingestion pathway