

UPDATED ATSDR POLICY GUIDELINE FOR DIOXINS  
AND DIOXIN-LIKE COMPOUNDS IN SOIL

Response to Peer Review Comments- October 2004

1. Charge #1

**Deletion of the 1ppb Action Level as the criteria for taking specific public actions, and retained only as a reference to the Superfund Dioxin Cleanup policy criteria.**

**Reviewer #1 Comments:** This change is justified and highly important. The document has a clear and concise statement explaining why this change is needed. It is inconsistent with the approach taken by ATSDR for evaluation of other chemicals. The Action Level is often misinterpreted as an ATSDR cleanup level. The Action Level is often misinterpreted as a trigger for public health actions that should be performed when the Screening Level is exceeded. In fact, when two numbers are available in policy, then the higher number is almost always the number used in any form of decision-making. This is invidious, and the deletion of the Action Level will restore the functionality of the Screening Level and unambiguously identify 1 ppb as an EPA cleanup criterion.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #2 Comments:** Comments: Very disconcerting. In -- this could/should trigger review of dozens of clean-ups requiring re-analysis of thousands of pieces of soil sampling data. This also leaves the incorrect impression that sites cleaned previously are still risky. Based on a number of published studies of -- and -- there has been almost no relationship found between exposure with documented body burdens and any health effects (see comments in body of draft document)

**ATSDR Response:** The objective of the deletion of the Action Level criterion was not to convey the message that past cleanups for dioxins in soil, based on 1 ppb, are no longer considered to be protective of public health. The communication plan that will accompany this revised policy guideline will clarify this point.

**Reviewer #3 Comments:** In my opinion, this is the most significant and beneficial change to the dioxin/dioxin-like revised policy. The confusion caused by declaring 1 ppb soil dioxin as an "action level," and subsequent

misinterpretation as criteria for clean up or a public health hazard, warranted revision. Correlating a 1 ppb action level with a public health hazard is not based in the toxicological or epidemiological literature and is potentially damaging to the credibility of health assessments and consultations. Furthermore, site-specific characteristics such as soil type, access to contaminated soils, demographics of nearby populations, sufficiency of sampling and background levels should be accounted for in public health assessments or consultations.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #4 Comments:** ATSDR's screening values are much higher than the values the -- has set for **Soil Cleanup Target Levels (SCTLs)** for -- and other hazardous waste sites. -- SCTL for TEQ dioxins is **7 parts per trillion for residential land use, and 35 parts per trillion for industrial land use**. In addition, the -- calculates TEQs using 1/2 the detection levels for all nondetected congeners if any congeners are measured. As a result, there tends to be at least an order of magnitude of difference in the numbers that are of concern to -- regulators versus the screening values we as a cooperative-agreement state health department are asked to use. Unless ATSDR is able to convince EPA and -- regulators that ATSDR's toxicological interpretations for TEQ dioxins are correct and EPA's and -- are not, my guess is that ATSDR's MRLs and other screening values will continue to be ignored when these other entities have jurisdiction. It is also likely our recommendations with respect to public health will likewise be ignored. It is my opinion that our section's continued use of these screening values may cause a credibility problem with our health assessments, both with our sister environmental regulating agency and the public.

**ATSDR Response:** There is certainly a difference between ATSDR Screening Levels and a regulatory soil cleanup level. There is a wide range of values that various states use as criteria for determining the need for site cleanups. While the underlying calculations of the Florida DEP values have not been provided, it is likely that there is a statutory requirement that the cleanup level be based on a specified cancer risk level. The CREG values that ATSDR uses in screening residential soil contaminations are based on EPA cancer slope factors and calculation of the soil concentration that corresponds to  $10^{-6}$  cancer risk. Since EPA has not yet finalized the Dioxin Reassessment, there is not a recognized cancer slope factor for dioxins. As a result, ATSDR does not have a CREG comparison value for screening dioxins in soil. The ATSDR Soil Screening Level of 50 ppt is derived from the MRL value of 1 pg/kg/day total TEQ. The critical endpoint for the MRL is neurobehavioral effects of dioxins in monkeys. The objective of the revisions to the soil policy guideline is not to make ATSDR screening level match state regulatory levels, but rather to ensure that the approach is consistent for all other chemicals in specific environmental media.

The issue of how to address non-detections for dioxins will be addressed in the revised policy guideline. While use of ½ the detection limit is a common practice for calculating exposure point concentration, it can lead to estimations of TEQ levels that far exceed the concentrations for dioxins that are actually detected. Therefore, the revised guideline is proposing not to use the method of ½ DL substitution for non-detection in health assessments.

## 2. **Charge #2**

**Retention of the 0.05 ppb Screening Level, the MRL-based EMEG for dioxin TEQ in soil, to be consistent with the approach for evaluating chemical contaminants in health assessments.**

**Reviewer #1 Comments:** Retention of the Screening Level is also justified in the draft *Policy Guideline*. The derivation of the MRL for 2,3,7,8-TCDD is consistent with well-established risk assessment policies for non-cancer effects used by ATSDR, EPA and other agencies. The use of the WHO-98 TEFs to evaluate dioxin-like compounds is well accepted. ATSDR has been careful to note the TEFs that are based on calculations based on modeling and/or in vitro data in the TEF table. It is worthwhile to note that the EPA has calculated that 5 chemicals (2,3,7,8-TCDD, 1,2,3,7,8-PentaCDD, 1,2,3,6,7,8-HexaCDD, 2,3,4,7,8-PentaCDF and PCB126) account for 70-80% of the TEQ in the human body and in food. The TEFs for all of these chemicals are based on in vivo data. The exposure assumptions used to calculate the EMEG from the MRL are conservative as is appropriate for a screening number. Health assessors are instructed to modify these exposure factors (e.g. frequency of soil contact which might be lower in northern states, bioavailability which is dependent upon the characteristics of the contaminated soil) as appropriate. The discussion of cancer risk in relation to the EMEG could be expanded upon. The document uses the FDA cancer potency slope calculated from Kociba (1978) to observe that the calculated lifetime incremental cancer risk to exposures to soil at the EMEG would be in the neighborhood of 1E-6. The EPA acceptable risk range is 1E-6 to 1E-4. Potency slopes calculated from the Kociba (1978) study by EPA range from 156,000 [mg/kg/day]<sup>-1</sup> to 1,400,000 [mg/kg/day]<sup>-1</sup>. Using these slopes, the EMEG is in the risk range or within a factor of 2 of the higher end of the range. Thus, the EMEG appears to be protective for cancer using very conservative assumptions (lifetime exposure to 100 mg/day of soil). The highest cancer potency estimates are based on comparative body burden estimates. In this context, the statement in the document noting that comparative body burden estimates are frequently used as a surrogate for human exposure, and calling for additional research on low dose effects in human populations is very important.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #2 Comments:** OK. Just don't drop the 1ppb "action" level. Dr. Renate Kimboroughs statement as quoted on p.5 has been incorrectly used by EPA and others as a simple trigger level to 1. begin clean up and 2. to consider a site "clean." Neither is correct. I was present at the meeting when Morris Kay (EPA VII administrator) first decided to use this "action" level as a clean-up level even after Dr. Kimborough explained her thoughts to him. He made the decision as a practical way to get to work and end the studying. I believe 1ppb is quite protective for the vast majority of persons possibly exposed through soil ingestion or inhalation. See my comment to change #1, above.

**ATSDR Response:** The proposed revisions to the policy guideline do not categorically question the protectiveness of the 1 ppb soil concentration. The objective of the revisions is primarily to make the method consistent with how all other chemicals are assessed and to address the confusion about prescriptively linking specific public health actions with levels of soil contamination.

**Reviewer #3 Comments:** Retaining the screening level of 0.05 ppb is adequate as a health protective approach and for consistency purposes for evaluating other contaminants in soil. The EMEG bioavailability factor of 100% is conservative, especially considering that bioavailability of 2,3,7,8-TCDD in corn oil was about 87% in a human volunteer (Poiger & Schlatter, 1986), that higher chlorinated congeners will be less bioavailable compared with lesser chlorinated congeners and that ingestion of dioxins via contaminated soil will further reduce bioavailability when compared to other vehicles of exposure. Furthermore, the MRL is based on results in monkeys with a sufficient uncertainty factor (90).

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #4 Comments:**

It is confusing that on page 3 paragraph 2 that the new policy states that animal studies have demonstrated cancer effects, yet ATSDR does not have a CREG for TEQ dioxins. It is my understanding that the Sveso studies have also shown associations with human cancer, especially breast cancer and other cancers for women.

**ATSDR Response:** In spite of the fact that TCDD is a known human

carcinogen, EPA does not support a cancer slope factor for dioxins. Therefore, ATSDR does not cite a CREG value in our comparison tables. However, the toxicological evaluation in ATSDR health assessments should certainly describe the known associations of dioxin exposure with human cancer. Background information on the carcinogenic hazards of dioxins is summarized in the Toxicological Profile for Chlorinated Dibenzo-p-Dioxins.

### 3. **Charge #3**

**Indirect exposure pathways, such as local dietary sources, could make a significant contribution to the overall dioxin exposure. As a result the guideline emphasizes the need for conducting a complete exposure pathways analysis for dioxins and dioxin-like compounds in site-specific health assessments.**

**Reviewer #1 Comments:** This is clearly true and important for health assessors to consider. Dioxin-like chemicals concentrate in lipids and accumulate in the food chain. The document correctly notes that exposures from garden produce are therefore less likely to be as intense as exposures from animal products. Because food exposures may be more important than direct exposures to contaminated soil, exposures via the food chain need to be evaluated even when the EMEG is not exceeded. In fact, when dioxin contamination occurs in water bodies or sediments, it is possible that there could be an important exposure from eating contaminated fish even in the absence of any soil contamination.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #2 Comments:** OK and important IF those exposure pathways are completed for newly discovered or un-remediated sites. It is not beneficial for remediated sites that used the 1ppb action level as a clean-up level. But see comments in body of document re: analytical limits.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #3 Comments:** The inclusion of dietary exposure as a result of site-specific dioxin contamination is necessary to adequately characterize a completed exposure pathway. The draft updated policy guideline mentions fish, eggs and dairy products that are known media for the accumulation of dioxin and dioxin-like compounds and correctly identifies plant uptake as insignificant. Future land-uses

may be an integral component to consider in assessing the food chain uptake of dioxins via contaminated soils.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #4 Comments:** No specific comment provided.

**Additional questions and comments:**

- 1. Does the revised document serve as effective guidance for assessing potential public health hazards associated with dioxin contamination in soil?**

**Reviewer #1 comment:**

Yes (  ) No (  ) Unsure (  )

Why?: The document clearly identifies and discusses the scientific and policy issues related to the evaluation of dioxin-like compounds in the environment. It states the major issues of interest for health assessment, and justifies the proposed policy. The revision removes the action level of 1 ppb TEQ, thereby removing a major source of confusion. Soil concentrations above the EMEG need to be evaluated and appropriate public health actions taken as a result of health assessment.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #2 comment:**

Yes (  ) No (  ) Unsure (  )

Why?: Not unless health assessors use common sense (see comment below).

**ATSDR Response:** ATSDR would anticipate that health assessors would always use common sense in evaluating environmental health hazards.

**Reviewer #3 comment:**

Yes (  ) No (  ) Unsure (  )

Why?: This revised document provides straight-forward guidance that serves to

1) reduce confusion about the 1 ppb “action level,” 2) maintain a consistent screening approach with other soil contaminants, 3) to better characterize complete exposure pathways and 4) to offer the health assessor greater flexibility in the consideration of site-specific factors to determine the risk posed by dioxin/dioxin-like compounds in soil.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #4 comment:** Comment and response addressed under Change #1 section.

**2. Do you have any other comments regarding the revised dioxin and dioxin-like policy guideline?**

**Reviewer #1 comment:** ATSDR is to be commended for a forceful, well-reasoned discussion and proposed policy to protect public health.

**ATSDR Response:** The comment supports the principal revisions in the policy guideline.

**Reviewer #2 comment:** Seems to me the problem isn't guidance, but as stated on p.1 last sentence, the “interpretation” of that guidance. Maybe persons using the guidance are not qualified to interpret it. Or, perhaps they are using their interpretation to further agendas not based on risk, but based on personal bias or ease of deferring to public pressure to rationalize “why bad things happen to good people.”

**ATSDR Response:** Comment noted.

**Reviewer #3 comment:** Perhaps a statement on background levels of dioxin/dioxin-furans as a result of natural processes such as forest fires would be useful. The confusion over background soil levels has been raised by several agencies in this region.

**ATSDR Response:** This comment raises a significant issue with regards to putting the discussion of site-specific contamination into context. Obviously, an important question is what level of dioxins what be expected if a site-specific source was not present. The workgroup agrees that the contribution of background sources should be noted as a general statement. We would refer the health assessor to the Toxicological Profile

for specific literature citations for evaluating site-specific conditions.

**Reviewer #4 comment:**

The new policy does not discuss TEQ dioxins' role as endocrine disrupters (at very low levels), nor the added effects of these chemicals with other known endocrine disruptors (PCBs and flame retardants) which are also environmentally persistent in soil, air, and food chains. The combined effects of endocrine disruptors are thought to adversely affect sex ratios (less males are born) and may have other long reaching effects that are not presently well understood nor extensively studied. Along these pharmacokinetic lines, the federal government's study of Agent Orange applicator (Operation Ranch Hand) has shown that dioxin exposure appears to have a causal role in adult-onset diabetes.

**ATSDR Response:** The Toxicological Profile is intended to provide a comprehensive review of the toxicological literature on dioxins. Information regarding specific modes of action of dioxins is summarized in that document. The revised policy guideline is not intended to represent a further review of that information. However, the critical endpoints that were considered in the derivation of the Soil Screening Level are presented in the guideline. An additional statement with regards to the hormonal impact of dioxin exposure has been included in response to this comment.