World Trade Center Indoor Environment Assessment: Response to Peer Review Comments on the Report for Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks

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Prepared by the Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Task Force Working Group

Contributors:

U.S. Environmental Protection Agency
Mark Maddaloni
Charles Nace
Peter Grevatt
Terry Smith
Dore LaPosta
John Schaum
Dana Tulis
Jennifer Hubbard

New York City Department of Health and Mental Hygiene
Nancy Jeffery
Ken Carlino
Jeanine Prudhomme
Chris D'Andrea
Caroline Bragdon
James Miller

Agency for Toxic Substances and Disease Registry
Sven Rodenbeck
Danielle DeVoney

New York State Department of Health
Robert Chinery

Occupational Safety and Health Administration
David Ippolito
Dan Crane

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Foreword

Following the collapse of the World Trade Center on September 11, 2001, federal, state, and municipal health and environmental agencies initiated numerous studies to assess environmental conditions in the area. A multi-agency task force was specifically formed to evaluate indoor environments for the presence of contaminants that might pose long-term health risks to local residents. As part of this evaluation, a task force committee was established to identify contaminants of primary health concern and establish health-based benchmarks for those contaminants in support of ongoing residential cleanup efforts in Lower Manhattan. In September 2002, the committee released a draft document titled "World Trade Center (WTC) Indoor Air Assessment: Selecting Contaminants of Potential Concern (COPC) and Setting Health-Based Benchmarks."

In October 2002, a panel of 11 experts conducted an independent peer review of the draft COPC document to ensure that the evaluations presented in the document were technically based and scientifically sound. A final report with peer reviewers' conclusions and recommendations was released in February 2003. The authors of the draft COPC document have reviewed and responded to all peer reviewer comments.

This report—or responsiveness summary—provides the formal responses to peer reviewer comments. EPA, through its chairmanship of the multi-agency committee that authored the response to peer review comments, assumes ownership and fully endorses the report's content. The responsiveness summary presents background on the peer review process, an overview of the peer reviewers' main conclusions and recommendations, and the document authors' responses to specific comments. In addition to preparing this responsiveness summary, which will become part of EPA's peer review record for the WTC site, document authors have prepared a revised, and final, COPC document. The final document presents the updated approaches for selecting COPC and setting health-based benchmarks, based on peer reviewer input.

Copies of the final COPC document can be obtained on-line at www.epa.gov/WTC. Copies of this report are available at www.tera.org. Inquires regarding this report should be directed to:

Mark A. Maddaloni Dr.P.H., DABT
U.S. Environmental Protection Agency, Region 2
290 Broadway
New York, NY 10007-1866
212-637-3590
maddaloni.mark@epa.gov

This report is just one response to environmental and public health concerns related to the WTC. Individuals interested in other studies and research projects related to this site should refer to the following Web pages:

< U.S. EPA: www.epa.gov/WTC
< ATSDR: www.atsdr.cdc.gov/
< NYCDOHMH: http://home.nyc.gov/html/doh/html/alerts/911.html

Acknowledgments

This document was produced by EPA under the direction of the COPC/Benchmarks Committee of EPA's Indoor Air Task Force. The organizations directly involved in the development of this document include the New York City Department of Health and Mental Hygiene, The New York State Department of Health, the Agency for Toxic Substances and Disease Registry, the Occupational Safety and Health Administration and EPA's Office of Research and Development, Office of Solid Waste and Emergency Response and Region 2 Office. In addition, valuable input was provided by individuals from the following academic institutions: Columbia University, CUNY, New York University and Rutgers University.

The New York Academy of Medicine graciously hosted the peer review of this document. The peer reviewers (Drs. Jerrold Abraham - SUNY Upstate Medical University, John Christopher - California EPA, Annette Guiseppi-Elie - Dupont Engineering, Lynn Goldman - The Johns Hopkins University School of Public Health, Hugh Granger - HP Environmental, Dennis Paustenbach - Exponent, Bertram Price - Price Associates, Charles Salocks - California EPA, Susan Youngren - Bergeson & Campbell and Mr. John Kominsky - Environmental Quality Management) provided insights and recommendations which have significantly enhanced the document's scientific soundness. Toxicology Excellence for Risk Assessment (TERA) facilitated the peer review process with aplomb. Finally, environmental advocates and the Lower Manhattan community at large provided valuable input that helped shape this document.

List of Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
ATSDR	Agency for Toxic Substances and Disease Registry
COPC	contaminant(s) of potential concern
CSF	cancer slope factor
EPA	U.S. Environmental Protection Agency
HEAST	Health Effects Assessment Summary Tables
IEUBK	Integrated Exposure Uptake Biokinetic
IRIS	Integrated Risk Information System
IUR	inhalation unit risk
$\mu g/m^3$	microgram per cubic meter
mg/m^3	milligram per cubic meter
MRL	ATSDR minimal risk level
NHANES	National Health and Nutrition Examination Survey
NIOSH	National Institute of Occupational Safety and Health
NJDEP	New Jersey Department of Environmental Protection
NYCDEP	New York City Department of Environmental Protection
NYCDOHMH	New York City Department of Health and Mental Hygiene
NYSDOH	New York State Department of Health
OSHA	Occupational Safety and Health Administration
PAHs	polycyclic aromatic hydrocarbons
PCM	phase contrast microscopy
PEL	OSHA permissible exposure limit
REL	NIOSH recommended exposure limit
RfD	reference dose
RfC	reference concentration
SVOC	semi-volatile organic compound
TERA	Toxicology Excellence for Risk Assessment
TLV	ACGIH threshold limit value
VOC	volatile organic compound
WTC	World Trade Center

I. Introduction

Following the collapse of the World Trade Center (WTC) towers and nearby buildings on September 11, 2001, federal, state, and municipal health and environmental agencies have been characterizing and evaluating levels of contamination near the site. Under EPA's leadership, these agencies participated in a task force to assess the potential impact to the indoor environment from contaminants that might pose long-term health risks to local residents. The working group is called the "World Trade Center Indoor Air Task Force Working Group." Agencies participating in this task force working group include the U.S. Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), the Occupational Safety and Health Administration (OSHA), the New York State Department of Health (NYSDOH), the New York City Department of Health and Mental Hygiene (NYCDOHMH), and the New York City Department of Environmental Protection (NYCDEP).

The task force working group formed a committee—the "Contaminants of Potential Concern (COPC) Committee"—to address potential contamination of the indoor environment near the WTC site. The primary activity of the COPC Committee was to prepare a document that identifies COPC for indoor environments and sets health-based benchmarks for long-term exposures. In September, 2002, the committee released its draft peer review document, titled "World Trade Center Indoor Air Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks" (COPC 2002). For ease of reference, the draft peer review document will be referred to throughout this report as "the draft COPC document." EPA decided to have the draft COPC document peer reviewed by a panel of independent experts to ensure that the committee's evaluations are technically based and scientifically sound.

This report is the COPC Committee's responsiveness summary to the independent peer review. Section II of this report presents important background on the peer review process, including an overview of the peer reviewers' main conclusions and recommendations. The COPC Committee's specific responses to the peer reviewers' findings are documented in Section III. In addition to preparing this report, which will become part of EPA's peer review record for the WTC site, the committee is also preparing a revised, and final, COPC document (COPC 2003). As EPA's peer review policy requires, this report explains how the peer reviewers' recommendations will be reflected in the final COPC document, or reasons are provided for why certain recommendations are not incorporated.

The final COPC document, therefore, presents the COPC Committee's updated approach for selecting COPC and setting health-based benchmarks. Copies of that report can be obtained by contacting EPA, using the contact information provided in the Foreword to this report. The report will also be available on the EPA Web site (www.epa.gov/WTC).

II. Overview of the Peer Review Process

The independent peer review was implemented through Toxicology Excellence for Risk Assessment (TERA), a contractor to EPA, in accordance with specifications in EPA's "Peer Review Handbook" (EPA 2000a). TERA identified 11 independent peer reviewers from different affiliations and with expertise in various relevant fields, including risk assessment, exposure assessment, indoor air sampling techniques, and toxicology. According to the peer review report, "most of the peer reviewers stated that they had no prior work activity related to the WTC disaster or any known conflicts and felt they could participate fully in the meeting" (TERA 2003).

The peer reviewers provided their feedback on the review document during a 2-day meeting on October 21–22, 2002, in New York City. The meeting, which was open to the public, was split into two general sessions: reviewing the approach used to select COPC, and reviewing the approach used to set health-based benchmarks. At the beginning of each session, authors of the draft COPC document gave brief presentations, after which the peer reviewers discussed and debated the scientific merits of the document. This open discussion was framed around a series of charge questions that TERA asked the peer reviewers to address. Observers were allowed to comment at designated times during the peer review meeting.

TERA released a final summary report in February 2003 that documents the discussions among the independent peer reviewers (TERA 2003). These discussions ultimately led to 16 specific conclusions and recommendations that are documented in the peer review report. To respond to the peer reviewers' comments, the COPC Committee addressed each of these conclusions and recommendations. When preparing our responses, we referred to the summary of the peer reviewers' discussions related to each conclusion or recommendation. Therefore, this responsiveness summary addresses the major themes and issues expressed throughout the peer review report, but our responses are framed around the final conclusions and recommendations.
In addition, the COPC Committee reviewed both verbal and written comments submitted by observers to the peer review meeting. Some observer comments addressed components of the WTC Clean-up Program that were outside the scope of the peer review. Substantive comments relating to the draft COPC document (e.g., data sources for COPC screening, target risk range) have been addressed in the course of responding to the peer reviewers' comments.

III. Responses to Peer Review Comments

When responding to peer review comments, EPA prepares (as per its guidance on peer review) a written record "responding to the peer review comments specifying acceptance or, where thought appropriate, rebuttal and non-acceptance" (EPA 2000a). This section presents the COPC Committee's responses to the peer reviewers' 16 main conclusions and recommendations: 7 that pertain to selecting COPC (see Section III.A), and 9 that pertain to setting health-based benchmarks (see Section III.B). Each conclusion and recommendation is addressed individually, and our response indicates what, if any, changes were made to the draft COPC document to address the comment. If no changes were made, our response explains why.

A. Responses to Comments on Selecting Contaminants of Potential Concern

The peer reviewers made seven conclusions and recommendations related to the COPC selection process in the draft COPC document. These are presented on pages 16–17 of the peer review report, and are reproduced below. Each conclusion and recommendation is followed immediately by the COPC Committee's response to the comment.

Comment COPC #1:

> The document should more clearly state the intended use of the COPC selection process.

Response:

> The selection of COPC was intended to inform the Indoor Air Residential Assistance - WTC Dust Clean-up Program, which we will refer to as the WTC Clean-up Program. In conventional hazardous waste site investigations, the COPC selection process is intended to reduce what is typically an extensive contaminant sampling list to a manageable "short list" of risk-driving chemicals. The risk from this "short list" is then calculated to determine if remedial action is warranted. Regarding the WTC, there was an a priori decision to institute a clean-up

program rather than launch a formal remedial investigation to determine if remediation of residential dwellings was necessary. The primary reason for this decision was to eliminate the time-consuming process of initiating a remedial investigation (i.e., developing a sampling and analysis plan, conducting representative sampling of residential dwellings, analyzing a large number of samples, and finally interpreting results) at a time when re-habitation of residential dwellings in Lower Manhattan was nearly complete. As a result of this decision, the COPC selection process associated with the WTC Clean-up Program assumed a somewhat modified purpose. Rather than serve as a process to determine the need for clean-up, the COPC selection process served to facilitate development of health-based benchmarks for the WTC Clean-up Program. By identifying COPC, benchmarks for individual contaminants could be developed for indoor air and settled dust. To summarize, first and foremost, the intent of the COPC selection process was to identify risk-driving chemicals and to establish specific health-based benchmarks for the WTC Clean-up Program.

As part of this initiative, the COPC selection process informed two complimentary studies that were undertaken as part of the WTC Clean-up Program. The first was the WTC Residential Confirmation Cleaning Study (EPA 2003a). This study was initiated to evaluate the effectiveness of various cleaning methods (e.g., high-efficiency particulate air vacuuming, wet wiping) used to clean residences. The COPC selection process provided the list of contaminants to sample for in the WTC Residential Confirmation Cleaning Study. It also enabled the development of health-based benchmarks for indoor air and settled dust so the effectiveness of cleaning methods could be assessed. The cleaning methods employed also served to guide the clean-ups of other heavily impacted unoccupied buildings. Another outcome of the WTC Residential Confirmation Cleaning Study was in streamlining the post-cleaning sampling needs of the WTC Clean-up Program. Although not a specific goal, this effort identified an indicator chemical (i.e., asbestos) that signaled the reduction of all COPC to concentrations below health-based benchmarks. With thousands of residents signed up for cleaning, the use of an indicator contaminant to establish cleaning effectiveness provided a powerful tool in facilitating the WTC Clean-up Program.

The other initiative that the COPC selection process informed was the WTC Background Study (EPA 2003b). The development of remediation goals is influenced by factors such as technical implementation, analytical detection limits, and the background concentration of contaminants in the environmental setting of interest. A literature review of contaminant background concentrations in residential dwellings was conducted to inform the WTC Clean-up Program. Limited information was obtained for asbestos in indoor air and lead and dioxin in settled dust, otherwise the search yielded very little useful data. It was therefore deemed advantageous to conduct a site-specific background study to inform risk management decisions regarding the setting of clean-up goals at health-based or background concentrations. Consequently, The COPC selection process directed the group of contaminants to be sampled for in the WTC Background Study. Conversely, the results of the WTC Background Study provides data to enhance the value of the final COPC document. That is, it provides an estimate of background for COPC in Lower Manhattan to be evaluated alongside health-based benchmarks.

Comment COPC #2:

The document should "include a clear presentation of the logic used to select COPC."

Response:

As noted in the previous response, the COPC selection process described in the draft COPC document was driven by the need to develop clean-up criteria for those contaminants with the potential to pose the greatest public health risk. The semi-quantitative approach initially used to select COPC examined the contaminants detected in environmental samples collected in Lower Manhattan and contaminants believed to be released from the WTC disaster (e.g., combustion by-products, building materials). COPC were originally selected based on a combined consideration of the substances' toxicities, the frequencies at which substances were detected, and the likelihood that detected substances were related to the WTC disaster.

Peer reviewers acknowledged the constraints under which the COPC selection approach was developed, but commented that the COPC list seemed to have been narrowed fairly rapidly and recommended that additional data sets be considered and the description of the process be more transparent. In response to this comment, the authors conducted a systematic review of the COPC selection process. This involved a careful re-examination of multiple supporting environmental data sets, consideration of newly available data sets, and a review of the exposure assumptions and toxicity criteria used in establishing screening values.

Though we made some modifications in approach, the final COPC list remains unchanged. The authors revised the COPC document, however, to more clearly present the steps taken and the logic followed in selecting COPC. We hope that these revisions will help readers fully understand the COPC selection process and will demonstrate that the selection process was comprehensive, technically sound, and, most importantly, protective of public health. Our conceptual approach for selecting COPC, including the underlying logic, is summarized below. Appendix B of the final COPC document describes in greater detail how each step was applied and what contaminants, by medium, were eliminated or retained for further consideration.

Review of multiple data sets to identify candidate substances. The collapse of the WTC released a very broad range of contaminants into the air, many of which deposited with settled dust on surfaces in Lower Manhattan, both indoors and outdoors. To gain the best possible sense of the contamination levels in indoor residential environments, the authors reviewed an extremely large set of sampling data describing environmental conditions at and near the WTC site between September 11, 2001, and the present. Our goal was to review data that might provide insights on the contamination levels inside Lower Manhattan residences. As a result, we reviewed a large set of bulk dust and settled dust sampling results, and we also reviewed ambient and indoor air sampling data, based on the premise that contaminants entered residences through atmospheric transport.

We reviewed sampling data collected by EPA, ATSDR, OSHA, NYCDEP, NYCDOHMH, the New York City Department of Education, the New Jersey Department of Environmental Protection, and independent investigators. A complete list of the data sources we reviewed is included in the final COPC document. Overall, we examined results from more than 500,000 environmental samples, with sampling results available for more than 300 contaminants. The contaminants included volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs), pesticides, polychlorinated biphenyls (PCBs), metals, asbestos, silica, other minerals, and synthetic fibers. Every contaminant identified in the sampling data was considered a candidate substance for the COPC selection process.

Initial screen to identify contaminants requiring further consideration. The authors used an initial screening procedure to identify the contaminants that require further consideration before being selected as COPC. This initial screening procedure identified contaminants that are most likely to be present in dust at levels greater than health-based screening values. This initial screening involved three steps:

< First, all VOCs were eliminated from the COPC selection process, because any VOCs that might have been released in or adhered to dusts from the WTC site have likely evaporated or greatly dissipated since the time that air emissions from the site were controlled (i.e., since the time, December, 2001, that the fires were extinguished).

< Second, all contaminants detected in fewer than 5% of samples were removed from the list of candidate contaminants, but only if the contaminant was analyzed for in more than 20 samples. This screening approach based on frequency of detection is consistent with EPA's guidance on human health risk assessment (EPA 1989). By requiring a minimum of 20 samples to apply the frequency of detection screening step, we believe we have addressed the peer reviewers' concern that the frequency of detection might not be an appropriate screening criterion because the "available data reviewed were limited" and the "goal of the screening process was to be inclusive." A review of the contaminants that were screened out by frequency of detection revealed that none were found at concentrations above health-based screening values.

< Third, for the contaminants that were not eliminated in the previous two steps, we compared the maximum concentration detected in each medium to corresponding health-based screening values. (Refer to our response to COPC #3 for further information on how these screening values were derived.) Three outcomes were possible for this step. If a contaminant's maximum concentration was lower than the corresponding screening value, that contaminant was eliminated from further consideration. If a contaminant's maximum concentration was greater than the screening value, then we evaluated the contaminant further in the secondary screening step, described below. If a contaminant did not have a toxicity value, and therefore did not have a screening value, we reviewed other relevant information (e.g., occupational or environmental standards, trends among sampling data, comparisons to background, the likelihood of the contaminant being related to site-specific releases) to determine whether the contaminant should be evaluated further.

Secondary screen to select COPC. For those substances exceeding health-based screening criteria in at least one sample, we reviewed findings across environmental media to assess representativeness of reported maximum concentrations, studied spatial and temporal trends, determined the relationship of detected concentrations to available background concentrations, and examined whether there was reason to believe a contaminant was site-related. Professional judgment entered into this part of the process, as the peer reviewers noted would be necessary. In general, contaminants with reported concentrations deemed representative of exposure conditions and detected above background (if appropriate comparison data were available) were retained as COPC. The final COPC document provides detailed justification for contaminants eliminated as part of the secondary screen.

This selection process yielded the final list of COPC:

< *Asbestos*
< *Dioxins*
< *Lead*
< *Polycyclic aromatic hydrocarbons (PAHs*)
< *Fibrous glass*
< *Crystalline silica*

Asbestos, dioxins, lead, and PAHs were selected as COPC because they were consistently detected across environmental media at concentrations above health-based screening values. *Fibrous glass* and *crystalline silica* also were selected as COPC, but from the list of contaminants that do no have health-based screening values. In the absence of consensus toxicity criteria to apply in the quantitative screening used for most other contaminants, we used environmental and occupational standards coupled with an evaluation of overall exposure potential knowing that these and other building materials were deposited in a large cloud from the collapse of the WTC. Section 2.3.2 of the final COPC document lists the specific reasons why fibrous glass and silica were selected as COPC.

As a final note, the committee reviewed preliminary data from settled dust wipe samples in Lower Manhattan residences which infrequently identified *mercury* at levels greater than health-based screening values. Further, *chromium* in ambient air has been shown to exceed health-based screening values, though chromium levels in available bulk and settled dusts collected in Lower Manhattan are not above health-based screening values. A more detailed discussion of the evaluation of environmental sampling data for *mercury* and *chromium* can be found in Appendix B of the final COPC document. In both cases, it is unclear whether detected levels are associated with the WTC collapse. Regardless, as part of the WTC Clean-up Program, EPA is conducting wipe sample testing for 21 non-COPC metals, including mercury and chromium in approximately 250 apartments.

Comment COPC #3:

The document should "more clearly describe the basis for the choice of toxicity values and exposure assumptions used to estimate COPC screening criteria."

Response:

Upon examination of peer reviewer comments, we agree that the document would benefit from a more detailed description of and justification for the toxicity values and exposure assumptions used in estimating WTC screening values. Therefore, the document will be revised to further describe the basis for developing air and dust screening values. The toxicity and exposure parameters used to develop screening values for bulk and settled dust will therefore be included in the final COPC document.

The methodology, risk equations, and exposure assumptions used in developing WTC screening values are consistent with established EPA risk assessment guidance. Exposure equations generally stem from EPA's Risk Assessment Guidance for Superfund (RAGS) (EPA

1989). For deriving screening values for residues on indoor surfaces (settled dust), we adapted EPA guidance for residential exposure assessment, originally developed to study pesticide residues (EPA 2001a). This approach was further supported by procedures and re-entry guidelines previously developed for scenarios evaluating fine dust particles more analogous to those associated with the WTC collapse (Kim and Hawley 1985; NJDEP 1993; Michaud et al. 1994; Radian 1999). Exposure assumptions used are those recommended in RAGS or supplemental risk assessment guidance, including EPA's Exposure Factors Handbook (EPA 1997b), Child-specific Exposure Factors Handbook (EPA 2002a), Dermal Exposure Assessment: Principles and Applications (EPA 1992), and RAGS Part E, Supplemental Guidance for Dermal Risk Assessment (EPA 2001b).

The final COPC document will present the following general framework used in deriving screening values:

< The consideration of cancer and non-cancer effects, with a target cancer risk of 10^{-4} and a hazard quotient of 1 for non-cancer endpoints—the more sensitive of the two being used to derive screening values.

< The evaluation of adult and childhood exposures, with child exposures factoring heavily into the development of screening values for *dioxin* and *PAHs* in settled dust.

< The use of the most current toxicity criteria on EPA's Integrated Risk Information System (IRIS) database. In the absence of IRIS toxicity criteria, the following hierarchy of toxicity data sources was used: EPA's Health Effects Assessment Summary Tables (HEAST), ATSDR's minimal risk levels (MRLs), provisional values derived by EPA's National Center for Environmental Assessment, and, in limited cases, the use of surrogate toxicity values or cross-route extrapolations.

Medium-specific approaches and assumptions are detailed in the final COPC document, as outlined below:

< *Air pathway.* Contaminants detected in ambient and indoor air were compared to the lower of the following IRIS values: EPA reference concentrations (RfCs) (for non-carcinogens) or air concentrations associated with a 10^{-4} cancer risk (based on inhalation unit risks [IURs]). In the absence of IRIS values, the hierarchy presented above was used.

< *Bulk dust pathway.* Screening values were developed for bulk dust based on a soil ingestion pathway scenario, considering both childhood and adult exposures. The exposure equations and age-specific assumptions used are detailed in Appendix A of the final COPC document. Oral toxicity values (EPA reference doses [RfDs] for non-carcinogens and cancer slope factors [CSFs]) were used when available. Otherwise, the hierarchy described above was followed.

< *Settled dust pathway.* Screening values were developed based on exposures associated with ingestion and dermal contact with dust residues on indoor surfaces. As per peer review comments, a childhood exposure scenario was incorporated into this pathway. Dose rates were estimated based on a number of assumptions—for example, the fraction of dust residues that can be transferred to the skin, daily skin loads, mouthing behaviors for different age groups, and dissipation of surface loading over time. All of these parameters and the justification for selected values are detailed in

Appendix D of the final COPC document. Toxicity criteria used included EPA's RfDs and CSFs.

Contaminants for which no consensus or provisional toxicity values are available were reviewed on a case-by-case basis. In some cases, occupational standards and environmental standards were considered in developing COPC screening criteria (e.g., crystalline silica and other minerals).

Comment COPC #4:

The document should "more clearly describe the limitations of the methods used to screen COPC."

Response:

Overall, we are confident that the COPC selection process used in evaluating WTC-related contamination enabled us to select appropriate indicator contaminants, leading to the development of benchmark criteria which support ongoing efforts to safely clean up residential environments in Lower Manhattan. The authors recognize, however, that limitations associated with the COPC selection process exist. The primary limitations include the nature of the environmental data sets used in the selection process and the absence of toxicity criteria for some contaminants. However, the general framework for selecting COPC was developed based on our complete understanding of these limitations. The impact of these factors on the outcome of the COPC selection process is described in more detail below. An uncertainty section will be added to the final COPC document to clearly describe these limitations.

- *Data limitations*. Extensive systematic sampling of indoor air and settled dust in Lower Manhattan residences had not occurred at the time the draft COPC document was released. However, partial results of sampling associated with the WTC Residential Clean-up Program will be available to inform the final COPC document. In selecting COPC, we drew from the much larger sampling data from other media to account for this shortcoming. We feel that these data are sufficient to identify those contaminants most likely to be present in indoor environments and to support the derivation of clean-up criteria. We agree with peer reviewer comments that ambient air monitoring data need to be interpreted with caution before being used to evaluate indoor environments. For example, peer reviewers expressed concern that samples collected weeks and months after the building collapse would not have characterized much of what made it into the residences as dust. Fortunately, as mentioned above, indoor air and residual dust sampling being conducted as part of EPA's WTC Residential Clean-up Program offer additional insight to the nature and extent of contaminants found in indoor environments.

  As described in our response to COPC #1, to promote a timely response to the WTC disaster, conventional remedial investigation approaches were not used to generate our study data. That is, an investigation of indoor environments with targeted sampling was not conducted. Instead, to expedite cleanup, we relied on existing data sets realizing that many of the data sets were generated independently, by multiple entities, for various purposes, and with varying data quality objectives. We recognize that sampling and analytical methods varied across some studies, and that limited results exist for some contaminants in some media. To the extent possible, we factored contaminant- and study-specific considerations into our final decisions on COPC (e.g., sample size, detection limits, etc.). Lastly, we also acknowledge, as noted by the peer reviewers, that environmental sampling data do not specifically "fingerprint" the possible unique pattern of substances that may have been released from the WTC collapse and settled in indoor dust. Nonetheless, we still screened hundreds of contaminants, many of which are known to be associated with building materials or thermal or chemical degradation products (e.g., asbestos, PAHs and other SVOCs, dioxins, and metals). Through a combined analysis of air and settled dust data, we believe that the process has enabled us to identify risk-driving contaminants within the indoor environment.

Absence of contaminant-specific toxicity criteria. Though toxicity values are not currently available for a subset of contaminants tested for and detected in some air and dust samples in Lower Manhattan, the COPC selected are indicative of the most prevalent, most toxic contaminants associated with the WTC releases. A wide range of contaminant classes were captured, among which some of the more toxic members were identified and screened (*e.g., dioxins, PAHs, metals*). Basing COPC selection on the contaminants with known toxicity criteria (and arguably some of the more toxic compounds) that are measured at higher levels than the contaminants in question is believed to be appropriate and reasonably health-protective.

The list of contaminants without toxicity criteria that were not carried through the COPC selection process include (1) essential nutrients (e.g., calcium, magnesium), which EPA generally does not carry through its risk assessments; (2) a limited number of specific phthalates and PAHs; (3) and SVOCs that are not conventionally measured to support EPA risk assessment. The lengthiest list of SVOCs for which no toxicity criteria exist comes from Lioy et al. (2002)—a study of three outdoor bulk dust samples collected in Lower Manhattan on September 16 and 17, 2001. Most of the SVOCs that do not have toxicity criteria were not consistently detected across the three samples. Further, the concentrations measured were consistently lower than other SVOCs (*e.g., PAHs*) that have been selected as COPC. Finally, because many of the SVOCs identified by Lioy are rarely considered in environmental sampling studies, we have no knowledge whether the measured levels are consistent with background concentrations in urban settings or if the levels are unusually high.

Uncertainty in deriving settled dust screening values. As described in the response to COPC #3 and detailed in Appendix D of the final COPC document, derivation of settled dust screening values required multiple assumptions in estimating exposure to surfaces, which add uncertainty to our analysis. For example, factors affecting surface loading and transfers to skin have not been well studied and are likely to be highly variable (e.g., characteristics of different surfaces, activities patterns related to surface contact, and surface cleaning techniques and frequency). As a result, limited data were available for many of the input parameters used to estimate dose from exposure to residues on surfaces. However, consistent with general human health risk assessment practice, every effort was made to select exposure input parameters that would define a reasonable maximum exposure and produce protective screening values. For the most part, upper-bound exposure estimates were used whenever available. Overall, we feel the process represents a reasonably protective approach.

Comment COPC #5:

The document should "include a spreadsheet or sample calculations to document how the screening values were calculated."

Response:

The final COPC document has been revised to present the results of the step-by-step screening process used in this assessment. The equations used in developing the screening values for bulk and settled dust are included, with all assumptions clearly stated. Sample calculations are now provided to illustrate the derivation process.

Comment COPC #6:

"COPC selection should primarily be based on a risk-based screening approach for settled dust and air pathways that uses exposure parameters appropriate for children and reflects toxicity endpoints relevant to children's health. The panel suggested three exposure scenarios: including a child at home for a 1-year exposure duration, an adult at home for a 30-year exposure duration (time-weighted average 6 years of child exposure parameters and 24 years of adult exposure parameters), and an adult at work for a 25-year exposure duration."

Response:

The authors agree that COPC selection should be based on a risk-based screening approach for the settled dust and air pathways and adjusted the process accordingly. The revised COPC selection process evaluates a chronic residential exposure scenario, considering both child and adult exposures. We did not, however, specifically evaluate exposures to a child at home for 1 year or to adult workers for the following reasons:

- The tiered approach in the original COPC document was designed to evaluate sub-chronic exposure (i.e., 1 year). That approach has been replaced in the final COPC document to consider chronic exposures only. The incorporation of child-specific exposure parameters in the chronic (i.e., 30 year) exposure scenario, as recommended by the peer reviewers, will be protective of sub-chronic exposure to more highly-exposed child receptors.

- A worker exposure scenario was not adopted due to the residential nature of the clean-up program. However, screening values developed for the residential exposure scenario are considered to be adequately protective of workers.

Consistent with peer reviewer recommendations, child exposure considerations now factor into our COPC selection process. The methodologies used to develop WTC screening values account for differences between adults and children with respect to exposure factors (e.g., body weight, intake rates, mouthing behaviors). For bulk dust, the chronic residential exposure scenario is time-weighted to include 6 years of child exposure and 24 years of adult exposure for screening carcinogens. A child soil ingestion scenario serves as the basis for non-cancer screening values. For the evaluation of residues on indoor surfaces, we considered continuous age-specific exposure parameters from age 1 through 31 for carcinogens and 1 through 6 for non-carcinogens.

Peer reviewers also noted that, ideally, the process needs to consider the critical exposure periods and toxicity endpoints relevant to children's health. Peer reviewers acknowledged, however, and we agree that development of additional toxicity criteria for children to support this COPC selection process is beyond the scope of this effort. Our screening process did consider, however, toxicity endpoints relevant to children's health where available (e.g., lead). As stated earlier, the critical studies and endpoints used in developing IRIS and alternate toxicity values served as the basis for our screening values. Currently, most consensus toxicity values are based on the evaluation of adult exposures, not early-life exposures, though EPA does factor in relevant information on reproductive and developmental endpoints (or the lack thereof) when deriving toxicity values.

It should be noted that research evaluating the significance of early-life exposures to toxic chemicals is ongoing by EPA and others. For example, EPA recently released draft guidance for assessing cancer susceptibility from early-life exposure to carcinogens (EPA 2003). Because most current cancer slope factors do not account for susceptibility differences with respect to early life stages, agency scientists are exploring the possibility of applying additional uncertainty factors when evaluating childhood carcinogenic risks to some (e.g., mutagenic) carcinogens. Much of the impetus for such an approach is the growing knowledge and understanding of how a particular carcinogen exerts its effect (i.e., its mode of action) and how a particular mode of action may increase the risk of tumor response if exposure occurs during early-life stages.

In the meantime, we acknowledge that the current approach of applying existing toxicity criteria to all age groups introduces some uncertainty to the evaluation biased toward an underestimation of risk. Nevertheless, the overall conservative assumptions built into standard risk assessment methodology used in the COPC selection process offer a health protective screen. As pointed out by one peer reviewer, "it would be hard to imagine a more conservative approach than applying Appendix D [settled dust screening values] with childhood parameters as a COPC screening process," which is the final approach that we used.

Comment COPC #7:

"The panel recognized that once risk-based screening criteria based on dust have been developed, the list of COPC could potentially change. In addition, the panel observed that additional sources of relevant data discussed during the meeting suggest that contaminants which should be further evaluated to determine whether they should be listed as COPC include phthalates, arsenic, beryllium, polybrominated diphenyl ethers, and polybrominated dibenzofurans, as well as other potential COPC identified in the public observer comments."

Response:

The inclusion of risk-based screening criteria for the dust pathway and consideration of data sets made available subsequent to the release of the draft COPC document did not change the final list of COPC. We examined the contaminants noted by peer reviewers with consideration to factors applied to all candidate contaminants. The specified contaminants were not included as COPC for the following reasons:

- *Phthalates*. Phthalates were sampled for and detected in a limited number of bulk dust samples. Phthalates for which toxicity criteria are available (e.g., benzyl butyl phthalate, bis[2-ethylhexyl phthalate], diethylphthalate, di-n-octylphthalate) were detected at levels orders of magnitude lower than respective screening values providing justification for their exclusion as COPC. Phthlates for which no toxicity criteria are available were reported at comparably low concentrations.

- *Arsenic.* Arsenic levels have been measured in 17 bulk dust samples and in 215 settled dust samples, but never detected at concentrations or loadings greater than corresponding health-based screening values. Arsenic has been detected in 64 out of 738 (9%) ambient air samples. Half of these detections exceeded health-based screening values, but generally fall within the range of arsenic levels reported in urban settings, based on our review of national and regional background data (ATSDR 2000). Because arsenic has not been detected at levels of potential health concern in dust samples and detected levels in ambient air are consistent with urban background, it has not been selected as a COPC. Note, however, as part of the WTC Clean-up Program, EPA will continue to analyze indoor dust samples for non-COPC metals, including arsenic.

- *Beryllium.* Beryllium was detected infrequently and at low concentrations. Beryllium was detected in only 0.1% of 738 ambient air samples and in none of the 215 settled dust samples. It was detected in 17 out of 28 bulk dust samples, but the maximum reported concentration (3.754 mg/kg) was considerably lower than the screening value (150 mg/kg).

- *Polybrominated diphenyl ethers (PBDEs).* Due to the use of PBDEs as a flame retardant in building materials and textiles, it is reasonable to consider this class of compounds as a possible WTC-related contaminant. Lioy et al. (2002) sampled for PBDEs in bulk dust. Though available results represent three samples only, PBDEs were detected at concentrations below the bulk dust screening value (150 mg/kg), which is based on the RfD for pentabromodiphenyl ether. The highest total concentration of PBDEs across available samples was 3.3 mg/kg.

- *Polybrominated dibenzo-p-dioxins and dibenzofurans (PBDDs/PBDFs).* Based on the presence of phthalates and PBDEs (albeit at relatively low concentrations), one peer reviewer suggested that PBDFs be considered or at least mentioned in the COPC document. No sampling results are available for PBDDs/PBDFs, nor do toxicity criteria exist for this class of compounds. Therefore, interpretation of data, if they were to exist, would be highly uncertain. We do know that this group of contaminants is more or less similar to the chlorinated dioxins and dibenzofurans (dioxins) in their persistence and toxicity (WHO 1998), which have been retained as a COPC.

B. Responses to Comments on Setting Health-Based Benchmarks

The peer reviewers made nine conclusions and recommendations related to how the COPC Committee proposed setting health-based benchmarks in the draft COPC document. These are presented on pages 32–33 of the peer review report, and are reproduced below. Each conclusion and recommendation is followed immediately by the Committee's response to the comment.

Comment BENCH #1:

> "The rationale and purpose of each tier should be more fully described in the document. Specifically, the document should describe the application for each tier and indicate how the benchmarks for that tier are constructed to fulfill the intended application. This recommendation particularly applies to the Tier II criteria. In addition, the document needs to more clearly describe the 'aggressive cleaning' versus 'diligent cleaning' that are used to define Tier I

compared with Tier II benchmarks and show a difference in risk would result from using these two different cleaning approaches."

Response:

A tiered approach for health-based benchmarks was initially intended to address sub-chronic, as well as chronic, exposures associated with the WTC collapse. At the time the draft COPC document was initially conceived (March 2002), it was 6 months post-disaster and the assessment of sub-chronic exposure was still a significant concern. However, the development of health-based benchmarks (tiered, or otherwise) were not specifically intended to address the methods or intensity of cleaning protocols associated with the WTC Clean-up Program. These engineering issues were evaluated in a separate study (The WTC Residential Cleaning Confirmation Study) (EPA 2003a). The inclusion of cleaning methods associated with each benchmark was more intended for illustrative purposes rather than as particular recommendations for cleaning. The authors regret the inclusion of cleaning methods in this context as it directs attention away from the primary purpose of the document (i.e., to identify COPC and set health-based benchmarks). The final COPC document will not include any recommendations on cleaning methods.

As previously mentioned, the tiered approach was originally intended to address multiple exposure scenarios. The WTC Clean-up Program that was put in place focused on long-term protectiveness from residual contamination in residential dwellings. As such, the Tier III benchmark (equating to a 30 year exposure duration) was most applicable to this purpose.

Also noteworthy is that The WTC Clean-up Program was available to any resident regardless of extent of residual contamination in their dwelling. Since this program was not linked to a particular level of risk that might be represented by a tiered benchmark approach, establishment of multiple tiers was deemed of less utility than originally construed. The Tier III benchmark which has and continues to serve as a benchmark for long-term habitability of residential dwelling is therefore the primary focus in revising the COPC document.

The peer review panel articulated the benefit of a tiered benchmark approach as potentially useful in the prioritization of clean-up actions/decisions. Since the decision was made to clean without the need for pre-cleaning sampling to establish an unacceptable level of risk, this potential benefit was not realized. Conversely, the peer review panel also expressed apprehension over the lack of clarity in how the tiered benchmarks would inform the WTC Clean-up Program. As per the meeting notes: "Some panelists considered whether the Tier I and Tier II criteria should be removed from the existing document, leaving just a single criterion for each COPC equivalent to the respective Tier III criteria." Upon reviewing the entirety of the peer review comments on this subject, the authors agree with the position of panel members as quoted above. Accordingly, the final COPC document will contain only Tier III (i.e., long-term) health-based benchmarks.

Comment BENCH #2:

"In general, the panel recommends using a risk-based approach to develop benchmarks for the COPC, but indicated that when a benchmark is based on occupational or existing environmental standards, the document should clearly describe the underlying risk assessment for the standard, and discuss how the scientific basis of the standard is relevant to the WTC situation. Also, it was suggested that the document specify a confidence level in each benchmark developed."

Response:

The comment applies to benchmarks based on occupational or existing environmental standards. The COPC document currently uses such standards to derive benchmarks for fibrous glass, silica and lead. Following are the responses to this comment for each of these contaminants:

Fibrous glass. The fibrous glass benchmark is based on the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) of 1 f/cc (ACGIH 2001). Fibrous glass was observed to be an upper respiratory tract and skin irritant to workers in environments where air sampling indicated greater than 1 f/cc fibers as measured by phase contrast microscopy (PCM) (ACGIH 2001; ATSDR 2002a). The ACGIH standard is written with the intention of preventing this irritant effect. To the COPC Committee=s knowledge, no quantitative risk assessment was used to establish this standard. Little data exist to provide a threshold below which fibrous glass would not be an airborne or contact irritant, especially when considering the effects on the general public, which may include sensitive individuals.

Irritant effects are not the only health effects possible from fibrous glass exposure. Fibrous glass less than 3 microns in diameter are respirable and available to enter and deposit in the pulmonary regions of the lung (ACGIH 2001). Clearance of these fibers from the lung will be determined by fiber solubility and length (ACGIH 2001; ATSDR 2002a). Fibers cleared from the lung have less potential to create long-term health effects. Although some animal studies have demonstrated both fibrotic and carcinogenic potential for glass and mineral wools (ACGIH 2001; ATSDR 2002a; IARC 1988), more recent studies do not fully support this finding. Although the potential for these adverse health effects is not the scientific basis of the ACGIH TLV, it is believed the resulting benchmark is adequately protective (see response to BENCH Comment 9). It should be noted this benchmark is lower than the proposed ATSDR chronic minimal risk level (MRL) for refractory ceramic fibers (0.03 f/cc), which are considered more toxic than the glass and mineral wools described in dust from both indoor and outdoor dust around the WTC. Therefore, there is fair confidence this level should be protective.

Lead. The COPC Committee identified an applicable and relevant existing standard to set a health benchmark for lead in interior dust. The Residential Lead-Based Paint Hazard Reduction Act (Title X) Final Rule (40 CFR, Part 745, 1/5/01) established uniform national standards for lead in interior dust. Thus, both EPA and the United States Department of Housing and Urban Development (HUD) have set a dust standard for lead of 40 $\mu g/ft^2$ for floors (including carpeted floors) and 250 $\mu g/ft^2$ for interior window sills. To support the development of a dust standard EPA performed an analysis of the Rochester Lead-in-Dust Study (HUD, 1995). At 40 $\mu g/ft^2$ a multimedia analysis shows a 5.3% probability that a child's blood lead level would exceed 10 µg/dl. Thus, this standard meets the criteria established by EPA (i.e., 95% probability to be below 10 µg/dl) (EPA 1994a) for managing environmental lead hazards. However, the COPC Committee opted to set the benchmark at the more stringent HUD screening level of 25 $\mu g/ft^2$.

Silica. The crystalline silica benchmark presented in the draft COPC document was based on the OSHA Permissible Exposure Limit (PEL) for "dust containing quartz." This standard varies with the crystalline silica content of the dust and applies to dust

samples which may contain as little as 1% crystalline silica. Because this standard is for respirable dust, and varies by crystalline silica content, different conditions would yield different standards viewed either as total dust or effective silica concentration. For example, in the case where the dust is 100% crystalline silica, the standard is 100 $\mu g/m^3$. In contrast, in the case where a dust is 1% crystalline silica, the PEL is 3.3 mg/m^3 for respirable dust containing crystalline silica. Because only 1% of this total dust is crystalline silica, the effective crystalline silica concentration in this case is 33 $\mu g/m^3$. This OSHA standard is based on the 1969 ACGIH TLV value, adopted by OSHA in 1971. Subsequent follow-up to the original occupational cohorts on which this standard was based and other cohorts studied show mixed results. Some studies uphold the standard and others show a need to lower it. OSHA is considering a change. Because of the complicated nature of the data and sampling issues, OSHA has not yet decided on a new standard. And until such time, the PEL stands in effect.

However, both the ACGIH and National Institute of Occupational Safety and Health (NIOSH) have examined the data and have lowered their recommended exposure limits to 50 $\mu g/m^3$. This is based upon concern that there appears to be more silicosis in exposed cohorts than was recognized by the older recommendation. A recent review by NIOSH of their recommended exposure limit (REL) indicates that adverse health effects may be observed in workers exposed at or below the current REL (NIOSH 2002). However, technical concerns regarding the ability to reliably measure respirable crystalline silica in the workplace below the REL (see response to BENCH #9) prevent NIOSH from lowering their REL at this time (NIOSH 2002). Although not the quantitative basis for the current REL, NIOSH reviewed several health effects associated with chronic exposure to crystalline silica in the workplace including: silicosis, lung cancer, emphysema and chronic obstructive pulmonary disease. A threshold for these health effects has not been defined although some analyses do provide exposure response relationships and suggest a point of departure for observable health effects. Cumulative exposure, peak exposure, duration of exposure and latency time have all been positively related to adverse pulmonary health effects. In light of these considerations, the benchmark for silica is now being based on the NIOSH REL. (See the response to BENCH #9 for additional information on the derivation of the silica benchmark from the REL.)

Comment BENCH #3:

"For defining the different tiers, the panel recommended that Tier I benchmarks be based on a 1-year exposure, child exposure parameters, and where available, child-specific toxicological endpoints. The panel recommended that Tier III benchmarks be based on a 30-year exposure, where 6 years are based on child exposure parameters and 24 years are based on adult exposure parameters."

Response:

As discussed in our response to BENCH #1, the Tier III benchmark which has and continues to serve as a benchmark for long-term habitability of a residential dwelling, will be the focus of the revised COPC document. Benchmark criteria have been developed therefore to evaluate chronic (30-year) exposures only, with consideration of childhood exposure within that time frame. For the evaluation of residues on indoor surfaces, we factored in continuous age-specific exposure parameters from age 1 through 31. Appendix D in the final COPC document details the approach and exposure parameters used in deriving benchmark criteria for long-term exposures.

Child-specific toxicological criteria were considered where available (*e.g., lead*). As described in the responses to COPC #6, EPA's IRIS database served as the primary source for toxicity criteria most of which are based on animal and human data looking at adult exposures. The final COPC document will note this factor as an additional uncertainty in the process. However, we feel that the approach used relied on the best available science and risk assessment methodologies and enabled the generation of reasonably protective benchmark criteria. As stated earlier, development of child-specific toxicity criteria for screening COPC and setting health-based benchmarks is beyond the scope of this project.

Comment BENCH #4:

"Panel members disagreed with the rationale provided in the document for using an upper level excess lifetime cancer risk level of 1×10^{-4} in calculating the benchmarks for each tier. The panel noted that the sampling and analysis limitations described in the document for asbestos that limit the risk evaluation to a 1×10^{-4} risk level could be easily overcome and lower risk levels could be achieved for other COPC. The panel did not address specifically the risk management decision of whether using a 1×10^{-4} versus a risk level of 1×10^{-5} or 1×10^{-6} would be most appropriate."

Response:

The level of 10^{-4} lifetime risk was chosen on the basis of practical sampling limitations particular for *asbestos*. The level specified by the document, 0.0009 fibers/cc, is near the practical detection level given the large scope of the WTC Clean-up Program. The reviewers suggested that a somewhat lower risk, perhaps as low as 10^{-6}, might be achieved by compositing multiple samples. Measuring to a risk level of 10^{-6} requires 100 times more air volume per sample.

The detection limit for a sample varies based on the volume of air which passes through the filter, and/or by the number of grids (i.e., area) on the filter read by the microscopist. Resources, both human and financial, prohibited the analysis of additional filter grids as a means of lowering detection limits. Still, lower detection limits could be achieved by higher volumes of air. However, in order to lower the detection limit 10 fold (to target a 10^{-5} risk instead of 10^{-4} risk) 10 times the air would need to be drawn through the filter. So a sample would run for 80 hours instead of 8, assuming the volumetric flow rate (already at the high end of the recommended range) of the sample remains constant. Similarly, a risk level of 10^{-6} would require a sampling time of 800 hours. In addition to the logistical problems of running a pump in someone's home for such an extended time, there are additional technical concerns.

In urban atmospheres, there are many substances in the air other than *asbestos* fibers, which interfere with detection of *asbestos* in ways that increase with the volume of air sampled. *Asbestos* is unlike chemical species analysis where samples might be combined. Non-fibrous dust and other general particulate matter collect on the filter along with any asbestos fibers. This dust obscures fibers, and because *asbestos* fibers are counted manually on a known surface area of filter, this limits the detectable level of *asbestos*. The authors acknowledge that running multiple pumps concurrently, in theory, might mitigate overloading potential and reduce total sample time. The WTC Clean-up Program was set up such that every room in a residential dwelling (with a minimum of three samples) would need to meet the clearance criteria before the residence was deemed effectively cleaned. Given that more than 6,000 individual residences signed up for the cleaning test only program, the prospect of running multiple pumps to obtain a single sample was determined to be beyond practical implementation. Additional discussion in support of a 10^{-4} risk level for asbestos and other carcinogenic COPC is presented in Appendix C of the final COPC document.

Comment BENCH #5:

"The panel recommended that for some COPC, the authors should develop benchmarks for contaminants on hard surfaces and benchmarks for contaminants on soft surfaces, instead of just developing a single benchmark for contaminants in settled dust. The panel noted that, although there are limited data available in order to recommend soft-surface benchmarks, some methods for this have been developed to address exposure to pesticides. These methods could be applied to the WTC situation. The panel recommended that for each COPC, the document clearly analyze the chemical properties and the potential exposure pathways to that contaminant before determining whether an air, hard-surface, or soft-surface benchmark is needed."

Response:

The committee generally agrees with this comment and has modified the assessment procedures to explicitly consider differences in exposure to soft and hard surfaces. The revised procedure has been adopted from EPA's pesticide guidance (as suggested in the comment) and treats the surfaces differently in terms of degree of particle transfer to skin and contact time. The comment also implies that the clearance criteria for the two surfaces may differ. The assessment procedure assumes a residence has both soft and hard surfaces and the total exposure results from contact with both surfaces. For the sake of simplicity, the committee decided to set equal criteria for the two surfaces. Also as suggested in the comment, this procedure is applied on a chemical-by-chemical basis and considers chemical properties such as dermal absorption.

It should be understood, however, that the procedures for estimating exposure to surfaces is highly uncertain. The factors affecting surface loading and transfers to skin have not been well studied and are likely to be highly variable. These include:

- Surface characteristics affecting deposition and removal (e.g., porosity, roughness, static charge)
- Activity patterns related to surface contact.
- Surface cleaning techniques and frequency.

These uncertainties are highlighted in the final COPC document, both in the newly included section on uncertainties and limitations and in Appendix D.

Comment BENCH #6:

"The panel suggested that the document more clearly describe how mixture toxicology is being considered in developing benchmarks."

Response:

Benchmark criteria were developed on a contaminant-by-contaminant basis. The final COPC document will explain why this approach was taken and is considered health protective, as summarized below.

The COPC Committee clearly recognizes that the residents in Lower Manhattan are not exposed to environmental contaminants singularly, but instead to combinations of chemical and physical agents. Development of benchmarks, however, was driven by a combined consideration of individual COPC-specific toxicity, background levels, and practicalities and limitations related to sampling. Mixture toxicology was not factored into the derivation process because little or no quantitative dose-response data exist regarding specific interactions across the WTC COPC (*asbestos, dioxins, lead, PAHs, fibrous glass, and crystalline silica)*[1].

We feel the contaminant-specific approach is health protective for the following reasons:

- # The process for developing benchmarks based on non-cancer effects sets concentrations well below observed effect levels and generally at or near no-observed-adverse-effect levels (NOAELs). Presumably, exposures to one or multiple substances below or near the NOAEL will not result in adverse effects (EPA 2000b).

- # The likelihood of interactions are increased if substances behave similarly toxicologically. We therefore qualitatively examined the toxicology of individual COPC to review what is known about target organ toxicity, mode of action, and any documented chemical interactions among WTC COPC. Review of EPA's toxicological reviews (including the 2000 dioxin reassessment) and ATSDR's toxicological profiles revealed the following:

    - < Target organs and critical effects resulting from ingestion and dermal exposures generally differ across individual COPC, though *asbestos, lead, dioxins, and PAHs* are all considered potential human carcinogens via the ingestion route. Each of these contaminants can affect a wide range of biological systems, but each generally exerts its effects via different mechanisms.

    - < At high concentrations, inhalation exposure to several of the COPC (*asbestos, fibrous glass, and crystalline silica*), as well as the small particulate matter released during the WTC disaster, has been shown to result in point of contact toxicity to the lung. Specific lung effects vary across these substances, ranging from acute irritant effects produced by fibrous glass to cancers of the lung associated with asbestos. Again, although uncertainty exists due to the limited study of chemical mixtures, exposures to COPC at or below benchmark concentrations—which are set at levels significantly lower than observable effect levels—would not be expected to produce effects individually or in combination.

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[1]Note that combined effects within dioxin and PAH mixtures were accounted for in the development of benchmarks using toxic equivalency (TEQ) approaches that account for the relative potency of the components of these complex mixtures. Toxicity equivalent factors used in this approach are based on our understanding of the most toxic component of each mixture (i.e., 2,3,7,8-TCDD for dioxins and benzo(a)pyrene for PAHs).

One EPA study looking at acute airway effects in mice exposed to WTC fine particulate matter (2.5 microns) provides some insights to the magnitude of total dust exposures leading to observable effects. This study revealed that components of WTC dust promotes respiratory inflammation at "high" doses only (EPA 2002). This study does not evaluate the effects of long-term or repeated exposures to lower levels of WTC dust and is not directly useful in the development of benchmarks.

Comment BENCH #7:

"For the air benchmark for lead, the panel recommended incorporating local exposure loading data into the IEUBK model."

Response:

The draft COPC document utilized average background concentrations for multi-media sources of *lead* based on national data for lead in drinking water, diet, soil and indoor dust as input parameters for the IEUBK Lead Model. As per the peer review recommendations, local data was researched for site-specific input parameters. The discussion below details the source, analysis and application of these data.

EPA developed the Integrated Exposure Uptake Biokinetic (IEUBK) Lead Model (EPA 1994) to evaluate multimedia *lead* exposure to children in residential settings. EPA established a goal of attaining a 95% probability that blood lead levels in children be less than 10 µg/dl (EPA 1994a). To meet the aforementioned goal, The IEUBK Lead Model was run using multimedia input parameters that are applicable to the residential community in Lower Manhattan. The following discussion details the basis for individual input parameters.

Lead in Drinking Water - The source of NYC's drinking water (the Catskill/Delaware and Croton systems) is remarkably low in lead. The average lead concentration is 1 µg/l in the Catskill/Delaware system and <1 µg/l in the Croton system (NYCDEP - Drinking Water Quality Test Results, 2001 - see www.nyc.gov/dep). However, the concentration of lead in tap water can be increased by lead containing components (pipes, solder) of a building's distribution system. Consequently, the Safe Drinking Water Act "Lead and Copper Rule" (Federal Register, June 7, 1991) requires large water systems to monitor led concentration at the tap. If more than 10% of the samples exceed the federal "Action Level" of 15 µg/l, corrective steps (e.g., source treatment, corrosion control) must be carried out. The IEUBK Lead Model is intended to run with input values that represent the average lead concentration in the environmental media of interest. As reported by NYCDEP, 2001, the median lead concentration from a total of 107 samples obtained at the tap was 3 µg/l. It should be noted that these samples represent a high bias in that they were obtained from homes where there is reason to believe that lead service lines exist. The median lead concentration in tap water city-wide is likely to be lower. However, for the purpose of this site-specific application of the IEUBK Lead Model, a value of 3 µg/l is used as a conservative central tendency estimate of lead in tap water.

Lead in Diet - No data could be located relating to the lead content in food items for residents living in Lower Manhattan. Since there is very little home gardening taking place in this community it was deemed appropriate to use data that reflects national trends for commercially available food items. EPA recently evaluated dietary lead content in children in support of revising default input parameters for the IEUBK Lead Model (EPA 2002). Lead residues in food were obtained from the Food and Drug Administration's (FDA's) Total Dietary Survey. Food consumption trends were obtained from the National Health and Nutrition Examination Survey (NHANES) . The average lead content in the diet of children 0 - 7 years old is 2.8 µg/day. Consequently, the input value of 2.8 µg/day was employed as the estimate of average daily lead intake from diet.

Lead in Soil - Numerous studies have been conducted to evaluate soil and street dust lead concentrations in New York City (NYCDOHMH, 2003). In the studies reviewed, soil/dust samples were taken by a variety of methods over a long period of time (1924 - 1993). Summary statistics were compiled by the NYCDOHMH based on whether the studies assessed known lead sources or background conditions. Ruling out studies on specific sources such as bridges, a median soil lead concentration of 200 ppm and street dust lead concentration of 895 ppm was reported. Data are lacking with regard to the relative contribution of street dust to a child's daily "soil" intake. Given this uncertainty, the median values of soil and dust were averaged to provide a composite soil/dust concentration of 548 ppm. This value was used as the soil lead concentration in the site-specific application of the IEUBK Lead Model

Lead in Indoor Dust - Although there exists a substantial amount of lead "load" data (i.e., mass per unit area - typically recorded in units of micrograms per square foot as per HUD reporting requirements) as a measure of lead contamination in residential dwellings, the IEUBK Lead Model requires lead concentration in settled dust to be reported in terms of concentration (i.e., mass per unit mass - typically recorded as parts per million). The WTC Background Study reported lead in house dust both in terms of lead load ($\mu g/ft^2$) and concentration (ppm) although more limited sampling was obtained of lead concentration (ppm) measurements. Nonetheless, because these data were specifically intended the assess background conditions in Lower Manhattan, they were used in the site-specific application of the IEUBK Model. The mean concentration of lead in settled dust in the WTC Background Study was 126 ppm (EPA 2003a). Consequently, this was the value used for lead in indoor dust for the site-specific application of the IEUBK Lead Model.

Site specific application of the IEUBK resulted in a reduction of the *lead* benchmark for indoor air form 1 $\mu g/m^3$ to 0.7 $\mu g/m^3$. See Appendix E of the final COPC document for data input spreadsheets and graphic display of model results.

Comment BENCH #8:

"The panel did not endorse the asbestos settled dust benchmark because the only relevant exposure pathway for asbestos is inhalation and K-factor methodology is, at this time, inadequate for predicting inhalation exposure from asbestos surface loading measurement. However, the panel did note that settled asbestos is a potential source of airborne asbestos if disturbed or not remediated."

Response:

The comment addresses the use of K-factors in the draft COPC document to derive Tier I benchmarks for *asbestos and fibrous glass* in settled dust. As our response to comment BENCH #1 indicates, we are now assigning one health-based benchmark to each COPC, rather than using three tiers of benchmarks for each contaminant. As per the peer review recommendations, the benchmarks for *asbestos and fibrous glass* in the final COPC document have been developed only for indoor air, and reflect an environmental risk-based paradigm and modified occupational standards, respectively. None of the benchmarks in the final COPC document are based on the K-factor methodology. The COPC Committee agrees with observations made by members of the peer review panel that due to the numerous factors that influence the relationship between fiber concentration in settled dust and indoor air, including surface porosity, activity patterns, air exchange rates and interior volume, benchmarks for *asbestos and fibrous glass* in settled dust should be omitted. Our responses to comments

BENCH #2 and BENCH #9 further discuss the rationale behind the final set of health-based benchmarks.

Comment BENCH #9:

"For setting benchmarks based on occupational standards, duration-based adjustment factors should be used that weigh chemical-specific issues. Specifically, the panel suggested that a duration adjustment of 4.2 is typical to extrapolate from occupational to environmental exposure, and that additional adjustments of 10 or 100 (for a total factor of 42 or 420) may be needed to address the underlying, chemical-specific biological factors (toxicokinetics and toxicodynamics)."

Response:

The comment applies to benchmarks based on occupational standards. The draft COPC document used such standards to derive benchmarks for *fibrous glass and silica*. Our responses to this comment for these two COPC follow:

- *Fibrous glass.* Although the TLV is based on irritant effects the resulting benchmark of 0.01 f/cc is believed to be protective for chronic residential exposure for glass and mineral wool. In developing the three tiered approach initially designed to prioritize and define the level of response needed in different environments surrounding the WTC area, the committee worked from the existing TLV. Anything above the TLV was not considered acceptable for residential use. The TLV was adjusted by a factor of ten for each Tier resulting in a total adjustment of 100 for the Tier III level. The committee did not specifically apportion this adjustment as a duration adjustment or an adjustment for application to a non-worker population. Although this total adjustment of 100 could be considered to cover the 4.2 duration adjustment, and an adjustment above that for application to non-worker population, there is considerable variation in how this second adjustment may be set. The Peer review committee itself recommends a range between 10 and 100 resulting in a total adjustment between 42 and 420. The question is not so much can we assign a specific number for the adjustment which is accurate, but rather is the resulting standard protective.

  Fibrous glass less than 3 microns in diameter are respirable and available to enter and deposit in the pulmonary regions of the lung (ACGIH 2001). Clearance of these fibers from the lung will be determined by fiber solubility and length (ACGIH 2001; ATSDR 2002a). Fibers cleared from the lung have less potential to create long-term health effects. Less soluble materials have a longer residence time in the lung and therefore have a greater potential to contribute to tissue damage or malignant disease. Within synthetic vitreous fiber (SVF) types, glass fibers and slag wool are considered the most soluble, and therefore least toxic. Mineral wool is less soluble than glass wool. The fibers observed in indoor and outdoor dust samples from the WTC area contained glass wool and mineral wool, both of which have lower biopersistence than other forms of synthetic vitreous fibers.

Although some animal studies have demonstrated both fibrotic and carcinogenic potential for glass and mineral wools (ACGIH 2001; ATSDR 2002a; IARC 1988), more recent studies do not fully support this finding.[2] Epidemiologic studies on workers exposed to fibrous glass do not provide consistent evidence of pulmonary effects, although some effects were noted (ATSDR 2002a; Bonn et al. 1993). Similarly, when assessing deaths due to lung cancer in workers exposed to glass wool, studies do not provide strong evidence for increased risk of cancer deaths attributable to the glass wool exposure.

The carcinogenic potential of fiberglass has been reviewed by several agencies. The IARC originally classified both glass and mineral wools as Group 2B carcinogens, possibly carcinogenic to humans, based on animal studies (IARC 1987). Similarly these materials were classified as carcinogens by the National Toxicology Program and the American Conference of Governmental Industrial Hygienists (ACGIH 2001; NTP 2001). However a review of the carcinogenic potential of these fibers by IARC in 2001, which takes into account updated human studies, animal inhalation studies, and mechanistic studies, recommends a change in this classification. The IARC has announced that the recent monograph designates both glass and mineral wool as Group 3, unclassifiable as to carcinogenicity in humans, because of inadequate evidence of carcinogenicity in humans and the relatively low biopersistence of the materials.

In contrast, the less soluble, and more biopersistent refractory ceramic fibers, are still considered potentially carcinogenic and are believed to more toxic than glass and mineral wools. A recent review of the toxicity of synthetic vitreous fibers by ATSDR proposes a Minimal Risk Level for chronic exposure of 0.03 f/cc for these refractory ceramic fibers (ATSDR 2002b). Although ATSDR did not set MRLs for glass and mineral wools, it notes that “insulation wools are markedly less durable and less potent than refractory ceramic fibers.” Therefore the benchmark of 0.01 f/cc for glass and mineral wools, which is lower, should be considered protective.

Silica. In response to other peer review comments on this document, as well as the current stage of clean-up and assessment projects ongoing in Lower Manhattan, it has been decided to remove the tiered approach provided to screen and prioritize clean-up and response efforts. Therefore the only benchmark needed for crystalline silica is that which would be protective for the general public in a chronic exposure scenario. No threshold has been established and it is possible health effects occur below the NIOSH REL of 50 :g/m3. Although duration adjustments and uncertainty factors can be applied to this REL to develop a benchmark for residential exposure, the resulting level would be well below practical sampling limits. Therefore this committee is recommending a benchmark of 5 :g/m^3, which is the lowest amount that can be reliably reported in a reasonable sampling time.

The level of this benchmark is technically limited by sampling constraints, including time and weight loading. It is based upon a reporting limit of 10 micrograms of crystalline silica with no more than about 3 milligrams of total dust on a single filter. (A reporting limit is the smallest amount of a substance for which a quantitative value can be

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[2]Early studies often relied upon injection and implantation studies, which may not accurately predict a pulmonary response from inhalation exposures. A review of inhalation studies indicates that glass wool did not cause pulmonary fibrosis or lung cancer in these animal studies (Bonn et al. 1993). A recent study by Hesterberg indicates no increase in pulmonary fibrosis or lung cancer even at doses of 222 f/cc, although cancer incidence in control animals was considered high.

determined.) More than about 3 milligrams of dust on the filter will decrease analytical sensitivity. Collection of 2 cubic meters of air over about 20 hours for a Dorr-Oliver cyclone at 1.7 L/min or about 13.3 hours using an SKC cyclone at 2.5 L/min will provide sufficient sensitivity to measure 5 µg/m^3 crystalline silica so long as the total dust weight on the filter does not exceed about 3 milligrams (an airborne dust concentration of 1.5 mg/m^3). Using either the nylon Dorr-Oliver or SKC Aluminum Cyclones, the following limits are possible:

Sampling Equipment (Size selection cyclones)	Duration of sampling	Volume of air (m^3)	Effective reporting limit (µg/m^3)
Dorr-Oliver (OSHA) at1.7 L/min	6 hours (360 min)	0.61	16.3
	8 hours (480 min)	0 .81	12.3
	10 hours (600 min)	1.02	9.8
	19.6 hours (1176 min)	2.0	5.0
SKC Aluminum (NIOSH) at 2.5 L/min	6 hours (360 min)	0.9	11.2
	8 hours (480 min)	1.20	8.4
	10 hours (600 min)	1.5	6.7
	13.3 hours (800min)	2.0	5.0

IV. References

American Conference of Governmental Industrial Hygienists (ACGIH). 2001. TLV Documentation: Manmade Vitreous Fibers (MMVF), 2001.

ATSDR. 1998. Toxicological Profile for Chlorinated Dibenzo-p-dioxins. Atlanta: U.S. Department of Health and Human Services. December 1998.

ATSDR 2000. Toxicological Profile for Arsenic. Atlanta: U.S. Department of Health and Human Services. September 2000.

ATSDR. 2001. Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures. Draft for Public Comment. Atlanta: U.S. Department of Health and Human Services. February 2001.

ATSDR. 2002a. Technical Briefing Paper: Health Effects from Exposure to Fibrous Glass, Rock Wool or Slag Wool. Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, Atlanta, GA. 2002.

ATSDR 2002b. Toxicological Profile for Synthetic Vitreous Fibers. Atlanta: U.S. Department of Health and Human Services. September 2002.

Bonn WB, Bender JR, et. al. 1993. Recent Studies of Man-made Vitreous Fibers: Chronic Animal Inhalation Studies. J Occup Med. 1993;35(2):101-113.

COPC 2002. World Trade Center Indoor Air Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks. Peer Review Draft. Prepared by the Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Task Force Working Group. September 2002.

COPC 2003. World Trade Center Indoor Environment Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks. Final Report. Prepared by the Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Task Force Working Group. May, 2003.

EPA 1980. Man-Made Vitreous Fibers and Health, In Proceedings from the Natrional Workshop on Substitutes for Asbestos. USEPA, EPA/560/3-80-001.

EPA 1986. EPA's Guidelines for the Health Risk Assessment of Chemical Mixtures. EPA/630/R-98/002. September 1986.

EPA 1989. Risk assessment guidance for Superfund. Volume 1. Human Health Evaluation Manual (Part A). Interim Final. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA/540/1-89/002. Washington D.C.

EPA 1992. Dermal Exposure Assessment: Principles and Applications. Interim Report. U.S. Environmental Protection Agency, Office of Health and Environmental Assessment. EPA/600/891/001/B.

EPA 1994. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model in Children. Office of Emergency and Remedial Response. EPA/540/R-93/081 Washington D.C.

EPA 1994a. Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities. OSWER Directive 9355.4-12. Washington D.C.

EPA. 1997a. Health Effects Assessment Summary Tables. FY 1997 Update. EPA-540-R-97-036. July 1997.

EPA 1997b. Exposure Factors Handbook. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. EPA/600/P-95/002Fa. August 1997.

EPA 2000a. Science Policy Council Handbook: Peer Review. U.S. Environmental Protection Agency, Office of Science Policy. EPA 100-B-00-001. December 2000.

EPA. 2000b. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. Risk Assessment Forum Technical Panel. EPA/630/R-00/002. August 2000.

EPA. 2000c. Draft Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Office of Research and Development.

EPA. 2001a. Science Advisory Council for Exposure. Policy Number 12 on Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Revised: February 22, 2001.

EPA. 2001b. Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment). Review Draft. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response EPA/540/R/99/005.

EPA 2002. IEUBK Dietary Intake Update. (Revised Draft, 12/02) Technical Review Workgroup for Lead. OSWER Washington D.C.

EPA. 2002a. Child-Specific Exposure Factors Handbook (Interim Report). U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. EPA-600-P-00-002B. September 2002.

EPA. 2002b. Toxicological Effects of Fine Particulate Matter Derived from the Destruction of the World Trade Center. National Health and Environmental Effects Research Laboratory. December 2002.

EPA 2003. Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens. External Review Draft. EPA/630/R-03/003. February 2003.

EPA 2003a. World Trade Center Residential Confirmation Cleaning Study (Draft Report, March 2003). USEPA Region 2, New York, NY.

EPA 2003b. World Trade Center Background Study (Draft Report, March 2003) USEPA Region 2, New York, NY.

Heisel EB and Hunt FE. 1968. Further Studies in Cutaneous Reactions to Glass Fibers. Arch Env Health. 1968;17:705-711.

HUD 1995. The Relation of Lead-Contaminated House Dust and Blood Lead Among Urban Children. Final Report to USHUD from the University of Rochester School of Medicine (Rochester, NY) and the National Center for Lead Safe Housing (Columbia, MD).

International Agency for Research on Cancer (IARC). nd. IARC Monographs Program Re-evaluates Carcinogenic Risks from Airborne Man-Made Vitreous Fibers, International Agency for Research on Cancer, World Health Organization, Lyon, France.

International Agency for Research on Cancer (IARC). 1987. Monograph Asbestos (Actinolite, Amosite, Anthophyllite, Chrysotile, Crocidolite, Tremolite), in IARC Monographs of the evaluation of carcinogenic risks to humans, International Agency for Research on Cancer, World Health Organization, Lyon, France 1987;Supp 7:106.

International Agency for Research on Cancer (IARC). 1988. Monograph on Man-Made Mineral Fibers, in IARC Monographs of the Evaluation of Carcinogenic Risks to Humans. International Agency for Research on Cancer. World Health Organization. Lyon, France. 1988;43:39.

Kim NK and Hawley J. 1985. Re-Entry Guidelines: Binghamton State Office Building. New York State Dept. of Health, Bureau of Toxic Substances Assessment, Division of Health Risk Control. Albany, NY. August. Document 0549P.

Lioy P, Wiesel CP, Millette JR, Eisenreich S, Vallero D et al. 2002. Characterization of the Dust/Smoke Aerosol that Settled East of the World Trade Center (WTC) in Lower Manhattan after the Collapse of the WTC September 11, 2001. Environ. Health Perspectives. July 2002;110(7):703-14.

Michaud JM, Huntley SL, Sherer RA, Gray MN, and Paustenbach DJ. 1994. PCB and Dioxin Re-entry Criteria for Building Surfaces and Air. Journal of Exposure Analysis and Environmental Epidemiology; 4(2):197-227.

Milette JR, Hays SM. 1994. Settled Asbestos Dust Sampling and Analysis. Lewis Publishers. New York

National Toxicology Program (NTP). 2001. Glasswool in Report on Carcinogens, 9th Edition. U.S. Department of Health and Human Services, National Toxicology Program, Research Triangle Park, NC. 2001.

NIOSH 2002. National Institute of Occupational Safety and Health. Health Effects of Occupational Exposure to Respirable Crystalline Silica. NIOSH # 2002-129. US Departmnet of Health and Human Services.

New Jersey Department of Environmental Protection (NJDEP). 1993. Technical Basis and Background for Cleanup Standards for Contaminated Sites. N.J.A.C. 7:26D (Draft).

NYCDOHMH 2003. Personal Communication with Ken Carlino - Lead Program. New York City Department of Health and Mental Hygiene. New York, NY.

Radian International (Radian). 1999. Development of Risk-Based Wipe Sample Cleanup Levels at the Claremont Polychemical Superfund site in Old Bethpage, New York. Prepared for the U.S. Army Corps of Engineers.

Stam-Westerveld EB, Coenraads PJ, Van Der Valk, et.al. 1994. Rebbing Test Response of the Skin to Man-Made Vitreous Fibers of Different Diameters. Contact Dermatitis 1994;31(1):1-4.

TERA 2003. World Trade Center (WTC) October 21–22, 2002, Peer Review Meeting Notes. Prepared by Toxicology Excellence for Risk Assessment. Prepared for the U.S. Environmental Protection Agency. February 7, 2003.

WHO. 1998. Environmental Health Criteria 205. Polybrominated Dibenzo-p-dioxins and Dibenzofurans.