Relative Bioavailability of Dioxin/Furan Mixtures in Soils[1] (Ingestion Pathway)

Issue

Ecology is considering establishing a default gastrointestinal absorption fraction[2] for dioxin/furan mixtures equal to 0.4 that would be used when establishing soil cleanup levels. Is this default value consistent with current scientific information?

Background

The Model Toxics Control Act (MTCA) Cleanup Regulation provides methods to establish residential (unrestricted land use) and industrial (restricted land use) soil cleanup levels (WAC 173-340-740 through -745). The gastrointestinal (GI) absorption fraction is one of several factors considered when establishing soil cleanup levels. The MTCA rule establishes a default GI absorption fraction of 1.0. This value is based on the assumption that soil-bound dioxin and furans are absorbed to the same extent as dioxin and furans administered in the studies used to establish the cancer slope factor and/or reference dose.

The Department received a wide range of comments on the June 2006 proposed rule amendments. Several organizations stated that the default GI absorption fraction was overly-conservative and inconsistent with available studies on the absorption of soil-bound dioxins and furans. They recommended that Ecology revise the rule to incorporate a default value that is less than 1.0.

MTCA Rulemaking Options

Ecology has considered three options for resolving this issue:

1. Continue to Use the Current Default Value: Under this option, Ecology would maintain the current MTCA rule language that establishes a GI absorption fraction of 1.0 that is applicable to dioxin/furan mixtures. Method B soil cleanup levels would continue to be established at a soil concentration of 6.7 ppt. Industrial soil cleanup levels would continue be established at a soil concentration of 875 ppt.
2. Revise the Rule to establish a new default GI Absorption Fraction for Dioxin/Furan Mixtures: Under this option, Ecology would revise the MTCA Cleanup Regulation to specify a default GI absorption fraction of 0.4 for mixtures of dioxins/furans (the current default value of 1.0 would continue to be applied to other hazardous substances). Method B soil cleanup levels

[1] Ecology's review of this issue is focused on the procedures for establishing soil cleanup levels based on soil ingestion/dermal contact and cancer risk. Ecology does not believe that similar adjustments are necessary for other exposure pathways (e.g. food/water ingestion and inhalation). At this point, Ecology is uncertain whether a similar adjustment would be appropriate when evaluating non-cancer risks resulting from soil ingestion and dermal contact. In making that determination, Ecology would consider the study design and results of the toxicological/epidemiological studies used to establish a reference dose.

[2] WAC 173-340-200 defines "Gastrointestinal absorption fraction" as "... the fraction of a substance transported across the gastrointestinal lining and taken up systematically into the body...".

would be established at a soil concentration of 17 ppt. Industrial soil cleanup levels would be established at a soil concentration of 2,200 ppt.

3. Revise the Rule to establish congener-specific default GI Absorption Fractions: Under this option, Ecology would revise the MTCA Cleanup Regulation to specify a default GI absorption fraction of 0.40 for Tetra-, Penta- and Hexa- congeners and 0.1 for Hepta- and Octa- congeners. Method B soil cleanup levels would be established at a soil concentration of 17 ppt. Industrial soil cleanup levels would continue be established at a soil concentration of 2,200 ppt. The TEQ concentrations (adjusted for relative absorption) used to evaluate compliance with the cleanup levels would be similar to the TEQ concentrations calculated using Option #2 because the higher chlorinated congeners are minor contributors to the overall TEQ value.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-740 and -745 to establish a default GI absorption factor of 0.4 that would be used when establishing soil cleanup levels for dioxin/furan mixtures (Option #2). Ecology's rationale for selecting this option includes the following:

- Scientific Basis: The National Academy of Sciences (2003) reviewed the factors that influence bioavailability of hazardous substances in different media and the methods for estimating the amount of administered material that is actually absorbed into the body. The NAS Committee concluded that adjustments to absorption factors for the soil-related exposure pathways (soil ingestion and soil dermal contact) may be reasonable because soil and soil organic matter may influence the absorption of these types of lipophilic mixtures. The NAS Committee estimated that the bioavailability of dioxin-like compounds from the soil reservoir varies from 20 to 40 percent.
- Scientific Studies: Ecology is proposing to use a GI absorption fraction[3] of 0.4 for dioxin/furan mixtures because (1) the cancer slope factor for TCDD was calculated using the administered dose levels; (2) EPA estimates that the test animals absorbed 80% of the administered dose; and (3) available studies indicate that soil-bound dioxins and furans are not absorb to the same degree as dioxin and furans in food, water and air. The proposed default value (0.4) was calculated by dividing 30% absorption (value used to characterize absorption of soil-bound dioxins and furans) by 80% (value used to characterize absorption of dioxin/furan in the toxicological study used to calculate the cancer slope factor). The basis for those values is summarized below:
    - Results from Human and Animal Studies Using Testing Regimes Similar to Those That Form the Bases For Toxicological Parameters: The current cancer slope factor for TCDD (156,000 mg/kg/day-1) is based on the result from a rat study. For these types of studies and exposure pathways, EPA has generally assumed that the absorbed dose is approximately 80 % of an administered dose. (ATSDR, 1998; EPA, 2000; EPA, 2003). For example, EPA used an 80% absorption value when calculating body burdens as part of the dioxin reassessment. EPA decided this was an appropriate value to use when performing these types of calculations because the majority of exposure occurs via the

[3] The GI absorption fraction represents the ratio of the degree of absorption of soil-bound dioxin/furan compounds relative to the degree of absorption of dioxin/furan compounds in the study(s) used to calculate the cancer slope factor. This is conceptually similar to the "absorption correction factor" used by EPA to estimate exposure and cancer risks associated with dioxin exposure resulting from soil ingestion and dermal.

food pathway. In their review of the EPA dioxin reassessment, the National Research Council (2006) noted that the values for bioavailability used to determine steady-state body burdens are uncertain with values ranging from 50% to 88%. The NRC panel concluded that "Overall the value proposed and used by EPA to calculate the body burden in humans at steady state (80% absorption) appear reasonable, although the data are limited." A table summarizing some of the gastrointestinal absorption efficiencies is presented at the end of this paper.

- Results from Studies Evaluating Absorption of Soil-Bound Dioxins and Furans: Ecology used a 30% absorption value to characterize the degree of absorption of soil-bound dioxins and furans. This value was used by EPA in the dioxin reassessment report and falls in the middle of the range of available studies (See table below). The proposed value is also consistent with a recent review by Paustenbach et. al. (2006). They reviewed available studies and concluded that the absorption of soil-bound dioxin and furans could be characterized as a lognormal distribution (range of 0.5 to 63%) with a mean value of 35% absorption representing the bioavailability from soils with a lower organic content.

Soil Bioavailability

Chemical	Species	Vehicle	% Absorption	References
2, 3, 7, 8-TCDD	Fisher 344 rats	50% Ethanol	~ 37 [%age of dose in liver]	Poiger & Schlatter, 1980
2, 3, 7, 8-TCDD	Fisher 344 rats	Aqueous suspension of activated carbon	≤ 0.07	Poiger & Schlatter, 1980
2, 3, 7, 8-TCDD	Fisher 344 rats	Aqueous suspension of soil	~ 16-24%	Poiger & Schlatter, 1980
2, 3, 7, 8-TCDD	Fisher 344 rats	Emulphor/95% ethanol/distilled Water (1:1:3)	~ 24%	Diliberto et al., 1996
2, 3, 7, 8-TCDD	Guinea pigs/rats;comp of soil w/ corn oil	Contam. Soils from Times Beach/Minker Stout	~ 50% less from corn oil	Lucier et al, 1986; McConnell et al., 1984
2, 3, 7, 8-TCDD	Rats	Contam. soils	Soil from Neward: 21%; NJ site 0.5%	Umbreit et al., 1986
2, 3, 7, 8-TCDD	Rats	Cont. soil/Times Beach	~ 43%	Shu et al., 1988

- EPA Guidance: Ecology believes the proposed approach is consistent with current EPA guidance. In the absence of chemical-specific absorption efficiencies, EPA recommends 80% absorption efficiency for volatile organic chemicals, 50% absorption efficiency for semi-volatile organic chemicals, and 20% for inorganic chemicals (EPA, 1998).

- EPA Dioxin Reassessment: Ecology believes that proposed approach is consistent with the approach used by EPA to estimate the cancer risks associated with soil ingestion and dermal contact. Specifically, EPA estimated that 30% of dioxin in ingested soil is absorbed and used an absorption correction factor of 0.375 (~0.4, 30% / 80%) in the risk characterization portion of the reassessment. (EPA, 2003) The absorption correction factor is the ratio of the degree of absorption of soil-bound dioxin/dibenzofuran compound relative to the degree of absorption of dioxin/dibenzofuran compounds in the study(s) used to determine the cancer slope factor.
- Expert Committee Reviews: The National Academy of Sciences (2003) reviewed the factors that influence bioavailability of hazardous substances in different media and the methods for estimating the amount of administered material that is actually absorbed into the body. The NAS Committee concluded that adjustments to absorption factors for the soil-related exposure pathways (soil ingestion and soil dermal contact) may be reasonable because soil and soil organic matter may influence the absorption of these types of lipophilic mixtures. The NAS Committee stated that bioavailability of dioxin-like compound from the soil reservoir varies from 20 to 40 percent. In their review of the EPA dioxin reassessment, the National Research Council (2006) noted a range of absorption efficiencies (50% to >80%) with 80% being a reasonable estimate for gastrointestinal absorption efficiency.

  The recently published Van den Berg paper (2006) noted that the relative effect potency determined for individual CDD and CDF congeners to help determine their toxicity equivalency factors are largely based on oral intake studies, often through the diet. Furthermore, the authors noted that toxicological studies using environmental abiotic matrices "are almost nonesistent." The lack of information on environmental matrix-specific bioavailability of CDDs/CDFs contributes to a high degree of uncertainty for risk assessment. The authors recommended that for the application of the WHO TEFs for calculating the total toxicity equivalent concentration (TEQ) in abiotic environmental matrices that the reduced bioavailability of mixtures of CDDs/CDFs be taken into consideration.

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Gastrointestinal Absorption of TCDD and Related Compound						
Chemical	**Species (Sex)**	**Dose**		**Vehicle**	**% Administered Dose Absorbed (Mean, Range)**	**Reference**
		µmol/kg	**µg/kg**			
Dioxins						
2, 3, 7, 8-TCDD	Sprague-Dawley rat (M)	0.16	50	Acetone:corn oil (1:7)	70	Piper et al., 1973
2, 3, 7, 8-TCDD	Sprague-Dawley rat (M/F)	0.003	1.0	Acetone:corn oil (1:25)	84, 66-93	Rose et al., 1976
2, 3, 7, 8-TCDD	Hartley guinea pig (F)	0.005	1.45	Acetone:corn oil (1:45)	50	Nolan et al., 1979
2, 3, 7, 8-TCDD	Golden Syrian hamster (M)	2.0	650	Olive oil	74	Olson et al., 1980
2, 3, 7, 8-TCDD	Human (M)	0.000003	0.001	Corn oil	87	Poiger and Schlatter, 1986
1, 2, 3, 7, 8-PeCDD	Sprague-Dawley rat (M/F)	0.03	9.2	Corn oil	19-71	Wacker et al., 1986
OCDD	Fischer 344 rat (M)	0.11 1.1 1.1 11	50 500 500 5000	o-dichlorobenzene:Emulphor (1:1) o-dichlorobenzene:corn oil (1:1) Corn oil suspension Corn oil suspension	12 15 2 5	Birnbaum and Couture, 1988
Furans						
2, 3, 7, 8-TCDF	Fischer 344 rat (M)	0.1 1.0	30.6 306	Emulphor:ethanol (1:1)	90 90	Birnbaum et al., 1980
2, 3, 7, 8-TCDF	Hartley guinea pig (F)	0.02	6	Emulphor:ethanol:water (1:1:8)	90	Decad et al., 1981
2, 3, 4, 7, 8-PeCDF	Fischer 344 rat (M)	0.1 0.5 1.0	34 170 340	Corn oil	~70 ~70 ~70	Brewster and Birnbaum, 1987
Adapted from Table 1-1, NAS Review Draft of EPA Dioxin Reassessment, Part II, Chapter one, Disposition and Pharmacokinetics (NAS, 2003).						