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U.S. Environmental Protection Agency Plan for Developing Interim Preliminary Remediation Goals for Dioxin in Soil

In May 2009, the U.S. Environmental Protection Agency's (EPA) Administrator, Lisa P. Jackson decided that EPA needs to accelerate work underway to reassess the human health risks from exposures to dioxin. EPA's *Science Plan for Activities Related to Dioxins in the Environment* (2009)¹ details a plan, with interim milestones, for completion of the Agency's dioxin reassessment. By the end of 2010, EPA expects to complete the dioxin reassessment and release it to the public, subject to further consideration of the science and the scope and complexity of the revisions that will need to be made.

Several key site-specific decisions involving dioxin may need to be made before the dioxin reassessment is finalized. EPA's Office of Solid Waste and Emergency Response (OSWER) will be reviewing current dioxin cleanup guidance set by the Agency and other entities, with the goal of recommending interim preliminary remediation goals (PRGs) informed by the latest science. These interim recommended PRGs would be used until EPA issues its dioxin reassessment and OSWER issues final recommended PRGs based on the reassessment. After publication of the dioxin reassessment and final PRG guidance, EPA will re-evaluate cleanup decisions at Superfund, Federal Facilities, Brownfields, and Resource Conservation and Recovery Act (RCRA) sites that were based on the interim PRGs to ensure that cleanups are protective.

What is a PRG?

Preliminary remediation goals (PRGs) are chemical-specific concentration goals for specific media (e.g. soil, sediment, water and air) and land use combinations at Superfund, Federal Facilities, Brownfields and RCRA sites. They serve as a target to use during the initial development, analysis, and selection of cleanup alternatives. These goals should both be protective of human health and the environment and comply with all applicable, relevant and appropriate regulations (ARARs) for all exposure pathways being addressed.

In developing these interim recommended PRGs, OSWER and EPA's Office of Research and Development (ORD) are reviewing current soil cleanup levels and dioxin toxicity values used by the states, the Agency for Toxic Substances and Disease Registry, and other countries. Based on this evaluation, OSWER may reconsider EPA's currently recommended PRGs for Superfund, Federal Facilities, Brownfields and RCRA sites,² which are 1 ppb (parts per billion) (or 1,000 ppt (parts per trillion)) for dioxin toxicity equivalents (TEQs)³ in residential soil, and a level within the range of 5 ppb (or 5,000 ppt) and 20 ppb (or 20,000 ppt) in commercial/industrial soil, where exposure is due to direct contact. Three key components of EPA's current recommended PRGs will be re-evaluated: the EPA dioxin toxicity value adopted in 1985, generic exposure assumptions, and the cancer risk level. OSWER intends to recommend interim PRGs informed by the latest science and the work of state and other agencies.

The proposed plan for the development of the OSWER interim recommended PRGs for dioxin in soil is as follows:

- Open public comment period on this OSWER plan for developing interim recommended PRGs

October 2009

- Interim recommended PRGs available for public comment in the Federal Register December 31, 2009
- End of public comment period February 2010
- Issuance of guidance that addresses interim recommended PRGs June 2010*

*Schedule subject to change based on the extent of public comments received.

EPA will make this information available to the public through the following: 1) the EPA Superfund program web site; 2) Clu-in, a web site maintained by EPA that has technical information related to cleanups; 3) postings on regional web sites and used at public meetings; and 4) distribution generally to the regions.

To comment on the proposed plan for developing interim recommended PRGs for dioxin in soil, please send comments to: OSWER_Dioxin_PRGs@epa.gov

Frequently Asked Questions

How are PRGs Used?

Consistent with the National Contingency Plan,⁴ PRGs generally are initial chemical-specific concentration goals for specific media (e.g. soil, sediment, water and air) and land uses at Superfund, Federal Facilities, Brownfields and RCRA sites. These goals normally should both be protective of human health and the environment and comply with all applicable, relevant and appropriate regulations (ARARs) for all exposure pathways being addressed.

Risk-based PRGs generally are developed using estimates for the toxicity of a chemical, as well as generic exposure assumptions. An example of an exposure assumption is exposure frequency, or the number of days in a year that a person is exposed to contamination. A generic exposure frequency of 350 days per year is typically used for Superfund, Federal Facilities, Brownfields, and RCRA sites for residential settings.

A PRG is usually calculated for cancer and for non-cancer effects. The more conservative value typically is then selected as the recommended PRG. PRGs for carcinogens commonly are set at levels that correspond to one in a million (1×10^{-6}) individual excess cancer risk⁵ as a point of departure. However, they may be revised to a different risk level within the acceptable risk range of 10^{-6} to 10^{-4} based on consideration of exposure factors, uncertainty, or technical issues. PRGs for non-carcinogens are typically set at a level corresponding to a hazard quotient⁶ equal to 1.0.

It is important to note that PRGs are not intended to act as site-specific cleanup levels; rather they are intended to serve as initial guidelines for use in scoping characterization and remediation alternatives at Superfund, Federal Facilities, Brownfields, and RCRA sites. Final cleanup levels for a site typically would be developed by modifying the

PRGs based on consideration of site specific factors (e.g., exposure frequency or acceptable cancer risk level).⁷

For specific information on how PRGs are calculated, see *EPA's Risk Assessment Guidance for Superfund (RAGS) Part B*, Chapter 1 and Chapter 3. Available online at: <http://www.epa.gov/oswer/riskassessment/ragsb/index.htm>

What are the current PRGs for dioxin in soil?

For Superfund, Federal Facilities, Brownfields, and RCRA sites, OSWER's 1998 soil dioxin guidance² recommends a PRG of 1 ppb (or 1,000 ppt) for dioxin toxicity equivalents (TEQs)³ in residential soil, and a level within the range of 5 ppb (or 5,000 ppt) and 20 ppb (or 20,000 ppt) in commercial/industrial soil, where exposure is due to direct contact. A range in levels has been recommended for commercial/industrial soil due to the greater variability in human exposures associated with these land uses.

The currently recommended PRGs are based on an EPA dioxin toxicity value adopted by the Agency in 1985. This toxicity value is considered a Tier 3 toxicity value under the 2003 OSWER memorandum on the hierarchy of sources of toxicological information⁸ that should be considered for site-specific risk assessments (the interim recommended PRGs will also be based on a Tier 3 toxicity value.) The categories for toxicity values are as follows:

- **Tier 1- EPA's Integrated Risk Information System (IRIS)**⁹
- **Tier 2- EPA's Provisional Peer-Reviewed Toxicity Values (PPRTVs)** – The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center develops PPRTVs, at the request of EPA's Superfund program, for chemicals not found in IRIS.
- **Tier 3- Other Toxicity Values** – Tier 3 includes additional EPA and non-EPA sources of toxicity information. Priority should be given to those sources of information that are the most current, the basis for which is transparent and publicly available, and which have been peer-reviewed.

The currently recommended PRGs are also based on generic exposure assumptions and cancer risk levels used at Superfund, Federal Facilities, Brownfields, and RCRA sites. The 1 ppb (or 1,000 ppt) represents a lifetime excess cancer risk of 2.5×10^{-4} for residential soil, and 5 ppb (or 5,000 ppt) represents a lifetime excess cancer risk of 1.4×10^{-4} for commercial/industrial soil.

Why is EPA considering modifying the existing PRGs for dioxin in soil?

While EPA finalizes its dioxin reassessment, OSWER and ORD have been asked to consider the newest science to help evaluate the protectiveness of current PRGs for dioxin in soil .

How will the interim PRGs for dioxin in soil be used?

The interim PRGs will be used to evaluate pending cleanup decisions. These decisions will be re-evaluated when the final PRGs for dioxin in soil are developed. As noted above, the interim PRGs being developed for dioxin are not site-specific cleanup levels. They are intended to serve as recommended PRG levels that can generally be used as a starting point in the process used for determining cleanup levels at Superfund, Federal Facilities, Brownfields, and RCRA sites. Final cleanup levels for a site would typically be developed by modifying the PRGs based on consideration of site-specific information (such as exposure frequency or acceptable cancer risk level) obtained as part of the site-specific baseline risk assessment.

¹ U.S. Environmental Protection Agency. May 26, 2009. EPA's *Science Plan for Activities Related to Dioxins in the Environment*. Press Release. Available online: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=209690>.

² U.S. Environmental Protection Agency. April 13, 1998. *Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites*. OSWER Directive 9200.4-26. Available at: <http://www.epa.gov/superfund/resources/remedy/pdf/92-00426-s.pdf>.

³ Toxicity equivalents consider the toxicity of the less toxic dioxin-like compounds as fractions of the toxicity of the most toxic compound (2,3,7,8-TCDD). Each compound is attributed a specific "Toxic Equivalency Factor" (TEF). This factor indicates the degree of toxicity compared to 2,3,7,8-TCDD, which is given a reference value of 1.

⁴ 40 CFR 300 Section 430(e)(2)(i)(A)(2)

⁵ Cancer risks normally are estimated as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to a contaminant. This incremental or excess individual lifetime cancer risk is generally expressed as the probability (e.g., 1×10^{-6} or one in a million) of an individual developing cancer.

⁶ A hazard quotient generally is the ratio of an exposure level for a single substance to a reference dose, which is an estimate of the daily exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime.

⁷ EPA's *Risk Assessment Guidance for Superfund, Part B, Development of Preliminary Remediation Goals* 1991, EPA/540/R-92/003

⁸ U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response. December 5, 2003. *Human Health Toxicity Values in Superfund Risk Assessments*. OSWER Directive 9285.7-53. Available at: <http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf>.

⁹ IRIS develops human health risk information for an EPA database that addresses potential human health effects that may result from long-term exposure to environmental contaminants. Dioxin toxicity values established based on the final dioxin reassessment will be incorporated into IRIS.