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REVIEW OF INTERNATIONAL SOIL LEVELS FOR DIOXIN

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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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