Update- ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil

The Agency for Toxic Substances and Disease Registry (ATSDR) has updated its Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil. The most significant change is the deletion of the 1-part per billion (ppb) action level criteria. This update does not reflect a change in the hazard assessment that established ATSDR’s 1998 Toxicological Profile and Minimum Risk Level (MRL) determination of the health concerns associated with dioxin exposure. The revised policy reflects ATSDR’s concern that the previously established action level had been misinterpreted.

STATEMENT OF ISSUES

In 1998, the Agency for Toxic Substances and Disease Registry (ATSDR) adopted a Final Policy Guideline for Dioxin and Dioxin-Like Compounds (De Rosa et al. 1999a). The 1998 policy guideline was accompanied by a Technical Support Document for ATSDR Policy Guideline (De Rosa et al. 1999b). The initiative to develop this policy guideline was based on a request from the U.S. Environmental Protection Agency (EPA) to evaluate the protectiveness of the EPA Superfund Policy for Dioxins in Residential Soils, which established 1 part per billion (ppb) (1,000 parts per trillion [ppt]) total dioxin toxicity equivalents (TEQ) as the starting point for making clean-up decisions. In addition, the 1998 policy guideline was to provide guidance to health assessors in evaluating the public health implications of dioxin and dioxin-like compounds (e.g., 2,3,7,8-tetrachlorodibenzo-p-dioxin [TCDD], chlorinated dibenzodioxins [CDDs], chlorinated dibenzofurans [CDFs], and other structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons) in residential soils near or on hazardous waste sites. As stated in the 1998 document, “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 1998 Policy Guideline established a screening level (≤0.05 ppb TEQ), an evaluation level (>0.05 ppb TEQ, <1 ppb), and an action level (>1 ppb TEQ) for dioxins in residential soil and made recommendations for specific considerations or public health actions.

Problems Regarding the 1998 Policy Guideline

Differences in the interpretation of the 1998 guideline have led to inconsistencies in the application of the screening and action levels to public health assessments. One problem has been the concept of an “action level” for public health activities. The action level has been interpreted by others as: 1) a soil concentration that defines a public health hazard, 2) an ATSDR clean-up level which implies the need for site remediation, or 3) an initial screening level that defines a safe level of exposure, below which there is no public health concern. None of these interpretations were either intended or appropriate.
In addition, the 1998 ATSDR action level triggered a set of recommendations for “potential public health actions”, including surveillance, research, health studies, community education, and exposure investigations. However, these actions should be activities to be considered by health assessors regardless of exceeding a 1 ppb level in soil. The 1998 ATSDR policy guideline established an action level, yet did not require that specific actions be conducted.

ATSDR has established environmental screening values for chemicals to be used by health assessors to assess exposures. No other chemical has an action level as was established for dioxins in soil in the 1998 policy guideline. This inconsistency alone has led to confusion regarding the appropriate screening value for soil dioxin levels.

OBJECTIVES OF REVISIONS TO THE DIOXIN SOIL POLICY GUIDELINE

ATSDR is updating the soil policy guideline for assessing exposure to dioxin and dioxin-like compounds in soil. Details about the health concerns for dioxins have not been revised as summarized in the Technical Support Document for ATSDR Final Policy Guideline: Dioxin and Dioxin-Like Compounds in Soil (De Rosa et al. 1999b) and in the ATSDR Toxicological Profile for Chlorinated Dibenzo-p-Dioxins (ATSDR 1998).

The 2005 ATSDR Dioxin and Dioxin-Like Compounds Soil Policy Guideline …

- **Deletes the 1 ppb action level as the criteria for taking specific public health actions.**
  
The 1-ppb dioxin soil concentration should not be used as a comparison value for defining public health hazards in public health assessments and consultations. The 1-ppb action level can be cited by health assessors as the Superfund Dioxin Cleanup policy criteria (EPA 1989, 1998).

- **Retains the 0.05 ppb screening level.**
  
The minimal risk level (MRL)-based environmental media evaluation guide (EMEG) of 0.05 ppb for dioxin TEQ in soil is retained as the basis for screening soil concentrations. Levels exceeding this screening level should be evaluated as described in the ATSDR Public Health Assessment Guidance Manual (PHAGM) (ATSDR 2005). This clarification will ensure that evaluation of dioxins and dioxin-like compounds in soil will be done in the same manner as all other soil contaminants.

- **Recommends exposure pathways analyses for dioxins and dioxin-like compounds.**
  
The focus of the guideline is the assessment of direct exposure to soil contamination, particularly soil ingestion. However, health assessors should be aware of the potential impact of indirect exposure pathways on exposed populations in site-specific health assessments. This document does not provide specific guidance on how these indirect pathways should be assessed. However,
the PHAGM document does provide assistance in evaluating indirect exposure pathways such as food chain contamination (ATSDR 2005).

**UPDATED GUIDANCE FOR ASSESSING DIOXINS IN RESIDENTIAL SOILS**

This update does *not* reflect a change in the assessment of health hazards associated with dioxin exposure as summarized in the 1998 ATSDR Toxicological Profile and in the derivation of the Minimum Risk Level (MRL). The revised policy reflects ATSDR’s concern that the previously established action level had been misinterpreted. ATSDR continues to review the scientific literature regarding dioxin toxicity to ensure that the MRL is protective of human health.

To identify chemicals that may present at levels of potential health concern at hazardous waste sites, ATSDR’s PHAGM describes the process for evaluating environmental sampling data for soil contaminants, including identification of chemicals of concern by comparing their concentration to a screening value or EMEG, characterization of exposure pathways and magnitude of exposure, and evaluation of public health hazard.

**Step 1: Comparison of Environmental Data to ATSDR Screening Value**

Studies in animals have demonstrated a wide range of health effects associated with dioxin exposure including death, cancer, and wasting, as well as hepatic, immunologic, neurologic, endocrine, reproductive, and developmental effects (ATSDR 1998, De Rosa et al. 1999b). An extensive body of research suggests that dioxins and DLCs are likely to act through a common mechanism of action to induce toxicity (ATSDR 1998). Based on this understanding, the relative potency of a number of DLCs compared to TCDD has been used to derive Toxicity Equivalent Factors (TEFs) for specific DLCs, as developed by the World Health Organization (Van Den Berg 1998). ATSDR uses TEFs to summarize the dioxin content of a soil sample as the total dioxin toxicity equivalents (TEQs), as described in the appendices and in the ATSDR Toxicological Profile for Chlorinated Dibenzo-p-Dioxins (ATSDR 1998).

The chronic-duration oral MRL of 1 picogram/kilogram body weight/day (pg/kg/day) for TCDD, or total TEQ, (ATSDR 1998) is based on neurobehavioral effects in monkeys (Schantz et al. 1992). A MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration and route of exposure (ATSDR 1996). Uncertainty factors of 90 (total) were used in calculations of the MRL (for additional details, see ATSDR 1998). This value is consistent with the tolerable daily intake (TDI) of 1-4 pg/kg/day for TCDD or total TEQs (WHO 1998), the TDI of 4 pg TEQs/kg/day (Japanese Environmental Agency 1999), and the tolerable weekly intake of 7 pg/kg/week of TCDD of total TEQs (European Union 2000).

Using the chronic MRL value (1 pg/kg/day), exposure assumptions for a child (soil ingestion rate = 200 mg/day and 10 kg body weight), and assumption of 100% bioavailability, an EMEG of **0.05 ppb** (50 ppt) TEQ was derived as a screening value for residential soils contaminated with dioxins and dioxin-like compounds.
As a comparison to the non-cancer endpoint of the MRL, the Food and Drug Administration (FDA) used the Kociba et al. (1978) study to derive a risk-specific dose of 0.057 pg/kg/day dioxin for a 1 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 0.04 ppb. This value is essentially equivalent to the ATSDR media-specific screening level/comparison value (EMEG) of 0.05 ppb.

Step 2: Exposure Pathways Analysis

Although this guidance update applies to situations involving direct exposure to dioxin and dioxin-like compounds in soil, all potential pathways of exposure should be considered in site-specific assessments, including indirect exposures (e.g., food chain pathways). Exposure pathways should be evaluated regardless of whether the soil EMEG is exceeded. The PHAGM contains a description of methods to identify potential and completed exposure pathways for direct soil contact and includes information to assist in the evaluation of indirect exposure pathways for soil contaminants. This evaluation of exposure pathways includes an assessment of the types of activities that people might engage in that could result in exposure to site contaminants. Land-use patterns that could impact the magnitude of exposure should also be considered.

Dioxins are lipid-soluble and have the ability to concentrate in fatty tissues as well as in high-fat-content foods of animal origin (e.g., dairy products and eggs). Therefore, in addition to direct soil contact, exposures to site-related dioxins and dioxin-like compounds could occur through locally produced food sources, particularly fish, eggs, and dairy products.

Another consideration for evaluating exposure is the potential for uptake into garden vegetables that may be grown in contaminated residential soils. Because of the low water solubility of dioxins and the protective layer of plant cuticles, uptake of dioxins from soil into plant tissue is very low. Therefore, consumption of garden-grown vegetables is generally considered to be an insignificant exposure pathway. However, contaminated soil that remains on the surface of either root or leafy vegetables during food preparation could result in exposure. The general public health practice of thoroughly washing or peeling vegetables before consumption will further reduce exposure to soil contaminants.

Step 3: Characterization of Exposure

The PHAGM also describes methods for evaluating the magnitude of exposure from specific activities that are identified in the exposure pathways analysis (ATSDR 2005). These methods include estimating the rate, frequency, and duration of activities that could result in exposure to site-related contaminants. Although these exposure estimates are not likely to differ between DLC’s and other contaminants, site-specific considerations may influence the impact of exposure to dioxins in soil.

One of the factors that determine the potency of dioxin toxicity from soils is the efficiency of absorption into the bloodstream from ingested soil or from soil adhering to skin. The
efficiency of this absorption process is referred to as “bioavailability” and is affected by specific characteristics of the contaminated soil Van den Berg. A critical factor in determining bioavailability is the organic content of the contaminated soil, with high organic content (e.g., >10% total organic carbon content) having a lower bioavailability than soil with low organic content (<1% total organic carbon) Van den Berg. In addition, dioxins in soil appear to be less bioavailable by at least a factor of 2 when compared with studies in which TCDD is given in an oil matrix (Shu et al. 1988). The dosing method used in the critical study for the chronic MRL value derivation (Schantz et al. 1992) involved the addition of TCDD, dissolved in oil, to the diet. It is likely that the relative bioavailability of TCDD in a dietary matrix would be less than from oil alone. However, without site-specific soil bioavailability measurements, data are insufficient to make default bioavailability adjustments for dioxins in soil.

For the general population that is not occupationally exposed to dioxins and DLCs, the predominant exposure pathway is from dietary sources. Therefore, the evaluation of exposure to site-related dioxins and DLCs represents an incremental increase in exposure above background levels. To provide some context for the characterization of exposure to dioxins and dioxin-like compounds in soils, it may be useful to compare the estimated site-related daily intake levels with the average daily intake that all populations are likely to experience. If sufficient information is available, estimates could be made of the contribution of site-specific intakes to overall body burden for populations of concern.

**Step 4: Hazard Evaluation**

When site conditions indicate that there are completed pathways of exposure to concentrations of dioxins and DLCs that exceed media-specific comparison values, health assessors should follow the approaches and procedures outlined in the PHAGM to determine if site conditions pose a public health hazard (ATSDR 2005).

**COMPARISON OF SOIL DATA TO REGULATORY CRITERIA**

On the basis of the results of a 2-year oral chronic toxicity and oncogenicity study in rats (Kociba et al. 1978), Kimbrough et al. (1984) proposed that 1 ppb of TCDD in residential soils to be a "level of concern," and recommended that 1 ppb serve as "a reasonable level to begin consideration of action to limit exposure." EPA also used the Kociba study to develop the Superfund Dioxin Residential Soil Policy level of 1 ppb TEQ, confirming that the cancer risk associated with exposure to this level was near the EPA target cancer risk range. Health assessors may refer to the 1-ppb level as an EPA regulatory level that can be used by EPA site managers as the basis for making cleanup decisions (EPA 1989, 1998).

**REFERENCES**

Department of Health and Human Services, Agency for Toxic Substances and Disease Registry.


Figure 1. Flowchart for Screening Dioxin and Dioxin-Like Compounds in Soil

**Evaluate soil sampling data**

Does average concentration exceed 50 ppt TEQ?

- Yes
- No

**Evaluate exposure pathways**

Are there completed past, current, or potential future exposure pathways (e.g., ingestion, inhalation, or dermal) for site-related soil?

- Yes
- No

**Soil dioxins are not considered a public health hazard for direct exposure. If applicable, consider potential indirect exposure pathways.**

**Evaluate the public health hazard:**
- exposure assessment
- hazard evaluation
Appendix A: Dioxin Toxicity Equivalency Factors (TEFs)

Dioxin and Dioxin-Like Compounds

Dioxin and dioxin-like compounds are structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons. Based on the number of chlorine-substituted positions, several congeners are in each group of chemicals. The most studied congener is 2,3,7,8-tetrachlorodibenzo-p-dioxin or (TCDD).

Toxicity equivalency factors (TEFs) were developed to compare the relative toxicity of individual dioxin-like compounds to that of TCDD (Table 1). 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 (1.0), whereas TEF values for all other dioxin-like compounds are less than one (with the exception of 1,2,3,7,8-PeCDD).

The toxicity equivalent (TEQ) is used to assess the risk for 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 TEQ is the sum of the TEQs for each of the congeners in a given mixture:

$$\text{Total TEQs} = \sum_{i=1}^{n} (C_i \times \text{TEF}_i)$$
Table 1. Recommended Toxicity Equivalency Factors (TEFs) for Chlorinated Dibenzo-<i>p</i>-dioxins (CDDs), Brominated Dibenzofurans (CDFs), and Dioxin-Like Polychlorinated Biphenyls (PCBs)

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<thead>
<tr>
<th>CONGENER</th>
<th>TEF</th>
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<tbody>
<tr>
<td>2,3,7,8-TCDD</td>
<td>1</td>
</tr>
<tr>
<td>1,2,3,7,8-TeCDD</td>
<td>1</td>
</tr>
<tr>
<td>1,2,3,4,7,8-HxCDD</td>
<td>0.1&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
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<td>0.1&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
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<td>0.1&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
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<td>0.01</td>
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<tr>
<td>OCDD</td>
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</tr>
<tr>
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<tr>
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</tr>
<tr>
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<td>0.1</td>
</tr>
<tr>
<td>1,2,3,6,7,8-HxCDF</td>
<td>0.1&lt;sup&gt;a&lt;/sup&gt;</td>
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</tr>
<tr>
<td>OCDF</td>
<td>0.0003&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>3,4,4',5-TCB (81)</td>
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<tr>
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<sup>a</sup>Limited data set.
<sup>b</sup>Structural similarity.
<sup>c</sup>Quantitative structure activity relationships (QSAR) modeling prediction from CYP1A induction (monkey, pig, chicken, or fish).
<sup>d</sup>No new data from 1993 World Health Organization (WHO) review.
<sup>e</sup><i>In vitro</i> CYP1A induction.

Appendix B: Glossary of Terms

Action level
A concentration of chemicals at which a consideration of action to interdict or prevent exposure occurs. Such actions include surveillance, research, health studies, community education, physician education, or exposure investigations. Alternatively, on the basis of the evaluation by the health assessor, none of these actions may be necessary.

“At-risk” population
A population at a potentially elevated risk because of physiological sensitivity and/or an increased exposure to a hazardous chemical.

BDDs
Brominated dibenzo-\(p\)-dioxins.

BDFs
Brominated dibenzofurans.

CDDs
Chlorinated dibenzo-\(p\)-dioxins.

CDFs
Chlorinated dibenzofurans.

Comparison value
Calculated concentration of a substance in air, water, food, or soil that is unlikely to cause harmful (adverse) health effects in exposed people. The CV is used as a screening level during the public health assessment process. Substances found in amounts greater than their CVs might be selected for further evaluation in the public health assessment process.

Dioxin
A term used interchangeably with 2,3,7,8-tetrachlorodibenzo-\(p\)-dioxin (TCDD).

Dioxin-like compounds
Compounds from a group of halogenated aromatic hydrocarbons that have molecules shaped like TCDD and produce similar toxic effects, as do certain other chlorinated dibenzo-\(p\)-dioxins (CDDs), 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 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 ATSDR estimate of daily human exposure to a hazardous substance at or below which that substance is unlikely to pose a measurable risk of harmful (adverse), noncancerous effects. MRLs are calculated for a route of exposure (inhalation or oral) over a specified time period (acute, intermediate, or chronic). MRLs should not be used as predictors of harmful (adverse) health effects.

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). In this document, 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.

TEQ
Toxicity equivalent (TEQ). In this document, a 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 (TEFi) for that compound. The total TEQ is the sum of the TEQs for each of the congeners in a given mixture:

\[ \text{Total TEQs} = \sum_{i=1}^{n} (C_i \times TEF_i) \]
WHO

World Health Organization.