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26 September 2003
Reference: 1922.05

Ms. Kimberly Tisa
TSCA Coordinator
US EPA Region 1
1 Congress Street, Suite 1100
Boston, MA 02114-1527



Subject: Response to EPA Comment - 10 September 2003 Letter
Revised Application for Risk-Based Disposal Approval
Former Raytheon Facility
430 Boston Post Road
Wayland, Massachusetts


Dear Ms. Tisa:

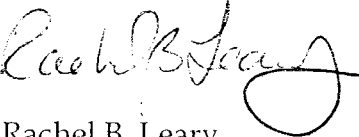
On behalf of Raytheon Company (Raytheon), Environmental Resources Management (ERM) is pleased to provide you with the attached response to comment regarding to the Risk-Based Disposal Application dated 23 December 2003. The purpose of this response is to address the comment presented in your 10 August 2003 letter to Mr. John Drobinski of ERM.

ENTRIX has prepared a response to the additional comment on the ecological assessment, in the attached document entitled "Responses to EPA Comments Dated September 15, 2003, Former Raytheon Facility, Wayland Massachusetts."

If you have any additional questions, comments or concerns, please contact either John Drobinski at (617) 646-7850 or Edwin Madera of Raytheon at (978) 440-1813.

Sincerely,


John C. Drobinski, P.G., LSP
Principal


Rachel B. Leary
Project Manager

enclosures: Response to Comments

ECOLOGICAL REVIEW OF APPENDIX C: ECOLOGICAL RISK CHARACTERIZATION UPDATE - DIOXINS IN THE RISK-BASED DISPOSAL APPROVAL APPLICATION FOR WETLANDS ADJACENT TO FORMER RAYTHEON FACILITY (5/7/03)

General Comment #10: Equation 4-1, Page 4-4. Since dioxins are known to bioaccumulate in the food web, a bioaccumulation factor may need to be added to equation 4-1, particularly for top-level predators such as the red-tailed hawk. If a bioaccumulation factor is not added to the equation, bioaccumulation should at least be addressed qualitatively in the text.

Original Response – A bioaccumulation factor does not need to be added to the equation since a bioaccumulation factor was used to estimate the concentrations in food web items already. A discussion of this has been added to the text as suggested.

Clarification to General Comment #10 (see e-mail on 9/09/03 from Ann Cyrus to Laura Casey) - My original comment was with regard to bioaccumulation of small mammals to predators rather than soil to plants or soil to small mammals. A couple sentences that discuss qualitatively the potential for bioaccumulation of dioxins from small mammals to predators (e.g. red-tailed hawk) would be sufficient to address this issue.

Revised Response – The reviewer correctly points out that potential bioaccumulation to top-level predators is an important consideration and we are in agreement. To address the issue of potential risk to a high-level predator such as a red-tailed hawk, one can either conduct a dietary exposure model and compare the results to a dietary-based toxicity reference value (TRV) or conduct a bioaccumulation model to estimate concentrations of COPECs in eggs and compare the results to an egg-based TRV or both. These two approaches are sometimes evaluated as independent lines of evidence. However, in this case, since both approaches rely on the same initial step of modeling from soil to small mammals, they are not independent lines of evidence. Moreover, bioaccumulation of COPECs into red-tailed hawk eggs was not modeled as part of this ERC because of the relatively great uncertainty of such an approach at this site (e.g., site use is considerably less than 100%, there is modeling uncertainty from soil to small mammals and additional modeling uncertainty from small mammals to red-tailed hawk eggs). Therefore, while there is a potential for bioaccumulation of dioxins to predators, the dietary model was selected as the most appropriate measurement endpoint to characterize potential risk. A discussion of this has been added to the text as suggested.

Bioaccumulation models are often fraught with uncertainty because bioavailability depends upon highly variable site-specific considerations such as soil type, pH, moisture, clay content, organic carbon, cation exchange capacity, and receptor-specific considerations such as uptake mechanisms. In particular, available data demonstrate very limited assimilation and accumulation of other COPECs into wetland vegetation and small mammals at this site. Thus, for this ERC, a very simple model was chosen in which a soil to biota accumulation factor was applied. Exposure to dioxins from inhalation and dermal contact were considered negligible for the purposes of this Stage II ERC for wildlife (*e.g.*, muskrats, mallards, red-tailed hawk, *etc.*). Direct ingestion of soil or sediment was considered for certain wildlife since wildlife may experience significant contaminant exposure through direct ingestion of soil or sediment.

To address the issue of potential risk to a high-level predator such as a red-tailed hawk, one can either conduct a dietary exposure model and compare the results to a dietary-based toxicity reference value (TRV) *or* conduct a bioaccumulation model to estimate concentrations of COPECs in eggs and compare the results to an egg-based TRV *or* both. These two approaches are sometimes evaluated as independent lines of evidence. However, in this case, since both approaches rely on the same initial step of modeling from soil to small mammals, they are not independent lines of evidence. Moreover, bioaccumulation of COPECs into red-tailed hawk eggs was not modeled as part of this ERC because of the relatively great uncertainty of such an approach at this site (*e.g.*, site use is considerably less than 100%, there is modeling uncertainty from soil to small mammals and additional modeling uncertainty from small mammals to red-tailed hawk eggs). Therefore, while there is a potential for bioaccumulation of dioxins to predators, the dietary model was selected as the most appropriate measurement endpoint to characterize potential risk.

Estimates of daily contaminant exposure experienced by individual receptor species were calculated using a modification of the generalized exposure model presented by Sample and Suter (1994). The generalized exposure model is depicted (Eq. 4-1):

$$ADD_{pot} = \frac{[(IR_{prey} \times C_{diet}) + (IR_{soil} \times C_{soil}) + (IR_{sed} \times C_{sed}) + (IR_{wat} \times C_{wat})] \times SUF}{BW} \quad \text{Equation 4-1}$$

Where:

ADD_{pot} = potential average daily dose (*e.g.*, mg/kg-d)

IR_{diet} = Amount of prey or vegetation ingested (kg/d)

C_{diet} = Concentration of chemical in prey or vegetation (mg/kg)

IR_{soil} = Amount of soil ingested (kg/d)

C_{soil} = Concentration of chemical in soil (mg/kg)

IR_{sed} = Amount of sediment ingested (kg/d)

C_{sed} = Concentration of chemical in sediment (mg/kg)

IR_{wat} = Amount of water ingested (L/d)

C_{wat} = Concentration of chemical in water (mg/L)

SUF = Site use factor (unitless) (foraging area/site area)

BW = Body weight (kg)

An area use factor was included in the exposure model for some species since some wildlife species were assumed to forage only a portion of the time at the site. For example, based on professional judgment, white-tailed deer would not likely use the site more than 20% of the time because there is not a resident population on the site and their foraging range is much larger than the size of the site. Likewise, red-tailed hawks would not be expected to forage entirely at the site because their foraging range is much larger than the site and they would not be expected to forage at this site during flooded conditions. Therefore an area use factor of 50% was assumed for the red-tailed hawks based on professional judgment.

In addition, for most COPECs in the Phase II report, a fractional absorption value was included in the exposure model to account for the fraction of the oral dose that is absorbed through the gastrointestinal tract. However, for the purposes of this ERC, this value was assumed to be 1.0, even though published studies indicate that it is likely less than 50% from soil, since contact with soil reduces the bioavailability of TCDD. Furthermore, the relatively great concentrations of organic carbon in this wetland soil would tend to decrease the bioavailability and fractional absorption values relative to many other kinds of soil. Finally, a bioaccumulation factor was not included in Equation 4-1 because the concentrations of TEQs for dietary items (e.g., plant and small mammal) were estimated using bioaccumulation factors already.

4.4 Effects assessment

4.4.1 Purpose

The purpose of this section is to summarize available toxicological data and establish toxicity reference values and benchmarks for dioxins in this ERC. It is beyond the scope of this ERC to provide a comprehensive review of dioxin toxicity data. In this section, only summary data relating to plants, birds and mammals are discussed. The limitations of these toxicity data are discussed. The information in this section will be utilized with data from the exposure assessment to conduct the risk characterization.

4.4.2 Toxicity Reference Values (TRVs)

The toxicity reference value (TRV) is the concentration of a chemical in water, food, or the tissues of a receptor that will not cause toxicity to receptors of concern. Ideally, TRVs are derived from chronic toxicity studies in which an ecologically relevant endpoint was assessed in the species of concern, or a closely related species. While TRVs can be expressed or defined as no observable adverse effect levels (NOAELs), the use of lowest observable adverse effect levels (LOAELs) is generally preferred for a Stage II ERC or baseline ERA as NOAELs by definition incorporate greater uncertainty than LOAELs (Sample et al., 1996). Alternatively, TRVs can be expressed as the geometric mean of the NOAEL and LOAEL to provide a conservative estimate of a threshold of effect (Tillitt *et al.*, 1996). For this ERC, values for dioxins are presented for both NOAELs and LOAELs for comparison. MCP guidance recommends selection of the lowest available LOAEL and the highest available NOAEL.

Sources of toxicological data that were reviewed to develop TRVs included primary peer-reviewed scientific literature, pertinent reviews (e.g., journal review articles, USFWS Contaminant Hazard Reviews, *etc.*), Draft Ecological Soil Screening Level Guidance (USEPA, 2000a), Oak Ridge National Laboratory report on benchmarks for wildlife, miscellaneous USEPA reports, and other relevant sources of information. In this ERC, endpoints such as effects on reproductive and developmental toxicity and reduced survival were evaluated and used whenever possible.

It is, therefore, essential to perform a critical evaluation of the applicability of the toxicological data to the site-specific receptors of concern and exposure pathways. TRVs derived in the same species are not available for the majority of wildlife receptors and, therefore, it is necessary to derive TRVs using

toxicological data for surrogate species in combination with uncertainty factors. Uncertainty concerning interpretation of the toxicity test information among different species, different laboratory endpoints, and differences in experimental design, age of test animals, duration of test, *etc.*, are addressed by applying uncertainty factors (UFs) to the toxicology data to derive the final TRV. For this ERC, general recommendations of Sample *et al.*, (1996), USEPA (1995), and USEPA Region 8 (Henningesen and Hoff, 1997) were considered for the derivation and use of uncertainty factors. The uncertainty factor approach used in this ERC is identical to what was used in the Phase II report (ENTRIX, 2001).

4.4.3 Aquatic Organisms - Summary

A screening-level type value was selected for protection of aquatic organisms based on estimated concentrations in surface water. The value that was selected (10 pg/L) is based on USEPA Region 4 Ecological Risk Assessment Bulletins - Supplement to RAGS (USEPA, 2003). This value is also consistent with protection of the most sensitive aquatic organisms (e.g., rainbow trout; USEPA, 1993).

4.4.4 Mammalian and Avian Wildlife Dietary Toxicity Reference Values (TRVs) - Summary

Dietary TRVs were determined by evaluating high quality toxicological studies. Whenever possible, to minimize the use of uncertainty factors, an attempt was made to focus on studies that evaluated test species that were as similar as possible to the avian and mammalian wildlife receptors of concern in this ERC. In addition, an attempt was made to identify studies that evaluated sensitive ecologically relevant endpoints (primarily effects on reproduction), similar exposure routes (primarily dietary), exposure duration (chronic and during sensitive life stages), and forms of chemicals as those expected at this site. Dietary TRVs for mammalian and avian receptors of concern at this site are summarized in **Table 4-1**. A description of the toxicological studies that were selected as most appropriate for the derivation of TRVs are discussed in this section, including derivation of TRVs from the original toxicological studies with the use of uncertainty factors.

Table 4-1. Summary of Mammalian and Avian Toxicity Reference Values (TRVs) for dioxins¹.

Receptor	TRV (ng/kg/d)	
	NOAEL	LOAEL
Mammals		
White-tailed deer	0.2	2
Meadow vole	1	10
Muskrat	1	10
Birds		
Mallard	2.8	28
Red-tailed hawk	2.8	28

¹Refer to **Table 4-2** and **Table 4-3** for calculations of species-specific TRVs from generic mammalian TRVs.

4.4.5 Toxicity Reference Values (TRVs) and Effect Benchmarks for Dioxins

4.4.5.1 Plants

Soil and tissue residue based phytotoxicity effect levels have not been developed for dioxins. Since the mechanism of toxic action for dioxins is primarily through the binding and activation of the intracellular Ah receptor, which is absent in plants, no adverse effects would be expected.

4.4.5.2 Mammals

A three-generation reproduction study in which Sprague-Dawley rats were exposed by diet to three doses of TCDD plus a control (0, 0.001, 0.01, 0.1 µg/kg/d) through a critical reproductive lifestage was conducted (Murray et al 1979). Conversion of concentrations in diet to a daily dose were not necessary because this information was provided in the study. No adverse effects were observed at a dose level of 0.001 µg/kg/d. At 0.01 µg/kg/d, adverse effects were observed including a decrease in fertility, litter size, gestation survival, postnatal survival, and postnatal body weight. Since the study considered dietary exposure during reproduction, the 0.01 and 0.001 µg/kg/d doses were considered to be chronic LOAELs and NOAELs, respectively. TRV derivations for mammalian receptors of concern are shown in **Table 4-2**.

Table 4-2. TRV derivations for mammalian receptors of concern.

Receptor of concern Study Chemical Reference	White-tailed deer		Meadow Vole		Muskrat	
	TCDD Murray et al., 1979		TCDD Murray et al., 1979		TCDD Murray et al., 1979	
	NOAEL	LOAEL	NOAEL	LOAEL	NOAEL	LOAEL
Reference TRV (ng/kg-d)	1	10	1	10	1	10
Test Species UCF	5 (rat)	5 (rat)	1 (rat)	1 (rat)	1 (rat)	1 (rat)
Duration UCF	1 (chronic)	1 (chronic)	1 (chronic)	1 (chronic)	1 (chronic)	1 (chronic)
Endpoint UCF	1 (reprod.)	1 (reprod.)	1 (reprod.)	1 (reprod.)	1 (reprod.)	1 (reprod.)
Total UCF	5	5	1	1	1	1
Final TRV (ng/kg-d)	0.2	2.0	1.0	10.0	1.0	10.0

Final TRV = Reference TRV / Total UCF

NA = not available

4.4.5.3 Birds

A reproduction study was conducted in which penned pheasants were exposed by i.p. injection to three doses of TCDD plus a vehicle control (0, 0.01, 0.1, 1.0 µg/kg/week) once per week for 70 d through a critical reproductive lifestage (Nosek et al 1992). Conversion of concentrations in diet to a daily dose are based on a body weight of 1 kg (as calculated in USEPA's Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife, 1995). No adverse effects were observed at dose levels up to 0.1 µg/kg/week (or 14 ng/kg/d). At 1.0 µg/kg/week (or 140 ng/kg/d), adverse effects were observed including a decrease in egg production and embryo mortality. Since the study considered exposure during reproduction, the 140 ng/kg/d and 14 ng/kg/d doses were considered to be the chronic LOAEL and NOAEL, respectively. TRV derivations for avian receptors of concern are shown in **Table 4-3**.