Texas Commission on Environmental Quality (TCEQ) Comments to the Science Advisory Board (SAB) Dioxin Review Panel for the October 27-29, 2010 Public Meeting Washington, DC

REGULATORY IMPLICATIONS OF USEPA'S DRAFT ORAL SLOPE FACTOR AND REFERENCE DOSE FOR DIOXIN AND THE PARADOX OF USEPA'S SURFACE SOIL DRAFT INTERIM PRELIMINARY REMEDIATION GOAL TARGET RISK/HAZARD LEVELS FOR DIOXIN VERSUS DIOXIN RISK/HAZARD FROM TYPICAL DIETARY EXPOSURE AND BREAST MILK INTAKE

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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 and their expert panels (e.g., SAB) to give full, thoughtful, and careful consideration and evaluation to the scientific and common sense merits of comments and recommendations from other experts (e.g., academia, industry, public sector, National Academy of Sciences) on their chemical assessments.

Draft EPA's Reanalysis of Key Issues and Response to NAS Comments

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). 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 draft interim preliminary remediation goals (PRGs).[2] This implies a significantly greater carcinogenic potency than previously estimated. 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 draft interim PRGs.[2,3] *In the comments below, TCEQ highlights the potential implications of these more conservative draft SFo and RfD values in the context of regulatory health-protective environmental media (e.g., surface soil, drinking water) levels, background concentrations, and food safety (e.g., dietary intake, fish, dioxin intake from breast milk for nursing infants).*

Surface Soil PRGs

The draft SFo and RfD values have significant implications for surface soil PRGs. USEPA's draft 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 (≈ 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] The draft interim residential PRG (72 ppt) is already 14 times lower than the current value (1,000 ppt) and the draft interim commercial/industrial worker (outside) PRG (950 ppt) is 5-21 times lower than the current PRG range (5,000-20,000 ppt).[2]

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 (lower end) commercial/industrial). Based on these draft SFo

and RfD values, the current residential PRG would represent regulatory unacceptable risk (≈ 1.7E-03) and hazard (HQ ≈ 20). The low end of the current commercial/industrial PRG range (5,000 ppt) would also represent regulatory unacceptable risk (≈ 1.9E-03) and hazard (HQ ≈ 8). *This calls into question the health protectiveness of previous site evaluations and cleanups by federal and state agencies, and 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. In fact, an October 26, 2009 USEPA internal briefing document indicates that if PRGs decrease 10-100 fold, which is within the range of the proposed draft interim PRGs, reassessment would likely be required at 104 federal Superfund dioxin sites (80% of the 130 dioxin sites), and 337 PCB Superfund sites would also be affected.[10] That internal document also indicates significantly higher analytical costs ($700-1,000 per sample) and inadequate US disposal capacity for dioxin-contaminated soil.

Lack of Sufficient and Clear USEPA PRG Implementation Guidance

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 USEPA guidance, inconsistent implementation of any revised PRGs is likely to result at historically evaluated/remediated sites and sites currently in various stages of remediation activities.*

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 (≈ 1.3E-04). *Using the draft reanalysis SFo results in the MCL being associated with a risk (≈ 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, use of a relative source contribution (RSC) factor for MCL goal calculations in conjunction with the RfD (Category II and III contaminants) results in a more realistic estimate of what the dioxin MCL would have to be for an overall ingestion hazard of 1.* The RSC is the proportion of the RfD that can be safely apportioned to the ingestion of water versus other exposure routes. 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 (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 dietary intake data to support example 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 hazard 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 HQ 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 HQ of 1.6.[8] *These types of analyses may raise public concerns about the safety of the US 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 US 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 the USEPA-recommended fish ingestion rate of 0.0175 kg/day, the acceptable fish tissue TEQ at a 1E-05 risk would be 0.04 ppt (ng/kg or pg/g). Recent data from a USEPA national lake fish tissue study indicates that over 50% of predatory fish samples (e.g., bass, trout, perch) and well over 95% of bottom-dweller fish samples (e.g., catfish, drum) would exceed this fish tissue concentration.[9] Around 15% percentage of predatory fish and 65% of bottom-dwelling fish would exceed the fish tissue concentration (0.4 ppt) associated with 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 ≈ 8E-10 µg/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.

Paradox of USEPA's Surface Soil PRG Target Risk/Hazard Levels for Dioxin versus Dioxin Risk/Hazard from Typical Dietary Exposure and Breast Milk Intake

USEPA's draft interim PRGs correspond to a dioxin intake (hazard quotient of 1 at the draft RfD) that is significantly less than TCEQ dioxin intake estimates for most nursing infants. For

example, based on average breast milk fat content (37.4 g lipid/1,000 mL),[12] the relationship between blood lipid and breast milk lipid toxicity equivalency quotient (TEQ) and a median and 90th percentile dioxin TEQ lipid content (10.9 and 14.15 pg/g lipid) for US women of childbearing age,[13,14,15] estimated median and 90th percentile dioxin TEQ breast milk concentrations are 0.4-0.6 pg/L (4-6E-10 mg/L). Using an average 1st-year breast milk intake rate (110 mL/kg-day),[12] estimated dioxin TEQ intake for a 0-1 year old would be around 45-67 pg/kg-day, equivalent to a HQ range of 64-96 (intake range divided by the draft RfD of 0.7 pg/kg-day). These estimated levels of infant dioxin TEQ intake are 64-96 times the HQ used to calculate the draft interim PRGs (HQ of 1). If the draft RfD is a scientifically-defensible value for hazard assessment, it would be nonsensical at a remediation site with a limited number of adults and/or children for USEPA to allow a maximum dioxin HQ of 1 (corresponding to the draft interim PRGs) when estimated HQs for US infants being breastfed, a recommended practice, can be orders of magnitude higher and would be clearly unacceptable in the context of dioxin intake from contaminated soil at a federal Superfund site. *The bottom line is that the draft interim PRGs would drive cleanups at assumed dioxin TEQ intake levels orders of magnitude less than estimated dioxin TEQ intake for breastmilk-fed infants when breastfeeding is a recommended practice for the health of infants.*

Additionally, the draft interim PRGs are associated with risk and/or hazard levels significantly less than those associated with many estimates of dietary exposure for the US population. Dietary dioxin intake is associated with HQs above the regulatory acceptable level (HQ of 1) used to calculate the draft interim PRGs. Also, estimated risk due to typical dietary exposure (> 1E-04) exceeds the upper end of USEPA's acceptable risk range and significantly exceeds the level of risk protection USEPA indicates is afforded by the draft interim PRGs (≈ 1E-05).[2] See the *Food Safety* section above for more detailed information.

The draft interim PRGs being associated with risk and/or hazard levels significantly less than those associated with typical dietary exposure for the general population and exposure from breast milk for nursing infants is a paradox given that USEPA will compel action to protect human health based on PRGs and yet the US Food and Drug Administration has declared the US food supply to be safe and recommends breastfeeding when estimated dioxin intake from food and breast milk is significantly higher that that associated with the PRGs.[16] This is tantamount to the federal government stating in one breath that workers at a Superfund site having an assumed dioxin intake greater than the RfD of 0.7 pg/kg-day is unsafe and justifies costly action and in the next breath stating that an estimated dietary intake range of around the RfD up to 5 times the RfD for the US population[7,5] and orders of magnitude higher for breastmilk-fed infants is somehow safe. These disparate conclusions regarding safe dioxin intake at remediation sites versus much broader dietary/breast milk exposure represent a federal dioxin risk assessment conundrum which would only be exacerbated by further lowering the draft interim PRGs pursuant to the draft RfD or SFo. Compared to estimated risk and hazard from dietary intake for adults, children, and breastmilk-fed infants, the draft interim PRGs do not appear to make much sense in terms of the largest opportunity for public health risk reduction.

Final Thoughts

While significant implications themselves do not speak to the scientific defensibility of the draft dioxin SFo and RfD, they emphasize the paramount importance of deriving the most scientifically-defensible and biologically-relevant toxicity factors possible by following important National Academy of Sciences (NAS) recommendations such as the appropriateness of a nonlinear carcinogenic assessment. This recommendation was solicited from NAS through USEPA charge questions, and to follow it would have significant impact on these implications, as a nonlinear carcinogenic assessment for dioxin may result in a cancer-protective intake level (e.g., 1-100 pg/kg-day) that is 10-100,000 times higher than intakes which would be considered acceptable using the draft USEPA linear, low-dose SFo and the 1E-04 to 1E-06 risk range (0.001-0.1 pg/kg-day).[1,11]

TCEQ urges the distinguished members of the SAB to give thoughtful scientific and common-sense consideration to these and other comments as the significant implications outlined in these comments demonstrate the scientific defensibility of the final SFo and RfD to be critical. Agreement with the ultimate final SFo and RfD values necessarily implies agreement with their ability to reasonably predict risk and hazard and agreement with the unavoidable conclusions, good or bad, regarding public exposure and health that will naturally follow.

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