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Report of the Peer Review Panel on the Risk Assessment for the Hazardous Waste Combustion Proposed Rule:

Response to Comments

July 1999

Office of Solid Waste
U.S Environmental Protection Agency
Washington, D.C. 20460

Preface

On April 19, 1996, the U.S. Environmental Protection Agency (EPA) proposed a rule to revise standards for hazardous waste combustors, specifically hazardous waste-burning incinerators, cement kilns, and lightweight aggregate kilns (61 FR17358). EPA conducted a risk assessment in support of the proposed rule. The risk assessment was described in the February 20, 1996 report, "Risk Assessment Support to the Development of Technical Standards for Emissions from Combustion Units Burning Hazardous Wastes: Background Information Document" prepared by Research Triangle Institute for EPA.

In accordance with EPA's peer review policy, EPA determined that the risk assessment for the proposed rule should be subject to a formal peer review. Consequently, the risk assessment was peer reviewed by an external panel comprised of three independent reviewers. The peer reviewers were not chosen by EPA. Instead, the peer reviewers were chosen by a third party using qualification criteria that were developed by EPA. The qualification criteria included general knowledge and experience in risk assessment as well as specific knowledge of particular subject areas thought to be important for the review. Individuals were sought that were recognized experts in their field. EPA prepared a charge that directed the peer reviewers to consider and comment upon a specific set of topics. However, the peer reviewers were not limited in the range of topics upon which they could choose to comment.

The peer review panel that was constituted consisted of the following three individuals:

Dr. Elizabeth Anderson
Sciences International, Inc.
Alexandria, Virginia

Dr. Venkat Rao
Science Applications International Corporation
Frederick, Maryland

Dr. Jim Wilson
Resources for the Future
Washington, D.C.

The purpose of this document is to give EPA's response to the peer review panel's comments and to describe how EPA addressed the panel's comments in the risk assessment for the final rule. The document follows the following format. The text of each of the peer review panel's comments is given. This is followed by EPA's response. The comments and responses are organized by the

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topical areas identified in the peer review charge. Appendix A gives the charge to the peer reviewers. Appendix B gives the complete text of the peer review panel's report.

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List of Acronyms

Ah	aryl hydrocarbon
BSAF	biota-sediment accumulation factor
DDT	dichlorodiphenyltrichloroethane
EPA	U.S. Environmental Protection Agency
GIS	geographic information system
HWC	hazardous waste combustor
MACT	maximum achievable control technology
PCB	polychlorinated biphenyls
PM	particulate matter
TCDD	tetrachlorodibenzo(p)dioxin
TEF	toxic equivalence factor
TEQ	toxic equivalents

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Response to Comments

A. Case Study Approach

Comment: The bounding risk estimates for approximating a hypothetical upperbound risk must be deleted. The bounding estimate adopted by the Agency to approximate a hypothetical upperbound risk violates the case-study objective of minimizing the number of generic, default, worst-case assumptions incorporated into the risk estimate. This approach is particularly troubling because the public places the greatest emphasis on the highest risk evaluated. If the Agency's concern is that the case-study approach is not representative of risk associated with the "worst offender" facility in a source category, then the Agency should continue to evaluate facilities to determine actual site risk instead of adopting a hypothetical bounding approach.

Response: *The purpose of the bounding estimates was to identify a level of risk that is unlikely to be exceeded at any actual facility. The bounding estimate was derived from the high end estimate by assuming the location of exposure was the same as the location where the highest modeled contaminant deposition was predicted to occur. EPA believes that such a scenario is plausible and, therefore, the bounding estimates are useful in determining a "not higher than" level of risk. In contrast, a worst case estimate is made by setting all or nearly all important model parameters to high end values. Such a scenario may very well be implausible and is likely to give risks that are well above the highest risk that would be experienced by anyone in the exposed population. Worst case estimates are generally not particularly useful for estimating a "not higher than" level of risk because the estimates are likely to be much higher than anything that could be hypothesized to occur in the real world.*

The revised risk assessment does not include bounding estimates. As recommended by the peer review panel, rather than making bounding estimates, EPA increased the number of facilities analyzed. In selecting facilities for analysis, EPA chose a sample size large enough to ensure at least a 90 percent probability that a facility in the upper 10 percent of the risk distribution would be sampled.

Comment: The nature and extent of divergence of a case-study approach from a conventional approach is marginal and its overall impact on risk numbers may be described, at best, as minimal. By recognizing the importance of case studies as the basis for EPA risk assessment, the Agency has embarked on a new course to steer away from the tendency of relying on worst-case assumptions. However, certain regulatory limitations pose restrictions on the nature and extent of adoption of case-study specific data and a review from that perspective indicates that there is not much deviation from the conventional risk assessment.

Response: *Risk assessments conducted for rulemaking purposes oftentimes do not utilize site-specific data. This is particularly true where the rulemaking is national in scope and there are a large number of affected entities. For example, a "model facility" may be used to represent a particular type of facility or category of sources. Generic or national level data may be used in the analysis and various assumptions may be made in the course of estimating exposures and risks.*

For the revised risk assessment, EPA used site-specific data for estimating mass emissions and for modeling air dispersion and deposition. EPA also used site-specific data for modeling runoff to surface waters. The number and location of individuals in the exposed population were determined from U.S. census data. Unlike the risk assessment for the proposed rule in which local officials were contacted to locate farms and determine the farm commodities produced, information on farms for the revised risk assessment was derived from county level Census of Agriculture data. This approach was necessitated by restrictions placed on information collection by U.S. government agencies from non-Federal entities. Exposure scenarios were constructed to represent various segments of the exposed populations (e.g., dairy farmers) using exposure factors derived from EPA's Exposure Factors Handbook. The exposure factors generally reflect national estimates and so may misrepresent actual exposures in a given locality. Data available to EPA generally do not permit a site-specific assessment of dietary intake, activity patterns, or mobility of the local population.

Comment: The panel recommended that the potential for over- or under-estimation of risk as deduced through individual case studies could be adjusted through a case mix and in that way derive more defensible national standards. It was not clear if such an effort was made in the selection of 11 case studies. Although it is evident that the case studies have a good mix of HWC facility category and geographic location, it was unclear how the more important region-to-region difference in exposure and human activity pattern is reflected in these selected studies.

Response: *For the revised risk assessment, EPA increased the number of facilities analyzed from 11 to 76. EPA used a stratified random sampling approach to select facilities for analysis in order to ensure that they would be representative of the facilities covered by the rule. However, EPA was not able to incorporate regional differences in exposure and activity patterns due to a lack of data to adequately characterize such differences, particularly for more highly exposed populations such as individuals that consume home-produced foods or recreationally-caught*

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fish. Instead, national level data were used for estimating exposure factors such as food intake rates and time of residence, as well as the incidence of such activities as home gardening. The uncertainty introduced by using national level data may be substantial for a given locale but is expected to have a smaller impact on the national distribution of risks.

Comment: As to the usefulness of using a case-study approach in developing/evaluating protectiveness of national emission standards, the risk panel felt that uncertainties will linger as long as the debate on microcosm as a true and total representation of the macrocosm is decided one way or the other .

Response: *For the revised risk assessment, a number of steps were taken to ensure that the analysis would be representative of the exposed population. Stratified random sampling was used to select facilities for analysis. Census data were used to determine the number and location of individuals exposed. Individual and population risks were weighted using facility sampling weights (as derived from sampling probabilities) and the size of the exposed population. The sampling design and application of census data should provide considerable assurance that the risk assessment gives an adequate representation of risks at the national level.*

B. Exposure Scenarios

Comment: Although the exposures scenarios were individually realistic, they tend to give a false picture of the amount of exposure expected because they include no information by which one can judge the likelihood that any particular scenario will be realized. In addition, the uncertainty introduced by failing to indicate the likelihood of each scenario or the number of people likely to be exposed through each scenario was not addressed explicitly.

Response: *For the revised risk assessment, the analysis was structured such that risks could be estimated at specific percentiles of the risk distribution. Risks were estimated at the 50^{th}, 90^{th}, 95^{th}, and 99^{th} percentiles. The underlying risk distribution reflects a number of different sources of variability, including differences in facility emissions and other site characteristics, differences in the number and location of exposed individuals, and, for certain risk driving pathways, differences in exposure factors between individuals. However, for certain receptor populations, such as recreational anglers, it was necessary to make certain assumptions about the location of exposure which introduces significant uncertainty in the risk estimates for a given percentile. For example, recreational anglers were assumed to be exposed through consumption of fish obtained from nearby bodies of water. To the extent that fishing activity occurs at other locations that may be less impacted by HWC emissions, the risks may be overstated at a given percentile. In this instance, the distribution more properly*

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reflects risks to anglers that fish primarily at local bodies of water. Such individuals may represent a relatively small percentage of recreational anglers.

Comment: The risk assessment document does not provide a clear overview of the approach adopted in the exposure assessment and its associated limitations in the use of case-study specific exposure data, and its uncertainties with the use of default exposure assumptions.

Response: *For the revised risk assessment, a discussion is included that gives an overview of the analytic framework used for the assessment. The discussion addresses such issues as the selection of sample facilities, the use of geo-referenced data such as census and other data, the approach for characterizing exposure, and the risk descriptors used in the assessment. As explained in the background document, exposure factors were selected from studies on populations that most resemble the populations of interest in the risk assessment. This includes dietary intakes for individuals who consume home-produced foods or recreationally-caught fish and individuals engaged in activities such as subsistence fishing and subsistence farming, as well as mobility factors (e.g, time of residence) for farm and non-farm households. However, it was not possible to obtain site-specific exposure data for use in the analysis. As indicated by the peer reviewers, the lack of such data introduces uncertainty in the risk assessment.*

Comment: The risk assessment document is unclear about the basis for the selection of exposure pathways and exposed groups and selection of land-use considerations. In addition, exposure scenarios for a highly sensitive sub-population and location in the vicinity of a case-study facility study should be accurately identified.

Response: *Exposure pathways for the revised risk assessment were chosen based on the information available for the site and the exposed population. U.S Census data were used to determine the number and location of farm and non-farm households. All individuals were assumed to be exposed via direct inhalation and incidental ingestion of soil. Individuals were also assumed to be exposed via drinking water if EPA had information that surface water was used for drinking water at a given site. Census of Agriculture data were used to determine the types of farms present at a given site. Choice of dietary pathways depended on the type of farm. For example, households that operate dairy farms were assumed to be exposed via consumption of home-produced milk. Beef farmers and their families were assumed to be exposed via consumption of home-produced beef. However, it was not possible using Census of Agriculture data to identify farms that produce more than one agricultural commodity and, therefore, could have exposures from consumption of more than one agricultural product, such as beef and pork. Subsistence farming was the only exposure scenario for which more than one dietary pathway was considered. Subsistence farms were assumed to*

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subsist entirely on home-produced foods, including meat, milk, fish, poultry, produce, and eggs. Because EPA had no information on the locations of subsistence farms, it was assumed that subsistence farms could be located anywhere in the vicinity of an HWC facility. Recreational anglers were assumed to be exposed via consumption of recreationally-caught freshwater fish. Bodies of water were chosen for analysis based in part on the likelihood of their being used for recreational purposes, including fishing, as indicated by the presence of geographic features such as roads, parking lots, and boat ramps. A body of water used for recreational angling was assumed to also be used for subsistence fishing. EPA recognizes that assumptions regarding the locations of subsistence activities creates considerable uncertainty in the risk results for these receptors. However, EPA believes it is important to consider the potential risk to individuals that may be engaged in subsistence activities.

C. Toxicity Equivalence

Comment: Application of TEQ in the risk assessment is an oversimplification of the exposure to chemical mixtures like dioxins with varying toxic potentials which act through similar mechanisms. Unlike exposures to individual chemicals on a one-at-time basis, "real world" exposure to chemical mixtures can be expected to alter considerably in exposures involving mixtures of dioxin congeners.

Response: The concept of toxicity equivalence between compounds having similar chemical structures and a common mechanism of action is one that has long been used by EPA and the scientific community for assessing risks from chlorinated dioxins and furans. While the TEQ approach is a simplification, the scientific community has recognized its utility for assessing risks from this class of chemical compounds. The approach uses toxic equivalence factors (TEFs) that relate the toxicity of individual chlorinated dioxin and furan congeners to that of 2,3,7,8-TCDD, the most studied compound of the class. The TEFs are derived from experimental data across a variety of toxicological endpoints that are mediated by binding to the Ah receptor. Although interactions between congeners such as competitive binding or other interactions may produce responses that differ from the simple additivity implicit in the TEQ approach, studies with mixtures at environmentally relevant levels have shown an additive response. While application of the TEFs and estimation of TEQs are subject to uncertainty, the TEQ approach remains the most feasible approach for assessing risks from this class of compounds.

Comment: The guidelines in the HWC Emissions Database (Volume II) to adopt detection limits for various congeners, when in most cases none will be emitted, may have an adverse impact on the final risk outcome for dioxin, particularly for the indirect exposure pathways.

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Response: *For the revised risk assessment, emissions of congeners that are below the limit of detection are assumed to be present at ½ the detection limit. This represents a middle course that avoids the conservatism that could be introduced by assuming congeners are present at their full detection limit yet accounts for the likelihood that the congeners are, in fact, present but at levels below the detection limit. Although the issue of compounds being present at levels below the limit of detection contributes to uncertainty, the uncertainty is insufficient to have a material effect on the findings and conclusions of the risk assessment which are driven by emissions of congeners that are present at levels well above the limit of detection.*

Comment: Use of the TEQ approach generally yields higher risk estimates for the more abundant and less toxic congeners of dioxins. However, a much more important problem is the gross error introduced by adopting TEQ as a true indicator of toxic hazard for exposures to dioxin mixtures. The risk assessment must address uncertainties associated with the use of TEQ approach, which it has stated explicitly (p. 157) will not be addressed.

Response: *The revised risk assessment includes a discussion of the uncertainties associated with the toxicity equivalence approach for assessing risks from chlorinated dioxins and furans. The analysis indicates that the primary risks are associated with the tetra, penta, and hexa-chlorinated furans. These congeners have toxicity equivalence factors that are within a factor of 10 relative to 2,3,7,8-TCDD.*

D. Atmospheric Deposition

Comment: The theoretical assumptions of the EPA model may yield estimates greater than actual values in most cases. For example, deposition rate may be in error because of the assumption that little or no TCDD, etc., deposits on the relatively large mineral particles (fly ash) in the gas stream, when it is known that such condensation occurs.

Response: *Measurement of stack gas emissions do account for any reduction in gas phase concentrations of TCDD and other dioxins and furans due to condensation on flyash and collection in the air pollution control device upstream of the point of sampling. Once the gases are emitted to the ambient atmosphere, re-partitioning between the vapor and particle phases is modeled by assuming equilibrium with ambient background levels of particulate matter (PM) at ambient temperatures. Therefore, the emission measurements and deposition models used in the HWC risk assessment do account for removal of TCDD on flyash and condensation on ambient particulate matter.*

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Comment: The greatest weakness in the Agency's theoretical and empirical approaches to modeling airborne emission is the lack of field data from representative cross-section locations.

Response: *The objective of the HWC risk assessment is to characterize the risks associated with HWC stack emissions. In order to be able to accomplish this, it was necessary to use models to relate HWC stack emissions to contaminant levels in various environmental compartments. Although field data are useful for model validation purposes, field data alone would not allow this objective to be accomplished. Macro level model validation efforts have been performed using available data and the results have shown reasonable agreement. These efforts employed ambient air data to model food chain concentrations for comparison with measured levels in agricultural commodities. As additional data become available, model validation efforts may indicate a need to further refine the models.*

E. Surface Water Modeling

Comment: More data need to be collected to refine steady-state aquatic models for contaminant-specific physico-chemical parameters such as environmental fate, transfer coefficients and uptake rate, and ecological parameters such as lipid content, life-span, mobility, and food-intake to estimate bioaccumulation.

Response: *If detailed site-specific data were available, these data could be used with more refined aquatic models to model the complex processes that lead to bioaccumulation in the aquatic environment and to reduce the uncertainty of the modeling analysis. However, such data are not available for use in the HWC analysis, necessitating the continued use of simple empirical models.*

Comment: Steady-state factors tend to overestimate actual field concentrations because very few aquatic organisms live long enough to come to equilibrium. Moreover, these models are best suited for a worst-case estimate, not for an average-case scenario.

Response: *The steady state assumption can lead to an overestimation of surface water concentrations. This is mitigated to a degree by the use of simple empirical relationships derived from field data to model bioaccumulation in the aquatic environment. Also, the steady state assumption is a greater limitation in larger bodies of water that have a long turnover time, such as drainage lakes. For the revised risk assessment, a surface water model has been used for modeling mercury water concentrations that does not assume steady state, although a simple empirical relationship continues to be used for modeling bioaccumulation (of methyl mercury) in fish. This is consistent with the modeling approach used in EPA's Mercury Study Report to Congress.*

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Comment: Use of sediment-to-fish bioaccumulation factors (BSAF) to characterize dioxin fish-tissue residue levels for water-bodies at the vicinity of each case-study facility is flawed to the extent that BSAFs for environmentally persistent compounds are empirically derived. Therefore, BSAFs are more suitable to estimate fish tissue concentrations within the species and water-bodies used in the derivation of the BSAFs.

Response: *The extrapolation of biota-sediment accumulation factors (BSAFs) from one body of water to another is subject to considerable uncertainty. In recognition of this, the revised risk assessment employs BSAFs for dioxins and furans that were derived from a study of surface waters in Connecticut where contamination is ongoing rather than the Great Lakes, where levels of dioxins and furans in fish are primarily the result of past contamination. Data from the Connecticut study show that BSAFs are considerably higher than for the Great Lakes and are much closer to values that would be expected based on equilibrium considerations. Because fish and sediment concentrations are not available to derive site-specific BSAFs for the bodies of water modeled in the HWC analysis, the revised risk assessment uses the BSAFs derived from the Connecticut study.*

F. Terrestrial Food Chain Modeling

Comment: Additional data collection efforts are required to address the air-to-plan-to-animal pathway model and the problem of vapor plant transfer.

Response: *Current evidence suggests that the air-to-plant-to-animal pathway is the most important exposure pathway for the general population, although other pathways may be important for certain subpopulations (such as persons who consume relatively large amounts of fish). The Science Advisory Board, in its review of the draft dioxin reassessment exposure document ("Estimating Exposures to Dioxin-Like Compounds") agreed that this conclusion is a reasonable hypothesis but that, with the data currently available, there remains significant uncertainty. The revised risk assessment takes the same general approach as the draft dioxin reassessment for modeling the air-to-plant-to-animal pathway and reaches a similar conclusion. However, more experimental data are needed to verify this result and further validate the models.*

Comment: Lack of field data that corroborate models' predictions is a major uncertainty in terrestrial food-chain models.

Response: *As indicated in the response to the previous comment, further validation of the terrestrial food chain models would reduce the uncertainty in the results and conclusions of the analysis. The revised risk assessment discusses the uncertainties related to the terrestrial food chain analysis, including*

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vapor-particle partitioning, air-to-plant uptake in forage and silage, and the use of biotransfer factors to model uptake and bioaccumulation in farm animals.

G. Total Exposure and Risk

Comment: Background exposures to dioxins generally exceed site-specific exposure levels attributed in the report as due to dioxin emissions from the HWCF. Moreover, there is no evidence to support the claim that long-range transport of emissions from HWC facilities are solely responsible for elevated background levels. Therefore, the risk assessment should not be restricted to individual facilities. Instead, such an assessment must consider total exposure from all recognized dioxin sources. With greater emphasis on data collection efforts and use of data display techniques such as the Geographical Information Systems (GIS), a comprehensive assessment of public health risks from multiple sources should be possible.

Response: The revised risk assessment assessed the risks from exposures to emissions that occur within 20 kilometers of HWCs. No analysis was attempted of the impacts that might occur from transport and deposition beyond this distance. Although the highest risks to individuals are expected to occur within this distance, risks to the general population may have been underestimated. Of particular concern is the potential for long-range transport of dioxins/furans and mercury. Although models are available for analyzing long-range transport of mercury emissions, the models have significant uncertainty. Long-range transport of dioxins/furans and their subsequent fate in the environment are subject to even greater scientific uncertainty. The revised risk assessment identifies long-range transport and the inability to fully assess background exposures as significant limitations of the assessment. It was not possible to perform a comprehensive assessment of exposures to all anthropogenic emission sources within the context of the risk assessment for the hazardous waste combustion rule.

Comment: Differences between the background and source-specific sources for persistent chemicals require additional considerations for three reasons: (1) persistent contaminants such as dioxins, DDT, polychlorinated biphenyls (PCBs), and mercury biomagnify in the environment; (2) biomagnification enhances the risk of cumulative toxic effects; and (3) background exposures may be more critical in the average-exposure groups.

Response: As indicated in the response to the previous comment, it was not possible to fully assess background exposures within the context of the risk assessment for the hazardous waste combustion rule. The effect of biomagnification in increasing the potential for exposure and heightening the risk from both background sources

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and HWCs is recognized. For this reason, the revised risk assessment identifies this as a significant limitation of the assessment.

H. Mercury Emissions

Comment: The preamble makes no case that mercury emissions pose a threat to human health at any level.

Response: *The adverse effects of mercury on humans are well documented. Numerous instances of mercury poisoning have been reported in the scientific literature. Environmental exposures to methyl mercury are of particular concern due to the ability of methyl mercury to bioaccumulate in the aquatic food chain and for inorganic mercury to be converted to methyl mercury. Epidemiological studies have established a clear relationship between methyl mercury exposures and serious adverse health effects. EPA has established a reference dose for methyl mercury (below which adverse effects are not expected) based on the epidemiological evidence. The reference dose is further supported by studies in laboratory animals. The scientific community has recognized for some time the relationship between increases in anthropogenic emissions of mercury and levels in aquatic sediments in remote lakes. The connection is further strengthened by modeling studies. The Science Advisory Board, in its review of EPA's Mercury Study Report to Congress, concluded that there is a plausible link between current anthropogenic emissions and human exposure. Therefore, it seems reasonable to conclude that mercury emissions could pose a threat to human health if exposures are high enough.*

Comment: EPA does not provide sufficient supporting evidence to reasonably conclude that adverse health effects associated with ingestion of fish are currently occurring.

Response: *EPA conducted an extensive assessment of human exposures from fish consumption for the Mercury Study Report to Congress using national survey data on the amount and type of fish consumed and mercury concentrations in fish. That study concluded that persons consuming relatively large amounts of fish could be exposed at levels which exceed the methyl mercury reference dose and, therefore, could be at risk. However, it is not possible to conclude with certainty the number of individuals that are so exposed or that adverse health effects are occurring at current levels of exposure. Ongoing epidemiological studies of fish consuming populations are expected to provide additional information important to the assessing risks from the ingestion of fish in the U.S.*

Comment: EPA does not provide a rationale to support the actual mercury limits being proposed for HWC facilities.

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Response: *The mercury emission standards for the final rule are based on the MACT process. In this approach, the performance of the maximum available control technology is determined by first identifying the technology used by the best performing sources and then determining the performance that can be achieved by all sources using that technology. Therefore, the emission standards are technology-based. The risk assessment for the final rule was used to assess whether the MACT standards are generally protective of human health and the environment. For the final rule, the risk assessment included a quantitative analysis of exposures and risks from mercury. However, the risk assessment was not used to set the level of the standard.*

I. Treatment of Uncertainty

Comment: The discussion on uncertainties is of a descriptive nature. Although a standard "add-on" section on uncertainty analysis might make risk assessment reports appear more complete, it is of very little value if none of those uncertainties were addressed consistently in the study.

Response: *For the revised risk assessment, a much greater emphasis was placed on identifying and describing the sources of uncertainty. This included the identification and description of different types of uncertainty, including decision rule uncertainty, model uncertainty, and parameter uncertainty. Although a discussion of uncertainty is most relevant in the context of risk characterization, issues impacting on uncertainty are identified and discussed throughout the risk assessment background document. These include statistical sampling, source characterization, fate and transport, human exposure, and risk.*

Comment: No quantitative analysis was performed to provide an indication as to the sensitivity of the risk estimates to uncertainties such as parameter, model, decision-rule and variability.

Response: *It was not possible to perform a quantitative uncertainty analysis for the revised risk assessment (although uncertainty associated with statistical sampling error was quantified). However, considerable attention was given to the sources of uncertainty in characterizing the risks from HWCs. This included detailed discussions of uncertainties related to emissions and site characterization, fate and transport modeling, human exposure, dose-response, and risk characterization. Furthermore, a number of modifications were made in the revised risk assessment which serve to reduce uncertainty. These included the use of stratified random sampling and statistical estimation techniques, the use of census data for characterizing exposed populations, and the use of probabilistic methods for characterizing exposure parameter variability.*

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Comment: As to TEQ's predictive value in the risk assessment of dioxin mixtures, the report must address uncertainties introduced through the use of the applicable assumption.

Response: *A discussion of the uncertainty associated with the TEQ approach for assessing risks from chlorinated dioxins and furans was included in the revised risk assessment. The discussion addressed the uncertainty introduced by the assumption of additivity inherent in the TEQ approach and the potential for interactions between individual dioxin and furan congeners, as well as uncertainty in the value of the toxicity equivalence factors (TEFs) themselves, as derived from in vivo and in vitro studies.*

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Appendix A

Charge to Peer Reviewers

1. The Agency elected to use a case study approach for characterizing individual risk in order to minimize the number of assumptions that have to be made and, in particular, to avoid the tendency of relying on worst case assumptions. How successful has the Agency been in applying the case study approach and how useful is this approach in evaluating the protectiveness of national emission standards?

2. The Agency's risk analysis employed various exposure scenarios in order to evaluate the range of the potential risks to human health (e.g., subsistence farmer, recreational fisher, typical resident, etc.). How reasonable are the exposure scenarios that were used in the analysis and do they cover the appropriate range of exposures of interest?

3. The Agency used a toxicity equivalence approach for estimating the carcinogenic potency of mixtures of polychlorinated dibenzo-p-dioxins and dibenzofurans. Toxicity equivalence is based on the premise that a series of common biological steps are necessary for most if not all of the observed effects of dioxins, including cancer. How appropriate is the use of the toxicity equivalence approach for estimating cancer risks from dioxin-like compounds?

4. The Agency used a combination of theoretical and empirical approaches for addressing the various mechanisms and pathways by which airborne emissions are removed from the atmosphere and deposited at the surface. What are the strengths and weaknesses of the approaches used? In particular, how reasonable are the approaches for estimating the deposition of dioxins to surface waters and watershed soils?

5. The Agency has employed a simple steady-state surface water model along with empirically-derived bioaccumulation factors for assessing risks from the consumption of drinking water and fish. What are the strengths and weaknesses of this approach for evaluating surface water impacts? In particular, how appropriate is the use of the steady-state model and sediment-to-fish bioaccumulation factors for environmentally persistent compounds such as dioxins?

6. The Agency has employed a series of terrestrial food chain models that rely on empirical estimates of bioconcentration and biotransfer factors for assessing risks from the consumption of meat, eggs, milk, and other food products. What are the strengths and weaknesses of these models? In particular, how reasonable is the air-to-plant-to-animal pathway model for assessing risks from the consumption of food products derived from beef and dairy cattle? the soil-to-animal pathway for assessing risks from free-range produced chickens and eggs?

7. Based on limited data on dioxin levels in various food products, background exposures generally exceed the exposures the Agency has modeled for hazardous waste incinerators and hazardous waste-burning cement kilns. It is generally acknowledged that stack emissions can be transported over long distances and impact distant locations and that actual exposures at any one location may be due to emissions from numerous sources. With what level of confidence can the Agency be sure that it's risk estimates have accounted for the major pathways of exposure from hazardous waste burning sources? Are there alternative approaches the Agency should consider in assessing total exposure and risk from such sources?

8. The Agency attempted to assess exposures and potential risks arising from mercury emissions and subsequent deposition and runoff to surface waters and bioaccumulation in fish. However, an internal Agency review concluded that a quantitative exposure and risk analysis for mercury would be so uncertain as to be of little practical value. Key uncertainties identified in the review were the form of the mercury emitted, the extent of local deposition relative to long-range transport, and the degree to which methylation and uptake in fish occur. Additional uncertainty exists regarding the risk associated with any given level of exposure to methyl mercury among fish consumers. Given these considerations and concerns about mercury at current environmental levels, the Agency decided to develop a qualitative rationale for imposing controls on mercury emissions. How successful has the Agency been in describing the potential benefits of controlling mercury emissions, as outlined in Part Seven of the preamble to the proposed rule?

9. The Agency recognizes the need to enhance and expand the discussion of uncertainty in the current draft of the risk assessment background document. In revising the document, what uncertainties, limitations, and key assumptions is it important be highlighted and what types of supporting information are needed?

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Appendix B

Review and Comments of the EPA's Peer Review Panel on the Risk Assessment in Support of a Proposed Rule for Technical Standards for Emissions from Combustion Units Burning Hazardous Wastes

Overview

The U.S. Environmental Protection Agency (EPA) has conducted a public risk assessment (RA) to support development of technical standards for emissions from hazardous waste combustion facilities (HWCF). EPA adopted a case-study based, multiple pathway approach to define and develop direct and indirect exposures to hazardous air pollutants, particularly for persistent contaminants like dioxins.

As a part of the proposed rule development process, EPA initiated a peer review by an independent team of subject experts to review the proposed rule preamble, appendices, and technical background document on public risk assessment. Separate reviews were performed by peer-review panels on the engineering and economic analysis areas of the proposed rule.

The risk panel members were tasked with conducting a comprehensive and critical review of the risk assessment document prepared in support of the proposed rule on HWCF. The primary task for the risk panel was to address a set of questions pertaining to the scientific basis and technical merit of the RA approach adopted by the Agency, and other broader issues concerning the uncertainties and limitations of the existing risk assessment process.

The risk panel was initially asked to review and comment only on the documents submitted by the Agency and only to the extent required by the panel charges set forth in the EPA's work assignment. However, EPA suggested that the panel review and comment on other relevant RA-related issues of the proposed rule.

The risk panel was comprised of three members (in alphabetical order):

Dr. Elizabeth L. Anderson, Ph.D. (Sciences International, Inc.,Alexandria, VA)

Dr. Venkat Rao, Ph.D. (Science Applications International Corporation, Frederick, MD)

Dr. Jim Wilson, Ph.D. (Resources for the Future, Washington, D.C.)

Per the review process set forth in the Agency's work assignment, the risk panel conducted an independent review of the risk assessment documents and prepared review comments for the panel charge for discussion at a peer-review panel meeting. The risk panel meeting was held Thursday, May 23, 1996 at the EPA headquarters in Washington, D.C. At this meeting, risk panel members deliberated on individual reviewer's comments and sought a consensus view on the panel charge. EPA representatives were present at this meeting to provide clarification or additional information on the risk panel charge.

This summary report includes key points of the risk panel's discussion at the peer review meeting together with Attachments 1-3: Review and Comments of Dr. Elizabeth Anderson (Attachment 1); Review and Comments of Dr. Venkat Rao (Attachment 2); and Review and Comments of Dr. Jim Wilson (Attachment 3).

Summary of Key Points of Discussion

Regarding the use of the case-study approach for characterizing individual risks, the risk panel agreed that the Agency has been successful in applying this approach. However, certain issues were pointed out by the panel.

* The bounding risk estimates for approximating a hypothetical upperbound risk must be deleted. The bounding estimate adopted by the Agency to approximate a hypothetical upperbound risk violates the case-study objective of minimizing the number of generic, default, worst-case assumptions incorporated into the risk estimate. This approach is particularly troubling because the public places the greatest emphasis on the highest risk evaluated. If the Agency's concern is that the case-study approach is not representative of risk associated with the "worst offender" facility in a source category, then the Agency should continue to evaluate facilities to determine actual site risk instead of adopting a hypothetical bounding approach. (Anderson).

* The nature and extent of divergence of a case-study approach from a conventional approach is marginal and its overall impact on risk numbers may be described, at best, as minimal. By recognizing the importance of case studies as the basis for EPA RA, the Agency has embarked on a new course to steer away from the tendency of relying on worst-case assumptions. However, certain regulatory limitations pose restrictions on the nature and extent of adoption of case-study specific data and a review from that perspective indicates that there is not much deviation from the conventional RA (Rao).

* The panel recommended that the potential for over- or under-estimation of risk as deduced through individual case studies could be adjusted through a case mix and in that way derive more defensible national standards. It was not clear if such an effort was made in the selection of 11 case studies. Although it is evident that the case studies have a good mix of HWCF category and geographic location, it was unclear how the more important

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region-to-region difference in exposure and human activity pattern is reflected in these selected studies (Rao).

* As to the usefulness of using a case-study approach in developing/evaluating protectiveness of national emission standards, the risk panel felt that uncertainties will linger as long as the debate on microcosm as a true and total representation of the macrocosm is decided one way or the other (Rao and Wilson).

The peer review panel determined that the exposed scenarios used in the RA were reasonable and, in each case, incorporated the pathways needed to conservatively cover the potential range of exposures. However, notable observations were made by some panel members.

* Although the exposures scenarios were individually realistic, they tend to give a false picture of the amount of exposure expected because they include no information by which one can judge the likelihood that any particular scenario will be realized. In addition, the uncertainty introduced by failing to indicate the likelihood of each scenario or the number of people likely to be exposed through each scenario was not addressed explicitly (Wilson)

* The RA document does not provide a clear overview of the approach adopted in the exposure assessment and its associated limitations in the use of case-study specific exposure data, and its uncertainties with the use of default exposure assumptions (Rao and Wilson).

* The risk assessment document is unclear about the basis for the selection of exposure pathways and exposed groups and selection of land-use considerations. In addition, exposure scenarios for a highly sensitive sub-population and location in the vicinity of a case-study facility study should be accurately identified (Rao and Anderson).

The peer review panel unanimously agreed that the use of the toxicity equivalence (TEQ) approach for dioxin congeners differential toxicities of various congeners of Dibenzo-p-dioxins and Furans (dioxins) requires additional consideration.

* Application of TEQ in the RA is an oversimplification of the exposure to chemical mixtures like dioxins with varying toxic potentials which act through similar mechanisms. Unlike exposures to individual chemicals on a one-at-time basis, "real world" exposure to chemical mixtures can be expected to alter considerably in exposures involving mixtures of dioxin congeners (Rao).

* The guidelines in the HWC Emissions Database (Volume II) to adopt detection limits for various congeners, when in most cases none will be emitted, may have an adverse impact on the final risk outcome for dioxin, particularly for the indirect exposure pathways (Anderson).

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* Use of the TEQ approach generally yields higher risk estimates for the more abundant and less toxic congeners of dioxins. However, a much more important problem is the gross error introduced by adopting TEQ as a true indicator of toxic hazard for exposures to dioxin mixtures. The RA must address uncertainties associated with the use of TEQ approach, which it has stated explicitly (p. 157) will not be addressed (Wilson).

With regards to the strengths and weaknesses of the approaches used for airborne emission, panel members identified lack of reliable data, uncertainties in the model estimates and model assumptions as important problems.

* The theoretical assumptions of the EPA model may yield estimates greater than actual values in most cases. For example, deposition rate may be in error because of the assumption that little or no TCDD, etc., deposits on the relatively large mineral particles (fly ash) in the gas stream, when it is known that such condensation occurs (Wilson).

* The greatest weakness in the Agency's theoretical and empirical approaches to modeling airborne emission is the lack of field data from representative cross-section locations (Anderson).

With regards to use of a simple, steady-state surface water model and bioaccumulation factors, the panel agreed that depending upon the type of steady-state aquatic model used in the study, the results could vary by several orders of magnitude. The panel members agreed that steady-state models tend to overestimate the nature and extent of risk.

* More data need to be collected to refine steady-state aquatic models for contaminant-specific physico-chemical parameters such as environmental fate, transfer coefficients and uptake rate, and ecological parameters such as lipid content, life-span, mobility, and food-intake to estimate bioaccumulation (Rao).

* Steady-state factors tend to overestimate actual field concentrations because very few aquatic organisms live long enough to come to equilibrium. Moreover, these models are best suited for a worst-case estimate, not for an average-case scenario (Wilson).

* Use of sediment-to-fish bioaccumulation factors (BSAF) to characterize dioxin fish-tissue residue levels for water-bodies at the vicinity of each case-study facility is flawed to the extent that BSAFs for environmentally persistent compounds are empirically derived. Therefore, BSAFs are more suitable to estimate fish tissue concentrations within the species and water-bodies used in the derivation of the BSAFs (Anderson).

With regards to the use of terrestrial food-chain models for assessing risks from consumption of meat, eggs, milk, and other food products, the risk panel agreed that data gaps on media- and contaminant-specific transfer coefficient introduce substantial ambiguity in this approach:

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*	Additional data collection efforts are required to address the air-to-plan-to-animal pathway model and the problem of vapor plant transfer. (Anderson and Rao).

*	Lack of field data that corroborate models' predictions is a major uncertainty in terrestrial food-chain models (Anderson and Rao).

The panel members deliberated on various aspects of the level of confidence in the Agency approach for estimating exposures from hazardous waste burning sources. The consensus reached by the panel was that the Agency may have accounted for all the major pathways of exposure from HWCF. However, relative contributions of background and HWCF sources on cumulative exposure was considered an intractable problem.

*	Background exposures to dioxins generally exceed site-specific exposure levels attributed in the report as due to dioxin emissions from the HWCF. Moreover, there is no evidence to support the claim that long-range transport of emissions from HWCF are solely responsible for elevated background levels. Therefore, RA should not be restricted to individual facilities. Instead, such an assessment must consider total exposure from all recognized dioxin sources. With greater emphasis on data collection efforts and use of data display techniques such as the Geographical Information Systems (GIS), a comprehensive assessment of public health risks from multiple sources should be possible. (Anderson and Rao)

*	Differences between the background and source-specific sources for persistent chemicals require additional considerations for three reasons: (1) persistent contaminants such as dioxins, DDT, polychlorinated biphenyls (PCBs), and mercury biomagnify in the environment; (2) biomagnification enhances the risk of cumulative toxic effects; and (3) background exposures may be more critical in the average-exposure groups (Rao).

With regards to the Agency approach in describing the potential benefits of controlling mercury emissions, the panel members were of the opinion that EPA had failed to reconcile the proposed reduction in mercury emissions with potential benefits to the aquatic environment. Further, the panel concluded that several issues require separate and extended discussion.

*	The preamble makes no case that mercury emissions pose a threat to human health at any level (Wilson).

*	EPA does not provide sufficient supporting evidence to reasonably conclude that adverse health effects associated with ingestion of fish are currently occurring (Anderson).

*	EPA does not provide a rationale to support the actual mercury limits being proposed for HWCF (Rao).

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With regards to uncertainties, limitations, and key assumptions used in the risk assessment, the risk panel was unanimous that considerable effort is required to integrate discussions on uncertainties throughout the report.

* The discussion on uncertainties is of a descriptive nature. Although a standard "add-on" section on uncertainty analysis might make RA reports appear more complete, it is of very little value if none of those uncertainties were addressed consistently in the study (Rao).

* No quantitative analysis was performed to provide an indication as to the sensitivity of the risk estimates to uncertainties such as parameter, model, decision-rule and variability (Anderson).

* As to TEQ's predictive value in the risk assessment of dioxin mixtures, the report must address uncertainties introduced through the use of the applicable assumption (Wilson).

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MEMORANDUM

Date: April 1, 1996

TO: Joe Van Gieson, Ph.D.
SAIC

FROM: Elizabeth L. Anderson, Ph.D.
Sciences International, Inc.

SUBJECT: Peer Review of EPA's "Risk Assessment Support to the Development of Technical Standards for Emissions from Combustion Units Burning Hazardous Waste: Background Information Document"

I have completed my review of the risk assessment document which prescribes a case study multipathway risk analysis methodology for assessing risk associated with three combustion source categories. I have organized my comments according to the issues listed as the charge to the risk panel.

1) *The Agency elected to use a case study approach for characterizing individual risk in order to minimize the number of assumptions that have to be made and, in particular, to avoid the tendency of relying on worst case assumptions. How successful has the Agency been in applying the case study approach and how useful is this approach in evaluating the protectiveness of national emission standards?*

The case study approach to characterizing individual risk does reduce the number of generic, default, worst-case assumptions that have to be made in the risk assessment process. However, this approach is still conservative in that the methodologies and assumptions used to characterize chemical emissions, fate and transport, exposure, and toxicity all lead to the overestimation of potential risk. Thus, it is misleading to characterize the case study approach as providing accurate risk estimates. I highlight this point because the Agency appears to be placing a relatively high degree of confidence in the risk ranges predicted for each source category and, more importantly, does not acknowledge the fact that the case study approach is still conservative.

In general, the Agency has been successful in applying the case study approach.
However, one outstanding concern is presented below:

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- In estimating the range of potential risks associated with each case study facility within a source category, the Agency analyzed three levels of exposure: central tendency, high end, and bounding. The central tendency level attempts to approximate a 50th percentile population exposure and risk. The high end level attempts to assess a 90th percentile population exposure and risk, and the bounding level analysis attempts to approximate a hypothetical upperbound risk. These bounding level exposure estimates are apparently made to determine an upperbound to the range of high end risk levels for a source category because "Although the bounding level of risk may be unlikely, it cannot be ruled out given the large number of hazardous-waste-burning facilities and the relatively small (case study) sample size." Irrespective of current land use in the vicinity of a case study facility, the bounding risk estimates are derived by assuming that all exposures for subsistence pathways occur at the location of maximum impact, or, for water bodies, from a hypothetical watershed located in the area of maximum impact. My concern is that, in essence, the bounding estimate violates the case study objective of minimizing the number of generic, default, worst-case assumptions incorporated into the risk estimate. This approach is particularly troubling because the public places greatest emphasis on the highest risk evaluated. If the Agency's concern is that the case study approach is not representative of risk associated with the "worst offender" facility in a source category, then the Agency should continue to evaluate facilities to determine actual site risk, rather than inappropriately attempt to characterize upperbound outlier risk with a generic, hypothetical bounding approach. Therefore, I recommend deleting the bounding risk estimates.

In summary, the case study approach provides a conservative measure of the likely range of risks associated with both current emission levels and proposed emission limits for each source category. While the case study approach is useful in evaluating the protectiveness of national emission standards, I do not recommend strict reliance upon the resulting quantitative risk estimates to determine their suitability. This is because the documented uncertainties within both the indirect exposure pathway models and chemical-specific input parameters must be considered when analyzing the implications of the derived quantitative risk estimates. Also, within the case study approach, it is important to understand that assumptions regarding site-specific conditions can drive risk. For instance, decisions regarding the placement of a subsistence farm, or choice of applicable exposure pathways, can drive the risk outcome. If these assumptions are made in a conservative manner, the risk outcome can potentially be vastly overestimated.

While the Indoor Air Quality/Total Human Exposure Committee of the Science Advisory Board (SAB) recommended that current methodologies not be used for quantitative site-specific risk assessment, I suggest an alternate approach. Namely, I recommend that the Agency better qualify the uncertainties inherent within the quantitative risk estimates derived in the study. In the assessment, the Agency indicates that, by combining 50th and 90th percentile values to describe input parameters, the case study approach for the high end analyses are comparable to the 90th percentile of the risk distribution. However, I suspect that these estimates may be located at a much higher percentile on the risk distribution. This should be investigated by performing

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stochastic (Monte Carlo) analyses to determine the percentile at which the deterministic upperbound risk estimates fall on the risk distribution when variability and uncertainty in key exposure model parameters are accounted for. In addition, the Agency should further examine the suitability and accuracy of the applied exposure models by comparing results to those obtained using alternate models and against validating field data, where available. Finally, for uncertainties that are not amenable to quantification (e.g., location of subsistence farmers, etc.), the Agency should provide a qualitative discussion of whether the assumptions made in the assessment tend to under or overestimate likely risk levels. In this manner, the audience will be provided with the information needed to evaluate the protectiveness of the proposed national emission standards.

2) *The Agency's risk analysis employed various exposure scenarios in order to evaluate the range of the potential risks to human health (e.g., subsistence farmer, recreational fisher, typical resident, etc.). How reasonable are the exposure scenarios that were used in the analysis and do they cover the appropriate range of exposures of interest?*

The exposure scenarios used in the analysis are reasonable and, in each case, incorporate the pathways needed to conservatively cover the potential range of exposures. While exposures occurring via dermal contact with soil and water are usually assessed, risks associated with these routes are typically negligible compared to those exposure pathways selected for analysis in the assessment.

In recognition of the fact that high end risk estimates are typically driven by the special subpopulation exposure scenarios (e.g., subsistence farmer), one concern related to the manner in which these scenarios were evaluated is discussed below:

! Because quantitative risk estimates for special subpopulation exposure scenarios are highly sensitive to the assumed location of exposure, it is critical that the actual location of special subpopulations in the vicinity of a case study facility be accurately identified. Review of the 11 case studies indicates that the special subpopulation locations have, in general, been conservatively identified in the study (e.g., the placement of subsistence animal farmers at the point of nearest agricultural land to the facility, with higher modeled impacts, in several instances). The choice of location can make the difference between a significant risk outcome and a low or insignificant outcome.

3) *The Agency used a toxicity equivalence approach for estimating the carcinogenic potency of mixtures of polychlorinated dibenzo-p-dioxins and dibenzofurans. Toxicity equivalence is based on the premise that a series of common biological steps are necessary for most if not all of the observed effects of dioxins, including cancer. How appropriate is the use of the toxicity equivalence approach for estimating cancer risks from dioxin-like compounds?*

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The use of the toxicity equivalence approach to evaluate the cancer risk of dioxin-like compounds reflects current scientific knowledge regarding the mechanism of action of these compounds. The EPA's Science Advisory Board (SAB) has concluded that the use of a toxicity equivalency approach to evaluate cancer risk is reasonable as long as congener specific data (physical and chemical properties) are used to estimate exposure. Consistent with EPA guidance and the recommendations of the SAB, the assessment does use congener specific data to model exposure before applying the toxicity equivalency factors. Therefore, until additional scientific data are available, I believe the toxicity equivalency approach for estimating cancer risks from dioxin-like compounds is most appropriate.

With respect to assessing dioxin-like compounds, I do have concern with one non-toxicity related issue. This concern revolves around the development of congener-specific emission rates for use within the assessment. As described in Volume II (HWC Emissions Database), stack test data were used to develop source category-specific emissions databases for use in the assessment. As acknowledged in Volume II, those chemicals with mostly nondetected stack test data do not provide as accurate an assessment of emissions as substances with mostly detected data. This is because the chemical is assumed to be emitted at the detection limit when, in reality, it may not be emitted at all (i.e., a low level of confidence is associated with the accuracy of the surrogate emission estimate). This factor is of particular concern for dioxin-like compounds due to the high frequency at which individual congeners are not detected during stack tests <u>and</u> the relatively high levels of risk that result from the adoption of detection limits within an assessment, especially for indirect exposure pathways.

4) *The Agency used a combination of theoretical and empirical approaches for addressing the various mechanisms and pathways by which airborne emissions are removed from the atmosphere and deposited at the surface. What are the strengths and weaknesses of the approaches used? In particular, how reasonable are the approaches for estimating the deposition of dioxins to surface waters and watershed soils?*

The greatest weakness in the Agency's theoretical and empirical approaches to modeling the deposition of airborne emissions is the lack of field data from a representative cross-section of locations (i.e., both rural and urban) to thoroughly validate the vapor/particle partitioning, deposition, and air-to-plant transfer models. Unfortunately, this problem is not easily remedied, especially for those chemicals with the potential for long range transport (e.g., dioxins). For such chemicals, direct deposition measurements in the vicinity of a facility will not necessarily correspond closely to facility-specific modeled estimates, due to the influence of other regional sources of the chemical. Thus, the development of techniques to assess the cumulative impacts of multiple sources across a region is considered to be an important step toward accurately assessing the deposition of airborne emissions. In summary, the approaches for estimating the deposition of dioxins to surface waters and watershed soils in the vicinity of a plant are only as valid as the data used to develop the models. Given the limited amount of information currently available to develop the empirical approaches, and the propensity for these data to have been collected in

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urban areas with multiple potential sources, the models are unreliable in accurately assessing the deposition of dioxins and cannot be represented as being reasonable without further verification.

5) *The Agency has employed a simple steady-state surface water model along with empirically-derived bioaccumulation factors for assessing risks from the consumption of drinking water and fish. What are the strengths and weaknesses of this approach for evaluating surface water impacts? In particular, how appropriate is the use of the steady-state model and sediment-to-fish bioaccumulation factors for environmentally persistent compounds such as dioxins?*

The major strength of the simple steady-state model for evaluating surface water impacts is that it incorporates fewer parameters that are hard to accurately characterize than kinetic models and, therefore, it is easier to apply. Clearly, the steady-state approach is most ideally suited to those contaminants that are not highly persistent and, therefore, can achieve equilibrium in environmental media within a relatively short period of time. For environmentally persistent compounds, an intrinsic weakness is related to the potential for long-term accumulation to occur in media that act as environmental sinks (i.e., soil and sediment), thus violating the assumption of equilibrium and underestimating surface water concentrations. Long-term observation of soil and sediment levels in the vicinity of a source would be required to assess the degree to which accumulation of environmentally persistent compounds affects the suitability of the steady-state assumption. At the current time such long-term observations have not been made and validated.

Clearly, as environmentally persistent compounds, the weaknesses in the steady-state model apply to dioxin congeners. However, one of the issues of greatest concern with regard to this family of chemicals is not related to the model but, rather, the lack of data available to characterize loss mechanisms, such as degradation, within the model. The relative abundance of the various dioxin homologues and congeners differs between sources and environmental sinks. As noted by EPA's SAB, most combustion sources generate a dioxin mixture with relatively high concentrations of tetrachloro- and pentachloro- dibenzofurans, whereas the environmental sinks are dominated by relatively high concentrations of octachlorodioxin. While only poor supporting data are available, it is likely that the more toxic lower molecular weight congeners are relatively rapidly degraded within the air, surface soil and surface water compartments by photolysis (EPA, 1994). Thus, with regard to dioxins, one of the greatest sources of uncertainty within the steady-state model is the potential overestimation of most toxic congener concentrations due to a lack of adequate data to accurately characterize decay. I recommend that the Agency collect additional data to more adequately characterize this mechanism.

Finally, the use of sediment-to-fish bioaccumulation factors (BSAFs) to characterize dioxin fish-tissue concentrations for water-bodies in the vicinity of each case study facility is flawed to the extent that BSAFs for environmentally persistent compounds are typically empirically derived. Therefore, BSAFs are most suitable to estimate fish tissue concentrations within the species and water bodies used to derive the BSAFs.

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6) *The Agency has employed a series of terrestrial food chain models that rely on empirical estimates of bioconcentration and biotransfer factors for assessing risks from the consumption of meat, eggs, milk, and other food products. What are the strengths and weaknesses of these models? In particular, how reasonable is the air-to-plant-to-animal pathway model for assessing risks from the consumption of food products derived from beef and dairy cattle and the soil-to-animal pathway for assessing risks from free-range produced chickens and eggs?*

Similar to modeling surface water concentrations, the "strength" of the terrestrial food chain models is that they are based on simple, empirically derived intermedia transfer factors (ITFs) and are, consequently, easy to apply. The biggest weakness in the models is related to the fact that the empirical relationships used to describe ITFs are derived from highly limited data sets and, therefore, are not robust. In fact, ITFs derived by different sources have been found to range several orders of magnitude due to variability among experiments, lack of knowledge with regard to metabolism and chemical partitioning processes, and reliability with which the ITF and explanatory variable (e.g., octanol-water partition coefficient) can be measured. Finally, the models have not been extensively validated against experimental data. Thus, the models cannot reliably estimate bioconcentration and biotransfer factors, particularly in environments significantly different from those in which the available data were collected.

With regard to the reasonableness of the air-to-plant-to-animal pathway model, the greatest area of concern is related to vapor plant transfer. I recommend that this approach be justified by further data collection before it is applied. In addition to the issues detailed above, potential inaccuracies are associated with the theoretical basis for the model, the fact that plant species differ in their uptake and volatility rates, and the likelihood that photodegradation is a significant decay phenomenon. These uncertainties, along with concerns related to the reliability of available empirical data and the lack of validation data, indicate that a significant amount of research is required before a reliable model to assess this pathway can be developed. While my level of concern is not as great, I believe that the soil-to-animal pathway, for assessing risks from free-range produced chickens and eggs, is similarly flawed by the lack of field data to validate the assumptions inherent within the models.

7) *Based on limited data on dioxin levels in various food products, background exposures generally exceed the exposures the Agency has modeled for hazardous waste incinerators and hazardous waste-burning cement kilns. It is generally acknowledged that stack emissions can be transported over long distances and impact distant locations and that actual exposures at any one location may be due to emissions from numerous sources. With what level of confidence can the Agency be sure that it's risk estimates have accounted for the major pathways of exposure from hazardous waste burning sources? Are there alternative approaches the Agency should consider in assessing total exposure and risk from such sources?*

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As previously discussed in 2), the Agency can associate a relatively high level of confidence that its site-specific risk estimates have accounted for the major pathways of exposure from hazardous waste burning sources (i.e., the site-specific exposure estimates are conservative). The finding that background dioxin exposure levels generally exceed the site-specific exposure levels the Agency has modeled for hazardous waste incinerators and hazardous waste-burning cement kilns is not surprising since these sources comprise a minority of the total sources contributing to background. It is likely that nearby non-hazardous waste-burning sources of these chemicals (e.g., coal-fired plants, etc.) are contributing to the observed levels. While long range dioxin transport is a potentially viable mechanism, there is no evidence to support the claim that long-range transport of emissions from hazardous waste-fired plants are solely responsible for elevated background levels. Therefore, I do not recommend that an assessment of total exposure and risk be restricted to these facilities. Rather, such an assessment should include all recognized dioxin sources. To assess total exposure and risk, I suggest that when better data become available from on-going measurements of dioxin concentrations in food, the Agency consider using a Geographical Information System (GIS) for analysis of these data. With such a system, the geographic distributions of dioxin emissions sources and dioxin levels in food can be mapped and quantitative questions asked (and tested statistically) regarding the relative contributions of local and more distant sources.

8) *The Agency attempted to assess exposures and potential risks arising from mercury emissions and subsequent deposition and runoff to surface waters and bioaccumulation in fish. However, an internal Agency review concluded that a quantitative exposure and risk analysis for mercury would be so uncertain as to be of little practical value. Key uncertainties identified in the review were the form of mercury emitted, the extent of local deposition relative to long-range transport, and the degree to which methylation and uptake in fish occur. Additional uncertainty exists regarding the risk associated with any given level of exposure to methyl mercury among fish consumers. Given these considerations and concerns about mercury at current environmental levels, the Agency decided to develop a qualitative rationale for imposing controls on mercury emissions. How successful has the Agency been in describing the potential benefits of controlling mercury emissions, as outlined in Part Seven of the preamble to the proposed rule?*

In Part Seven of the preamble to the proposed rule, the Agency has concisely described its basis for concern over potential adverse health impacts to occur as a result of documented nationwide mercury impacts on surface water quality and, in particular, fish tissue concentrations. The Agency has also concisely presented their estimate that hazardous waste burning incinerators, cement kilns and light weight aggregate kilns currently contribute approximately 10 percent of national mercury emissions, and that the proposed standards would result in a 3 percent reduction in total anthropogenic U.S. mercury emissions. However, EPA has totally failed to reconcile this proposed reduction with potential benefits to the aquatic environment. Instead, the Agency states that any reduction will help reduce mercury levels in fish over time and, therefore, reduce the likelihood of adverse health effects occurring in fish-consuming populations. While this general statement does allude to potential health benefits being associated with the control of

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anthropogenic mercury emissions, the Agency does not provide sufficient supporting evidence to reasonably conclude that adverse health affects related to fish ingestion are currently occurring. This is of particular concern given the recent findings by the National Institute of Environmental Health Scientists (NIEHS) that no adverse effects are observed in humans exposed to methyl mercury at the levels currently regulated by EPA. Finally, EPA's argument does not provide a logical rationale to support the actual mercury limits being proposed for hazardous waste burning incinerators, cement kilns and light weight aggregate kilns.

9) *The Agency recognizes the need to enhance and expand the discussion of uncertainty in the current draft of the risk assessment background document. In revising the document, what uncertainties, limitations, and key assumptions is it important be highlighted and what types of supporting information are needed?*

The current uncertainty section qualitatively identifies each of the major sources of uncertainty (parameter, model, decision-rule and variability) within the risk assessment. However, no quantitative analyses are performed to provide an indication as to the sensitivity of the risk estimates to these uncertainties. This is a critical issue because throughout the document EPA identifies the average risk estimate as representing the 50th percentile of the individual risk distribution and the high end estimate as representing the 90th percentile of the individual risk distribution. I suggest that analyses be performed to assess the sensitivity of these deterministic risk estimates to uncertainty and variability inherent within model input parameters. I suggest the following tiered approach to performing this analysis: 1) assign a probability distribution function (PDF) to each parameter; 2) using the range of each PDF within the modeling methodologies, determine which parameters most strongly influence risk; 3) for the risk driving pathways with the greatest parameter sensitivity, perform stochastic analyses (e.g., Monte Carlo) to determine more accurately the 50th and 90th percentiles of individual risk.

In addition to parameter uncertainty, the risk estimate sensitivity to uncertainties within exposure models selected for use within the analysis should be assessed. This assessment can be done by comparing the risk assessment results to estimates following the application of alternate models (e.g., assuming equilibrium between aquatic compartments in estimating fish tissue concentrations versus adopting a kinetic model). When available, actual plant and animal tissue data should be compared to modeled exposure point concentrations to validate the accuracy of available models. Finally, a comparison of modeled air concentrations to available monitoring data may be warranted to ascertain the appropriateness of adopting source category wide data to characterize emissions from a selected case study facility. This approach may also be useful in assessing the conservatism introduced into the assessment by assuming a chemical is emitted at its detection limits when not detected during a stack test. This is particularly important for those chemicals associated with a relatively high level of risk when emissions at the detection limit are assumed (e.g., dioxin-like compounds). If this is not practical, then at a minimum the Agency should assess the uncertainty in the risk estimates that is introduced by assuming emissions at the detection limit for chemicals rarely detected during stack tests. Finally, for uncertainties that are

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not amenable to quantification (e.g., location of subsistence farmers, etc.), the Agency should provide a qualitative discussion of whether the assumptions made in the assessment tend to under or overestimate likely risk levels.

Summary

Given the conservatism within many of the values used to characterize input parameters and within the modeling methodologies adopted in the analysis, it is likely that the location of the average and high end risk estimates are really much higher on the true risk distribution. While quantitative uncertainty analyses can help identify the sensitivity of risk estimates to parameter and model uncertainties, the revised section must also highlight other significant uncertainties that are not amenable to quantification. Examples of uncertainties within the case study approach that warrant analysis include accuracy of emission inventories (particularly the effect of high frequencies of non-detects), validity of models, characterization of input parameters, choice of suitable exposure pathways, placement of subsistence farms, etc. Uncertainties inherent within these components are critical because, if sufficiently large, they may drive the ultimate risk assessment outcome. Thus, in analyzing uncertainties, EPA should indicate the likely extent that assumptions made within the risk assessment are likely to over or underestimate risk. In this manner, the uncertainty section will provide the reader with information necessary to judge the level of confidence that should be placed on the deterministic risk estimates developed in the study.

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Review and Comments on The Risk Assessment Support to the Development of Technical Standards for Emissions From Combustion Units Burning Hazardous Wastes

The U.S. Environmental Protection Agency has conducted a risk assessment (RA) to support development of technical standards for emissions from hazardous waste combustion facilities (HWCF). EPA has chosen a multiple pathway approach to define and develop indirect exposures to hazardous air pollutants, particularly for persistent contaminants like dioxins.

As a part of the regulatory development process, the RA documents in support of the proposed revised technical standards for HWCF were reviewed to address a set of questions pertaining to the technical merits of the RA approach adopted by the Agency and other broader issues concerning uncertainties and limitations of the current Agency methods.

Approach:

Reviewer's response to questions to the risk panel on the RA under review, herein referred to as "EPA RA," are narrated both as specific and general comments. Whereas specific comments are those that directly pertain to the issues concerning the Agency's proposed rule, general comments address some general scientific issues and technical clarification(s), if so required, that might facilitate a broader understanding of the scientific and technical implications of the Agency's proposed rule.

EPA Question 1:

The Agency elected to use a case study approach for characterizing individual risk in order to minimize the number of assumptions that have to be made, and in particular, avoid the tendency of relying on worst case assumptions. How successful has the Agency been in this approach?

Reviewer's Response

Data from a total of 11 case studies, comprised of 4 hazardous waste incinerators (HWI), 5 hazardous waste-burning cement kilns (CK) and 2 hazardous waste-burning lightweight aggregate kilns (LWA), were used to construct exposure assumptions for risk assessment.

Use of a case-study approach for risk assessment purport to have the advantage of being less conservative as compared to the extreme scenarios used in conventional. Although use of site-specific data collected on various hazard and exposure parameters are considered more appropriate by the Agency (EPA, 1989), most often remedial investigations/feasibility studies (RI/FS) adopt EPA-recommended default values due to non-availability of site-specific data. Nevertheless, even if site-specific data was made available for the EPA RA it is not always easy to include case-study based exposure data obtained from survey and questionnaire into a RA for regulatory purposes. The EPA RA performed to test compliance of the proposed rule under the RCRA, and is not a research exercise to develop better scientific methods for exposure and risk assessment.

The regulatory restraints the RA to support rule making process, and other limitations in the EPA RA process may preclude effective use of site-specific data for some reasons.

First, a case-study approach may not necessarily address the conservatism built into a model such as the ISCSTDFT Air Dispersion Model, which was used here. Several critical input parameters of ISCSTDFT are not amenable for modification on a site-specific manner. For example, no assumptions regarding degradation of contaminants during transport process are made. Most often, models erroneously assume that contaminants remain unaltered during the entire process of air transport, deposition, and subsequent mobilization in aquatic and terrestrial media. These and other similar assumptions are carried through during the course of a RA exercise.

Second, exposure analysis data from case-studies may not support EPA RA conducted for regulatory purposes. Survey and questionnaire based information on exposed population, exposure frequency, duration of exposure, and fraction exposure to contaminated media have such large regional variations that it is always difficult to build regulations at the national level based on regional exposure information. For example, the fraction ingestion of fish by the Puerto Rican population is so different from that of those living in the mid-west that RAs using unique exposure data from a case study to other situations may be less meaningful.

Except for the facility-specific engineering parameters for the HWCFs used in the air dispersion model, it is not clear as to how the case-study information was incorporated into exposure assessment. A review of the exposure frequencies used the EPA RA indicate that the central tendency and high end exposure parameters are those recommended by the Agency's *Exposure Factor Handbook* (1990) and other similar guidance documents, on standard Agency default assumptions on exposure duration and fraction exposure to contaminated media (Tables II.3 [page 69]; II.4 [page 70]; II.5 [page 73]; and IV.1: page 123). However, the default exposure assumptions in the EPA RA are an improvement over the earlier default values (EPA, 1989). Similarly, exposure factors for inhalation of air (Table II.3), ingestion of soil (Table II.4) and dietary pathways are adopted from standard Agency documents (Tables II.5-12).

Finally, case-study specific information on receptor location and associated exposure parameters are less useful if EPA RA is based on the highly exposed high-end of the population. For instance, Table 1 summarize the HWCF-type, location, and land-use in the vicinity of 5 kms from

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the site for 11 facilities in the case studies. There are several interesting site-specific differences among these case studies.

Differences in land-use, location, receptor location and exposure scenarios vary with the location. Although Though 3 out of 11 sites are located in industrial areas, industrial and commercial exposure scenarios are not used in the risk assessment. Similarly, child exposure scenarios are incomplete (see, answer to Question No. 3 for details).

Table 1

Location and Land-Use Information on Case Studies

Case	HWCF type [location]	Land Use (within 5 km)	Terrain use	Location
A	HWI [LA]	Industrial/rural	No	Commercial/Industrial
B	CK [SC]	Forest	No	Forest
C	CK [IN]	Agricultural	Yes	Agricultural/residential
D	CK [MO]	Agricultural	Yes	Agricultural
E	HWI [MN]	Agricultural	No	Agricultural
F	CK [MI]	Forest	No	Forest
G	HWI [TX]	Industrial	No	Industrial
H	CK [PA]	Agricultural	No	Agricultural
I	HWI [CA]	Industrial/residential	Yes	Industrial/residential
J	LWA [NY]	Suburban/rural	Yes	Suburban/rural
K	LWA [NC]	Suburban/rural	No	Rural/forest

Despite all refinement in the construction of case-study specific exposure pathways, the critical variables, i.e., contaminant concentrations and exposure assumptions (frequency and duration of exposure) are high end high and conservative default EPA assumptions, respectively.

Therefore, the nature and extent of divergence of case study approach from conventional approach is marginal and its overall impact on risk numbers may be described, at best, as minimal. By recognizing the importance of case studies as the basis for EPA RA, the Agency has embarked on a new course to steer away from the tendency of relying on worst-case assumptions. However, certain regulatory limitations pose restrictions on the nature and extent of adoption of case-study

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specific data and a review from that perspective indicate that there is not a whole lot of deviation from the conventional RA.

EPA Question 2

How useful is the case study approach in evaluating the protectiveness of national emission standards?

Reviewer's Response

Case studies offer the distinct advantage of being (a) relatively small sample size with minimal variation, (b) ideally suited to provide useful site-specific data for RA, (c) reliable so as to support the inherent assumptions of RA and, (d) depending upon the selection criteria, representative of the larger national scene. As a good sampling strategy is considered truly representative of the nature and extent of contamination at a site and remedial decisions based on the analysis of sample points reliable and technically defensible, ideal case studies may be a representative microcosm of a larger nation-wide problem. Case studies of HWCF sites covering broad range of facility-specific engineering and operational data, meterological and environmental data, demographic and human activity pattern data may form a sound basis for developing national emission standards.

Use of observational case studies is a classical approach adopted by clinicians and social scientists to base decision on medical and social intervention strategies. In the absence of clinically controlled studies, extensive medical data collected from case studies serve as an alternate source of evidence both for beneficial or adverse impact of clinical intervention strategies. Use of data collected from case studies for setting environmental standards is akin to the clinical and social intervention strategies.

Despite all these advantages, case studies may fail to capture the extreme scenarios creating problems for developing national standards. The advantages of case studies (i.e., small sample size, site-specific data and small spread in the data) could at the same time limit its scope for developing national standards. Since national standards are expected to be address potential impact of most extreme conditions of pollution and develop measures that are protective of the most sensitive population, case studies may not provide the range of data points required to statistically estimate the protectiveness of national standards for the 95th or even greater percentile of the population.

The risk of overestimation or under estimation of risk as deduced through individual case studies could be adjusted through a case mix and in that way derive more defensible national standards. It is not clear if such an effort was made by the investigators in the selection of 11 eleven case studies. Although it is evident that the case studies have a good mix of HWCF category and

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geographic location of the facilities, it is not clear how the more important region-to-region difference in exposure and human activity pattern are reflected in these selected studies (Table 1).

As to the usefulness of using case study approach in developing/evaluating protectiveness of national emission standards, the uncertainties will linger as long as the debate on microcosm as a true and total representation of the macrocosm is decided one way or the other.

EPA Question 3

How reasonable are the exposure scenarios that were used in the analysis and do they cover the appropriate range of exposures of interest?

Reviewer Response

The EPA RA has adopted a comprehensive range of exposure scenarios and exposed groups:

! Subsistent farmers and residential exposure scenarios are have accounted a good range of exposure pathways;
! The definition of a subsistent and typical exposure group is well defined and characterized. This is consistent with other studies reporting elevated dioxin levels in human adipose tissue, blood, and milk samples for those living close to a HWCF (Beck et al 1994);
! EPA RA has aptly placed greater importance on indirect exposure pathways through a multimedia contaminant pathway approach.
! All EPA-recommended standard direct exposure pathways are included in the risk analysis.

However, the EPA RA does not identify potential sensitive sub-populations and others for a detailed risk analysis. A major lacunae in the EPA RA is the absence of child exposure scenarios for all subsistent farmers groups. Except for subsistent dairy farmer child group there are no other child group in the RA. Inclusion of a subsistent farmer child group for all the subsistent farmer categories was considered necessary for the following reasons:

! The subsistent dairy farmer child group reported in the risk assessment document consistently demonstrate a higher level of risk. Table 2 is a summary of the combined risks for all indirect pathways for the baseline, proposed floor, proposed beyond-the-floor (BTF), and alternate floor conditions. Note that the risk estimates for the subsistent dairy farmer child group is almost always higher than its corresponding adult group (subsistent dairy farmer). By extension, this might be the case with other subsistent farmer pathways.

! Indirect exposure to dioxins through ingestion of cow's milk is an important pathway and is more so for young children. Researchers have pointed out the importance of milk pathway for dioxin risk assessment (Copeland et al. 1994; Fries and Paustenbach, 1990).

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However, EPA RA does not have milk exposure pathways for infants and young children under subsistent farmer and typical farmer and resident categories.

What was the basis for the selection of exposure pathways and exposed groups? Was it based solely on case study profiles or a combination of standard and case-study driven pathways. If case study results were included in the definition of exposure pathways, what were the notable departures from the conventional approach? EPA RA is clear on these issues, although review question 1 seek response as to the success of the Agency in using a case study approach for the RA.

As stated earlier, it is not clear if land-use considerations were included in the identification of exposure assessment? A total of 3 out of 11 HWCF sites in the case studies are located in industrial areas. However, industrial (occupational/workers exposure) and commercial exposure pathways are not included in the EPA RA. Moreover, what are the future land-use plans at these sites? Conversion of residential areas for industrial/commercial development may pose a new set of future worker's exposure scenarios.

EPA Question 4

The Agency used a Toxicity equivalence approach for estimating the risks for PCDDs. How appropriate is the use of TEQ for dioxin-like compounds?

Reviewer Response

Yes. Use of toxicity equivalence (TEQ) for chemicals belonging to similar structural classes and with similar biochemical mechanisms of action is a scientifically valid approach. The Agency has adopted TEQ to perform dose-response analysis and risk assessment for chemical groups such as polyaromatic hydrocarbons (PAHs) polychlorinated biphenyls (PCBs), and for the congeners of dibenzo-p-dioxins and dibenzofurans (PCDD/PCDFs).

The scientific underpinnings are extensive for the development of TEQ for various PCDD/PCDF, and is primarily based on the toxicity of the most potent congener in the PCDD/PCDF family) 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD):

! TCDD exert its effects through interaction with a specific intracellular protein, the arylhydrocarbon receptors, also known as *Ah* receptor.

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- The relative binding affinities of TCDD and congeners correlate with potencies to induce several *Ah* receptor-mediated enzyme activities and toxic effects such as hepatomegaly, thymic involution, and possibly immunosuppression and reproductive consequences.

- *Ah* receptor-mediated early events are directly or indirectly correlated with most of the toxic effects induced by TCDD and congeners;

Therefore, the dose-response relationships at the molecular level (binding and saturation of the *Ah* receptor), subsequent biochemical events (activation of nuclear and enzymatic pathways) and adverse clinical effects are proportional to the toxic potency of various congeners, which in turn depend on their affinity for the Ah receptor. This forms the core of the TEQ scheme.

Although TEQ approach for risk assessment rests on sound scientific principles, its application in the RA is an oversimplification of the exposure to chemical mixtures like dioxins with varying toxic potentials but acting through a similar mechanisms. Unlike exposures to individual chemicals on a one at time basis, "real world" exposure to chemical mixtures can be expected to alter considerably in exposures involving mixtures of TCDD and congeners:

- Experimental data from *in vivo* and *in vitro* studies indicate that dioxin congeners and planar PCBs *(a)* may effectively compete with TCDD for the *Ah* receptors (Brown et al. 1994), *(b)* produce biochemical and toxicological effects similar to those of TCDD, albeit at higher concentrations (Safe, 1990), and *(c)* competitive binding to the *Ah* receptor is governed by the structural features of the competing ligands (Couture et al. 1988).

- In the presence of congeners with weak toxicologic potencies and binding affinities comparable to those of TCDD, mixtures of TCDD and congeners might potentially create a competitive environment for binding to *Ah* receptors. Instead of receptor complexes of a single ligand, multiple ligand species-receptor complexes may be formed.

- Our earlier efforts at SAIC to model the binding of congeners to the *Ah* receptor in the low-dose range for the formation of fractions of *Ah* receptor-congener complexes indicated that the percent contribution of toxic congeners was significantly higher when model algorithms were used. The percent contribution of higher congeners with low toxicity was considerably reduced when model algorithms were used. Our preliminary results indicate that the standard approach tend to overestimate the combined total risks of higher congeners with low toxicity, but underestimate the risks of more toxic congeners (Rao and Unger 1995a and 1995b).

- A previous analysis by our group on the interactive effects of binary combinations of carcinogens and tumor promoters indicated that PAHs belonging to similar structural classes revealed a predominance of antagonism suggesting the possibility of competition for binding sites by structural analogs (Rao, 1991). Such a mechanism was invoked by

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earlier investigators to explain observed inhibition of PAH-induced skin carcinogenesis in the presence of structurally similar and less potent or non-carcinogenic PAH (DiGiovanni et al. 1980).

These and other evidence on the interactive effects of carcinogenic chemical require some modification on the congener's impact on the TCDD-based TEQ for dioxin risk assessment. Our published papers recommend a modification of the TEQ scheme to incorporate the potential differences in *Ah*-receptor-ligand formation depending upon the competitive binding of TCDD and other congeners. A discussion on the potential impact of exposure to mixtures of congeners of PCDDs/PCDFs on the risk outcome must be addressed in a technical attachment with EPA RA.

EPA Question 5

A combination of theoretical and empirical approaches were used for addressing the various mechanisms and pathways by which airborne emissions are removed from the atmosphere and deposited at the surface. What are the strengths and weakness of the approaches used? In particular, how reasonable are the approaches for estimating the deposition of dioxins to surface waters and watershed soils?

Reviewer Response

Environmental fate and transport processes are crucial in the determination of final exposure-point concentrations of contaminants in environmental media. EPA RA has estimated end-point concentrations using a combination of sampling and modelling approaches. First, air samples collected during trial emission runs for HWCFs were used as the basis for extrapolating the end-point concentrations in the soil, water, and air (for direct exposure pathways). Second, using a set of transfer coefficient, obtained largely from published literature, multimedia migration of dioxins and its potential concentrations in beef, poultry, pork, produce, and milk was estimated (for indirect exposure pathways).

Between the known values of dioxins in the air samples from trial emission runs and the final estimates of potential risk lies a large)in fact a very large)number of complex environmental transport and fate process governed by physicochemical and ecological processes. EPA RA has tackled this large data gap using a combination of theoretical and empirical processes.

Environmental transport and fate models such as the ISCSTDFT Air Dispersion Model are essentially based on the physicochemical characteristics of chemicals and abiotic media such as air, water, and soil. Studies have shown that physicochemical properties, aqueous solubility, octanol/water partition coefficient (K_{ow}), vapor pressure (Henry's Constant), and volatilization coefficients.

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ISCSTDFT Air Dispersion Model was run using the "default" model options for all case studies. The uncertainties built into the default values propagate all throughout the dispersion calculations.

Chemical properties such as aqueous solubility may offer crucial insights into the potential for ionization (pKa) and consequent bioavailability of a chemical species in living tissues. Chemical reactivity such as susceptibility for hydrolysis (in the presence of hydroxyl radicals in the atmosphere, soil and water), photo-oxidation (in the presence of UV light-generated radical species), oxidation (in the presence of oxy- , or peroxy- radicals in the atmosphere and soil), complexation, and chelation (in the presence of chelating agents in the soil and aquatic media) determine the steady-state concentrations of a persistent chemical species in the environment.

Literature is replete with efforts to develop environmental transport models based on physico-chemical properties. Also, there are numerous studies aimed at validating the environmental model predictions. However, the uncertainties associated with the model are likely to affect the final outcome. Note that although there are good interrelationships between physicochemical variables of a contaminant and its concentrations in the abiotic and biotic samples, there is no way to accurately predict the endpoint concentrations of a contaminant released from a HWCF located 5 meters or 5000 meters away. Environmental samples collected to validate model predictions are shrouded with uncertainties due to a large standard deviations in the contaminant concentrations.

Additionally, model validations for biotic systems becomes more complicated due to a complex interrelationship between various ecological variables (look for additional discussion under Reviewer's Response to EPA Questions 7-9).

EPA Question 6

Agency employed a simple steady-state surface water model along with empirically-derived bioaccumulation factors for assessing risks for consumption of drinking water and fish. What are the strengths and weakness of this approach?

Reviewer Response

Use of a combination of steady-state aquatic model with empirically-derived bioaccumulation factors for assessing risks for consumption of drinking water and fish is a standard industry practice.

In principle, use of steady-state surface water models for estimating the transport and fate characteristics of dioxins and other contaminants is as valid as using air dispersion models for characterizing the transport and deposition of airborne contaminants in the atmosphere. By

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extension, the uncertainties built into a steady-state aquatic model propagate just as those in a air model. However, the robustness of some aquatic models have be confirmed by independent data collection and validation efforts and in that sense some types of aquatic models (such as the fugacity model) may have certain advantages over the others.

But a discussion on relative strengths and weakness of such an approach is possible only on general scientific strengths and weakness of the parameters used in the development of a aquatic model and availability of independent data that validate or repudiate the model predictions.

Most of the aquatic models used in EPA RA for estimating contaminant transport and fate in aquatic media rely more on the physicochemical parameters of a contaminant and the media in question (water in this case) as the basis for its transport and ultimate fate. For instance, K_{ow} is extensively used to predict transport and fate in aquatic media.

Figure 1 illustrate one of our earlier studies on the interrelationships between K_{ow} and whole-body residue of contaminants in fish samples. Our analysis of the data presented in the figure indicated that for chemicals with a high log K_{ow} (such as dioxins) water solubility limits aqueous transport of the chemical, although its diffusion across the membrane is a rapid process (Rao et al. 1996). Model predictions such as these have been confirmed by experimental data. This is just one example the relevance of physicochemical properties used in environmental transport models to predict end-point concentrations.

Although this simplified physicochemical scheme to understand a complex process such as environmental transport and fate provided a preliminary basis for model development, it is far from being complete. Our extensive analysis of contaminant transport and fate in East Fork Poplar Creek (EFPC, Oak Ridge) indicated that ecological variables played a much more crucial role in determining the ultimate fate of contaminants. To date, there is very limited success in integrating ecological variables into an aquatic model. Scientists have also attempted, but with less success, to extend pharmacokinetic models for dioxins to include environmental compartments for aquatic systems (Boon et al. 1994).

It is relevant to note that depending upon the type of steady-state aquatic model used in a study, the results could vary by several orders of magnitude. For example, Maddalena et al. (1995) reported that by increasing the number of compartments from 4 to 7 in the new fugacity model, termed CalTOX, steady-state concentrations of dioxins in water differed by more than 3 orders of magnitude. For mobile aquatic organisms such as fish these differences could be far greater posing considerable uncertainty in the model-derived values. This example illustrate the inherent weakness of ecological parameters in steady-state models for performing public and ecological risks analysis for aquatic media.

EPA Question 7

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How appropriate is the use of the steady-state model and sediment-to-fish bioaccumulation factors for environmentally persistent compounds such as dioxins?

Reviewer Response

Use of steady-state models and bioaccumulation factors (BAF) estimated from sediment-to-fish ratios are in vogue in ecological risk assessment. As stated earlier in my response to EPA Question No. 6, aquatic models based on the physicochemical parameters of a contaminant and a simplified pharmacokinetic two-compartment models)to account for differences such as fat:water ratio, size of the compartment, and clearance rate)are used to extrapolate concentrations of dioxin in the sediment/water column and its tissue residue levels in aquatic organisms. Although insufficient, this approach might help in refining the ecological RA approach.

Both field-derived and estimated BAF values are recommended by the Agency for (a) derivation of water quality criteria, (b) setting standards for effluent water quality from industrial discharge and, (c) public and ecological risk assessment.

However, use of BAF and/or steady-state models to estimate sediment-to-fish have notable problems:

! BAF for dioxin and similar persistent chemicals exhibit a wide range. For example, the BAF values for dioxin range from as low as 1000 to 189,000 l/kg (Sherman et al. 1992). Since BAF is the process by which persistent contaminants such as DDT, PCBs, mercury, or dioxins biomagnify in the ecosystem, more than one set of factors contribute to BAF values. Our studies in EFPC indicated that ecological variables such as mobility of the aquatic organism, life-span and eating habit were as critical as the physicochemical properties such as K_{ow}, or total lipid content.

! Estimated Bioconcentration factors (BCF) based on ratio of the concentration of contaminant in the abiotic media (water/soil/sediment) and exposed organism does not account for exposure through the more important food-chain pathways. BAF values most often reflect a much higher contribution of food-chain pathways rather than concentrations of contaminants in abiotic media (water/soil/sediment). Models have so far been unsuccessful in simulating the food-chain pathways and ratios between organism and environmental media are less useful in this regard.

! The uncertainties built into a steady-state aquatic model propagate contributing to the observed wide variations in estimated BCF or BAF values for dioxins.

! Use of BAF without a dose-response analysis makes very little sense in ecotoxicological assessment. This is a major shortcoming in the entire ecological EPA RA process.

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EPA Question 8

Agency has employed a series of terrestrial food chain models that rely on empirical estimates of BCF and biotransfer factors for assessing risks from consumption of meat, eggs, milk and other food products. What are the strengths and weakness of these models?

Reviewer's Response

Multimedia exposure assessments in the EPA RA are based primarily on a set of hypothetical exposure conditions and estimates for total uptake of a contaminant by a potentially exposed individual(s). In order to do so, Agency has adopted has adopted BAF and transfer coefficient values from the published literature to estimate the concentrations of dioxin congeners in meat, poultry and dairy products, fish and produce.

Use of terrestrial food chain models is more advantageous than mere BCF and BAF values because these values are available only for some organisms such as fish and game species. Additionally, food chain models could be developed for a site-specific ecosystem and form the basis for identifying the exposure points and associated concentrations in the food chain and refine exposure pathways.

Data gaps on contaminant-, media-, and receptor-specific transfer coefficients introduce a lot of ambiguity in this approach:

! Transfer coefficient, defined as the rate of transfer of a contaminant from the abiotic media to biological receptors, or from a prey to predator. Transfer coefficients are used as a measure to quantify selective bioaccumulation of persistent contaminants in the food chain. However, environmental media and tissue concentration data alone are incomplete to understand the dynamics of dioxin or mercury mobility in the environment. For example, herbivorous animals do not bioaccumulate as much dioxins (and mercury) as carnivores mammals and piscivorous birds. This is largely due to the selective biomagnification of these persistent contaminants in the carnivores food chain. In the absence of contaminant- and receptor-specific transfer coefficients, risk assessors employ EPA-recommended standard values. These values are either model simulated estimates or a default value for an other contaminant.

! Among the factors influencing concentrations of dioxins in food and other biotic receptors affecting indirect exposure: (a) the animal feeding and management systems; (b) bioavailability of dioxins in the receptor; (c) metabolism and pharmacokinetics of dioxins in farm animals; and (d) food consumption levels by humans. These factors have the

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highest impact on the final outcome. Unfortunately, the current iterations of food chain models cannot integrate these factors into the calculations.

! Data gaps on transfer coefficients and model-related uncertainties built into a terrestrial food chain model propagate through the entire EPA RA process introducing large uncertainties in the risk estimates. The relatively primitive approach adopted in the ecological RA cannot adequately address these uncertainties in the final hazard (or risk) estimates.

EPA Question 9

How reasonable is the air-to-plant-to-animal pathway model for assessing risks from the consumption of food products derived from beef and dairy cattle? and for assessing risks from free-range produced chickens and eggs?

Reviewer's Response

The relative advantages/disadvantages of using air-to-plant-animal pathway model for assessing risks from consumption of beef and dairy products are essentially similar to those described in response to EPA Questions 7 and 8.

With the growing importance of indirect exposure pathways (dietary exposure) in RA, use of air-to-plant-animal food chain models are gaining increasing recognition. Air-to-plant-to-animal pathway models have been described in published literature for dioxin and related compound. For example, Lorber et al (1994) reported development and validation of a air-to-beef food chain model for dioxin-like compounds used in a combination of congener-specific BCF and assumptions on exposure pathways. The model-predicted value of 0.36 ng/kg compared favorably with observed concentrations of dioxin TEQ in whole beef (0.48 ng/kg). Moreover, the model attributed 80% of the final beef concentrations of dioxin-like compounds to vapor-phase transfers to vegetation that cattle consume. This example illustrate the relative merits of using air-to-plant-to-animal food chain models in dioxin RA.

Data gaps on contaminant-, media-, and receptor-specific transfer coefficients and other model-related uncertainties introduce significant ambiguities in this indirect approach:

! The validity of model-predicted air-to-plant-to-animal values of contaminants largely depend on the reliability of various transfer coefficients used by the model algorithms. Since contaminant and biotic receptor-specific values are not available for most cases, models have resorted to default values which forms a major source of model-related uncertainty. For example, Lorber et al (1994) paper pointed out the importance of vapor-

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phase dioxin deposition on dioxin values in beef samples. Although this information is a further refinement of the exposure assessment process, its final impact on risk numbers may not be significant as long simplistic EPA-recommended default transfer coefficients are used in RA.

- Researchers have pointed out the importance of dioxin deposition on forage-to-cattle-to-beef pathways (Fries and Paustenbach, 1990). It is not clear as to what an extent EPA RA has considered dioxin deposition on forage in the food chain pathway models?

- Data gaps on transfer coefficients and model-related uncertainties built into the food chain model propagate through the entire RA process introducing large uncertainties in the risk estimates. The relatively primitive approach adopted in the ecological RA cannot adequately address these uncertainties in the final hazard (or risk) estimates.

EPA Question 10

Dioxin exposure from background sources normally exceed those estimated as due to exposure to incinerator emissions. What are the uncertainties here? How confident can be Agency be that its risk assessment has accounted for the major pathways of exposures from the incinerator source? Are there alternate approaches that the Agency should consider in assessing total exposure and risk from such sources?

Reviewer's Response

In the case of chronic exposures to contaminants, which is the goal of a RA exercise, differences between the background and source-specific sources for persistent chemicals require additional considerations for three reasons.

First, risk estimates under all the proposed alternatives for all HWCFs in the EPA RA are above the baseline levels for several categories of exposed population. It is not clear if baseline assessment actually refers to background levels. However, from a RI/FS perspective these are not the same. Whereas "background" refers to risks from sources other than those attributable to a contaminated site, "baseline" refers to background plus those risks attributable to a contaminated site but prior to remedial action(s). Therefore, what does the "baseline" numbers represent in the EPA RA? If they are based on test run data, then what we have is a comparison between unmitigated baseline (test run data) and mitigated (MACT floor etc.) scenarios. If that is the case, then risk estimates for the proposed floor are higher than those for baseline data, although risks for proposed BTF and alternate floors are lower than the baseline values. This requires additional clarification (Table 1).

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Second, persistent contaminants such as dioxins, DDT, PCBs, and mercury, biomagnify in the environment. The unique physicochemical characteristics (lipophilicity, relative stability) and ease of biotransformation (methylation of mercury) enable these chemicals to remain unaltered in the biotic receptor, accumulate due to continuous exposure from ubiquitous sources, and biomagnify due to food chain pathways. Humans, whether subsistent or typical exposure categories (as defined in the EPA RA), are exposed to source(s) with biomagnified levels of contaminant.

Even if the food chain and terrestrial models succeed in simulating transfer rates and contaminant levels in the biotic receptors, it is difficult to predict bioaccumulation and biomagnification in terrestrial ecosystems. Our analysis of the EFPC data indicated that whereas PCB levels were below the detection levels in the aquatic samples, fish samples collected from the same creek demonstrated very high levels of several congeners of PCBs. A simple aquatic model for water-to-fish failed to predict the observed levels of PCB residues. Since most of the PCB residue in the fish samples came from the food chain pathways, a larger and more comprehensive analysis of the ecosystem was required to identify the trajectory of PCB mobility at the study location.
Third, a higher level in background exposure compared to risks from exposure to incinerator emission alone is not a surprise for the reason cited earlier. Since dioxins like mercury and PCBs bioaccumulate in the environment, the biotic receptors progressively accumulate these contaminants and integrate larger populations separated by great distances into a higher risk level. Therefore, higher background risk levels does not automatically mean that the facility is safe. Persistent contaminants are an exception to that sort of analysis.

Moreover, biomagnification of contaminants may produce cumulative toxic effects. And in that case, it is desirable to minimize exposure to cumulative toxicants such as dioxins, whether it is from the HWCF emissions, or from other background sources.

EPA Question 11

How successful has the Agency been in describing the potential benefits of controlling mercury emissions, as outlined in Part Seven of the preamble to the proposed rule? The Agency developed a qualitative approach for imposing controls on mercury emissions. How successful the Agency has been in describing the benefits of this approach (as it is in part seven of the preamble to the proposed rule)?

Reviewer's Response

Section 4b of the Regulatory Impact Analysis (Part 7) of the proposed rule describe potential public health and ecological benefits of mercury level's reductions in the proposed rule. The discussion under section 4b on mercury benefits outlines the Agency's bases for estimating the

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hazard quotient, a qualitative noncarcinogenic endpoint used in EPA RA for noncarcinogenic chemicals.

As a noncarcinogen, mercury RA is based on hazard quotient values for various routes of exposures and a combined hazard, defined as hazard index (HI), for all the potential exposure pathways. There are some inconsistencies in the section 4b that require additional clarification:

! Section 4b state that mercury's oral reference dose (RfD) as 1E-4 mg/kg-day. According to the Agency's Integrated Risk Information System (IRIS), the standard source for toxicological parameters for regulatory RA, there is no oral RfD for metallic mercury (page 514). However, a oral RfD of 3E-04 mg/kg-day for inorganic mercury ($HgCl_2$) is available in the IRIS. This value is based on a rat study (endpoint: glomerular nephritis). This value is actually under review. So it is not clear as to from where the Agency obtained a new oral RfD of 1E-4 mg/kg-day for mercury?

! The oral RfD of 1E-4 mg/kg-day is based on a human study (Iraqi study) with developmental neurological abnormalities as the end point (page 514). It is not clear in the EPA RA as to how developmental effects, a toxic end point that the Agency treats as a unique end point and outside of systemic effects, was actually used here to derive a RfD for general systemic effects?

! The Agency definition of bioaccumulation as "ratio of the total mercury concentration in fish tissue to the total concentration in filtered water (page 513-514)" is more accurately a definition for bioconcentration factor. Bioaccumulation refers more to the ratio of the total mercury residue levels of a representative ecosystem member compared to its concentration(s) in the lower members of the food chain. This is particularly an important distinction for mercury because its concentrations in fish almost always high even in instances where its levels in water are below detection limits.

In dealing with the environmental toxicity of mercury, we are confronted with two fundamental problems. First, the volatility of mercury compounds. Volatility of mercury makes it a somewhat unique environmental toxicant. Mercury deposited on land re-vaporize fairly rapidly which is partially enhanced in areas heated by sun light.

Second, the potential ecological threat of mercury due to its mobility in the environment and bioaccumulation in the wildlife. In particular, conversion of metallic mercury to complexed species and biotransformation by bacteria into short-chain alkyl mercury compounds.

Field investigations have indicated that the tissue concentrations of mercury are higher in terrestrial mammalian samples collected from areas contaminated with mercury as compared with those from background population. Among the terrestrial animals, carnivorous species

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bioaccumulate higher levels of mercury (Methylmercury) than herbivorous species. This relationship is likely to apply to human exposures to mercury as well.

Several ecotoxicological studies have indicated a poor correlation between soil concentrations and tissue levels of mercury. However, a good correlation exists between relative distribution of mercury in the ecosystem population connected by food-chain. Our studies at the EFPC indicated that mercury bioaccumulation is a selective process, primarily through food chain pathways. These uncertainties create considerable difficulties in mercury RA.

Tissue concentrations are less meaningful if considered without additional information on the intricate balance of food-chain in the ecosystem population. General information on the ecosystem population and their inter-relationships in the food chain is a crucial factor in the interpretation of ecotoxicological data, for this information will form the basis for establishing protective environmental concentrations.

The qualitative approach described under Section 4b is actually the Agency's approach for performing RA for noncarcinogenic chemicals. There are several problems with the use of HI as a surrogate risk indicator:

! The hazard quotient approach for noncancer risk assessment does not consider the dose-response characteristics of the toxicant. Since RfD is based on doses that correspond to the lowest-observed-adverse effect- (LOAEL), or no-observed-adverse effect levels (NOAEL), the responses at higher dose exposures are not available for risk characterization.

! Hazard quotient approach poses serious limitations on the risk management decision process. The cut-off approach does not provide the risk managers with information on the nature and extent of risk in borderline exposure scenarios that yield hazard quotients marginally above Agency's acceptable levels of 1.

! Derivation of RfD involve identification of effects described as systemic. Unlike carcinogens, the dose-response of noncarcinogenic chemicals have a threshold, a level below which there are no adverse effects. Although some researchers claim that a threshold dose exists even for carcinogens, for RA purposes it is assumed that there is no threshold dose for a carcinogen. So far, it is not clear as to how the problem of threshold effect is addressed in the definition of adverse effects for noncarcinogens.

These issues require a separate and more extended discussion (as an attachment) to the rule and included with other documents in the public docket.

EPA Question 12

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Agency recognizes the need to expand the discussion on uncertainties. What uncertainties, limitations, and key assumptions are important to be highlighted and what types of supporting information are needed?

Reviewer's Response

The Agency has described the uncertainties and limitations associated with the EPA RA in Section IVC of the RA document (pages 153-165). The discussion is in considerable detail and most of it is of a descriptive nature that is normally found as a standard attachment in most RA documents. Although a standard "add-on" section on uncertainty analysis might make RA reports appear more complete, its of very little value if none of those uncertainties were addressed at least in some way in the RA. For instance, the Agency has recognized the limitations of using a highly conservative set of assumptions in the definition of a "maximally exposed individual." But EPA RA has used most of the default exposure assumptions that are regarded as conservative.

There is substantial scientific literature on the importance of using a probability density function (PDF) instead of a single point estimate of cancer risk (or hazard quotient). Nonetheless, EPA RA has resorted to point-risk estimates. The Agency must make an effort to introduce PDF approach for performing RA.

Multimedia exposure to ubiquitous contaminants such as dioxins, mercury, etc., will continue to be a major area of uncertainty in the RA of HWCF sites. These persistent contaminants travel long distances, remain stable for extended periods, and bioaccumulate in the ecosystem. Therefore, population exposure to these classes of contaminants are bound to increase with time, irrespective of whether a known source of pollution (such as a HWCF facility) is mitigated or not.

Cumulative toxicity will have an overall impact on the exposed population, the nature and extent of extent of which is yet to be discerned at this time. However, sensitive human sub-populations and ecosystem species may demonstrate serious adverse effects due to cumulative toxic effects. The cumulative impact of all sources of dioxins in the environment including HWCF is a major source of uncertainty that is yet to be captured in an algorithm for inclusion in RA.

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Reviewer: Venkat Rao, Ph.D. **Date: March 12, 1996**

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June 6, 1996

MEMO TO: Joe Van Gieson, SAIC

FROM: Jim Wilson

SUBJECT: Comments on EPA risk assessment / draft Proposed Rule

The following comments are sent pursuant to an agreement between SAIC and Resources for the Future regarding a peer review of certain EPA documents. Some overall and summary comments will be followed by comments addressing the nine issues raised by EPA.

GENERAL AND SUMMARY COMMENTS

Risk assessments are done to inform decisions. The introductory section of the risk assessment document should always include a description of the decision it is intended to support, and, whenever possible, a summary of the decision alternatives being considered. In this case, it was not clear if the intent of the document was to have been a comparison about the relative risk reduction offered by the two decision options, or a judgment that one or both meets the safety standards required in RCRA, or something else.

In most respects this risk assessment presents a very good example of standard EPA contractor practice. Aside from the discussion of uncertainties, that part of the assessment done by the contractor is quite workmanlike. The criticisms that might be offered are minor.

However, problems arise with the treatment of assumptions and of the use of the "Reference Dose" (RfD), "Risk-specific Dose" (RsD), and related administrative measures.

The RfD and similar measures represent exposures that can be considered safe. Exposure at the RfD, for a lifetime, is judged to pose no or a negligible risk to those so exposed. The product of an RFD and an estimate of exposure thus does not produce a "risk" or predicted incidence of injury. EPA has defined the risk at the RFD as zero, so this product is identically zero. One can conclude, based on the product of an exposure times an RfD or RsD, that the exposure poses no risk

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and thus conclude that no further action is required. One cannot conclude that further reduction in exposure reduces risk.

This conclusion holds even more strongly for the Hazard Index (HI) and the related “Toxicity Equivalent Quantity” (TEQ). If these sums equal zero or the “negligible risk” level, then it is appropriate to conclude that no further risk management is warranted. If these sums exceed zero/negligible risk, all that can be concluded is that further analysis is necessary.

Note that EPA’s policy statement on use of TEQs states quite clearly that this tool is only to be used as a “worst case” or “upper bound” screen, to separate cases where no action is necessary from those in which further analysis is required before reaching conclusions. (*Cf.* D. Barnes, F. Kutz, D. Bottimore, D. Grant, H. Greim, J. D. Wilson, and E. Bretthauer, "International Toxicity Equivalency Factors (I-TEFs) method of risk assessment for complex mixtures of dioxins and related compounds", *in* E. Bretthauer, H. Krauss, and A. di Domenico, Eds., *Dioxin Perspectives: A Pilot Study on International Information Exchange on Dioxin and Related Compounds*. New York: Plenum Press (NATO Challenges of Modern Society series) Vol. 16, 1991, pp. 97-122.)

Note also that the assessment does not follow EPA’s policy on risk characterization. An adequate risk characterization will describe the consequences of choosing alternatives to key assumptions; this was not done. (The instructions from EPA suggest that they are aware of this deficiency.)

Some specific comments regarding hydrogen chloride:

1. The report evinces more than a passing amount of confusion about this substance that galls any chemist. In the vapor phase HCl exists as the molecular form properly referred to as “hydrogen chloride”. In solution in water it ionizes completely, and is properly referred to as “hydrochloric acid”. The properties of the one are not those of the other. Emitted from the facilities subject to this report is the vapor form, so the relevant health effects summary should be addressed to this form. Thus the description of the manufacture and use of its aqueous solution seems quite irrelevant. (I note that the EPA documents quoted refer to “hydrogen chloride”.)

2. The toxicology of hydrogen chloride is well understood; for instance, the mean lethal concentration in air is almost the same as hydrogen cyanide, and the toxic effects are precisely those to be expected from a strong acid condensing on tissues. Thus I find it exceedingly surprising that EPA reports “low confidence” in the *very* protective RfC that is quoted (p. 120).

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SPECIFIC ISSUES TO BE ADDRESSED*:*

1. *How useful is the case study approach in evaluating the protectiveness of the national emission standards?* The case study seems to have been successfully employed to show that the "floor" standards are adequately protective.

2. *How reasonable are the exposure scenarios employed and do they cover the appropriate range of exposures?* These scenarios are individually realistic; as they are employed, they give a false picture of the amount of exposure expected because they include no information by which one can judge the likelihood that any particular scenario will be realized. In addition, the uncertainty introduced by failing to indicate the likelihood of each scenario or the number of people likely to be exposed through each scenario was explicitly not addressed in the assessment, a gross failing.

3. *How appropriate is the use of toxicity equivalents for estimating cancer risks from dioxin-like compounds?* Toxicity equivalent factors are expressly not to be used to estimate risks. Their only scientifically valid use is to estimate an upper bound, and that is to be used only for screening purposes. This use as an estimator renders the estimate of risk invalid.

4. *How reasonable are the approaches used to estimate deposition?* These approaches will yield an estimate greater than actual in most cases, but the error thus introduced is small compared to the gross error introduced by using TEQ as an estimator of response. Note that the deposition rate may be in error because of the assumption that little or no TCDD, etc., deposits on the relative large mineral (fly ash) particles in the gas stream. It is known that such condensation occurs, and that a large fraction of the TCDD, etc., produced in fires reports to the mineral particulate fraction.

5. *How appropriate is the use of steady-state bioaccumulation factors?* Steady-state factors will overestimate actual field concentrations because almost no wild fish live long enough to come to equilibrium. Thus this method suffices for a worst-case estimate but not an average-case estimate. Overestimation also occurs because of the assumption that TCDD, etc., are not tightly bound to mineral particles, as noted above.

6. *How reasonable are the terrestrial food-chain models?* I have limited experience with these models; based on that experience, I would consider them reasonable as models..

7. *Have the models successfully accounted for exposure from the incinerator sources?* Yes. No further analysis of potential sources is needed. In fact, because the analysis assumes that dioxin-like compounds are present in the vapor phase as pure particles, instead of being adsorbed onto larger particulates, the present analysis overstates actual exposure.

8. *How successful has the Agency been in describing benefits from reducing mercury emissions?* The Agency has successfully shown that reductions beyond the floor do not lead to a significant reduction in mercury exposures: the reduction is almost certainly smaller than the uncertainty in

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the estimate of total mercury intake from all sources, so it is insignificant by definition. However, the Preamble makes no case that the mercury emissions pose a threat to human health at any level. If "success" is to be judged by the persuasiveness of this argument, it fails completely.

9. *What uncertainties, limitations, and key assumptions need to be discussed in the risk characterization?* The revised characterization need address only those uncertainties and assumptions that are material to the conclusions drawn by the risk assessment. Two dominate:

- TEQ's predict response. The TEQ methodology was devised as a means of identifying safe emission situations so that further regulation or analysis was not needed and these could be dropped out of regulatory schemes. The technical basis for this assertion follows: First, the system is based on an activity of the type substance, 2,3,7,8-TCDD, that represents the safe exposure level. Thus, as noted above, the product of any TEF and an exposure does not represent risk. Second, because TEFs of various dioxin-like compounds are derived from median-response ratios, predictions at very small levels of response -- near what would be considered safe -- are not predicted. (Because not all dose-response curves are strictly parallel, the ratios that hold near the median response do not hold away from the median, and thus at low exposures the TEFs are not predictive.) The report states specifically (p. 157) that the uncertainties introduced through use of this assumption will not be addressed; this is unacceptable.

- The exposure scenarios labeled "central tendency" actually represent such exposures. The calculations include numerous standard "exposure factors" many of which do not represent the central tendency of the normal human variance, and other assumptions that are far from the median. Examples:
  - inhalation rate equals 20 m^3 /d for all adults;
  - fishermen eat 0.1 g dirt per day;
  - a child ingests 14 g/d of home-produced vegetables and fruits;
  - all the dioxin-like substances are emitted as pure particles and are thus readily available to be ingested and biomagnified;
  - RfDs represent the median toxic response.

The report states that EPA's "Exposure Factors" are assumed to be exact, and any uncertainty deriving from this assumption will not be addressed (p. 164). It appears nowhere to contemplate or recognize the true nature of RfDs and related measures of safe exposure. These are treated as though they represent measures of toxicity rather than identifying exposures that are considered to present no or negligible risk. It also appears not to recognize the assumption that TCDD and related substances exit from stack gas streams as vapor and condense into essentially pure particles before deposition. This forms the basis for assuming that all dioxins emitted are available for uptake by cattle, chicken, etc., and thus are ingested. There exists evidence that a large fraction of these substances condense onto mineral substrates (fly ash), from which they only very slowly desorb in aqueous media. The

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uncertainty and exaggeration introduced by assuming, incorrectly, that all of these represent central tendencies needs very much to be addressed.

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