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Region 6 Risk Management Addendum - *Draft Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*

Addendum
Region 6 Risk Management

What's Covered in the Risk Management Addendum:

- Introduction
- Target Levels
- Estimation of Health Effects for Lead
- Infant Exposure Through Breast Milk
- Acute Exposure
- Cumulative Risk

Risk characterization must exhibit the core values of transparency, clarity, consistency, and reasonableness. Therefore, this Region 6 Addendum to the Human Health Risk Assessment Protocol (HHRAP) (U.S. EPA 1998) provides discussions and numeric target levels to support the user in risk management decisions.

TARGET LEVELS

In order to evaluate potential health risks, U.S. EPA has established targets within which the Agency strives to manage risks. To evaluate potential carcinogenic risks, the Agency generally uses a risk range of 10^{-4} to 10^{-6}, and to evaluate the potential for non-cancer health effects, the Agency generally uses a hazard index/quotient of 1.0. However, for purposes of RCRA combustion permitting decisions, U.S. EPA Region 6 has modified the target levels (see discussions below) to reflect the contribution of background levels of contamination (U.S. EPA 1994c). If detailed information on background sources are available for a particular area, this information may be used to develop an alternative approach for incorporating background exposure levels into the risk assessment.

Also, the potential for adverse health effects associated with exposure to lead cannot be addressed in terms

of risks and hazards. Target levels of lead concentrations in soil and air have been established by using alternative means. These target values are not a discrete indicator of observed adverse effect. If a calculated risk falls within the target values, U.S. EPA Region 6 may, without further investigation, conclude that a proposed action does not present an unacceptable risk. A calculated risk that exceeds these targets, however, would not, in and of itself, indicate that the proposed action is not safe or that it presents an unacceptable risk. Rather, a risk calculation that exceeds a target value triggers further careful consideration of the underlying scientific basis for the calculation.

Target Levels for Carcinogens

For the purposes of RCRA permitting decisions, U.S. EPA Region 6 recommends, consistent with U.S. EPA (1994c), the narrowing of the acceptable risk range to 10^{-5} to 10^{-6}; primarily to account for exposure to background levels of contamination. As a result, the total individual risk associated with exposures to potential carcinogens released from a single facility should not exceed 1.0×10^{-5}.

Target Hazard Level

As described above for risks, for the purposes of RCRA permitting decisions and consistent with U.S. EPA (1994c), U.S. EPA Region 6 recommends a modified target hazard level, to account for background contributions, from an *HQ* or *HI* target value of 1.0 to a target value of 0.25. This modification eliminates the need to collect background COPC concentration data before completing the risk assessment, by assuming that COPC emissions from hazardous waste emission units result in incremental increases of existing background COPC concentrations, which are, by default, assigned an *HI* or *HQ* value of 0.75. Although background COPC *HQ* or *HI* values might not equal 0.75, as a result of this modified target level, either the *HQ* (for a single COPC) or the *HI* (for multiple COPCs or pathways) resulting from combustion unit emissions should be less than 0.25. An *HQ* or *HI* equal to or exceeding 0.25 indicates a potential for noncarcinogenic health effects. However, an *HQ* or *HI* equal to or exceeding 0.25, rather than necessarily indicating that noncarcinogenic health effects can or will occur, indicates only that there is a potential for noncarcinogenic effects, based on a specific set of exposure, model, and toxicity assumptions.

ESTIMATION OF POTENTIAL HEALTH EFFECTS FOR LEAD

Toxicity factors (for example, *RfDs*, *RfCs*, or *SF*s) are not available for lead. Therefore, consistent with U.S. EPA (1994c), U.S. EPA Region 6 recommends that the potential for adverse health effects associated with exposure to lead be characterized through a direct comparison with media-specific health-based levels. Specifically, U.S. EPA Region 6 recommends target levels for lead in soil and air of 100 mg/kg and 0.2 $\mu g/m^3$, respectively. The soil target level of 100 mg/kg is based on U.S. EPA guidance (1994e) that indicates that soil lead levels less than 400 mg/kg, based on lead concentrations in blood as discussed below, are not of concern for remediation purposes. U.S. EPA Region 6 has incorporated a margin of safety into the risk assessment process by allowing only 25 percent of the remediation threshold lead level to be attributable to operation of a hazardous waste combustion unit. Similarly, the protective air standard of 0.2 $\mu g/m^3$ is based on 25 percent of the National Ambient Air Quality Standard (NAAQS) quarterly average air concentration of 1.5 $\mu g/m^3$ (40 CFR Part 50.12) translated to an annual-basis value (0.9 $\mu g/m^3$).

Estimates of the potential for human health effects associated with potential exposure to lead are typically based on lead concentrations in blood. U.S. EPA (1994e) recommended that lead exposures be limited so that 95 percent of the sensitive subpopulation (children) will have blood level concentrations below 10 μg/decaliter (μg/dL). U.S. EPA (1994a) has developed a mathematical model, called the "Integrated Exposure U/BK [IEUBK] Model," to estimate lead levels in the blood of children on the basis of total lead uptake from exposures through diet, drinking water, air, and soil. When run with standard recommended default values (these generally represent national averages, or "typical" values), U.S. EPA's IEUBK model predicts that no more than 5 percent of children exposed to a lead concentration in soil of 400 mg/kg will have lead concentrations in blood exceeding 10 μg/dL (U.S. EPA 1994a; 1994e).

INFANT EXPOSURE THROUGH BREAST MILK

Infants that are breast-fed may be exposed to contaminants through breast milk if the nursing mother has been exposed. The potential for exposure is especially great for dioxin-like compounds, which are highly lipophilic and are likely to accumulate in breast milk. Available guidance presents procedures and

equations that can be used to estimate (1) the concentration of dioxin-like contaminants in the mother's milk, and (2) the average daily dose (ADD) for a breast-feeding infant. The procedures and equations used to assess infant exposure through breastmilk are complex.

Significant limitations remain in the estimation of infant exposure to lipophilic compounds through the ingestion of breast milk, and the characterization of risks associated with those exposures. U.S. EPA Region 6 currently recommends calculating infant exposures to and risks associated with such infant exposures for only 2,3,7,8-TCDD Toxicity Equivalent Quotient (TEQ). U.S. EPA Region 6 currently advocates that estimates of the infant average daily dose (ADD_{inf}), calculated on the basis of an averaging time of 1 year, be compared to an average infant intake target level ($ADD_{i/m}$) of 60 pg/kg-day of 2,3,7,8-TCDD TEQ. The history and basis of this target level is presented in the following paragraphs.

U.S. EPA (1994l) is the source of most of the procedures and equations proposed for calculating exposures to lipophilic contaminants (primarily dioxin-like contaminants). This document states that a study of 42 U.S. women (Schecter, di Domenico, Tirrio-Baldassarri, and Ryan 1992) found an average of 16 parts per trillion (ppt) of 2,3,7,8-TCDD TEQ (3.3 ppt of 2,3,7,8-TCDD) in the lipid portion of breast milk.

Based on the average concentration of 16 ppt of 2,3,7,8-TCDD TEQ in breast milk, the ADD_{mat} can be back-calculated as 1.45 pg/kg-day. This intake estimate is consistent with the range of background intake of 1 to 3 pg/kg-day of 2,3,7,8-TCDD TEQ, based on dietary analysis (U.S. EPA 1994d).

Although research was and remains incomplete in the area of calculating risk for infant exposures to dioxin-like compounds in breast milk, U.S. EPA (1994d) suggests characterizing the risk by comparing the ADD_{inf} for 1 year of breast milk exposure to the background ADD_{mat} for dioxins of 0.5 pg/kg-day. However, the value presented for ADD_{mat} is based only on potential exposure to 2,3,7,8-TCDD and is not directly comparable to estimates of 2,3,7,8-TCDD TEQ intake.

U.S. EPA (1994b) refers to, and replicates, the procedures and equations for estimating potential infant exposure to dioxin-like compounds through ingestion of breast milk, which were presented originally in U.S. EPA (1994d). The document states, “One method of risk characterization, and the method used in

this document, is comparison of the *ADD* (ADD_{inf}) to the average adult background level for dioxin exposure, 0.5 pg/kg-day."

Most recently, guidance prepared by the NC DENR summarized procedures for estimating and characterizing risks associated with infant exposure to dioxin-like compounds through ingestion of breast milk (NC DENR 1997). The final version of the NC DENR guidance (NC DENR 1997), references that the *Risk Assessment Support to the Development of Technical Standards for Emissions from Combustion Units Burning Hazardous Wastes* estimates "...that the average background infant dose is 50/pg/kg-day of 2,3,7,8- TCDD TEQ".

The following points can be drawn from the preceding discussion:

- All four documents consistently present and use the equations used to estimate the concentration of 2,3,7,8-TCDD TEQ in breast milk, based on an estimate of ADD_{mat}.
- All four documents consistently suggest that the significance of the estimated ADD_{inf} be characterized by comparing it to some estimate of average or background ADD_{mat}.
- The definition of ADD_{mat}, or "that resulting from background" or "the average adult background exposure level," may not have been consistently stated in previous draft guidance documents. U.S. EPA's Dioxin Exposure document (U.S. EPA 1994d) and *Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Waste* both present a value for ADD_{mat} of 0.5 pg (2,3,7,8-TCDD only)/kg-day.

Based on the above discussion, it is clear that some confusion regarding this issue has simply been due to the evolving nature of methodologies to address the risks to breast-feeding infants from dioxin. U.S. EPA Region 6 advocates the equations originally included in U.S. EPA (1994d) for estimating the concentration of 2,3,7,8-TCDD TEQ in breast milk, based on average maternal 2,3,7,8-TCDD TEQ intake. More specifically, U.S. EPA Region 6 recommends evaluating the significance of estimated ADD_{inf} values by comparing them to estimates of the ADD_{inf} exposed through ingestion of breast milk from a mother receiving an average 2,3,7,8-TCDD TEQ exposure rather than to estimates of ADD_{mat}. This comparative average infant intake variable is referred to as $ADD_{i/m}$, and it is estimated as 60 pg/kg-day, based on an average 2,3,7,8-TCDD TEQ concentration of 16 ppt in breast milk.

ACUTE EXPOSURE RESULTING FROM DIRECT INHALATION

In addition to long-term chronic effects, short-term or acute effects should be considered from direct inhalation of vapor phase and particle phase (including particle-bound) COPCs. It is assumed that short-term emissions will not have a significant impact through the indirect exposure pathways (as compared to impacts from long-term emissions). Therefore, acute effects are only evaluated through the short-term (maximum 1-hour) inhalation of vapors and particulates exposure pathway of the acute risk scenario.

Acute hazard quotients (AHQ_{acute}) should be calculated at the selected acute exposure scenario locations for COPCs specific to emissions from each source and from all facility sources combined. For AHQ_{acute} values greater than 1, the permitting authority should consider the need to implement permit requirements to ensure protectiveness of the receptor populations that may reasonably be expected to be exposed. Where AHQ_{acute} values significantly exceed 1, the permitting authority may incorporate specific conditions or may deny the permit.

CUMULATIVE RISK

The HHRAP is intended *only* to evaluate the risks resulting from stack and fugitive emissions associated with hazardous waste combustion units. The evaluation of all risks associated with a facility, and with other facilities and environmental factors in the surrounding area—commonly referred to as cumulative risk—is beyond its scope. U.S. EPA Region 6, however, recognizes that this is an issue of great interest to community and environmental groups throughout the country. The following discussion presents an introduction to cumulative risk and existing U.S. EPA Region 6 policy regarding this issue.

Cumulative Risk Defined

Cumulative risk involves the evaluation of all "involuntary" risk to which a receptor may be subject. In addition to the risks resulting from the operation and emissions associated with hazardous waste combustion units—which are evaluated in the HHRAP—receptors may be exposed to a variety of

environmental risks via releases of COPCs from, among other sources, (1) automobile exhaust emissions, (2) leaking underground storage tanks, (3) untreated sewage, (4) agricultural land runoff, (5) industrial process air emissions, and (6) conventional (nonhazardous waste or fossil fuel) combustion-related air emissions. The total risk from all possible sources of COPCs is termed "cumulative risk." Other cumulative risks arising from the operation of a hazardous waste combustion unit, such as ground water contamination caused by a leaking storage tank or surface water contamination caused by runoff from a CKD landfill, are also beyond the scope of the HHRAP.

The HHRAP distinguishes between facilities operating single hazardous waste combustion units and those operating multiple hazardous waste combustion units. U.S. EPA Region 6 advocates that risk assessments for facilities operating multiple hazardous waste combustion units at a single site evaluate the total affect of hazardous waste combustion and ancillary waste handling operations. The primary objective of this assessment is to ensure that facilities operate these units in a manner that is protective of human health and the environment. It is appropriate to evaluate the incremental risk introduced by hazardous waste combustion operations at the entire facility, because the risk resulting from the emissions of multiple units could be of the same magnitude or greater than the emissions from a single unit at the facility. That is, U.S. EPA Region 6 does not encourage facilities to use multiple units with low individual risks that, if the facility was able to use a single unit—would result in a single high, unacceptable risk.

Evaluation of Cumulative Risk

Cumulative risk has not historically been evaluated by U.S. EPA Region 6, and no guidance is available from U.S. EPA regarding the evaluation of this issue. U.S. EPA Region 6 has historically evaluated risks on a media-specific basis, stemming from the development of the organization around the various media-and program-related laws and activities: (1) water-related issues under the Clean Water Act, (2) air-related issues under the Clean Air Act, (3) the evaluation of various hazardous waste management activities under Resource Conservation and Recovery Act, and (4) the evaluation of risks resulting from historical or abandoned hazardous waste disposal sites under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also referred to as Superfund. New media-specific regulations are typically based on the evaluation of the expected health benefits resulting from the

elimination of COPCs in that medium rather than from an entire community or industry.

New programs being evaluated by U.S. EPA, such as the Common Sense Initiative, are being implemented to determine whether the evaluation and regulation of specific industries or facilities as a group may result in more effective protection of human health and the environment. These activities, however, are in their infancy.

To summarize, U.S. EPA Region 6 does not typically evaluate risk other than incremental risk from individual operations, waste streams, or processes. Where there is site-specific concern, and as the science of risk assessment matures, U.S. EPA Region 6 may complete risk assessments that account for risk from (1) other pollutants and other processes at a facility, (2) numerous sources of a single pollutant in a specific community, or (3) all sources of all pollutants in a community.

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