

REGULATORY IMPLICATIONS OF USEPA'S DRAFT ORAL SLOPE FACTOR AND REFERENCE DOSE FOR DIOXIN

Haney JT¹, Aplin MA²

¹ Toxicology Division, Texas Commission on Environmental Quality (TCEQ), 12100 Park 35 Circle, Austin, TX 78753, USA; ² Technical Support Section, Remediation Division, TCEQ, 12100 Park 35 Circle, Austin, TX 78753, USA

Introduction

The assessment of the carcinogenic and non-carcinogenic potential of chemicals has great implications both in a regulatory context and in the public's perception of risk. In particular, the United States Environmental Protection Agency (USEPA) draft oral cancer slope factor (SFo) and oral reference dose (RfD) for 2,3,7,8-tetrachlorodibenzo-p-dioxin (dioxin) are more conservative than currently used values and have significant implications. Given their important role in the protection of public health, regulatory risk assessors have a duty to perform the most scientifically-defensible assessments possible. Regulatory risk assessors often err on the side of health-protectiveness and use conservative defaults when conducting chemical toxicity assessments, which has the potential to significantly overestimate risk or hazard. Overestimating the risk or hazard of a chemical may result in diverting public, industry, and government attention and resources away from chemicals that may represent more of a public health risk. Conversely, harm to public health may also result from significantly underestimating chemical risk or hazard. Thus, it is critically important for regulatory risk assessors to give full, thoughtful, and careful consideration and evaluation to the scientific merit of comments and recommendations from other experts (e.g., academia, industry, public sector, National Academy of Sciences) on their chemical assessments.

USEPA recently made available for public comment their draft report, "Draft EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments," hereafter referred to as the draft reanalysis.¹ The draft reanalysis provides a draft SFo for dioxin. Additionally, USEPA provides a draft RfD for dioxin for the first time. Toxicity factors, such as SFo and RfD values, play an important role in risk assessment and the regulation of chemicals, setting of health-protective environmental media concentrations (e.g., surface soil, drinking water, surface water), and in determining other safe levels (e.g., food, fish tissue).

Materials and Methods

The USEPA draft SFo and RfD values for dioxins are among those toxicity factors that have significant implications in a regulatory context and in the public's perception of risk. The SFo (1E+06 per mg/kg-day) given in the draft reanalysis is 6.4 times higher than that used (1.56E+05 per mg/kg-day) for the interim preliminary remediation goals (PRGs).² This implies a significantly greater carcinogenic potency. With regard to health effects other than cancer, the draft RfD (7E-10 mg/kg-day) is 30% lower than the Agency for Toxic Substances and Disease Registry (ATSDR) chronic minimal risk level (1E-09 mg/kg-day) used for the interim PRGs.^{2,3} Some potential implications of these more conservative draft SFo and RfD values were explored in the context of regulatory health-protective environmental media (e.g., surface soil, drinking water) levels, background concentrations, and food safety. The comments contained herein represent the personal opinions of the presenters and are not official TCEQ comments.

Results and Discussion

Surface Soil PRGs - The draft SFo and RfD values have significant implications for surface soil PRGs. USEPA's interim PRGs were ultimately based on noncancer effects.² However, the more conservative SFo from the draft reanalysis may result in cancer risk-based PRGs becoming the critical final PRGs. For example, at risk levels of 1E-06 and 1E-05, the new residential PRGs could be around 0.6 and 6 parts per trillion (ppt), respectively. These cancer-based PRGs would be significantly lower than what the new noncancer-based residential PRG could be (\approx 50 ppt). For the commercial/industrial worker (outside), new PRGs at risk levels of 1E-06, 1E-05, and 1E-04 could be

around 2.7, 27, and 270 ppt, respectively, which are significantly lower than what the new noncancer-based commercial/industrial PRG could be (≈ 665 ppt). If USEPA decides to be protective at the $1E-05$ excess risk level (similar to the interim PRGs), this may result in new residential and commercial/industrial worker surface soil PRGs that are over 150 times lower than the current PRGs (1,000 ppt for residential land use and 5,000 ppt (lower end of the range) for commercial/industrial land use).⁴ Using the draft SFO and a target risk level of $1E-05$, TCEQ surface soil cleanup values would be similarly decreased (e.g., surface soil values based on incidental ingestion for residential and commercial/industrial land use would be around 6.1 and 29 ppt, respectively).

The new residential PRG could possibly be within the range of background concentrations.² For example, potential new $1E-06$ and $1E-05$ risk level residential PRGs (≈ 0.6 and 6 ppt) are within the range of reported rural mean concentrations (0.2-11.4 ppt).² This may imply to the public that background soil dioxin levels at many residential properties are unsafe and unnecessarily alarm the public about everyday background exposures. The potential new $1E-06$ risk level commercial/industrial worker (outside) PRG (≈ 2.7 ppt) is also within the range of rural mean concentrations. Remediation of sites using residential or commercial/industrial PRGs within the range of background would not be feasible from a compliance perspective and could routinely result in costly studies to determine site-specific background concentrations. For example, it would be difficult to establish compliance criteria other than site-specific background if site concentrations are routinely greater than PRGs.

Previously Evaluated/Remediated Sites - Since the draft SFO and RfD values would significantly lower surface soil PRGs, they have significant implications for sites previously evaluated or remediated using the current PRGs (1,000 ppt residential; 5,000 ppt commercial/industrial). Based on these draft SFO and RfD values, the current residential PRG would represent regulatory unacceptable risk ($\approx 1.7E-03$) and hazard ($HQ \approx 20$). The low end of the current commercial/industrial PRG range (5,000 ppt) would also represent regulatory unacceptable risk ($\approx 1.9E-03$) and hazard ($HQ \approx 8$). This calls into question the health protectiveness of previous site evaluations and cleanups by federal and state agencies. This also implies that a reevaluation of historically-addressed sites may be necessary using updated PRGs. Historically-addressed sites would fall into three general categories:

- Sites previously evaluated and determined not to need cleanup based on comparisons of representative concentrations to the current PRGs may need to be remediated when reevaluated using updated PRGs;
- Surface soil concentrations left in place at sites remediated to the current PRGs may significantly exceed updated PRGs calculated using new SFO and RfD values and may require further evaluation; and
- Sites contaminated with polychlorinated biphenyls (PCBs), including dioxin-like PCBs, but for which only Aroclor data are available may have to be re-sampled and reassessed.

Situations such as these, which require reevaluation of sites, may require costly re-sampling and remediation at multiple sites.

It is difficult to discern the specifics of how USEPA will require implementation of the updated PRGs by federal and state agencies based on the two pages of relevant implementation guidance (specifically on draft interim PRGs) provided thus far.² For example, USEPA guidance does not specifically state whether USEPA intends to use updated PRGs to formally reevaluate CERCLA and RCRA corrective action sites that have already been evaluated and/or remediated using current PRGs. While the guidance does indicate that USEPA regions “may consider” finalized interim PRGs when determining cleanup levels at CERCLA and RCRA sites, and “should consider” them when performing five-year reviews of CERCLA sites to determine whether the original remedy stated in the Record of Decision remains protective,² USEPA does not specifically or clearly state what it means to “consider” new PRGs (e.g., formal reevaluation of remaining soil concentrations versus something less, using the actual PRG values as cleanup values). For state-lead RCRA sites, the guidance, “encourage[s] states to use the dioxin levels recommended in this guidance as starting points in developing soil cleanup levels, unless they have developed their own standards or guidance.”² USEPA does not elaborate on what is meant by states using new PRGs as, “starting points in developing soil cleanup levels.” Without clear guidance, inconsistent implementation of the new PRGs may result.

Drinking Water - The draft SFO has implications for the federal maximum contaminant level (MCL) for dioxin and whether it is considered health protective. Using the current SFO (1.56E+05 per mg/kg-day), risk associated with drinking water ingestion at the analytical practical quantitation limit-based MCL (3E-08 mg/L) is essentially at the high end of the risk range deemed acceptable by USEPA ($\approx 1.3E-04$). Using the draft reanalysis SFO results in the MCL being associated with a risk ($\approx 8.6E-04$) that is significantly higher than the upper end of the USEPA acceptable risk range (1E-04). This implies that for adequate protection against cancer effects, a revised federal MCL could be no higher than approximately 3.5E-09 mg/L.

The draft RfD has potentially significant implications for the health protectiveness of the MCL. Using the draft RfD results in the MCL being associated with a hazard quotient (HQ of 1.2) that is slightly greater than 1. However, a relative source contribution (RSC) factor is used for MCL goal calculations in conjunction with the RfD (Category II and III contaminants). The RSC is the proportion of the RfD that can be safely apportioned to the ingestion of water versus other exposure routes. Use of a RSC will result in a more realistic estimate of what the dioxin MCL would have to be for an overall ingestion hazard of 1. While USEPA typically uses a default of 20% in the absence of adequate data (and as a floor), there are exposure data for dioxin to derive a chemical-specific RSC, although a specific value is not necessary for this example. Many estimates of dietary intake (toxicity equivalency quotient or TEQ) exceed the RfD, especially for children.^{5,6,8} These data suggest that on top of dietary intake there is no room for additional exposure through water ingestion. However, 1% may be assumed as the RSC for the sake of an example. Other intake estimates suggest that a RSC of around 17% for adults could be used,⁷ so the USEPA floor of 20% is used for an additional example. Use of RSCs from 1-20% in a MCL goal calculation would result in water concentrations that are 6-122 times lower than the current MCL. This suggests that the MCL may need to be significantly reduced for adequate health protection when dietary exposure is considered.

Food Safety - Various dietary intake estimates would indicate that average adult and child intake may exceed the draft RfD, especially for children.^{5,6} For example, for a child age 1-5 years the intake rate (TEQ) is approximately 3.6 pg/kg-day,⁵ yielding a hazard quotient of around 5, which is often considered unacceptable by regulatory agencies. Even excluding dioxin-like PCBs which account for about 50% of the TEQ in foods and using zero for nondetects, the mean dietary intake for children ages 1-5 (1.09 pg/kg-day) is associated with a hazard quotient of 1.6.⁸ These types of analyses may raise public concerns about the safety of the U.S. food supply, especially if the public interprets the exceedance of a regulatory value as equivalent to an expectation of the occurrence of adverse health effects.

The draft SFO may also raise concerns about food safety given that risk from average dietary intake is above the acceptable excess risk range (1E-06 to 1E-04) established by USEPA. For example, assuming an average adult intake of 65 pg/day (≈ 0.93 pg/kg-day) over a lifetime,⁵ the risk based on the draft SFO would be 9.3E-04. Considering the greater intake of children on a body weight basis,⁵ the lifetime (70 year) risk would be around 1.2E-03. Even excluding dioxin-like PCBs which account for about 50% of the TEQ in foods and using zero for nondetects, all mean dietary intakes for various groups of children (ages 1-5, 6-11, 12-19) and adults (child/adult range of 0.33-1.09 pg/kg-day) exceed the intake level (0.1 pg/kg-day) associated with the upper end of acceptable risk (1E-04).⁸ Based on the same data and treatment of nondetects, the range of dietary intakes for various groups of children and adult "low consumers" of meat, poultry, and fish (0.16-0.76 pg/kg-day) also exceed the intake level associated with the upper end of acceptable risk.⁸ No 10th percentile for any group is less than the dietary intake associated with a risk of 1E-04 (0.1 pg/kg-day) based on the draft SFO.⁸ Analyses such as these using the draft RfD and SFO would imply that the U.S. diet, particularly beef, milk, and dairy, results in dioxin hazard and risk that are considered unsafe and unacceptable from a regulatory perspective and could undermine consumer confidence. Public perception and concern could potentially lead to legal requirements such as testing/publishing data on food items, tolerance levels in foods, enforceable standards in processed foods and packaging, animal/saturated fat limits for certain foods (e.g., meat products, school meals/milk), etc.

A specific food safety concern has to do with human health risks associated with consumption of fish. Based on the draft SFO and equations in TCEQ's current remediation program guidance which assume a fish ingestion rate of 0.010 kg/day (roughly two fish meals per month), the acceptable fish tissue TEQ (at 1E-05 risk) would be 0.07 ppt (ng/kg or pg/g). Recent data from a USEPA national lake fish tissue study indicates that perhaps close to 50% of predatory fish samples (e.g., bass, trout, perch) and about 95% of bottom-dweller fish samples (e.g., catfish, drum) would exceed this fish tissue concentration.⁹ Some percentage of predatory fish (perhaps around 10%) and bottom-dwelling fish (around 50%) would also exceed the upper end of USEPA acceptable risk range (1E-04). Such analyses could imply to the public that fish are unsafe to eat since calculated risk from the consumption of a relatively large percentage of fish would exceed regulatory acceptable levels, and could result in more fishing advisories and bans due to measured dioxins/furans and dioxin-like PCBs in fish tissue.

Another implication of the draft SFO (and RfD) pertains to environmental media concentrations (e.g., sediment, surface water) that are calculated to be protective of human health based on the uptake of contaminants into fish tissue and subsequent human ingestion. These may include:

- Sediment dioxin concentrations protective of the human ingestion of fish tissue for a remediation site;
- Surface water quality standards protective of the human ingestion of fish (e.g., the National Ambient Water Quality Criterion for dioxin based on fish uptake could decrease from 5.1E-09 to \approx 8E-10 μ g/L); or
- Both sediment and surface water concentrations protective of the human ingestion of fish (e.g., Total Maximum Daily Load (TMDL) projects).

Using the draft SFO (and RfD) would result in significantly decreased acceptable concentrations.

Acknowledgments

These comments represent the personal opinions of the presenters and are not official TCEQ comments.

References

1. United States Environmental Protection Agency. (2010); Draft EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments. National Center for Environmental Assessment; Office of Research and Development; USEPA. Washington, DC. EPA/600/R-10/038A.
2. United States Environmental Protection Agency. (2009); Draft Recommended Interim Preliminary Remediation Goals for Dioxin in Soil at CERCLA and RCRA Sites. Office of Superfund Remediation and Technology Innovation; USEPA. Washington, DC. OSWER 9200.3-56.
3. Agency for Toxic Substances and Disease Registry. (1998); Toxicological Profile for Chlorinated Dibenzop-dioxins (CDDs).
4. United States Environmental Protection Agency. (1998); Approach for Addressing Dioxin in Soil at CERCLA and RCRA sites. Memo from Timothy Fields, EPA Acting Administrator, to Regional Directors. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. OSWER Directive 9200.4-26.
5. United States Environmental Protection Agency. (2000); Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. National Center for Environmental Assessment; Office of Research and Development; USEPA. Washington, DC. EPA/600/P-00/001Bc.
6. Charnley G, Doull J. (2005); *Food Chem. Toxicol* 43:671-679.
7. Lorber M, Patterson D, Huwe J, Kahn H. (2009); In Press. *Chemosphere* doi:10.1016/j.chemosphere.2009.08.016
8. National Academy of Sciences. (2003); Dioxins and Dioxin-Like Compounds in the Food Supply, Strategies to Decrease Exposure. Committee on the Implications of Dioxin in the Food Supply; Food and Nutrition Board; Institute of Medicine; National Academy of Sciences, Washington, DC.
9. United States Environmental Protection Agency. (2009); The National Study of Chemical Residues in Lake Fish Tissue. Office of Water; Office of Science and Technology; Washington, DC. EPA/823/R-09/006.