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Dioxin and Dioxin-Like Compounds in Soil, Part 1: ATSDR Interim Policy Guideline

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PURPOSE

The Agency for Toxic Substances and Disease Registry (ATSDR) has adopted this interim policy guideline to assess the public health implications of dioxin and dioxin-like compounds in residential soils near or on hazardous waste sites. These compounds include

- 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD)
- Chlorinated dibenzofurans (CDFs)

- Other structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons.

These substances are defined under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, commonly known as Superfund. This interim policy guideline will provide a clear and consistent understanding of ATSDR's current approaches and judgments regarding hazards posed by the presence of TCDD and its less toxic dioxin-like congeners, the CDDs and CDFs, in residential soils. Likely users of this interim policy guideline include

- ATSDR and state-based health assessors
- ATSDR partners including relevant federal, state, and local health and environmental entities
- Concerned community groups.

INTERIM POLICY GUIDELINE

This interim policy guideline is based on a current understanding of the toxicology and epidemiology associated with TCDD and its congeners (see "Background" section) and on exposure potential when soil is the primary medium of interest. This guidance is consistent with the Technical Support Document for ATSDR Interim Policy Guideline: Dioxin and Dioxin-Like Compounds in Soil (ATSDR 1997) and with the ATSDR Public Health Assessment Guidance Manual (ATSDR 1992). They explain how to use comparison values to select contaminants for further evaluation and then draw conclusions about the public health implications of the contaminants. Assessments of public health implications are based on considerations of site-specific factors affecting the extent and characteristics of exposure and on the toxicology and epidemiology of the compounds selected for evaluation.

This guidance for dioxin and dioxin-like compounds is unique because of the potency of TCDD itself, and the need to consider the total potency of all dioxin and dioxin-like compounds detected in soil. The toxicity of a dioxin-like compound is commonly referred to in terms of its dioxin toxicity equivalency factor (TEF). See "Background" section for further information.

These guidelines and procedures apply to human exposure for direct ingestion of soils contaminated with dioxin and dioxin-like compounds in residential areas and may not be appropriate for other exposure scenarios. The guidance will be evaluated in view of new data that may become available. The science basis for the guidance is outlined in the "Background" discussion.

Step 1. Screening for contaminants of concern

Review soil sampling data and compare levels against dioxin comparison values (environmental media evaluation guide or EMEG for children) that are not site-specific. If one or more soil sampling values exceed the screening value of 50 parts per trillion

(ppt) of toxicity equivalents (TEQs), further site-specific evaluations are needed as described next and in Table 1.

If samples exceed this screening value, then ATSDR generally assumes that further evaluation is required. However, even if samples are below these values, ATSDR policy states that it may still be necessary to conduct a more detailed site-specific evaluation under the following conditions:

- community health concerns
- health assessor's concerns about other combinations of contaminants.

Step 2. Evaluating potential exposure pathways

Further evaluation includes the most critical aspect of health hazard evaluations, that is, the determination of likelihood, extent, and duration of exposure of populations. Thus, the health assessor uses the following to determine the existence of a potential or completed exposure pathway--past, present, or future:

- site visits and observations
- detailed review of data packages for land use scenarios, contaminant locations, and site locations
- evaluation of receptor populations and potential points of contact.

If a completed or potentially completed exposure pathway is identified, then the extent of exposure and public health implications are further evaluated.

Site-specific exposure scenarios based on site-specific factors are evaluated in conjunction with relevant toxicologic, epidemiologic, and medical information. This involves assessing site-specific information about the likelihood, frequency, routes, and levels of exposure to contaminants, and the populations that are likely to be exposed.

Where estimated levels of exposure in soil fall in the range of greater than 50 ppt to less than 1 part per billion (ppb) TEQs (Table 1), a weight-of-evidence approach is recommended to evaluate the exposure and the public health implications of the exposure.

Health assessors must ask the following questions:

- How extensive is the contamination?
- Is the contamination isolated or widespread?
- Is the contamination in surface soils or areas easily accessible to children or adults? Is it in areas with no vegetation or in any other areas?
- At this site, how often (daily, weekly, monthly) and for what length of time (months, years, lifetimes) would exposures be likely to occur?

Many of these estimates depend on professional judgment and experience regarding the likelihood of exposures from soils in different kinds of sites. For further information on the evaluation process see ATSDR (1992).

Interpretation of health guidance values. The policy incorporates information on exposure potential from residential soils and residential exposure scenarios. It should be noted that the levels (in TEQs) ≤ 50 ppt (0.05 ppb), > 0.05 ppb but < 1 ppb and ≥1 ppb in residential soils are guidance values and should not be construed to indicate that actual health effects will occur. The policy provides a protective framework for evaluating the health implications of exposures to dioxin and dioxin-like compounds in residential soils on a site-specific basis.

Table 1. ATSDR's decision framework for sites contaminated with dioxin and dioxin-like compounds

Because the toxicity of dioxin and dioxin-like compounds is assumed to be elaborated through a common receptor-mediated mechanism, levels greater than 50 ppt TEQs* are used to determine whether further site-specific evaluation for dioxins is to occur based on the maximum soil concentrations identified at the site. A level of 1 ppb TEQs is used to determine the potential need for public health actions on a site-specific basis and on the basis of adequate sampling and measured or projected human exposure--past, present, or future--as determined by the health assessor.

SCREENING LEVEL	EVALUATION LEVELS	ACTION LEVEL**
≤ 50 ppt (0.05 ppb) TEQs	**> 0.05 ppb but < 1 ppb TEQs**	**≥1 ppb TEQs**
• The EMEG for TCDD is 50 ppt • This is based on an MRL of 1 pg/kg/day for TCDD (ATSDR 1989). • For screening purposes 50 ppt TCDD is assumed to be equivalent	Evaluation of site-specific factors, such as • Bioavailability • Ingestion rates • Pathway analysis • Soil cover • Climate • Other contaminants • Community concerns • Demographics • Background Exposures	Potential public health actions considered, such as • Surveillance • Research • Health studies • Community education • Exposure investigations

to 50 ppt TEQs		

* The toxicity equivalent (TEQ) of TCDD is calculated by multiplying the exposure level of a particular dioxin-like compound by its toxicity equivalency factor (TEF). TEFs are based on congener-specific data and the assumption that Ah receptor-mediated toxicity of dioxin-like chemicals is additive. The TEF scheme compares the relative toxicity of individual dioxin-like compounds to that of TCDD, which is the most toxic halogenated aromatic hydrocarbon.

** A concentration of chemicals at which consideration of action to interdict/prevent exposure occurs, such as surveillance, research, health studies, community education, physician education, or exposure investigations. Alternatively, based on the evaluation by the health assessor, none of these actions may be necessary.

Step 3. Defining public health implications/actions

Where exposures to concentrations in residential soils exceeding 1 ppb TEQs are significant, ATSDR health assessors should consider judging the site a public health hazard and consider site-specific public health recommendations/actions to prevent or interdict exposures (Table 1).

BACKGROUND FOR INTERIM POLICY GUIDELINE

Dioxin and dioxin-like compounds. Dioxin and dioxin-like compounds are structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons. Depending on the number of chlorine-substituted positions, there are several congeners in each group. The most toxic and the most studied congener is TCDD.

Toxicity equivalency factors (TEFs) were developed to compare the relative toxicity of individual dioxin-like compounds to that of TCDD (Tables 2 and 3). This comparison is based on the assumption that dioxin and dioxin-like compounds act through the same mechanism of action. The TEF for TCDD is defined as one, whereas TEF values for all other dioxin-like compounds are less than one. Toxicity equivalents (TEQs) are used to assess the risk of exposure to a mixture of dioxin-like compounds. A TEQ is defined as the product of the concentration, C_i, of an individual "dioxin-like compound" in a complex environmental mixture and the corresponding TCDD toxicity equivalency factor (TEF_i) for that compound. The total TEQs is the sum of the TEQs for each of the congeners in a given mixture:

$$\text{Total TEQs} = \sum_{i=1}^{n} (CI \times TEF_i)$$

Adverse health effects. Studies in animals demonstrated a wide range of effects associated with dioxin exposure including death, cancer, and wasting, as well as hepatic, immunologic, neurologic, reproductive, and developmental effects. In contrast to laboratory results, direct exposure information is not available in human studies; therefore, body burden is used as a surrogate. Body burdens in some animal studies were in the same range as those associated with adverse health effects in human studies. For more information, see Technical Support Document for ATSDR Interim Policy Guideline: Dioxin and Dioxin-Like Compounds in Soil (ATSDR 1997). These results underscore the need for research to elucidate the toxicity at low doses to human populations and to evaluate exposures in at-risk populations (see Appendix 1) in view of total body burdens of dioxin and dioxin-like compounds.

Screening level for dioxin and dioxin-like compounds in soil. While identifying levels of potential concern to human health, ATSDR considers a spectrum of contaminant concentrations. In general, *screening levels* are concentrations used to select contaminants of concern at hazardous waste sites that are taken forward in the health assessment process for further evaluation (screening levels are also called comparison values; see Appendix 1 - Glossary).

Table 2. Recommended Toxicity Equivalency Factors (TEFs) for CDDs and CDFs

CDDs	EPA current recommended values		CDFs	EPA current recommended values
monoCDDs	0		monoCDFs	0
diCDDs	0		diCDFs	0
triCDDs	0		triCDFs	0
2,3,7,8-TCDD other tetraCDDs	1 0		2,3,7,8-tetraCDF other tetraCDFs	0.1 0
2,3,7,8-pentaCDD[a] other pentaCDDs	0.5 0		1,2,3,7,8-pentaCDF 2,3,4,7,8-pentaCDF other pentaCDFs	0.05 0.5 0

2,3,7,8-hexaCDD[a] other hexaCDDs	0.1 0		2,3,7,8-hexaCDF[a] other hexaCDFs	0.1 0
2,3,7,8-heptaCDD,[a]other heptaCDDs	0.01 0		2,3,7,8-heptaCDF[a] other heptaCDFs	0.01 0
octaCDD	0.001		octaCDF	0.001

[a] Any isomer that contains chlorine in the 2,3,7,8-positions
Source: derived from EPA 1989.
CDDs = chlorinated dibenzo-*p*-dioxins; CDFs = chlorinated dibenzofurans; TCDD = tetrachlorodibenzo-*p*-dioxin

Table 3. Recommended Toxicity Equivalency Factors (TEFs) for Dioxin-Like PCBs

PCB	WHO proposed interim values a		PCB	WHO proposed interim values [a]
3,3',4,4'-TCB	0.0005		2,3,3'4,4',5-HxCB	0.0005
3,3',4,4',5-PeCB	0.1		2,2,3',4,4',5'-HxCB	0.0005
3,3',4,4',5,5'-HxCB	0.01		2,3',4,4',5,5'-HxCB	0.00001
2,3,3',4,4'-PeCB	0.0001		2,3,3',4,4',5,5'-HpCB	0.0001
2,3,4,4',5-PeCB	0.0005		2,2',3,3',4,4',5-HpCB	0.0001
2,3',4,4',5-PeCB	0.0001		2,2',3,4,4',5,5'-HpCB	0.00001
2',3,4,4',4-PeCB	0.0001		-	-

[a] Interim values proposed by World Health Organization/International Programme on Chemical Safety
Source: derived from Ahlborg et al. 1994
PCB = polychlorinated biphenyl; TCB = tetrachlorinated biphenyl; PeCB = pentachlorinated biphenyl;
HxCB = hexachlorinated biphenyl; HpCB = heptachlorinated biphenyl

A minimal risk level (MRL) is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration and route of exposure. These substance-specific estimates, which are intended to serve as screening levels, are used by ATSDR health assessors and others to identify contaminants and potential health effects that may be of concern at hazardous waste sites. The intermediate-duration oral MRL of 1 picogram/kilogram/day or pg/kg/day for TCDD (ATSDR 1989) was based on reproductive effects in rats. The intermediate-duration oral MRL was also adopted as a chronic oral MRL. Based on this value, an EMEG of 50 ppt (0.05 ppb) TCDD, which is equivalent to 50 ppt (0.05 ppb) TEQs, was derived for exposure from contaminated soil. Uncertainty factors of 1000 (total) were used in the calculations of the MRL (for further details, see Appendix 3 of the Technical Support Document). Based on a review of more recent literature, ATSDR scientists conclude that the MRL of 1 pg/kg/day is approximately two orders of magnitude below the noncancer health effect levels observed in recent studies. This is also true for cancer effect levels.

Evaluation levels for dioxin and dioxin-like compounds in soil. *Evaluation levels* are concentrations > 50 ppt (0.05 ppb) but < 1 ppb TEQs at which site-specific factors, including, but not limited to, bioavailability, ingestion rates, pathway analysis, soil cover, climate, other contaminants, community concerns, demographics, and background exposure, are considered in a deliberative process to assess the nature and extent of contamination and its impact on the community. Such an evaluation process may prompt further assessment at the next level where actions are considered. The evaluation levels are to be used as a framework to guide procedures for that judgment process. Thus, judgments in the evaluative phase are linked to actions where consideration is given to interventions from a public health perspective.

Action level for dioxin and dioxin-like compounds in soil. *Action levels* are concentrations of chemicals at which consideration of action to interdict exposure occurs; 1 ppb TCDD in residential soil was identified by Kimbrough et al. (1984) as a "level of concern," and recommended as "a reasonable level to begin consideration of action to limit exposure." Kimbrough et al.'s (1984) conclusions were derived in part from an evaluation of the carcinogenic potential of TCDD, based on a 2-year oral chronic toxicity and oncogenicity study in rats (Kociba et al. 1978). With the advancement of knowledge about dioxin-like chemicals and their assumed common mechanism of toxicity, the TEQs were introduced into the risk assessment process. Since then, 1 ppb of total dioxins (expressed as TEQs) in soil has been used as an action level by ATSDR.

The Kociba et al. (1978) study also served as the basis for the Food and Drug Administration's (FDA's) derivation of a risk-specific dose of 0.057 pg/kg/day dioxin for a l in a million (10-6) upper-bound risk estimate for cancer (FDA 1990). Using a typical default value of 70 kg for average body weight and 100 milligrams/day (mg/day) for soil consumption, FDA's 0.057 pg/kg/day risk-specific dose corresponds to a soil concentration of 40 ppt. This value is marginally lower, but from a risk assessment perspective, it is essentially equivalent to the ATSDR media-specific screening level/comparison value (EMEG) of 50 ppt.

As noted previously, ATSDR's EMEG is based on the MRL of 1 pg/kg/day TCDD, which is approximately two orders of magnitude below any health effect levels demonstrated either experimentally or in epidemiologic studies for both cancer and noncancer health end points. The conservative (i.e., protective) nature of both the MRL and the EMEG reflects adjustments made for recognized areas of uncertainty, perhaps spanning two to three orders of magnitude. As such, the EMEG and the MRL, on which the EMEG is based, are below levels of exposures associated with demonstrated health effects and are therefore considered to be protective of human health. The EMEG of 50 ppt (0.05 ppb) is at the low end of the range reflecting currently recognized areas of scientific uncertainty; this range is 50-50,000 ppt (or 0.05-50 ppb), which is based on the 1,000-fold uncertainty factor used to derive the MRL.

Conclusions. ATSDR concludes that the action level of 1 ppb (TEQ) for dioxin and dioxin-like compounds, when coupled to a site-specific context of evaluation for the range > 50 ppt (0.05 ppb) to < 1 ppb TEQs in residential soil, is protective of public health and continues to represent a level at which consideration of health action to interdict exposure, including cleanup, should occur. This conclusion is based on ATSDR's review and evaluation of

- more recent experimental and epidemiologic research findings
- ATSDR's historical use of the term "action level"
- the range of health guidance values developed by ATSDR including the MRL and EMEG
- the limitations and uncertainties of ATSDR's health guidance values and the scientific data
- on which these values are based.

ATSDR considers this action level to be both reasonable and protective for the following reasons:

- ATSDR's MRL is approximately two orders of magnitude below effect levels in
- experimental and epidemiologic studies.
- Cancer risk-specific doses and screening values for end points other than cancer are
- essentially equivalent from a risk assessment perspective.

WHERE TO FIND MORE INFORMATION

For more information on the historical and scientific background of dioxin in soil values, their proper use, and data on limitations associated with these numbers, please refer to Dioxin and Dioxin-Like Compounds in Soil, Part II: Technical Support Document for ATSDR Interim Policy Guideline (De Rosa et al., Toxicology and Industrial Health VOL. 13, No. 6, pp. 769-804, 1997)

Alternatively, this and related material are available through the ATSDR Information Center by calling 1-800-447-1544 or by Faxing 1-404-639-6359. You can also e-mail the ATSDR Information Center directly.

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APPENDIX 1 - GLOSSARY

Action level

A concentration of chemicals at which consideration of action to interdict/prevent exposure occurs, such as surveillance, research, health studies, community education, physician education, or exposure investigations. Alternatively, based on the evaluation by the health assessor, none of these actions may be necessary.

"At-risk" population

A population at a potentially elevated risk due to physiological sensitivity and/or increased exposure to a hazardous chemical.

BDDs

Brominated dibenzo-*p*-dioxins

BDFs

Brominated dibenzofurans

CDDs

Chlorinated dibenzo-*p*-dioxins

CDFs

Chlorinated dibenzofurans

Comparison value

A concentration used to select contaminants of concern at hazardous waste sites that are taken forward in the health assessment process for further evaluation (The terms comparison value and screening level are often used synonymously.)

Dioxin

A term used interchangeably with 2,3,7,8-tetrachlorodibenzo-*p*-dioxin or TCDD

Dioxin-like compounds

Compounds from a group of halogenated aromatic hydrocarbons that have molecules shaped like TCDD and produce similar toxic effects, such as certain other chlorinated dibenzo-*p*-dioxins (CDDs) and certain chlorinated dibenzofurans (CDFs), polychlorinated biphenyls (PCBs), polybrominated biphenyls (PBBs), brominated dibenzo-*p*-dioxins (BDDs), and brominated dibenzofurans (BDFs).

Dioxins

A term used interchangeably with chlorinated dibenzo-*p*-dioxins

EMEG

An environmental media evaluation guide (EMEG) is a media-specific comparison value that is used to select contaminants of concern at hazardous waste sites.

HazDat

ATSDR's Hazardous Substance Release/Health Effects Database

MRL

A minimal risk level (MRL) is an estimate of the daily human exposure to a hazardous substance that is likely to be without an appreciable risk of adverse noncancer health effects over a specified route and duration of exposure.

PBBs

Polybrominated biphenyls

PCBs

Polychlorinated biphenyls

Screening

The process of initially identifying potentially important chemical contaminants and exposure pathways by eliminating those of known lesser significance.

TCDD

2,3,7,8-Tetrachlorodibenzo-*p*-dioxin

TEFs

Toxicity equivalency factors (TEFs) are based on congener-specific data and the assumption that the toxicity of dioxin and dioxin-like compounds is mediated by the Ah receptor and is additive. The TEF scheme compares the relative toxicity of individual dioxin-like compounds to that of TCDD, which is the most toxic halogenated aromatic hydrocarbon.

TEQs

Toxicity equivalent (TEQ) is defined as the product of the concentration, CI, of an individual "dioxin-like compound" in a complex environmental mixture and the corresponding TCDD toxicity equivalency factor (TEF_i) for that compound. The total TEQs is the sum of the TEQs for each of the congeners in a given mixture:

$$\text{Total TEQs} = \sum_{i=1}^{n} (CI \times TEF_i)$$

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