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August 10, 2006

Department of Ecology
Toxics Clean-up Program
P.O. Box 47600
Olympia, WA 98504-7600

Attn: Jim Pendowski
Peter Kmet

RE: Proposed Amendments to the MTCA Cleanup Regulation Addressing Policies and Procedures for Certain Types of Chemical Mixtures

This letter constitutes the comments of the Association of Washington Businesses (AWB) on the pre-proposal to amend the Model Toxics Control Act (MTCA) Clean-up Regulation (Chapter 173-340 WAC). The AWB appreciates that Ecology has taken the additional step to allow all stakeholders the opportunity to review and comment on this proposal prior to the publication of proposed rule amendments scheduled for late summer. AWB also appreciates the opportunity to review the Background Document dated July 2006. This additional step provides a much-needed opportunity to reflect on the practical aspects of this highly technical issue.

Overall Concerns

AWB's primary concern is that Ecology is proposing a change to the current MTCA clean-up levels for mixtures of certain substances that, at least in the case of dioxin mixtures, is more than a *thousand-fold* more stringent than EPA clean-up levels and recommendations of the Agency for Toxic Substances and Disease Registry (ATSDR). These federal recommendations are already designed to protect to well below any observed health effects, and include an extra measure of stringency to account for scientific uncertainty.

Ecology has not provided a rationale for the health or environmental needs and benefits for such a stringent proposal. In fact there is nothing in the technical support document that speaks to our state specific issues.

Ecology's proposal could result in a high percentage of urban soils being brought into the clean-up program with many unintended consequences that are not being discussed as part of the technical supporting information. As a practical matter, the proposal will result in clean-up levels below background in many urban and even rural residential areas. Washington state background soil levels are consistent with soil levels found around the country based on EPA surveys.

Nor has Ecology given an explanation for the urgency of this rulemaking in advance of the upcoming 5-year review of the MTCA rules scheduled to commence this fall. For example, are there sites that pose specific risks now that warrant a more stringent approach? If so, wouldn't it make sense to evaluate regulatory alternatives, such as the approaches recommended by ATSDR for taking into account site-specific needs rather than a one-shoe-fits-all approach? These are the types of policy alternatives that AWB would expect would be brought to the table for discussion as part of a more deliberative process or the upcoming 5-year review. It is simply not realistic to address alternative regulatory approaches in this short, speedy late summer rulemaking proposal.

AWB has similar concerns regarding PAHs and PCBs but was limited in time to fully address. Our initial understanding is that the issues for PAHs and PCBs may actually be more significant than those we have identified for dioxin. Again this situation argues for a more deliberative process.

AWB does support the concept of updating the science. For example, Ecology is considering updating the toxicity equivalency factors (TEF) to reflect new thinking. However, AWB urges Ecology to be more complete in its explanations of that science, particularly the limitations of these factors for use in evaluating risk due to exposure to these substances in soils. AWB endorses the NCASI comments which also include a more in-depth discussion of these issues.

Further explanation and comments are provided in the attachment "Specific Concerns."

Conclusions

- AWB is concerned that without further information on actual need, Ecology should proceed more slowly and address both the practical and scientific issues.
- Without addressing these concerns, Ecology is risking developing a regulation that will drive costly clean-ups to standards lower than met by background samples of soils in the state, particularly for urban areas.
- AWB does not view the proposal as narrowly focused as asserted by Ecology. Rather AWB views the proposal as raising significant policy issues that are more appropriately addressed in the context of a more deliberative process or the pending 5-year review.

Sincerely,

Grant Nelson

Attachments

SPECIFIC CONCERNS

Summary of Ecology's Proposal as AWB Understands It

The summary of the rulemaking and the background document describe EPA methodology for evaluating clean-up levels for mixtures of dioxins/furans and state that current MTCA rules, adopted in February 2001, allow use of the EPA methodology. Ecology then explains it has an unpublished guidance adopted later in 2001, specifying how to use the EPA methods.[1] However, Ecology does not explain that the unpublished guidance can result in clean-up levels far more stringent than the EPA methodology and the original rules.

In one particular situation, Rayonier was able to demonstrate the legally applicable standard is derived from the adopted state rules rather than unpublished guidance. In the resulting settlement Ecology "agreed that Rayonier's approach was an acceptable interpretation of the current MTCA rule (P. 12 Background Document)." Apparently Ecology now wishes to codify an approach more similar to the unpublished guidance.

The essence of the change is as follows. Currently MTCA establishes an overall target risk level of $1x10^{-5}$ for mixtures of carcinogens and $1x10^{-6}$ for individual carcinogens. Where there are multiple carcinogens of varying toxicities, adjustments must be made in clean-up levels for one or more carcinogens to be more stringent than $1x10^{-6}$ to satisfy the overall target risk level. The proposal would classify mixtures of certain similar carcinogens (dioxins, PAHs or PCB congeners) as a single substance; therefore the target risk level would be $1x10^{-6}$.

AWB has compared key clean-up levels and guidance at the federal level to the results of the existing and proposed rules in the attached chart. AWB has also included comparison of Washington background soil levels to national surveys.

[1] Apparently the unpublished procedures were developed in 2001 and the incorporated into a larger guidance document, "Clean-up Levels and Risk Calculation " or "CLARC Guidance" in 2006

AWB Summary Comparisons

	Dioxin Concentration TEQ ppt
Federal	
Environmental Protection Agency	
EPA clean up standard for dioxin mixtures in commercial/industrial use soils	5,000 to 20,000 ppt Or 5-20 ppb
EPA clean up standard for dioxin mixtures in residential soils	1,000 ppt
ATSDR Health Guidance Values	
1. Screening level (if one or more samples exceed, then further evaluation)	$\leq$50 ppt
2. Evaluation of site-specific factors	50-1000 ppt
3. Action level	1000 ppt
National Soil Surveys (EPA Dioxin Reassessment)*	
Urban soil – overall mean using a sample size of 270 with a range of means of 2 to 21 ppt TEQ	9.3 $\pm$ 10.2 ppt (means)
Rural soil – overall mean using a sample size of 354 with a range of means of 0.11 to 5.7 ppt TEQ	2.7 ppt (means)
Ecology' s Approach	
Clean up standard Ecology agreed is current law in settling a recent legal challenge. Clean up standard for mixtures of dioxin in soil for unrestricted (residential) use **	66.7 ppt max
Clean up standard Ecology is proposing for mixtures of dioxin in soil for unrestricted use	6.67 ppt
Ecology's clean up standard for individual carcinogens including individual dioxins expressed as one form of dioxin called 2,3,7,8-TCDD – current law, no changes proposed	6.67 ppt (2,3,7,8-TCDD – Not a TEQ)
Background dioxin mixtures in Washington State (Rogowski et al. 1999)	0.03 to 22 ppt
Background dioxin mixtures in British Columbia (Van Oostdam and Ward (1995)	<1 to 50 ppt

TEQ = All dioxins present in a mixture are converted to the equivalent concentration of 2378 TCDD, the most studied form of dioxin.

ppt = Parts per trillion or one pound of dioxin in a trillion pounds of soil

Rule making also includes PCBs and PAHs. This summary only addresses dioxins.

* "Exposure and Human Health Reassessment of 2.3.7.8 Tetrachlorodibenzo-P-Dioxin TCDD and Related Compounds National Academy of Science (NAS) Review Draft" EPA, Part 1, Vol 2 P 3-191

**For dioxin mixtures only. If other carcinogens are present, this value could be lower. (explain???)

Rogowski, D., S. Golding, D. Bowhay, and S. Singleton. 1999. Screening survey for metals and dioxins in fertilizer products and soils in Washington State. Final Report. Washington State Department of Ecology, Olympia, WA.

Van Oostdam, J.C., and J.E.H. Ward. 1995. Dioxins and furans in the British Columbia environment. BC Environment, Victoria, BC. April 3, 1995. 154 pp.

AWB has the following concerns:

1. **Ecology must clearly state that it is proposing a rule that is more than a *thousand* fold more stringent than federal clean-up standards and what the expected health benefits are to the residents of Washington State**

Ecology must explain the relative stringency of the proposed rules as compared to the current rules and federal guidance. This explanation is essential to an informed response by stakeholders and the general public.

Ecology's announced intention to treat mixtures of dioxins like a single chemical effectively pushes the dioxin clean up standard from 66.7 ppt to 6.67 ppt. This is far below that used nationwide by EPA and ATSDR which are already deemed highly protective.

ATSDR provides the following caveat in interpreting its health guidance values:

> "This policy incorporates information on exposure potential from residential soils and residential exposure scenarios. It should be noted that the levels (in TEQs) $\leq$50 ppt (0.05 ppb), >0.05 ppb but < 1 ppb and $\geq$ 1 ppb in residential soils are guidance values and *should not be construed to indicate actual health effects will occur*. This 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." *Emphasis added.*

ATSDR also notes that the guidance is several orders of magnitude below any health effect demonstrated in either experimental or in epidemiologic studies for both cancer and non-cancer endpoints. Further adjustments were made for recognized scientific uncertainty.

Given the conservative nature of the federal guidelines, Ecology should produce a discussion of the health and environmental benefits it envisions will occur and the scientific basis to support its thinking. The technical support document currently contains no such discussion.

AWB is attaching both the EPA and the ATSDR guidance as part of these comments.

2. **Ecology must provide a practical reason why the proposed rules are necessary for pending clean-ups and why it is necessary to fast track the rules**

Ecology's Background Document states that it has been evaluating and establishing clean-up levels following the unpublished guidance since 2001 and implies that the proposed rule is needed so as to avoid interpretations under the current MTCA rules along the lines of the recent Rayonier settlement.

In order to better understand the need for the proposal in terms of improving or preserving the public health and the environment, AWB requests that Ecology produce:

- a summary of the clean-up sites where it has applied the unpublished guidance to mixtures of dioxin compounds since 2001

- a summary of pending clean-up sites involving dioxin compounds where it intends to apply the unpublished guidance prior to completing the 5 year rule review scheduled to commence in late 2006
- a statement of benefits Ecology expects to obtain relative to the increase in clean-up costs and
- a comparison to local background dioxin soil levels in urban residential neighborhoods.

The proposal would result in clean-up levels of 6.67 ppt TEQ instead of 66.7 ppt TEQ for dioxin mixtures. Ecology has found that background levels of dioxin mixtures in soils around the state range for 0.03 to 22 ppt TEQ; in British Columbia, the range of 53 background soils was from <1 to >50 ppt TEQ. Based on national data, background levels in residential neighborhoods could be significantly higher due to the effects of proximity to combustion sources (gasoline and diesel engines and backyard burning). This will be particularly true along residential driveways and roadways in general.

AWB is concerned that *any* rule proposing clean-up standards to below potential background levels is a recipe for anomalous outcomes and poses the potential for unnecessary expense. Given this possibility, AWB suggests that Ecology take the time to produce the analyses of past and pending sites as suggested above and consider including the proposal as part of the 5 year review and a comprehensive assessment of risk needs.

3. **Ecology's proposal may be scientifically flawed. The TEQ approach is relevant to risk pertaining to foodstuffs, but not soil (abiotic media) as proposed by Ecology.**

AWB appreciates Ecology's examination of the "Toxicity Equivalency Factors (TEFs)" and objective to use updated science. In the limited time available, AWB cannot comment on the issue of the use of the EPA-89 TEF values, the WHO 98 or the recently published WHO 2005 values. AWB is concerned that Ecology is overlooking some caveats included in the discussion of the WHO 2005 values in how these apply in evaluating health effects due to exposure to soil containing dioxin.

AWB incorporates by reference the comments prepared by Dr. Jeff Louch of NCASI. In particular the World Health Organization (WHO 2005) has recently completed an evaluation of TEFs for dioxins and dioxin-like compounds. As part of this review, WHO notes that the *TEF/TEQ construct is relevant to risk incurred from ingestion of foodstuff and that using it for characterizing risks associated with exposure to abiotic media containing dioxins is inappropriate.*

Specifically the authors question direct application of the WHO TEFs for assessment of (certain dioxin congeners) *present in soil, sediment or fly ash* as leading to inaccurate assessment of the potential toxic potency.

As described in more detail in Dr. Louch's comments, a dioxin mixture in food would have greater bioavailability (i.e., more would be absorbed into the blood) than a mixture in soil, assuming the soil is ingested. It would be possible to correct for the difference using certain factors.

AWB would like Ecology to back up and consider from a policy standpoint where this leads. It may make more sense to consider a more reasonable risk level for clean-up standards in the first place.

For further information, Ecology may wish to consider a pending report noted in the July 7th edition of *Inside EPA* about an upcoming report due August 15th that will discuss newer thinking that will speak to the bio-availability of dioxin in soil to humans.

4. **Ecology's proposal to consider dioxin mixtures a single carcinogenic substance is inconsistent from a policy standpoint with other regulations and the implications have not been dealt with.**

AWB is concerned that dioxins and furans are widely distributed by air deposition to soils across the state due to a variety sources including automobiles, trucks, power production, forest fires, and back yard burning. In addition, AWB recognizes that there can be localized processes that are present or past contributors to community soils, including municipal waste incinerators, medical waste incinerators, and wood-fired boilers. Each source has its own particular combinations of dioxin and furan congeners.

Dioxins are chemical compounds that can have 75 possible configurations based on the combinations in which chlorine atoms can attach to the eight available carbon atoms on the two benzene rings that make up this molecule, making them chemically distinct. Furans are closely related compounds also having two benzene rings that can have up to 135 different configurations based on the combinations in which chlorine atoms can attach to their benzene rings. These different configurations are known as congeners. The congeners differ in the location and number of their chlorine atoms.[2]

Federal regulations recognize that dioxin and furan congeners are distinct chemical substances. For example:

- 40 C.F.R.§302.4 establishes a "reportable quantity" only for the congener 2378TCDD under the Comprehensive Environmental Response, Compensation and Liability Act program for reporting hazardous substance releases to EPA.
- 40 C.F.R. §372.65(c) makes 2378TCDD, six other specific dioxin congeners and ten furan congeners subject to use or manufacture reporting under the Emergency Planning and Community Right to Know Act (EPCRKA)

Different sources result in a different combination of congeners. Consequently, a mixture high in furans and octa-dioxins may "fingerprint" to a certain combustion source, whereas other congener mixtures may fingerprint to other sources.

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[2] "*Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo p-Dioxins and Dibenszofurans (CDDs and CDFs) and 1989 Update,*" Risk Assessment Forum, EPA, Washington, D.C. publication number EPA/625/3-89/016 ("EPA CDD/CDF Guidance").

AWB is concerned that treating mixtures of dioxin congeners as a single substance may lead to anomalous results. An owner of a site slated for clean-up could easily be held accountable for clean-up of congeners not associated with the on-site process, but rather from common urban sources such as fuel exhaust and outdoor burning. In addition, the approach proposed by Ecology increases the potential that locations off-site will be judged contaminated, and thus pull additional area into the cleanup process even though these areas may not be impacted by the associated cleanup site.

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ATTACHMENTS

1. EPA OSWER Directive 9200.4-26, "Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites," April 13, 1998
2. ATSDR "Dioxin and Dioxin-like Compounds in Soil, Part 1: ATSDR Interim Policy Guideline," De Rosa et al, Aug 21 1997

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 13 1998

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive 9200.4-26

MEMORANDUM

SUBJECT: Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites

FROM: Timothy Fields, Jr. Acting Administrator /s/
Office of Solid Waste and Emergency Response

TO: Director, Office of Site Remediation and Restoration
Region I
Director, Emergency and Remedial Response Division
Region II
Director, Division of Environmental Planning and Protection
Region II
Director, Hazardous Waste Management Division
Regions IX
Director, Waste Management Division
Region IV
Director, Waste, Pesticides, & Toxics Division
Region V
Director, RCRA Multimedia Planning & Permitting Division
Region V
Director, Superfund Division
Regions III, V, VI, VII
Assistant Regional Administrator, office of Ecosystems Protection and Remediation
Region VIII
Director, Hazardous Waste Program
Region VIII
Director, Office of Environmental Cleanup
Region X
Director, Office of Waste and Chemical Management
Region X

PURPOSE

The purpose of this Directive is to recommend preliminary remediation goals (PRGs) or starting points for setting cleanup levels for dioxin in soil at Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) corrective action sites. These recommended levels are to be used pending the release of the U.S. Environmental Protection Agency (EPA) comprehensive dioxin reassessment report and cross-program assessment of the impacts of the report. One ppb (TEQs, or toxicity equivalents) is to be generally used as a starting point for setting cleanup levels for CERCLA removal sites and as a PRG for remedial sites for dioxin in surface soil involving a residential exposure scenario. For commercial/industrial exposure scenarios, a soil level within the range of 5 ppb to 20 ppb (TEQs) should generally be used as a starting point for setting cleanup levels at CERCLA removal sites and as a PRG for remedial sites for dioxin in surface soil. These levels are recommended unless extenuating site-specific circumstances warrant a different level.

The dioxin levels discussed in this Directive are also generally recommended for actions taken under RCRA at corrective action sites. The recommended levels of 1 ppb (TEQs) for residential soils and within the range of 5 ppb to 20 ppb (TEQs) for commercial/industrial soils should generally be used as starting points in setting soil cleanup levels at RCRA corrective action sites. These levels are generally consistent with soil cleanup levels set at RCRA facilities throughout the country where dioxin is a principal contaminant of concern at the facility. However, because states are the primary implementors of the RCRA Corrective Action program, this Directive does not prescribe specific procedures for implementation under RCRA.

This Directive sets forth the policy basis for these recommended levels and prescribes procedures for implementing these recommendations.

BACKGROUND

To date, EPA has generally selected 1 ppb as a cleanup level for dioxin in residential soils at Superfund and RCRA cleanup sites where dioxin is a principal contaminant of concern at the facility. EPA has also, to date, generally selected a cleanup level for dioxin within the range of 5 ppb to 20 ppb for commercial/industrial soils at Superfund and RCRA cleanup sites where dioxin is a principal contaminant of concern at the facility. The levels that EPA has selected at these sites are protective of human health and the environment. Based on presently available information, and using standard default assumptions for reasonable maximum exposure scenarios, the upper-

bound lifetime excess cancer risk from residential exposure to a concentration of 1 ppb dioxin is approximately 2.5 x 10^{-4}, which is at the higher end of the range of excess cancer risks that are generally acceptable at Superfund sites. The calculated upper-bound excess cancer risk associated with a lifetime commercial/industrial exposure to 5 ppb, or the lower end of the range recommended for commercial/industrial soils, is approximately 1.3 x 10^{-4}, which is also within the CERCLA risk range. It should be noted that there is more difficulty in generalizing about the cancer risk associated with commercial/industrial cleanup levels than there is with residential cleanup levels due to the greater variability in exposures associated with commercial/industrial scenarios. Accordingly, the consultation process for Superfund sites referenced in the implementation section of this Directive should be used to ensure the selection of appropriate, protective dioxin levels at CERCLA commercial/industrial sites. Similarly, for RCRA corrective action sites, please refer to the implementation section of this Directive.

EPA is presently completing work on a comprehensive reassessment of the toxicity of dioxin, to be embodied in the documents entitled "Health Assessment Document for 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds" and "Estimating Exposure to Dioxin-like Compounds." The reassessment report, which is scheduled to be issued in 1998, will represent the culmination of an Agency-wide effort to collect, analyze and synthesize all of the available information about dioxin. It has undergone significant internal and external review and is one of the most comprehensive evaluations of toxicity of a chemical ever performed by the Agency. Following release of the report, the Office of Solid Waste and Emergency Response (OSWER) will participate in a cross-program review of the implications of the report for the regulation and management of dioxin by EPA. We anticipate that this review will culminate in OSWER guidance addressing the management of dioxin at CERCLA and RCRA sites.

The Office of Solid Waste and Emergency Response does not believe it is prudent to establish new, and possibly varying, precedents for Superfund or RCRA dioxin levels just prior to the release of this reassessment report. As with any other pollutant, it is important that EPA ensure appropriate national consistency in remediation efforts. The Agency has used 1 ppb as a residential cleanup level and between 5 ppb and 20 ppb as a commercial/industrial cleanup level at CERCLA and RCRA cleanup sites for dioxin in soil in the past; it is anticipated that OSWER will be issuing guidance, informed by the reassessment effort, that will provide a basis for the selection of dioxin cleanup levels in the near future. In the interim, for sites that require the establishment of a final dioxin soil cleanup level prior to the release of the reassessment report and

development of OSWER guidance, EPA should generally use 1 ppb (TEQs) as a starting point for residential soil cleanup levels for CERCLA non-time critical removal sites (time permitting, for emergency and time critical sites) and as a PRG for remedial sites. EPA should generally use a level within the range of 5 ppb to 20 ppb (TEQs) as a starting point for cleanup levels at CERCLA non-time critical removal sites (time permitting, for emergency and time critical sites) and as a PRG for remedial sites for commercial/industrial soil. These levels should also be used as starting points in setting soil cleanup levels at RCRA corrective action sites.

For CERCLA remedial sites, consistent with 40 CFR § 300.430(f)(5)(iii)(D), EPA should commit to reviewing Records of Decision (RODs) (i.e., RODs in which this Directive has been used to develop dioxin soil cleanup levels) promptly following the release and analysis of the reassessment report and OSWER guidance, and, if necessary, to making changes to the RODs and cleanup actions, based on the information contained in the reassessment report and in the OSWER guidance. Similarly, in the case of non-time critical removal actions (time permitting, for emergency and time critical actions), EPA should commit to reviewing Action Memoranda promptly following the release and analysis of the reassessment report and OSWER guidance, and, if necessary, to making changes to the Action Memoranda and cleanup actions, based on the information contained in the reassessment report and the OSWER guidance. EPA should similarly commit to reviewing RCRA cleanup decisions (i.e., decisions for which this Directive has been used) promptly following the release and analysis of the reassessment report and OSWER guidance.

IMPLEMENTATION

Regional management should consult with the appropriate Office of Emergency and Remedial Response (OERR) Regional Centers on all proposed Fund and Potentially Responsible Party-lead site decisions under CERCLA, including other Federal agency-lead and state-lead site decisions, involving the development of dioxin soil cleanup levels for non-time critical removal sites (time permitting, for emergency and time critical removal sites) and remedial sites. Consultation should be initiated at the risk assessment stage. For Federal agency-lead sites, OERR will, in turn, notify the Federal Facilities Restoration Reuse Office of ongoing consultations. The Office of Site Remediation Enforcement will provide support if enforcement issues are identified. For consultation procedures, refer to the OSWER "Headquarters Consultation for Dioxin Sites", 9200.4-19, December 13, 1996, plus the OSWER "Consolidated Guide to Consultation Procedures for Superfund Response Decisions", 9200.1-18FS, May 1997.

In the case of EPA-lead RCRA corrective action sites, Regions should provide the Office of Solid Waste Permits and State Programs Division (OSW/PSPD) with proposed dioxin soil cleanup levels (i.e., prior to notice and comment) in order to ensure appropriate implementation of this Directive. For state-lead RCRA corrective action sites, it is also recommended that states use the dioxin levels recommended by this Directive as starting points in setting soil cleanup levels. States are encouraged to share their approaches with the Regions in a manner consistent with established procedures for EPA support and oversight of state RCRA Corrective Action programs.

The levels in this Directive are recommended unless extenuating site-specific circumstances warrant different levels, a more stringent state applicable or relevant and appropriate requirement (ARAR) establishes a cleanup level at CERCLA sites, or a more stringent state requirement applies at RCRA sites. We recommend that levels other than 1 ppb (TEQs) for residential soils and outside the range of 5 ppb to 20 ppb (TEQs) for commercial/industrial soils be used only where evidence exists that risks posed by the site differ from risks estimated using standard national default guidance values. These recommendations apply to RCRA corrective actions, CERCLA non-time critical removal actions (time permitting, for emergency and time-critical actions) and CERCLA remedial actions where cleanup levels are to be developed for dioxin in soil, regardless of whether dioxin itself drives the decision-making process.

The recommended levels found in this Directive, generally considered protective of human health and the environment, apply to surface soils. Please note that with respect to human health, these levels are based on the direct contact exposure pathway. The recommended levels in this Directive do not apply to other exposure pathways, such as migration of soil contaminants to ground water or to agricultural products. While the focus of this Directive is on soils, these recommended levels also apply to sediments in the event that this environmental medium is considered to be a direct exposure pathway for human receptors.

This document provides guidance to EPA staff. The guidance is designed to communicate national policy on dioxin cleanups for soil. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

If you have any questions concerning this Directive, please contact either Marlene Berg at (703)603-8701 in Headquarters or Elmer Akin of Region 4 at (404)562-8634, as Marlene and Elmer are

co-chairs of the Superfund Dioxin Workgroup. For the RCRA Corrective Action program, please contact Robert Hall of the Office of Solid Waste Permits and State Programs Division at (703)308-8484. Attached, for your information, is a list of Regional points of contact who are serving on the dioxin workgroup.

Attachment: Superfund Dioxin Workgroup: Regional Points of Contact

cc: Mike Shapiro, OSWER
Peter Grevatt, OSWER
Steve Luftig, OERR
Elaine Davies, OERR
Larry Reed, OERR
Gershon Bergeisen, OERR
David Bennett, OERR
Bruce Means, OERR
Betsy Shaw, OERR
Paul Nadeau, OERR
Tom Sheckells OERR
Murray Newton, OERR
John Cunningham, OERR
Dave Evans, OERR
Joe LaFornara, OERR
Mark Mjoness, OERR
Jim Woolford, FFRRO
Elizabeth Cotsworth, OSW
Barry Breen, OSRE
Tudor Davies, OW
Craig Hooks, FFEO
Earl Salo, OGC
Bill Sanders, OPPT
Bill Farland, ORD
Regional Counsel, Regions I-X
Peggy Schwebke, Region 5
Superfund Dioxin Workgroup

Toxicology and Industrial Health **VOL. 13, No. 6, pp. 759-768, 1997**

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

Christopher T. De Rosa, David Brown, Rosaline Dhara, Woodrow Garrett, Hugh Hansen, James Holler, Dennis Jones, Denise Jordan-Izaguirre, Ralph O'Connor, Hana Pohl, and Charles Xintaras

Agency for Toxic Substances and Disease Registry,
U.S. Department of Health and Human Services
Atlanta, Georgia

Approved:

/s/
Barry L. Johnson
Assistant Administrator

Effective Date:
August 21, 1997

Note: While the original publication dates on some ATSDR's documents may not appear to be current, the information in the document is valid and may still provide relevant information.

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) $\leq$ 50 ppt (0.05 ppb), > 0.05 ppb but < 1 ppb and $\geq$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 to 50 ppt TEQs	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

* 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:

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

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 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 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:

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

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