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



OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

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MEMORANDUM

SUBJECT: Transmittal of "Frequently Asked Questions on the Update to the ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil"

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Matt Hale, Director

TO: Superfund National Policy Managers, Regions 1-10

The purpose of this memorandum is to transmit the fact sheet describing the Agency for Toxic Substances and Disease Registry's (ATSDR) recently issued "Update to the ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil."

The attached fact sheet provides frequently asked questions regarding the impact of ATSDR's updated soil dioxin policy on Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites and Resource Conservation and Recovery Act (RCRA) corrective action sites. ATSDR updated its 1998 residential dioxin soil policy in order to eliminate confusion regarding interpretation of ATSDR's "evaluation", "screening" and "action" levels. ATSDR's update is not based on new scientific data or reanalysis of existing data. The update does not impact the process used for conducting risk assessments or developing cleanup decisions at CERCLA sites and RCRA corrective action sites. The Office of Solid Waste and Emergency Response (OSWER) preliminary remediation goal (PRG) of 1 ppb dioxin for residential soil¹ has not changed and is recommended until the Agency updates its risk assessment for dioxin.

¹ Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites. Office of Solid Waste and Emergency Response Directive 9200.4-26. April 13, 1998. <u>http://www.epa.gov/superfund/resources/remedy/pdf/92-00426-s.pdf</u> As a reminder, as per the OSWER directive for soil dioxin¹, regions should continue to consult with the appropriate OSWER programs offices when developing dioxin soil cleanup levels for non-time critical removal sites (time permitting, for emergency and time critical removal sites) and for remedial sites.

The fact sheet can be found at the following web site: http://www.epa.gov/swerrims/riskassessment/superfund hh characterization.htm

For questions regarding the fact sheet, please contact Marlene Berg at 703-603-8701.

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Frequently Asked Questions on the Update to the ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil

INTRODUCTION

The Agency for Toxic Substances and Disease Registry (ATSDR) issued an update (October 15, 2008) to its policy guideline for dioxin and dioxin-like compounds in residential soil (ATSDR, 2008; 73 Fed. Reg. 61,133). The purpose of this update is to eliminate confusion regarding the interpretation of ATSDR's "evaluation," "screening" and "action" levels for dioxin. The update eliminates ATSDR's action level criterion for dioxins in residential soil that was intended to trigger the consideration of specific public health actions. However, ATSDR continues to consider health risks associated with levels of dioxins in soil below 1 ppb to be low under most residential scenarios where the primary exposure pathway is incidental ingestion through direct exposure to soil. In such instances, ATSDR public health recommendations may include community health education or limiting access to contaminated areas. The purpose of these frequently asked questions are to explain this ATSDR update in relation to EPA's activities at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites and Resource Conservation and Recovery Act (RCRA) corrective action sites.

This update does not change ATSDR's Toxicological Profile (ATSDR, 1998) or ATSDR's minimal risk level (MRL) for dioxin established in 1998 (Appendix A in ATSDR, 1998). This update also does not impact the process used for conducting risk assessments or developing cleanup decisions at CERCLA and Resource Conservation and Recovery Act (RCRA) sites. The U.S. Environmental Protection Agency's (EPA) preliminary remediation goal (PRG) for dioxin in residential soil has not changed and remains at 1 ppb (EPA, 1998).

<u>Background</u>. In 1998, ATSDR developed a policy guideline for dioxin and dioxin-like compounds in residential soil. The 1998 policy was developed to assist ATSDR health assessors in evaluating the public health implications of dioxin and dioxin-like compounds in residential soils near or on hazardous waste sites. The 1998 guideline established three levels as criteria for comparing dioxin levels in residential soil: a screening level, an evaluation level and a public health action level. The 1998 guideline also recommended, for levels between 0.05 ppb and 1 ppb TEQ, evaluation of site-specific factors, and for levels over 1 ppb TEQ, consideration of specific public health actions. The 1998 policy guideline is only available, in hard copy, as Appendix B to the Toxicological Profile for Chlorinated Dibenzo-p-Dioxins. ATSDR has updated the 1998 dioxin soil guideline in order to be consistent with its more recent *Public Health Assessment Guidance Manual* (PHAGM) (ATSDR, 2005).

FREQUENTLY ASKED QUESTIONS

Q: What is the role of ATSDR and EPA at contaminated sites?

A: EPA determines cleanup standards at CERCLA and RCRA corrective action sites, while ATSDR advises EPA and other Federal and state agencies, and the public, on the health impacts of CERCLA sites.

Q: What is the objective of ATSDR's updated policy?

A: The objective of this update is to provide consistency with the ATSDR *Public Health Assessment Guidance Manual* (PHAGM) (ATSDR, 2005) and eliminate the confusion regarding interpretation of residential dioxin soil levels that exceed the ATSDR established screening level of 0.05 ppb.

Q: Why is ATSDR updating its 1998 residential dioxin soil policy?

A: The 1998 policy (placed as Appendix B to ATSDR's *Toxicological Profile for Chlorinated Dibenzo-p-dioxins (CDDs)* (ATSDR, 1998)) recommended three levels as criteria for comparing dioxin levels in residential soil: a screening level of 0.05 ppb, an evaluation level of between 0.05 ppb and 1 ppb, and an action level of 1 ppb. Use of the 1998 policy led to confusion in applying these criteria and subsequently resulted in inconsistent application of the guideline. ATSDR updated the policy guideline to be consistent with the more recent ATSDR PHAGM (ATSDR, 2005), which recommends the use of screening levels for all chemicals, thus ensuring that ATSDR evaluation of residential soil dioxin is consistent with other contaminants. As ATSDR does not develop "action levels," the dioxin action level of 1 ppb has been eliminated. With the deletion of the 1 ppb action level, the evaluation level, or range between screening level and action level, has been eliminated as well.

Q: When does ATSDR's update go into effect?

A: ATSDR's update is in effect, with issuance in the Federal Register on October 15, 2008 (73 Fed. Reg.61,133), with minor edits announced on Nov. 28, 2008 (73, Fed. Reg.72, 484). The update has been incorporated into Appendix B of the on-line version of the Toxicological Profile for Chlorinated Dibenzo-p-Dioxins (ATSDR, 1998). The update document can also be found at the following link: http://www.atsdr.cdc.gov/substances/dioxin/policy/Dioxin Policy Guidelines.pdf

http://www.alsor.ede.gov/substances/dioxin/poney/Dioxin_Foney_Outdonnes.pdr

Q: Does the elimination of ATSDR's public health action level of 1 ppb impact EPA's residential soil preliminary remediation goal also established at 1 ppb?

A: ATSDR continues to consider health risks associated with levels of dioxins in residential soil below 1 ppb to be low under most scenarios where the primary exposure pathway is incidental ingestion through direct exposure to soil. At sites where dioxin levels are between 0.05 ppb and 1 ppb, ATSDR recommends that appropriate public health activities may include community health education and/or site access restrictions.

Q: What does ATSDR's updated policy recommend?

A: The updated policy recommends that ATSDR health assessors evaluate, on a sitespecific basis, residential dioxin soil levels that exceed the ATSDR established screening level of 0.05 ppb, as described in the ATSDR PHAGM (ATSDR, 2005). ATSDR defines a screening level as follows: a concentration in air, soil, or water (or other environmental media), which is derived from ATSDR's minimal risk level for dioxin (MRL) and below which adverse non-cancer health effects are not expected to occur. Separate levels can be derived to account for acute, intermediate, or chronic exposure durations.

The level of 0.05 ppb is an ATSDR screening level for dioxin and dioxin-like compounds (including 2,3,7,8-tetrachlorodibenzo-*p*-dioxin and other structurally related halogenated aromatic hydrocarbons) based on non-cancer risks associated with the ingestion of soil in residential settings. In addition to evaluating dioxin with respect to soil ingestion, ATSDR health assessors, in applying the 2005 PHAGM, ensure that comprehensive evaluation of dioxins include the consideration of scenarios and relevant screening levels where dioxins may enter the food chain pathway.

ATSDR continues to consider health risks associated with levels of dioxins in soil below 1 ppb to be low under most residential scenarios where the primary exposure pathway is incidental ingestion through direct exposure to soil. In such instances, ATSDR public health recommendations may include community health education or limiting access to contaminated areas.

Q: How does the updated policy affect ATSDR's scientific assessment of the toxicity of dioxin?

A: ATSDR's scientific assessment of dioxin toxicity and ATSDR's MRL for dioxin have not changed. ATSDR's soil dioxin policy is not based on new scientific data or reanalysis of existing data.

Q: What is EPA's policy for evaluating dioxin in residential soil at CERCLA sites and RCRA corrective action sites?

A: EPA generally uses 1 ppb dioxin as a starting point for setting cleanup levels at RCRA corrective action sites and Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) removal sites (i.e., non-time critical removal sites and, time permitting, for emergency and time critical sites) and as a preliminary remediation goal (PRG) for CERCLA remedial sites for dioxin in surface soil involving a residential exposure scenario (EPA, 1998). The recommended level of 1 ppb is based on the direct contact exposure pathway for human health. This level does not apply to other exposure pathways, such as migration of soil contaminants to ground water or to agricultural products. The 1 ppb level is recommended unless extenuating site-specific circumstances warrant different levels or a more stringent state applicable or relevant and appropriate requirement (ARAR) establishes a cleanup level at CERCLA sites.

The recommended level of 1 ppb is to be used pending the release of EPA's comprehensive dioxin reassessment report and cross-program assessment of the impacts of the report.

EPA regional management should continue to consult with the appropriate Office of Solid Waste and Emergency Response (OSWER) programs 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. The Office of Site Remediation Enforcement will provide support if enforcement issues are identified.

In the case of EPA-lead RCRA corrective action sites, Regions should provide the appropriate Office of Solid Waste programs with proposed dioxin soil cleanup levels (i.e., prior to notice and comment). For state-lead RCRA corrective action sites, it is also recommended that states use the 1 ppb dioxin level as a starting point in setting residential soil cleanup levels. States are encouraged to share their approaches with EPA Regions in a manner consistent with established procedures for EPA support and oversight of state RCRA Corrective Action programs.

For consultation procedures, refer to the OSWER Guidance on Non-NPL Removal Actions Involving Nationally Significant or Precedent-Setting Issues (EPA, 1989), the OSWER Headquarters Consultation for Dioxin Sites (EPA, 1996), plus the OSWER Consolidated Guide to Consultation Procedures for Superfund Response Decisions (EPA, 1997).

Q: How does ATSDR's updated policy impact the CERCLA and RCRA risk assessment process?

A: The ATSDR update does not impact the process used for conducting risk assessments or developing cleanup decisions at CERCLA sites and RCRA corrective action sites. Specifically, the update does not alter the use of EPA's PRG for dioxin in residential settings; the soil PRG remains 1 ppb.

Q: What is the status of EPA's comprehensive reassessment of dioxin?

A: In 2003, EPA released a comprehensive reassessment of dioxin exposure and human health effects. A National Academy of Sciences (NAS) expert panel reviewed this reassessment and identified three key areas for improvement: 1) justification of approaches to dose-response modeling for cancer and noncancer endpoints; 2) transparency and clarity in selection of key data sets for analysis; and 3) transparency, thoroughness, and clarity in quantitative uncertainty analysis. EPA is in the process of planning its response to the NAS comments.

Q: What are the implications for EPA of the ATSDR update on exposure pathways other than direct ingestion?

A: One of the purposes of the ATSDR update is to provide for a strengthened emphasis on exposure pathway analysis beyond direct soil contact. Dietary sources and indirect exposure pathways may make a significant contribution to dioxin exposure. Assessing both direct and indirect exposure pathways should result in a more comprehensive evaluation of exposure conditions at residential sites with dioxin contamination. EPA believes that the updated ATSDR policy is consistent with the Agency's policy of recommending 1 ppb as a starting point for developing a dioxin cleanup level in residential soil. EPA's recommendation is based on direct contact with surface soil. Other exposure pathways may be of importance at dioxin sites, resulting in the need for additional site-specific evaluation.

Q: Who should be contacted for information?

A: Content expert contact:

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REFERENCES

- U.S. Department of Health and Human Services. 1998. *Toxicological Profile for Chlorinated Dibenzo-p-Dioxins*. Agency for Toxic Substances and Disease Registry, Atlanta, GA. Available at: <u>http://www.atsdr.cdc.gov/toxprofiles/tp104.pdf</u>.
- U.S. Department of Health and Human Services. 2005. *Public Health Assessment Guidance Manual*. Agency for Toxic Substances and Disease Registry, Atlanta, GA. Available at: <u>http://www.atsdr.cdc.gov/HAC/PHAmanual/index.html</u>.

- U.S. Department of Health and Human Services. 2008. Update to the ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil. Agency for Toxic Substances and Disease Registry, Atlanta, GA. Available at: <u>http://www.atsdr.cdc.gov/substances/dioxin/policy/Dioxin_Policy_Guidelines.pdf</u>
- U.S. Environmental Protection Agency. 1989. *Guidance on Non-NPL Removal Actions Involving Nationally Significant or Precedent-Setting Issues*. Office of Solid Waste and Emergency Response, Washington, D.C. OSWER Directive 9360.0-19. Available at: <u>http://www.epa.gov/superfund/policy/remedy/pdfs/93-60019-s.pdf</u>
- U.S. Environmental Protection Agency. 1996. *Headquarters Consultation for Dioxin Sites.* Office of Solid Waste and Emergency Response, Washington, D.C. EPA 540/F-97/014. Available at: <u>http://www.epa.gov/superfund/policy/remedy/pdfs/92-00419-s.pdf</u>
- U.S. Environmental Protection Agency. 1997. Consolidated Guide to Consultation Procedures for Superfund Response Decisions. Office of Solid Waste and Emergency Response, Washington, D.C. EPA 540/F-97/009. Available at: <u>http://www.epa.gov/superfund/policy/remedy/sfremedy/hqconsult.htm</u>.
- U.S. Environmental Protection Agency. 1998. *Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites*. Office of Solid Waste and Emergency Response, Washington, D.C. OSWER Directive 9200.4-26. Available at: <u>http://www.epa.gov/superfund/policy/remedy/pdfs/92-00426-s.pdf</u>.