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U.S. EPA Response to Comments on the Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities (EPA530-D-98-001A, July 1998)

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DISCLAIMER

This document provides U.S. EPA responses to peer and public comments received on the Peer Review Draft of the Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities (HHRAP, July 1988). This *Response to Comments* Document includes summaries of public comments received on the HHRAP and EPA responses to the summary comments. Since the comments have been summarized, some individual comments may be not be explicitly visible and should not be taken as being intentionally ignored by EPA. However, all individual public and peer comments received were considered in finalizing the HHRAP.

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ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADI	Average Daily Intake
AEFA	Average Emission Factor Approach
AEGL	Acute Exposure Guideline Level
AIEC	Acute inhalation exposure criteria
ATEL	Acute Toxicity Exposure Levels
BAF	Bioaccumulation Factor
BaP	Benzo(a)pyrene
BEHP	Bis (2-ethylhexyl) phthalate
BIF	Boiler and industrial furnace
BSAF	Biota Sediment Accumulation Factor
BTEX	Benzene, Toluene, Ethyl benzene, Xylene
CAA	Clean Air Act
CARB	California Air Resources Board
CCC	Chlorine Chemistry Council
CCSE	Center of Combustion Science and Engineering
CFR	Code of Federal Regulations
CKD	Cement kiln dust
COPC	Compounds of Potential Concern
CRQL/CRDL	Contract required quantitation limit / Contract required detection limit
CRWI	Coalition for Responsible Waste Incineration
CSF	Cancer Slope Factor
DNOP	Di (n) octyl phthalate
DOE	U.S. Department of Energy
DRE	Destruction and removal efficiency
EDL	Estimated Detection Level
EMPC	Estimated Maximum Possible Concentration
EPA	Environmental protection agency
EPACA	US EPA Correlation Approach
ER	Sediment Enrichment Ratio
ERPG	Emergency Response Planning Guide
GAQM	Guide for Air Quality Management
GC	Gas Chromatograph
GRAV	Unspeciated gravimetric compounds
HCL/CL	Hydrogen Chloride and Chlorine Gas
HEAST	Health Effects Assessment Summary Tables
HEPA	High Energy Particulate Air
HHRAP	Human Health Risk Assessment Protocol
HQ	Hazard Quotient
HWIR	Hazardous Waste Identification Rule
IDL	Instrument Detection Limit

IEUBK	Integrated Exposure Uptake Biokinetic Model
ISCST3	Industrial Source Complex Short-Term Model
LDAR	Leak Detection and Repair
MACT	Maximum Available Control Technology
MACT	Maximum Available Control Technology
MDL	Method Detection Limit
MF	Metabolism Factor
MPRM	Meteorological processor for regulatory models
MS	Mass Spectrometry
NAAQS	National Ambient Air Quality Standards
NCEA	National Center for Environmental Assessment
ND	Non-Detect
NESHAPS	National Emissions Standards for Hazardous Waste Air Pollutants
NIOSH	National Institute of Occupational Safety and Health
OAQPS	Office of Air Quality Planning and Standards
OCDD	Octa Chloro Dibenzo Dioxin
OEHHA	Office of Environmental Health Hazard Assessments
ORD	Office of Research and Development
OSHA	U.S. Occupational Safety and Health Administration
OSW	Office of Solid Waste Management
PAH	Polynuclear aromatic hydrocarbon
PCBs	Polychlorinated Biphenyls
PCDD	Polychlorinated dibenzo(p)dioxin
PCDF	Polychlorinated dibenzofuran
PCRAMMET	Personal computer version of the meteorological preprocessor for the old RAM program
PIC	Product of Incomplete Combustion
POHC	Principal organic hazardous constituent
PSD	Particle Size Distribution
QC	Quality Control
RC	(this) Response to Comments (document)
RCRA	Resource Conservation and Recovery Act
RDL	Reliable Detection Level
REL	California EPA Air Toxics Hot Spots Program acute reference exposure levels
RLIS	Runoff Loading from Impervious Surfaces
RME	Reasonable maximum exposure
RP	Relative potency
RPF	Relative Potency Factor
SAB	EPA's Science Advisory Board
SCAPA	Subcommittee on Consequence Assessment and Protective Actions
SCDM	Superfund Chemical Data Matrix
SQL	Sample quantitation limit
SRA	Screening Ranges Approach
TB	Trial Burn
TCDD	Tetrachlorodibenzo(p)dioxin

TEEL	Temporary Emergency Exposure Limit
TEFs	Toxicity Equivalency Factors
TEQ	Toxicity equivalent quotient
TIC	Tentatively identified compound
TNRCC	Texas Natural Resource Conservation Commission (now TCEQ; Texas Commission of Environmental Quality)
TOE	Total Organic Emission
TRIM	Total Risk Integrated Methodology
TSS	Total Suspended Solids
UCL	Upper Confidence Level
URF	Unit Risk Factors
USLE	Universal Soil Loss Equation
USGS	United States Geological Survey
UTM	Universal transverse mercator
VOC	Volatile organic compound
WHO	World Health Organization
WTI	Waste Technologies Industries

VARIABLES

B	Biotransfer factor
Ba	Bioavailability factor
Ca	Air Concentration
Cyv	Unitized yearly average concentration from vapor phase
Ds	Deposition term
Dydw	Unitized yearly average wet deposition (s/m^2-yr)
Dydp	Unitized yearly wet deposition from particle phase (s/m^2-yr)
Dywwv	Unitized yearly (water body and watershed) average wet deposition from vapor phase (s/m^2-yr)
Dytwp	Unitized yearly (water body and watershed) average total (wet and dry) deposition from vapor phase (s/m^2-yr)
Fv	Fraction in vapor phase
kb	Benthic burial rate constant
K_{ow}	Octanol – water partition coefficient (mg COPC/L Octanol)
kp	Plant surface loss coefficient (yr^{-1})
ks	Soil loss constant
kse	COPC loss constant due to soil erosion (yr^{-1})
ksg value	COPC loss constant due to biotic and abiotic degradation (yr^{-1})
kwt	water body dissipation rate
L_{dif}	diffusion load to water body
Pd	Direct Deposition
Q	COPC emission rate (g/s)
RfC	Reference Concentration
RfD	Reference dose
Rp	Relative potency
TOC_{VOC}	Stack concentration of volatile TOC, including speciated and unspeciated compounds (mg/m^3)
VG_{ag}	Empirical correction factor for aboveground produce (forage and silage) (unitless)
$VG_{rootveg}$	Empirical correction factor for root vegetable (unitless)
V_p	Vapor Pressure
X_e	Unit soil loss (kg/m^2 - yr)

1.0 INTRODUCTION

In the September 30, 1999, preamble to the proposed Maximum Achievable Control Technology (MACT) rule, the U.S. Environmental Protection Agency (EPA) recommended that site-specific risk assessments be conducted as part of the Resource Conservation and Recovery Act (RCRA) permitting process for hazardous waste combustion facilities as necessary to protect human health and the environment. Often, the determination of whether or not a permit is sufficiently protective can be based on its conformance to the applicable technical standards specified in the regulations. However, since the time the regulations for hazardous waste incinerators (1981, 40 CFR Part 264, Subpart O) and boilers/industrial furnaces (1991, 40 CFR Part 266, Subpart H) were issued, information has become available to suggest that these performance standards may not fully address potentially significant risks. In many cases, risks from indirect exposures may constitute the majority of the risk from a hazardous waste combustor. This key portion of the risk from hazardous waste combustion emissions was not appropriately taken into account when the hazardous waste combustion standards were developed. In addition, uncertainty remains regarding the types and quantities of non-dioxin products of incomplete combustion (PICs) emitted from combustion units and the risks posed by these compounds.

The RCRA "omnibus" authority of §3005(c)(3) of RCRA, 42 U.S.C. §6925(c)(3) and 40 C.F.R.§270.32(b)(2) gives the U.S. EPA both the authority and the responsibility to establish permit conditions on a case-by-case basis as necessary to protect human health and the environment. Performance of a site-specific risk assessment can provide the information necessary to determine what, if any, additional permit conditions are necessary for each situation to ensure that operation of the combustion unit is protective of human health and the environment. Under 40 C.F.R. §270.10(k), the RCRA permitting authority may require a permit applicant to submit additional information (e.g., waste feed analysis, emissions data, operating parameters) that U.S. EPA needs to establish permit conditions under the omnibus authority. In certain cases, U.S. EPA may also seek additional testing or data under the authority of RCRA §3013 (where the presence or release of a hazardous waste "may present a substantial hazard to human health or the environment") and may issue an order requiring the facility to conduct monitoring, testing, analysis, and reporting. Any decision to add permit conditions based on a site-specific risk assessment under this authority must be justified in the administrative record for each facility, and the implementing agency should explain the basis for the conditions.

We developed the "Human Health Risk Assessment Protocol (HHRAP) for Hazardous Waste Combustion Facilities" to explain how we recommend performing risk assessments of hazardous waste combustion facilities. The HHRAP is intended as the guidance for personnel conducting risk assessments, and an information resource for permit writers, risk managers, and community relations personnel. The HHRAP supports the U.S. EPA Office of Solid Waste (OSW) mission to provide permitting authorities for hazardous waste combustion facilities with state-of-the-art methodology in predicting the risk associated with human exposure to compounds found in the air, soil, and water. The document also provides guidance to risk assessors dealing with direct and indirect exposure from contaminants emitted from stationary combustion sources. The HHRAP has been developed as national

guidance to consolidate information presented in other risk assessment guidance and methodology documents previously prepared by U.S. EPA and state environmental agencies. In addition, the HHRAP addresses issues that have been identified while conducting risk assessments for existing hazardous waste combustion units. This U.S. EPA Response to Comments Document contains Agency responses to public and expert peer reviewer comments received on the Peer Review Draft of the HHRAP (U.S. EPA, 1998a, EPA530-D-98-001).

1.1 BACKGROUND

U.S. EPA Region 6 developed the Peer Review Draft HHRAP (U.S. EPA, 1998a, EPA530-D-98-001) document for the Center of Combustion Science and Engineering (CCSE) in coordination with the Office of Solid Waste. The foundation for the procedures and methodologies outlined in the HHRAP were first developed by the Office of Research and Development (ORD) and the Office of Solid Waste in previous versions of combustion risk assessment guidance. The State of North Carolina's combustion risk assessment methodology was also evaluated in preparation of the HHRAP. The interim final draft version of the HHRAP, published in July 1998, was originally initiated in response to the desire of the Region 6 Multimedia Planning and Permitting Division to implement an up-to-date and technically sound hazardous waste combustion permitting program. The decision to incorporate guidance on a full range of national combustion risk assessment issues into the HHRAP was encouraged and supported by the Director of the Office of Solid Waste.

1.2 PUBLIC COMMENT AND PEER REVIEW

Draft versions of the HHRAP underwent extensive internal peer review by U.S. EPA and state personnel. A list of these reviewers can be found in Appendix A. An open public comment period followed the internal review. In October 1998, EPA's Office of Solid Waste issued a *Federal Register* Notice of Availability and Request for Comment on the HHRAP (FR 10/30/1998, Volume 63, Number 210). Twenty-eight commenters, including individual businesses, federal and state agencies, universities, environmental and public interest groups, and trade associations, submitted about 600 individual comments on the HHRAP. A list of the public commenters can be found in Appendix A. All public comments were organized by topic and then summarized into individual issues for U.S. EPA to address. These issues and associated U.S. EPA responses are contained in Section 2 of this Response to Comments document.

U.S. EPA determined that the HHRAP is a "major scientific and technical work product" and thus, the Office of Solid Waste requested the HHRAP undergo an independent, external peer review. The peer review was conducted according to U.S. EPA's Peer Review Guidance document (1998b, EPA 100-B-98-001). Based on public comments received, U.S. EPA identified 30 major issues raised by the public that required technical input and opinion from external peer reviewers to address. A total of nine scientists familiar with issues associated with multi-source, multi-pathway risk assessments for hazardous waste combustion facilities were selected to address the major issues. A list of these peer reviewers can be found in Appendix A. The 30 major issues were provided to the external peer review panel members,

according to their five areas of expertise. These areas of expertise included combustion engineering, atmospheric modeling, human health toxicology, human health exposure, and chemical fate and transport. The peer review panel first responded to the 30 major issues in writing. The written comments demonstrated a consensus among the panel members on 13 of the major issues. The peer review panel members' responses to these 13 major issues have been summarized in Section 3.1 of this Response to Comments document. The remaining 17 issues required further discussion among the panel members to reach consensus. Therefore, a peer review workshop, which included limited public participation, was held to address these 17 major issues. The workshop was held in Dallas, TX on May 24 and 25, 2000. Summarized in Sections 3.2 through 3.5 of this Response to Comments document are the consensus opinions of the peer reviewers on the 17 major issues discussed during the workshop.

In addition to addressing the 30 major issues given to the external peer review panel, the panel members were also invited by EPA to provide any other comments they wished to make regarding any part of the Peer Review Draft HHRAP (1998a, EPA530-D-98-001), hereafter referred to as the draft HHRAP. Each of the panel members provided individual comments directed at specific sections of the draft HHRAP. These individual panel member comments have been summarized and incorporated with the public comments under the appropriate topical areas in Section 2 of this Response to Comments document.

Based on input from the public and external peer reviewers, U.S. EPA has revised and finalized the HHRAP.

1.3 REPORT ORGANIZATION

This Response to Comments document has been organized into four major sections:

- **Section 1** is an introduction with a brief overview of the comment/response process that U.S. EPA followed in finalizing the HHRAP.
- **Section 2** contains summaries of written public comments received on the draft HHRAP. Section 2 also incorporates summaries of written comments, specific to particular sections of the draft HHRAP, received from individual external peer reviewers.
- **Section 3** contains summaries of the external peer reviewers' responses to the 30 major issues raised by the public and requiring expert technical input. These summaries derived from the written comments and the peer review workshop discussion.
- **Section 4** contains references cited in this Response to Comments document.

Appendix A contains the names of the reviewers of the draft HHRAP, representing federal and state agencies, the public, and the external peer review panel.

2.0 SUMMARY OF PUBLIC AND INDIVIDUAL PEER COMMENTS

Throughout Section 2 of this Response to Comments (RC) document, we have mapped the public comments to the applicable sections of the draft HHRAP. Where appropriate, we have also mapped the public comments to one or more of the 30 major issues given to the external peer review panel to address.

In Section 2, we have organized summaries of public comments into *subsections* according to Chapters 1 through 9 and Appendices A, B, and C of the draft HHRAP. Specific sections of the draft HHRAP chapters with which the public comments are generally associated are provided **[in brackets]**. The reader should note that these referenced sections from the draft HHRAP may not coincide with the same section numbers in the Final HHRAP due to revisions made to the draft HHRAP.

Under each *subsection* in Section 2, we have organized the public comment summaries by topical issues. Some of these public comments are specifically related to the 30 major issues given to the external peer review panel to address. For these particular public comments, we have provided **(in parentheses)** a reference to the location within Section 3 of this RC document where the reader can find that specific major issue addressed by the external peer reviewers.

In addition to summarizing the public comments in Section 2, we have also incorporated into Section 2 summaries of specific comments related to the draft HHRAP that were provided by individual peer reviewers, in addition to their responses to the 30 major issues they were given.

2.1 POLICY, OBJECTIVES, AND PURPOSE

Policy includes EPA's approach to the broad issues generally applicable to the HHRAP and implementation of the risk assessment process as a whole. A wide range of comments on broad issues was received. These issues were categorized as:

- General Policy;
- HHRAP Objectives; and
- Model and Chemical Data Validation.

2.1.1 Policy, Objectives, and Purpose - General Policy Issues

General policy issues raised by commenters included the:

- Application of the HHRAP as guidance, not as regulation;
- Purpose of the HHRAP for use by the regulated community;
- Focus of HHRAP;
- Authority of EPA to require risk assessments;

- Impacts of implementing the Maximum Achievable Control Technology (MACT) rule;
- Criteria to determine when risk assessments are necessary;
- EPA NCEA Guidance;
- Data reporting schedules;
- Use of Confidential Business Information;
- Application of risk offsets; and
- Inclusion of off-site sources in the risk assessment.

Issues: General Policy - Guidance versus Regulation
It was recommended that EPA should make it clear on a continuing basis suggestions in guidance documents cannot be 'rigidly' followed as if they are regulations.

EPA Response:
EPA's Office of Government Council has recommended changes that we've incorporated into HHRAP Chapter 1 to further enunciate that the HHRAP is guidance, not a regulation. We also reviewed the tone throughout the protocol. We modified the language where appropriate, to stress the function of the HHRAP as guidance, not regulation.

Issues: General Policy - Science Policy Decisions
The draft HHRAP reflects numerous policy decisions that were made in developing the risk assessment methodologies. It is difficult, if not impossible, to conduct a full technical review of the HHRAP without a consideration of the science policy decisions that have guided its development. Therefore, policy considerations and other risk management factors that affect the HHRAP methodologies should be explicitly identified and their relevance discussed.

EPA Response:
The HHRAP methodology is guidance and contains recommendations, not policy. Every effort was taken to document recommended methodology such that a guidance user could identify and modify where appropriate recommended methods.

Issue: General Policy - Purpose of the HHRAP for Use by the Regulated Community
It was recommended that the stated purpose of the HHRAP should explicitly include use by the regulated community because the document will be used by many facilities. Inclusion of the regulated community gives EPA an opportunity to explain and justify conservative assumptions and reduce the perception of an overly conservative risk assessment process, which could well have severe repercussions to that group. Additionally, at several points in the draft HHRAP, the phrase "Agency consensus" was used. This entire process would work more effectively if the consensus could be widened to include the regulated community.

It was recommended that HHRAP Chapter 1 Introduction discuss the applicability of the HHRAP to other types of combustion facilities and clearly spell out the caveats about the relevance of using the HHRAP guidance for risk assessments of other combustion facilities. The draft HHRAP clearly states it is intended for use in evaluating hazardous waste combustors. However, it is obvious that the methodology

can and probably will be used at other facilities, such as medical waste incinerators, waste-to-energy plants, etc.

EPA Response:
Comment noted. The stated target audience for the HHRAP includes risk assessors and risk managers, without specifying the various groups to which these individuals are affiliated. Risk assessors might be employed by the permitting authority, but might also work for the facility, or a contractor hired by the facility or interested community organization. The External Peer Review process is implemented to widen consensus to include the regulated community. The words "Agency consensus" are no longer used in the HHRAP.

It is gratifying that both the regulating and regulated communities consider the HHRAP methodology so valuable as to apply it beyond its intended purpose. However, discussing the use of the HHRAP beyond its stated purpose is beyond the scope of this document. Possible expansion of the scope will have to wait for future additions of the Protocol.

Issue: General Policy - Focus of the HHRAP
It was suggested that in the draft HHRAP Chapter 1, Introduction, the first sentence presents a misleading message about what a risk assessment is and what it does. While risk assessment is a type of science, it is a "tool" used to evaluate health impact. It is not, as stated, "a science used to evaluate..." Also, the sentence erroneously implies that a risk assessment is only used to evaluate health impacts from exposure to emissions from hazardous waste combustion facilities. It was recommended that the sentence should clarify the issues indicated above.

It was also noted that on page 1-1, sentence 5 of the Introduction makes an important distinction between the relative focus of the HHRAP on direct inhalation risk versus risk through indirect pathways. This sentence should be clarified and expanded because this is an important consideration. For example, why is the primary focus on indirect pathways?

EPA Response:
We've removed the referenced sentences. The definition for risk assessment in the HHRAP is adopted directly from the National Academy of Sciences, "Risk Assessment in the Federal Government" (1983). A section has been added to Chapter 1 to more clearly state the use of the document.

Issue: General Policy - EPA and Permitting Authority
Commenters believed that EPA's authority to require risk assessments is limited by RCRA's omnibus provisions. EPA cannot make legally binding decisions based on the use of indirect exposure assessment. Also, the decision regarding whether population risk estimates should be considered is not one that rests with the permitting authority, but one that should be made by the applicant (draft HHRAP Chapter 7, page 7.2).

EPA Response:
A facility is not required by the guidance or by regulation to conduct a risk assessment. It is the permitting authority that is required to write operating permits that are protective of human health and

the environment. A risk assessment is one tool used by permit writers on a site-specific basis to ensure that permit conditions are protective of human health and the environment under the omnibus authority 40 CFR Section 270.32(b)(2). We are unaware of a method other than risk assessment to evaluate protectiveness. If site-specific conditions warrant evaluation of population risks to develop unit-specific permit conditions protective of human health and the environment, a risk assessment that considers population effects could be conducted. The permitting authority does not have the authority to require a facility to conduct such an assessment, but may conduct or contract out such a risk assessment if the facility chooses not to conduct its own.

Issue: General Policy - MACT Rule

It was suggested that it would be helpful if the HHRAP and the related EPA "Guidance on Collection of Emissions Data to Support Site-Specific Risk Assessments at Hazardous Waste Combustion Facilities" (U.S. EPA, 1998c) could address potential changes to trial burns, risk burns, and risk estimation activities that would allow performance testing required by the forthcoming Maximum Achievable Control Technology (MACT) rule for hazardous waste combustors to be coordinated with the collection of data for use in risk assessments. In particular, these changes could relate to the potential effects of installing carbon adsorption emissions control systems for mercury and dioxin/furan emissions and systems for improved particulate emissions control.

It was also recommended that decisions to require risk assessments should generally be deferred until after implementation of the MACT rule because with the lower emissions following MACT compliance, risk assessments should not be routinely required.

EPA Response:

The suggestion has been forwarded to the authors of the emissions data guidance. With regard to the recommendation, MACT standards are technology based and not risk-based. RCRA requires that permits for hazardous waste burning combustion units be protective of human health and the environment. We are unaware of a method other than risk assessment to evaluate protectiveness. The national risk assessment performed to initially evaluate the MACT standards did not conclude that the standards, when implemented, would be protective of human health and the environment for all units.

Issue: General Policy - Criteria for Implementing Risk Assessments

It was recommended that EPA provide further guidance on the circumstances under which a risk assessment does or does not need to be performed. Commenters did not agree that EPA's omnibus authority should be used to require risk assessments at all facilities, regardless of the demonstration of need. They recommended that EPA include on the list of criteria on draft HHRAP page. 1-3:

- Objective criteria only and not the level of public interest or community involvement.
- Whether the incremental emissions from burning hazardous waste are anticipated to increase risk from an industrial facility when compared to its baseline emissions from non-hazardous waste combustion.
- Risk assessments already completed should be used to identify the exceptional cases where risk assessments may be warranted. Specifically, there is a strong body of evidence that demonstrates

hazardous waste combustion cement kilns do not pose unacceptable risks to human health and the environment.

- Risk that is already controlled through stringent regulations limiting operations and/or emissions.
- A change in the wording of the second bullet: "several factors" to "whether the facility is known to exceed any final technical standards." Sometimes it may be difficult to determine "whether the facility is exceeding any final technical standards" unless the risk analysis is performed. The suggested wording more precisely indicates the intended purpose of this statement.

EPA Response:
Chapter 1 now states that the HHRAP does not determine when a site-specific risk assessment should be performed. U.S. EPA's most recent recommendations for when, or if, a site-specific risk assessment should be considered can be found in documentation of the MACT rule, published on September 30, 1999 Federal Register (U.S. EPA, 1999a).

Many pre-existing risk assessments were performed to support permitting under the BIF Rule. These risk assessments only addressed the inhalation exposure pathway. Since then, information has become available which suggests that evaluating the inhalation pathway alone would not necessarily lead to permit conditions protective of human health and the environment.

Issue: General Policy - EPA NCEA Guidance
It was recommended that discussion be added in the HHRAP about what connection there is between the HHRAP and the U.S. EPA NCEA guidance, Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustion Emissions, mentioned in Section 1.3. Should the NCEA methods and data be integrated into or coordinated with the approaches in the HHRAP? Section 1.3 should also include the "Risk Assessment for the Waste Technologies Industries (WTI) Hazardous Waste Incineration Facility (East Liverpool, Ohio)" (U.S. EPA, 1997a, EPA905-R97-002) as one of the reference documents used to prepare the HHRAP because it appears that much of the methodology was developed and/or applied in the WTI study.

In many places, the draft HHRAP states that the methodology derives from the U.S. EPA NCEA guidance document, but this document is not available for review. It was felt that it is inappropriate for EPA to refer to unpublished supporting documentation.

EPA Response:
The "Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions" (U.S. EPA, 1998d, EPA/600/R-98/137) also known as the "MPE" document, was published after the release of the draft HHRAP. The final version of the protocol discusses the relationship between the protocol and the MPE, as well as the WTI study.

Issue: General Policy - Reporting Schedules
It was noted that the draft HHRAP states "Monthly, quarterly, or annual reports which document long-term operations will likely be required of the facility." Since the permit conditions will likely be based on annual averages (e.g., mass feed limitations, temperature, or gas flow rates), it was suggested that reporting requirements should be no more frequent than the averaging time outlined in the permit.

EPA Response:
Comment noted. This should be worked out with the permitting authority.

Issue: General Policy - Confidential Business Information
It was suggested that language should be inserted into the text stating that only information that is not confidential business and that is relevant to the risk assessment should be included in the facility description.

EPA Response:
The HHRAP does not ask for confidential business information or data irrelevant to the risk assessment for compiling basic facility information.

Issue: General Policy - Risk Offsets
It was suggested that risk offsets should be recognized for displaced fuel combustion.

EPA Response:
The topic of risk offsets is beyond the scope of the HHRAP.

Issue: General Policy - Inclusion of Off-Site Sources
It was noted that the draft HHRAP describes the need to include all RCRA combustion and other RCRA units in the risk assessment, whether or not a particular unit is being permitted. It was recommended that the risk assessment conducted for a given facility should not be required to characterize risk from off-site sources (draft HHRAP Chapter 2, page 2-1).

EPA Response:
The HHRAP recommends that the permitting authority and the facility agree upon the units to be evaluated in the risk assessment. There is no requirement in the HHRAP to characterize risk from off-site sources. However, this might be considered on a site-specific basis by the permitting authority.

2.1.2 Policy, Objectives, and Purpose - HHRAP Objectives

Issues raised with regard to objectives stated in the HHRAP included:

- Meeting the Guidance Objectives;
- Figure 1.1;
- Flexibility;
- Completeness;
- Reasonableness;
- Efficient Use of Time and Resources;
- Implementation Practices; and
- Clarification / Editorial.

Issue: HHRAP Objectives - Meeting Guidance Objectives
Commenters believed that the draft HHRAP fails to meet its own primary objectives.

EPA Response:
We disagree. The HHRAP has been successfully implemented for numerous risk assessments. Although any process which requires integration of several technical disciplines (i.e. combustion engineering, air modeling, terrestrial fate and transport modeling, exposure assessment, toxicology) may be viewed as cumbersome and unreasonable, regional and state personnel have been implementing the guidance since the draft was released and have not found the guidance, with the exceptions brought out in the external peer review, particularly burdensome to use. Specifics of exceptions are addressed in our responses to technical comments.

Issue: HHRAP Objectives – Figure 1.1
With regard to draft HHRAP Figure 1.1, commenters:

- Thought it would be helpful for the uninitiated if there were a narrative description accompanying the flow diagram depicted in Figure 1-1 that would convey the type of information that flows between boxes and particularly the products of the Risk and Hazard Characterization step.
- Recommended adding a sentence to the end of the first full paragraph on draft HHRAP page 1-4, Section 1.1 to indicate "The organization of this document follows closely the process outlined in Figure 1-1."
- Suggested that sometimes the Exposure Scenario Selection may be based on the Estimation of Media Concentrations, especially considering site-specific characteristics. Would it be more appropriate to have the "Exposure Scenario Selection" box interweaved below that for "Estimation of Media Concentrations," or at least have data from "Estimation of Media Concentrations" feeding into "Exposure Scenario Selection"? There might be some concern that the Scenario Selection would exclusively drive the Media selections. This should be a two-way process.

EPA Response:
Figure 1.1 is meant as a graphical representation of the risk assessment process documented in the HHRAP. Each box in Figure 1.1 contains a reference to the sections in the HHRAP in which a detailed narrative can be found.

Issue: HHRAP Objectives - Flexibility
One commenter recommended more guidance be provided in draft HHRAP Section 1.1 to help in deciding if and how modifications to the protocol should be made. While he was generally in favor of retaining flexibility in the HHRAP for site-specific modifications, the flip side is that for a guidance document ("a set of user-friendly procedures for performing risk assessments"), much is left for the risk assessor to figure out.
Commenters were of the opinion that the HHRAP is portrayed as risk assessment guidance even though most of its information and algorithms reflect methodology once considered by EPA as only screening-level guidance. Moreover, the new guidance is structured differently than risk assessment guidance typically issued by EPA. Specifically:

- A tiered approach is not included.

- There is very limited allowance for site-specific information.
- Specified receptors are required regardless of whether they exist at a particular location.
- The methodology relies on correlation algorithms that are very poorly validated for the range of chemicals included in the guidance.

It was specifically recommended that EPA use a three-tiered risk assessment approach that includes a screening risk assessment to determine which sources are of potential concern, a second tier that is more detailed with site-specific data and is only required when the first tier indicates potential problems. The third tier would allow the use of probabilistic methods, such as Monte Carlo analysis, if the permittee desires to reduce the degree of conservatism to a more defined and reasonable level.

EPA Response:
The guidance was written to be flexible and can be applied to a continuum of tiers. There is full flexibility in the allowance for site-specific data. Nevertheless, we further modified the HHRAP to stress that site-specific data should always be preferred over default values provided in the guidance. For example, if detailed site-specific information is available up front for mercury fate and transport modeling, there is nothing to prevent this information from being used in the risk assessment. However, if site-specific information changes the end result from a hazard quotient of 0.001 to 0.000001, it may not make sense to spend the time and money to obtain this site-specific information. Specified receptors are recommended in the risk assessment evaluation, they are not required. It is our position that specified receptors should be assumed to be present until proven otherwise, rather than the other way around. We agree that some of the correlation algorithms are poorly validated for a few chemicals, and we are currently updating these correlations. However, algorithms in the guidance are based on the best available science currently available and except for a few instances, provide a reasonable estimate of exposure.

Issue: HHRAP Objectives - Reasonableness
It was suggested that the scope of the risk assessment should be limited to those pathways, which are significant, demonstrated, and scientifically defensible. Commenters believed that conducting risk assessments according to the HHRAP guidance would result in overly conservative estimates of risk. Some of the specific issues raised that contribute to this overly conservative approach include:

- Using default values instead of site-specific data in the risk assessment models;
- Applying worst-case values to default parameters used in the risk assessment models;
- The ineffectiveness of a screening-level tool that finds unacceptable risk based on emissions quantified at non-detect and laboratory contamination levels; and
- The compounding effect of using a combination of trial burn data, non-detects, a TOE adjustment, and RDLs, which will unnecessarily overestimate emission rates and associated risks.

The risk assessment approach of winnowing insignificant pathways has recently become the de facto scientific paradigm in recent EPA risk assessment guidance. For example, before initiating a risk assessment, most facilities first screen the site to identify high-risk chemicals of concern (COCs) and exposure pathways. The Presidential/Congressional Commission on Risk Assessment and Risk Management's reports, Framework for Environmental Health Risk Management and Risk Assessment (1997a) and Risk Management in Regulatory Decision-Making (1997b), strongly recommend this

approach to wisely use valuable resources, time, and effort to conduct a risk assessment. To conduct a risk assessment for every conceivable permutation of exposure just because computer spreadsheet software is available may be a waste of valuable resources and divert attention from truly protecting the public health.

A major problem with EPA's overall approach was cited to be the confusion about whether the purpose of this HHRAP is to produce a screening level or a realistic, site-specific risk assessment. Specifically, confusion arises from the apparent contradiction of statements on pages 1-6 and 5-89 in the draft HHRAP. Page 1-6 states that "the use of existing and site-specific information early in, and throughout, the risk assessment process is encouraged..." while page 5-89 states that "after completing a risk assessment based on the default parameter values recommended in this guidance, risk assessors may choose to investigate the use of site-specific parameter values..."

EPA Response:
Default values are presented in the guidance as a starting point. The use of site-specific data is always preferred over default assumptions. However, it is time consuming and expensive to obtain site-specific values for all parameters in the complicated fate and transport models. In addition, many default inputs can vary by several orders of magnitude and have little to no effect on the risk assessment results. We will continue to recommend use of site-specific inputs where practical and where these inputs could significantly affect results of the risk assessment. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option or other alternative to that recommended in the HHRAP. Although any process which requires integration of several technical disciplines (i.e. combustion engineering, air modeling, terrestrial fate and transport modeling, exposure assessment, toxicology) may be viewed as cumbersome and unreasonable, regional and state personnel have been implementing the guidance since the draft was released and have not found the guidance, with the exceptions brought out in the external peer review, particularly burdensome to use. Specifics of exceptions are addressed in our responses to technical comments. The statement in Section 5.8 has been changed to be consistent with the recommendation in Chapter 1.

Issue: HHRAP Objectives - Efficient Use of Time and Resources
Commenters believed that conducting a risk assessment according to the HHRAP guidance would result in an inefficient use of time and resources. Some of the issues they raised in this regard include:

- First requiring completion of calculations using the recommended default input parameters, then supplementing with site-specific information.
- The requirement for evaluation of all COPCs and pathways and inclusion of insignificant emission sources, such as fugitives, emergency stack openings, and waste feed cutoffs. The focus should be on areas that have real risks and a significant role in risk assessment calculations, rather than including the many areas that have minimal to no impact or only perceived risks.
- The level of assessment being described is difficult to justify with respect to actual risks. It is important to note that even the most extensive risk assessments performed are showing that there are very few constituents driving the risk assessment, even using worst case assumptions. Many

issues described in the draft HHRAP and recommended to be performed are costly, but are not relevant when put in perspective with the actual risks.

- The recommendation that risk be continually evaluated. The process, as described on draft HHRAP pages 1-7, 6-3, and 9-2, is seemingly iterative and never ending and filled with policy statements that suggest setting additional permit limits which overarch all other limits set by actual environmental regulations. The implication is that facility permits will become a moving target based on perceived risks, and facilities will be subjected to a resource intensive and costly risk assessment process.

EPA Response:
As guidance, the HHRAP requires nothing. Rather, it makes recommendations on how to perform and report a transparent, scientifically defensible human health risk assessment. Because the HHRAP provides default parameters, it is neither inefficient nor costly to evaluate them in the risk assessment. In fact, we believe that evaluating default values in the risk assessment will help focus where it makes sense to expend efforts to collect site-specific data and refine the risk assessment. Chemical-specific data are provided in the guidance such that, if applied through a computer program, it takes an insignificant amount of time to evaluate all chemicals (that satisfy the 6-step approach detailed in HHRAP Chapter two) rather than writing up detailed justifications of why some compounds should not be evaluated. If a chemical is not of concern, it is far easier to let its own fate, transport, exposure, and toxicity eliminate it from concern than it is to justify why it shouldn't even be evaluated. A facility is not required by the guidance or by regulation to conduct a risk assessment. It is the charge of the permitting authority to issue a permit protective of human health and the environment. EPA is unaware of a methodology other than risk assessment with which to evaluate protectiveness. Therefore, the permitting authority may conduct or contract out a risk assessment. Should a facility choose to conduct its own risk assessment, we recommend that they work with their permitting authority to minimize the number of iterations necessary to complete the assessment.

Issue: Protocol Objectives - Implementation Practices
Because the HHRAP calls for using conservative default criteria and assumptions, with actual data being used only if the estimated risks are deemed unacceptable, some commenters feared that implementing agencies will feel compelled to insist on use of default assumptions and parameters, resulting in the overestimation of risks, and use of results from the worst case scenario, not the more realistic one. This may also lead to incorrect information landing in the public domain, which can unduly raise third-party concerns and cloud already highly technical issues.

It was stated that furthermore, some EPA Regions and state agencies are increasingly requiring facilities to include worst-case parameter values for emissions and risk assessments. The implementation has evolved to the point that a facility's limits are being set based on performance of the trial burn, plugging the results into the risk assessment, and accepting limits more stringent than BIF based on hypothetical worst case assumptions. The commenters believed that some of the impetus for these overly conservative requirements by regulators is misleading broad statements in EPA guidance documents suggesting concern of risks and making far-reaching recommendations. For example, the discussion in the draft HHRAP Section 2.2.1, (p. 2-4, last paragraph) cautions about the "highly toxic" nature of hazardous

waste combustion emissions. Also, paragraph 2 on page 2-7 suggests several additional criteria that can be required along with risk assessment.

EPA Response:
The HHRAP sets out our recommendations (including the reasoning behind those recommendations) for conducting and reporting a transparent and scientifically defensible risk assessment. Whenever guidance is issued (as opposed to regulation requiring strict adherence), there is always a variation in the implementation across regional and state permitting authorities. To help bring consistency to implementation efforts, we've offered training to regional and state personnel. Also note that neither the guidance nor the regulations require industry to conduct a risk assessment. Lastly, limits required under the BIF rules were developed considering only the inhalation exposure pathway. Since then, scientific literature, as described in the HHRAP, does not support that evaluation of the inhalation exposure pathway alone would lead to permit conditions protective of human health and the environment.

2.1.3 Policy, Objectives, and Purpose - Model and Chemical Data Validation

General issues that were raised with regard to validation of HHRAP risk assessment models and chemical data include:

- Application to Real Sources;
- Setting Permit Limits;
- Peer Review;
- Model Validation; and
- Chemical Parameters.

Issue: Model and Chemical Data Validation - Application to Real Sources
It was recommended that the HHRAP guidance be applied to real sources and its reasonableness evaluated prior to issuing the final guidance document.

EPA Response:
We agree. EPA and state permitting authorities have applied the guidance to numerous sources, and many of the revisions to the final guidance are the result of actual application. See response to technical issues for details on specific revisions. We agree that additional validation of the model would be good, but this is beyond the scope of the HHRAP.

Issue: Model and Chemical Data Validation - Setting Permit Limits
It was believed that the risk assessment process should not be used to set practical limits on operating parameters because the process has not been validated to the point where it can be used to set these limits.

EPA Response:
We are unaware of a process other than risk assessment to evaluate the protectiveness of permit limits to human health and the environment.

Issue: Model and Chemical Data Validation - Peer Review
It was recommended that the HHRAP be quality assured before it is released or allowed to be used for regulatory purposes. EPA should conduct an independent peer review of the algorithms and numerical parameters used in the HHRAP. Chemical-specific parameter values and recommendations should be critically reviewed.

EPA Response:
The draft HHRAP was put forth as the best available guidance that could be offered at the time of its release. The HHRAP went through an extensive internal EPA and state review prior to release as a draft document. Public comments were received and an external peer panel reviewed the draft HHRAP. The public and peer panel comments have been summarized in this response to comments document, and the HHRAP has been revised accordingly. Appendix A parameters have been reviewed in their entirety and have been corrected or updated where appropriate. The HHRAP embodies our considered recommendations based on the best available science at the time the document was written. If better science can be supported, modifications to recommendations in the HHRAP are encouraged.

Issue: Model and Chemical Data Validation - Model Validation
It was believed that while parts of the model (the air dispersion portion) have been in use for a number of years and continually get refined, EPA has yet to rigorously validate any of the models in this guidance. It was recommended that equilibrium-partitioning methods be thoroughly validated.

EPA Response:
We strongly disagree that the model has not been validated for air concentrations (See studies done by EPA to support the Cumulative Exposure Project (USEPA, 1999b), the National Air Toxics Assessment (USEPA, 2001a) and the Model Evaluation Results for AERMOD (Paine et al., 1998)). Validation of the deposition portion of the model is less documented, but has generally been found to provide results within one order of magnitude. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option or other alternative to that recommended in the HHRAP.

Issue: Model and Chemical Data Validation - Chemical Parameters
EPA was urged to develop a single Agency-wide chemical database of physicochemical and toxicological parameters. Many of the toxicological and physicochemical parameters relied on in the draft HHRAP are inconsistent with other EPA values and need thorough review and revision.

It was recommended that TEFs should be considered an interim method and complemented by long-range planning to develop better toxicity data. EPA's comments regarding the resources needed for toxicity evaluations (p. 2-45) are valid justification in the short run for using relative potency factors of PAHs, coplanar PCBs, and polychlorinated dioxins and furans, but this does not mean that EPA should refrain from long-range planning to conduct detailed toxicity and bioassay studies.

EPA Response:
We agree with this premise, however, it was not within the scope of development of the HHRAP. Appendix A parameters have been reviewed in their entirety and have been corrected or updated where

appropriate. The majority of parameters are taken directly from the Superfund Chemical Data Matrix (SCDM) and all parameters are referenced such that other values for each parameter may be evaluated and considered in a risk assessment.

2.1.4 Policy, Objectives, and Purpose - Clarification / Editorial

Issue: Clarification – Oral Dose
Clarification was requested about the meaning of "one oral dose" on draft HHRAP page 1.1.

EPA Response:
The definition for the term "dose" was adopted directly from the National Academy of Sciences, "Risk Assessment in the Federal Government" (1983).

Issue: Clarification – Trial Burn Issues Placement
It was recommended that the discussion on page 1-7, Section 1.2 Related Trial Burn Issues be better left for Chapter 2 Facility Characterization because it is a very specific issue that seems to be out of place in the introductory chapter.

EPA Response:
We've removed the section on "Related Trial Burn Issues" from Chapter One.

2.2 IDENTIFYING EMISSION SOURCES AND COMPOUNDS OF POTENTIAL CONCERN [draft HHRAP Section 2]

Burning hazardous waste typically emits combustion by-products from a stack. Additional types of emissions that may be of concern include (1) process upset emissions, (2) accidental releases, (3) general RCRA fugitive emissions, and if the facility is a cement kiln (4) cement kiln dust (CKD) fugitive emissions. Each of these emission source types can result in generating compounds of potential concern (COPCs), which need to be evaluated during risk assessment. The COPCs to be addressed can vary from one combustion unit to the next, depending on a number of factors.

Comments regarding emission sources and compounds of potential concern (COPCs) are categorized into the following topical issues:

- Estimating Stack Emissions;
- Estimating RCRA / CKD Fugitive Emissions;
- Identifying Compounds of Potential Concern (COPCs);
- Chemical-Specific Issues; and
- Clarification / Editorial.

2.2.1 Emission Sources and COPCs - Estimating Stack Emissions [draft HHRAP Section 2.2]

Issues with regard to estimating hazardous waste combustion facility stack emissions include:

- Data Collection;
- Trial and Risk Burns;
- Total Organic Emission (TOE) Rate;
- Multiple Stacks;
- Previously Operated Facilities; and
- Process Upsets.

Issue: Estimating Stack Emissions – Data Collection (See RC Sections 3.2.2, 3.2.4 and 3.2.5)
Issues were raised with regard to what statistical measures, detection limits, and types of data are most appropriate for estimating emission values for COPCs. These issues included:

- Clarifying the definition of the "95th percentile emission rate."
- Whether the method detection limit (MDL), reliable detection limit (RDL), or zero should be used for the concentration of non-detected compounds.
- To require all current and historical stack sampling information for use in the risk assessment, as suggested in the Draft HHRAP, is inappropriate and an inefficient use of resources.
- Several terms in Draft HHRAP Section 2.5 need to be better defined and clarified with regard to various types of sample blanks, such as method blank, reagent blank, trip blank, field blank, and instrument blank.
- The Draft HHRAP should be modified to permit use of statistical comparisons of blank results and sampling data.
- Agreement with the Draft HHRAP approach to exclusion of chemicals typically considered laboratory contaminants, especially for phthalates. It was suggested that chemicals should be excluded as COPCs if they are present in all samples at concentrations less than five times that found in the blanks.

It was felt the HHRAP appears to have an undue emphasis on being able to say with legally defensible certainty that actual stack emissions from a given facility are less than those used in the facility's risk assessments. To meet this objective, the HHRAP requires that RDL values be used for non-detect COPC stack compounds even when an unbiased estimate of actual concentration (in the form of J-values) is available. It appears that in an effort to have bulletproof COPC stack concentration numbers, the best information available is ignored and replaced by frequently much higher RDL values. Why disregard this information, especially when it may jeopardize the usefulness of the overall process, i.e., facilities with few, if any, hits could fail the risk assessment? The best possible estimate of actual risk should be produced, and conservative assumptions should be used in the face of uncertainty. EPA should implement the risk assessment process in a manner that is and appears to be outcome-independent.

EPA Response:
The issue of average versus maximum emission rates was submitted to the external peer review panel, who recommended against using the 95% UCL due to lack of data to generate an appropriate statistic for this parameter. The issue of detection limits, their definitions, and use were also addressed during the

external peer review. Recommendations by the peer reviewers were used to modify the HHRAP accordingly. See section 3.2.2 of this Response to Comments document for further discussion of the peer reviewer response.

We revised the HHRAP to recommend using all relevant data in the risk assessment.

We have made editorial changes to the HHRAP, as appropriate, with regard to information about sample blanks. We do not think it is appropriate to make statistical comparisons between blank results and sampling data due to the limited blank sample size.

The only outcome that the HHRAP encourages is the consistent production of transparent, scientifically defensible risk assessments.

Issue: Estimating Stack Emissions – Trial and Risk Burns [draft HHRAP Section 2.2.1]

Issues were raised regarding the use of "maximum" or "normal" operating conditions, presumably generated during a trial burn or risk burn, to perform a risk assessment. Issues included:

- The questionable appropriateness of using trial burn data for estimating long-term risks because they are gathered under worst case operating conditions. Using average emissions and normal operating conditions may yield better long-term risk estimates.
- The requirement for the use of the "worst case" waste for the risk burn contradicts other HHRAP statements that the risk assessment would use reasonable approaches. The text should be revised to include consideration of the volume of the waste stream and the frequency with which each waste stream is burned.
- The use of hazardous waste fuels in the cement process should not be represented the same as facilities that incinerate ""highly toxic"" wastes.
- The permitting authority may require that trial burn data be used over risk burn data, given the variability of waste streams or the presence of highly toxic constituents. The decision to use trial burn /risk burn data should be made in the pre-trial/pre-risk burn phase to avoid unnecessary waste of resources.
- Limiting use of risk burn to facilities with entirely homogenous waste feed streams is overly restrictive.
- Using a combination of trial burn data, non-detects, a TOE adjustment, and RDL's may result in overestimating emission rates and associated risks.
- Limiting use of "data-in-lieu" for only on-site units is overly restrictive.
- The HHRAP should clearly note that the BIF adjusted Tier 1 approach is an allowable option.
- Organic emission samples collected during periods of POHC spiking are not representative of emissions without 'spiking'. Comparing emission estimates from risk and trial burns is not reasonable and will obscure the true risk.
- The HHRAP should reflect that a burn at "normal" conditions should result in a minimum of additional permit conditions. Such conditions should be long-term and minimize the reporting burden.

It was noted that on Page 1-3 the HHRAP states: "Any decision to add permit conditions based on a site-specific risk assessment under this authority must be justified . . . and the implementing Agency should explain the basis for this condition." However, on Page 2-5, the HHRAP states: "If a facility desires to receive a permit with no limits other than those traditionally based . . . on a trial burn (TB), then risk testing should be conducted at trial burn or worst case conditions." Elsewhere on the page and elsewhere in the HHRAP it is stated that TB risk data are expected to have higher emissions than would occur at normal conditions. Furthermore, no consideration is given in the statement about added permit conditions as to the level of risk shown in that facility's risk assessment. For example, if a facility conducted a risk burn (not a trial burn) showing a risk of 1.0×10^{-7}, why would permit conditions be needed since a risk $<10^{-5}$ would seem to be protective without additional limits?

***EPA Response*:**
As stated in Section 2.2.1.2 of the draft HHRAP, the risk burn does not replace the trial burn for conducting the destruction and removal efficiency (DRE) testing. We consider the risk burn as an additional operating condition of the trial burn. In some cases, due to highly variable waste, it is not practical to determine normal operating conditions and worst-case waste. Under these situations, the HHRAP recommends using trial burn data. Testing conditions of a risk or trial burn are left up to a facility and should take into account the flexibility desired in the operating permit.

Worst-case wastes are used to evaluate potential risks, not necessarily to set permit limits. This allows a facility the flexibility in its operating parameters. The recommendation to use worst-case waste in the risk burn is employed to provide a facility the maximum flexibility in its operating permit and to ensure that all waste types are evaluated at a facility. Worst-case waste under normal operating conditions allows for a reasonable approach that also ensures that one can evaluate protectiveness of operating conditions in reference to human health and the environment.

The HHRAP is guidance and contains no requirements. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

It was never our intention to suggest that only data from on-site units could be used to generate data-in-lieu of information. We've further clarified this issue in the HHRAP.

The comment regarding the BIF adjusted Tier 1 approach is more appropriate to the trial/risk burn guidance. Tier numbers are only used in the risk assessment with respect to starting points at which to develop risk-based limits.

An example was provided in the draft HHRAP to evaluate whether or not worst-case waste has been selected for use in the risk burn. No mention of spiking is provided in the example.
The permitting issue is not a risk assessment issue. EPA Region 6 developed a permitting manual, which may be helpful in addressing this issue.

We've revised the referenced text in Draft HHRAP Chapter 2 to clarify the relationship between trial burns and risk burns, and to remove recommendations regarding the facility's strategy for conducting testing as related to permit conditions because this is really facility- and permitting authority-specific.

Issue: Estimating Stack Emissions - Total Organic Emission (TOE) Rate [draft HHRAP Section 2.2.1] (See RC Section 3.2.3)

The Draft HHRAP states that EPA developed the total organic emissions (TOE) test to account for unidentified organic compounds. The Commenters raised several potential problems with using TOE data to evaluate the potential risks from the unidentified fraction of organic compounds in the stack gas, including the assumption of similar toxicity and chemical properties between the known and unknown compounds. Recommendations included limiting evaluation of the unknown organics to the uncertainty section of the risk assessment and for EPA providing more discussion on:

- The uncertainties or potential problems that may arise when using TO_{voc} and TO_{svoc} portions of the test;
- The basis for using the reliable detection limit (RDL) and estimated detection limit (EDL) or if there is flexibility to apply more reasonable assumptions; and
- Whether it is acceptable to use either the SW-846 EDL or the laboratory EDL.

It was also recommended that EPA not require determination of the TCO and GRAV fractions of its TOE method because of major deficiencies in the GRAV determination and redundancy of TCO when Method 8270 TICs are determined.

EPA Response*:*

Use of the TOE method is a policy decision made to encourage facilities to conduct analyses that identify as much of the mass being emitted from units as practically possible. The issue of TOE was presented to the external peer review panel. Recommendations of the panel were used to revise the HHRAP accordingly. See section 3.2.1 of this Response to Comments document for more discussion of the peer reviewer response.

Issue: Estimating Stack Emissions - Multiple Stacks [draft HHRAP Section 2.2.2]

Commenters point out that risks from facilities that have multiple stacks are not necessarily cumulative. It depends on the placement of the receptor for each stack. Because the potential receptor location will vary due to the height of the stack, operating parameters, etc., it is unlikely that the same potential receptor will be selected for all stacks.

The HHRAP does not clearly indicate when emissions from other RCRA treatment facilities should be included in the risk evaluation, and it appears at odds with the guidance document addendum. It was also suggested that inclusion of other emissions should be made on case-specific basis.

EPA Response:

When choosing exposure scenario locations, the HHRAP recommends identifying the receptor locations with the highest air concentrations & deposition rates for each source (e.g., stack) separately AND for all sources combined.

We agree that the receptor location of maximum exposure for one stack is not necessarily the receptor location of maximum exposure for another stack, even if both stacks are at the same facility. That is one reason it is valuable to assess each source separately. As discussed further in the HHRAP, this may lead to assessing risk at multiple locations.

However, any one location is impacted, to a greater or lesser extent, by ALL sources. It is therefore appropriate to also assess locations by summing the air concentration and deposition rate contributions of all sources to each location. Because concentration and deposition are defined with multiple parameters (e.g., wet vapor deposition, dry vapor deposition), each with its own point of highest impact, this may lead to assessing multiple receptor locations. Please see the HHRAP for further discussion.

The addendum described in the comment is not part of the HHRAP, but is EPA Region 6 guidance. The unit to be evaluated in the risk assessment is a site-specific decision and should be agreed upon between the facility and regulatory authority.

Issue: Estimating Stack Emissions - Previously Operated Facilities [draft HHRAP Section 2.2.4]
Clarification was requested regarding estimating stack emissions from previously operated facilities. For example, is EPA interested in recovering information about units in the past that were operating but now closed along with evaluation of new and/or existing units? For an existing unit that has been operating for a number of years, should all the prior years be evaluated? How would all the necessary information be obtained for the risk assessment? Clarification was also requested about whether sampling data can be used in lieu of or in addition to modeling and fate and transport data to determine risk from previous operations.

EPA Response*:*
This is a site-specific decision to be made with the permitting authority. Guidance is provided in Draft HHRAP Section 2.2.4 for how this information might be used. Additional information is beyond the scope of the HHRAP. Facilities should provide historic operating information as requested on a site-specific basis to be negotiated with the permitting authority. Further information on data-in-lieu is available in Draft HHRAP Section 2.2.1.1.

Issue: Estimating Stack Emissions - Process Upsets
[draft HHRAP Section 2.2.5] (See RC Section 3.2.1)
The HHRAP suggests using process upset default values of 2.8 for organics and 1.45 for metals if no site-specific data are available, based on a California Air Resources Board (1990) document, to adjust emission rates in the risk assessment. These factors were calculated based on the assumption that emission rates are 10 times higher during upset conditions than during normal operations, and the facility operates in the upset mode for 5% to 20% of the time. Commenters questioned the validity of these assumptions and values of the derived process upset factors, as well as some of the operating conditions included in the term upset. It was also suggested that any use of upset conditions should be confined to the uncertainty section of the risk analysis until data show otherwise and that the use of upset factors should be dropped until data can be produced to prove that such emission scale-up factors are appropriate.

EPA Response:
The use of process upset factors was addressed by the external peer review panel. For further discussion, see section 3.2.4 of this Response to Comments document. Upset factors are generally changed based on historical information provided by a facility, as noted in Section 2.2.5 of the Draft HHRAP. The HHRAP recommends generating site-specific upset factors whenever possible. The HHRAP is guidance and will continue to contain no requirements. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

2.2.2 Emission Sources and COPCs - Estimating RCRA / CKD Fugitive Emissions [draft HHRAP Sections 2.2.6, 2.2.7 and 2.2.8] (See RC Section 3.3.2)

Commenters differed in their opinions about whether RCRA fugitive emissions should be included in the risk assessment. Some recommended that cement kiln dust (CKD) fugitive emissions should be quantitatively evaluated because of the metals loading of CKD which may present a risk through both direct and indirect exposure pathways. Others questioned whether fugitive emissions estimates would be meaningful to making risk assessment decisions, especially when balanced against the time and cost of obtaining the estimate. It was also suggested that:
Fugitive emission estimates could lead to misleading interpretations of risk if conservative default approaches are used to estimate the fugitive emissions;

- Fugitive emissions from sources already controlled under 40 CFR 264 Subparts AA, BB, and CC or the Clean Air Act (CAA) should not be incorporated into the risk assessment;
- The risk from a RCRA facility fugitive emissions are already addressed in the development of the leak detection and repair (LDAR) regulations;
- EPA has not demonstrated a need to consider fugitive emissions impacts based on any real impact or equivalent risk;
- Inclusion of CKD fugitive emissions in the risk assessment is not warranted; and
- EPA should acknowledge the distinct differences in cement kilns with regard to fugitive emissions, so that cement kiln facilities are not required to address issues that have previously been resolved and do not apply to cement kilns.

EPA mentions 4 techniques for fugitive emissions from process equipment in RCRA service: Average Emission Factor Approach (AEFA), Screening Ranges Approach (SRA), US EPA Correlation Approach (EPACA) and Unit Specific Correlation Approach (USCA). Three of these techniques, the SRA, EPACA, and USCA were questioned for several reasons. One commenter offered examples of how it estimates RCRA fugitive emissions at its facilities.

More information was requested to address data requirements and calculation techniques needed to perform an analysis for cases in which process equipment in close proximity are grouped into a combined source and fugitive emissions are estimated when components within the single group handle wastes of different composition.

EPA Response:
We've edited the HHRAP to recommend considering the CKD samples collected during maximum waste metal feed rate conditions from the trial burn, risk burn and/or certification of compliance tests when evaluating CKD fugitive emissions.

We've evaluated fugitive emissions from tanks and other RCRA equipment and have not always found the risk to be low. Neither the CAA nor current RCRA programs evaluate these emission sources on a site-specific basis. Therefore, we'll continue to recommend considering units regulated under 40 CFR 264 Subparts AA, BB, and CC in the risk assessment. The state and federal LDR programs are not set up based on site-specific risk. Leak detection programs do serve as a means to adjust emission factors, thus allowing credit in the risk assessment. Including fugitive emissions in a risk assessment is not an extensive exercise and is routinely performed for large facilities in a day. Most if not all facilities should already be collecting information to model fugitives under the TRI, NEI, or other state program. The HHRAP allows for an up-front qualitative assessment for CKD via comparison of site-specific data to those used in the national risk assessment. If site-specific information is similar to those used in the national assessment, no further risk analysis is recommended. The HHRAP has been designed such that permits can be written that are protective of human health and the environment. If data exist under other regulations that assure the protectiveness of the permit, they should be considered.

As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Sources may be grouped to allow for a reduction in air modeling runs. When grouping sources, a single emission rate is calculated by summing total fugitive emissions from individual unit. Therefore, individual waste streams are accounted for in the grouping methodology. The grouped sources are then modeled as an area source as noted in Chapter 3.

2.2.3 Emission Sources and COPCs - Identifying Compounds of Potential Concern (COPCs) [draft HHRAP Sections 2.3 and 2.4]

The guidance outlines a series of steps to be followed in developing a list of COPCs to be evaluated in the risk assessment. Commenters raised issues, including:

- How to handle non-detected compounds that are contained in the waste feed;
- What factors should indicate COPC elimination early in the risk assessment process; and
- How to determine surrogate toxicity values for some tentatively identified compounds (TICs).

Issue: Identifying COPCs - Non-Detects (See RC Section 3.2.5)
Commenters recommended that EPA should provide a discussion on how to handle COPCs that are initially present in the hazardous waste feed stream but cannot be sampled and/or analyzed in stack emissions by known methods. With regard to handling COPCs present in the waste feed but not detected in the stack emissions, commenters offered the following:

- A discussion should be included in the HHRAP on whether it is appropriate to calculate waste-based emission rates and if so, how waste-based emission rates should be calculated.
- A reality check should be used to compare a calculated value of a potentially emitted chemical, based on the quantity in the waste feed and engineering operations, against the detection limit used resulting in non-detects. If the detection limit is appropriately low enough, then non-detected chemicals should be eliminated from the list of COPCs.
- Constituents not detected under trial burn conditions should not be carried any further in the quantitative risk estimates beyond hazard identification simply because of the type of waste that is incinerated.
- Setting an arbitrary number (e.g., 30) of the largest tentatively identified compounds (TICs) may force identification of peaks that are so small they can not be easily separated from the background. Furthermore this arbitrary number fails to consider potency. The largest peak may not be the chemical of greatest concern while the smallest peak could be the chemical of greatest concern. It was suggested that peaks less than 10% of the nearest internal standard should be ignored.
- It was suggested that chemical class evaluations be used as part of the determination of potential TIC emissions.
- Non-detects from emissions data sets should only be discussed in the uncertainty section of the risk assessment. The contribution of non-detects to the estimated risk should be featured in the conclusion of the risk assessment report to help decision makers decipher the breakdown of the risk estimate.
- COPCs that are never detected in any stack sampling run should be distinguished from those detected in at least one run.
- EPA should determine the minimum detection limits for compounds, such as dioxins, furans, and PAHs using standard sampling and analysis protocols.
- It was noted that detection limits can and do drive risks, even at the extremely low detection levels currently achieved in laboratories. Furthermore, the science and technology of risk assessments has evolved to the point that constituent levels substantially below detection levels are driving the risk assessment.

EPA Response:
The comment regarding how waste-based emission rates should be calculated is beyond the scope of the HHRAP. We've forwarded this comment to EPA's Office of Research and Development.

The "reality check" and other suggested approaches may be acceptable on a site-specific basis. However, we don't recommend such approaches in the HHRAP because we believe it's preferable to carry a compound through the risk assessment and allow factors, such as quantity and fate and transport characteristics, to show if the risk falls below levels of concern.

The distinction between COPCs never detected and those detected in at least one stack emissions sampling run is provided in the HHRAP following Step one of the COPC selection process. The external peer review panel addressed the issues of detection limits, their definitions, and use. Recommendations of the peer reviewers were used to revise the HHRAP. See section 3.2.3 of this Response to Comments document.

Detection limits become a concern for two PAHs, one phthalate, and mercury. The uncertainty in risk estimates for the two PAHs and one phthalate are high due to: 1) the lack of data supporting biotransfer up the food chain for compounds with high Kow values, and 2) the lack of information concerning metabolism of these compounds. Biotransfer equations have been updated for the beef and milk exposure pathways and other biotransfer equations have been capped at the high and low end of the Kow range used to generated those equations. As with any risk assessment method, uncertainty exists and will need to be dealt with through advances in the state of the science or risk management decisions. We've provided additional information in the HHRAP for all of these compounds to help understand the potential risk associated with these cases. We've modified mercury fate and transport equations based on external peer review comments, alleviating detection issues for this chemical. See section 3.5.1 of this Response to Comments document for more discussion about mercury.

Issue: Identifying COPCs - Elimination Factors

It was suggested that COPCs recommended for evaluation via the indirect food-chain pathway be limited to those expected to persist or bio-accumulate. Environmental degradation of pollutants should be considered and used as a tool to reduce the number of COPCs. Commenters contend that addressing a long list of COPCs is time-consuming and burdensome, and is not an effective use of resources, especially when one understands that the risk contribution of almost all of the constituents is minimal.

EPA Response*:*

The HHRAP is guidance and contains no requirements. Given that the fate, transport, and toxicity information is provided in the HHRAP, we believe it to be much more efficient to run the selected COPC's through the risk assessment process, rather than go through the arduous process of justifying their elimination from the assessment.

Issue: Identifying COPCs - Surrogate Toxicity Values
[draft HHRAP Section 2.4.] (See RC Section 3.4.6)

Although the use of toxicity equivalency factors (TEFs) is supported by some commenters, some suggested that TEFs should be considered only as an interim measure. EPA was urged to conduct long-range planning to conduct detailed toxicity and bioassay studies.

Given EPA's experience, the Agency was asked if there are typical compounds or categories of compounds likely to be found as tentatively identified compounds (TICs), and what advice can EPA offer on the choice of surrogate compounds for chemicals and classes of chemicals that frequently are found in TIC studies. Clarification was requested regarding how EPA determines a compound is "similar" with regard to obtaining surrogate toxicity values. Additionally, commenters questioned how surrogate toxicity values should be used qualitatively and how this should be used in risk management decision making with regard to permit applications. Finally, commenters requested EPA to clearly indicate how to qualitatively evaluate COPCs with no toxicological data in the uncertainty section of the risk assessment report.

A definition was requested to better define what is meant by "compounds that have no toxicological data." It was also suggested that additional guidance would be helpful regarding the use of preliminary toxicity data (data that has not undergone full peer review and obtained consensus approval, and is

therefore not incorporated into EPA's Integrated Risk Information System (IRIS) or the Health Effects Assessment Summary Tables (HEAST) in the uncertainty portion of the risk assessment. For example, would coordination with EPA's Environmental Criteria and Assessment Office be suggested?

***EPA Response**:*
We note the comment regarding long-range planning for future studies.

The HHRAP presents the state-of-the-science. Currently TIC analysis in risk assessment is highly uncertain. Additional guidance on selecting surrogate toxicity information and risk management implementation is beyond the scope of the HHRAP.

A hierarchy of recommended sources of toxicity information is presented in HHRAP Appendix A.

2.2.4 Emission Sources and COPCs - Chemical-Specific Issues [draft HHRAP Section 2.3]

This section includes chemical-specific public comments that are not generally summarized under other issues in this Response to Comments document. The chemicals discussed in this section include:

- Dioxins and Furans (PCDD/PCDF);
- Polynuclear Aromatic Hydrocarbons (PAHs);
- Polychlorinated Biphenyls (PCBs);
- Hexachlorobenzene and Pentachlorophenol;
- Volatile Organic Compounds (VOCs);
- Metals;
- Hydrogen Chloride and Chlorine Gas (HCl/Cl);
- Phthalates;
- Criteria Pollutants; and
- Radionuclides

Issue: Chemical Specific - Dioxins and Furans [draft HHRAP Section 2.3.1]
Issues related to quantifying dioxin and dioxin-related exposures include:

- Fat and dioxin content in human mother's milk;
- Benchmark values for dioxins;
- Contact fraction for exposure assessment;
- Dioxin/Furan Formation; and
- Fluorine, Bromine, and Sulfur PCDD/PCDF Analogs

Human Milk **(See RC Section 3.4.7)**

- The HHRAP overestimates the amount of fat in mother's milk by 25% to 30%. It was suggested that the milk fat intake should be reduced from 32 grams per day to 18.2 grams per day.
- The HHRAP overestimates the average one-year concentration of dioxin TEQs in mother's milk by 35%. A correction for the natural degradation in the concentration of dioxin in mother's milk

during nursing would reduce the concentration of dioxin in mother's milk by an average of 35% over the first year of nursing.

- EPA should consider reducing the 2,3,7,8-TCDD TEQ concentrations using more recent data.
- EPA should provide guidance on how results from the margin of exposure analysis should be interpreted.
- EPA should provide a strategy for evaluating background dioxin content in human milk and a recommended approach for nursing infants.
- EPA was urged to make it explicitly clear in the HHRAP that breast feeding is safe and should be encouraged, and if a mother's average daily dose of PCDD/PCDF is not associated with an unacceptable cancer risk, and therefore safe, the nursing infant's dose is also safe. As currently drafted, the HHRAP could give readers the mistaken impression that breastfeeding is not safe.

EPA Response: Human Milk

In response to comments regarding the fat and dioxin content in milk, as with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

As for the updating of the toxicity equivalency factors (TEFs), we have adopted the World Health Organization TEFs (World Health Organization, 1997) in the HHRAP.

Evaluation of how breast milk margin of exposure data should be interpreted is considered risk management and beyond the scope of the HHRAP.

For the evaluation of non-cancer effects in nursing infants, we continue to recommend that exposure be compared with the national average background level of 60 pg/Kg/day for nursing infants.

The purpose of the HHRAP is to provide methodologies for evaluating whether breast-feeding is safe in site-specific situations.

Benchmark Values **(See RC Section 3.4.5)**

For the non-carcinogenic risk assessment of dioxin congeners, the HHRAP requires that the annual daily dose for all receptors be compared to a value of 1 pg TEQ/kg/day for adults, which is stated to be the national background exposure level. While such a benchmark may be appropriate for non-carcinogenic risk assessment of average residents, it was believed that it is not appropriate for non-carcinogenic risk assessment of the following receptors: adult subsistence farmers, child subsistence farmers, and infants consuming mother's milk. It was recommended that the non-carcinogenic benchmarks for dioxin congeners be modified from 1 pg/kg/day, which may be appropriate for an adult resident, to 2 pg/kg/day for an adult subsistence farmer and to 3 pg/kg/day for a child subsistence farmer.

It was suggested that EPA should defer to the final Dioxin Reassessment for national average background exposure levels and for review of dioxin/furan sources and trends in the environment. Earlier references should be deleted from Draft HHRAP Section 2.3.1. Additionally, EPA was urged to exclude from the

HHRAP any non-cancer evaluation of dioxin because the draft Dioxin Reassessment has not been finalized and EPA has not yet responded to the 1995 Science Advisory Board's extensive critique of the reassessment, particularly with regard to non-cancer effects.

A change was suggested in the wording in Draft HHRAP Section 2.3.1.2, first paragraph to "If exposure due to the facility's emissions during the exposure duration of concern are low compared to background exposures, then the emissions are not expected to cause an increase in non-cancer effects." This would be a change to the current language in the Draft HHRAP, which says that the emissions will not cause health effects.

EPA Response: Benchmark Values
This issue was addressed during the external peer review. The peer panel agreed that it is reasonable to use 1 pg/kg/day. See Section 3.4.4 of this Response to Comments document for further details. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Authors of the Dioxin Reassessment (EPA/600/P-00/001B) have reviewed the Draft HHRAP. The only non-cancer assessment recommended in the Draft HHRAP is a margin of exposure comparison of dioxin in breast milk and background levels noted in the U.S.

We agree with the suggested language change and have revised the HHRAP to reflect that emissions causing low exposure are not expected to increase non-cancer effects.

Contact Fraction

It was suggested that the contact fraction for subsistence farmers should be changed from 100% to 40% for milk and 44% for beef, as determined by U.S. Department of Agriculture (USDA) and as cited in the draft Dioxin Reassessment. Issues of conservancy are already covered by the choice of the subsistence farmer and other factors.

EPA Response: Contact Fraction
As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Dioxin/Furan Formation

It was noted that facilities have seen an increase in requests for testing for dioxins/furans during trial burns under many different conditions because the formation inhibition mechanisms for dioxins/furans are not completely understood. The result is that trial burns are being used like a research project to test various hypotheses, and this is an inappropriate use of resources. To include the many theories in the uncertainty section of the risk assessment report is also beyond what was believed to be reasonable. Additionally, more discussion was recommended about the relationship between chlorine feeds to combustors and dioxin emissions.

EPA Response: Dioxin/Furan Formation
We agree, and we have changed the HHRAP to recommend a site-specific decision made in consultation with the permitting authority. More information about the relationship between chlorine feeds and dioxin emissions can be found in the references cited in the HHRAP. Expanding the existing discussion in the Draft HHRAP is beyond the scope of the HHRAP.

PCDD/PCDF Analogs

The inclusion of bromine, fluorine, and sulfur PCDD/PCDF analogs in the risk assessment was questioned. EPA has no approved method for sampling or analysis of these constituents. Without an approved, verified analytical method, no evidence of formation in combustion emissions, and no information regarding potential toxicity, commenters seriously question the intent, value, or usefulness of attempts to collect the proposed analytical data. They contend that this effort would be an ineffective use of resources.

EPA Response: PCDD/PCDF Analogs
There is nothing in the HHRAP that suggests an analytical method will need to be developed by individual applicants. However, we've revised the HHRAP to reflect that this is a site-specific decision to be made in consultation with the permitting authority, that includes careful consideration of the state-of-the-science at the time.

Background Level Impacts

It was noted that with regard to section 2.3.1.2 PCDD/PCDF Non-cancer Hazards, the inherent assumption is that background exposure levels do not cause significant non-cancer effects in humans. Although, there are suggestive data to indicate that this may not be correct, there is certainly no conclusive evidence to indicate that in fact background exposure levels have any non-cancer effects in humans. Nevertheless, terminology that indicates this one way or the other should be avoided. This is a significant issue that should be clarified especially since (1) an assumption, that is not conservative, is made that background levels have no toxicity, and (2) the "background" levels in the area of concern are not likely to be known and there is no specific directive to determine these. It should also be clearly indicated whether using 1 pg/kg/day as a benchmark inherently assumes that this levels of exposure assumes no level of risk or an acceptable level of risk. In either case, the basis of this assumption needs to be clearly stated.

EPA Response: Background Level Impacts
The Agency does not have a reference dose with which to estimate the likelihood of non-cancer health effects from exposure to dioxin congeners. The language in the referenced section has been updated to lessen the implication that background levels of dioxin are safe. However, we do believe that comparison of incremental exposure to a national background helps put potential risk from facilities emissions into context and may be useful in a risk management decision.

Issue: Chemical Specific - Polynuclear Aromatic Hydrocarbons (PAHs) [draft HHRAP Section 2.3.2] (See RC Section 3.2.2)

Several issues specific to PAHs were raised. These included:

- To avoid confusion, chemical-specific inputs for benzo(a)pyrene (BaP) only should be provided in Appendix A (i.e., data for the other six carcinogenic PAHs should be removed). The chemical-specific inputs in Appendix A, Table A-3-20 were questioned.
- It was recommended that emission rates be calculated for each of the individual carcinogenic PAHs and that their specific fate and transport factors used to model movement through the various media. This is critical because each PAH will be distributed differently based on their different chemical characteristics. These individual PAH values would then be summed to obtain an equivalent total concentration of BaP, used to evaluate risk.
- It was noted that one source of modeling uncertainty lies in the selection of chemical-specific model parameters. Specifically, although PAHs are known to be metabolized by animals and fish, EPA estimates biotransfer factors using K_{ow}-based correlations that assume no such metabolism which, in turn, overestimates the concentrations of PAHs in animal tissues and food products. Some of these types of errors can be identified from the literature using empirical knowledge of exposure potential for various chemicals. EPA has used this technique with some success in the dioxin reassessment, and it was recommended that similar empirical checking of model estimates be applied to as many COPCs as possible, especially those frequently predicted to be risk drivers.
- It was noted that there are 7 PAHs included in the EPA TEF methodology, and the Draft HHRAP requires inclusion of PAHs in quantitative risk estimates even if these compounds are not detected in trial burn emissions. Commenters believed that in cases when all 7 PAHs and most other aromatic hydrocarbons are not detected, inclusion of PAHs in quantitative risk estimates is scientifically indefensible because there is a low probability that all PAHs are present in the emission stream and all are below detection limits. It was recommended that in such cases, the potential PAH formation should be discussed in the uncertainty section of the risk assessment.
- It was pointed out that organic emissions, such as PAHs, monitored from the main stack in cement kilns typically originate from organics in the raw materials (e.g., limestone, shale, and clay) used in the cement manufacturing process and not from fuels. Because there are statements in the HHRAP indicating that baseline operations do not emit organic constituents, it was recommended that EPA should describe the known phenomena of organic emissions derived from naturally occurring raw materials, differentiate the process emissions from those derived from hazardous waste combustion and hazardous waste constituents.
- It was recommended that the discussion in Section 2.3.2 on carcinogenic versus non-carcinogenic PAHs is confusing and needs clarification. Paragraph 1 states that all PAHs are considered carcinogenic but paragraph 7 refers to non-carcinogenic PAHs. One suggestion was to delete "…may be emitted" from paragraph 7, last sentence.
- It was noted that if the terminology in the HHRAP is vague, the chemicals will be largely ignored unless specific guidance is given. For instance, in Section 2.3.2 Polynuclear Aromatic Compounds, page 2-46, line 13, "...emissions data indicate that ...," it has not been clarified what a "significant" amount of non-carcinogenic PAH is.

EPA Response:
Chemical-specific parameters have been reviewed in their entirety and have been corrected or updated where appropriate. We disagree with the comment suggesting that fate and transport characteristics of only BaP should be made available. Fate and transport characteristics of different PAH congeners result in different distribution characteristics in the environment. It is important to model each congener separately before normalizing them to BaP equivalents.

We agree with the comment regarding calculation and modeling of individual carcinogenic PAHs, and have made this change in the HHRAP.

We've endeavored to do similar empirical checking of the model. Several examples include PAH metabolism, phthalate metabolism, dioxin biotransfer, etc. We've made some changes to the HHRAP in response to these efforts. The HHRAP, however, is only guidance and is meant to help provide a well-documented, consistent approach to risk assessment. As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

The HHRAP is guidance and contains no requirements. Given that the fate, transport, and toxicity information is provided in the guidance, we believe it to be much more efficient to run the selected COPC's through the risk assessment process, rather than go through the arduous process of justifying their elimination from the assessment.

The recommendation to describe organic emissions from naturally occurring materials is beyond the scope of the HHRAP.

With regard to Draft HHRAP Section 2.3.2, paragraph one indicates the commonly detected PAH's listed in that paragraph are considered to be carcinogenic. Paragraph 7 focuses on potential non- carcinogenic effects of the same PAHs, rather than suggesting the existence of separate PAHs.

Issue: Chemical Specific - Polychlorinated Biphenyls (PCBs)
[draft HHRAP Section 2.3.3] (See RC Section 3.2.2, 3.4.6)

Issues raised about PCBs include:

- It was suggested that EPA replace the existing language in the Draft HHRAP on Toxicity Equivalent Factors (TEFs) for the coplanar PCBs with the most recent World Health Organization TEFs that were made available at Dioxin '97, 17th International Symposium on Chlorinated Dioxins and Related Compounds, Indianapolis, Indiana, USA, August 25-29, 1997.
- The values for chemical-specific inputs for Aroclor 1016 and 1254 provided in Appendix A, Table A-3-13) were questioned.
- It was recommended that EPA provide an explanation about why it is not necessary to include PCBs in the risk assessment when hazardous waste with low chlorine content is burned. Concern was expressed about limiting automatic inclusion of PCBs as COPCs to only three situations: (1) combustion units that burn PCB-contaminated wastes or waste oils; (2) highly variable waste

streams, such as municipal and commercial wastes for which PCB contamination is reasonable; and (3) highly chlorinated waste streams.

- The narrative and table on page 2-50 of the Draft HHRAP was judged to be inconsistent and confusing. It was recommended that the HHRAP clearly state that the SF = 0.4 be used for the water ingestion pathway given that only the lower chlorinated PCB congeners are soluble in water. The more highly chlorinated PCBs will adhere to soil and sediments and the SF = 2 should be applied to evaluate risks through the food chain, sediment, or soil exposures unless at least 99.5 percent of the mass of the released PCB mixture has fewer than four chlorine atoms per molecule.
- It was noted that neither toxicity nor environmental fate of PCBs can be accurately predicted on the basis of chlorine content alone.
- Commenters supported limiting which sources should consider PCBs as a COPC, but they disagreed that PCBs are COPCs for sources burning highly chlorinated wastes.
- Cement kiln industry commenters state they do not believe that the low levels of PCBs found in cement kiln waste feeds warrant inclusion in testing or the risk assessment. Furthermore, the combustion characteristics of cement kilns would readily destroy 99.999+% of any organic fuel component, as demonstrated repeatedly by DRE testing at cement kilns.
- It was noted that the risk assessment approach requiring that coplanar PCB congeners be analyzed in combustor emissions and evaluated in the risk assessment with dioxin toxicity equivalent factors (TEFs) is highly controversial and not generally accepted by the toxicological community.
- It was noted that it is inappropriate to evaluate potential non-carcinogenic effects of PCBs by using the oral reference dose (RfD) for Aroclor 1254 or Aroclor 1016.
- It was suggested that EPA should assess the risk of coplanar PCB emissions as PCBs rather than as dioxins.

EPA Response:
The issue of using TEFs for coplanar PCBs was addressed during the external peer review. Accordingly, we've revised the HHRAP according to the latest World Health Organization information. See Section 3.4.5 for more discussion. Appendix A parameters have been reviewed in their entirety and have been corrected or updated where appropriate.

With regard to hazardous waste feed with low chlorine content, this is a site-specific decision to be made by the permitting authority. We've made recommendations in the HHRAP where the science is clear and left the decision open to a site-specific determination in other cases.

With regard to the remaining comments about PCBs, the HHRAP is guidance and does not require anything. As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Chemical Specific - Phthalates [draft HHRAP Section 2.3.5]
EPA was commended for its improved approach to the inclusion of phthalates but aspects of that approach were questioned. Specifically:

- Does the metabolism factor (MF) of 0.01 recommended for bis (2-ethylhexyl) phthalate (BEHP) in the beef and milk pathway apply to any other phthalate identified as a COPC, such as di-(n)-octylphthalate? Previously, none of the phthalates, if listed as COPCs, were included in the beef and milk pathway because of their rapid metabolisms and low bioaccumulation potential.
- The K_{ow} value for di-n-octyl phthalate (DNOP) in Table A-3-64 is theoretically calculated and is not substantiated as a measured value. The use of the theoretical K_{ow} for DNOP in the calculation of the air-to-plant transfer constant (Bv_{ag}) results in an unrealistically high value for Bv_{ag}. It is more appropriate to set the K_{ow} for DNOP equal to that of bis (2-ethylhexyl) phthalate, which is chemically similar and has a measured K_{ow} value.

EPA Response:
No, the MF for BEHP is not also recommended for DNOP. The HHRAP recommends one MF for BEHP and another for "all other COPCs." DNOP would fall within the latter category. We've added additional discussion regarding metabolism of DNOP. As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Draft HHRAP chemical-specific parameters have been reviewed in their entirety and have been corrected or updated where appropriate.

Issue: Chemical Specific - Hexachlorobenzene and Pentachlorophenol [draft HHRAP Section 2.3.6]
Commenter issues regarding hexachlorobenzene and pentachlorophenol include:

- Identification in the Draft HHRAP of hexachlorobenzene as a risk driver may be the result of faulty fate and transport modeling. The assumptions of previous risk assessments of hexachlorobenzene based on EPA guidance were questioned and it was suggested that those risk assessments most likely overestimate risks at receptor locations near facilities, perhaps by several orders of magnitude.
- Clarification is needed in Draft HHRAP Section 2.3.6, which provides recommendations on when to include or exclude hexachlorobenzene and pentachlorophenol as COPCs in the risk assessment.

EPA Response:
As with many parameters and equations provided in the HHRAP, we've included the scientific basis and references underlying our discussion and recommendations regarding hexachlorobenzene and pentachlorophenol. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative (e.g. a different fate & transport model) they consider more appropriate than that recommended in the HHRAP.

The guidance recommends measuring the stack gas concentrations of hexachlorobenzene and pentachlorophenol. Including these compounds in the risk evaluation is left up to the permitting authority.

Issue: Chemical Specific - Volatile Organic Compounds (VOCs) [draft HHRAP Section 2.3.7]
Commenters contend that evaluation of VOCs through the indirect food chain pathways is not technically defensible. VOCs are not hazards via indirect exposure pathways, and should be included as COPCs for only the direct inhalation pathway. According to EPA Region 6, "One argument for excluding these COPCs (VOCs) from evaluation is that there is no empirical evidence that VOC emissions pose a hazard via indirect pathways. U.S. EPA OSW agrees that it is not aware of such evidence; however, OSW is similarly unaware of a lack of evidence to the contrary."

For chemicals that do not appreciably deposit from the air, or are chemically degraded when they do deposit, the use of EPA's fate and transport models is more likely to produce misleading results than to identify potentially important exposure pathways. For example, conservative default values for VOCs are given in Draft HHRAP Appendix B without appropriate justification. Contrary to EPA's opinion, inclusion of VOCs does represent a significant amount of work for little return.

It was noted that based on the discussion of VOCs in Section 2.3.7 Volatile Organic Compounds, it is not exactly clear what information, if any, is necessary for the risk assessment report. A clear statement should be made.

EPA Response:
Given that the fate, transport, and toxicity information is provided in the guidance, we believe it is more efficient to run the subject COPCs through the risk assessment process, rather than go through the arduous process of justifying their elimination from portions of the assessment. In addition, if chemicals do not transport up various exposure routes, the fate and transport properties of these chemicals will cause them to result in insignificant risk.

The same information is needed for the subject COPCs as is for all other COPCs: chemical/physical and toxicological parameter values sufficient to complete the calculations using the recommended equations. We've modified the HHRAP text to further clarify this.

Issue: Chemical Specific - Metals
General: It was suggested that expansion of the metals list beyond the 10 BIF metals should only be done on a site-specific basis. It was also suggested that zinc is not justified for consideration in the risk assessment.

EPA Response: General
We agree. See the text box just prior to Draft HHRAP Section 2.2.1.2. Similarly, consideration of zinc should be made on a site-specific basis in consultation with the permitting authority.

Chemical-specific comments were received for the following metals:
- Chromium;
- Lead;
- Mercury; and
- Nickel

Chromium **[draft HHRAP Section 2.3.8.1]**
The section on chromium valence was considered by some to be confusing, particularly with regard to the recalculation of risk estimates based on the trivalent assumption if an unacceptable risk is derived using the hexavalent assumption. Some commenters disagreed with EPA's default recommendation that 100 percent of chromium should be assumed to be in the hexavalent state, in the absence of facility-specific speciation data. Commenters believed that this assumption is conservative, and they asked if it is supported by data from facilities that have tested for both valences of chromium. It was suggested that EPA use medium-specific chromium speciation information that is readily available in the open literature in place of the overly conservative assumptions recommended in the Draft HHRAP. Commenters also stated that metals speciation is only valid if substantiated by fate and transport characteristics, and EPA should provide a consistent, uniform approach to metals speciation.

EPA Response: Chromium
EPA considers it best to use measured, speciated emissions data in the risk assessment. If site-specific speciated emissions data are unavailable, a default speciation may be generated. Percentages of chromium assumed to be hexavalent were assessed during the peer review process. We've evaluated data available in the MACT database and derived a method to generate a default speciation. We've incorporated the new method into the HHRAP, including a detailed write-up on how we derived the method (Appendix D of the Final HHRAP).

As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Lead **[draft HHRAP Section 2.3.8.2]**
It was recommended that EPA must emphatically state that lead must always be fully evaluated as a COPC in the risk assessment because there is a significant level of risk from lead via indirect exposure pathways. CAA permits typically do not address exposure from indirect pathways, and they generally consider only inhalation pathways using protocols that are not as rigorous as EPA's guidance for hazardous waste combustion risk assessments.

It was noted that EPA suggests the use of the IEUBK model for evaluating potential exposure to lead. The routine use of the IEUBK model was seriously questioned with regard to addressing lead impacts from incinerator emissions. Issues included:

- Multi-pathway risk assessment predicts lead concentrations in many different environmental media, but these media concentrations do not directly correspond to the inputs appropriate to the IEUBK model. Commenters recommended that EPA should offer guidance about how the IEUBK model is to be run with regard to changes in exposure parameters and model default assumptions developed within the rest of the risk assessment. They suggested that a detailed section should be provided in the HHRAP in one or both of the chapters on exposure and risk characterization.
- Often calculated concentrations in soils from such emissions are quite low and the current version of the IEUBK model may not adequately handle such low impacts. Commenters suggested that, as specified in USEPA 1994, a guidance value of 400 mg/kg should be retained for soil impacts,

where calculated soil levels of 400 mg/kg or less would not require further evaluation and levels exceeding 400 mg/kg would be subjected to the IEUBK modeling.

- It was noted that the requirement to evaluate lead by inputting the estimated soil concentration to the IEUBK model ignores other exposures to emitted lead, such as exposures through the food chain. However, the IEUBK model has the ability to include lead exposures via inhalation, drinking water consumption, and ingestion of foodstuffs. Commenters suggested that the model users could input site-specific levels of lead estimated in air, drinking water, and foodstuffs to estimate a blood lead level in children due to multiple media.

EPA Response: Lead
The comment is noted regarding the need to always evaluate lead as a COPC in the risk assessment.

Detailed recommendations on what assumptions to use in the IEUBK model are site-specific. A screening method for addressing this is presented in the risk management addendum developed by EPA Region 6. Development of guidance about how the IEUBK model is to be run with regard to changes in exposure parameters and model default assumptions is beyond the scope of the HHRAP.

Mercury **[draft HHRAP Section 2.3.8.3] (See RC Section 3.5.2)**
There is agreement with EPA Region 6 that mercury should be evaluated in accordance with the information provided in the Mercury Study Report to Congress (U.S. EPA, 1997b). However, differences of opinion with U.S. EPA Region 6 were raised with regard to the implementation of this guidance in the equations used to calculate mercury concentrations in fish and plant media. Specifically, commenters did not agree with the technique used to calculate total load to the water body for the fish pathway, and they did not understand the rationale behind the root uptake equation for plant matter pathways.

The discussion on modeling methods and partitioning for mercury was considered somewhat confusing. It was suggested that a brief summary might help clarify what is being modeled in the risk assessment.

The approach outlined in the HHRAP was considered generally consistent with exposure and risk assessment methods in other guidance and regulatory reports evaluating mercury risks. However, commenters believed there are a number of difficulties with the default values EPA would have the risk assessor use for various parameters as well as with certain details of the methods.

EPA Response: Mercury
Mercury fate and transport were addressed during the external peer review. See Section 3.5.1 of this Response to Comments document for more discussion. We have made several mercury-related changes to the HHRAP, including:

- *Including dry deposition of vapor in the air model;*
- *Changing where the 85/15 speciation split is made; and*
- *The recommended accumulation factor applied to mercuric chloride.*

Further discussions and examples of mercury modeling can be found in proceedings of the IT3 conference (Kaleri, C.J. 2000. "Implementation Issues: Mercury Transport & Fate, Combustion Risk

Assessments in Region 6." Proceeding of the 12th International Conference on Incineration and Thermal Treatment Technologies. May 14-18). This reference has been added to the HHRAP.

As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. This allows a facility to evaluate whether they come up with a more appropriate alternate or site-specific value other than that recommended in the protocol.

Nickel **[draft HHRAP Section 2.3.8.4]**

It was suggested that EPA should substantiate the policy change whereby nickel in stack emissions is now to be treated as carcinogenic. It was also noted that nickel and selenium requirements were not achieved through rulemaking.

EPA Response: Nickel

We note these comments. As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Expansion of the metals list beyond the 10 BIF metals is considered on a site-specific basis. See the Draft HHRAP text box just prior to Section 2.2.1.2

Issue: Chemical Specific - Hydrogen Chloride and Chlorine Gas [draft HHRAP Section 2.3.10]

It was noted that although there is discussion in the Draft HHRAP about some of the general toxicology of hydrogen chloride and chlorine gas, EPA does not come to any conclusion about how the risk assessment process should evaluate these emissions. This is in contrast to other similar sections (for example, the preceding section 2.3.9 dealing with particulate matter). It was suggested that the HHRAP should state specifically what combustion facilities need to address in their risk assessments regarding the measured level of emissions of hydrogen chloride and chlorine gas.

EPA Response:

The HHRAP includes a discussion of hydrogen chloride and chlorine gas in order to educate the facility and permitting authority. The decision to include these chemicals in the risk assessment is a site-specific determination to be made by the permitting authority and is beyond the scope of the HHRAP. If the site-specific decision is made to quantitatively assess them, chemical-specific parameter values for both hydrogen chloride and chlorine gas are available in the HHRAP companion database.

Issue Chemical Specific - Criteria Air Pollutants [draft HHRAP Section 2.3.11]

Issues that were raised regarding the inclusion of Clean Air Act (CAA) criteria air pollutants in the quantitative risk assessment include:

- The decision about whether to include criteria air pollutants in the risk assessment should not be left up to the individual permitting authority. Typically, any area listed by a guidance document becomes another issue that the facility has to prove and negotiate to omit it from the risk assessment.

- It was suggested that because neither Table A-3 and Table A-4 of the Draft HHRAP, IRIS, nor HEAST lists toxicity values for sulfur dioxide, nitrogen dioxide, ozone, and carbon monoxide, it is impossible to include these compounds in the quantitative risk assessment.

EPA Response:
The HHRAP is guidance and not regulation. Regulatory implementation structures are such that, in the case of RCRA, the decision about what to evaluate in the risk assessment is always left up to the permitting authority.

We've further clarified our recommended process for deciding which COPCs to quantitatively evaluate, which to qualitatively evaluate, and which to drop from consideration.

Issue: Chemical Specific - Radionuclides [draft HHRAP Section 2.3.13]
Given that the radionuclide dose calculations are currently being accepted by regional EPA and state regulators for the National Emissions Standards for Hazardous Waste Air Pollutants (NESHAPS) process, it was suggested that it would be helpful if flexibility could be added to the HHRAP to also allow risk to be estimated using accepted dose-to-risk conversion factors. This would reduce the unnecessary duplication of effort and would help improve consistency between the two EPA-required assessments, i.e., the NESHAPs radiological dose assessment and health risk assessment for mixed waste combustors (both which are made available for public review). Commenters noted that while the slope factor approach would result in more realistic risk estimates, using dose-to-risk conversion factors will provide comparable results within the error bounds of the overall assessment.

EPA Response:
The HHRAP is consistent with the guidance used in the Superfund program and not NESHAPS. The HHRAP only provides a brief overview of radionuclides. A separate guidance would need to be developed to conduct a risk assessment of a facility emitting these constituents.

2.2.5 Emission Sources and COPCs - Clarification /Editorial

Issue: Clarification - Wildlife
It was asked if wildlife is also of concern with reference to page 2-33, line 8 from the bottom. Although this is clearly a "human health" risk assessment protocol, it might be indicated that either another document deals with this issue or there is too little data to approach such a protocol.

EPA Response:
Comment noted. As stated in the comment, the HHRAP is clearly a protocol for assessing potential "human health" impacts.

Issue: Clarification - 95th Percentile
It was recommended to delete or modify the sentence "The lesser of the 95th percentile or maximum stack gas concentration from the three trial burn runs should be used to develop the emission rate estimate

used in the risk assessment" (page 2-5, second paragraph) because the 95th percentile cannot be higher than the maximum concentration.

EPA Response:
We've deleted the subject sentence.

Issue: Clarification – Non-Cancer Effects
It was recommended that line 4 on page 2-43 read "...not expected to result in a significant increase in non-cancer effects above that already observed in U.S. population." The reader should realize that there is a significant background in non-cancer effects in the U.S. population that may be due to differing genetics, exposure to chemicals etc. Actually, it seems inappropriate not to have an RfD for these chemicals. On the other hand, if an RfD is not available (from any source) and there is reasonable evidence to indicate that the analyses for risk using the cancer slope factor is conservative enough to protect against non-cancer endpoints, then this should be clearly stated.

EPA Response:
We've modified the subject sentence. We've noted the balance of the comment.

Issue: Clarification - PCBs
It was recommended, with regard to section 2.3.3 Polychlorinated Biphenyls: page 2-47, lines 1-3 from bottom, eliminating "that" in "…to confirm that the absence...." to make the sentence clearer. Also, it should be more definitive whether or not the permitting authority should confirm the absence of the PCBs. The way the sentence is written, the permitting authority has the option to confirm. Either indicate which should be done, or provide some guidance into the process by which the decision is made. The commenter suggested that given the potential toxicity of the PCBs the recommendation should be that the absence should be confirmed.

EPA Response:
We've modified the subject sentence. We've also further clarified our recommendation regarding confirming the absence of these compounds from stack emissions. It is only a recommendation, however, and the permitting authority may or may not abide by it.

Issue: Clarification – Non-Coplanar PCBs
In Draft HHRAP Section 2.3.3.1 Carcinogenic Risks, the last paragraph on page 2-49 and first two paragraphs on page 2-50 were considered confusing because it is not clear if they refer specifically to the non-coplanar PCBs. Part of this could be clarified if there was a separate section for the non-coplanar PCBs. In addition, in most cases "non-coplanar" PCBs should be specified. For example, in the "Criteria for Use" Table on page 2-49, the slope factor 2 is indicated for early-life exposure by all routes to all PCB mixtures. Does this really mean all PCB mixtures or just the non-coplanar PCBs? Likewise, on page 2-50 in lines 4, 5, and 8, is it correct as is, or is non-coplanar PCBs meant? Section 2.3.3.2 Potential Non-Cancer Effects is somewhat clearer because only mixtures are discussed. However, since section 2.3.1.2 specifically designates guidance for PCDD/PCDF non-cancer hazards, it would seem appropriate that the coplanar PCBs be assessed for non-cancer hazards as described in 2.3.1.2. If this is done, then 2.3.3.2 should be changed to indicate how the non-cancer hazards should be approached for non-coplanar PCBs.

EPA Response:
We've further clarified our recommendations.

Issue: Clarification – Trial Burn Estimates
It was recommended that with regard to Draft HHRAP Section 2.2.1.1 Estimates from Trial Burns:

- Page 2-4, lines 7-8 from bottom, "Trial burn tests are designed to produce emission rates higher than anticipated under normal operating conditions," something should be added here to indicate why this should be the case. If it is because of the conditions required for these tests, a simple phrase should be added to indicate this. Also somewhere in this section it should be indicated that waste feeds used during trial burns should be similar to those used during normal operations.
- Page 2-5, 2nd full paragraph, "High POHC..." should state some conclusion. It begins by stating one aspect of the trial burn, then goes on to indicate something opposite by the PCDD and PCDF example.

EPA Response:
We address the subject further in the paragraphs below the referenced sentence. We've modified the structure of the section for clarity.

Issue: Clarification – Process Upsets
It was recommended that clarification or addition be made to Draft HHRAP Section 2.2.5 Emissions from Process Upsets, page 2-14, lines 3-5 from bottom, "U.S. EPA (1994i) indicates that upsets are not generally expected to significantly increase stack emissions over the lifetime of the facility." because it sounds like EPA is not concerned about acute risks.

EPA Response:
Comment noted. It wasn't our intention to suggest any opinion regarding acute risks in this portion of the HHRAP.

Issue: Clarification – Appendix A Values
It was noted that in Draft HHRAP Section 2.3 IDENTIFYING COMPOUNDS OF POTENTIAL CONCERN, pages 2-36 and 2-37, many of the table numbers as indicated in Appendix A are incorrect here.

EPA Response:
Comment noted. We've done an editorial review of the HHRAP, modifying where appropriate.

Issue: Clarification - Estimated Maximum Possible Concentration (EMPC)
Regarding the use of EMPC for contaminants analyzed by isotope dilution gas chromatography / mass spectrometry (GC/MS), it was suggested that use of alternative quantitation ions should be permitted if the signal-to-noise ratio of the ion signal is at least 2.5 and if the tune data indicate that the mass spectrometer is operating within specification. Such actions to reduce the EMPC would be far more cost effective than the suggested additional sample cleanup and/or reanalysis.

EPA Response:
We agree and have added language to the HHRAP to this effect.

Issue: Clarification – COPC Elimination Steps
The HHRAP text and Appendix A do not appear to agree with the flowchart in Draft HHRAP section 2.3. The instructions on COPC deletion in step 3 may be eliminated without first asking whether these COPCs are potential PICs, which is inconsistent with the flowchart.

EPA Response:
We agree and have modified both the text and the figure to more clearly state our recommended process.

Issue: Clarification - Radionuclides
In the second sentence of the second paragraph of Draft HHRAP Section 2.3.13, it could be noted that air submersion is a significant exposure pathway only for certain radionuclides that emit high-energy beta particles, such as krypton-85. In the first sentence page 75, it may be helpful to clarify that Federal Guidance Report #11 provides dose conversion factors for internal pathways (ingestion and inhalation). External dose conversion factors are given in Federal Guidance Report #12., page 6-2, Equation 6-1. It. would be helpful to note that the denominator in this equation (BW x AT) does not apply for radionuclides.

EPA Response:
The HHRAP only provides a brief overview of radionuclides. A separate guidance would need to be developed to conduct a risk assessment of a facility emitting these constituents.

Issue: Editorial
- Section 2.2.1.3 - First full paragraph: "phthalates" is misspelled.
- Section 2.2.1.3 - In the definition of Fraction 2, one must assume that the temperature range given "between 100C and 300C" is inclusive. Recommendation: The subject sentence should read "...between 100C and 300C (inclusive)."
- Section 2.2.4 - Paragraph 1, line 5: It is unclear when it is appropriate to add previous years of operation to the anticipated time period.
- Section 2.2.7 - Step 1: Determining and Empirical Emission Factor Comment: The empirical emission factor is misstated the second time as "0.107" rather than "1.07."
- Section 2.3.1 - Paragraph 4, line 3 (Polychlorinated Dibenzo(p)dioxins and Dibenzofurans): It is unclear to what "their" refers.

EPA Response:
Comments noted. Editorial errors have been reviewed and corrected where applicable.

2.3 AIR DISPERSION AND DEPOSITION MODELING [draft HHRAP Section 3]

Air dispersion models are mathematical constructs coded into computer programs that approximate the physical processes in the atmosphere directly affecting the dispersion of gaseous and particulate emissions from the stack of a combustion unit. The calculated air concentrations and deposition rates of the emitted constituents are, in turn, used to estimate potential human health risks associated with the

facility releases. In Chapter 3 of the draft HHRAP, we provide guidance on the use of the standard U.S. EPA Industrial Source Complex Short-Term (ISCST3) air dispersion model the Agency expects to use in most situations, as well as several preprocessing computer programs that prepare and organize data for use in the ISCST3 model.

An extensive range of comments was received regarding air dispersion and deposition modeling. These comments were categorized into general modeling issues and eight other specific modeling topical issues, including:

- Determining Spatial Locations;
- Surface Roughness Height (Length);
- Building Facility Characteristics
- Chemical Partitioning of Emissions;
- Estimating Dry Deposition of Vapor and Vapor Emission;
- Estimating Wet Deposition;
- Stack Temperature; and
- Clarification / Editorial.

2.3.1 General Air Dispersion and Deposition Modeling Issues

General comment issues include:

- Model Limitations;
- Model Validation;
- Selecting Parameter Values;
- Default vs. Site-Specific Parameters;
- Modeling Conservation of Mass;
- Number of Modeling Runs;
- Acute Scenario Modeling; and
- Air Dispersion and Deposition Model History.

Issue: General - Model Limitations
It was suggested that EPA emphasize the limitations of available air dispersion and deposition algorithms, and recognize that EPA models are frequently applied to situations for which they are not designed, leading to possibly highly erroneous predictions. EPA dispersion models for multi-pathway risk assessment are at best screening algorithms and should be described as such. Furthermore, EPA should suggest alternative air dispersion models that may also be appropriate for use.

EPA Response:
We agree that the HHRAP should suggest alternative air dispersion models. We've added a discussion of air models other than ISCST3 to the HHRAP, with a description of when they may be appropriate models of choice. Chapter 8 in the HHRAP is devoted to discussing uncertainty in the risk assessment that includes uncertainty in the air model.

Issue: General - Model Validation

It was noted that although EPA has continued to refine the air dispersion and deposition model and make it more sophisticated, EPA has made no efforts to validate or improve the accuracy of the model, and therefore the model should not be used extensively for a regulatory purpose (i.e., permitting activities). Additionally, commenters note specifically:

- There are insufficient field data to identify suitable inputs for these algorithms.
- The Plume Depletion algorithm has not been adequately tested.
- The draft HHRAP states that executable file "ISCST3.EXE" must be replaced with the latest version provided on the EPA bulletin. The version of ISCST3 provided with the ExInter 1.0 is not the latest available version and its results will not be consistent with current EPA requirements.

EPA Response:

We strongly disagree that the model has not been validated for air concentrations (See studies done by EPA to support the Cumulative Exposure Project (1999b), the National Air Toxics Assessment (2001a) and the Model Evaluation Results for AERMOD (Paine et al., 1998). Validation of the deposition portion of the model is less documented, but has generally been found to provide results within an order of magnitude. With regard to any specific algorithm provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. The HHRAP has been updated with the latest version of ISCST3 and the discussion of ExInter1.0 has been deleted.

Issue: General - Selecting Parameter Values

It was recommended that EPA discuss how to choose appropriate stack conditions (low temperature and flow rates) and receptor spacing, how to collocate multiple source exposures, the methodology for addressing multiple source upsets, and the benefits of creating a database to find the actual point of maximum exposure.

EPA Response:

The HHRAP presents methodologies flexible enough to adapt to site-specific situations. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific or other alternative more appropriate than that recommended in the HHRAP.

Issue: General - Default vs. Site-Specific Parameters

It was noted that the draft HHRAP seems to rely heavily on default assumptions, although EPA generally requires the use of site-specific data whenever possible. The HHRAP should specifically provide for the option of using a more refined approach as required and more sophisticated models for portions of the assessments.

EPA Response:

The HHRAP provides default values for ease of use. As emphasized throughout the HHRAP, we encourage the use of site-specific information early in, and throughout the risk assessment process.

Conservative assumptions should be made only when needed to ensure that emissions from combustion units do not pose unacceptable risks. (See HHRAP page 1-6).

Issue: General - Modeling Conservation of Mass (See RC Sections 3.3.1, 3.5.4 and 3.5.5)
It was recommended that provisions be included in the HHRAP to assess conservation of mass in areas, such as dispersion and deposition modeling and exposure assessment. They recommend multi-pathway analysis be revised because it mixes steady state and non-steady state modeling which can result in violations of conservation of mass.

EPA Response:
We've made an extensive effort to provide the most accurate yet implementable guidance for conducting risk assessments. Although there is a mixing of steady state with non-steady state assumptions within the HHRAP, every effort has been made to bound estimates and preserve conservation of mass. The question of mass balance was submitted to the external peer review panel (For more details see EPA response to the external peer reviewers), and conservation of mass checks have been incorporated throughout the HHRAP. We've revised our recommendations regarding dry deposition of vapor based on comments received regarding the conservation of mass. The external peer review panel found conservation of mass to be not affected by the soil erosion loss equal to zero except at the tops of hills. Conservation of mass may be violated in food items, but are within the error bars of biotransfer parameters. We continue to refine biotransfer equations to reduce error and minimize violation of the conservation of mass. As with many equations and parameters provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority using a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: General - Number of Modeling Runs [draft HHRAP Sections 3.7 and 3.10]
It was recommended that EPA clarify the discussion in draft HHRAP Section 3.7 regarding the number of modeling runs needed per stack source and per fugitive emission source.

EPA Response:
We agree that the discussion about the number of modeling runs on the bottom of page 3-64 is confusing, and have modified it. We recommend that stack sources be modeled using vapor, particle, and particle-bound air modeling runs, while fugitive sources be modeled using only vapor runs in the example presented.

Issue: General - Acute Scenario Modeling [draft HHRAP Section 3.11]
It was suggested that modeling of acute risks adds no additional complexity to the air modeling because the required output is obtained during the same runs for determining the average annual vapor and particle concentrations and depositions. However, it was noted that there is little guidance provided in draft HHRAP Section 3.11 on performing acute scenario modeling. It was recommended that EPA suggest an acute scenario modeling strategy, such as a tiered approach to isolate the maximum air concentration both onsite and offsite.

EPA Response:
The HHRAP was developed to be flexible to site-specific situations. The modeling approach presented in

the HHRAP allows the risk assessor to use the existing ISCST3 air model output to screen for acute effects. The ISCST3 one-hour emissions, for the worst-case metrological conditions, are used to estimate the maximum air concentration. The air modeling approach is also flexible enough to account site-specific meteorological conditions and temporal variations in emissions.

Issue: General - Air Dispersion and Deposition Model History [draft HHRAP Section 3.1.1]
It was noted that EPA mistakenly asserts that models were not available for multi-pathway risk assessment prior to 1990 (draft HHRAP, page 3-3), and does not adequately discuss in the draft HHRAP the status of specific EPA model use after 1990.

EPA Response:
The HHRAP states that before 1990, several air dispersion models were used by U.S. EPA and the regulated community. These models were of limited utility in risk assessments because they considered only concentration, and not the deposition of contaminants to land. The HHRAP has been updated to include the latest version of the ISCST3 and a discussion of other air models that may be more appropriately used on a site-specific basis.

2.3.2 Determining Spatial Locations [draft HHRAP Sections 3.2 and 3.7]

Issue: Determining Spatial Locations
It was suggested that modelers should be made aware that data used for analysis or as direct input to the model runs that have spatial attributes, such as spatial coordinates or association with specific locations, must be spatially consistent to be of any value. Specifically:

- Using a single data set by itself poses no inconsistencies and any consistent coordinate system (i.e., State Plane Feet) should be allowed for air modeling.
- When multiple data sets are compared, EPA recommends using Universal Transverse Mercator (UTM) coordinates for all spatial locations to properly align the data. Commenters recommend the HHRAP makes explicit that UTM is a map coordinate projection of geographic coordinates and the horizontal datum of the geographic coordinates from which the UTM coordinates were projected must be known. Since it is most likely that modelers will need to translate data to a single reference, modelers should be made aware that there are many computer programs available, some free and some at cost, that will, with varying degrees of accuracy, project coordinates from geographic coordinates to UTM coordinates. The U.S. Geographic Survey and US Army Corps of Engineers have reputable and widely used programs (NADCON and CORPSCON) with user guides and source computer code available.

EPA Response:
The coordinate system recommended in the HHRAP was suggested to provide consistency. Other coordinate systems can be implemented provided they are done so consistently.

2.3.3 Surface Roughness Height (Length) [draft HHRAP Sections 3.2 and 3.6]

Several comments were received with regard to air modeling using surface roughness height. Commenters expressed a broad range of opinion, ranging from suggesting establishment of a simplified default method for determining surface roughness heights using a reference table containing average values, based on land use type, to the assertion that the draft HHRAP unrealistically simplifies the treatment of surface roughness height and should be revised to allow use of well established methods to compute this input. Following are comments addressing both sides of the issue.

Issue: Surface Roughness Height - Simplified Default Modeling Approach
Commenters advocating a more simple approach to modeling surface roughness height assert that:

- Inclusion of the terrain elevations significantly increases both the level of effort to set up the modeling and the run time of the ISCST3 model without appreciably influencing the outcome of the air modeling results or having a significant impact on risk assessment. It was suggested that inclusion of terrain elevations should be made on a site-by-site basis.
- The required level of detail is questionable in the methodology for determining the surface roughness height at the application site, as specified in the draft HHRAP, starting on page 3-11. Based upon EPA's sensitivity analysis (Secrest, 1997) only some variation, generally within 20%, is shown in results when varying the surface roughness height. Moreover, these sensitivities were modeled at extreme points (0.001 meter representing all water area and 1.3 meters representing all forest area) in comparison to the EPA default value of 0.1 meter.

EPA Response:
We do not recommend a simpler, reference table approach to determining surface roughness height because sensitivity analysis has shown surface roughness to be a rather sensitive parameter, and we do not feel there is sufficient difficultly in the site-specific surface roughness calculation to warrant this simpler approach. However, sensitivity analysis (see U. S. EPA Region 6 web page) also shows that although surface roughness might have a substantial effect on air modeling output, the effect on a risk assessment is generally less than a factor of two, which in most cases is not considered severe. Studies completed to date suggest the air model provides reasonable estimates of deposition, but we agree that more work could be done in validating the deposition portion of the air model.

Issue: Surface Roughness Height – Modeling with Site-Specific Parameter Values
Commenters claiming the draft HHRAP oversimplifies the treatment of surface roughness height raised the following issues:

- The implications of using average values for surface roughness height and other parameters, such as albedo, Bowen ration, anthropogenic heat flux, and fraction of net radiation absorbed at the ground, are difficult to gauge. It was recommended that EPA engage in a study of model sensitivity to explore this matter.
- How representative is the EPA recommended default value of 0.1 meter for surface roughness height?

- How can the default value of 0.1 meter be considered without approval when the deposition algorithms are quite sensitive to the surface roughness height, which can vary over several orders of magnitude and have large effects on the modeled dry deposition flux value?
- EPA recommends using a calculated weighted-average value for surface roughness height based on land use characteristics in different directions from the modeled facility. It was recommended that the prediction of particle deposition consider the local surface roughness height at the receptor location.
- Depending on the topography of an area, the 1:250,000 digital elevation model (DEM0) 90-meter spacing data, which have an accuracy of 8 to 15 meters, may not be accurate enough as the sole source of data for receptors within 10 km of the source. It was recommended that potential problems with digital elevation data be addressed by incorporating more accurate terrain data if the 90-meter spacing DEM data are not adequate for the evaluation.

EPA Response:
The HHRAP is guidance and there is no requirement to determine surface roughness height or any other parameter by the methodology in the guidance. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP. In most cases we would not question the default value of 0.1 meters for surface roughness height. However, where appropriate, a site-specific value may be developed in consultation with the permitting authority. We agree that more accurate terrain data should be incorporated if the 90-meter spacing DEM data are not adequate for the evaluation.

Issue: Surface Roughness Height - (Length) Definition
It was recommended that the definition for surface roughness length contained in the PCRAMMET User Guide be used instead of a definition from some other reference.

EPA Response:
We no longer recommend using PCRAMMET, instead recommending the use of MPRM to generate the input data ISCST3 needs to run properly. Therefore, definitions in the HHRAP, including surface roughness height, appropriate to MPRM have replaced those appropriate for PCRAMMET.

2.3.4 Facility Building Characteristics [draft HHRAP Sections 3.2 and 3.7]

Issue: Facility Building Characteristics - Modeling Building Contours
It was recommended that EPA building wake algorithms be revised because they do not reasonably support open or rounded aerodynamic structures and have overestimated impacts of a number of common industrial structures.

EPA Response:
As with many parameters and equations provided in the HHRAP, the scientific basis and reference for the building wake algorithms are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: Facility Building Characteristics - Modeling Stack Height
It was recommended that stacks exceeding 60 meters in height be modeled at their actual stack height and not limited to 60 meters as stated in the Guide for Air Quality Models (U.S. EPA, 1996). The purpose of the GAQM is to address the National Ambient Air Quality Standards (NAAQS) on a regional basis and independent of location, whereas the draft HHRAP addresses risk at specific locations. There is no inconsistency between modeling a stack taller than 60 meters at its actual height for the HHRAP and modeling the same stack at 60 meters for NAAQS analysis.

EPA Response:
The HHRAP recommends using actual stack height. Section 3.6.2.2 recommends using the height above the plant base elevation. We cannot find any point where the HHRAP recommends using a stack height of 60 meters for stacks actually taller than 60 meters.

2.3.5 Chemical Partitioning of Emissions [draft HHRAP Sections 3.4, 3.7, and 3.9]

Issues raised under chemical partitioning of emissions include:
- Particle Phase Partitioning;
- Determining Particle Size Distribution;
- Determining Particle Density; and
- Cost of Collecting Particle Density Data.

Issue: Emission Chemical Partitioning - Particle Phase Partitioning
(See RC Sections 3.3.1, 3.3.3, 3.3.4 and 3.3.6)
Particle deposition should consider the most appropriate particle size distribution, which may not in fact be that of stack emissions. For some chemicals that might partition in the air, it is debatable whether the particle distribution in the stack or in ambient air is of greater relevance. More specifically:
- It was recommended that EPA should consider the matter and offer recommendations regarding the conditions, if any, where it is appropriate to consider a general particle size distribution for ambient air within deposition modeling, and develop a method that estimates site specific partitioning fractions based on both the background particles and the particles actually emitted.
- Partitioning of chemicals between the particulate and vapor phases is scientifically invalid because it is based on ambient particles rather than site specific particle emission rates. The partitioning fraction (Fv) between the vapor and particle phases for each chemical is assumed constant, regardless of the mass, rate, and size of the particles emitted from the source. The Fv values are based on equilibrium between the vapor phase and the surface area of background particles in the air, not the actual particles being emitted. Since the Fv values are scientifically invalid, the COPC concentrations in the vapor and particle phases and deposition rates that are derived from them are

also incorrect. Because this approach omits the particles emitted from the source, it will overestimate the concentrations of chemicals in the vapor phase and underestimate the amounts in the particle phases for most facilities.

EPA Response:
Part one of the comment requests conditions where a general particle size distribution could be used For facilities with stack test results which indicate mass amounts lower than the detectable limit (or the filter weight is less after sampling than before), the HHRAP recommends using a single mean particle size diameter of 1.0 microns to represent all mass (e.g., particle diameter of 1.0 microns or a particle mass fraction of 1.0) in the particle and particle-bound model runs. Part two of the comment addresses the scientific validity of the partitioning fraction (Fv). We believe the method for chemical partitioning recommended in the HHRAP is the most appropriate existing method. A detailed discussion of the scientific basis for the recommended method can be found in Appendix A of the HHRAP. A facility can propose and justify to the permitting authority an alternative method for use on a case-by-case basis.

Issue: Emission Chemical Partitioning - Determining Particle Size Distribution
(See RC Sections 3.3.1 and 3.3.6)

Comments were received requesting that EPA provide acceptable approaches for measuring or determining default values for particle size distribution. Values for particle size distribution are required as model inputs to calculate dry deposition. The related EPA trial/risk burn guidance document, "Guidance on Collection of Emissions Data to Support Site-Specific Risk Assessments at Hazardous Waste Combustion Facilities" (U.S. EPA, 1998c) did not provide any clear direction on measuring particle size distribution, stating "widely accepted methods for determining particle size-size distribution is not yet available." Also, a number of facilities have attempted to measure particle size distribution but with limited success. In lieu of measured values, the draft HHRAP recommends default values for particle size distribution. Commenters raised various issues about the use of default values, including:

- For low emitting sources, the draft HHRAP recommends a default of one particle size of 1 µm be used for the particle size distribution because, EPA reasons, there is particulate mass in the stream but it is all small and in the range of 1 µm and smaller. It was questioned whether the default value of 1 µm is valid for a low emitting source without emission testing. These commenters have taken samples from a low-emitting source over a long sampling time, and found very small concentrations of detectable particles much larger than 1 µm. These results illustrate the dilemma of choosing between a default value that might not be representative and costly long-period sampling of extremely low emissions that may be of little significance in the risk assessment.
- It was recommended that EPA provide acceptable approaches in the HHRAP and trial/risk burn guidance for measuring particle size distribution and particle density for HEPA systems that have highly variable waste feed. One suggested alternative would be to assume a default particle size distribution for uncontrolled emissions at a generic incinerator (available in California Air Resources Board (1990) reports, EPA's AP-42 (1995a), and the scientific literature), and make modifications via spreadsheets based on the penetration fraction through the specific air pollution control devices at the given facility. Including an example of this type of spreadsheet calculation in the guidance would be helpful.

- Given the information from the sensitivity analysis and the difficulty of developing accurate particle size distribution data with existing methods, it was strongly recommended that the default particle size distribution be changed to reflect the fact that best measurements to date indicate that 80% of the particles are less than 2 microns. This will more accurately reflect the state of the art for coarse particle removal and will create more accurate deposition estimates. Measuring particle size distribution will become even more inconsequential when facilities install equipment to meet the new MACT PM standard, at which time; it is likely that virtually all particles emitted from all facilities will be below 1 micron.
- The draft HHRAP states that "a minimum of three particle size categories (>10 µm, 2-10 µm, and <2 µm) detected during stack testing are required for air modeling." Commenters ask whether the ranges stated, i.e., >10 µm, 2-10 µm, and <2 µm, are a requirement as well. The range requirement may not be practical because there may be instances when the particles in the sample train do not fit within each of the three ranges.
- A sensitivity analysis of the ISCST3 model to the number of particle size categories (Secrest, 1997) shows that the model is not sensitive to the number of particle size categories as long as the same range of sizes is included. Stated another way, it did not matter whether there were 3 or 9 particle size categories as long as the range of categories did not change from the base case (0 to 15 micron diameters). Therefore, commenters question the draft HHRAP recommendation that 8 to 10 particle size distribution values produced from the stack results be used during the air modeling (though it does state a minimum of 3 are required for air modeling). Computer run time is increased for every particle size added.

EPA Response:
The distribution of particulate by particle diameter will differ from one combustion process to another, and is greatly dependent on the:

- *Type of furnace;*
- *Design of the combustion chamber;*
- *Composition of the feed fuel;*
- *Particulate removal efficiency;*
- *Design of the APCS;*
- *Amount of air in excess of stoichiometric amounts that are used to sustain combustion; and*
- *Temperature of combustion.*

However, based on these variables, the particle size distribution cannot be calculated, but only directly measured or inferred from prior data. Unfortunately, few studies have been performed to directly measure particle size distributions from a variety of stationary combustion sources. We therefore recommend that existing facilities perform stack tests to identify a site-specific particle size distribution.

The "Guidance on Collection of Emissions Data to Support Site-Specific Risk Assessments at Hazardous Waste Combustion Facilities" (U.S. EPA, 1998e, EPA/600/6-90/003) has been updated (i.e., "Risk Burn Guidance for Hazardous Waste Combustion Facilities" (U.S. EPA 2001b, EPA530-R-01-001)), and now contains detailed and tested methods for measuring particle size distribution. Data can always be submitted in lieu of actual measurement of particle size distribution, along with documentation to justify

why it is acceptable for use in the air model. The example particle size distribution we use in the HHRAP has been clearly labeled as an example and not a default particle size distribution.

The HHRAP is a guidance document and clearly recommends that a minimum of 3 particle size distributions are necessary. The eight to 10 particle size categories mentioned in the comment are what is typically measured by the cascade impactor methodology, and if they are measured, there appears to be no reason not to use them in the air model. We disagree that computer run time is a critical factor in

choosing the particle size distribution values. The number of partitions can be negotiated with the permitting authority.

Issue: Emission Chemical Partitioning - Determining Particle Density
Guidance was requested on appropriate methods for measuring or determining default values for particle density. Values for particle density are required as model inputs to calculate dry deposition, but there does not appear to be any effective stack sampling methods to measure particle density. Commenters raised issues about measuring particle density and using alternative default values for particle density in lieu of measured values. These issues include:

- The draft HHRAP assumes the particle density is the same for all sampling cuts. How does EPA propose the particle bound mass fractions be apportioned if a particle density can be determined for each sample cut, and the density varies from sample cut to sample cut?
- Should the default value of 1 g/cm^3 to be used as representative in all cases since the mass of samples is typically on the order of milligrams, and the dry deposition flux is approximately linearly proportional to particle density?
- It was recommended that EPA acknowledge in the HHRAP that particles emitted from cement kiln stacks are not similar to those of other combustion devices. A more appropriate default density value for the cement kiln industry would be 3.0 g/cm^3.

EPA Response:
We recommend that site-specific measured data on particle density be determined for all existing sources when possible. Determining particle density is part of the trial/risk burn guidance. With regard to any specific parameter provided in the HHRAP, the scientific basis and reference are provided. We acknowledge the variation in particles emitted from each type of facility. A facility can evaluate whether to propose and justify to the permitting authority an alternative to that recommended in the HHRAP.

2.3.6 Estimating Dry Deposition of Vapor and Vapor Emission [draft HHRAP Sections 3.4, 3.6, 3.7 and 3.9]

Issue: Estimating Dry Deposition - Dry Deposition Vapor Velocity
Several comments were received questioning the values and methods for determining the dry deposition vapor velocity, as contained in the draft HHRAP. Issues include:

- The approach for computing deposition velocities is too subjective and should be revised to reference an established method that will promote consistency.
- EPA's recommended single deposition velocity of 3 cm/s used to calculate the deposition of all vapors derives from measurements involving nitric acid, a highly soluble compound that readily deposits from the atmosphere. This assumption likely overestimates the vapor-phase deposition of hexachlorobenzene and other gases.
- EPA should develop a generic but representative range of parameters for use with draft algorithms for gaseous deposition built into a test version of the ISCST3 code to estimate some typical or average deposition velocities for categories of vapors that can be distinguished by values of Henry's Law constants (the most critical gas-specific parameter), and use the results of the most appropriate run for each chemical of interest.
- EPA has not considered the direct effect of temperature on dry deposition vapor phase diffusion. For instance, how can direct vapor transfer occur at the same level for a frozen or liquid surface? In the northern part of the country, many surface water bodies will only reach the assumed temperature of 25^{o} C (about 78^{0} F) for a brief portion of the year.

EPA Response:
Dry deposition of vapor was re-evaluated during the external peer review of the HHRAP, and alternative default dry depositions of vapor velocities have been provided. Furthermore, dry deposition of vapor has been included in the ISCST3 model (as opposed to a post-process mechanism), along with new recommended default values and literature citations upon which they are based. As with many default values provided in the HHRAP, the scientific basis and reference are provided. This HHRAP is guidance and allows a facility to evaluate whether to propose and justify to the permitting authority using site-specific values, or other alternatives to those recommended in the HHRAP.

Issue: Estimating Dry Deposition - Dry Deposition and Vapor Emission from Soils (See RC Sections 3.3.5 and 3.5.4)
Comments were received about the EPA's recommended application of dry vapor phase deposition and diffusion in equations for estimating soil concentrations, as contained in the draft HHRAP. These include:

- The HHRAP should more explicitly state in the text that the dry vapor phase diffusion load to soil (Ldif) parameter contained in draft HHRAP Equation 5-lA for calculating soil concentrations is no longer accounted for in the recommended equations for calculating soil concentration (i.e., equations 5-1C through 5-lE) because the Ldif term contributes negligibly to the soil concentration and can be reasonably excluded from the soil concentration calculation.
- To be conservative in the face of uncertainty, EPA recommends a value of 0 for the soil COPC loss constant due to volatilization (ksv). This assumption, in combination with the recommended dry deposition velocity of 3 cm/s for all volatile organic compounds, simulates a one-way flux of vapor from the air into soils. This is not consistent with known fate and transport properties of many vapors, and implies that the soil acts as a sponge to remove vapors from the atmosphere. For instance, equilibrium-like transport behavior of environmentally persistent chemicals such as polychlorinated biphenyls (PCBs) demonstrates the inconsistency of EPA's approach.

EPA Response:
The dry deposition of vapor was addressed during the external peer review of the HHRAP. Changes have been made according to recommendations of the external peer review panel. Both the ksv and dry deposition of vapor velocity sections of the HHRAP have been revised.

Issue: Estimating Dry Deposition - Dry Deposition and Vapor Emission from Water (See RC Section 3.3.5)
It was argued that dry deposition of vapors to the water body is modeled incorrectly. In the draft HHRAP, the equation to estimate dry deposition of vapors Ldif to the water body considers a one-way transfer of the pollutant from the air into the water body. However, mass transfer from the air into the water body should be modeled as the product of a mass transfer coefficient and the difference between two concentrations, that in the air and the effective concentration in the water, which serves as a resistance to mass transfer across the air-water interface. Given the way that EPA's model is constructed, loadings into the water body from soil erosion and runoff could be large enough to serve as a source of emissions to the air from the water body. By not allowing for the outward flux of vapors from the water to the air, EPA's model in some cases could incorrectly predict the trapping of a volatile chemical within the surface water body.

EPA Response:
This issue was reviewed during the external peer review of the HHRAP. Assuming that volatile chemicals are trapped in the water body (as suggested in the comment) would result in a conservative estimation of drinking water and fish concentrations. If this tended to result in risk/hazard levels above the benchmark, a more detailed site-specific fate and transport analysis could be conducted. However, we are unaware of any case where this has actually occurred. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to recommend and justify to the permitting authority a site-specific value or other alternative to that recommended in the HHRAP.

Issue: Estimating Dry Deposition - Meteorological Inputs to Dry Deposition of Vapor Modeling
Comments were received addressing modeling of meteorological parameters required to execute dry deposition of vapor algorithms included in the latest ISCST3 model. These include:

- The basis for the intended update of the dry deposition algorithm by using hourly solar radiation data and leaf area index is not explained and should not be implemented without substantiation and review.
- EPA states that only the Meteorological Processor for Regulatory Models (MPRM) program is scheduled to be updated to include the necessary solar radiation and leaf area index parameters required in calculating dry vapor deposition for use in risk assessment. The HHRAP should clarify that the facility "might be required to collect onsite meteorological data" if the MPRM is the only option for using dry deposition of vapor in future risk assessments.

1) It was recommended that the HHRAP contain a discussion explaining the necessity of processing each year of meteorological data for each season and combining the results into a season-specific meteorological file. Because of seasonal variations, an annual average surface roughness or other site-specific parameter, such as wind speed, precipitation amounts, and temperature should not be used to process meteorological data. Using an annual average file would overestimate depositions

during the winter months and underestimate depositions during the summer months as site specific parameters change dramatically for each season.

EPA Response:
We've clarified the use of the MPRM. Concentrations and exposure in the HHRAP are based on long-term equilibrium assumptions. Variations in results based on seasonal effects are accounted for with site-specific inputs to the air and terrestrial fate and transport models. The HHRAP now recommends using MPRM as opposed to PCRAMMET to accommodate more currently available meteorological data for use within ISCST3 to calculate dry deposition of vapor. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

2.3.7 Estimating Wet Deposition [draft HHRAP Section 3.7] (See RC Section 3.3.5)

Issue: Estimating Wet Deposition
Commenters acknowledge the wet deposition model has been improved by allowing use of more accurate precipitation data. However, the EPA needs to consider new information on wet deposition before finalizing the draft HHRAP. The model used for wet deposition of vapors needs to be revised to consider water solubility and other factors. There is only a very weak scientific basis for the scavenging coefficients used to compute wet deposition rates. The assumed relationship between wet deposition and precipitation rate should be verified or revised to take non-linearities into account.

EPA Response:
In most situations, we recommend the latest version of the ISCST3 air model, which has been revised since the draft HHRAP was released. However, as air modeling advances, one should always take into account the most recent state-of-the-science. The comment regarding consideration of water solubility will be forwarded to OAQPS for further refinements in their air models. This issue was reviewed during the external peer review of the HHRAP, and the expert peer review panel did not believe that wet precipitation rates are linearly proportional. However, the panel could not recommend another methodology. As with many parameters provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

2.3.8 Stack Temperature [draft HHRAP Sections 3.5 and 3.7]

Issue: Stack Temperature:
Several comments were received about modeling stack temperature. The issues raised include:

- The statement in the draft HHRAP, that the stack exit temperature is the most critical parameter for influencing the concentration and deposition rates, is misleading because there are many parameters that can have a significant impact on the calculation of concentrations and deposition fluxes.

Further, the stack temperature will not play a dominant role in the plume rise if the plume rise is due to momentum flux and not buoyancy flux.

- Because, in theory, risk burn results should not be significantly different from run to run, it was proposed that the arithmetic mean of the temperatures and velocities from the multiple risk burn runs be used as inputs to the model.
- Stack temperature will remain constant in the modeling. Only the ambient temperature will vary from hour to hour. It was recommended that the EPA discuss the choice of stack temperature for the analysis in the HHRAP. To be conservative, it would be appropriate to choose the lowest operational stack temperature to decrease buoyancy induced plume rise, increasing air concentrations and depositions. Consideration may want to be made when choosing a meteorological data period with either average or above average annual temperatures for the area to also reduce plume rise.

EPA Response:
The relative importance of stack temperature is a matter of opinion and has no effect on results. Stack temperatures in the field have not been found to vary much among trial/risk burn runs. In most cases, the average velocity and temperature are used in the source parameters. If these numbers differ significantly during the trial or risk burn, a site-specific decision would need to be made. EPA's GAQM recommends using 5 years of meteorological data to simulate long-term average meteorological conditions.

2.3.9 Clarification / Editorial

Issue: Clarification - Meteorological Data

- Draft HHRAP Section 3.5.1.5 - Is pressure adjusted to surface elevation? If so, it would appear to be important for high-altitude locations.
- Draft HHRAP Section 3.5.1.6 - ISC addendum 99155 incorporates a dry gas deposition algorithm.
- Draft HHRAP Section 3.5.2 - "Upper air data" and "mixing height data" are NOT equivalent terms.

EPA Response:
Surface pressure referred to in the Draft HHRAP is the same as station pressure. The statement should more accurately read the "MPRM preprocessor for ISCST3 requires station pressure" since MPRM uses station pressure to compute Monin-Obukhov Length and Friction Velocity, then passes these two boundary layer parameters into ISCST3 to perform dry particle deposition. Station pressure is not an explicit meteorological input into ISCST3. The requirement for station pressure is to compute the air density at station pressure. Air density is used by MPRM to compute Monin-Obukhov Length and Friction Velocity, which in turn are used in ISCST3 for computing dry particle deposition velocity due to gravitational settling. At higher station elevations, air density is reduced from sea level. Conceptually, less dense air will have less resistance to deposition and result in higher deposition velocities at higher elevation. However, in theory and application, variations in deposition velocity are negligible except for very small particles between 0.1 and 1.0 micron diameter. For the 1-micron particle size, nominal effects on dry particle deposition as a consequence of variations in station pressure are expected. The latest

version of ISC has been incorporated into the HHRAP. The reference of upper air data as mixing height data has been corrected.

Issue: Clarification - PCRAMMET model issues

- Draft HHRAP Section 3.6.1.1 - This discussion is confusing. "L" in urban areas for nighttime stable conditions should have a (positive) maximum value that is smaller for more built-up cities than for less built-up cities (i.e. the former have less stable nighttime conditions).
- Draft HHRAP Section 3.6.1.3 - The discussion of aerodynamic surface roughness and the sensitivity of atmospheric concentrations to this term is confusing and misleading.
- Draft HHRAP Section 3.6.1.6 - Bowen ratio is not a "measure of surface moisture;" rather it is defined as the ratio of the sensible heat flux to the latent heat flux. The latter is sensitive to soil moisture.
- Draft HHRAP Section 3.6.1.8 - This discussion is misleading. M-O length is sensitive to net radiation. The "fraction of net radiation absorbed" is a misnomer.

EPA Response:
The current version of ISCST3 utilizes MPRM rather than PCRAMMET. Comments were incorporated into the updates of the MPRM input parameters.

Issue: Editorial

- Draft HHRAP Section 3.7.5 – EPA's recommended use of terrain grid files is not necessary.
- Draft HHRAP Section 3.8 - The discussion of run times for different computers is out of date.
- Draft HHRAP Section 3.9.1 - The reference to "theory" in the 3rd sentence might be better stated as "rationale" or some such term.
- Draft HHRAP Section 3.9.1.2 - First line: Equation 3-1 should read 3-2.
- Draft HHRAP Section 3.9.3.1 - The reference to "five percent" is unclear.
- Draft HHRAP Section 3.10 - The height of the fugitive source is defined as "one-half …"
- The heading of Draft HHRAP Table 3-1 and the text on page3-20 are inconsistent (Chapter 3, page 3-19).
- There is a typo on Draft HHRAP page 3-21. "If particle density is held constant (such as 1 g/m^3)" should read "1 g/cm3."

EPA Response:
Editorial changes where made as suggested above.

2.4 EXPOSURE SCENARIO IDENTIFICATION [draft HHRAP Section 4]

To conduct a risk assessment, the appropriate exposure scenarios must be identified. An exposure scenario is defined as a collection of exposure pathways to which a single, hypothetical receptor may be subjected. Common human exposure pathways for hazardous waste combustion facilities include inhalation of contaminants directly from the air and ingestion of contaminated media, such as water, soil, or food.

Comments regarding exposure scenario identification were categorized into:

- General Issues;
- Foodstuff Ingestion;
- Acute Risk Assessment;
- Selecting Exposure Scenario Locations;
- Special Populations;
- Land Use; and
- Clarification / Editorial.

2.4.1 Exposure Scenario Identification – General Issues

General issues include:

- Identification of realistic receptors; and
- Inclusion of all potentially exposed populations.

Issue: General - Identification of Realistic Receptors (See RC Section 3.4.4)
Commenters suggested that it is unrealistic to require a new or existing combustor to quantitatively evaluate in the risk assessment the subsistence farmer, the subsistence farmer child, the resident, the resident child, the subsistence fisher, the subsistence fisher child, and the acute risk scenario. A more realistic approach might be to characterize risk for actual or hypothetical rural residents or farmers who consume some home-produced food, but who are not actually subsistence farmers. A more realistic risk assessment can identify the most affected locations and the types of people most likely to be affected at those locations.

EPA Response:
Review of this issue during the external peer review concluded that the subsistence terminology is not consistent with the actual mass per day amounts of ingested food items evaluated in the recommended exposure pathways. The daily consumption amounts associated with the farmer scenario, which help to define the scenario, are more comparable to reasonable versus subsistence amounts. The HHRAP has been revised to remove references to "subsistence" farming.

Issue: General - Inclusion of All Potentially Exposed Populations
Additional guidance and details were requested regarding:

- Information that should be gathered during the evaluation of the receptors of concern. It was recommended that there be specific requirements for the risk assessment to recognize and evaluate all potentially exposed populations, including sensitive populations.
- When and how the subsistence fisher and subsistence fisher child scenarios should be evaluated, what documentation should be relied on for the presence of subsistence fishers, and how the results must be assessed.
- Ensuring comprehensiveness by acknowledging the importance of including scenarios that may be unique to specific populations, such as Native Americans.

- The draft HHRAP statement that workers from the facility under direct evaluation in the risk assessment are excluded in most cases because there are other guidance and regulations for occupational exposures to hazardous waste and hazardous waste combustion emissions within the facility boundary (e.g., OSHA). The statement in the draft HHRAP (Section 4.1, page 4-3, 1st paragraph, last sentence) that "there might be some instances (e.g., acute risk) where worker exposure at nearby facilities or commercial areas within the assessment area are considered within the risk assessment" might imply that a requirement could exist to directly evaluate workers in the risk assessment in some undefined cases. It would be helpful to define these cases or cross-reference to another section that does this, and to define when workers are explicitly excluded because they are covered by other guidance and regulations.

EPA Response*:*
The HHRAP is guidance and contains no requirements. Whether or not the fisher pathway should be evaluated in a risk assessment is a risk management decision. Site-specific data, such as fish consumption rates for Native American populations, is one of many considerations, which may need to be addressed. Sections 4.1.3 and 4.2 have been written to allow and promote this kind of evaluation. We've further clarified our recommendations regarding when to include or not include a worker scenario in a risk assessment.

2.4.2 Exposure Scenario Identification - Foodstuff Ingestion

Issues pertaining to foodstuff ingestion include:
- Amount and kinds of food ingested; and
- Calculation of methyl mercury intake.

Issue: Foodstuff Ingestion - Amount and Kinds of Food Ingested
It was recommended that risk assessors be allowed to prepare a realistic, site-specific risk assessment that does not include hypothetical worst-case receptors. For example, the draft HHRAP provides examples of food consumption factors, but these values are actually higher than those that can be found in the EPA Exposure Factors Handbook (U.S. EPA., 1997c). If farmers are living within the vicinity of the incinerator, the farmers do not necessarily obtain all of their food from the farm.

EPA Response:
We've further clarified our recommended process for estimating consumption rates. These rates are average, rather than worst case rates. Nevertheless, the HHRAP is guidance and contains no requirements. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. Site-specific data, along with supporting documentation, can always be submitted to the permitting authority for further consideration.

Issue: Foodstuff Ingestion - Calculation of Methyl mercury Intake (See RC Section 3.5.2)
The approach to calculating methylmercury ingestion was questioned. The draft HHRAP requires that a risk assessment assume that 2% of soil-deposited divalent Hg is methylated and that 15% of the steady-state Hg concentration estimated for surface water bodies is methylated. A bioaccumulation factor (BAF) of 6,800,000 must be used for methylmercury to estimate Hg concentrations in fish. Uptake into fish of elemental mercury or divalent mercury is not considered. Exposure through fish consumption is then evaluated for a hypothetical subsistence fisher. It was suggested that the default values are too high, the directions for use of the BAF are incorrect, and the fish consumption pattern is incorrect.

EPA Response:
We re-evaluated the environmental fate & transport of mercury, including methylation of divalent mercury. The external peer review also addressed these subjects, and the HHRAP was modified per peer comments. However, the particular items mentioned in the comment were not changed. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

2.4.3 Exposure Scenario Identification - Acute Risk Assessment

Issues pertaining to assessment of acute risks include:
- Including acute risk exposure assessment;
- Availability and selection of criteria for acute exposure;
- Calculating acute and long-term fugitive emissions;
- Health effects from short-term exposures;
- Particulate Matter Inhalation;
- Cumulative risk calculation; and
- Site workers.

Issue: Acute Risk Assessment - Including Acute Risk Exposure Assessment (See RC Section 3.4.1)
One commenter lauded including assessment of non-cancer health risks posed by brief (e.g., one-hour) inhalation exposures to airborne chemicals. Another commenter suggested that a careful, independent approach to acute health risk assessment should be developed.

Other commenters questioned the utility of estimating acute risks for the following reasons:
- Since the acute risk scenario evaluates the effects of direct inhalation of vapors and particles from short-term exposures, it is most likely to result in an extremely small lifetime exposure.
- Acute standards are not available for all chemicals, and many of the available acute standards are controversial.
- Acute toxicity standards are generally much higher than the corresponding chronic RfDs or RfCs.
- Since it is unclear how this information would be used in permit decision-making, evaluating this scenario would increase the level of effort while making only a questionable contribution to the overall evaluation of risks at any facility.

- Acute exposures can be substantially overestimated, based on the methods shown. The guidance should also allow alternative methods.

EPA Response:
Comments noted. The issue of evaluating acute toxicity was addressed during the external peer review, and we've revised the HHRAP, taking into account the most recent science in the area of acute risk assessment. As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Acute Risk Assessment - Availability and Selection of Criteria for Acute Exposure (See RC Section 3.4.1)
The draft HHRAP states that "no one single organization or methodology has developed acute values or benchmarks for all of the potential compounds of concern." The same can also be said of chronic toxicity data, so there is no point in making this statement. The acute inhalation exposure criteria, Acute Exposure Guideline Levels (AEGLs) and Emergency Response Planning Guides (ERPGs), are only available for a limited number of compounds. Their derivation is also highly controversial in the scientific community, and many of the published values are the subject of ongoing litigation with USEPA. Therefore, due to the conservative nature of acute inhalation exposure criteria, the acute hazard quotient may significantly overestimate hazards associated with acute inhalation exposure to stack or fugitive emissions.

With regard to the recommended use of AEGL, ERPG, ATEL, Temporary Emergency Exposure Limit (TEEL), and SCAPA toxicity-based approach values (in order of preference) as acute toxicity benchmarks for evaluating acute hazards from emissions from hazardous waste incinerators, it was suggested that AEGL, ERPG, TEEL, and SCAPA toxicity-based approach values are inappropriate. Noting that they were developed for use in emergency response situations involving accidental chemical releases, the assumptions on which these benchmarks are based (i.e., that an individual will be exposed for only a one-hour period followed by a recovery period of two to four weeks and that there are no background exposures) are inappropriate. ATEL criteria (also called Acute Reference Exposure Levels) were recommended as the most appropriate for evaluating acute hazards from emissions from hazardous waste incinerators which can occur for a longer duration than one hour and more frequently than every two weeks.

It was noted that criteria cited in the draft HHRAP are out of date, and suggested that since all sources of the proposed Acute Inhalation Exposure Criteria (AIEC) continually develop and revise acute exposure criteria, the HHRAP should explicitly state that risk assessors should obtain the most current values.

It was also suggested that evaluating a smaller number of constituents in more depth would be better than including the large number of constituents for which there is limited toxicity data.

EPA Response:
The state of development of acute toxicity benchmarks may not be known as well to most of the risk assessor users as it is to the person providing the comment and therefore, the sentence remains in the HHRAP.

The issue of the most appropriate criteria was addressed during the external peer review, and we've revised the HHRAP, taking into account the most recent science in the area of acute risk assessment. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Regarding the suggestion to limit the assessment to a smaller number of constituents, given that the fate, transport, and toxicity information is provided in the HHRAP, we believe it is more efficient to run the selected COPCs through the risk assessment process, rather than go through the arduous process of justifying elimination of COPCs from the assessment.

Issue: Acute Risk Assessment - Calculating Acute and Long-term Fugitive Emissions
The suggestion was made that acute and long-term fugitive emission rates for components handling dedicated, invariable waste streams be calculated and speciated identically. Components handling multiple or variable waste streams require different calculations for acute and long-term speciated fugitive emission rates. A long-term fugitive emission rate should be speciated according to the volume-weighted average annual composition of waste passing through a fugitive component. An acute fugitive emission rate should be speciated according to the most "conservative" (with regard to toxicity values and volatility) waste stream handled by the fugitive component.

EPA Response:
Calculating acute emission rates for fugitive emissions is beyond the scope of the HHRAP.

Issue: Acute Risk Assessment - Health Effects from Short-term Exposures (See RC Section 3.4.1)
It was suggested that the term "acute effects" is ambiguous. It could mean either short-term effects from short-term exposures, or the effects that result from acute exposures since it is possible for short-term exposures to induce long-term and/or irreversible effects in addition to immediate, reversible effects. It was recommended that a more robust explanation of the range of potential effects of concern due to brief exposure be included in the HHRAP.

EPA Response:
This is beyond the scope of the HHRAP.

Issue: Acute Risk Assessment - Particulate Matter Inhalation
Is particulate matter (e.g., PM10 or PM2.5) to be assessed with respect to one-hour inhalation exposures? If so, EPA should be aware that none of the sources of AIEC include particulate matter, nor does Occupational Safety and Health Administration (OSHA), National Institute of Occupational Safety and Health (NIOSH), or (ACGIH) have a relevant short-term criterion.

EPA Response:
Acute exposure to PM10 and PM2.5 in not addressed in the HHRAP. However, speciated particulate matter is evaluated with respect to one-hour exposures. The HHRAP has been revised taking into account the most recent science in the area of acute risk assessment. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Acute Risk Assessment - Cumulative Risk Calculation
Additional information was requested regarding the calculation of an acute hazard index, noting that the draft HHRAP indicates that a COPC's acute hazard quotient should be compared to a target level of 1. Does this mean that for the acute analysis, the COPCs should be evaluated separately and not summed to obtain an acute hazard index, keeping in mind that if the acute exposure results in injury to a particular organ, then evaluating the COPCs separately may underestimate risk from acute exposure?

EPA Response:
This is not part of the HHRAP, but rather part of the U.S. EPA Region 6 Risk Management Addendum (July 1998; http://www.epa.gov/earth1r6/6pd/rcra_c/protocol/r6add.pdf).

Issue: Acute Risk Assessment - Site Workers
Clarification was requested regarding whether non-facility workers who work on or adjacent to a site where a combustion facility is located or will be located should be evaluated in the acute assessment.

EPA Response
We've further clarified our recommendations regarding when and when not to assess workers in a risk assessment. In addition, please remember that the HHRAP is guidance and contains no requirements. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

2.4.4 Exposure Scenario Identification – Selecting Exposure Scenario Locations

Issues pertaining to selecting exposure scenario locations include:
- Use of a Cartesian grid to model receptor exposure;
- Defining the radius of evaluation;
- Calculation of single point exposures; and
- Cumulative risks from multiple stacks.

Issue: Selecting Exposure Scenario Locations – Receptor Grid
Issues regarding receptor grids include:
- The computer requirements to meet the needs of the model based on a Cartesian grid of 100 meter spacing from the stack to 3 km from the stack and of 500 meter spacing from 3 km to 10 km from

the stack are prohibitive and excessive, requiring too much computer time to evaluate. The receptor grid specified in previous guidance, which resulted in more than 2000 nodes seemed more than adequate.

- It was suggested that there may be more than one way to design a receptor grid, depending on the location of sources and receptors, and a statement should be added to the HHRAP to allow for alternative receptor grid node arrays if approved by appropriate permitting agencies.
- Clarification was requested regarding how receptor locations are to be defined. It is assumed that the selection of receptor locations is unchanged from earlier versions of guidance in that, based on land use evaluations, actual or reasonable future receptors are located and then maximum model deposition rates or air concentrations within that area are identified. However, this is not clearly stated in the draft HHRAP.

EPA Response:
We strongly disagree that computer run time is a factor. Since the time of this comment, the computer clock speed has greatly improved. Also, runs can be broken up and run on multiple computers at once. Currently, using actual terrain data, runs are being completed in less than 8 hours. We agree with the recommendation that alternate receptor grid node arrays may be appropriate. Selection of receptor locations is a site-specific decision. Default selection guidance of receptor locations is presented in Section 4.3 of the HHRAP.

Issue: Selecting Exposure Scenario Locations - Defining Radius of Evaluation
It was suggested that by recommending in the draft HHRAP that the exposure setting be defined by a 50-km radius, many water bodies and properties that would not be impacted by emissions from a facility could be included. A radius of 3 to 10 km represents an adequate area in which to evaluate any emissions from a combustor facility. Evaluating a 50-km radius would significantly increase the level of effort without any effect on the risk assessment outcome.

Further clarification was requested regarding facilities on large controlled sites, such as a DOE site that may be as large as 800 km^2, about whether it would be appropriate to further extend the limit of the ISCST3 modeled receptor grid node array to reflect the fact that areas that could be assumed to be residential may be more distant.

EPA Response:
The draft HHRAP states that efforts should be focused within a 3-km radius of the facility. However, when drinking water sources or the closest farm or water body fall outside of this radius, it may be essential to evaluate these potential exposure pathways and/or receptors. In response to the request that a larger radius be used for a controlled site, please note that the recommendation in the guidance is for a minimum of 10-km. Also recommended in the guidance, depending on site-specific conditions, the potential future land use of a currently controlled site may affect numerous choices in the risk assessment, including the size of the ISCST3 receptor grid.

Issue: Selecting Exposure Scenario Locations - Single Point Exposures
It was suggested that air quality impacts are too focused on maximum single-point exposures, and should instead rely on a distribution.

EPA Response:
EPA Guidance for probabilistic risk assessments, "Guiding Principles for Monte Carlo Analysis" (U.S. EPA, 1997d, EPA/630/R-97/001), recommends a deterministic evaluation be performed at the screening level, which is consistent with the HHRAP methodology. Also, concentration difference at grid nodes spaces 500 meters apart have been shown to have little variation. Distributions can be used. However, the EPA guidance states that they should be used along side deterministic evaluations. Practical implementation of the HHRAP has shown that distributions are of more use in evaluating uncertainty of a few key parameters in a sensitivity analysis after completing the deterministic analysis.

Issue: Selecting Exposure Scenario Locations - Multiple Stacks
The validity of considering cumulative emissions from multiple stacks was questioned. It was suggested that to assume risks are cumulative requires that the receptor be the same for all stacks. Because this is not the case, each stack should be assessed separately, not cumulatively.

EPA Response:
If a facility has multiple stacks, the HHRAP recommends performing air dispersion modeling for each stack separately. This modeling generates air concentrations and deposition rates at various points (potential receptor locations) within the study area for each stack (or source) separately. When choosing exposure scenario locations, the HHRAP recommends identifying the receptor locations with the highest air concentrations and deposition rates for each source separately, as well as for all sources combined.

We agree that the receptor location of maximum exposure for one stack is not necessarily the receptor location of maximum exposure for another stack, even if both stacks are at the same facility. That is one reason it is valuable to assess each source separately. As discussed further in the HHRAP, this may lead to assessing risk at multiple locations.

However, any one location is impacted to a greater or lesser extent by all sources. It is therefore appropriate to also assess locations by summing the air concentration and deposition rate contributions of all sources to each location. Because concentration and deposition are defined with multiple parameters (e.g., wet vapor deposition, dry vapor deposition), each with its own point of highest impact, this may lead to assessing multiple receptor locations. Please see the HHRAP for further discussion.

2.4.5 Exposure Scenario Identification - Special Subpopulations

Issues regarding characterization of risks to sensitive subpopulations include:

- Assessing risks to sensitive subpopulations;
- Describing the subsistence farmer;
- Ingestion of breast milk; and
- Identification of sensitive subpopulations.

Issue: Special Subpopulations - Assessing Risks to Sensitive Subpopulations
The requirement that "the risk assessment may need to directly address special subpopulations in impacted areas because of characteristics of the exposure setting or to address specific community concerns." was considered vague and unnecessary, because the assumptions specified in the draft HHRAP have been developed to protect human health, including special subpopulations.

EPA Response:
The HHRAP is guidance and contains no requirements, although the evaluation of sensitive individuals may be warranted, depending on site-specific conditions. We made the recommendation because we consider it wise to at least consider the issue of special subpopulations.

Issue: Special Subpopulations - Subsistence Farmer Description
It was recommended that a clear description of the subsistence farmer be provided because this class, or their children, will probably drive the assessment for many compounds. Such factors as the likelihood of the farm resident consuming products from a combination of species would be influenced by choice. A hypothetical construct for the subsistence farmer might be worthwhile to reduce misunderstanding and to provide a degree of uniformity among assessments.

EPA Response*:*
Review of this issue during the external peer review concluded that the daily consumption amounts associated with the farmer scenario, which help to define the scenario, are more comparable to reasonable versus subsistence amounts. The HHRAP has been revised to remove references to "subsistence" farming. We've also further clarified the definitions of all recommended exposure scenarios, including the farmer and farmer child.

Issue: Special Subpopulations - Ingestion of Breast Milk
It was recommended that a discussion about the relevant aspects concerning the ingestion of breast milk exposure pathway be included in the HHRAP as a separate section in the chapters on exposure scenarios, media concentrations, and quantifying exposure. Although it is stated in draft HHRAP Chapter 4 that the ingestion of breast milk exposure pathway is evaluated separately in Chapter 2 (Facility Characterization), infant exposure to PCDDs and PCDFs via the ingestion of their mother's breast milk is only briefly discussed in Chapter 2 and Appendix C. In any event, a full evaluation of breast milk exposures would be out of place in Chapter 2.

EPA Response:
In addition to discussions in Chapter 2 and Appendix C, the nursing infant exposure pathway is discussed in Chapter 4 under the adult exposure scenarios.

Issue: Special Subpopulations - Identification
In the draft HHRAP on page 4-10, top paragraph from previous page, it is specifically indicated that "...special subpopulations in such areas should be identified." Guidance was requested regarding how these subpopulations are to be identified and who is responsible for this. It was also suggested that consideration and discussions be included in the HHRAP for subpopulations, such as:

- Those whose activities may result in the assessment of additional exposure pathways or adjustment of consumption rates to reflect behavioral patterns, such a Native Americans;
- Those outside the assessment area, such as downstream, that may be using water contaminated in the assessment area (draft HHRAP Section 4.1.2 Water Bodies and Their Associated Watersheds, page 4-6, line 7 and page 4-7, line 9);
- Children with asthma; and
- Those populations significantly exposed to similar types of chemicals from other sources for which the risk might be additive.

EPA Response:
The HHRAP suggests identifying special subpopulations in the assessment area, based on the location of schools, hospitals, nursing homes, day care centers, parks, community activity centers, etc. If available information indicates there are children exhibiting pica behavior (defined for risk assessment purposes as "an abnormally high soil ingestion rate") in the assessment area, these children could represent a special subpopulation. Fetuses, infants and children, and the elderly are examples of human life stages (i.e., subpopulations) that might be more sensitive to COPC exposure. You might consider some Native American groups to be a special subpopulation because their focus on fish as a food source increases their exposure. Our recommendations in the HHRAP, such as the protective nature of the recommended exposure scenarios (see Section 4.2) and the use of RfDs developed to account for toxicity to sensitive receptors, also protect the health of special subpopulations. However, we cannot guarantee that all subpopulations are covered. You may also need to specifically address special populations that are located in impacted areas because of unique characteristics of the exposure setting or to address particular community concerns. For example, a day care center or hospital may be located in an area that is directly impacted by the facility stack emissions. Receptors at these locations may be especially sensitive to the adverse effects and/or the exposure setting may be particularly conducive to exposure.

2.4.6 Exposure Scenario Identification – Land Use

Issue: Land Use - Identifying Future Land Use
Although the draft HHRAP requires that the risk assessment be performed for all six required receptors and perhaps additional receptors at both current and future exposure scenario locations, it was noted that the draft HHRAP does not provide explicit guidance regarding future land use designations. For current land use, local data sources can be consulted to determine areas that are residential or agricultural and water bodies that are frequented by fishers. However, for future land use, considerable professional judgment is required. For example, should future use based solely on zoning be addressed or should only the future use that is planned, funded, etc., be included? The extent to which future scenarios should be evaluated should also be clarified.

EPA Response:
The HHRAP is guidance and contains no requirements. Determining future land use is a site-specific decision. We provide potential ways of gathering information to address this issue in Section 4.1.1 of the HHRAP.

2.4.7 Exposure Scenario Identification – Clarification / Editorial

Issue: Clarification - Child Scenario
Clarification was requested with regard to the terms adult fisher child and adult resident child scenarios. The terms should be corrected to be "child of the adult fisher" or "child of the adult resident." It was the reviewers' understanding that the child scenario in the draft HHRAP is not the adult fisher/resident as a child (as indicated by the text where the child is described as the "adult resident child scenario"). If so, then it would only be appropriate to add the cancer risk of the child to that of the adult to obtain a cumulative lifetime cancer risk. Rather, the child scenario is evaluated separately, as indicated earlier in the text, to address increasing concerns regarding infant and child exposures. It was recommended that this issue should be clarified by indicating that the child is the child of the adult fisher/resident and not the adult fisher/resident child scenario.

EPA Response:
Terms utilized in the HHRAP have been changed to farmer child, fisher child, and resident child. We have further clarified their definitions as the child member of a farmer, fisher, or resident family.

Issue: Clarification - Particulates
There are inconsistencies in the draft HHRAP with regard to particulates and acute inhalation risks. For instance, Section 7.5 refers to "vapor phase and particle phase COPCs," whereas section 4.2.7 refers to "vapors and particles" and Table 4-1 refers to "vapors and particulates." If EPA simply means the total vapor and particle-bound concentrations of specific chemicals, then the wording should be clarified.

EPA Response:
We've made the terms consistent in the HHRAP sections noted.

Issue: Clarification - Arbitrary Safety Factors
A reference in the draft HHRAP to the use of "arbitrary safety factors" is unclear and requires clarification.

EPA Response:
Reference to the use of arbitrary safety factors has been removed from the HHRAP.

Issue: Editorial
- Draft HHRAP Table 4-1 Recommended Exposure Scenarios for Evaluation in a Human Health Risk Assessment: By including the "c" footnote, this table indicates that the ingestion of breast milk pathway should be included for all of the child scenarios. This appears to be a typographical error, as a child would not be able to breast-feed an infant.
- Draft HHRAP Section 4.2 Recommended Exposure Scenarios: The word "conducive" used in the fourth sentence of the second paragraph should be replaced.

EPA Response:
Comments are noted. We have reviewed editorial errors and made corrections to the HHRAP, where applicable.

2.5 ESTIMATING MEDIA CONCENTRATIONS [draft HHRAP Section 5]

To complete the exposure assessments described in Section 4 of the draft HHRAP, concentrations of COPCs in relevant media must be determined. These media include air, soil, produce, beef and dairy products, pork, chicken and eggs, and drinking water and fish. In Chapter 5 of the draft HHRAP, EPA provides guidance on equations for estimating COPC concentrations in these media, as well as on recommended parameter values for these equations.

An extensive range of comments was received regarding the equations and parameters. These comments were categorized into:

- General Modeling Issues;
- Recommended Input Values for Equation Parameters;
- Equations for Estimating COPC Levels in Various Media;
- Conservation of Mass;
- Screening of COPC; and
- Clarification / Editorial.

2.5.1 General Modeling Issues

General modeling issues included:

- Model Validation;
- Use of Site-Specific Models;
- Climate Issues;
- Approaches for Cancer versus Non-cancer Effects;
- Modeling of Water Bodies;
- Incorporation of Metabolism into Models; and
- Development of New Models.

Issue: General - Model Validation

Air: It was noted that EPA builds upon the air dispersion and deposition modeling (draft HHRAP Chapter 3) to estimate COPC concentrations in various environmental media that people might contact. By necessity, EPA relies on a series of sequential (sometimes linked) models, which are a combination of theoretical and empirical algorithms. These models remain largely unvalidated. In reviewing similar models for the Hazardous Waste Identification Rule, EPA's Science Advisory Board (SAB) recognized the crucial need for model validation. Commenters recommended that EPA act on the SAB's recommendation and develop an internal, multidisciplinary effort to validate multi-pathway transport models where possible, and then apply the models consistently across the various regulatory programs.

Water: It was noted that the water body modeling should be validated because the models are highly theoretical. The assumed equilibrium in the distribution of COPCs between the water column and sediment layer has not been subject to verification, but is critical to the accuracy of model predictions. While the processes are modeled as steady-state, they are actually time-dependent, varying by season and

individual storm event. The consequences of implicitly averaging this time-dependence are not known. It is recommended that EPA examine all aspects of the water body modeling against empirical data, where possible.

Beef and Dairy: It was stated that the models used to estimate COPC levels in beef and dairy products are based on flawed assumptions.

EPA Response:
Air: Comment noted.

Water: Comment noted. Water body modeling has been reviewed by EPA's Office of Research and Development, which has commented that the modeling as given is appropriate. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Beef and Dairy: All equations have been reviewed and updated as appropriate. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: General - Use of Site Specific Models
It was recommended that to assess infiltration rates, the HHRAP should allow for site-specific models to determine infiltration. Such models have been used for this purpose in other regulatory programs. In addition, resuspension of particulates and revolatilization of volatile and semi-volatile COPCs are not adequately addressed and need to be reassessed.

EPA Response:
We agree. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. We agree that resuspension of particulates and revolatilization of volatile and semi-volatile chemicals could be important on a case-by-case basis, and have given the HHRAP the flexibility to include addressing them in a risk assessment on a site-specific basis.

Issue: General - Climate Issues
It was noted that EPA has not addressed climatic differences that impact many of the model parameters. While EPA has provided some equations in which site-specific values can be inserted, these are relatively few and the impact of such substitution is unclear. It is recommended that EPA conduct sensitivity analyses on these equations and simplify, where possible.

In addition, much of the exposure via the water-related pathways appears to be dependent on a large number of parameters that do not distinguish between warm (e.g., Texas) and cold (e.g., northern Minnesota) climates. In considering deposition to surface water as well as issues such as dilution, EPA

should examine whether it has accounted for the different climatic conditions in the country that could lead to seasonal variations that could affect many parameters, including direct deposition.

It was suggested that in draft HHRAP Section 5.7.1.2, page 5-66, use of an annual average water body temperature of 25^0 C is unduly high. The annual average water temperature in most parts of the country is more likely to be 10^0 C to 15^0 C.

Vapor phase diffusion (dry deposition) should be affected by winter conditions. Temperature has a direct effect on this parameter, but the assumption is made that all surface water bodies have a temperature of 25° C (or approximately 78° F).

EPA Response:
Site-specific data are not only allowed, but also encouraged, throughout the HHRAP. If the air and terrestrial fate and transport models in HHRAP are applied properly, they should account for differences among regions with varying climates. Concentrations and exposure in the HHRAP are based on long-term equilibrium assumptions. Variations in results based on seasonal effects are accounted for with site-specific inputs to the air and terrestrial fate and transport models. Equations have been simplified where possible. However, default values provided for many parameters could be replaced by site-specific information, if available. Sensitivity analyses are encouraged on a site-specific basis. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. EPA also notes that deposition in various weather conditions is accounted for in the air model.

The water body temperature used to calculate vapor phase COPC diffusion (dry deposition) load to a water body can be site-specifically added in a calculation. A default value of 25 C was recommended to be consistent with previous EPA guidance.

Dry deposition of vapor was re-evaluated during the external peer review, and alternative default deposition velocities have been provided.

Issue: General - Approaches for Cancer versus Non-cancer Effects
The draft HHRAP states that separate soil concentrations are required for carcinogenic chemicals and non-carcinogenic chemicals, because averaging chemical dose over the lifetime assesses carcinogenic risks and non-carcinogenic effects are assessed by the use of a Reference Dose. The last year of the combustor's operation must be used for the non-carcinogenic soil concentration, because this yields the highest chemical concentrations. This requirement will result in two entirely separate risk assessments with double calculations for all exposure pathways that have soil concentration as an input, including soil ingestion, produce ingestion, beef ingestion, milk ingestion, pork ingestion, poultry ingestion, egg ingestion, and fish ingestion.

In addition, in the section “Calculating Cumulative Soil Concentration,” EPA states, "non-carcinogenic COPCs are based on a reference dose rather than a lifetime exposure." Chronic reference doses are specifically derived to be protective of long-term exposures (7 years to lifetime for chronic). It is

recommended that the sentence be corrected to indicate that the hazard quotient associated with non-carcinogenic effects is based on threshold and not as currently stated.

EPA Response:
A detailed evaluation of the soil concentration equations has been conducted by EPA's Office of Research and Development and is available upon request, but is beyond the scope of the HHRAP. Also, as with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. For the sentence regarding hazard quotients, we agree and have corrected the sentence.

Issue: General - Modeling of Water Bodies
For the modeling of water bodies, commenters noted that partitioning of organics should use the total organic carbon concentration in the water column, rather than just the suspended fraction, because organics will sorb onto both soluble and particulate carbon in the water column and be washed out of the system.

EPA Response:
Comment noted. Water body modeling has been reviewed by EPA's Office of Research and Development, which has commented that the modeling is appropriate as given. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: General - Incorporation of Metabolism into Models
It was stated that relevant information may be overlooked in favor of the application of uniform procedures among chemicals (e.g., lack of consideration of metabolism of COPCs, such as PAHs). It was recommended that empirical checking of model estimates be applied to as many COPCs as possible, especially those predicted to be risk drivers, and that metabolism factors should be established for COPCs based on available pharmacokinetic data.

Phthalate metabolism: Whether the metabolism factor (MF) for bis(2-ethylhexyl)phthalate should be applied to other phthalates, such as di-n-octyl phthalate, was questioned.

EPA Response:
EPA's Office of Solid Waste has endeavored to empirically check the model, including PAH and phthalate metabolism. Some changes have been made to the HHRAP in response to these efforts. The HHRAP, however, is only guidance and is meant to help provide a documented consistent approach to risk assessment. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

No MF for di-n-octyl phthalate is given in the HHRAP.

Issue: General - Development of New Models
EPA was urged to consider focusing its resources on coordinated development of the TRIM Multi-pathway Model and to coordinate and build on the existing expertise and evolving approaches to multi-pathway modeling.

EPA Response:
Comment noted.

Issue: General - Animal Feed
It was recommended that the terms used for animal feeds be defined consistent with those normally used in agriculture. Such factors as which feeds are used would be influenced by choice. The use of the terms "forage" and "silage" in the draft HHRAP do not appear to be consistent with the definitions used in the animal production industry and in academic animal science. "Grain" is satisfactory, but the more usual term is "concentrate." Swine are not fed silage and this plant type should be removed from Section 5.5.1.2. Realistically, ground grains with the appropriate protein, mineral, and vitamin supplements are the only feeds used for swine and poultry. As noted for concentrates in cattle, it is likely that these feeds would be obtained from a source off-site for most small operators.

EPA Response:
The terms "forage," "silage," and "grain" were adopted to be consistent with past usage throughout EPA guidance documents. The feeding of silage to hogs is documented in the literature and referenced in the HHRAP.

Issue: General - Cattle Exposure Pathways
It was recommended that the HHRAP should indicate whether inhalation and water consumption are considered significant sources of exposure of contaminants to cattle (draft HHRAP page 5-18). If not, then the basis of this should be stated. If so, then a cross-reference should be given to the specific section where this is discussed.

EPA Response:
This issue was put before the external peer review panel, which concluded these exposure pathways for cattle were not significant. The reasoning presented by the panel was that: 1) for water, COPC's, which would tend to bioaccumulate would not be in the water column, but rather be in the sediments, and 2) for air, direct concentrations inhaled and not bioaccumulated in the food chain would be insignificant.

Issue: General - Produce Exposure Pathway
It was recommended that providing a reference indicating the basis for root uptake of COPCs to be the primary mechanism through which aboveground-protected produce becomes contaminated, as indicated in Section 5.3.1 Aboveground Produce Concentration Due to Direct Deposition (Pd), page 5-25.

EPA Response:
We've modified the HHRAP to reference the source for this assumption (i.e., "Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions" (U.S. EPA, 1998d).

Issue: General - Soil Loss Constant
It was noted that in the statement in draft HHRAP Section 5.2.2 Calculating the COPC Soil Loss Constant (ks), page 5-9, lines 1-10, "...a first-order loss constant may be adequate to describe the loss of COPC from soil..." it is not clear what "may be" means in terms of the error to the overall process. It should be indicated here how this assumption affects error on this parameter, and whether there could or could not be significant differences if kinetics other than first-order were considered.

EPA Response:
What is indicated in the referenced section is that a first order kinetic loss may be adequate to describe the loss of COPC from soil at the low concentrations generally associated with hazardous waste combustion. Zero order or second order kinetics may be more appropriate on a site-specific basis. References for this assumption are provided in the HHRAP.

2.5.2 Recommended Input Values for Equation Parameters

Commenters provided input on many of the parameters for the equations given in Chapter 5 of the draft HHRAP. Some commenters recommended specific values for parameters, while others recommended that EPA make more use of site-specific information rather than focusing on default values. The comments on site-specificity are discussed first. Next, parameter-specific comments are presented.

Issue: Input Values - Feed Intake
It was noted that the discrepancy in feed intake values used for various animal species has arisen because values that were reported in individual research studies were selected for application on a more general basis. Feed intake is a complex function that involves animal size, growth rate, productivity (milk or eggs), energy, density of the feed, and ambient temperature (National Research Council, 1987). It might be useful to establish "standard animals" for each species. This would ensure uniformity in the factors used for converting data in the literature to the form used in the assessment. The National Research Council publication provides a comprehensive review the feed intake literature for all species of interest, and it should be considered the most authoritative document on this subject.

EPA Response:
Comment noted.

Issue: Input Values - Soil Ingestion
It was stated that the soil ingestion values presented in the draft HHRAP should be considered maximum values. In practice the values may be considerably less with changes in the assumptions concerning site-specific conditions and the normal range of animal management practices.

EPA Response:
The soil ingestion values for cattle presented in the HHRAP are average values, not maximum values. Documentation of how they were derived is presented in the HHRAP such that site-specific conditions can be compared to the default assumptions presented.

Issue: Input Values - Runoff Loading
It was noted that in draft HHRAP Section 5.7.1.3 Runoff Load from Impervious Surfaces, page 5-67, runoff loading from impervious surfaces (LRI) is assumed to occur with perfect efficiency. While this may be appropriate for a surface adjacent to surface water bodies, runoff from more distance surfaces are likely to be considerably less efficient. An adjustment for large watersheds, similar to that applied to sediment transport, should be considered.

A correction should be applied to the impervious watershed area to account for such issues as gutters, which generally disperse water.

EPA response:
The total watershed area that contributes water to a water body can be very extensive relative to the area impacted from facility emissions. When evaluating an area, the HHRAP recommends that the risk assessor consider evaluating an effective watershed rather than the entire watershed area. The area extent of a watershed is generally defined by topographic highs that result in down slope drainage into the water body. Many times this is within a few hundred feet of the water body due to the presence of dikes or roads. The effective watershed is generally not expansive, and therefore, impervious runoff is very efficient. Gutters from roofs can as easily drain to roadways as they do to yards. The estimation of the amount of a watershed that is impervious is site-specific, as recommended in the HHRAP.

Issue: Input Values - Specific Parameters
Issues were raised regarding the following parameters:

- Untilled mixing;
- Contact fractions for beef and milk;
- Fraction of wet deposition that adheres to plant;
- Water body loadings due to direct deposition;
- Plant Surface Loss Coefficient (kp);
- Correction factors for calculating plant uptake to account for the ratio of surface area of skin to whole plant;
- Percentage of plant material consumed by beef;
- Correction factors for hay, grain, and corn;
- Default sediment foc values; and
- Use of VG_{ag} and $VG_{rootveg}$ as empirical correction factors for organic uptake.

EPA response:
As with many parameters and equations provided in the HHRAP, the scientific basis and reference for our recommendations are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative more appropriate than that recommended in the HHRAP.

Issue: Input Values - Produce Interception Fraction
EPA's calculated value for the default interception fraction of 0.39 for the edible portion of produce in the draft HHRAP does not appear to be correct. It is recommended that EPA review its calculations.

Algorithms to calculate plant uptake due to particulate deposition include a term for the interception fraction of the edible portion of above ground vegetation, Rp. Input values presented in the guidance reflect estimations based on an algorithm for pasture grass. No data were presented for above ground crops nor were any data presented to indicate whether the value for pasture grass is appropriate for other species.

EPA response:
Calculations have been verified to be correct. As noted in the HHRAP, one of the primary uncertainties associated with this variable is whether the algorithm, based on studies of pasture grass, accurately represents aboveground produce. Baes et al. (1984) noted that their approach to developing class-specific Rp values is "at best ad hoc," but stated that this approach was justified, because the consequences of using Rp estimates that are independent of productivity are "serious."

Issue: Input Values - Bioavailability Factors
It was recommended that risk assessors be allowed to use appropriately documented bioavailability factors. It is further recommended that EPA modify the equation labeling to identify that trial burn emission rate Q is unadjusted so that it may not be directly incorporated into the media concentration equations.

A default soil bioavailability factor (Bs) of 1 should not be recommended for all COPCs, given that data on relative bioavailability are readily available in the open literature for a number of chemicals. In addition, the definition of Bs appears to be incorrect.

The draft HHRAP assumption that the bioavailability of all chemicals is 100% must be changed to prevent overestimates of exposure, particularly for nonvolatile compounds.

EPA response:
We agree with the first comment.

Soil ingestion is unlikely to be a determining factor driving a risk at a level of concern. Soil bioavailability factors for soil ingestion are not well presented in the literature. However, if documentation can be provided, facilities can provide data to support use of a chemical specific bioavailability factor. The definition for Bs has been changed.

The assumption of 100% bioavailability is a conservative default assumption. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility has the option to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Input Values - Dioxin Congener Photodegradation
The HHRAP should consider photodegradation of dioxin congeners on plant surfaces.

EPA response:
We do not believe that the amount of dioxins adhered to plant surfaces significantly affects risk estimates, but as with other parameters, site-specific values may be applicable.

Issue: Input Values - Soil Loss
The draft HHRAP concludes that the soil loss due to volatilization constant should be set equal to zero until more applicable models are identified and validated. EPA should further evaluate the source of the equations originally proposed for calculating the volatilization loss to determine their applicability or identify other suitable equations in the literature. In addition, the terms for runoff and leaching are inadequate to address total soil loss. There are situations where EPA's default value of zero for the erosion loss rate constant kse is inappropriate.

EPA response:
The ksv term has been revised from supporting a default of zero to providing a chemical-specific equation to calculate the ksv. The erosion loss rate constant kse is set equal to zero as a default, citing essentially equivalent erosion rates onto and off of impacted receptor sites.

Issue: Input Value – Degradation Rate Constants
For several COPCs, ksg values (degradation rate constants) are set at zero because of "lack of data." If there are insufficient data in the single reference cited by EPA, EPA should (1) identify data gaps, (2) solicit data from interested parties, (3) use degradation data from structurally similar compounds, or (4) estimate needed rate constants using available methodology.

EPA response:
When a ksg value is not provided, it is assumed to be zero. If a chemical is found to be a risk driver that has a ksg equal to zero, a literature search may be warranted. To date, EPA is unaware of any instance where this is the case. Using degradation data from structurally similar compounds might be approved on a site-specific basis, at the discretion of the permitting authority.

Issue: Input Value - Fish Pathway
EPA has made a clear demarcation between water column concentrations and benthic sediment concentrations. A similar distinction should be made between the type of fish consumed (i.e., a bottom feeding fish species is more likely to be affected by sediment content than a non-bottom feeder).

EPA response:
Choice of the trophic level of fish eaten is a site-specific determination. The HHRAP provides a screening default approach to help focus where site-specific information may be most effective. Bottom feeding fish are not necessarily more tied to sediment concentrations than pelagic fish. Fish are tied to exposure mostly through their food source. Concentrations of chemicals in the food source will depend on which food chain a chemical will travel and the extent of accumulation.

Issue: Input Value - Fish Lipid
The draft HHRAP requires that a value of 7% for fish lipid be used, which is unreasonably high for warm water locations and should not be required input.

EPA response:
We disagree. The HHRAP recommends a default value of 7%, but it does not require it.

Issue: Input Value – Total Suspended Solids (TSS)
EPA recommends that water body-specific measured total suspended solids (TSS) values be used. No recommended default value is provided and, for the majority of water bodies, this value will not be readily available.

EPA response:
A method to calculate TSS for lakes and ponds is provided in the HHRAP. We disagree that measured concentrations are not available for streams and rivers. This is standard data collected by the States and USGS.

2.5.3 Equations for Estimating COPC Levels

Several comments were received with regard to the equations for estimating media concentrations of COPCs given in Chapter 5. Commenters expressed a broad range of concerns, ranging from the scientific defensibility of the algorithms presented in Chapter 5, to more specific comments on algorithms related to fate and transport.

Issue: Estimating COPC Levels - Flawed Equations (See RC Sections 3.5.3, 3.4.3 and 3.5.5)
Commenters recommended that the pork, chicken, and fish algorithms undergo substantial revision, as equations for several of the media are flawed. Specifically, it was noted that the soil concentration algorithms are not scientifically defensible, and the pork and chicken algorithms are based on multiple, flawed assumptions. The approach in the draft HHRAP for estimating COPC concentrations in fish is inconsistent with other guidance and scientific literature on chemical accumulation in fish. In addition, it was stated that there is no accounting for chemical or biological degradation in the various equations in this section.

EPA Response:
We disagree with the view that the soil concentration equations are flawed. A detailed evaluation of the soil concentration equations has been conducted by EPA's Office of Research and Development and is available upon request, but is beyond the scope of the HHRAP. For the other media mentioned, all equations have been reviewed and updated as appropriate. EPA states that degradation is accounted for in the soil equations. The assumption of ksv equal to zero has been replaced by an equation which calculates ksv. The erosion loss rate constant, kse is set equal to zero as a default citing essentially equivalent erosion rates onto, and off of, impacted receptor sites. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Estimating COPC Levels - Considering COPC Concentration in Water
It was recommended that consideration be given to normalizing the concentration of TSS by its organic

carbon content as well as the dissolved organic carbon content. Both of these parameters have been found to be important in predicting the bioaccumulation of hydrophobic organic COPCs, and are considered in EPA evaluations of that phenomenon.

EPA Response:
The HHRAP recommends site-specific determination of TSS, as this parameter has been found to vary by more than two orders of magnitude across water bodies. Site-specific values should account for organic carbon content, as well as dissolved organic carbon content.

Issue: Estimating COPC Levels - Overall Total Water Body Dissipation Rate Constant
It was suggested that in draft HHRAP Section 5.7.4.2, page 5-75, the overall water body dissipation rate (kwt) could include losses due to biotic and abiotic degradation. While it may be reasonable to neglect degradation in the water column due to the short residence times implied by the calculations, it is less appropriate in aquatic sediments where residence times can be significant and losses due to degradation have been documented.

EPA Response:
Biotic and abiotic degradation in sediments are chemical specific, and highly variable based on site-specific parameters. It is also unclear whether breakdown products of COPC's are less toxic than the parent compounds. As with all equations and recommended values in the HHRAP, site-specific values can be documented and utilized in the risk assessment.

Issue: Estimating COPC Levels - HHRAP Equations May Result in Increased Risk (See RC Section 3.5.3)
The following equations included in the draft HHRAP may result in higher concentrations in the relevant media and overall increase in risk:

- A new equation for produce concentration due to root uptake for below ground produce is contained in the draft HHRAP which will result in higher concentrations in produce, and therefore, in higher risk values.
- Equations for estimating the COPC concentrations in pork, eggs, and poultry are included. While the inclusion of these pathways will increase the final risk, they are not expected to drive the risk because their concentrations and associated risks should be less than those resulting from the ingestion of the beef and milk pathways.
- Equations for forage, silage, and grain consumption by beef and dairy cattle are included in the draft HHRAP. Previous guidance included only consumption of forage. This will result in higher concentrations in beef and dairy cattle, and therefore higher risk values.

EPA Response:
Comments noted.

Issue: Estimating COPC Levels - Biotransfer Equations (See RC Section 3.5.3)
Several commenters were concerned that the guidance on biotransfer is flawed. Specifically, it was noted that:

- EPA has recently questioned the use of the Travis and Arms algorithm for certain highly lipophilic compounds. In a recent memorandum, EPA noted that the Travis and Arms (1988) algorithms yield increasing biotransfer values with increasing $\log K_{ow}$ while opposite trends have been reported for dioxin congeners with $\log K_{ow}$ values ranging from 6.5 to 8.0. As a result, EPA recommended against using the Travis and Arms algorithms for these highly lipophilic agents. There may be several COPCs included in the draft HHRAP with $\log K_{ow}$ values exceeding 6.5. The use of the Travis and Arms algorithms for these chemicals is highly questionable.
- The correlation algorithms developed by Travis and Arms to calculate biotransfer factors for beef and milk involved only 36 chemicals for beef and 28 for milk. The scientific validity of extending correlation data from limited data to the large number of potential COPCs is questionable. Furthermore, the coefficient of linear regression for the Travis and Arms algorithms was only 0.81 for beef and 0.74 for milk, suggesting considerable variability. Finally, the default cattle consumption rate should not be used in conjunction with the Travis and Arms biotransfer rate.
- Algorithms to estimate constituent concentrations in beef and milk include the quantity of plant material consumed by plant type. EPA recommends use of 1 1.8 kg DW/d for beef cattle and 20.0 kg DW/d for dairy cattle. These quantities include forage, silage and grain. These algorithms also include factors for feed-to-beef biotransfer (Ba beef) and feed-to-milk biotransfer (Ba milk). These biotransfer factors were calculated from the correlation algorithms presented in Travis and Arms (1988). Travis and Arms developed their correlation algorithms from available bioconcentration studies in beef and dairy cattle. To develop their biotransfer factors, Travis and Arms multiplied the constituent concentration in feed (mg/kg) by a feed consumption rate (kg/d) to arrive at daily intake (mg/d). As such, biotransfer factors are defined as follows: Biotransfer Factor = concentration in beef tissue (mg/kg) / daily constituent intake (mg/d). However, it is important to note that feed consumption rates were NOT measured in the studies used by Travis and Arms. As such, these authors used assumed feed consumption rates of 8.0 kg DW/d for beef cattle and 16 kg DW/d for dairy cattle. Based on these assumed ingestion rates, Travis and Arms developed the correlation equation used in the guidance relating Ba-beef and Ba-milk to $\log K_{ow}$. It is clearly inappropriate to use a different set of consumption rates in the guidance than those used for the underlying correlation algorithm developed by Travis and Arms. EPA should either reduce feed consumption rates in the guidance to be consistent with those used by Travis and Arms or recalculate the Travis and Arms (1988) correlation algorithm using the consumption rates presented in the draft HHRAP.
- A correction factor is needed in the plant uptake algorithm for particulate deposition. Plant uptake algorithms for vapors include an air-to-plant biotransfer factor, B. These were calculated using an algorithm derived from studies in azalea plants with a very limited number of chemicals. Only 14 organic compounds were examined in these studies. Thus, the air-to-plant transfer algorithm used in the method reflects a correlation equation based on a limited number of chemicals. It is scientifically and mathematically invalid to use a correlation algorithm derived from such a limited number of chemicals to calculate transfer factors for the approximately 200 chemicals which fall into very diverse chemical classes covered by the HHRAP.
- The use of the soil-to-aboveground plant transfer approach developed by Travis and Arms (1988) is technically insupportable for many of the COPCs recommended for evaluation.

- The combination of the equations for calculating COPC concentrations in beef, pork, chicken and eggs and the method of estimating the biotransfer factors results in substantial underestimation of dioxin concentrations in these tissues. This may also be true for other COPCs.
- To develop biotransfer factors for pork and chicken, biotransfer factors for beef were adjusted by the ratio of pork or chicken fat content to the fat content of beef. EPA provides no data to justify use of such adjustments. With the known anatomical differences and the expected absorption differences among species, EPA should review the proposed methodology and provide justification for use of ruminant biotransfer factors for any non-ruminant species.

EPA Response:
We disagree that the method for estimating biotransfer factors for pork and chicken are flawed. The basis for these estimates is consistent with lipid partitioning theory. The HHRAP has been revised to include newly developed biotransfer equations for beef and milk. Caps have also been implemented for other biotransfer equations at the high and low ends of the K_{ow} range used to develop the biotransfer equations. EPA continues to work on refining and updating biotransfer equations to reduce error and minimize violation of the conservation of mass. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Estimating COPC Levels - Description of the Evolution of the Equations
Commenters observed that draft HHRAP Chapter 5 includes the reasoning behind the selection of the equations used to estimate the concentration in media due to the deposition of stack emissions. However, it was recommended that soil modeling equations be presented in a more informative manner. As currently written, the presentation of the various equations to estimate COPC concentrations in soil is confusing, especially since only a few of the equations (5-1 C, 5-1 D, and 5-1 E) are ultimately recommended for use. The commenters recommended that if the earlier equations (5-1, 5-1A, and 5-1 B) are presented for historical perspective, some description of the evolution of the equations should be given. In addition, the deposition term in equations 5-1 C, 5-1 D, and 5-1 E includes both wet and dry deposition of both particles and vapors; none of the earlier equations contain all four terms.

EPA Response:
The purpose of presenting multiple soil concentration equations is to differentiate the different equations presented in previously released guidance documents. A detailed evolution of the equations is beyond the scope of the HHRAP. However, one has been prepared by EPA's Office of Research and Development and is available upon request.

Issue: Estimating COPC Levels - Equations for Plants
Several issues were raised regarding the algorithms for estimating COPC levels in plants. These issues include:

- The exposure pathways include contamination of plants from volatilization from the soil. However, subsequent discussion on the mechanisms of uptake in aboveground plants does not include this pathway. It is recommended that this discrepancy be clarified.

- The overall intake from depositions and vapor transfer to plants does not consider the duration of depositions (years of facility operation) as presented in the equations. For facilities with a very short lifespan (e.g., 3 years), this will greatly overestimate cancer and non-cancer risks. The equations model deposition and vapor transfer to plants as if they continue over the entire exposure duration. It is recommended that the HHRAP include the duration of operations to more accurately depict actual exposures. This may be done by averaging the plant concentrations similar to that of the soil concentrations in Section 5.3 or by calculating two separate intakes in Section 6.1 for the periods during operations and after operations.
- Only one equation is provided for modeling uptake into belowground produce (draft HHRAP Equation 5-20B). However, this equation should only be applied when modeling uptake for organic compounds. It is recommended that language be added which indicates that Equation 5-20A should be used for evaluating uptake of metals into belowground produce.
- It is unclear whether the plant uptake algorithm for particulate deposition describes particulate deposition onto plants and subsequent consumption of particulate material along with plant material or whether there is an implicit assumption that particulate constituents are absorbed through leaf or vegetable/fruit skin. If direct consumption of particulate material is assumed, there appears to be an implicit assumption that fruits and vegetables are not washed, peeled, or cooked prior to consumption. While this assumption may be appropriate for animal feeds, it is clearly inappropriate for fruits/vegetables consumed by humans. However, if absorption is assumed, EPA has provided no data to address the bioavailability of particulate material for absorption, nor has EPA included a correction factor (as was included in air-to-plant and root uptake algorithms) to address dilution of COPCs throughout the plant.
- The use of the root uptake correlation equations developed by Briggs et al. (1982) is technically insupportable for many of the compounds recommended for evaluation

EPA Response:
We agree that uptake in above-ground plants from volatilization from soil requires clarification and have revised the Chapter accordingly. We have also added language indicating that Equation 5-20A should be used for evaluating uptake of metals into below-ground produce. For duration of deposition and regarding root uptake correlations, as with many other parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. We note that direct consumption of plants is assumed and that consumption rates of food are adjusted for preparation including preparation and cooking losses.

Issue: Estimating COPC Levels - Dry Vapor Phase Diffusion to Soil and Water (See RC Section 3.3.5)
The equation (draft HHRAP equation 5-lA) for calculating soil concentrations contains a dry vapor phase diffusion load to soil (Ldif) that is no longer accounted for in the recommended equations for calculating soil concentration (Equations 5-1C through 5-lE). Although the use of the Ldif term contributes negligibly to the soil concentration and can be reasonably excluded from the soil concentration calculation, this should be more explicitly stated in the text.

Commenters also noted that dry deposition of vapors to the water body is modeled incorrectly. The equation to estimate dry deposition of vapors (Ldif) to the water body considers a one-way transfer of the COPC from the air into the water body. This is an incorrect method for estimating mass transfer. Instead, mass transfer from the air into the water body should be modeled as the product of a mass transfer coefficient and the difference between two concentrations - that in the air and the effective concentration in the water, which serves as a resistance to mass transfer across the air-water interface. Given the EPA model construction, loadings into the water body from soil erosion and runoff could be large enough to serve as a source of emissions to the air from the water body. By not allowing for the outward flux of vapors from the water to the air, EPA's model in some cases could incorrectly predict the trapping of a volatile chemical within the surface water body.

EPA Response:
The dry deposition of vapor to soil was addressed during the external peer review of the HHRAP. Changes have been made according to recommendations of the external peer review panel. Regarding dry deposition of vapors to water, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. We developed the HHRAP with the objective of acquiring information necessary to aid a permit writer in constructing a permit for hazardous waste burning facilities that allows the setting of emission or waste feed limits that are protective of human health and the environment. If volatile chemicals were trapped in the water body, a conservative estimation of drinking water and fish would result. If this is a problem, a more detailed site-specific fate and transport analysis could be conducted. However, we are unaware of any actual case where this situation has occurred.

2.5.4 Conservation of Mass

The following issues related to conservation of mass were raised:

- General Issues;
- COPC Degradation in Soil;
- Soil Erosion;
- COPCs in Produce;
- COPCs in Chickens and Eggs; and
- Combining Steady State and Non-Steady State Models.

Issue: Conservation of Mass - General
The methods in the draft HHRAP do not account for conservation of mass. Commenters recommended that mass balance be incorporated into the exposure assessment.

EPA Response:
The question of mass balance was addressed during the external peer review. Conservation of mass checks have been put throughout the HHRAP. Dry deposition of vapor has been revised based on comments received regarding the conservation of mass. We have refined biotransfer equations to reduce

error and minimize violation of the conservation of mass.

Issue: Conservation of Mass - COPC Degradation in Soil (See RC Sections 3.5.4 and 3.5.5)
Commenters pointed out internal inconsistencies with the soil and plant equations in the draft HHRAP, resulting in violations of conservation of mass. Specifically, there is no provision for COPC degradation in soil, despite noting COPCs uptake by plants, consumption by animals, and runoff and erosion. Commenters were concerned that this may result in "double counting" these COPCs. Commenters recommended that EPA carefully examine all of the equations to ensure that the principles of conservation of mass are obeyed and that the terms and equations are used in a consistent manner throughout the HHRAP.

EPA Response:
We disagree that the HHRAP does not allow for both biotic and abiotic degradation in soil. The HHRAP provides chemical-specific values to help the user estimate loss due to degradation.

Issue: Conservation of Mass - Soil Erosion (See RC Sections 3.5.4 and 3.5.5)
Commenters recommended that erosion and volatilization pathways be included in the soil loss equation. The draft HHRAP does not include loss due to erosion and volatilization. While eliminating erosion from the soil loss equation, the draft HHRAP includes it as an input to water bodies, violating the conservation of mass. The soil volatilization factor, ksv, has been temporarily set to 0 for all chemicals, resulting in the unlikely situation in which VOCs end up driving the risk through root uptake into plants.

Soil modeling assumptions should be consistent with other aspects of environmental fate and transport modeling. Recommendations for two of the soil loss coefficients are inconsistent with other parts of the draft HHRAP, and could, under certain conditions, result in substantial overestimates of COPCs. The value of 0 for kse (draft HHRAP page 5-12) is recommended because soil can erode both onto and away from a soil parcel (erosion from a soil parcel can be replaced by soil erosion onto it from an adjacent parcel). However, by not accounting for erosion of soil before it enters the water body (i.e., by assuming kse = 0), EPA is double-counting a portion of the COPC load. EPA is effectively assuming that COPCs build up in soil without any loss due to erosion, then erode to the water body, but then effectively remain at a constant concentration in soil because the losses to the water body have not been considered.

The EPA recommendation that kse be set equal to zero results in higher soil, water, and fish concentrations.

The draft HHRAP states that Kse should be set equal to zero in soil COPC concentration calculations for the fish pathway. However, a convincing argument for inclusion or exclusion is not included in the guidance document and needs justification.

EPA Response:
The ksv assumption of zero has been replaced by an equation to calculate ksv. The external peer reviewers concluded that setting erosion equal to zero would not affect the conservation of mass at the tops of hills.

With regard to the second and third comments, this issue was addressed during the external peer review. The peer reviewers disagreed with the commenters. Soil erosion is not set equal to zero for the loading to the water body. It is set equal to zero for determining soil concentrations. The peer reviewers disagreed with the conclusion that this results in higher soil concentrations, with the possible exception of at the top of a hill.

We agree that a convincing argument for setting Kse equal to 0 is warranted. Further justification has been added.

Issue: Conservation of Mass - COPCs in Produce (See RC Section 3.5.4)
EPA's model for deposition of COPCs to vegetation fails to account for removal of COPCs from the vegetation (for example, by rain), thus violating conservation of mass. In addition, the scientific foundation for the model parameters is limited. Further, the draft HHRAP relies on partitioning equations and coefficients to estimate concentrations in the different media, with assumptions of steady-state conditions. The use of equilibrium equations and coefficients can lead to mass balance problems. For example, for some of the PAHs, the air-to-plant transfer coefficients are so large that they can result in more material in the plants than is emitted from the facility. The commenters are concerned that the magnitude of error introduced by these assumptions might be quite large for vegetation with high surface area and that such error could be magnified in subsequent models that consider consumption of plants by animals. The commenters recommend that both equations used to estimate media concentrations and the equations used to calculate the coefficients should be re-evaluated.

EPA Response:
This issue was addressed during the external peer review. Conservation of mass can be violated as COPC's are transferred into food items, but it is within the error bars of biotransfer parameters. To specifically address this issue, EPA commissioned a study to revise and update the biotransfer factors for beef and milk. In addition, biotransfer factors for plants are capped at the transfer factor associated with the highest and lowest log K_{ow} values in the Travis and Arms studies. EPA expects these updates to dramatically reduce the error bars at the extremities of the Log Kow/biotransfer factor relationship. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Conservation of Mass - COPCs in Chickens and Eggs (See RC Section 3.5.3)
Certain COPCs (e.g., PAHs) may undergo metabolism, for example by chickens (as well as other animals). EPA should reconcile its model predictions with empirical knowledge whenever possible. The commenters recommend that EPA's models be evaluated against pharmacokinetic data and other information that might lead to departures from the assumed behavior of K_{ow}-based models of bioaccumulation that consider solely the lipophilic nature of organic chemicals.

EPA Response:
A mass balance check performed on the chicken and egg pathway showed that predicted COPC concentrations are within the error of the recommended biotransfer factors. We will continue our effort to update and revise the biotransfer equations. As with many parameters and equations provided in the

HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. Although it is agreed that PAHs are metabolized to some extent, we are also concerned that the toxicity of the metabolites is not being directly assessed, and therefore, it is reasonable to maintain the current biotransfer factors until more scientific research can support adoption of a metabolism factor.

Issue: Conservation of Mass - Combining Steady State and Non-Steady State Models (See RC Section 3.5.4)

It was recommended that the multi-pathway analysis be revised because of the combination of steady state and non-steady state modeling that can result in violations of the conservation of mass.

EPA Response:

We have made an extensive effort to provide the most accurate yet implementable guidance for conducting risk assessments. There is a mixing of steady state with non-steady state assumptions within the guidance. However, every effort has been made to bound estimates and preserve conservation of mass. The question of mass balance was addressed during the external peer review, and conservation of mass checks have been included throughout the HHRAP.

2.5.5 Screening of VOCs

The issue raised under the screening of COPCs relates to the inclusion of volatile organic compounds (VOCs) in indirect exposure pathways. The draft HHRAP recommends that VOCs should be modeled through both the direct and indirect exposure pathways in the combustion risk assessments. While VOCs are clearly COPCs for the direct inhalation pathway, the evaluation of VOCs through the indirect food-chain pathways is not technically defensible. According to EPA Region 6, "One argument for excluding these COPCs (VOCs) from evaluation is that there is no empirical evidence that VOC emissions pose a hazard via indirect pathways. U.S. EPA OSW agrees that it is not aware of such evidence; however, OSW is similarly unaware of a lack of evidence to the contrary."

Further, it was noted that carrying VOCs, such as benzene and toluene, through multi-step food chain models is erroneous if K_{ow}-based correlations are used to predict biotransfer factors. Similar to polycyclic aromatic hydrocarbons, many VOCs are metabolized, and not simply transferred to and from the fatty tissues of animals. Thus, even if certain VOCs were ingested by a pig, those VOCs would not necessarily result in human exposure via consumption of pork. Finally, many of the K_{ow}-based correlations are derived from data on lipophilic compounds, which generally have high values of K_{ow}. Chemicals with low K_{ow} values, such as benzene require such correlations to be extrapolated outside of the range of K_{ow} for which they are applicable. Commenters recommended VOCs not be evaluated via the indirect exposure pathways, and should only be included as COPCs for the direct inhalation pathway:

EPA Response:

Given that the fate, transport, and toxicity information is provided in the guidance, we believe it is more efficient to run the selected COPCs through the risk assessment process, rather than go through the

arduous process of justifying elimination of COPCs from portions of the assessment. In addition, if chemicals do not transport up various exposure routes, the fate and transport properties of these chemicals will cause them to result in insignificant risk.

2.5.6 Estimating Media Concentrations - Clarification / Editorial

Issue: Clarification - Figure on Concentrations of COPCs in Pork
Draft HHRAP Figure 5-5 implies that the concentration of COPC in the grain and silage ingested by swine comes from root uptake only. The text, however, suggests that the silage is also affected by direct deposition and vapor transfer of COPCs. It was recommended that EPA consider revising the figure to more clearly indicate that silage concentrations are affected by root uptake, direct deposition, and vapor transfer, and that grain concentrations are affected by root uptake only.

EPA Response:
Figure 5-5 has been updated to reflect the concerns in the comment.

Issue: Clarification - Summary Table for the Model Results
It was suggested that in draft HHRAP Chapter 5, it would be useful to have a summary (perhaps in tabular form) at the end indicating whether data are available which indicate whether the predicted values using the models and assumptions presented in the chapter have been shown to agree or disagree with actual field measurements. Presenting these data, even though it is likely to be very limited, would present some confidence in the process.

EPA Response:
Comment noted. Although we agree that this would be a valuable effort, it is beyond the scope of the HHRAP.

Issue: Clarification - Consistent Computation of Deposition Velocity
The present approach for computing deposition velocities is too subjective to be used effectively. The draft HHRAP should be revised to reference an established method that will promote consistency.

EPA response:
Default dry deposition of vapor velocities has been changed and documentation provided.

Issue: Clarification - Particulate Inhalation
With regard to Section 5.1, the draft HHRAP is unclear about whether it suggests that all particles are inhaled, irrespective of size. If so, then why? We know that the smaller particles are more effectively inhaled than the larger.

EPA Response:
All particles are inhaled irrespective of size. Size does however affect transport of a particle in the atmosphere, and it is unlikely that a large fraction of what is being inhaled with respect to a combustion

unit is in the large particle size range. Also note that not all toxics that are inhaled have a primary effect on the lungs. For example, nasal tumors are a common health endpoint for several inhaled toxics.

Issue: Clarification - Unit Soil Loss (X_e)
The draft HHRAP indicates that parameter values used in calculating X_e should be re-evaluated if the calculated benthic burial rate constant (kb) value exceeds 1.0. However, no recommendations are provided to detail how to do the re-evaluation.

EPA response:
Based on experience, the value calculated for X_e is the most likely reason for determining a large and potentially unrealistic benthic burial rate. Information about determining site-specific values and variables for calculating Xe are in the references cited in Section 5.7.2. We've clarified this in Section 5.7.4.7.

Issue: Clarifications - Appropriate Annual Soil Concentration
The use of the potentially highest annual soil concentration over the operating lifetime of the unit for evaluation of non-carcinogenic effects does not seem appropriate. The highest annual level over the exposure duration of each adult receptor is recommended as an alternative.

EPA response:
We agree. We've changed the HHRAP to recommend the highest annual level over the exposure duration of each adult receptor.

Issue: Editorial
Editorial issues include:

- The draft HHRAP states that an above ground correction factor (VGag) of 0.01 should be used. However, the text of Section 5.3.2 (page 5-33) needs to be changed to reflect this assumption, as it currently states that 0.001 is being used for lipophilic organics.
- Draft HHRAP Section 5.7.4.1, 2nd & 3rd paragraphs following Equation 5-36C parameters, requires clarification to explain exactly when and how the parameter values used in calculating X_e should be re-evaluated, as well as when Equation 5-37 should be used to determine Obs and when the recommended value should be used.
- Draft HHRAP page 5-75: EPA states at the top that the bed sediment porosity is based on a bed sediment concentration of 1 kg/L. In the subsequent paragraph, EPA states that "... 0.1 kg/L is a reasonable concentration for most applications of the bed sediment." Please clarify.
- A metabolism factor is included in the estimation of the chemical concentration in beef, milk, and pork to account for loss of the chemical from fat and muscle. EPA recommends a value of 0.01 for bis(2-ethylhexyl)phthalate and 1.0 for all other COPCs.
- Better descriptors are recommended for unitized yearly average wet deposition (Dydw) and (Dyww) in draft HHRAP Equation 5-1B.
- Draft HHRAP Section 5.3.1.2, page 5-29, line 2: a constant is missing.

- Draft HHRAP Section 5.2.3, Equation 5-11, Calculating the Deposition Term (Ds) Comment: The term Cyv is reported in the wrong units. Recommendation: Cyv should be in units of ug-s/g-m3.for proper unit cancellation. These are also the units generated by the dispersion modeling.
- Draft HHRAP Section 5.3.1.2 Calculation of COPC Concentrations in Produce 2: the units of the parameter kp (yrs^{-1}) should be indicated in the text and in the gray box on page 5-29.
- Draft HHRAP Section 5.7 Calculation of COPC Concentrations in Drinking Water and Fish: A typographical error exists in the description of the parameter Dytwp on page 5-65. The parameter should refer to total particle deposition rather than total vapor deposition.

EPA response:
Comments have been noted, and editorial errors and text revisions have been corrected, where applicable. The 0.1 kg/L has been changed to 1 kg/L in the text.

2.6 Quantifying Exposure [draft HHRAP Section 6]

The calculation of COPC-specific exposure rates for each exposure pathway evaluated includes the following factors:

- The estimated COPC media concentrations calculated in Chapter 5;
- Consumption rate;
- Receptor body weight; and
- The frequency and duration of exposure.

This calculation is repeated for each COPC and for each exposure pathway included in an exposure scenario.

Comments regarding quantifying exposure were categorized into:

- General Comments;
- Exposure Duration;
- Exposure Pathways (Inhalation, Dermal, Ingestion, and Water); and
- Clarification / Editorial.

2.6.1 Quantifying Exposure - General

General issues pertaining to quantifying exposure include:

- Corrections and recommendations; and
- Assumptions that may overestimate risk.

Issue: General - Corrections and Recommendations
General comments related to corrections include:

- The statement that 'a receptor is exposed via the indirect exposure pathways for as long as the receptor remains in the assessment area.' is not entirely correct (draft HHRAP Chapter 6, page 6-

13). In the equations provided, the exposures resulting from indirect exposures would be identical for facilities that operate 1 year or 40 years. Indirect exposures may or may not continue after the facility ceases operation.

- Draft HHRAP Chapter 6 should include a summary of specific recommendations and processes to follow for quantifying exposure. Much of this may consider site-specific factors and the type of metric to be used for carcinogenic versus non-carcinogenic endpoints. Nevertheless, the specific guidelines should be made.
- EPA should coordinate and build on the existing expertise and evolving approaches to multi-pathway modeling.

EPA Response:
The statement on page 6-13 has been changed from "is exposed" to "may be exposed." We disagree with the characterization that exposure would be identical regardless of facility emission duration. The period before emission, duration of emissions, and duration of exposure are all time-related components of the recommended equations for estimating soil concentrations. These time-dependent soil concentrations then contribute to other indirect exposure media concentrations. In any individual year during facility operation, COPC losses from the soil do not necessarily equal depositions, and concentrations tend to build with time. When emissions (and hence depositions) cease, soil concentrations and the indirect exposure media concentrations dependent on them tend to decrease.

Recommended exposure rates and frequencies are presented and referenced in Chapter 6. Specific guidelines on how to generate site-specific exposure factors are beyond the scope of the HHRAP.

We note the comment regarding coordinating and building on existing expertise and evolving approaches.

2.6.2 Quantifying Exposure - Exposure Duration

Issues pertaining to quantifying exposure duration include:

- Combined exposure from childhood through adulthood; and
- Use of highest annual soil concentration.

Issue: Exposure Duration - Combined Exposure from Childhood through Adulthood
The draft HHRAP discusses the scenario in which a child is exposed to facility emissions and then grows to adulthood with additional exposure. However, a recommended approach for addressing this issue is not provided.

EPA Response:
Exposure duration recommendations are presented. They do not include a mixed scenario of 6 years child and 24 years adult. This could be a scenario evaluated on a site-specific basis. Averaging-time recommendations are presented in HHRAP Section 6.5, with further clarification provided in Appendix C.

Issue: Exposure Duration - Use of Highest Annual Soil Concentration
The use of the potentially highest annual soil concentration over the operating lifetime of the unit for evaluation of non-carcinogenic effects was questioned. Given permit renewal requirements, EPA will have several opportunities to review incinerator operation and subsequent potential impacts prior to the end of the incinerator's service. It was noted that the application of a maximum annual soil concentration deviates from the intended non-cancer hazard analysis when facilities with short life spans are evaluated. As an alternative, the highest annual level over the exposure duration of each adult receptor was recommended.

EPA Response:
As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. We agree with the recommendation of the highest annual level over the exposure duration of each receptor as an alternative, and we've changed page 5-4 of the HHRAP accordingly.

2.6.3 Quantifying Exposure – Exposure Pathways

Comments were received regarding issues related to the following exposure pathways:
- Inhalation;
- Dermal;
- Ingestion (pica behavior); and
- Water

Issue: Exposure Pathways – Inhalation
Issues related to quantifying inhalation exposure include:
- It is incorrect to assume that 100% of the inhaled particles are retained and taken up by the body.
- Draft HHRAP Section 6.2.1, the 4th paragraph Air Exposure Pathways indicates that direct inhalation exposures are preferentially characterized by using inhalation unit risk factors (URF) and RfCs. This section should explain whether inhalation CSFs and inhalation RfDs are to be converted to URFs and RfCs, respectively, if these toxicity data are the only values available.
- Any site-specific conditions or setting characteristics that may require consideration of the soil inhalation pathway resulting from dust resuspension should be indicated in draft HHRAP Section 6.2.3.3, page 6-9.

EPA Response*:*
As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP. With regard to how direct inhalation exposures are characterized, this information is provided in Section 7.3 and chemical-specific examples are provided throughout Appendix A. Although we do briefly discuss inhalation of

resuspended dust in Section 6.2.3.3, a full discussion of an exposure pathway we do not normally recommend is beyond the scope of the HHRAP.

Issue: Exposure Pathway - Dermal
Issues pertaining to quantifying dermal exposure include:

- The draft HHRAP statement "available data indicate that the contribution of dermal exposure to soils to overall risk is typically small," should be revised to state that "available data indicate that the contribution to overall risk from dermal exposure to soils impacted from hazardous waste combustion facilities is typically small relative to contributions resulting from exposures via the food chain."
- The validity of using the highest annual average soil concentration to calculate dermal exposure was questioned, as this contradicts several other discussions concerning the non-carcinogenic hazard analysis. A revision of the methodology was recommended to be consistent with the exposure period to be evaluated (7 years to 70 years) and average daily exposure levels over the specific exposure duration derived for use with the RfDs/RfCs.

EPA Response:
With regard to the statement "available data indicate…" we have changed the HHRAP as suggested. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Exposure Pathway - Ingestion
It was recommended that draft HHRAP Section 6.2.3.1 Soil Ingestion include a statement indicating that pica behavior must be considered as part of the risk assessment and that the lack of this consideration be supported by documentation, rather than consideration only on a case-by-case and site-specific basis. Based on what is presented in the draft HHRAP, it seems unreasonable to rule out pica behavior, especially since it is considered "a normal part" of a child's development and children may be one of the most susceptible groups. Without such a statement, this potential source of exposure may be largely ignored.

EPA Response:
We disagree. For risk assessment purposes, pica is typically defined as "an abnormally high soil ingestion rate" and is believed to be uncommon in the general population. If available information indicates that there are children exhibiting pica behavior in the assessment area, and you determine that these children represent a special subpopulation potentially receiving significant exposure, it may be prudent to include these children in the risk assessment. We recommend you make this evaluation on a case-by-case basis, based on site-specific exposure setting characterization.

Issue: Exposure Pathway - Water
Issues pertaining to quantifying the water exposure pathway include:

- It is not clear how contaminant concentrations in cistern water are to be estimated, nor does it seem possible to make accurate estimates. It was noted that the area of the cistern would not be likely to

collect a significant amount of contaminants. This pathway could result in overly conservative risk assessments. In the event that it is necessary to maintain consideration of exposure to drinking water via cisterns, clarification is needed on whether this pathway should only be considered in cases where a cistern was actually observed during a site visit or when use of a cistern has been specifically reported.

- Additional guidance was requested about how water bodies should be included in the evaluation of the water exposure pathway. This is particularly important when faced with a location which is surrounded by numerous surface water bodies large and small. For example, the following conditions should be considered:
  - The predominant wind direction, if applicable.
  - Flow rates, in that flowing water bodies (with large flow rates) tend to have lower estimated COPC concentrations because of a greater rate of volumetric replacement. This is not to say that rivers should be excluded from evaluation.
- Priority should be given to those water bodies for which relevant risk pathways are complete (e.g., trophic level 4 fish occur and are likely to be sought by anglers) while the average rate of COPC deposition to watershed is high relative to the likely dilution available. This can present a challenge as these criteria tend to be mutually exclusive. An extensive fishery may depend on a large watershed while the highest COPC concentrations are likely to occur in small watersheds located close to the source.
- The discussion in draft HHRAP Section 6.2.4 should also be placed in Section 4.1.2 since it will assist the risk assessor in selecting the appropriate water bodies for analysis.
- Different RfDs can be applied for the evaluation of PCBs and it was noted that the draft HHRAP does not address which RfD to use when evaluating ingestion of water-soluble (lower chlorinated) congeners. The recommendation is for the use of the RfD for Aroclor 1016 of $7x10^{-5}$ milligram per kilogram-day to evaluate the non-carcinogenic PCBs in the water ingestion pathway, given that only the lower chlorinated PCB congeners are soluble in water. This approach would be consistent with recommendations concerning the evaluation of carcinogenic PCB congeners in the water ingestion pathway. (See RC Section 3.4.5)
- Further clarification is needed on the use of safety factors for the water ingestion pathway, given that only the lower chlorinated PCB congeners are soluble in water. The more highly chlorinated PCBs will adhere to soil and sediments and the safety factor of 2 should be applied to evaluate risks through the food chain, sediment, or soil exposures unless at least 99.5 percent of the mass of the released PCB mixture has fewer than four chlorine atoms per molecule.

EPA Response:
We disagree with the comment regarding cistern water. Cistern water may be a viable exposure pathway in some site-specific situations. How or to what extent a cistern is considered is up to the permitting authority. The HHRAP provides guidance as to what should be considered. The quantitative evaluation of water concentrations in cisterns has been clarified.

Selection of the water bodies to be evaluated is a site-specific decision. The HHRAP provides several potential variables to consider when selecting water bodies in the assessment.

Chapters 3 through 6 should be reviewed when selecting water bodies for the assessment. Air modeling (Chapter 3) and environmental fate and transport (Chapter 5) are just as important when selecting water bodies to evaluate as are exposure scenario selection (Chapter 4) and exposure pathway evaluation (Chapter 6).

The issue of evaluating coplanar PCB congeners was reviewed during the external peer review. The peer review panel agreed that evaluating coplanar PCB congeners using dioxin toxicity equivalency factors (TEFs) is appropriate and reasonable. The peer review panel also agreed that using the health benchmarks for Aroclor 1254 and Aroclor 1016, depending on the congener composition of actual emissions, is reasonable. We recommend using the World Health Organization (WHO) TEFs for dioxin and furan congeners.

As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. With regard to safety factors for the water ingestion pathway, a facility may evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

2.6.4 Quantifying Exposure - Clarification / Editorial

Issue: Clarification - Consumers of Contaminated Food
In draft HHRAP Section 6.2.2.3 Percentage of Contaminated Food, page 6-6, it is assumed that no other receptors in addition to the subsistence farmer and subsistence farmer child consume the contaminated animal tissues. Is there some basis for this assumption? If so, it should be referenced.

EPA Response:
Section 6.2.2.3 of the draft HHRAP referenced earlier guidance in recommending particular exposure pathways for each exposure scenario. We've modified Section 6.2.2.3 to deal exclusively with the title subject: the percentage of a particular food type to assume is contaminated. The issue of which exposure pathways (i.e., food types) to assign to which exposure scenarios is now dealt with exclusively in HHRAP Chapter 4, Section 4.2 (Recommended Exposure Scenarios).

Issue: Clarification - Dose Metric
More discussion was recommended in draft HHRAP Section 6.1 GENERIC EXPOSURE RATE EQUATION, pages 6-1 to 6-2 about the proper dose metric to be used for quantifying exposure, and the HHRAP should consider characteristics of the particular chemical, as well as the endpoint(s) of concern. Dose to the receptor can be quantified in a variety of metrics, such as daily intake, total body burden, or body burden averaged over a given period of time. The metric used should clearly match the particular toxic endpoint. Developmental effects may use a metric which describes exposure at a particular time of development. On the other hand, responses such as cancer may be best described either by an exposure over time or a particular body burden. The appropriate metric used may also depend on the half-life of the particular chemical.

EPA Response:
The discussion in Section 6.1 of the HHRAP is meant only as a generic intake rate overview specific only to what is generally utilized in risk assessment practice. Variations of this equation as they pertain to receptor and chemical specific exposures are presented in detail through Appendix C.

2.7 RISK AND HAZARD CHARACTERIZATION [draft HHRAP Section 7]

Risk characterization is the probability that a receptor will develop cancer, based on exposure to chemicals over time. Risk calculations are based on cancer slope factors that are estimates of lifetime probabilities of an individual developing cancer as a result of exposure to particular levels of a potential carcinogen. The risk characterization is then compared to an acceptable target risk level, usually in the range of 1×10^{-4} to 1×10^{-6}.

Hazard characterization is a measure, calculated as a ratio, of a receptor's potential exposure relative to a standard exposure level, typically the reference dose (*RfD)* or reference concentration (*RfC)*. Often (but not always), a hazard ratio above 1 is generally considered unacceptable. However there are additional analyses that can be performed, such as subdividing hazards by target organs.

For multiple chemical exposures, risks and hazards are generally added together. There is flexibility inherent in the risk and hazard characterization process, so that site-specific information can be included.

Comments regarding risk and hazard characterization were categorized into:
- General Issues;
- Risk and Hazard Toxicity Factor Determination;
- Route-to-Route Extrapolation of Toxicity Benchmarks;
- Inhalation Toxicity Benchmarks;
- Non-cancer Effects Estimation; and
- Clarification / Editorial.

2.7.1 Risk and Hazard Characterization - General

General comment issues include:
- Additive effects of contaminants of potential concern (COPCs);
- Impacts of background and other man-made sources;
- Use of average daily contaminants of potential concern intake (ADI) via inhalation in calculating cancer risk and Hazard Quotient (HQ);
- Characterization of receptors;
- Incremental lifetime cancer risks;
- Consideration of radionuclides;
- IEUBK model application for lead risks;
- Probabilistic risk assessment;

- Application of site-specific data in risk and hazard characterization;
- Separate carcinogenic and non-carcinogenic soil calculations;
- Integrated risk assessment process;
- Contaminants derived from raw materials; and
- Evaluation of non-cancer dioxin hazards.

Issue: General - Additive Effects of COPCs
It was suggested that the statement in draft HHRAP section 7.3, page 7-6, "This summation methodology assumes that the health effects of the various COPCs to which a receptor is exposed are additive" is a very conservative assumption, especially for different endpoints of concern. Although the possibility exists, there is only very limited evidence for any of the health effects of these chemicals to be additive, and in fact, it is probably unlikely for many health effects.

EPA Response:
The HHRAP recommends a conservative assumption of additivity as a first cut in the risk assessment, but also allows for grouping by target organ.

Issue: General - Background and Other Man-made Sources
It was suggested that background exposure levels and exposure from other man-made sources are issues not adequately addressed in the draft HHRAP (Section 7.3, page 7-6, lines 4-5). The draft HHRAP suggests that consideration of other sources should be largely left up to the discretion of the permitting authority. It was recommended that a requirement be made to at least consider other sources of exposure. This would necessitate a statement in the HHRAP that the hazard quotient (HQ) has or has not been adjusted based on the determined, or at least estimated, absence or presence of other significant sources of exposure. The importance of other sources should also be considered for cancer risk, but may be especially important for effects where thresholds are involved, especially if the exposure is near such a threshold.

EPA Response:
We consider the issue of whether/how to include background to be a risk management decision, and therefore beyond the scope of the HHRAP. An example of how background and cumulative risk are being addressed is presented in the Region 6 Risk Management Addendum (U.S. EPA Region 6, 1998, EPA-R6-98-002).

Issue: General - Use of ADI in Calculating Cancer Risk and Hazard Quotient [draft HHRAP Appendix C]
Comments suggested that total air concentrations of COPCs, along with unit risk factors (URFs), are more appropriate than using the average daily intake (ADI) in the calculation of cancer risks and hazard quotients.

EPA Response:
Using the ADI allows for altering the exposure duration, that is built into the URF. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A

facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: General - Characterization of Receptors
A concern was expressed that calculations based on hypothetical receptors are overly conservative, or that assumptions in the risk assessment do not reflect the distribution of receptors relative to the location of the stacks within the facility. Based on the draft HHRAP text which states that risks and hazards from all combustion units be summed across all receptor exposure pathway combinations for each receptor, one commenter questioned the reasonableness of summing risks and hazards from multiple stacks and using the assumption of collocation of all receptors, which is unlikely to be supported by site-specific data.

EPA Response:
The draft HHRAP recommends basing the evaluation of receptors on current and reasonable potential land use (See draft HHRAP Section 4). Furthermore, receptors are located where they live or could reasonably be expected to live in the future. Exposure is through appropriate direct and indirect pathways for that receptor. It does not and should not be interpreted that all receptors live at one location. This may be done for a conservative screening, but is far from the procedures recommended in the draft HHRAP.

Issue: General - Incremental Lifetime Cancer Risk
The text should make clear that the assessment of cancer risks is for incremental risks over a lifetime.

EPA Response:
We agree, and have made the recommended changes.

Issue: General - Consideration of Radionuclides
Additional equations relevant to calculating risks due to radionuclides, as found in NESHAPS, should be added to the HHRAP.

EPA Response:
The HHRAP is consistent with the guidance used in the Superfund program rather than NESHAPS. The

HHRAP only gives a brief overview of radionuclides. A separate guidance would need to be developed to conduct a risk assessment of a hazardous waste combustion facility emitting these constituents.

Issue: General - IEUBK Model Application for Lead Risks
Several concerns about application of the IEUBK model to address lead impacts from incinerator emissions included:

- The current version of the IEUBK model is inadequate for screening purposes. It was suggested that the 1994 USEPA guidance value of 400 mg/kg be applied first as a screening value, and the IEUBK model be applied when levels exceed 400 mg/kg.
- Lead should be evaluated by media-specific health-based criteria, such as USEPA Region 6's values for soil (100 mg/kg) and air (0.2 pg/m^3).

- Site-specific levels of lead estimated in the air, drinking water, and foodstuffs should be included when applying the IEUBK model.

EPA Response:
Detailed recommendations on what assumptions to apply to the IEUBK model are site-specific. A screening method for addressing this is presented in the risk management addendum developed by EPA Region 6. Development of guidance on how to implement the IEUBK model with regard to changes in exposure parameters and model default assumptions is beyond the scope of the HHRAP.

Issue: General - Probabilistic Risk Assessment
It was suggested that the use of probabilistic risk assessment (Monte Carlo Analysis) be more strongly supported as an option for risk analysis.

EPA Response:
Consistent with other U.S. EPA guidance, the HHRAP allows for probabilistic risk assessment, but recommends that a deterministic assessment be done as well. Experience in conducting risk assessments for combustion facilities has shown that probabilistic assessments are most valuable in the sensitivity analysis of sensitive parameters for compounds and exposure pathways driving the risk.

Issue: General - Application of Site-specific Data to Risk and Hazard Characterization
Concern was expressed that the flexibility inherent in the recommended risk and hazard characterization will cloud the certainty of the risk estimate.

It was recommended that site-specific conditions that would indicate calculation of population risks should be specified in the last sentence of the 1st full paragraph on page 7-2 of the draft HHRAP.

EPA Response:
As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Developing methodologies to capture the site-specific conditions that may validate the appropriateness of calculating population risks is beyond the scope of the HHRAP.

Issue: General - Separate Carcinogenic and Non-carcinogenic Soil Calculations
Requiring separate soil concentrations for carcinogenic chemicals and non-carcinogenic chemicals requires separate calculations for all exposure pathways that have soil concentration as an input.

EPA Response:
A detailed evaluation of the soil concentration equations has been conducted by EPA's Office of Research and Development and is available upon request, but is beyond the scope of what is presented in the HHRAP. Also, as with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: General - Integrated Risk Assessment Process
Consideration of the reasonableness of the risk assessment should be integral throughout the risk assessment process, and not just a final consideration.

EPA Response:
We agree. This is why it was so important for us to clearly document the parameters and procedures set forth in the HHRAP. A facility is then able to evaluate the basis for the parameter, offer an alternate parameter, if applicable, and be able to evaluate the uncertainty of the parameter used in the risk assessment.

Issue: General - Contaminants Derived from Raw Materials
The guidance document requires that the evaluation consider emissions from raw materials and cements, in addition to the hazardous material products. The commenter assumed this is to understand potential emissions from the manufacturing process to better assess the incremental risk from hazardous waste combustion.

EPA Response:
This assumption is correct.

Issue: General - Evaluation of Non-cancer Dioxin Hazards [draft HHRAP Section 2.3] (See RC Section 3. 4.4)
It was suggested that EPA exclude from the HHRAP the non-cancer evaluation of dioxin, in particular because the draft Dioxin Reassessment has never been finalized.

EPA Response*:*
The only non-cancer assessment recommended in the HHRAP is a margin of exposure comparison of dioxin in breast milk and background levels noted in the U.S. Authors of the Dioxin Reassessment have reviewed the HHRAP.

2.7.2 Risk and Hazard Toxicity Factor Determination

Risk and hazard toxicity factor determination issues include:

- Selection of COPCs;
- Realistic and current toxicity values;
- Basis of toxicity values;
- Absorption assumptions;
- Calculation of toxicity factors;
- Separate versus cumulative target organ toxicity;
- Evaluation of products of incomplete combustion (PICs); and
- Toxicity equivalent factor (TEF) values for coplanar PCBs, PCDD, and PCDF.

Issue: Toxicity Factor Determination - Selection of COPCs
It was suggested that the criteria air pollutants (sulfur dioxide, nitrogen dioxide, ozone and carbon monoxide) should not be included in a quantitative risk assessment because they lack toxicity factors. No toxicity values are listed in draft HHRAP Appendix A, IRIS, or HEAST.

EPA Response:
Availability of chemical-specific toxicity information is a criterion in our recommended 5-step process for choosing which COPCs to assess in a risk assessment (see HHRAP Chapter 2 Facility Characterization). We recommend performing a quantitative risk assessment on any chemical that satisfies all criteria in our 5-step process. As with many parameters and equations in the HHRAP, we've provided the scientific basis and reference behind our process. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: Toxicity Factor Determination - Realistic and Current Values
Comments regarding the selection of toxicity factors for use in assessing risks and hazards included:

- The suggestion that available toxicity values may not match real-world exposures. In some instances, toxicity values cannot be applied to the hazardous waste incineration model because the likely exposure scenarios do not match.
- A noted discrepancy in the draft HHRAP regarding the order of preference for obtaining health benchmarks. A different order is specified in Volume I, Sections 7.2 and 7.3 as compared to Appendix 3. Specifically, Agency for Toxic Substances Disease Registry (ATSDR) is not mentioned in Appendix 3. Additionally, the most recent edition of HEAST is not referenced.
- Toxicity values are subject to change over time with the addition of new data, and updates are needed. Tables containing out-of-date toxicity values should be removed.

EPA Response:
We have revised the hierarchy of recommended sources of toxicity information, and have updated the references. The hierarchy of recommended sources of toxicity information is presented in Appendix A. The HHRAP has been revised taking into account the most recent science.

We recommend using the best available data throughout the risk assessment process. Any part of the guidance can and will go out of date, however, seldom do toxicity factors change by significant amounts across the board. Therefore, the numbers provided serve as a useful sounding board with which to conduct an initial analysis. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: Toxicity Factor Determination - Basis of Toxicity Values
Comments regarding the basis for the derivation of toxicity values include:

- The tables do not indicate whether the reference doses are based on chronic or subchronic data, and it was recommended that these references be included.

- Cancer toxicity data for COPCs not classifiable as carcinogens have been labeled as "ND", which is misleading.
- More detailed information should be provided on how to determine chemical-specific parameters for COPCs not included in draft HHRAP Appendix A3.

EPA Response:
The reference we have provided for each value can be used to investigate the basis of the toxicity information. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

The methods we used to obtain chemical-specific parameters, including the scientific bases, references, and equation, are provided in the draft HHRAP. Similar methods and references may be followed to obtain information on more chemicals. The chemicals presented in the draft HHRAP are those typically measured by the analytical methodologies carried out in a trial or risk burn.

Issue: Toxicity Factor Determination - Absorption Assumptions
It was noted that in the draft HHRAP, 100% absorption for route-to-route extrapolations is generally assumed. Therefore, the basis for requiring chronic RfDs or RfCs be applied to subchronic exposures was questioned, and clarification was requested about the justification for modifying the absorption factor.

EPA Response:
Assuming 100% absorption is a screening assumption to be used when chemical-specific data are not available. Also note, that the HHRAP is guidance and does not require chronic RfD's or RfC's be applied to sub-chronic exposures. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: Toxicity Factor Determination - Calculation of Toxicity Factors
A question was raised about the statement that risk assessors should develop acute inhalation exposure criteria (AIECs) for compounds not addressed by available criteria.

EPA Response:
The HHRAP does not state that AIECs should be calculated but only states that they can be calculated, and it provides a reference with the method to do so.

Issue: Toxicity Factor Determination - Separate versus Cumulative Target Organ Toxicity
The question was raised about when it is appropriate to evaluate target organ toxicity for individual COPCs versus cumulative COPCs. The evaluation of COPCs separately could result in underestimating risk.

EPA Response:
This is not part of the HHRAP, but rather part of the risk management addendum developed by EPA Region 6.

Issue: Toxicity Factor Determination - Evaluation of PICs
The basis of categorizing chemicals with regard to low, medium, or high toxicity was questioned. It was suggested that such classification might be used to eliminate PICs.

EPA Response:
Whether or not to evaluate PIC's is a site-specific decision. General metrics, which can be used in such an evaluation, are presented in Section A1.7. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

Issue: Toxicity Factor Determination - TEF Values for Coplanar PCBs, PCDD and PCDF
[draft HHRAP Section 2.3] (See RC Section 3.4.6)
The toxicity equivalency factors (TEFs) listed for coplanar PCBs, PCDD, and PCDF do not reflect the most up-to-date revisions made by the World Health Organization (WHO) (draft HHRAP Chapter 2, pages 2-42 and 2-49). These TEFs are based on the most recent science and were made available at Dioxin '97, 17th International Symposium on Chlorinated Dioxins and Related Compounds, Indianapolis, Indiana, USA, August 25-29, 1997.

It was suggested that it is not appropriate to evaluate potential non-carcinogenic effects of PCBs by using the oral reference dose (RfD) for Aroclor 1254 or Aroclor 1016 (draft HHRAP Chapter 2, page 2-51).

EPA Response:
We have edited the HHRAP to reflect the most up-to-date TEFs. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority a site-specific option, or other alternative to that recommended in the HHRAP.

2.7.3 Route-to-route Extrapolation of Toxicity Benchmarks [draft HHRAP Sections 7.2 and 7.3, Appendix A.3] (See RC Section 3.4.2)

Route-to-route extrapolation issues included:

- Caution should be exercised when making route-to route extrapolations;
- The need for additional information on how to conduct a qualitative route-to-route extrapolation;
- The suggestion that route-to-route extrapolation should not be conducted because of the inherent uncertainty; and
- Clarification about the application of route-to-route extrapolation to carcinogens.

Issue: Route-to-Route Extrapolation - Cautions for Using Route-to-Route Extrapolations
Commenters suggested caution should be exercised in the calculation of CSFs from URFs or of URFs from CSFs assuming route-to-route extrapolation because in many cases, COPCs can elicit route-of-entry

effects or undergo first-pass metabolism in the respiratory system. Similarly, caution should be exercised in the calculation of RfDs from RfCs or of RfCs from RfDs

It was recommended that data from the National Center for Environmental Assessment (NCEA) research effort be incorporated into the HHRAP to more accurately define where route-to-route extrapolations would be appropriate.

EPA Response:
We agree that caution should be exercised in conducting route-to-route extrapolations. The NCEA authors of the "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" (1994a, EPA/600/8-90/066F) were consulted on the methodology presented in the HHRAP and agreed with it as a screening methodology. This issue was reviewed during the external peer review, and the peer reviewers also agreed with it as a screening methodology.

Issue: Route-to-Route Extrapolation - Additional Information
It was suggested that additional information should be provided regarding how a qualitative assessment of route-to-route extrapolation should be performed.

EPA Response:
We've added to this section a reference to the EPA document, "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" (1994a, EPA/600/8-90/066F), to provide insight into what should be considered in evaluating route-to-route extrapolations.

Issue: Route-to-Route Extrapolation - Inherent Uncertainty
It was suggested that it is inappropriate to use oral toxicity values to evaluate inhalation risk or hazard because these calculations are not scientifically valid or they contradict other EPA guidance (draft HHRAP Chapter 7, page 7-4). If route-to-route extrapolations are to be performed, information should be given to scientifically defend the method used for each individual chemical.

EPA Response:
The HHRAP recommends that caution be exercised in calculating RfDs from RfCs or RfCs from RfDs assuming route-to-route extrapolation, since in many cases, COPCs can elicit route-of-entry effects or undergo first-pass metabolism in the respiratory system (U.S. EPA 1994a, EPA/600/8-90/066F). However, the HHRAP recommends evaluating as many COPCs as possible in the risk assessment. Hence, there is a need to conduct route-to-route extrapolations.

The authors of the Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry were consulted on the methodology presented in the HHRAP and agreed with it as a screening methodology. This issue was reviewed during the external peer review, and the peer reviewers also agreed with it as a screening methodology.

Issue: Route-to-Route Extrapolation - Application to Carcinogens
It was noted that the draft HHRAP contains route-to-route extrapolation to assess non-carcinogenic effects from inhalation in the absence of RfCs. However, it seems that the same is not done for carcinogens as there is no discussion in draft HHRAP Section 7.2. It was recommended that EPA examine why route-to-route extrapolation for carcinogenic COPCs is not contained in Section 7.2.

EPA Response:
Section 7.2 of the peer review draft of the HHRAP presents one example of route-to-route extrapolation. We discuss all methods of route-to-route extrapolation used in the HHRAP in Appendix A Section A3.6.3.

2.7.4 Inhalation Toxicity Benchmarks

Issues that were raised regarding inhalation toxicity benchmarks included:
- Inhalation RfD versus Inhalation RfC; and
- Calculation of RfC and URFs from RfDs and CSFs

Note that several comments about inhalation toxicity benchmarks are included in this Response to Comments document, Section 2.7.3 Route-to-Route Extrapolations.

Issue: Inhalation Toxicity Benchmarks - Inhalation RfD versus Inhalation RfC
Clarification is needed on the difference between the inhalation RfD and the inhalation RfC, and how the inhalation RfD is to be used in risk assessment.

EPA Response:
The inhalation RfD is used in the risk assessment so that site-specific exposure durations can be assessed. RfC's are not sensitive to exposure duration. The inhalation RfD differs from the oral RfD in the toxicity information used to derive it. Our recommendation has been revised to utilize the RfC rather than the inhalation RfD. We provide an equation to calculate the inhalation RfC from the RfD in HHRAP Appendix A, Section A3.6.3.

Issue: Inhalation Toxicity Benchmarks - Calculation of RfC and URFs from RfDs and CSFs
Several questions were raised about the methodology for calculating RfCs from RfDs, mainly the methodology to convert CSFs and RfDs to URFs and RfCs, as well as what procedure should be used if CSFs and RfDs are not available. Clarification is needed regarding whether the CSF is to be calculated from the URF only when the URF is available and if not, whether the URF should be calculated from the oral CSF.

EPA Response:
The HHRAP includes information to calculate URFs and RfCs in Section 7.3, and chemical-specific examples are provided in Appendix A. The procedure for handling the calculations in the absence of CSFs and RfDs is explained in A3.6.3 under number 6 b.

2.7.5 Non-cancer Effects Estimation

Issues regarding estimation of non-cancer effects included:

- Selection and inclusion of COPCs and the identification of target organs;
- Calculation of hazard quotients (HQs); and
- Consideration of long-term/lifetime exposures in the calculation of HQs.

Issue: Non-cancer Effects Estimation - Selection of COPCs and the Identification of Target Organs
EPA was asked to provide the basis and the method used to identify target organs for specific chemicals included in draft HHRAP Table A-2. How COPCs and target organs might be excluded from Table A-2 should also be explained.

EPA Response:
We present Table A-2 as a starting point for the refined assessment of non-carcinogens. As stated in Table A-2, the list of chemicals is by no means exhaustive. It is correct that more than one target organ is often listed. This seems reasonable in that there are different routes of potential exposure.

We've provided a general description of how critical effects are used in selecting RfD and RfC values following the target organ table in Appendix A-2.

Issue: Non-cancer Effects Estimation - Calculation of Hazard Quotients (HQs)
It was suggested that there may be contradictions in the recommendations for calculating the Hazard Index. The text should be reworded so that average exposure duration is calculated.

EPA Response:
We've reviewed the subject text and found no contradictions. As with many parameters and procedures provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Non-cancer Effects Estimation - Consideration of Long-term/Lifetime Exposures
The statement in the draft HHRAP suggesting that hazard assessments for non-carcinogenic COPCs are not based on lifetime exposures is incorrect, as chronic reference doses are derived to be protective of long-term (7 years to lifetime) exposures.

EPA Response*:*
We agree, and have corrected the sentence.

2.7.6 Risk and Hazard Characterization - Clarification / Editorial

Issue: Editorial
In draft HHRAP Chapter 7 Introduction, 2nd paragraph, 2nd sentence: Change "and" to "an". In the 3rd

sentence, add "during his lifetime" after "developing cancer."

EPA Response:
Comments have been noted, and editorial errors and text revisions have been corrected, where applicable.

2.8 UNCERTAINTY INTERPRETATION FOR HUMAN HEALTH RISK ASSESSMENT [draft HHRAP Section 8]

Uncertainty may be introduced into a health risk assessment at all of the stages described in the draft HHRAP. It may be classified into four types: variable uncertainty, model uncertainty, decision-rule uncertainty, and variability. Some sources of uncertainty may be quantifiable. Others may not. In both cases, it is important for risk assessments of facilities that burn hazardous wastes to fully explain the areas of uncertainty in the risk assessments and to identify the key assumptions used in conducting the assessments.

Comments received regarding uncertainty in risk assessments included:
- General Issues;
- Qualitative Uncertainty;
- Quantitative Uncertainty; and
- Clarification / Editorial.

2.8.1 Uncertainty Interpretation - General Uncertainty Comments

General issues included:
- Completeness of the Guidance;
- Uncertainty's Effects on Estimation of Exposure; and
- Uncertainty and Risk Management.

Issue: General - Completeness of the Guidance
It was suggested that the discussion in draft HHRAP Chapter 8 about the need for uncertainty analyses is neither sufficient in detail nor emphasis to convey that this is an integral and necessary element of the risk assessment process. It was recommended that EPA incorporate both sensitivity studies and uncertainty analyses into its risk assessment protocol. Uncertainty of a given variable, parameter, or process should be assessed relative to its impact on the overall uncertainty in the associated risk that results from all sources, and it should be further assessed relative to the uncertainty in each of the other components of the risk assessment process. This means that uncertainty of a variable needs to be considered in the context of the sensitivity of the estimated risk to that variable and its uncertainty.

EPA Response:
Descriptions of both qualitative and quantitative methods for conducting uncertainty analyses are presented in the HHRAP. Sensitivity studies are one tool a risk assessor can use to quantitatively bound the uncertainty of an input parameter. The HHRAP includes references to sensitivity studies, about which EPA is aware, within the technical sections to which they pertain (e.g., ISCST3 air model input sensitivity analysis in Chapter 3). Within the HHRAP, we've identified uncertainties and limitations within the discussion of specific technical issues (e.g., TOE, estimates of emission rates, COPC selection process, quantifying non-detects) as they are presented in their respective sections. We present the limitations associated with parameter values and inputs to equations in Appendices A, and B and C, respectively.

Issue: General - Uncertainty's Effects on Estimation of Exposure
It was stated that uncertainty about indirect exposure pathways would result in overestimating exposure. Specific examples were requested about when risk estimates would be considered overly conservative.

EPA Response:
The HHRAP provides a formal discussion of uncertainty in Chapter 8 and descriptions of all of the parameters used to calculate risk and estimate exposure in Appendices A, B and C. We acknowledge that uncertainty may result in overestimation or underestimation of risk.

Issue: General - Uncertainty and Risk Management
It was noted that uncertainty in a risk assessment might exist because of the lack or quality of information about pathways and the toxicity of chemical substances. Concern was expressed that, although the draft HHRAP provides qualitative and quantitative guidance to assess uncertainty and variability in the risk assessment process, it does not detail how the uncertainty in these parameters and in general may affect permitting decisions and the risk management process.

EPA Response:
How uncertainty in a risk assessment is interpreted is a risk management decision, beyond the scope of the HHRAP. Section 8.5 provides a description of the materials we recommend be summarized and presented to the permit writer for introduction into the decision making process.

Issue: General - Uncertainty and Risk Management
It was suggested that risk assessments should only be performed for facilities and units that are part of the permitting process.

EPA Response:
This is a risk management decision, and beyond the scope of the HHRAP.

2.8.2 Uncertainty Interpretation - Qualitative Uncertainty [draft HHRAP Section 8.3]

Issue: Qualitative Uncertainty - TICs
Clarification was requested about how information from tentatively identified compounds (TIC) could be used in uncertainty analysis.

EPA Response:
The state-of-the-science for TIC's has been presented in the HHRAP. Currently, TIC analysis in risk assessment is highly uncertain.

2.8.3 Uncertainty Interpretation - Quantitative Uncertainty [draft HHRAP Section 8.4]

Issue: Quantitative Uncertainty - Quantitative Uncertainty Analysis
It was stated that quantitative uncertainty analysis might require more work than is reasonable for assessing risk. The extensive level of quantitative assessment described in the draft HHRAP should not be required to account for uncertainty.

EPA Response:
The HHRAP presents only guidance. The level of detail necessary for a risk assessment is site-specific and should be negotiated with the permitting authority. (Examples of risk assessment reports accepted by permitting authorities are available on the EPA Region 6 web site.)

Issue: Quantitative Uncertainty - Probabilistic versus Deterministic Analyses
It was stated that the HHRAP should allow for the use of distributional analysis and probabilistic methods instead of relying on deterministic analysis. The use of maximum single point exposures in air quality impacts was specifically noted as an area where distributional analysis would be more effective. It was suggested that risks and hazards should be presented as distributions rather than point estimates, and EPA should conduct a general sensitivity and uncertainty analysis before finalizing the draft HHRAP.

EPA Response:
As guidance, the HHRAP is not in the position of "allowing" or "disallowing" anything. The HHRAP is flexible enough to include probabilistic risk assessment, but recommends that a deterministic analysis be performed as well. Experience in conducting risk assessments for combustion facilities has shown that probabilistic assessments are most valuable in the sensitivity analysis of the most sensitive parameters, such as compounds and exposure pathways driving risk. Deterministic evaluations are effective in helping to identify these sensitive parameters.

Issue: Quantitative Uncertainty - Adequacy of the Guidance
It was recommended that the HHRAP include more information on how to conduct a quantitative uncertainty analysis, unless the reader is referred to another source (e.g., EPA's "Draft Risk Assessment Guidance for Superfund Volume 3 - Part A: Process for Conducting Probabilistic Risk Assessment" (1999c)). It was noted that the reader is not given any guidance in the draft HHRAP for deciding when a detailed quantitative treatment of uncertainty is required. While there is enough guidance in Chapter 8 about the qualitative description of uncertainties, there is no discussion about how this type of information should be incorporated into the risk-based decision making process.

EPA Response:
We've modified the HHRAP to refer the reader to EPA's "Draft Risk Assessment Guidance for Superfund Volume 3 - Part A: Process for Conducting Probabilistic Risk Assessment" (December 1999c). Whether

a detailed quantitative treatment of uncertainty is required is a decision of the permitting authority. Interpretation of how qualitative uncertainty analyses are incorporated into the risk-based decision making process is also the responsibility of the permitting authority.

2.8.4 Uncertainty Interpretation – Clarification / Editorial

Issue: Clarification - "Typical" Accuracies
Draft HHRAP Section 8.5: It was stated that the sentence on "typical" accuracies of dispersion model estimates is arbitrary without further clarification of the conditions under which such accuracies are achieved. Many situations achieve much poorer accuracies.

EPA Response:
A reference is provided for use of the word typically as follows: "When applied properly, air dispersion models are typically accurate to ± 10 to 40 percent and can be used to yield a "best estimate" of air concentrations (Title 51 CFR Appendix W)."

Issue: Clarification - Relative Quantification
Draft HHRAP Section 8.5, page 8-7, lines 5-6 from bottom: It was recommended that some relative quantification of what is meant by high, medium, and low effect be given. For instance, will a high effect give an uncertainty of 2 orders of magnitude versus 5-fold?

EPA Response:
A relative quantification of what is meant by high, medium, and low is beyond the scope of the HHRAP. The relative quantification of the magnitude of an effect is parameter-specific and while a variation of one order of magnitude for one input parameter may be considered low, for another input parameter one order of magnitude may be quite high.

Issue: Editorial
Draft HHRAP Section 8.5, 2nd paragraph: TOE (total organic emissions) is not included in the acronym list

EPA Response:
We've added TOE to the acronym list.

2.9 COMPLETION OF RISK ASSESSMENT AND FOLLOW-ON ACTIVITIES [draft HHRAP Section 9]

Issue: Follow-on Activities - Activities Following the Risk Assessment
It was suggested that the statements in Section 9.2, page 9-2, last paragraph leave too much to the discretion of the facility and/or permitting authority. This section should specify a minimum amount of time between reviews and the types of changes in process and procedure that would require a review of the facility.

EPA Response:
The recommendations made by the commenter are the purview of the permitting authority.

Issue: Follow-on Activities - Conclusions
It was suggested that it might be useful to include in the Conclusions the major sources of uncertainty and an estimate of how many fold the error might be.

EPA Response:
The HHRAP recommends that the conclusions interpret the results of the risk and hazard characterization in light of the uncertainty analysis.

2.10 CHEMICAL SPECIFIC DATA (draft HHRAP Appendix A)

Draft HHRAP Appendix A details a range of chemical specific data in four areas:

- Chemicals for consideration as compounds of potential concern (COPC);
- Target organs and critical effects for compounds with reference doses;
- Compound specific parameter values; and
- Acute benchmarks.

A significant number of comments were received regarding the chemical specific data. These comments included:

- Accuracy and Completeness of Data;
- Accuracy of Equations;
- Inconsistencies;
- COPCs and PICs;
- Missing Material; and
- Specific Issues.

Issue: Chemical Specific Data - Accuracy of the Data in Appendix A
It was generally noted that draft HHRAP Appendix A had numerous errors. Commenters felt that some of the values in Appendix A conflicted with the chemical specific data found in other EPA documents and guidance, and that the guidance lacked internal consistency. Commenters recommended that EPA undertake a review of the data to ensure consistency and accuracy and that EPA establish one set of physical, chemical, and toxicological parameters that has been both internally and externally peer reviewed.

EPA Response:
Appendix A parameters have been reviewed in their entirety and have been corrected or updated where appropriate.

Issue: Chemical Specific Data - Errors and Incomplete Information

Commenters noted errors and incomplete information in chemical-specific parameters in the following areas:

- Acute inhalation exposure criteria are cited incorrectly or are out of date.
- Chemical-specific inputs for Aroclor 1016 and 1254 are incorrect.
- Chemical-specific inputs for Benzo(a)Pyrene are incorrect.
- Chemical-specific inputs for 2,3,7,8-Tetrachlorodibenzo(p)dioxin are incorrect.
- The values for the fraction of dioxin congener assumed to be in vapor state are incorrect for 2,3,7,8-TCDD and OCDD.
- The biota sediment accumulation factor (BSAF) values on draft HHRAP page A-3-38 all have the same name.
- The dioxin toxicity equivalency factors (TEFs) are not based on the most recent World Health Organization recommended TEFs.
- The TEFs for polychlorinated biphenyls are not based on the most recent World Health Organization recommended TEFs.
- The tables in draft HHRAP Appendix A do not indicate whether the listed reference doses are chronic or sub-chronic.
- It is misleading for COPCs not classifiable as carcinogens to be labeled "ND," implying that cancer slope factors are not available for them.
- The last paragraph of draft HHRAP Section 5.3.2 should state that VGag is 0.01 for lipophilic COPCs rather than the 0.001 shown. The correct value of 0.01 is stated in the second to the last paragraph in Section 5.3.2.1.
- The vapor pressure (Vp) shown for 2,3,7,8-TCDD in draft HHRAP Table A-3-176 does not correspond with that recommended by EPA in the referenced document (cited as U.S. EPA, 1994a in the draft HHRAP). The referenced document shows that EPA recommends a Vp of 7.4×10^{-10} mm Hg at 25^0C (9.7×10^{-13} atm). These values are presented on page 2-13 (Volume II) and page 7-66 (Volume 3) in USEPA (1994a).

EPA Response:

Appendix A parameters have been reviewed in their entirety and have been corrected or updated where appropriate. TEFs have been updated with the latest information from the World Health Organization.

With regard to the lack of subchronic and chronic detail for the reference doses, the reference for each RfD value is provided and can be used to investigate the basis of the toxicity information.

With regard to COPCs not classifiable as carcinogens, as with many parameters and equations provided in the HHRAP, the scientific basis and references are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

With regard to the VGag and Vp values, editorial errors have been reviewed and corrected where applicable.

Issue: Chemical Specific Data - Accuracy of Equations
Commenters noted apparent inaccuracies in draft HHRAP Appendix A equations:

- Appendix A-1, Section A3.6.3 Explanation of Calculated Toxicity Benchmark Values Comment: There is a typographical error in the equation for calculating the inhalation URF (A3.6.3 5). If it is the inhalation URF that is being calculated, then this same number cannot be part of the equation.
- Equation 5-1C should reduce to a form similar to equation 5-lE when T1 is zero. This is not the case, and hence equation 5-1C should be checked for computational and dimensional correctness.
- The formula for the fraction of a COPC in the vapor phase (Fv) in draft HHRAP Table B-1-1 (page 9 of 11) has an error. The correct formula is presented in equation A-3-10 in Appendix A-3.

EPA Response:
Comments noted. Editorial errors have been reviewed and corrected, where applicable.

Issue: Chemical Specific Data - Inconsistencies
Commenters noted the following areas where draft HHRAP Appendix A was different from other sections of the draft HHRAP:

- Commenters found an inconsistency between draft HHRAP Figure 2.3 and the information presented in Appendix A for considering COPCs and PICs.
- The order of preference for obtaining health benchmarks is different in Appendix A than that described in the body of the guidance.
- Appendix A fails to reference the 1997 version of HEAST as being preferred to the 1995 version.
- Appendix A references different material from the body of the text with regard to soil concentration factors for aboveground produce. The reference does not appear in the document.
- Draft HHRAP Section 2.3, page 2-38, line 5 references Table A-1.9-5, but this table is missing from Appendix A.

EPA Response:
Appendix A parameters have been reviewed in their entirety and have been corrected or updated where appropriate. Figure 2.3 was correct, and the Appendix was modified to reflect that fact. The order of preference for obtaining health benchmark information has been updated so that it is consistent. The 1997 version of HEAST is noted as being preferred over the 1995 version. The references have been clarified. Reference to Table A-1.9-5 has been removed from the text in Chapter 2.

Issue: Chemical Specific Data - COPCs and PICs
Commenters noted the following problems with the information provided in draft HHRAP Appendix A regarding COPCs and PICs:

- The information provided in Table A-1 is not useful for identifying COPCs from hazardous waste emissions. The information provided in Table A1:9-1, Table A1:9-2A, and Table A1:9-2B is confusing.
- The guidance does not specify how to determine chemical-specific parameters for COPCs not included in Appendix A.

EPA Response:
Tables A-1.9-1 through A-1.9-5, and all references to them, have been removed from the HHRAP

Methods including the scientific basis and reference for obtaining chemical-specific parameters and equations are provided in HHRAP. Similar methods and references may be followed to obtain information on more chemicals. The chemicals selected for presentation in the HHRAP are those typically measured by the analytical methods carried out in a trial or risk burn.

Issue: Chemical Specific Data - COPCs and PICs
Commenters stated that compounds with low toxicity values are listed as those that were deleted from the list of PICs. Clarification was requested about how to determine whether a compound has a low, medium, or high toxicity.

EPA Response:
Evaluation of PICs is a site-specific determination. General metrics that can be used in such an evaluation are presented in Section A1.7. As with many parameters and equations provided in the HHRAP, the scientific basis and references are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Chemical Specific Data - Material Missing from a Previous Draft
It was noted that a table in the Appendix of a previous draft of the HHRAP document had been removed. This table contained an extensive list of chemicals for consideration as COPCs.

EPA Response:
Comments received on the original draft requested that the table be removed so that it could not be misinterpreted in the selection of COPCs. We agreed with the potential for confusion, and removed table.

Issue: Chemical Specific Data - PAH
Commenters stated that, to avoid confusion, chemical-specific inputs for benzo(a)pyrene (BaP) only should be provided in Appendix A, and the data for the other six carcinogenic PAHs should be removed.

EPA Response:
We disagree. Fate and transport characteristics of different PAH congeners result in different distribution characteristics in the environment. It is important to model each congener separately before normalizing them to BaP equivalents.

Issue: Chemical Specific Data - Applicability of Partition Coefficients for Soil Water
It was stated that the draft HHRAP default sediment foc values might be too high for many water bodies in Texas.

EPA Response:
As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Chemical Specific Data - The Use of Route-to-Route Extrapolation Values (See RC Section 3.4.2)
EPA was requested to consider specifying exactly what should be included in the qualitative analysis that discusses route-to-route extrapolation of toxicity benchmarks.
Commenters requested that route-to-route extrapolation values not be included in the chemical specific input tables as their inclusion gives them almost equal significance to verifiable RfCs. Alternatively, if route-to-route extrapolation values are included in the chemical specific inputs, the fact that the values are uncertain and potentially unverifiable should be emphasized in each of corresponding input tables.

EPA Response:
A reference to the EPA document, "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" (1994a, EPA/600/8-90/066F) has been added to provide insight as to what one should consider in the evaluation of route-to-route extrapolations.

The HHRAP clearly states that rout-to-route extrapolations should be used with caution. Authors of the "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" were consulted on the methodology presented in the HHRAP and agreed with it as a screening methodology. This issue was reviewed during the external peer review, and the peer reviewers also agreed with it as a screening methodology.

Issue: Chemical Specific Data - Modifying IRIS Risk Values
Appendix 1A of the updated Exposure Factors Handbook (EPA/600/P-95/002Fa, August 1997) discusses procedures for ensuring that assumptions about population parameters in the dose-response analysis are consistent with the population parameters used in the exposure analysis. It may be necessary to adjust the IRIS values for certain contaminants.

EPA Response:
Comment noted. As with all parameters and methodologies presented in the HHRAP, documentation and references are provided such that one can make a determination of when new science or site-specific parameters are more appropriate than the recommended default.

Issue: Chemical Specific Data - Explanation of Calculated Toxicity Benchmark Values
Draft HHRAP Table A-3: For “Health Benchmarks,” the type of toxic effect on which the benchmark values are based should be briefly indicated for each compound. Where values are missing, it is assumed that values for these health benchmarks are not available. If so, it would be useful to clearly indicate this in a key at the beginning of the table. It is noted that for the halo-substituted dibenzodioxin and dibenzofurans, no health benchmarks are listed. These values should be calculated on the basis of TEFs in comparison to the 2,3,7,8-tetrachlorodibenzo-p-dioxin (as has been performed for the PAHs).

EPA Response:
Each table in Appendix A is footnoted to indicate whether a value is not applicable or whether there is no data available. For dioxin and furan congeners, TEF values are provided in Appendix A in order to calculate toxicity using the TCDD health benchmarks.

Issue: Chemical Specific Data - Compound Specific Parameter Values
HHRAP Page A-3-33, section A3.5.4.2: The exact difference between BAF as defined here and BCF as defined in A3.5.4.1 is not clear. This should be explained in simple terminology.

EPA Response:
The difference noted in the HHRAP between a BCF and a BAF is that a BCF accounts for chemical transfer from the water through the gills, whereas a BAF accounts for chemical transfer from water and sediment through the gills as well as chemical transfer through food consumption. BCF's and BAF's will generally be similar for chemicals that do not bioacumulate in the food chain as well as and at low torphic levels of the food chain.

Issue: Chemical Specific Data - Compound Specific Parameter Values
Draft HHRAP Page A-3-2, last sentence: Was any consideration given to variability? Depending on the variability and goodness of the data, using the geometric mean often may not be the best approach.

EPA Response:
Compound-specific parameters were selected following the hierarchy found in the Superfund Chemical Data Matrix (SCDM). They do consider variability and where the geometric mean was not appropriate, it was not utilized.

2.11 MEDIA CONCENTRATION EQUATIONS (draft HHRAP Appendix B)

Issue: Media Concentration Equations - USLE Cover Management Factor (C) Value
Draft HHRAP page B-256: The USLE cover management factor (C) can be a very important aspect of the estimation of erosion loading to a water body (Renard et al., 1997). Application of a C value of 0.1 for an entire watershed is much more appropriate than higher values especially as most row crops are estimated to justify a C of 0.1. Higher values are likely to be overly conservative.

EPA Response:
The HHRAP recommends that the universal soil loss equation (USLE) for cover management be determined and documented on a site-specific basis.

Issue: Media Concentration Equations - COPC in Air and Water
Draft HHRAP B-251: The draft HHRAP separately considers diffusional loading to the water body and volatilization losses from the water body. Consideration should be given to collapsing these two approaches to estimate their net effect given COPC concentrations in air and water.

EPA Response:
Comment noted. The recommendation was passed on to the EPA's Office of Research and Development.

Issue: Media Concentration Equations - Sediment Enrichment Ratio (ER)
Draft HHRAP page B-211: The sediment enrichment ratio (ER) is intended to account for the more ready erosion of light, relatively high organic soils. While this phenomenon has been observed in agriculture, it has not been demonstrated at the low concentrations and diverse watersheds likely to be of interest to the HHRAP. More support should be provided for an estimate of ER of 3 for organic compounds. This might include review of the agricultural literature or a comparison of COPC concentrations on in-situ soils versus those being eroded.
EPA Response:
Comment noted. The recommendation was passed on to the EPA's Office of Research and Development.

2.12 RISK CHARACTERIZATION EQUATIONS [draft HHRAP Appendix C]

Issue: Risk Characterization Equations - Inhalation Cancer Risk Calculation
Draft HHRAP Table C-2-1 Inhalation Cancer Risk for Individual Chemicals: The draft HHRAP states that Cancer $Risk_{(i)}$ = ADI $CSF_{(i)}$. It was recommended that the total COPC air concentration (Ca) be directly used with unit risk factors (URFs), where available, rather than calculating an internal dose from inhalation of air concentrations of these COPCs ("Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" (1994a, EPA/600/8-90/066F)).

EPA Response:
The HHRAP has been revised such that the total COPC concentration in air is directly used with unit risk factor. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

Issue: Risk Characterization Equations - Inhalation Hazard Quotient
Table C-2-2 Inhalation Hazard Quotient for COPCS: Noncarcinogens Issue. The HHRAP states that $HQ_{(i)} = ADI_{(i)} / RfD_{(i)}$. It was recommended that the total COPC air concentration (Ca) be directly used with reference concentrations (RfCs), where available, rather than calculating an internal dose from inhalation of air concentrations of these COPCs ("Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry" (1994a, EPA/600/8-90/066F)).

EPA Response:
The HHRAP has been revised such that the total COPC concentration in air is directly used with reference concentrations. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

3.0 PEER REVIEW COMMENTS ON MAJOR ISSUES RELATED TO THE DRAFT HHRAP

This section contains summaries of the external peer reviewers' responses to 30 major issues provided to them by EPA. These major issues were based on public comments on the draft HHRAP for which EPA wanted outside expert input and opinion to fully address the public comments. The 30 issues are organized to generally map to topics discussed in specific chapters in the draft HHRAP, primarily Chapters 2 through 6 and Appendices A, B, and C. Of the 30 major issues, the peer reviewers had written comments for 13 issues that demonstrated consensus among the peer review panel members. These written comments are summarized in Section 3 as "***Summary of Peer Review Written Comments***." The remaining 17 major issues were addressed in the peer review workshop, held in May 2000. For each of these 17 issues, a summary of the general consensus reached by the peer panel during their workshop discussion is provided. The workshop consensus opinions are presented in Section 3 as "***Workshop Synopses***."

3.1 GENERAL ISSUES

The external peer reviewers were given six general issues to address about the format and content of the draft HHRAP. The peer reviewers responded to these issues in writing. The general issues were not discussed during the peer review workshop. The following sections summarize the written responses received from the external peer reviewers regarding the general issues. The issues include:

1. Organization and Documentation;
2. Alignment and Purpose of Methods;
3. Scientific Soundness;
4. Credibility of Results;
5. Major Data Gaps and Limitation; and
6. Long-Term Research.

3.1.1 General Issue 1: Organization and Documentation

Comment on the organization of the section you reviewed. Is the presentation of information clear and concise considering the technical complexity of the subject and intended audience?

Summary of Peer Review Written Comments:
The unanimous opinion of the external peer review panel was that the draft HHRAP procedures are generally well written and completely described. Considering the technical complexity of the material, the draft HHRAP is presented in a clear and relatively concise manner, and the organization follows a logical format. The level and presentation of the material are appropriate for an intended audience of risk practitioners. It should also be a useful resource for permit writers, risk managers, and community relations' personnel, to varying degrees.

EPA Response:
Comment noted.

3.1.2 General Issue 2: Alignment of Purpose and Methods

Does the purpose of the HHRAP as stated in the Introduction (Draft HHRAP Chapter 1) accurately reflect the presented methodologies and scope?

Summary of Peer Review Written Comments:
The external peer review panel cited the stated purposes in the HHRAP to be:

- Provide an explanation of how risk assessments should be performed at hazardous waste combustion facilities and to provide a comprehensive source of data needed to complete the assessment;
- Provide risk assessors with a tool for completing quality, consistent, and defensible risk assessments in a short amount of time;
- Provide the tools needed to clearly communicate the procedures, results, and limitations of the risk assessment process; and
- Present a user-friendly set of procedures for performing risk assessments.

With regard to these stated purposes, the peer reviewers offered the following comments.

While the HHRAP provides an understanding of the risk assessment process and is a general guidance, reading the HHRAP alone does not equip one to do a risk assessment. The HHRAP does pull together existing methodologies and points to where all the details can be found if one wishes or needs to do a risk assessment. However, there are many cases, such as at complex sites and facilities, where site-specific conditions will warrant additional analyses, for which little or no guidance is provided in the document, and expert judgment on the part of the risk assessor will be extremely important.

EPA Response:
Although any process which requires integration of several technical disciplines (i.e., combustion engineering, air modeling, terrestrial fate and transport modeling, exposure assessment, and toxicology) to complete can be viewed as cumbersome and unreasonable, regional and state personnel have been implementing the guidance since the draft was released and have not found the guidance, with the exceptions brought out in the external peer review, particularly burdensome to use. Specifics of exceptions are addressed in the responses to technical comments made by the peer reviewers in Sections 2 and 3 of this Response to Comments document.

3.1.3 General Issue 3: Scientific Soundness

Evaluate critically the scientific aspects (within your expertise) of the document, including methodologies, exposure factors and scenarios, parameters and defaults, and risk characterization.

Interpretations of scientific conclusions should be based on sound biological principles and accurate and legally defensible scientific support.

Summary of Peer Review Written Comments:
In general, the external peer reviewers agreed that overall, the draft HHRAP represents a comprehensive presentation of methodologies and variables reflecting over a decade of interagency research dedicated to the field of risk assessment of combustor emissions. EPA and EPA Region 6 should be commended for developing an outstanding risk assessment guidance document that is very detailed and comprehensive. The breadth and depth of information presented in this guidance document is unprecedented as a stand-alone EPA risk assessment guidance document. With some key exceptions noted by the peer reviewers, generally dealt with during the external peer review workshop, the methods and assumptions represent a reasonable position based on scientific consensus and available data. Scientific aspects of the exposure-related sections appear to conform to accepted EPA approaches for conducting risk assessments, much of which has also been reviewed and supported by the Science Advisory Board.

EPA Response:
Comment noted.

3.1.4 General Issue 4: Credibility of Results

Give your opinion whether the risk assessment supports not only a credible interpretation of what is known, but also a credible interpretation of the hazard and risk that is predicted.

Summary of Peer Review Written Comments:
The credibility of the interpretations will depend on how the results of the risk assessment are applied. The conservatism of the assumptions and the uncertainties and gaps in the underlying data will generally overstate the risk. Thus, it is important that the results and uncertainties are properly described and characterized. The results of the assessments can only be used as general guides for decision making and should not be viewed as definitive results used as the sole basis for making decisions.

EPA Response:
Comment noted.

3.1.5 General Issue 5: Major Data Gaps and Limitations

As with any risk assessment, there are always additional data and method development efforts that could be undertaken to reduce the level of uncertainty. However, are there any major data or methodological gaps within this guidance specific to the sections reviewed that would preclude using the HHRAP for regulatory decision-making? If so, how should they be addressed?

Summary of Peer Review Written Comments:
In response to this question, the external peer reviewers stated that the seriousness of these methodology and data gaps is a function of the degree of uncertainty that can be tolerated in the final assessment. If the risk assessment is only used as one factor of many in making a decision, the data gaps become less serious.

EPA Response:
Comment noted.

3.1.6 General Issue 6: Long-Term Research

What long-term research would you recommend that could significantly improve risk assessments of this type in the future?

Summary of Peer Review Written Comments:

1) It is important to develop methods to integrate cumulative risk estimates from ambient air and other pathways, to provide a basis for comparing the contributions from various sources and for contrasting the risk levels among different locations with different types of sources. The next important step would be to develop approaches for conducting integrated assessments that consider different types of possible effects; not only human and ecological health risks, but also social, cultural, and economic impacts.

2) Methods for assessing childhood risks need to more directly account for children's unique susceptibilities and sensitivities to specific contaminants and chemical mixtures. In particular, there is a need to improve knowledge regarding the relative importance of exterior dust and soil as lead exposure sources for children in various residential environments.

3) Further evaluate the idea of simply reducing the acceptable risk range and hazard benchmark level as a means to realistically account for background contributions from exposures to a wide range of contaminants.

4) There is a need for chemical mixture-related research, especially with respect to predicting the health effects of the unidentified organic compounds in the total organic emissions fraction. The most relevant research would be toxicity studies of the whole mixture of emitted chemicals from representative facilities.

5) Because of the uncertainty associated with including unspeciated total organic emission data when estimating stack emission rates, research is also needed to evaluate this component of the facility characterization. For example, what is the composition of the gravimetric fraction typically, and how appropriate is the approach for attributing a risk to this unknown portion of emissions?

6) Because of the increasing involvement of stakeholders in the risk assessment and management process, improved approaches are needed for managing environmental risk data and communicating risk-related information. A variety of tools should be utilized and further developed (e.g., World-Wide Web, geographic information systems) to not only disseminate risk results, but also facilitate an exchange of information with various stakeholder groups.

7) There is a need to collect environmental monitoring data for model input parameters that drive the exposure assessment to validate the modeling approach. In particular, fate and transport data are needed to track long-term exposures and health effects from combustion emissions. Large-scale epidemiological studies should be carried out to verify that the health effects results predicted by these risk assessments are valid.

8) To address the substantial uncertainties inherent in mercury risk assessments, EPA's Mercury Research Strategy (U.S. EPA, 1999d, NCEA-I-0710) identified a prioritized list of research needs. This report describes a research program that provides information, methods, models, and data for addressing key scientific questions, which are clearly needed to reduce the uncertainties in the HHRAP approach to estimating mercury exposures and risks.

9) Assess how well the route-to-route extrapolations of slope factors and reference doses actually work and if there are additional parameters that could improve this.

10) The litmus test for any risk assessment is to compare the predicted risks with the actual incidence of health effects. For example, when applying the conventional EPA risk assessment methodology (similar to the HHRAP) to estimate risks for exposure to naturally occurring levels of arsenic in U.S. soils using the 95UCL of the mean background concentration, it is estimated there would be slightly more than 1 million cases of arsenic-induced tumors (lung cancer, hyperplastic keratosis, etc.) every year. Since we obviously do not observe 1 million cases of arsenic-induced cancer from soil in the United States each year, it is apparent the risk assessment model is incorrect. Likewise, a long-term study needs to be initiated at hazardous waste combustion facilities to confirm that the HHRAP model is correctly predicting risk estimates. It would be difficult to conduct epidemiological studies for cancer, but biomarker studies could be used to at least determine whether exposures are actually occurring. It will also be necessary to confirm that the modeled concentrations actually exist in all the environmental media for all the intake sources in the risk assessment. A sensitivity analysis needs to be conducted to confirm that the indirect pathways are truly significant and warrant inclusion in the risk assessment. The sensitivity analysis should not be mathematical, but should be based on actual biological measurements from foodstuffs (e.g., eggs, chickens, meat, milk, etc.)

11) Priorities for long-term research should be based on the toxicity and volume of compounds released from an incinerator. Also, as a long-term goal, there should be continuing reviews of the literature so that new information on persistence, metabolism, and transport can be incorporated in a timely manner. Efforts should also be made to draw inferences concerning metabolism and bioaccumulation in farm animals from the results of research with laboratory animals.

12) There has been an effort in recent years to evaluate polychlorinated biphenyls (PCBs) as individual compounds rather than as Aroclor mixtures, especially for those congeners with dioxin-like activity. Serious consideration should be given to providing individual PCB congener data in Appendix A for those PCBs of greatest toxicological concern.

13) Risk assessments of this type would benefit greatly from the research being performed on fate and exposure of pesticides. In particular, the agricultural literature contains many efforts at quantifying mass balance of pesticides in various media and in adjacent locations following controlled applications. While significant portions of the existing methodology (e.g., the application of the Universal Soil Loss Equation) derive from the agricultural disciplines, much work has been done since the development of these simple algorithms. A major uncertainty and likely bias toward high exposures in the existing methods is the efficiency of constituent runoff (contributed by the parameterization of the sediment delivery ratio, the sediment enrichment ratio, and the extremely high efficiency of runoff from impervious surfaces). This uncertainty could very likely be reduced by a careful review of the current literature on pesticide runoff from croplands. Behavior of pesticides in adjacent, uncultivated areas subject to over-spray should also be a productive topic for further review.

14) The risk assessment methodology should integrate the recent findings and models of mercury fate and transport. Of particular relevance are the ongoing research efforts in south Florida and by the Electric Power Research Institute, both of which are examining the importance of atmospheric loadings, watershed processes, aquatic geochemistry, and the structure of the food chain in the accumulation of mercury in fish tissue. The efficiency of mercury runoff from the watershed to the water body should be evaluated in the context of these studies. These issues are the most likely ones to contribute to uncertainty in assessing risks due to mercury emissions.

EPA Response:
Comments noted. EPA will forward these recommendations to its Office of Research and Development.

3.2 COMBUSTION ENGINEERING [draft HHRAP Chapter 2]

Issues regarding combustion engineering that were addressed by the external peer review panel include:

- Process Upsets;
- Selecting COPCs;
- Unspeciated Total Organic Emissions (TOE);
- 95th Percentile Emission Rates; and
- Quantifying Non-detect Compounds.

3.2.1 Combustion Engineering: Process Upsets

Comments were received regarding guidance presented for considering process upsets in estimating emission rates (draft HHRAP Section 2.2.5). Is additional detail and clarification of guidance specific to this issue required?

Summary of Peer Review Written Comments:
The default CARB upset factors are excessively conservative, and worse than "worst case maximum potential risk." Existing studies indicate a very large discrepancy between the CARB default values and actual field results regarding frequency and duration of upsets. No hazardous waste combustion facility would be allowed to operate in upset conditions for 20% (organics) and 5% (metals) of the time. Also, hazardous waste combustion is prohibited under RCRA during startup and shutdown periods by the automatic waste feed cut off (AWFCO) system. Available technical information indicates that upset emissions are not close to 10-times normal emissions. Upsets occur fairly frequently during trial burn/risk burn (TB/RB) sampling conditions with minor apparent impact on measured concentrations. However, many smaller, simpler facilities have the disadvantage of not having upset duration data or emissions estimates during upset conditions. Thus, per guidance, these less threatening facilities would be required to use the excessively conservative CARB default values. This approach would be very difficult to defend in a court.

EPA Response:
The HHRAP is guidance and will continue to contain no requirements. Historic information has been provided and used routinely to adjust the default-upset factors. However, the HHRAP recommends generating a site-specific upset factor, where possible. As with many parameters and equations provided in the HHRAP, the scientific basis and reference are provided. A facility is then able to evaluate whether to propose and justify to the permitting authority an alternative they consider more appropriate than that recommended in the HHRAP.

3.2.2 Combustion Engineering: Selecting COPCs

Comments were received regarding guidance presented for selection of compounds of potential concern (COPCs) (Section 2.3). Review and comment on the combustion engineering aspects of the COPC selection process presented in the guidance. These aspects would include guidance provided regarding inclusion of (1) compounds initially present in the hazardous waste feed stream and not completely destroyed in the combustion process, (2) compounds that are formed during the combustion process, and (3) compounds in the waste feed stream that should be evaluated as potential products of incomplete combustion (PICs) precursors.

Summary of Peer Review Written Comments: A. Methods of Selecting COPCs
Response to this question considers two methods of selecting COPCs: (1) selection of COPCs using analytical results from test burn/risk burn (TB/RB) on existing facilities, and (2) selection of COPCs for a pre-TB/RB emissions inventory for a new or currently non-operating facility.

(Method 1) Selection of COPCs from Analytical Results from TB/RB on Existing Facilities: This process/procedure is well defined in Section 2.3 of the guidance document. Overall, this is a very reasonable approach. The primary suggestion was to add a discriminator phase to the second step (i.e., Review the waste stream analysis and add as a COPC any compound present in the waste even if that compound is not detected in the stack sample analytical results), with a provision for excluding compounds that may be present in the waste in low concentrations. The relative thermal refractivity of the COPC of interest should also be considered, e.g., Class 1 compounds from the University of Dayton System might use 4-9s DRE. Less refractive compounds, such as nitrobenzene, might use 5-9s DRE.

(Method 2) Selection of COPCs for New or Currently Non-Operating Facilities: In the current draft guidance, essentially nothing is said concerning how the pre-RB/TB emission inventory should be prepared. Estimating the stack concentration of organic constituents fed with the waste is relatively straight-forward using a DRE-type calculation (i.e., Mass Feed Rate of Constituent i x 0.0001 = Mass Emission Rate of constituent i in the stack). However, identifying and estimating COPCs which could be emitted as PICs is much less clear.

The guidance should provide a short procedure that lays out an approach that EPA would accept, without requiring, for example, any nitrogen-containing compound from Table A-1 in the draft HHRAP to be included as a COPC if organic nitrogen is present in the waste. While these types of PICs could be present conceptually, some means of selecting more likely candidates is needed, especially in view of EPA's use of high RDL values to estimate low concentration COPCs.

EPA Response:
With regard to Method 1, the proposed approach may be acceptable on a site-specific basis. However, we don't recommend this approach in the guidance because we believe it's preferable to carry a compound through the risk assessment and allow factors, such as quantity and fate and transport characteristics, to demonstrate quantitatively if the risk falls below levels of concern. Additionally, determining the deminimus concentration of a compound as it applies to potential risk would depend on the toxicity characteristics of the individual compound, as well as site-specific exposure characteristics.

With regard to Method 2, the permitting process for new hazardous waste combustion facilities includes submitting information of sufficient detail for the regulatory authority to evaluate compliance with existing regulations, guidance, and standards of protectiveness. Stack (or other source) locations and dimensions, design flow and emission rate estimates, waste feed characteristics, surrounding building dimension data, facility plot plans, and terrain data are frequently reviewed and used in a pre-operation risk assessment. This will assist in decision-making and designing permit requirements.

We generally recommend reviewing design, emission rates, waste feed characteristics, and other design data, along with supplementary documentation, to make sure they're representative, accurate, and comprehensive. Good engineering practice dictates a check of, and comparison with, data from similar existing units. Stack test reports for facilities of similar technology, design, operation, capacity, auxiliary fuels, waste feed types, and APCSs can be useful to estimate COPC emission rates for new facilities that haven't been constructed. In addition to design data, particle size distribution data from a similar type unit that's operational may be useful. Estimated emission rates used to complete pretrial burn risk

assessments are frequently compared to the measured emission rates from actual trial burns completed after the new facility receives a permit and is constructed.

If surrogate data from similar facilities aren't available, some state environmental agencies enforce emission rate limits based on state laws. Since these limits can't be exceeded, you might use them to develop emission rate estimates for the risk assessment. A trial or risk burn could then demonstrate that facility emissions are less than those considered in the permit and risk assessment.

Summary of Peer Review Written Comments: B. Selecting Specific COPCs
The following comments pertain to the guidance provided on the seven categories of potential COPCs:

PCDD/PCDF and PAHs: The peer reviewer agreed that dioxin/furan sampling and analysis are important and should be included in the first TB/RB/RA for every HWC facility. This comment is based on the assumption that EPA will not insist on detection limits for non-detects that would suggest significant risk even from non-detects. Test every facility at least once. Retest for dioxin/furan at appropriate re-permitting, etc., stages, but only when the first test reveals a credible risk. One reservation to this pertains to COPCs which have driven risk assessments only because they were included at very high RDL concentrations. This comment also applies to the other constituent categories such as PAHs, PCBs, etc.

EPA Response: PCDD/PCDF and PAHs
With regard to PCDD/PCDF, guidance for quantifying dioxin and furan non-detects is consistent with that of other similar compounds. Using RDL's is based on the data quality objective of setting an achievable permit limit.

With regard to PAH's, PCB's, etc., the high risk values at detection limits were the result of conservative biotransfer factors and not the detection limits. With the adoption of the new biotransfer equations in the HHRAP (see discussion below), we don't expect that risks above regulatory levels of concern will result from evaluating compounds at their reliable detection limits.

PCBs: With few exceptions, the peer reviewers agreed with guidance concerning stack testing for PCB. However, the last sentence on Page 2-47 does not appear to agree with the previous discussion, i.e., consider requiring stack testing for PCBs even if the conditions favorable for emitting PCBs do not exist at a given site. Also, "highly chlorinated waste stream" needs some further definition, i.e., >60% Cl. Further, the presence or possible presence of PCBs in the waste should also have a threshold level. The presence or possible presence of PCBs at 100 ppm may not warrant stack testing for PCBs for risk assessment purposes when DRE reductions are considered. It should also be noted that the references to PCB stack gas emissions being equal to or greater than those for dioxins and furans is based solely on mass and not on the toxicity of the PCBs. Further, a review of selected referenced documents indicates that some of the data may be in error. If PCB testing is conducted, it should examine the coplanar PCBs, which are reported to exhibit dioxin-like toxicity. Review of the limited available literature examining the 2,3,7,8-TCDD TEQ contribution due to PCBs suggests that PCBs are insignificant PICs of non-PCB waste streams.

EPA Response: PCBs
With regard to PCBs, comment noted. We've continued reviewing the issue of PCB emissions from combustors, and have revised the HHRAP to include (1) a summary of a study indicating de novo PCB formation based upon Stieglitz et al., 1989, and (2) a summary of a study indicating PCB formation in combustion units to be similar to dioxin and furan formation (Lemieux et al., 1999).

Nitroaromatics, HCB and PCP: The procedure for including these compounds appears to be reasonable, especially if a waste concentration threshold is provided. For instance, 10 ppm nitrobenzene in the waste would be very unlikely to result in increased risk, especially after considering that these compounds must survive a >99.99% DRE combustion process.

Phthalate: The peer reviewer disagreed that the absence of these compounds in the stack "should always be verified by stack testing." Some knowledgeable practitioners in the combustion engineering field believe that detected phthalates in a stack sample are usually the result of laboratory, sampling, or sample transport extraction from plastics used or from cross-contamination from the background. These possible false positives can be risk drivers in the risk assessment process. The same concept of a threshold concentration in the waste should also apply here. Even if a facility burns plastics, phthalates are generally used in low concentrations and the phthalates present must survive a >>99.99% DRE process (for phthalates, the '>>' symbol is added due to their combustible nature) to reach the stack.

VOCs: This section is weak overall, but may be the best possible at this time. The substantial database available to EPA should be mined to provide a more focused view of VOCs as a risk driver in risk assessments. Results of current risk assessments have generally shown that VOCs are not risk drivers.

EPA Response: Nitroaromatics, HCB and PCP; Phthalate; and VOCs
With regard to Nitroaromatics, HCB and PCP, and VOCs, comments noted. With regard to Phthalates, the high-risk values at detection limits were the result of conservative biotransfer factors. With the adoption of the new biotransfer equations in the HHRAP (see discussion below), we do not expect that risk above regulatory levels of concern will result from evaluating compounds at low levels.

3.2.3 Combustion Engineering: Unspeciated Total Organic Emissions (TOE)

Comments have been received by the EPA regarding the guidance presented for inclusion of the "unknown" or unspeciated Total Organic Emission (TOE) data when estimating stack emission rates (Section 2.2.1.3). Considering the technical complexity of the TOE issue, is guidance on quantifying unspeciated TOE data for use in the risk assessment adequate and presented clearly? Provide comments as to whether the guidance on assigning toxicity values to the "unknown" or TOE portion of the emissions is adequate and scientifically sound.

Peer Review Workshop Synopsis
The external peer reviewer panel reached a consensus. The peer reviewers believed that EPA should evaluate the TOE issue qualitatively in the Uncertainty Chapter of the draft HHRAP and that it would still

be conservative. In addition, development of new analytical methods is needed to get better numbers for doing a risk assessment.

The peer reviewers recommended that an approach be taken to better characterize the unknown mixtures.

They also recommended that guidance should focus on looking more closely at the unspeciated fraction, rather than saying that the risks here are unacceptable.

EPA Response:
The HHRAP states that organic compounds that cannot be identified by laboratory analysis cannot be defensibly treated as COPC's in the risk calculations. However, these compounds might still contribute significantly to the overall risk, and so it is reasonable to consider them qualitatively in the risk assessment. The HHRAP recommends using the TOE factor in the uncertainty section of the risk assessment report to evaluate the risks from the unknown fraction of organics. Both regulated industry and U.S. EPA have expressed some concern that the gravimetric fraction may over-report the organic fraction. It has been suggested that the gravimetric fraction may consist of organic and/or inorganic mass not directly attributable to organic incinerator emissions. The U.S. EPA Office of Research and Development (ORD) National Risk Management Research Laboratory (NRMRL) recently conducted a series of experiments to investigate this issue. The results indicate that it is indeed possible for inorganic mass to become soluble and ultimately be retained in the TOE train methylene chloride extract. More importantly, the ORD/NRMRL research identified and demonstrated techniques for successfully mitigating this problem. Characterization of unknown mixtures is an ongoing area of research at EPA and as new methodologies are developed it seems appropriate to incorporate them into the risk assessment. Although the HHRAP states that the permitting authority might not request analysis of the organic compounds with all possible analytical methods, it also says one may wish to consider the effects that gaps in compound-specific identification may have on the computation of the TOE factor. We agree that the better the upfront characterization of emissions is, the better the risk characterization will be and the less of an impact the TOE analysis will have.

3.2.4 Combustion Engineering: 95th Percentile Emission Rate

Comments have been received by the EPA concerning the definition of the 95th percentile emission rate in the risk assessment (Section 2.2). Provide comments as to whether the guidance on quantifying emission rates of compounds for use in the risk assessment is adequate and scientifically sound. Should the guidance specify use of the 95th percentile or the 95th upper confidence limit (UCL) of the mean?

Peer Review Workshop Synopsis
The external peer review panel appeared to be in agreement about the use of the mean or max instead of the 95th UCL, but did not reach consensus about using the 95th percentile for quantifying compound ~~of~~ emission rates. This was primarily due to the limited number of proposed data sets found in the guidance document.

EPA Response
We've altered the HHRAP to recommend that, for the chronic portion of the risk assessment; you have the option of using either the long-term average or maximum emission rates. The emission rates are to be adjusted for process upsets and represent long-term averages. Long-term average emission rates are typically based on tests of the combustor burning representative, yet worst-case or challenging feeds, at operating conditions that are representative of normal operating conditions over a long-term period. This is an update to Section 8.1.2 of the Risk Burn Guidance for Hazardous Waste Combustion Facilities. For the acute portion of the risk assessment, we generally recommend using the maximum emission rates, adjusted for process upsets.

3.2.5 Combustion Engineering: Quantifying Non-detect Compounds

Comments were received regarding guidance presented for quantifying non-detect compounds when estimating stack emissions rates (Section 2.4). Is the guidance on quantifying non-detect compounds for use in risk assessment adequate and scientifically sound? Provide comments on the recommendations of detection limit related issues: (1) can instrument detection limit (IDL) be substituted for the method detection limit (MDL) in determining the Reliable Detection Level (RDL) for metals, (2) can sample condensates be combined to lower detection limits without affecting the quality assurance and control of the data generated from analysis, and (3) how should J-flagged or qualified data be used if it's below the calculated RDL?

Peer Review Workshop Synopsis
The external peer review panel recommended using one-half of the MDL for organic non-detect compounds. The panel did not support the use of the RDLs and SQLs in the risk assessment. They were willing to support the use of RDLs if the compound was a "risk driver" in the risk assessment. For metals analysis, they felt that the IDL was appropriate in determining the RDLs for metals.

The peer reviewers agreed that the use of non-detects should be discussed additionally in the Uncertainty chapter of the HHRAP. If a non-detect indicates a risk, it should be discussed in the uncertainty section of the risk assessment report. If the use of an RDL shows a risk, the risk assessor should rerun the risk assessment with the MDL or one-half of the MDL and explain this in the uncertainty section of the report. It was also recommended that the risk assessment report should not discuss the risk associated with non-detect compounds until the uncertainty section.

A recommendation was made that EPA should inform the public more about the use of RDLs. It was believed that the public does not understand the concept. Additional communication regarding RDLs with a larger group of the regulated community could make a tremendous difference in the understanding of and resistance to RDLs, rather than thinking EPA is wrong in their use.

Parts #2 and #3 of this major issue question were not discussed by the external peer reviewers during the workshop.

EPA Response:
The HHRAP will continue to recommend using RDLs in the risk assessment based on the data quality objectives of the assessment. Although we agree that using one-half the MDL for organic non-detected compounds would result in a more accurate calculation of risk, one purpose of the risk assessment is to determine an acceptable permit limit. Since facilities would not be able to meet permit limits set at one-half the MDL, we recommend evaluating the RDL in the risk assessment.

We've modified the HHRAP to recommend using the Instrument Detection Limits (IDLs,) rather than Reliable Detection Level (RDL) for metals (see Section 2.4.2, Use in the Risk Assessment of Data Reported As Non-Detect). We've added this recommendation because the peer review draft HHRAP did not specifically address quantification of non-detects for metals.

3.3 AIR DISPERSION AND DEPOSITION MODELING (draft HHRAP Chapter 3)

Issues regarding air dispersion and deposition modeling that were addressed by the external peer review panel include:

- Modeling Vapor Phase, Particle Phase, and Particle-Bound Phase Emissions;
- Estimating Fugitive Emissions and Acute Exposure;
- Particle and Vapor Phase Emission Partitioning;
- Air Modeling Input Default Values;
- Dry Vapor Phase Deposition Modeling; and
- Particle Size Distribution.

3.3.1 Air Dispersion and Deposition Modeling: Modeling Vapor Phase, Particle Phase, and Particle-Bound Phase Emissions

Comments were received on guidance presented for conducting separate modeling runs for evaluating vapor phase, particle phase (mass weighting), and particle-bound phase (surface area weighting) emissions (Sections 3.4 and 3.9.3). Review and comment on guidance presented for modeling vapor, particle, and particle-bound phases. Does conducting separate modeling runs for each emissions phase noted above provide better resolution of air parameter inputs for use in the risk assessment? Also, review and comment on the scientific validity regarding use of the fraction in vapor (Fv) for partitioning emissions between particle and vapor phases.

Summary of Peer Review Written Comments:
The issue is not whether separate model runs are required. Rather, the issue would appear to be whether it is important to distinguish among the atmospheric concentration of each of the three phases. In terms of indirect exposure through deposition and uptake, as well as direct exposure through inhalation, it is important to distinguish between the vapor and particle phases for COPCs. With reference to direct exposure, it is important to apportion airborne particle concentrations according to particle size and number. There is an in-house version of ISC called HWIR that provides outputs of airborne

concentrations and surface deposition by particle size, which can be used with some difficulty to apportion airborne concentrations and surface depositions according to phase, particle size, and source, although this requires each phase and particle size(s) to be treated as a separate source group in the ISC model. OAQPS has indicated a willingness to consider making more widely available the HWIR version of the code.

EPA Response:
Comment noted. The HHRAP has been updated to include the latest version of ISCST3.

3.3.2 Air Dispersion and Deposition Modeling: Air Dispersion Modeling Charge: Estimating Fugitive Emissions and Acute Exposure

Comments were received regarding guidance and examples provided for air dispersion modeling and estimating of fugitive emissions (Sections 2.2.6 and 3.10) and acute exposures. Review and comment on guidance presented for air modeling of fugitive emissions and emissions used to evaluate acute exposure. Will conducting air dispersion modeling of fugitive emissions add unwarranted complexity to the risk assessment due to the setup and air model runs required considering the usefulness of information obtained in estimating potential risks? For facilities permitted under RCRA Subpart AA, BB, and CC that have already met requirements for monitoring and evaluating fugitive emissions, is it reasonable to assume that volatile emissions from these sources would be released in quantities that would result in an off-site impact?

Summary of Peer Review Written Comments:
The draft HHRAP does not focus on truly acute events, except to incorporate their emissions into "long-term average emission rates adjusted for upsets … or reasonable maximum emission rates measured during trial burn conditions." The ISCST3 dispersion model has the ability to deal with certain types of events that yield acute exposure, particularly those where the emissions can be appropriately characterized by hourly averages. However, for true acute risk assessment, a non-steady state dispersion model (e.g., ALPUFF) may provide a more representative estimate of concentration and deposition given this model's ability to treat time-varying emissions and time-and space-varying meteorological fields.

The peer reviewer did not view assessing risks from fugitive emissions as necessarily complex or unwarranted. Given the nature of the risk assessment process and the goal of providing the public with objective information, this analysis is reasonable and appropriate. The need to model fugitive emissions can best be addressed through consideration of the sensitivity of the risk to these emissions and their associated uncertainties.

EPA Response:
We recommend using the latest version of the ISCST3 model in most situations to conduct air dispersion and deposition modeling for conducting a risk assessment (see introduction of Chapter 3, Air Dispersion and Deposition Modeling). Review of this issue by the External Peer Review Panel concluded that the latest version of ISCST3 is the appropriate air model to support conducting a risk assessment. We agree that the ISCST3 is only useful to deal with certain types of acute exposure events appropriately

characterized by hourly averages. Additional modeling of acute emissions may be warranted in site-specific situations.

3.3.3 Air Dispersion and Deposition Modeling: Particle and Vapor Phase Emission Partitioning

Comment on the scientific validity regarding use of the fraction in vapor (Fv) for partitioning emissions between particle and vapor phases.

Summary of Peer Review Written Comments:
If the fraction in vapor, Fv, can be reasonably well described or defined, then it is appropriate to use this parameter to partition emissions between particle and vapor phases. The challenge is to define a representative fraction through measurements in the hot plume environment where this fraction is likely to undergo significant change.

EPA Response:
Comment noted. We agree that the Fv would be difficult to determine in a hot plume. However, the HHRAP assumes the plumes will equilibrate to ambient conditions and portions of semi-volatiles will adhere to the surface area of particles and the remaining portions will remain in the vapor state. Fv values in the HHRAP are based on a compounds fraction of vapor at ambient conditions (25 degrees C).

3.3.4 Air Dispersion and Deposition Modeling: Air Modeling Input Default Values

Comment on default values provided in the guidance air modeling inputs.

Summary of Peer Review Written Comments:
It was assumed the question pertains to the appropriateness of the default values contained in Tables 3-1 through 3-4.

Table 3-1 provides generalized particle-size distribution data. The default size distribution intended for use at facilities with electrostatic precipitators or bag houses appears appropriate in a generic sense for the finer sizes. However, the larger (15 micron) particles may be too heavily represented since they are typically effectively captured by particle control systems. EPA was urged to provide clear guidance regarding where and when either the default size distribution or a source-specific distribution is allowable.

Table 3-2 provides representative values of the albedo for different surface types during each of the four seasons. As default values, they are appropriate.

Table 3-3 provides representative seasonal values of the daytime Bowen ratio. This is a difficult parameter to estimate without site-specific precipitation and wind data. Using site-specific data wherever possible was recommended. Note also that Bowen ratio is incorrectly defined on page 3-35. It is the ratio of the sensible heat flux to the evaporative or latent heat flux at the ground surface.

Table 3-4 estimates default values of the anthropogenic heat flux for different types of urban areas. These are appropriate for use as default values. There are more recent summary papers that might be referenced here as well, e.g., the work of Klysik et al. (1999).

EPA Response:
We've modified the title of Table 3-1 and the HHRAP text to clarify the role of Table 3-1 as hypothetical data, and to recommend that the data in Table 3-1 ***not*** *be used as a default particle size distribution when modeling site-specific emissions. We've also corrected the definition of Bowen ratio as recommended.*

3.3.5 Air Dispersion and Deposition Modeling: Dry Vapor Phase Deposition Modeling

Comments have been received regarding recommendations on (dry) vapor phase deposition modeling (draft HHRAP Sections 3.1.1 and 3.5.1.7; and 5.7.1.2).

- Is the guidance provided for estimating (dry) vapor phase deposition technically valid as applied?
- Review and comment on the scientific validity regarding the assumption that wet deposition and precipitation rates are linear.
- Are the equations to estimate dry deposition of vapors (L_{dif}) to water bodies technically valid or do they incorrectly consider only one-way transfer of pollutants from the air to the water body?

Peer Review Workshop Synopsis

1) The peer reviewers agreed the draft HHRAP guidance is not technically valid because it's out of date. Specifically, at the time the Peer Review Draft HHRAP was written, there were unresolved issues among experts about modeling dry deposition. Therefore, U.S. EPA decided to use a calculated or literature value estimate of deposition velocity for vapor transport to the ground. One issue with this approach is that the balance of mass is not maintained because the deposited mass is not taken into account in the air concentration modeling.

2) The peer reviewers recommended using the more updated 1999 ISCST3 model. The dry vapor deposition velocity can be inputted directly into this version of ISCST3, rather than incorporating it into the Appendix B estimating media concentration equations (see Section 3.1.1, History of HHRAP Air Dispersion Models). The peer reviewers concluded that including the dry vapor deposition velocity directly into the ISCST3 modeling provides a better representation of conservation of mass because the revised model accounts for the mass depletion due to deposition. The peer reviewers commented that the value of 3-cm/sec-deposition velocity used in the draft HHRAP to represent every compound is unrealistically conservative. Based on their experience and review of the literature, measured values are generally much lower than 3 cm/sec.

3) In theory, wet deposition and precipitation rates are believed to not be linearly proportional. However, the peer reviewers concluded that in practice, it is appropriate for risk assessment applications to use empirical relationships that relate wet deposition to precipitation rate in a linear fashion. The peer reviewers concluded that it is necessary to default to this practical assumption

because the hydrometeor and in-cloud scavenging process parameters are very difficult to measure and model.

4) The peer reviewers believe the 2-way transfer of pollutants between air and water bodies should be considered. However, the peer reviewers believe this is not a first-order problem, considering the other uncertainties in the whole risk assessment process.

EPA Response:

*1) We've modified the HHRAP to recommend inputting the dry vapor deposition velocity directly into the latest version of the ISCST3 model, rather than incorporating it into the Appendix B estimating media concentration equations (see Section 3.1.1, History of HHRAP Air Dispersion Models). This change also requires that the product term of the dry deposition velocity and unitized yearly average air concentration from vapor phase (Vdv * Cyv) be replaced with the ISCST3 air parameter value for dry vapor deposition.*

It is important to note that although we recommend inputting the dry vapor deposition velocity directly into the ISCST3 modeling, the user still has the option to execute the dry gas deposition algorithms within ISCST3 to calculate a deposition velocity. However, the user is cautioned to read Section 3.1.2 (Preprocessing Programs) and Section 3.4.6 (Solar Radiation), which note additional data needs, and potential limitations. Executing the dry gas deposition algorithms within ISCST3 to calculate a deposition velocity may also require the user to conduct compound-specific air modeling runs and deviate from the unit emission rate approach as outlined in the HHRAP.

The HHRAP provides alternative default dry deposition of vapor velocities. We've revised both the ksv and dry deposition of vapor velocity sections of the HHRAP. As advances are made in air modeling, one should always take into account the most recent state-of-the-science. The modeling reported in the Mercury Study Report to Congress (U.S. EPA, 1997b) used a value of 0.3 cm/s for nighttime dry deposition of divalent mercury, but used daytime values ranging from 0.20 to 4.83 cm/s depending upon atmospheric stability and land-use category. The daytime values were based on data developed from nitric acid data, not from measurements of divalent mercury. U.S. EPA (1997b) used an average ISC model-calculated dry deposition velocity of 2.9 cm/s for divalent mercury vapor and 0.06 cm/s for elemental mercury. Higher values were expected for chemicals with greater reactivity than acetic acid or formic acid, but no measured values were identified for any organic compounds higher than 1.1 cm/s. As a result, we recommend the default of 2.9 for divalent mercury. We recommend a dry vapor deposition velocity of 0.5 centimeter per second (cm/s) for organic contaminants, chlorine, and HCl. The recommended dry vapor deposition velocity value of 0.5 cm/s for organic contaminants is consistent with the range specified for pesticides (0.01 - 1.1 cm/s) and dioxins and furans (0.27 - 0.78 cm/s).

2) We acknowledge the practicality of assuming linearity between wet deposition and precipitation rates while recognizing that in theory, they are not linearly proportional.

3) Assuming that volatile chemicals are trapped in the waterbody encourages conservative estimates of drinking water and fish concentrations. If this tended to result in risk/hazard levels above the benchmark, a more detailed site-specific fate and transport analysis could be conducted. However, we're unaware of any case where this has actually occurred. As with many parameters and equations provided in the HHRAP, the scientific basis and reference is provided. A facility is then able to evaluate whether 2-way transfer of pollutants between air and water bodies is sufficiently important to risk assessment outcomes to recommend and justify to the permitting authority a site-specific method, or other alternative to that recommended in the protocol.

3.3.6 Air Dispersion and Deposition Modeling: Particle Size Distributions

Comments have been received by EPA regarding guidance on determination of stack-specific particle size distributions recommended for use in the air dispersion modeling (Section 3.4). Provide comments as to whether inclusion of stack-specific particle size distributions are warranted, or could general or default distributions be applied without inducing additional uncertainty in the risk assessment?

Peer Review Workshop Synopsis
The external peer review panel recommended that the HHRAP use four or five sets of data as a categorical set of default choices, which would be better than using the single default distribution. Data profiles should be obtained for the different categories among waste incinerators, boilers, liquid or solid waste fuel incinerators, etc. If these data profiles are not available, particulate size distributions (PSDs) need to be divided into different categories for evaluation. However, stack specific analysis may still be required for some facilities.

EPA Response:
We included the generalized particle size distribution in Table 3-1 in the HHRAP to document example calculations. We've modified the title of Table 3-1 and the HHRAP text to clarify the role of Table 3-1 as hypothetical data, and to recommend that the data in Table 3-1 ***not*** *be used as a default particle size distribution when modeling site-specific emissions.*

3.4 EXPOSURE ASSESSMENT [draft HHRAP Chapter 4 & 6, Appendix C]

Issues regarding exposure assessment that were addressed by the external peer review panel include:

- Acute Inhalation Exposure Criteria (AIEC) Values and Evaluating Acute Toxicity;
- Route-to-Route Extrapolation;
- Atmospheric Degradation of Contaminants;
- Exposure Scenario Locations;
- Non-Carcinogenic Risk of Dioxins Benchmark;
- Using TEFs for Coplaner PCBs;
- Dioxins in Breast Milk; and

- Inhalation Rate Value.

3.4.1 Exposure Assessment: Acute Inhalation Exposure Criteria (AIEC) Values and Evaluating Acute Toxicity

Comments were received regarding guidance presented for evaluation of acute toxicity and the Acute Inhalation Exposure Criteria (AIEC) values presented in the draft HHRAP (Appendix A-4). Review and comment on issues pertaining to evaluating acute toxicity and recommended AIEC values, specifically (1) should AIEC values presented in Appendix A-4 be removed to prevent use of potentially out-of-date values, (2) should AIEC values be updated to include values provided in California Office of Environmental Health Hazard Assessments (OEHHA) 1998 revised draft, (3) should a more complete description of the effects of concern when evaluating acute risks be provided, and (4) are OEHHA's Reference Exposure Levels (REL) comparable to other AIECs. Comment on the hierarchy of AIEC values recommended in the guidance, including the use of Acute Exposure Guideline Levels (AEGL) at the top of the hierarchy. [1]

Summary of Peer Review Written Comments:
The purpose of the acute exposure scenario is the important factor in determining which values are the most appropriate, and it was recommended that the draft HHRAP sections dealing with the acute exposure scenario be revised to clearly specify the purpose of the scenario. If the goal of the acute exposure scenario is to estimate the risks from upset conditions, it was recommended that the draft HHRAP be revised after reconsidering how to best accomplish that goal. It would be useful if EPA created and maintained a web page with links to web pages with the current values, and referred to that web page in the HHRAP. Links to support documents would also be good.

[1] The AEGLs characterized as "short-term threshold or ceiling exposure values intended for the protection of the general public, including susceptible or sensitive individuals, but not hypersusceptible or hypersensitive individuals." The AEGL-1 value is "the airborne concentration (expressed as parts per millions (ppm) or milligrams/cubic meter of a substance at or above which it is predicted that the general population, including ``susceptible'' but excluding ``hypersusceptible'' individuals, could experience notable discomfort. Airborne concentrations below AEGL-1 represent exposure levels that could produce mild odor, taste, or other sensory irritations." AEGL values are given for specific durations of exposure (0.5, 1, 4 and 8 hr). The HHRAP assumes a 1-hr exposure duration, so the 1-hr values would be appropriate.

The Relative Exposure Levels (REL) values were established by California Office of Environmental Health Hazard Assessments 1998 draft. RELs are defined as "The concentration level at or below which no adverse health effects are anticipated for a specified exposure duration is termed the reference exposure level (REL). RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact." RELs are based on 1 hr exposure.

Emergency Response Planning Guides (ERPGs) have been developed by the American Industrial Hygiene Association. Unlike the RELs and AEGLs, the ERPGs do not include safety factors and they are designed to predict response (and therefore plan appropriate emergency responses), not protect health. ERPG-1 is defined as "the maximum concentration in air below which it is believed nearly all individuals could be exposed for up to one hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined objectionable odor." ERPGs are based on a 1 hr exposure. Temporary Emergency Exposure Limit (TEEL) values are estimated from existing data, such as toxicity and lethality data and occupational exposure limit values and are meant to serve as substitutes for ERPGs until ERPGs are developed. TEELs are developed by the Department of Energy.

The order in which the different guidelines should be consulted is a difficult question, particularly without knowing the objective of the acute risk scenario. Assuming the acute exposure scenario is to consider the immediate effects of the emissions that occur on a routine basis, the REL values seem most suited to the purpose and would take precedence over ERPG-1 values. The ERPGs are geared towards accidental releases, not releases that occur from predictable operations, which for a hazardous waste incinerator are upset conditions such as start-up, shut-down, and other upsets as described in the draft HHRAP. In contrast, the REL values consider the effects to the population from non-emergency routine releases.

To address the question of comparability of the RELs to other AIECs, the values for a variety of compounds from the various guidelines were compared. The characterization of the AEGL-1 and REL values for some compounds suggest that they would result in similar values. Other comparisons show that with the exceptions of vinyl chloride and acrylic acid, the REL values are more conservative than are the ERPG-1/TEEL-1 values, and often considerably so.

The California OEHHA comments that the REL values are designed for preparation of risk assessments for non-emergency routine releases and that the AEGL values are for emergency planning purposes. The approach taken in determining the REL focuses on the most sensitive effect. Both use similar techniques to adjust for time of exposure. The ERPG-1 value allows an individual to experience transient, mild adverse effects. Thus, it is not intended to be as protective as the REL. The TEEL-1 values are extrapolated from other toxicity values and incorporate simplifying assumptions. Nonetheless, excluding an outlier in each sub-group (vinyl chloride in the TEEL-1 group and chloroform in the ERPG-1 group), TEEL-1 and ERPG-1 each predicted the REL similarly (the ratio of REL to TEEL-1 or ERPG-1 was 15% for TEEL-1 vs. 11% for ERPG-1; 12% for the two combined).

The acute toxicity risk assessment is done using a hazard quotient. For that, effects are summed for a particular response. To do that, the risk assessor must know to what response each guidance value applies. This is clearly specified for the AEGL-1 and the REL values, but not for the TEEL-1 values. To be able to use the TEEL-1 values, the effects of concern would need to be provided.

EPA Response:
EPA has created a database to maintain current values of toxicity and fate and transport parameters. After reviewing the existing hierarchical approaches, we now recommend the following approach. Because of the daily operations of most combustion units and the potential for upset conditions to sometimes occur during operations, we consider acute values that address intermittent exposures more appropriate and more protective than values that are based on the assumption that acute exposures will be one-time only. We recommend using values from all of the sources that are based on one-hour exposures:

1. Cal/EPA Acute RELs *- the concentration in air at or below which no adverse health effects are anticipated in the general population, including sensitive individuals, for a specified exposure period (On-Line Address – http://www.oehha.ca.gov/air/pdf/acuterel.pdf)*

2. Acute inhalation exposure guidelines (AEGL-1) *- "the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience*

notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure."
(On-Line Address – http://www.epa.gov/oppt/aegl/chemlist.htm)

3. Level 1 emergency planning guidelines (ERPG-1) *- "the maximum concentration in air below which it is believed nearly all individuals could be exposed for up to one hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined objectionable odor."*
(On-Line Address – http://www.bnl.gov/scapa/scapawl.htm)

4. Temporary emergency exposure limits (TEEL-1) *- "the maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing other than mild transient adverse health effects or perceiving a clearly defined odor."*
(On-Line Address – http://tis-hq.eh.doe.gov/web/Chem_Safety/teel.html)

5. AEGL-2 values *- "the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape." AEGL-2 values are to be used only if lower ERPG-1 or TEEL-1 values are not available. (On-Line Address – http://www.epa.gov/oppt/aegl/chemlist.htm)*

The hierarchy is presented in order of preference, from 1 (most preferred) to 5 (least preferred). The HHRAP now recommends using the Acute Reference Exposure Levels (Acute RELs, developed by Cal/EPA) as the first choice for acute inhalation values. If no acute REL value is available for a given COPC, you can work down the list in order. If no AEGL-1 value is available, but an AEGL-2 value is available, select the AEGL-2 only if it is a more protective value (lower in concentration) than an ERPG-1, or a TEEL-1 value if either of these values is available. If no acute values are available for a COPC, an acute value can be developed following the toxicity-based approach used by SCAPA (Tier 5).

3.4.2 Exposure Assessment: Route-to-Route Extrapolations

Comments have been received regarding assumptions governing determination of route-to-route extrapolations of toxicity benchmarks presented in the draft HHRAP (Appendix A-3). Provide comments as to whether route-to-route extrapolation is appropriate and conservative in determining benchmark values for use in an initial screen of potential toxicity of compounds for which peer reviewed toxicity benchmarks are not available.

Peer Review Workshop Synopsis
The external peer review panel encouraged EPA to employ route-to-route extrapolations for toxicity during the first run of the risk assessment. If a chemical develops a significant risk during the first run, the risk assessor should review the defensibility of the extrapolation for the "risk drivers."
Peer reviewers noted that route-to-route extrapolations did not consistently underestimate or overestimate toxicity. They suggested that it may be necessary during the risk assessment process to examine the extrapolations to see if they indicate that something in the analysis should have been done differently.

The peer review panel also recommended that TELs could be used as additional guidance for chemicals for which there is not a reference dose or reference concentration. TELs could help the risk assessor in selecting the appropriate values and risk drivers.

EPA Response:
Comment noted. EPA will continue to use route-to-route extrapolations as a screening methodology.

3.4.3 Exposure Assessment: Atmospheric Degradation of Contaminants

Comments were received regarding the guidance on assessing contaminant losses due to atmospheric degradation. Should atmospheric degradation be incorporated, and if so, which documented methodologies and associated parameter values should be included in the guidance for implementation? Would changes to the guidance for air dispersion modeling be required?

Peer Review Workshop Synopsis
The peer review panel agreed that degradation does occur in the atmosphere and that, in theory, it should be in the HHRAP. However, there are no models currently available to calculate atmospheric degradation sufficiently.

EPA Response:
Comment noted.

3.4.4 Exposure Assessment: Exposure Scenario Locations

Comments were received on guidance provided for selection of exposure scenario locations (Section 4.3.). Provide your comments to this subject.

Peer Review Workshop Synopsis
The external peer review panel agreed that the term subsistence needs to be better defined in the HHRAP. They agreed that the HHRAP needs to have flexibility built into the subsistence exposure scenario, and the default values for the subsistence exposure scenario need to be reevaluated.

EPA Response:
We've deleted the descriptive "subsistence" from the recommended exposure scenarios (see Section 4.2, Recommended Exposure Scenarios, and Appendix B). Review of this issue during the external peer review concluded that the subsistence terminology isn't consistent with the actual mass per day amounts of ingested food items evaluated in the recommended exposure pathways.

3.4.5 Exposure Assessment: Non-Carcinogenic Risk of Dioxins Benchmark

Comments were received concerning the recommendation to evaluate non-carcinogenic risk of dioxins by comparing exposures to national average background exposure levels, using 1 pg/kg/day for adults (Section 2.3.1.2). Is the recommended benchmark appropriate for evaluating non-carcinogenic risk of dioxins for adults?

Peer Review Workshop Synopsis
The external peer review panel basically agreed that it is reasonable to use 1 pg/kg/day, with the caveat that there may actually be health effects at this level.

EPA Response:
Comment Noted

3.4.6 Exposure Assessment: Using TEFs for Coplaner PCBs

Comments were received regarding the recommendation to evaluate coplaner polychlorinated bi-phenyls (PCBs) congeners in the risk assessment using dioxin toxicity equivalency factors (TEFs) (Section 2.3.3). Is the guidance for evaluating coplaner PCB congeners in the risk assessment using TEFs scientifically valid? Also comment on the technical validity of the recommendation to use toxicity benchmarks for Arochlor 1254 and Arochlor 1016 for evaluating other PCB congeners.

Peer Review Workshop Synopsis
The external peer review panel agreed that evaluating coplanar PCB congeners in the risk assessment using dioxin TEFs is appropriate and reasonable. They also agreed that using Aroclor 1254 and Aroclor 1016 is a reasonable estimation, depending on the congener composition of actual emissions.

EPA Response:
We've modified the HHRAP to recommend using the World Health Organization (WHO) toxicity equivalency factors (TEF) for dioxin and furan congeners. TEF values for the 17 congeners are listed in the following table.

Dioxin Congener	TEF (unitless)	Furan Congener	TEF (unitless)
2,3,7,8-Tetrachlorodibenzo(p)dioxin	1	2,3,7,8-Tetrachlorodibenzofuran	0.1
1,2,3,7,8-Pentachlorodibenzo(p)dioxin	1	1,2,3,7,8-Pentachlorodibenzofuran	0.05
1,2,3,4,7,8-Hexachlorodibenzo(p)dioxin	0.1	2,3,4,7,8-Pentachlorodibenzofuran	0.5
1,2,3,6,7,8-Hexachlorodibenzo(p)dioxin	0.1	1,2,3,4,7,8-Hexachlorodibenzofuran	0.1
1,2,3,7,8,9-Hexachlorodibenzo(p)dioxin	0.1	1,2,3,6,7,8-Hexachlorodibenzofuran	0.1
1,2,3,4,6,7,8-Heptachlorodibenzo(p)dioxin	0.01	1,2,3,7,8,9-Hexchlorodibenzofuran	0.1
1,2,3,4,6,7,8,9-Octachlorodibenzo(p)dioxin	0.0001	2,3,4,6,7,8-Hexachlorodibenzofuran	0.1
		1,2,3,4,6,7,8-Heptachlorodibenzofuran	0.01
		1,2,3,4,7,8,9-Heptachlorodibenzofuran	0.01
		1,2,3,4,6,7,8,9-Octachlorodibenzofuran	0.0001

Source: WHO. 1997. Meeting on the Derivation of Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs, and Other Dioxin-like Compounds for Humans and Wildlife. Institute of Environmental Medicine, Karolinska Institute. Stockholm, Sweden. June 15-18. Draft Report, July 30, 1997.

Van den Berg et al. 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and Wildlife. Environmental Health Perspectives, Volume 106, Number 12:775-792.

3.4.7 Exposure Assessment: Dioxins in Breast Milk

Comment on the guidance for addressing the non-cancer effects from dioxins and furans (Section 2.3.1.2). Is the default value for breast milk fat intake for the breast milk pathway appropriately set, or are there new data available to suggest that different value may be more appropriate? Is there enough scientific evidence to show that depletions in the concentration of dioxin in breast milk over the first year of nursing should be accounted for in this pathway?

Peer Review Workshop Synopsis

The external peer review panel stated that there may be enough literature to account for the depletion of 30-50 percent of dioxin over the first year, and they felt that EPA should look at the relevant studies in relation to this topic. It was not clear to the panel that the cited research was referenced in the draft HHRAP.

EPA Response:
EPA's review of the data did not indicate there was enough data in the literature to derive a factor to account for dioxin concentration depletion in breast milk, nor was any provided by the peer review panel.

3.4.8 Exposure Assessment: Inhalation Rate Value

The EPA would like to solicit comments from the panel on their attempts to incorporate the most current risk assessment guidance. For instance, an inhalation rate of 15 cubic meters per day ("Exposure Factor Handbook" (U.S. EPA 1997c)) has been proposed, as opposed to the 20 cubic meters per day used by the Superfund Program. Does the panel have any recommendations about the necessity for this document in applicability of the values?

Peer Review Workshop Synopsis
The external peer review panel did not reach a consensus on the use of a particular inhalation rate, but they did agree that 20 cubic meters of air was generally too high to be representative of a daily average adult inhalation rate. Some of the peer reviewers recommended using RFCs rather than converting air concentrations into a dose of milligrams per kilogram per day. Peer reviewers also generally agreed that using inhalation rates should be guided by the type of risk (chronic and carcinogenic elements) and the most appropriate inhalation rate for long-term exposure.

EPA Response:
We've modified the HHRAP to recommend using RfC's rather than converting air concentrations into a dose of milligrams per kilogram day.

3.5 ENVIRONMENTAL FATE AND TRANSPORT [draft HHRAP Chapter 5, Appendices A&B]

Issues regarding exposure assessment that were addressed by the external peer review panel include:

- Water Ingestion by Cows;
- Speciating and Modeling Mercury;
- Biotransfer (Ba) Values;
- Organic Compound Conservation of Mass;
- Losses to Soil due to Erosion; and
- Acute Benchmarks Based on Mild Adverse Health Effects.

3.5.1 Environmental Fate and Transport: Water Ingestion by Cows Pathway

Comments were received regarding not including the water ingestion by cows as a potential COPC uptake mechanism (Sections 4.2 and 5.4). Should ingestion of contaminated water by cows be included in the

calculation of exposure concentrations in beef and milk? If ingestion of contaminated water by cows is included as a pathway, will adjustments to the recommended Ba_{beef} and Ba_{milk} values be required?

Summary of Peer Review Written Comments:
Assuming the same source of water, direct exposures of human receptors to contaminants in drinking water is likely to be a more significant pathway than secondary exposures from meat and milk. Because the draft HHRAP focuses on the most significant exposure pathways, it is probably not necessary to account for the ingestion of contaminated water by cows unless pasture grasses are also irrigated with contaminated groundwater from shallow wells or surface water. Exposure pathways involving groundwater are not generally evaluated for combustion units, unless site-specific conditions dictate otherwise (e.g., infiltration of COPCs into very shallow aquifers). The water component of oral ingestion is not an important consideration for hydrophobic compounds like PCDD/Fs and PCBs because the low solubility of these compounds limits the potential intake. Compounds with lower log K_{ow} values might be present in surface waters consumed by animals, but it is likely that these compounds would not be accumulated because of rapid rates of metabolism and/or urinary excretion.

EPA Response:
EPA agrees with the external peer review panel and won't recommend including ingestion of contaminated water by cows in the calculation of exposure concentrations in beef and milk.

3.5.2 Environmental Fate and Transport: Speciating and Modeling Mercury

Comments were received regarding guidance presented for speciating and modeling of mercury in the risk assessment (Section 2.3.8.3, Appendix B, and Appendix C). Provide comments on the technical validity of key elements of mercury modeling.

Peer Review Workshop Synopsis
According to the external peer review panel, the total mercury loading of a combustion facility in the watershed is overestimated using the processes and equations outlined in the draft HHRAP. One reason for this overestimation is the way Equation B-4-27 in the draft HHRAP guidance is written, where the concentration of methyl mercury in fish is being determined by the dissolved water concentration of both methyl mercury and inorganic mercury times the bioaccumulation factor (BAF) for methyl mercury. A second reason is that the use of the Universal Soil Loss Equation (USLE) model overestimates the soil erosion factor, thereby overestimating the runoff of methyl mercury into the surface water. In addition, it appears that the derivation and application of the draft HHRAP equations do not account for the methylmercury contributions from wetlands.

The external peer reviewers also concluded that the draft HHRAP modeling methods appear to violate mass balance requirements. In some applications of the draft HHRAP guidance, more mercury has been calculated in soil and going into a water body than was originally present in the system, giving the appearance that the facility being modeled is creating mercury.

The peer reviewers recommended that the HHRAP guidance should focus on modeling of mercury more than the speciation of mercury, emphasizing improvement in deposition and runoff/erosion parts of the modeling effort. The USLE erosion model was specifically mentioned again as needing adjustment.

A recommendation was also made to not assume that every fisher and recreational fisher is eating Tier 4 fish in every water body.

EPA Response:
We've modified the HHRAP to recommend estimating the dissolved water concentration for divalent mercury C_{dw} (Hg2+) and methyl mercury C_{dw} (MHg) (see Table B-4-24) by applying the default mercury speciations (15 percent methyl mercury and 85 percent divalent mercury) directly to the dissolved water concentration calculated for divalent mercury versus speciating each water body loading, as currently provided in the draft HHRAP and August 2, 1999 errata. This results in a C_{dw} (Mercury Total) being calculated using the fate and transport parameters specified for mercuric chloride (see Appendix A-3 COPC tables for mercuric chloride). Then, as indicated below, C_{dw} (Mercury Total) should be apportioned based on an 85 percent Hg2+ and 15 percent MHg speciation split in the water body (consistent with Chapter 2 of the draft HHRAP).

$C_{dw}\ Hg2+ = C_{dw}\ (Mercury\ Total) * 0.85$

$C_{dw}\ MHg = C_{dw}\ (Mercury\ Total) * 0.15$

We now recommend estimating the concentration of mercury species in fish (C_{fish}) using species-specific bioaccumulation factors and dissolved water concentrations. This requires revising the equation in Table B-4-27 (provided specifically to calculate C_{fish} (MHg)) as follows:

$C_{fish\ Hg2+} = C_{dw\ Hg^{2+}} * BAF_{fish\ (Hg^{2+})}$

$C_{fish\ MHg} = C_{dw\ MHg} * BAF_{fish\ (MHg)}$

3.5.3 Environmental Fate and Transport: Biotransfer (Ba) Values

Comments were received regarding the recommended determination and application of biotransfer (Ba) values, including (Chapter 5, Appendix A-3, and Appendix B). Considering the scientific literature currently available, provide comments on the technical validity of guidance presented for determination and application of Ba values, Ba_{egg} values for PAHs, Ba_{beef}, and Ba_{milk}. For biotransfer values for lipophilic compounds, such as PAH's and dioxins, are the equations presented in Travis and Arms (1988) and Baes et al. (1984) for the estimation of Ba values appropriate as applied in the guidance? Considering how the applicable bioconcentration values reported in Stephens et al. (1995) were determined, should the total feed consumption rate of 0.2 mg/kg be multiplied by the fraction of feed found in the soil, 0.1 before calculating the $Ba_{chicken}$ and Ba_{eggs} for dioxins?

Peer Review Workshop Synopsis
Panel discussions on this charge focused on a number of different issues.

2) The external peer review panel agreed that the Ba values should refer to total dietary intake. The value for the concentration in the total diet already includes soil. They also agreed that water should be considered for compounds when appropriate. For lipophilic compounds, however, water solubility is so low that it essentially supplies no input to the equation.

3) As to using the high dose verses the low dose in the Stephens' equation, the external peer review panel concluded that the high dose should be used. In the case of the high-dose value, the equation would still be essentially linear, unless very high doses are obtained that have toxicological effects on the animal. If the low dose is used, computational problems can arise for many of the congeners. Using the low dose may also result in relatively large analytical errors in the data sets.

4) With regard to soil consumption values for free-range chickens, the external peer review panel concluded that studies conducted on wild turkeys indicate a default value of between 9 and 10 percent of dietary intake. Since wild turkeys and free-range chickens are closely related, the guidance default value of ten percent for free-range chickens is a good assumption and should be used as an upper bound. However, if the guidance is going to be consistent in relation to all species, the bioconcentration factor (BCF) value should be based on total dry matter intake.

5) With regard to those compounds with log K_{ow} values greater than 6, the external peer review panel agreed that bioaccumulation decreases. They noted research on dioxins and PCBs which demonstrate that, as chlorination in the compound increases, the dietary uptake of the compounds in the body decreases. Thus, the panel concluded that bioconcentration decreases as the degree of chlorination increases.

   In addition, the external peer review panel noted that the log K_{ow} values do not indicate whether a compound is being metabolized in the body, which appears to be a weakness in the Travis equations. Compounds that are metabolized do not bioaccumulate. Therefore, it was recommended that the risk assessor look at any compounds that are indicating a high risk and determine if the risk assessment should be adjusted to account for those that are likely to be metabolized.

   As to the log K_{ow} values themselves, the external peer review panel agreed that there is no guidance on how to select them. Therefore, it is hard to put any correlation together for the log K_{ow} values if the numbers are not coming from the same laboratory using the same method for the derivation of the data. In saying that, the peer review panel conceded that there was no one best method to obtain log K_{ow} values.

6) The external peer review panel concluded that there were three major problems with using the information derived from bioaccumulation research of substances in beef tissue (Ba_{beef}). First, in that research, the majority of the animals were diary cows, which are lactating. Lactation would change the nature of the bioaccumulation process and would not represent tissue concentrations in

non-lactating animals. Second, the duration of the research was not long enough to have reached a steady state on tissue concentrations. Third, the research did not take in to account that animals typically are growing. The research ignored the fact that growing animals consume more feed as they grow. Instead, researchers assumed a constant milligram per day intake.

7) With regard to the values for pork, the external peer review panel did not find specific problems, but they noted that there is still the same growing animal problem as encountered with beef. They recommended that, because there are not many good data on persistent compounds in pork, if a compound found in pork tissue is driving the risk assessment, the risk assessor should carefully examine the factors most affecting the risk calculation.

8) With regard to the Ba values for PAH's and phthalates, the external peer review panel concluded that there was enough literature data to indicate that these compounds would never show up in beef, milk, or eggs. PAHs and phthalates are readily metabolized in the body. If they do show up in that tissue, it would probably be the result of post-contamination.

EPA Response:
We've modified the HHRAP to recommend reducing the biotransfer factor values for chicken ($Ba_{chicken}$) and poultry eggs (Ba_{eggs}) by one order of magnitude for all dioxin and furan congeners reported in the Appendix A-2 COPC tables (see Section A.2.5.3, Biotransfer Factors for $Ba_{chicken}$ and Ba_{egg}).
Based on the significant comments received during the peer review concerning biotransfer factors, we commissioned a study to validate the Travis and Arms beef and milk biotransfer factors. Comments noted by the peer reviewers were taken into account when designing the study. This study did validate the Travis and Arms equations for a limited range of K_{ow} values, but indicated a large variability associated within the data set. The study also generated non-linear biotransfer equations to replace the Travis and Arms equations and dramatically reduce variability in the data set. We've updated the HHRAP with the new biotransfer equations for beef and milk. In addition, all biotransfer equations (including plant biotransfer equations) have been capped at the highest and lowest K_{ow} value used in generating the equations. We believe this is a conservative cap that lessens the possibility of violating conservation of mass.

3.5.4 Environmental Fate and Transport: Organic Compound Conservation of Mass

Comments were received stating a violation in conservation of mass exists based on guidance presented for calculating exposure concentrations of some organic compounds via indirect pathways, based on not accounting for removal of the contaminant fraction assumed to deposit on vegetation (Sections 5.2 and 5.3, Appendix A-3, and Appendix B). Does application of the recommended Ba values violate conservation of the mass of contaminants emitted to mass concentrated in plant or tissues?

Peer Review Workshop Synopsis
The external peer review panel agreed that a violation in the conservation of mass has occurred based on the equations for calculating exposure concentrations. The potential solution for dioxin and other organic vapors would be to transform the air modeling equations so that you subtract out the mass in the air as the

contaminants accumulate elsewhere. The panel recommended that EPA develop a check to ensure mass balance. The panel also recommended that EPA expand the incorporation of the approach that is being used for surface water. Using that approach everywhere, EPA would have a limit to the rate of transfer from the air and to the soil, plants, and water, and a boundary limiting the movement of material from one pathway to another.

EPA Response:
As noted more than a decade ago in EPA guidance for calculating health risks associated with indirect exposure to emissions, fate and transport and food chain algorithms that don't rigorously maintain mass balance checks can result in mass balance violations for certain compounds in certain exposure situations. EPA guidance has generally implied that modelers conduct mass balance checks to ensure that reasonable predictions are being made. However, we recognize the need for more internal mass balance checks within the biotransfer algorithms.

To address the above issue, we've revised sensitive and affected parameters of the fate and transport models we recommend in the HHRAP. For example, uptake factors for most organic compounds are calculated using regression equations derived from empirical data sets that correlate to compound specific octanol/water partitioning coefficient (K_{ow}) values. Sometime those data sets were rather limited, and compounds with K_{ow} values well outside the range of the data set are the most common examples of potential mass balance violations. To limit this problem, uptake factor values for compounds with K_{ow} values outside the range of empirical data used to derive the correlation equations have been bound more in line with the upper or lower values of the empirical data set.

Additionally, the HHRAP provides literature-documented ranges of site-specific input parameters and, where appropriate, bounding values to help the risk assessor perform mass balance checks. For example, the range of USLE rainfall (or erosivity) factors documented in the literature is between 50 and 300 yr^{-1}. Values outside of this range would need to be evaluated closely to prevent potential mass balance violations in the calculation of unit soil loss. An example of a bounding parameter would be the default value provided in the HHRAP for the suspended solids deposition rate utilized to prevent erroneous errors from implying that streams will fill in from sedimentation to and unrealistic level.

3.5.5 Environmental Fate and Transport: Losses to Soil Due to Erosion

Comments were received regarding the guidance on accounting for losses to soil due to erosion (Sections 5.2.2 and Appendix B). Are the presented recommendations regarding losses to soil due to soil erosion technically valid for evaluation of all terrestrial exposure scenarios?

Peer Review Workshop Synopsis
The external peer review panel suggested a reasonable approach to deal with soil erosion is to assume that erosion to an area is equal to that from an area and thereby set erosion equal to zero. However, the HHRAP should also provide an equation for calculating loss due to erosion for site-specific situations in which this assumption is not the case.

EPA Response:
We'll continue to recommend that the loss from soil due to erosion be set equal to zero. This is based on the assumption that soil in a specified area will lose as much soil contaminant (erosion out of the area) as it will gain in soil contaminant from erosion into the area of concern. If this assumption is not met, the HHRAP provides an equation that can be used with the Universal Soil Loss Equation to estimate loss of contaminant due to erosion. We also recommend using the Universal Soil Loss Equation (USLE) to calculate the amount of contaminant entering a water body via erosion. The USLE is calculated on a site-specific basis.

3.5.6 Environmental Fate and Transport: Acute Benchmarks Based on Mild Adverse Health Effects

U.S. EPA solicited comments from the peer review panel on attempts to set acute benchmarks based on mild adverse health effects, such as irritation.

Peer Review Workshop Synopsis
The Panel recommended that EPA contact the States about their frequencies of upset events, and evaluate whether they occurred frequently enough to warrant use of an acute benchmark based on mild adverse health effects.

It was suggested that EPA could improve the assessment of the likelihood of mild acute health effects by using two approaches: (1) evaluating upset conditions combined with the worst meteorological conditions and (2) evaluating upset emissions over typical atmospheric conditions.

Another suggestion was that EPA could use the 95th percentile value, and that would be a blend between the worst case and things that occur more frequently. It would still give the HHRAP a conservative value. This method was further substantiated by the fact that several States have taken the percentile approach to determine acute benchmarks.

The point was made that mild health effects, even if not debilitating to individuals, may result in hundreds of visits to local hospital emergency rooms, and be something that should be considered seriously when setting acute benchmarks.

EPA Response:
After evaluating the comments from the external peer review panel, we decided to stay with the approach of recommending acute benchmarks based on mild health effects. We realize that better modeling and exposure assessment methodologies may be appropriate in some cases, but the HHRAP methodology is presented only as a broad screen of acute effects. The methodology in the HHRAP was selected based on ease of implementation and screening capabilities. The air dispersion modeling conducted to evaluate chronic health effects generates maximum one-hour air concentrations used in the acute assessment. We believe that using the maximum one-hour air concentration and the mild health effects acute benchmark will provide a reasonable screening method without being too burdensome on facilities.

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Appendix A

Public and Peer Reviewers of the
***Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (HHRAP)**
Peer Review Draft, July 1998

A1. Internal U.S. EPA and State Reviewers

The Peer Review Draft HHRAP (U.S. EPA, 1998a) was developed by the U.S. Environmental Protection Agency (EPA) Region 6 and the Office of Solid Waste. Jeff Yurk from EPA Region 6 was the primary author/editor of this document with Tetra Tech EM, Inc, providing the bulk of the background research under Contract No. 68-W-99-018. Karen Pollard and Timothy Taylor of the Office of Solid Waste provided authorship, editorial input, and overall coordination with experts in other EPA Regions, Headquarters, and the Office of Research and Development. The following U.S. EPA and state agency personnel provided comments on earlier draft versions of the HHRAP.

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A3. External Peer Reviewers

On May 25 and 26, 2000, an external peer review workshop was held. The peer review and workshop was organized, convened and conducted by Tech Law, an EPA contractor under the EPA contract number: 68-W-99-017. Panel members and reviewers at this workshop include the following.

EXTERNAL PEER REVIEWERS

1. Combustion Engineering
   Dr. William Schofield (Focus Environmental)

2. Atmospheric Modeling
   Dr. Walter Dabberdt (National Center of Atmospheric Research)

3. Human Health Toxicology
   Dr. Thomas A. Gasiewicz (University of Rochester)
   Dr. Mary Davis (West Virginia University)

4. Human Health Exposure
   Dr. James P. Butler (Argonne National Laboratory/University of Chicago)
   Dr. Richard L. DeGrandchamp (University of Colorado)
   Mr. Steven Washburn (Environ Corporation)

5. Chemical Fate and Transport
   Dr. George F. Fries (U.S. Department of Agriculture (retired))
   Dr. Douglas Smith[1] (ENSR International)

The following team supplied comments to panel member Dr. Douglas Smith
   Dr. Ishrat Chaudhuri, DABT (ENSR International)
   Dr. Don Fontaine (Dow Chemical)
   Dr. Lucy Fraiser (MFG, Inc.)
   Dr. Andrew Friedmann (ENSR International)
   Mr. Marcus Garcia (ENSR International)
   Dr. Mark Gerath (ENSR International)
   Dr. Ken Heim (ENSR International)
   Dr. Michael Mills (ENSR International)
   Ms. Betsy Ruffle (ENSR International)