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Workshop Report

The importance of problem formulations in risk assessment: A case study involving dioxin-contaminated soil

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ABSTRACT

The need to remediate contaminated soils is typically accomplished by applying standard risk assessment methods followed by risk management to select remedial options. These human health risk assessments (HHRAs) have been largely conducted in a formulaic manner that relies heavily on standard deterministic exposure, toxicity assumptions and fixed mathematical formulas. The HHRA approach, with its traditional formulaic practice, does not take advantage of problem formulation in the same manner as is done in ecological risk assessment, and historically, has generally failed to emphasize incorporation of site-specific information. In response to these challenges, the National Academy of Sciences recently made several recommendations regarding the conduct of HHRAs, one of which was to begin all such assessments with problem formulation. These recommendations have since been extended to dose response assessment. In accordance with these recommendations, a group of experts presented and discussed findings that highlighted the importance and impact of including problem formulation when determining the need for remediation of dioxin contamination in soils, focusing in particular on exposure assessment is described.

1. Introduction

Problem formulation, first developed for ecological risk assessment (e.g., US EPA, 1998a) and subsequently adopted for cumulative human health risk assessments (HHRAs) (e.g., US EPA, 2003a), has become a systematic planning step for identifying the major factors to be considered in a particular assessment. Especially important, is the issue of problem formulation around relevant exposure pathways and how one assesses their actual impact on risk (NAS, 2009).

A robust problem formulation outcome will greatly assist assessors, managers, and interested parties in identifying the most logical risk-management options for protecting human health (NAS, 2009). Problem formulation has become the stated[1] foundation for risk assessment and is applicable to other aspects of risk assessment, such as dose–response assessment. On a more tactical level, the key question is how problem formulation augments and improves the current "cookie-cutter" manner in which risk assessments have historically been conducted in the past (*i.e.*, plugging in default deterministic exposure assumptions into standard algorithms and calculating a risk number that contains substantial uncertainty).

The most widely used approach for assessing potential human health risks associated with contaminated soils is to use deterministic values (*i.e.*, single point estimates). Site-specific data for each of these input parameters would presumably impart less uncertainty in the risk characterization but site-specific data are oftentimes unavailable, impossible to obtain, too costly, or take too long to obtain. For some soil contamination concerns, when there is the potential for food to be grown or raised on contaminated soil, it is the food exposure pathway that is of interest. Probabilistic methods could be applied and would allow one to develop information on variability and uncertainty in exposure and risk estimates. Sometimes, as in the case of lead-contaminated soil, toxicokinetic models can be employed (US EPA, 2002a) or biomonitoring data can be obtained. To this point, a number of studies

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[1] Many risk assessment scientists would argue that problem formulation has always been an integral part of risk assessment, but few would question the value of increased emphasis on this aspect of the overall effort to assess risk.

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have looked at the connection between blood level and exposure to contaminated soil. For dioxin-contaminated soil, a generalization taken from such biomonitoring studies is that soil exposure does not constitute a completed exposure pathway, since blood levels of residentially exposed populations do not differ from controls after adjustment for body mass index, age, and sex. In contrast, food pathways affected by dioxin contamination, can slightly increase blood levels over blood levels attributable to background exposures (Garabrant et al., 2009a; Tohyama et al., 2011; Kimbrough et al., 2009; Pirard et al., 2005; Karouna-Renier et al., 2007; Dahlgren et al., 2007; Aberg et al., 2010; Riss et al., 1990).

To explore problem formulation in the context of soil exposure and risk assessment, a scientific session, focusing specifically on dioxin-contaminated soil as a case-study, was held at the 37th Annual Summer Meeting of the Toxicology Forum in Aspen, Colorado, July 10–14, 2011. The soil session presentations covered five related problem formulation issues. Specifically:

- Options for theoretical risk assessment approaches available for characterizing exposure and risks from dioxin-contaminated soil.
- Use of toxicokinetics to improve soil exposure estimates and risk assessment.
- Regulatory approach to characterizing and mitigating exposure and risk at dioxin contaminated sites.
- Assessment of exposures to dioxins in residents, including children, living near a dioxin-contaminated soil site based on biomonitoring.
- Role of dioxin contamination in soil and house dust in relation to the body burden of dioxins which adopts the use of biomonitoring data as an important additional component to standard risk assessment approaches.

This paper proposes an exposure assessment, problem formulation framework to go beyond the simple deterministic methods currently employed in assessing contaminated soil exposures and risk. The full report from this meeting is available at http://www.tera.org.

2. The range of theoretical risk assessment approaches for characterizing exposure and risks from dioxin-contaminated soil

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Soil Screening Values (SSVs), e.g., Preliminary Remediation Goals (PRGs), Risk-Based Concentrations (RBCs), Soil Screening Levels (SSLs), and Direct Contact Criteria (DCC), are essentially risk assessment calculations performed in reverse (*i.e.*, solving for soil concentration based on a specified degree of risk or hazard). For example, US EPA defines PRGs as "*. . .concentration goals for individual chemicals for specific medium and land use combinations*" (US EPA, 1991a). SSVs for 2,3,7,8-tetrachlorodibenzo(p)dioxin (dioxin or TCDD) toxic equivalents (TEQs) have been calculated by multiple regulatory agencies over the past three decades (Table 1). Most recently, US EPA (2009a) has proposed interim PRG values that are orders of magnitude lower than the values previously adopted by the agency.

Based on the NAS (2009) recommendations for advancing risk assessment that placed emphasis on problem formulation, the impact of including a problem formulation step in the soil screening methodology for polychlorinated dibenzo(p)dioxins/furans (PCDD/Fs) has been examined and an example SSV derivation that incorporates site-specific information and Monte Carlo methods is summarized.

Table 1
Soil screening values for TEQs in soil.

Year	Agency	Value (ppb)	Note*	Refs.
1984	USDA	1	Reasonable action level based on risk and analytical limitations	Kimbrough et al. (1984)
1998	US EPA	1	Residential exposure (CR = 2.5×10^{-4})	US EPA (1998b)
		5–20	Worker exposure (CR = 1.3–5.2×10^{-4})	
1999	ATSDR	1	Action level	De Rosa et al. (1999)
2009	US EPA	0.0037	Residential exposure (CR = 1×10^{-6})	US EPA (2009a,b)
		0.017–0.037	Worker exposure (CR = 1×10^{-6})	
		0.072	Residential exposure (HI = 1)	
		0.95–2	Worker exposure (HI = 1)	

CR – cancer risk; HI – hazard index.

Briefly, key aspects for PCDD/Fs problem formulation for HHRA are as follows:

- *Temporal trends* – PCDD/Fs are ubiquitous in the environment and in human tissues. However, available data on emissions, environmental and food levels, and human body burdens of dioxins in the general population indicate a several-fold reduction in exposures and body burdens in the general population over the three decades from 1970 to 2000 (Hays and Aylward, 2003).
- *Exposure pathways* – The default assumption in soil screening assessments is that direct contact with soil reflects an important exposure pathway. However, for background exposures to PCDD/Fs in the U.S., dietary pathways (meat, fish, dairy, etc.) contribute greater than 90% of total exposure, while exposures to PCDD/Fs in soil represent a minor pathway (along with water ingestion, inhalation of air, and vegetable fat intake in "other" pathways) (Lorber et al., 2009).
- *Dose measures* – The default approach for soil screening risk assessment is to assess exposures and toxicity in terms of external dose (e.g., mg/kg-day). However, persistent chemicals such as PCDD/Fs are best assessed using an internal dose measure such as tissue or body burden, which reflects both past and recent exposures.
- *Populations at risk* – By default, early-life exposures (*i.e.*, typically ages 0–6 years for child resident, 0–30 years for a child/adult resident) serve as the focus of soil screening assessments. However, based upon the mode of action for cancer endpoints (*i.e.*, tumor promotion), late-life exposures are expected to be more important, in which case a more appropriate 30-years period would correspond to ages 45–75 years. For reproductive/developmental endpoints, a more appropriate 30-year period to assess would be reproductive years (*i.e.*, 20–50 years of age).

Three distributions (nonlinear cancer, linear cancer, noncancer of SSVs) were calculated using Monte Carlo methods (Fig. 1). As shown in this figure, the US EPA's proposed and previously used SSVs for PCDD/Fs fall below the first percentile for all three distributions, suggesting that the 1 ppb [or 1000 parts per trillion (ppt)] value is health protective.

Using current SSV methodology, along with site-specific data for Midland, MI, best available scientific information and tools, a SSV of 1 ppb for PCDD/Fs remains protective of human health for cancer and noncancer endpoints (Kirman et al., 2011). However, without including a proper problem formulation step, risk management decisions based upon soil screening methodology may