Report of the Independent Expert Review Panel Meeting for the Sudbury Area Human Health Risk Assessment

September 20-21, 2006
Collège Boréal
Sudbury, Ontario

Peer Review Organized by
Toxicology Excellence for Risk Assessment
(http://www.tera.org/peer/)

December 20, 2006

NOTE

This report was prepared by scientists of *TERA* and reviewed by the Independent Expert Review Panel (IERP) members. The members of the panel served as individuals on this panel, representing their own personal scientific opinions. They did not represent their companies, agencies, funding organizations, or other entities with which they are associated. Their opinions should not be construed to represent the opinions of their employers or those with whom they are affiliated.

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Executive Summary

An Independent Expert Review Panel (IERP) met in Sudbury Ontario on September 20-21, 2006 to review the Sudbury Area Human Health Risk Assessment (Sudbury HHRA). The Sudbury Soils Study and human health and ecological risk assessments have been undertaken to determine if there are unacceptable human health or ecological risks associated with metal and arsenic levels present in the Sudbury, Ontario area. The assessment was prepared by the Sudbury Area Risk Assessment (SARA) Group. Based on the available information for Sudbury, the study will provide a measure of the risk level from metals and arsenic in soils, and may determine site-specific soil guidelines for the Sudbury area.

The purpose of the meeting was for a panel of experts to provide a comprehensive evaluation of the science and conclusions of the human health risk assessment. The panel of seven experts collectively had experience in multimedia and site assessments, toxicology of metals and arsenic, bioavailability, environmental geochemistry, metal(loid) speciation in soils and mine waste, and mineralogical analysis, probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dust, and the calculation of soil clean up goals. The peer review meeting was organized by Toxicology Excellence for Risk Assessment (*TERA*), who selected the independent experts on the panel.

The panel reached consensus that the overall approach used for the Sudbury HHRA was generally consistent with common practice, drew upon the best and most appropriate procedures from various jurisdictions, and focused on current and future risk to the Sudbury population. There were areas however, where the assessment used different approaches and the panel commented on the appropriateness of the chosen approaches. The panel found the environmental data collection to be an extensive effort that provided community-specific data to use instead of defaults. The conceptual model was well done and exposure pathways of concern properly identified. The panel identified numerous areas of the report that would benefit from a clearer presentation of information.

The panel thought that the study's objectives – to look at health risks currently present for future and existing exposure conditions were addressed. The panel recommended a better description and justification for selection of the chemicals of concern, consideration of several additional sources of exposure to the chemicals of concern, and a more complete explanation for the communities of interest and resulting exposure point concentrations.

The panel discussed the input data and assumptions, the sources of the data, and the strength of the support for their use. The panel concluded that most of the data and assumptions used were appropriate (and appropriately conservative) for the stated objective of the study. For a few of the inputs, the panel suggested alternatives or recommended further investigation to determine the best data or assumptions to use. The panel recommended the authors more clearly present the data used to determine the reasonable maximum exposure and central tendency exposure estimates.

The panel thought that overall the calculations of exposure and risk associated with metals from sources of concern (i.e., smelting and mining) are health protective. Given the approach taken and the assumptions, the risk of adverse health effects is likely to be lower than what is

calculated in this report. The estimates are health protective in that they would be more likely to overestimate risk than underestimate risk, as is the intent of a risk assessment. If the panel recommendations are followed, the accuracy and usefulness of the study for making risk management decisions will be improved. The panel recommended that the details of the assessment and underlying data selections need to be more clearly described in the human health risk assessment report. In communicating the results to the public, the panel thought it very important that the authors clearly explain how much exposure and resulting risk is from the mining and smelting activities, and how much is from background sources, such as market foods, common to all Ontario residents.

1. Participants

Authors and Presenters

Sudbury Area Risk Assessment (SARA) Group

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[1] Affiliations are listed for identification purposes only. Panel members served as individuals on this panel, representing their own personal scientific opinions. They did not represent their companies, agencies, funding organizations, or other entities with which they are associated. Their opinions should not be construed to represent the opinions of their employers or those with whom they are affiliated.

Dr. Joyce S. Tsuji
Exponent

Observers

A list of observers is found in Appendix A.

2. Background

This peer review meeting has been organized by Toxicology Excellence for Risk Assessment (*TERA)*. *TERA* is an independent non-profit organization with a mission to protect public health through the best use of toxicity and exposure information in the development of human health risk assessments. *TERA* has organized and conducted peer review and consultation meetings for private and public sponsors since 1996 (see www.tera.org/peer for information about the program and reports from meetings). The purpose of this peer review is to have a panel of experts carefully evaluate the science and conclusions of the human health risk assessment. The Sudbury Soils Study and human health and ecological risk assessments have been undertaken to determine if there are unacceptable human health or ecological risks associated with metal and arsenic levels present in the Sudbury area. Based on the available information for Sudbury, the study will provide a measure of the risk level from metals and arsenic in soils, and may determine site-specific soil guidelines for the Sudbury area.

The human health and ecological risk assessments were prepared by the SARA Group, which consists of scientists from Cantox Environmental Inc., Gartner Lee Limited, SGS Lakefield, Goss Gilroy Inc., RWDI, 4DM, Frontline Communications, and Lesbia Smith, MD. The Study is overseen by a Technical Committee, comprised of Inco Ltd. and Falconbridge Ltd., the Ontario Ministry of the Environment, the Sudbury & District Health Unit, the City of Greater Sudbury, and the First Nations and Inuit Health Branch of Health Canada. Inco Ltd. and Falconbridge Ltd. have paid for the risk assessment and this peer review.

The independent peer review panel included seven scientists who have expertise in the key disciplines and areas of concern. Each panelist is a well-respected scientist in his or her field. Collectively, the panel has expertise in multimedia and site assessments, toxicology of metals and arsenic, bioavailability, environmental geochemistry, metal(loid) speciation in soils and mine waste, and mineralogical analysis, probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dust, and the calculation of soil clean up goals. *TERA* was solely responsible for the selection of the panel members. Each panel member has disclosed information regarding potential conflicts of interest and biases related to the Sudbury Soils Study and its sponsors. *TERA* carefully evaluated these disclosures when selecting panel members and selected a panel without conflicts of interest. Short biographical sketches and disclosure statements for panel members are provided in Appendix B.

The panel met in Sudbury Ontario on September 20-21, 2006. The panel received the review package approximately two months prior to the meeting to ensure adequate time to carefully

review the document and prepare for the meeting discussions. Materials sent included Volume I– Background, Study Organization and 2001 Soils Survey and Volume II – Human Health Risk Assessment (Parts A and B). Review materials also included compact discs, including data and reports from the soil surveys, and sub appendices for Part B (appendices). *TERA* developed a "charge to peer reviewers" document that outlined the key questions and scientific issues that need to be discussed by the panel in order to evaluate the quality and completeness of the risk assessment. A copy of the charge is found in the meeting materials document found in Appendix B.

A *TERA* scientist drafted this meeting report. Its purpose is to summarize briefly the panel's discussions and recommendations. The report was reviewed by the panel members prior to finalization. The meeting report serves as a record of the peer review and assists the authors in making revisions to their assessment.

3. Introductions, Conflict of Interest, and Meeting Process

The meeting began with brief panel introductions and a discussion of conflict of interest and bias issues. No panel members had conflicts of interest or biases. The discussion then addressed the four broad areas of the assessment: data collection and site characterization, exposure assessment, hazard assessment, and risk characterization. To start each discussion section, the SARA Group made a short presentation. Copies of the slides used for these presentations are found in Appendix C. Dr. Dourson, the panel chair, explained that panel discussions would be structured around the issues and questions addressed by the Charge to Peer Reviewers (located in Appendix B).

Members of the Technical Committee and Public Advisory Committee were invited to observe the panel meeting process. As the purpose of the IERP meeting is to have the expert panel discuss the assessment and reach conclusions on the science and the quality, the discussions were limited to the panel members. To ensure the panel's independence, observers were asked to refrain from discussing the assessment or related issues with the panel members.

4. Panel Discussion

The IERP panel's discussions were organized around the questions and issues posed in the "Charge to Reviewers" in four areas: Data Collection and Site Characterization; Exposure Assessment, Hazard Assessment; and Risk Characterization (a copy of the charge may be found in Appendix B). The meeting then concluded with the panel discussing their overall conclusions and recommendations. These discussions are summarized below by section. Within each section, the numbered charge questions are presented in bold text and the panel's specific conclusions and recommendations are found in the text boxes.

4.1 Data Collection/Site Characterization

1. Have all appropriate Chemicals of Concern (COC) been included in the risk assessment?

- The panel recommended that the authors clearly identify the objective criteria that were used to screen the data to determine which metals should be carried forward, and to provide the rationale for each selection or exclusion. In particular, the panel thought that the selection of chemicals of concern for a human health risk assessment is more appropriately based upon human health criteria and information rather than ecologically-based criteria. The panel noted that in some cases, chemicals with few exceedences were chosen as chemicals of concern, while other chemicals with more exceedences were not chosen.
- The panel questioned whether selenium would have been selected if human health criteria were used rather than ecological criteria.
- The panel recommended expansion of the discussion on other metals that might be enriched in the area from the local geology or due to mining and smelting activities. These are metals that are beyond the generic set usually monitored. Panel members did not have particular concerns about specific metals, but recommended that a fuller discussion be included to assure the reader that the suite of metals examined was adequate and that any unique characteristic of the area would not dictate further chemicals of concern.
- The panel identified mercury, manganese, uranium (chemical or non-radiological properties), and cadmium as possible additional chemicals of concern. The panel recommended that the authors evaluate the data for these chemicals against their objective selection criteria (including human health criteria) and make a determination if any of these chemicals should be included.

The panel made a number of recommendations regarding selection of chemicals of concern. The panel recognized that the SARA Group was provided with selection criteria and a list of chemicals from the Technical Committee; but thought that additional explanation is needed in the HHRA regarding the selection of chemicals of concern. The panel members thought it inappropriate to use ecological screening criteria for chemicals of concern for a human health risk assessment; criteria for screening should have been based on human exposure and health effects.

The panel members recognized the difficulty for the authors having to use pre-determined criteria from the Technical Committee for chemical selection, but suggested several additional chemicals should be evaluated for completeness of the analysis. The panel recommended that the authors clearly describe the criteria used to evaluate potential chemicals of concern and discuss the rationale for each chemical's inclusion or exclusion.

Panel members discussed the potential for mercury to be a chemical of concern. For mercury, the panel noted that the key question is whether there is a net input from smelter operations that

adds to the environment levels and could lead to an increased human health risk in the population. A panel member pointed out that if mercury is emitted from the smelters, levels are likely to be declining due to declining emissions. Panel members were concerned about mercury because inorganic mercury emissions may be transformed to methyl mercury (e.g., in lake sediments) and that methyl mercury is of particular concern for the fetus because of its neurotoxicity. The SARA Group indicated that mercury had not been measured directly in soils or air for this study. While it had not been considered as a chemical of concern, it was measured in fish tissue and biota and the levels were fairly low. Metals were not measured in lakeshore sediments for this study, but there are some data available for mercury. Previous studies have shown that mercury in Sudbury area fish was inversely related to distance from the smelter. The SARA Group thought that this might be due to the presence of selenium. Panel members noted that selenium may reduce the toxic effect of mercury but does not reduce the level of mercury measured in fish. Panel members thought that airborne transport of mercury on fine particles could account for greater deposition further from the smelter than closer to the smelter as a result of settling patters and particle sizes. However, it is uncertain whether the observed relationship is related to selenium interactions, particulate bound mercury deposition, acidity or other factors such as a higher natural level of mercury in soil and sediment further away from the plant. Another panel member noted that fish measurements indicate whether a current exposure pathway is a concern, and the sediment will tell you if there will be future exposure pathways, but given the low levels of methyl mercury in inner lakes and reduction in emission over time, basing a decision on current information would be sufficient.

A panel member thought that manganese was eliminated prematurely and did not agree with the authors' rationale for exclusion (that it is normally present in the environment, is essential, and there are no Ontario Ministry of the Environment (MOE) criteria to screen it with). The panel recommended the authors use the United States Environmental Protection Agency (US EPA) Integrated Risk Information System (IRIS) human health values to screen manganese levels (U.S. EPA, 2006). After the meeting, two panel members provided clarifying information regarding the IRIS manganese reference dose (RfD).

> The IRIS RfD for manganese is based on exposure via food. IRIS recommends that a modifying factor of 3 be applied to this RfD when assessing exposure via water or soil (see section 1.A.3. or IRIS entry). If one were to go "by the book", one would use the non-food RfD and screening levels when assessing soil. That being said, an argument could be made for using the food RfD value. In the IRIS file, the discussion regarding the modifying factor is based on a concern that unfasted people absorb more manganese via water than food. This is a reasonable concern. However, it is highly unlikely that a person would absorb more manganese from soil than from food. Soil has mineral constituents such as iron and calcium and organic matter, which would tend to bind manganese and reduce gastrointestinal absorption. Another panel member clarified that the issue is not whether manganese is ingested in food or in water, it is whether there is food in the digestive tract when manganese is ingested. The bioavailability of manganese ingested in water, with a meal, is lower than when manganese is ingested in water during a fast. Thus, bioavailability of manganese ingested in water (and, possibly, soil) can be expected to be a function of the temporal patterns of water ingestion and meal consumption.

A panel member noted that uranium (primarily U-238) is found elsewhere in parts of Ontario at high levels where there is emergent Canadian Shield (e.g., Tweed, Ontario). The panel member noted that U-238 will accumulate in the kidney and it is the chemical properties (not radiological properties) that are a potential concern. Cadmium also affects the proximal tubules of the kidney and that the authors should consider the potential for additive health effects if both cadmium and uranium exposures occur concurrently.

2. **Were the appropriate types of data and analyses necessary to assess the extent of contamination collected and performed, and did they adequately characterize the distribution and concentration of COCs in each of the media of interest?[1] [pages 5-8]**

   Footnote[1] For example - Was the sampling (e.g., soil surveys, air monitoring, etc.) designed and conducted in a way to adequately characterize the distribution and concentration of COC in each of the media of interest? Were the appropriate major data gaps identified and have the relevant media been tested or estimated? Is there an adequate description of the sampling methodologies and did they follow a standard method? Were the methods appropriate for Sudbury? Do the study reports include a description of quality assurance and quality controls measures for each study?

- The panel was very impressed by the extensive data collection from the relevant media and potential exposure sources.
- The panel identified several additional sources to be considered in the assessment.
  - The panel recommended that the authors address attic dust more thoroughly, and, in particular, explain why it was excluded as a potential source of exposure, and implications of the exclusion (e.g., potential exposures resulting from remodeling, etc). The panel did not recommend sampling of attic dust.
  - Outdoor surface dust should also be addressed as it is an exposure pathway of particular concern for children and because it can affect remediation decisions. The panel recommended several possible approaches - comparing indoor dust samples from near and remote areas from smelting operations, obtaining and analyzing outdoor surface dust samples, or obtaining dust fall data from the companies, if it is available.
- The authors should clarify how background exposure levels were determined and used in the HHRA.

Panel members thought that the data collection efforts were very extensive and appropriate. They thought that attic dust can be a potential source of exposure and could reflect historic deposition. The SARA Group indicated that attic dust was not sampled or analyzed and that they excluded this source from the assessment due to its intermittent and short-term exposure. Panel members noted that if an attic is accessed infrequently it will be an insignificant source, but attic dust can be a more significant source if remodeling is done that introduces the attic dust to the living space.

A panel member stated that the current methodologies for site assessments do not consider outdoor dust and there is no simple way to include it; but it is important for sites with operating

smelters. SARA authors indicated that outdoor dust had not been directly measured, but they had assumed it was re-suspended and captured with the soil samples. The panel member noted that outdoor dust is an important potential route of exposure from hand-to-mouth transfer, not re-suspension, particularly for children playing outdoors. At sites without an operating smelter, the outdoor dust concentration will be similar to soils and represent the historic deposition. However, with an operating smelter, outdoor dust levels are replenished and knowledge of these levels is important for remediation considerations. A panel member noted that outdoor dust information can also shed light on biomonitoring results, but went on to say that in this case the urinary arsenic results in Sudbury indicate that an additional significant exposure source is not likely. The panel recommended several possible approaches that could be used for evaluating outdoor dust - comparing indoor dust samples from near and remote areas from smelting operations (consider particle size), obtaining and analyzing outdoor surface dust samples, or obtaining dust fall data from the companies, if it is available.

Panel members were concerned about the depth of background soil samples, noting that soil concentrations at depth are not representative of background surface levels, that human activity could result in contamination at depth as well as natural processes that can cause elements to move in a soil profile, and that the soil at the depths used may also be very low in organic matter and dissimilar from surface soil. Surface soil typically may contain higher metals concentrations than at depth even with no anthropogenic sources because organic matter would tend to bind metals. The SARA Group authors clarified that the HHRA used Ontario typical background concentrations from MOE data for exposure to the chemicals of concern and did not use the measurement of soils at depth to represent background. They had not found any distinctive difference between what was measured in Sudbury and Ontario typical, and therefore used Ontario typical. In further discussion of the soils study, the authors noted that the soils were screened to 355 microns (per MOE guidance) and that the concentration in this fine fraction is what was used in the risk assessment, leading to a more health conservative result. A panel member noted that several metals were enriched in the fine fraction, but not as marked as is often seen.

Panel members also noted that the document needs to explain more clearly how soil samples were collected from residential properties. Procedures used to composite samples and their sampling locations (e.g., front, back, or side yard) should be described.

3. The authors evaluated the available sampling data and for each media calculated the exposure point concentrations (Volume II, Section 4.1.1). Are the exposure point concentrations appropriate?

- The panel thought that the HHRA needed a more complete explanation of how the communities of interest were chosen and explanation of the distribution of soil data within these communities. The panel thought that further discussion is needed about the likelihood of portions of the communities or even individual properties having much higher levels of contamination than the exposure point concentration values for each overall community.
- The panel recommended that a single consistent statistical descriptor be used as the exposure point concentration term throughout the assessment, that is, the 95% UCL on the arithmetic mean.

Panel members were not clear on the methodology used by the authors to calculate the exposure concentrations in soils and suggested that it be more clearly explained. Specifically, they expressed concerns over the aggregating community-wide data to generate exposure point concentrations for soil, particularly for areas within 1-2 kilometers of smelters that might have a different exposure situation than the larger community of interest as a whole. The authors noted that they addressed this by also looking at the maximum concentration for each identified community of interest and that Chapter 10 of Volume 1 provides maps of each "community of interest" marking the locations and concentration of samples. They also noted that most of the communities of interest cover small areas of less than 1.5 km^2. A panel member asked if the sampling was random, or clustered to capture higher concentrations, noting that use of the 95% upper confidence limit (95% UCL) may result in an exposure point concentration that overestimates average exposure. The authors thought the sampling was random. Another panel member observed that the data appear to have little variability and no outliers, and this provides confidence that these are the appropriate communities of interest. Another panel member noted that the two values (arithmetic and geometric means) are similar in large data sets and may not reflect the presence of some high concentrations. Panel members thought the data and evaluation of any outliers needs to be better explained to address the concern of potential areas of high concentration. A panel member noted that the issue of potential areas of higher concentration needs to be addressed in Volume 2 when presenting exposure concentrations as representative of all exposures in the community.

Panel members thought that the report needs more explanation to justify that the calculation of 95% UCLs from the soil data does not ignore properties close to the sources that may be at the high end of the distribution. In some cases, the maximum sample value is much higher than the exposure concentration, which indicates that there may be properties or an area of the community that is not represented by the exposure point concentration, based on community-wide upper confidence limit. The authors have indicated that the higher samples were more randomly occurring and do not appear to be concentrated in certain areas of the community, but this needs to be better demonstrated in the report.

A panel member pointed out that while it probably does not make a difference in the exposures, the HHRA used only the front yard soil samples for the comparison of house dust soil levels to outdoor soil, while the usual method is to take an average based upon usage of all yard areas. The panel member suggested that the authors compare indoor dust to a composite of front, side, and back yard samples (proportional to usage). The SARA Group indicated that they only have front yard data for houses with dust samples and could not do this, but perhaps they could analyze pair wise comparisons.

Statistical methods for exclusion of outliers were discussed and a panel member noted that reliance on statistical methods alone for exclusion is not appropriate, but only if there are laboratory or collection reasons for excluding data. Outliers can still be valid data points.

Panel members thought that the methodology used to calculate exposure concentrations was confusing and needs to be made clearer in the text. In addition, panel members found that the draft assessment used three different statistical descriptors for the exposure point concentration and switched them around, creating confusion for the reader. The panel recommended that the a single consistent statistical descriptor be used throughout and the appropriate statistic for characterizing exposure is the 95% UCL on the arithmetic mean, assuming a log normal distribution if the data are log normal (as is usually the case). Panel members thought that tables displaying data need more descriptive titles and explanations of what is shown (e.g., in Table 4.1 all communities were combined and the term "mean" needs further explanation).

4. Are there any concerns or limitations of these studies that affect the usefulness of the data in the Human Health Risk Assessment (HHRA)?

- The panel did not have significant additional concerns regarding limitations of the data sampling and surveys that affect the usefulness of the data for the HHRA. They suggested that improvements should be made in carrying forward key information from Volume I and the appendices into Volume II, and that a clearer presentation of the information is needed throughout the documents.

The panel thought the studies conducted (e.g., soil, dust, and air sampling) provided useful data for the HHRA, but a retrospective analysis will always uncover additional enhancements or suggestions of ways the studies could have been done differently.

4.2 Exposure Assessment

1. **Does the conceptual model (Volume II, Section 2.1.7) adequately demonstrate the potential human receptors and the related exposure pathways?**

    - **The assessment identified five communities of interest (Copper Cliff, Coniston, Falconbridge, Sudbury Central or core, and Hanmer, as well as First Nations people living in these communities). Has the study area been adequately separated into unique exposure communities? Was the selection of communities of interest appropriate?**
    - **Were all appropriate potential exposure pathways evaluated and was the selection of pathways appropriate and defensible? Was the justification for excluding exposure pathways reasonable? (Volume II, Section 2.1.5)**

- Panel members thought that the conceptual model was well done and that the exposure pathways of concern were properly identified.

See comments on attic dust and outdoor surface dust under Data Collection Question 2 above.

- The panel thought that additional discussion is needed to explain whether further biomonitoring would be useful. They suggested that the blood and breast milk discussions be expanded and provided the authors with suggestions of literature that attempts to correlate exposures with the biological monitoring. They suggested integrating information from the IEUBK model, occupational data (if available), and the Falconbridge urinary arsenic study into a discussion that presents the rationale for and against additional biomonitoring.

A panel member noted that breast milk was briefly discussed as an exposure source for newborns and infants in Chapter 2 and it was determined that there was no need to consider mother's milk any further as an exposure pathway. While acknowledging biomonitoring might have been outside the scope of the project, panel members expressed concern that exposure estimates are based on different sources and have many caveats and, as a consequence, validation with blood, breast milk and urine biomonitoring might be useful to validate the estimates and to reassure the readers of the study that actual measurements confirmed the estimated exposure calculations. It was further noted that biomonitoring can add to the public's confidence. Other panel members thought that the metal concentrations in Sudbury were not high enough to detect a difference between the exposed community and an outlying community. One would need a large study population with the most sensitive receptors (e.g., children). Another panel member noted that

the available data on arsenic in urine and lead in blood could be used to help determine what might be in breast milk. Panel members suggested studies from other smelters or metals sites (e.g., Hwang et al., 1997; Tsuji et al., 2005) be consulted.

An observer suggested a number of studies that may help in this analysis (McNeely et al., 1972; Hopfer et al., 1989; Sunderman et al., 1988, 1989; Nieboer et al., 1992; Sunderman, 1993; Templeton et al., 1994; Smith-Sivertsen et al., 1997, 1998; Thomassen et al., 1999; Odland et al., 1999).

The panel recommended that although blood and breast milk concentrations for measured contaminants were low and probably need not be sampled further; more explanation should be provided in the report to make this case. They suggested using literature that correlates exposures and biological monitoring, and integrating information from the IEUBK model, occupational data (if available), and the Falconbridge urinary arsenic study into a discussion that presents the rationale for and against additional biomonitoring.

- The panel recommended that the authors more fully explain and differentiate how much exposure and risk is from the facilities and how much is from background.

A panel member noted that the stated objective is to determine whether soil poses a human health risk. However, the HHRA combined exposures from soil and other sources, including market basket foods. Presenting the total exposure (and resulting risk) may mislead the public. Panel members thought that it is clear that the exposures resulting from the mining and smelting operations are smaller when compared with exposures from other sources. Panel members understood and agreed that the total exposure needs to be described, but thought that further work is needed in the document to separate more clearly the sources of the exposure. Stating that the total risk is greater than one in one million may lead people to believe this is an unusual situation, and it needs to be made clear that this risk is mostly from background exposures, unrelated to the mining/smelting operations. One panel member noted that the authors did separate exposures and in particular liked the approach of discussing the fraction of total factors that could be altered in the community. Other panel members noted that the Executive Summary of the HHRA should clearly differentiate the exposure and risk from the various sources. More specific panel recommendations on how to present this information more clearly are discussed under Risk Characterization Question 1.

- The panel recommended that the rationale for not including the accidental ingestion of sediment while swimming and playing on the lakeshores, be more fully explained in the assessment.

A panel member questioned whether accidental ingestion of sediments was considered as a potential pathway of exposure (potential for children splashing in shallow water and accidentally consuming sediment as a result) and asked if shoreline soils or shallow sediments were sampled. The SARA Group explained that soil study did not sample the sediments, but that they had briefly evaluated this pathway qualitatively and screened it out. They based this decision on their previous experience and the belief that ingestion of sediments would be adequately covered in soil consumption issues. They also noted that beach sand is brought in from outside the area, thereby amending the sediments. In addition, Sudbury has a limited swimming season.

See Data Collection Question Number 3 above for the panel recommendation that a more complete explanation is needed for how the communities of interest were chosen.

2. **Do the selected exposure scenarios (background, typical Greater Sudbury Area resident, First Nations resident, and recreational hunters/anglers) sufficiently cover the situations, behaviors, and conditions under which receptors are likely to be exposed?**

- The panel thought that the selected exposure scenarios were complete and appropriate.
- The panel discussed the First Nations exposures, including the estimates of fish and game consumption. A panel member cautioned that the values from Richardson (1997) are high and that some of those data are based on harvest, not consumption. The panel mentioned that more recent provincial data may be available and should be consulted.
- The panel recommended that the authors look at total protein intake associated with these intakes and evaluate the plausibility of the overall exposure.

Panel members noted that consumption of 1000 grams of protein per day is equivalent to over two pounds per day. This might be reasonable for an occasional meal, but not on a daily basis over time. Panel members also noted that the assessment tries to be all inclusive, perhaps overly so (e.g., including background exposures from food). Dermal exposure is likely negligible for the metals of interest. Comparison of risk assessment data to biomonitoring data at sites for arsenic (e.g., Walker and Griffin, 1998) and lead (U.S. EPA, 1995; Weston, 1996) indicate that risk assessment assumptions for the oral pathway are more than adequate to account for dermal exposure as well.

- The panel suggested the authors consider smokers (cadmium intake) and those who take vitamins (selenium or manganese intake) to see if exposures from those routes are significant when added to environmental and food sources (i.e., total daily intake from all sources). Discuss in Chapter 2 if appropriate.

The panel did not consider smoking or vitamins to be a likely significant source of exposure, but suggested addressing it for the sake of completeness.

3. The assessment identified receptors of interest (male and female receptors in five life stages, and lifetime). Do these receptor categories adequately characterize the population?

- In general, the panel was not comfortable with the stretching of the exposure data to fit different categories of age and the separation by gender.
    - They noted that breaking down into the five selected age categories creates problems in determining the most appropriate intakes when the available exposure parameters are not divided into the same categories (e.g, soil ingestion rates for infants vs. toddler).
    - The panel was also concerned about the suitability of these five selected age categories when carried forward to the risk characterization, especially when specific toxicity information is not available for these age categories or life stages. The panel noted that the use of chronic lifetime risk reference values for comparison with less-than-lifetime exposures is generally a conservative approach and health protective.

Panel members did not disagree with the breakdown of exposure categories by age and recognized there may be some utility in doing so. However, they were concerned with carrying forward the five selected age categories to the risk characterization when appropriate toxicity and exposure parameter value information for the specific age groupings is generally not available. This issue is discussed further under 4.3 Hazard Assessment, Question 4 and 4.4 Risk Characterization, Question 1.

- The panel noted that the gender difference in the risk estimates is only the result of using different body weights in the exposure assessment equations.

Panel members pointed out that separating by gender over-interprets the data and ascribes more information than one can presume from the toxicity values. The toxicity criteria use an average body weight of males and females and thus average gender body weights should be used.

- The panel requested clarity for the cancer dose response assessments.

The panel requested better description of the cancer dose-response assessment values as the upper bound on risk. Furthermore, the text should also state that these upper bound risks are unlikely to be exceeded, and that the real risk is likely to be less, and may even be zero.

4. **Are the selected receptor characteristics (Volume II, Tables 2.1 to 2.5; Appendix B; and Volume II, Section 6.5) and values the most appropriate for use in this assessment?**

AND

8. **For each combination of pathway and receptor, were the assumptions and exposure input parameters appropriate and were the most appropriate intake rates calculated? (Volume II, Section 4.1.6, Chapter 2; Appendix B and O)**

- The panel recommended a clearer presentation of the data that were used for the reasonable maximum exposure (RME) and the central tendency exposure (CTE). A summary table should be provided with each algorithm that identifies what data and assumptions are used for each pathway and why each was chosen.

To allow the reader to duplicate easily each risk estimate, the authors should compile all of the exposure assumptions that are used for each medium and pathway. For example, for exposure to soil, exposure assumptions for the ingestion, inhalation, and dermal pathways should be provided. All of the information necessary to replicate the intake and risk estimates should be located centrally in the document where they can be readily found.

- The panel noted that combining a number of high-end assumptions should be avoided because this may result in greatly overestimated risks. In the absence of sufficient site-specific data, the panel recommended that the assessment use MOE, US EPA, and/or other established default values for receptor characteristics when Sudbury specific values are not available, noting that the US EPA Superfund default values for key parameters attempt to take into consideration the issue of compounding conservatism (overestimation) from use of multiple upper percentiles. However, the assessment should acknowledge that many of US EPA defaults are conservative (health protective). Although US EPA recognizes this issue, very few of their default assumptions are central tendency values and using these default values has the potential to overestimate risk, particularly for pathways with a number of assumptions.

The panel expressed concerns about compounding of conservatism, but noted that it is difficult to assess the degree of conservatism because the information in the report is not summarized in one location (e.g., providing input data with the algorithms). They noted that use of the multiple upper percentiles for the receptor characteristics is conservative (i.e., health protective), perhaps overly so. The goal for the reasonable maximum exposure is to select a combination of high-end and central tendency values that will combine to represent the reasonable maximum exposure individual. A panel member noted that the US EPA Superfund program defines the reasonable maximum exposure to represent at most the 95^{th} to 99^{th} percentile and attempts to address the problem of over conservatism by recommending defaults for key parameters, including soil ingestion, body weight, and surface area. However, another panel member noted that although body weight and surface area are central tendency values, the vast majority of other default parameters are high-end assumptions that in combination yield overestimates of reasonable maximum exposure. This problem is most evident for pathways with numerous input parameters (especially dietary pathways). The panel recommended the authors avoid combining multiple high-end assumptions and consider the MOE or US EPA defaults when Sudbury specific data are not available, but also note that compounding overestimation would result even for US EPA default values. Although US EPA recognizes this issue, very few of their default assumptions are central tendency values and using these default values has the potential to overestimate risk, particularly for pathways with a number of assumptions. The assessment should acknowledge that many of EPA defaults are conservative (health protective).

- The panel suggested that the soil ingestion rates be reexamined and that the authors incorporate information from the wider literature to support a selected soil ingestion rate.

The panel pointed out that breaking down intakes by smaller life stages leads to awkward soil ingestion rates. They noted that there are solid soil ingestion data for the child from 6 months to 6 years, but this age category should not be further sub-divided. In particular, panel members were puzzled to see in Tables 2.1 and 2.2 that the 'soil plus dust' ingestion rate for infants <6 months (0.085 g/day) was greater than that for preschool children aged 7 months to 4 years

(0.044 g/day). They noted that older children are more mobile and have more access to hand-to-mouth contaminated surfaces; one would expect their exposure to be greater than the non-mobile infant.

The panel members discussed a number of other exposure values and assumptions. The homegrown vegetable intake estimates appear to be based on consumer only data from short-term survey data for each vegetable type. Nevertheless, the panel thought using consumer only data for all produce types is unrealistic because the same individual would not consume each produce vegetable type at the daily rates assumed. A panel member suggested that given the extreme variation in the consumption of blueberries, a 75% value may be more stable for the reasonable maximum exposure, and noted that one can multiply a few 75%s together to get a 95% reasonable maximum exposure. Panel members were also concerned about overestimating dietary intakes (as discussed under Exposure Question 2). A panel member also noted that the authors should make it clear in the text on page 4-67 that the 227 g serving size assumed for local wild game was based upon data from the Great Lakes Sport Fish Survey. Panel members also noted that the basis for some assumptions were not clearly explained and should be (e.g., winter soil intake rate), and that soil ingestion rate data cover both outdoor soil and indoor dust so there is no need to separate soil versus dust rates.

5. **Background exposure was derived from monitoring programs in Ontario and across Canada. Were the values calculated for the Typical Ontario Resident (TOR) appropriate? (Volume II, Section 4.1.2)**

- The panel cautioned that the Richardson background data are older and that the Province may have more recent and specific data.

A panel member pointed out that there are likely a number of good surveys now available from sport fish and game animal consumer studies in Ontario. These would provide better reference values for consumption of wild foods than the older data sources provided in the report. References were provided after the meeting for some of these studies and others could be located through an electronic database search.

6. **Was the approach to developing the market basket estimated daily intakes reasonable and were they estimated appropriately? Is it appropriate to add these local exposures to local foods consumed? (Volume II, Section 4.1.3 and Appendix D).**

- The panel was concerned with overestimation of food intakes from use of multiple values based upon the upper 95% confidence limit on the arithmetic mean (95% UCLM). They suggested "ground truthing" (i.e., verifying the reasonableness) of the food data and suggested four possible approaches:
    - Base on caloric intake.
    - Compare market basket surveys of metal intakes to what is found in the Sudbury study.
    - Use the mean values of market basket surveys throughout Canada to establish an upper confidence limit of these means.
    - Use empirical distribution of individual person estimates of metal intakes derived from combining the Richardson study and Total Diet Studies.

Panel members thought adding the 95% UCLM values for 11 food groups was overestimating food intake and therefore the amount of exposure from food. They suggested several methods to address this issue. For market basket information, a panel member suggested several references for inorganic arsenic (Yost et al., 2004; Meacher et al., 2002; Schoof et al., 1999). In addition, the US Department of Agriculture has published studies on other elements. A panel member also noted that every five years Health Canada conducts market basket contaminant concentration surveys, which would be a source of more recent data. A panel member noted strong agreement that the Dabeka data (Dabeka and McKenzie, 1995; JWEL, 2004) are not valid or relevant due to the use of stainless steel cooking utensils. The SARA authors noted that in the HHRA they did not add local exposures to local foods, they substituted the intake rates so that they would not double count.

7. **Are the evaluation of indoor environmental exposures based upon indoor dust survey and use of soil-to-indoor dust regression relationships reasonable?**

- The panel suggested that the authors look at non-linear models for soil to house dust prior to log-normalizing the data.
- The panel suggested including in Table 3.28 some summary statistics on minimums and maximums that went into the regression. The regression equation has more limited value for prediction when values are outside the range.

The authors clarified that in calculating the relationship of outdoor soil and indoor dust for lead, they first plotted in linear space. The statistical fit, however, was not acceptable and so they log transformed the data and reapplied the linear model. Panel members suggested that a bi-phasic approach might allow the non-transformed data to fit better. One panel member stressed that the authors should have made every attempt to examine the data in linear space. If a linear regression of the data was not possible, they should have explored non-linear regression techniques. Only when all attempts in linear space failed, should they have gone to log-transforming the data set. There are two reasons for this. One, the relationship between inorganics in outdoor soil and indoor dust may vary as a function of concentration. A simple linear regression of the log-transformed data would not capture this and may result in under- or overestimating the relationship depending on the concentration. Second, the equations used to estimate the SSRGs would have to be re-arranged. The panel agreed that the use of a linear regression of soil levels to house dust levels with a threshold for internal sources of exposure is reasonable.

After the IERP meeting, a panel member noted an additional thought—"This suggests that the mathematical analysis leading to calculated SSRGs involves the relationship between soil and dust element levels. Does this assume that dust contains a significant component of soil? The peculiar bioaccessibility results seem to contradict this idea, and I recall (though not in detail) one of the authors suggesting that soil and dust seemed quite different in this study. If the authors decide not to calculate SSRGs, then this point is moot." Another panel member further commented-- "As [the previous panel member] suggested, the mathematical model for deriving the soil to dust coefficient does assume that the metal levels in indoor soil are derived from outdoor soil. The y-intercept of the slope represents the contribution of metals from non-soil sources. If the results of the bioavailability studies for soil and dust are correct, then [the previous panel member] raises a very important question. Specifically, what if the metals in dust are not coming from outdoor soil? I think an examination of the data via non-linear regression in linear space could also shed some light on this. If the metals in indoor dust are not coming from outdoor soil, this raises an important consideration for risk managers whose authority only extends to contamination associated with hazardous releases."

The panel also discussed the methods used to collect the indoor dust, noting that use of vacuums with HEPA (High-Efficiency Particulate Air) filters is customary in the panel members' experience. SARA authors confirmed they were primarily interested in concentration but did look at loading as well, and collected data from three areas where children played the most in each house. A panel member noted that carpet may contain materials tracked into a home over time, with areas closest to the front door (or most used door) having the greatest proportion of outdoor soil.

Another panel member noted that co-located yard soil samples were taken from the front yard of properties to compare to indoor dust samples, but that this is not the conventional method. If yard soil differs between front yard and other parts of the property and multiple entrances and windows contribute to indoor dust concentrations, the use of the front yard sample alone is a less accurate comparison. Lack of significant difference between front yard and back yard samples overall addresses whether there is a systematic bias in the data, but does not address possible inaccuracies for individual yards.

9. **Have potentially highly exposed populations been identified and addressed adequately?**

- The panel agreed that potentially highly exposed populations were identified and addressed adequately.

10. **Do you have any further concerns or comments regarding the exposure assessment?**

The panel had no further comments.

4.3 Hazard Assessment

1. **Are the potential human health hazards of the COCs adequately addressed? (Appendix A and CD-1).**

AND

2. **Were the most appropriate exposure limits identified and were the rationales for the selections defensible for each of the COCs?[2] (Volume II, Section 4.1.8)**

[1] For example - Is the use of the use of urinary arsenic study results and epidemiological data in the weight of evidence approach for evaluating arsenic health risks reasonable? Is the use of the IEUBK model and approach used for lead reasonable? Section 3.5 discusses metal speciation of the COCs and the weight of evidence approach used. Were the analyses appropriate to resolve the questions regarding speciation?

- The panel found that the summary of health hazard information found in the Appendices was quite thorough, but in some cases they recommended further information be provided and that the basis for selection of the exposure limits be clearly presented.
    - Several of the COCs are essential elements and each chemical chapter should begin with a discussion of essentiality and the recommended daily allowances.
    - The authors appropriately surveyed the available risk values, but should make it more clear at the outset which organizations were consulted for each chemical. The authors should make it very clear which values they carried forward to the risk characterization and why.
- Chapter 3 should be improved to better explain and highlight the work found in the appendices.

The panel discussed that there is much valuable information presented in Appendix A, but that the presentation of the information could be standardized and clarified as noted above. Additional information from other appendices should be used to improve the discussions in Chapter 3.

Arsenic

Arsenic:

- The panel recommended that the authors include additional information on the epidemiological data from the US and other countries, particularly at lower doses, both from drinking water exposures and from communities near smelters.
- Further information and discussion on mode of action for arsenic should be included.

A panel member noted that while the mode of action for arsenic is not completely understood, the most recent information and reviews on inorganic arsenic point to all possible mechanisms of toxicity being threshold or non-linear. There may even be modes of action at low doses that are beneficial. The member recommended that the authors consider published studies on arsenic and background, including a recent review by Snow et al. (2005). An additional recommendation concerned evaluation and discussion of more of the literature, including that on low level arsenic exposures that do not indicate effects (particularly for non-smokers), other studies conducted in populations around arsenic smelters, and work by Lamm and colleagues on low-level exposures in the US (Lamm et al., 2004). Lamm and colleagues also reevaluate the southwest Taiwanese data (which form the basis for the EPA cancer values) and indicate that high dose to low dose extrapolation without consideration of well water source (e.g., artesian or non-artesian) is misleading (Lamm et al., 2006; Lamm and Kruse, 2005). This panel member thought that additional evidence should be provided to help the public to understand whether risks that exceed specified goals are unsafe (e.g., epidemiological studies of populations in the US and elsewhere with sufficient nutrition, which are exposed to arsenic in drinking water or from living near smelters); and review of mode of action evidence regarding the shape of the dose-response curve at high doses versus low doses for inorganic arsenic and its metabolites (e.g., Schoen et al., 2004; Snow et al., 2005; Cohen et al., 2006).

The urinary arsenic study included relatively few young children in the population under the age of seven who would have been expected to have the greatest exposure to soil. Consequently, comparisons to urinary arsenic biomonitoring studies in other communities exposed to arsenic in soil should be used to support the findings. A panel member provided the authors with a list of key references that should be evaluated and included in the arsenic section and referred them to US EPA's website for its current deliberations on arsenic as well as information submitted to the record US EPA's Science Advisory Board for consideration (http://www.epa.gov/sab/panels/arsenic_review_panel.htm).

One panel member questioned the chronic inhalation recommended exposure limit (REL) for arsenic of the California EPA (which is based on developmental toxicity effects), noting that reasonable consumption assumptions would lead to a comparable inhalation intake in mg/kg-day that is 70-fold less than the safe dose after oral exposure. If this is correct, one has to ask why malformations are not being seen from the oral route.

The panel briefly discussed a number of other issues concerning arsenic. Regarding essentiality of arsenic, panel members discussed that arsenic might be essential to humans, based on some animal evidence, but the exact mechanism of essentiality has not been established and deficiencies in human populations have not been reported (likely because any essential level is below background arsenic levels). The panel also discussed that US EPA's Science Advisory Board has an ongoing review of US EPA's revised assessments for arsenic and are debating the oral cancer slope factor. However, even if the oral cancer slope factor from the Taiwanese data is adjusted, this will not a have a significant impact on risk management conclusions based on this HHRA, because the background exposure from diet is so high.

Cobalt

Cobalt

- The panel recommended that the authors examine the Dutch (RIVM) assessment of cobalt and consider it for use in this HHRA, rather than the US EPA provisional values.

For cobalt, one panel member questioned the use of the provisional values from the US EPA and thought the cobalt slope factor was high. The member noted that the bronchial and alveolar tumors in mice are not usually used for human health risk assessment and that if one compares the US EPA value to the recommended daily allowance (RDA), it indicates a cancer risk of 1 in 100,000 at the RDA, which does not make sense. It was also noted that the Dutch (RIVM) consider cobalt a threshold carcinogen and encouraged the authors to examine the RIVM assessment and consider it for use in this assessment.

Copper

Copper

- The panel agreed that the copper information was adequate and appropriate, but that newer multi-country epidemiology studies and the discussions within the US National Research Council Committee on Copper in Drinking Water (NRC, 2000) related to the potential genetic predisposition to higher environmental copper levels should be discussed in the toxicity profile.

A panel member questioned the statement in the HHRA that available human studies of the effects of copper on the liver suggest that these are unlikely to occur at lower doses than those that cause gastrointestinal effects (chronic oral exposure), i.e., how could longer-term exposures continue, if gastrointestinal effects are occurring? The National Research Council committee (NRC 2000) discussed the issues and concluded that chronic copper toxicity appears to be associated with environmental exposure in combination with genetic sensitivity.

Lead

Lead

- The panel thought that the use of the IEUBK model and MOE approaches used for lead were not unreasonable; however, they recommended that the description for the MOE lead value needs to be further expanded and it should be clearly shown how the authors got from the 10 ug/dL blood level to the 1.85 mg/kg body weight/day dose. The exposure point concentration terms identified in Chapters 4 and 6 are not consistent and this should be checked and corrected.

One panel member ran the model with the values given and found the exposure assumptions were fine but discovered that the exposure point concentration terms differed between pages 4-24 and the results given in Chapter 6.

Nickel

Nickel

- The panel suggested that the assumption of the nickel oxide potency being protective for the uncharacterized nickel species needs to be better described in the document.
- Two members of the panel agreed to provide the authors with a recommendation regarding use of the Seilkop and Oller work for the nickel inhalation cancer potency.
- The panel suggested that available information regarding prevalence of nickel sensitivity in the local community be discussed in the document.

The panel discussed nickel and a panel member noted that the oral reference dose was appropriate, but that the discussion of nickel species and carcinogenicity was confusing. It was not clear what risk values were selected for use in calculating and characterizing risk.

A panel member noted that the US National Toxicology Program bioassays on nickel showed clear differences in cancer potential for different solubility and supported distinguishing between nickel oxide and nickel subsulfide. It was noted that the soluble forms are negative for direct carcinogenicity, although they may be relevant for cancer promotion. The authors noted that in the HHRA it was assumed that all the oxidic, soluble, and uncharacterized nickel forms have the same potency as nickel oxide. They thought that since it is not known what the uncharacterized

forms of nickel are, assuming all forms have the potency of nickel oxide should account for the toxicity of the total nickel species.

Panel members noted that the document was unclear with regard to what cancer risk values were most appropriate to be used for nickel. The authors indicated that for nickel oxide and nickel subsulfide, they calculated risks using several available government values, as well as the carcinogenicity estimates of Seilkop and Oller (Seilkop and Oller, 2003; Seilkop, 2004). Two panel members volunteered to further review the Seilkop and Oller work and provide a recommendation for the nickel inhalation cancer potency. After the meeting, two panel members conducted additional review of the nickel documentation in the assessment document and appendices. They also contacted the author of the Seilkop (2004) reference for clarification regarding the derivation of the cited potency value. The two panel members provided the SARA Group with additional analyses to help clarify some of the scientific issues regarding selection of a nickel potency value. The panel members, however, did not make a specific recommendation, but asked the SARA Group to consider the additional information and analyses when finalizing the risk assessment. The panel members' analyses and correspondence with the SARA Group are available upon request to *TERA@tera.org*.

A panel member noted that Appendix A states that nickel is an essential element but that no reference or rationale is provided for this statement and nickel dietary recommendations have not been established for humans. It is also stated (page A5-A6, second paragraph) that preventing chronic lung inflammation may avoid nickel carcinogenicity. The levels at which chronic lung inflammation occurred should be identified in the text.

A panel member noted that developing an RfD for nickel dermatitis would be difficult. The panel asked whether there is any information on prevalence of nickel dermatitis in Sudbury. A representative from the Sudbury District Health District, Mr. Ido vettoretti, noted that they have received no unusual complaints regarding nickel contact dermatitis in the many years he has worked at the Health Unit and have not seen evidence of a community problem with nickel sensitivity. However, he noted that they have had incidents of sensitivities due to body piercing as a result of the use of lower quality jewelry and other skin reactions were infrequently noted during sexual health clinic visits that were felt to be the result of contact with metals clasps and fasteners on clothing that were in frequent contact with skin. Dr. Evert Nieboer of McMaster University, and a consultant to the Sudbury District Health District, noted a detailed dermal sensitivity study some years ago by colleagues from Norway around a nickel refinery, where the population showed no unusual sensitivity. He also noted that clinical exams in industry (with higher exposures) do not reveal problems. He thinks other exposures drive nickel dermatitis more than exposure through soil. After the meeting, he suggested a number of references for the authors to consider (Smith-Sivertsen et al., 1999, 2002; Nieboer et al., 1984; Menne, 1992; Gawkrodger, 1996). Dr. Nieboer also mentioned a number of publications by Nordic researchers about associations between cumulative exposure to water-soluble nickel and lung cancer risk (Andersen et al., 1996; Anttila et al., 1998; Grimsrud et al., 2000, 2002, 2003, 2005)

Selenium

Selenium

- The panel agreed that the hazard information in the HHRA for selenium was adequate.

Speciation

- The panel discussed the speciation efforts at length. The panel recognized the difficulty in identifying and quantifying the species of nickel present in the air filters and dust samples and agreed that the 10% nickel subsulphide proportion used by the authors for air was likely a high estimate (very health protective), but could not determine a better value to use. By using an overestimate, the panel recognized that the resulting risk estimates increase.

The panel discussed the speciation efforts and commended the authors for the extensive efforts to better identify what species were present in the air filters and dust samples, and in what proportions. They recognized the difficulty in analyzing the samples. The authors used an upper-bound estimate of the amount of nickel subsulphide in the air filters of 10% and an upper bound estimate for indoor dust was estimated of 2%. One panel member thought that the analysis was adequate to indicate that there was some nickel subsulphide in these media but not very much, and that quantifying the amount present is almost impossible. Given this situation, the panel member thought the estimations of 2% and 10% are acceptable to use.

- A panel member noted that the work on speciation was very well done and thorough, and that the presentation of the information was transparent and complete. There are several important cautionary statements on methods in Appendix I, which are helpful, and these should also be communicated in the main body of the text.
- A panel member noted that the samples were complex and the analyses difficult and it is apparent that the laboratories worked hard to identify what is present using several different appropriate methods. However, there are significant limitations to the use of these methods for the types of samples and the low concentrations, which makes estimating the percentage of nickel subsulphide and other species very difficult.
- A panel member noted that the Tessier analysis indicates that other nickel species are present beyond what was looked for, and that the analysts did not look for non-nickel compounds that contain nickel (e.g., iron or manganese oxides with adsorbed nickel).

The panel discussed the speciation work at length. They thought the work well done, but challenging. One panel member suggested that several cautionary statements found in Appendix I be carried forward to the main report, including:

1. Page 6, section 3.1, last paragraph on page, beginning "it should be noted that wet extraction procedures have presented....." This refers to the sequential extraction procedures.

2. Page 10, section 3.1.2, under Method Considerations, bullet beginning "EDS (energy dispersive spectrometry) measures elemental data with a detection limit of..."
3. Page 23-24, conclusions and recommendations, 2a and 2b, regarding correlation between mineralogical and Tessier (sequential extraction) results, also point 5 regarding caution in interpreting leaches.
4. Lamoureux report, page 8 of 25, last paragraph in conclusions.

One panel member stated that the sequential leach speciation work on dusts may be difficult to interpret, noting that the procedure was designed for aquatic sediment samples and not for dust.

3. **Was bioavailability and bioaccessibility of the COCs in the various media addressed appropriately? Volume II, Section 3.4 and Appendix J describe the *in vitro* site-specific oral bioaccessibility studies conducted. Were the relative absorption factor (RAF) values selected appropriately (Volume II, Section 4.1.9)? Has the information been incorporated correctly in the assessment?**

The panel discussed the use of *in vitro* bioaccessibility results for the various elements in soils. A panel member provided some history on the development of the bioaccessibility models for metal(loids) in soil by the Solubility Bioavailability Research Consortium (SRBC), noting that the multi-group efforts were to validate bench-top or *in vitro* assays to substitute for very expensive animal studies testing site soils. The Consortium developed protocols and validated these with animal data. For lead, a strong correlation was seen, but for arsenic and other metals and organics, the correlations were poor. Another panel member reported that at the recent International Society for Exposure Assessment meeting in Paris, it was apparent that there is much greater acceptance in Europe of *in vitro* methods for metals other than lead. Furthermore, for some of these chemicals it is not practical to conduct *in vivo* studies as the soil concentrations are not high enough and the animal studies are not sensitive enough – or as in the case of nickel, there are not enough highly contaminated sites.

- The panel was concerned with the use of the *in vitro* methods for other than lead. Panel members agreed that there is an abundance of evidence to show that oral bioavailability of some metals (e.g. arsenic and lead) can be lower when the metal is in soil than when it is in water or food, and that the absorption fraction for ingestion of these metals in soil and dust should be adjusted for calculating risk based on toxicity dose-response relationships for the metal in water or food. However, the panel expressed less confidence in reliance on the *in vitro* bioaccessibility assay for deriving the adjustment factors for metals other than lead.

- The panel recommended that the *in vitro* results shown in Table 3.8 be used to modify the site-specific bioavailability of lead in soil (if the SBRC protocols were followed). The panel further recommended that the SARA Group use the single-phase gastrointestinal extraction data for lead and not the 2-phase results.

- The panel suggested the following approach be used for soils (for all metals but lead) - that the authors calculate risk first with the assumption that the relative bioavailability is 100%. For those chemicals of concern with results above a hazard quotient of 1, do a full examination of the available literature from other sites, data on mineralogy of the soils, speciation, and bioavailability and develop a weight-of-evidence discussion with regard to bioavailability. The panel members differed on whether this analysis should be presented in the primary calculations or be presented in the uncertainty discussion, but all agreed that both should be presented.

For lead, the panel agreed that *in vitro* methods have been validated and the results presented for the single-phase gastrointestinal extraction for lead should be used for soil as long as the laboratory followed the SBRC protocols. The panel members disagreed with the SARA Group's choice of the two-phase results for lead, noting that for lead only the gastrointestinal extraction is supported by the literature and that there is a strong correlation between gastric stage results and animals studies.

Panel members agreed that making an adjustment of relative bioavailability (the absorption fraction, AF) is appropriate, and noted that for arsenic and lead, the bioavailability of these metals in soil can be much lower than water. This finding has been supported by human studies. The panel members did not all agree that the *in vitro* bioaccessibility results (for metals other than lead) provided an adequate basis for deciding how the adjustment should be made or the magnitude of the adjustment. The panel did agree that all the information should be considered in a weight-of-evidence determination. Some panel members thought that the *in vitro* results (for metals other than lead) could be presented and discussed in the uncertainty section.

- The panel was concerned that the results of the bioaccessibility studies showed that lead and other metals are less extractable from house dust than from soils. Panel members were uncomfortable with these findings and thought the weight of evidence did not explain the results. The panel suggested that if there is dust sample material left, to send lead and nickel samples to another laboratory; lead would be the control.

In addition to the discussion regarding whether *in vitro* bioaccessibility data for any element other than lead can be used in the HHRA, the panel discussed the summary of bioaccessibility results (Table 3.8) which showed significant differences between soil and dust. The panel members were uncomfortable with these results and questioned the large difference in bioaccessibility of the dust versus the soils. They noted that the much lower bioaccessibility of dust relative to soil is the opposite of what has been observed at others sites in the panel members' experience. The panel discussed why this may be. A panel member noted that one interpretation of the 10-fold difference between soil and dust is that the soil is making a small contribution to the metal found in the dust and then questioned whether this possible interpretation made sense. The SARA Group authors noted that higher organics present in dust (e.g., shedding cells and other organics not related to emission sources) make it more difficult to extract the metals. Another panel member was not sure enough is known to relate *in vitro* soil acid and neutrality with bioavailability of lead, and therefore the dust falls into the unvalidated realm, including for lead. The panel member could not think of a reason why the data would not be valid, except for Table 3.8 showing such a big difference between the dust and soil values.

Panel members suggested that, if there are samples of soil and dust left, that they be sent to another laboratory (perhaps John Drexler's laboratory) to repeat the test, using the previous lead results as a control. Another panel member cautioned that these data (regarding soil versus house dust levels) could ultimately be embedded in the literature and become a reference for use by other scientists and evaluators in the future. Therefore, it is important to make sure this finding is valid. It was proposed that the work, if confirmed, should be published and be subjected to scientific peer review.

A panel member offered an additional suggestion -- that the *in vitro* results may be useful to determine if there is geographic variability in bioaccessibility across the region tested or if there is variation with the metal concentration in the soils. One could look to see if the results are uniform or clustered. This is a potential use of the assays even if agreement cannot be reached on the predictive ability of the tests for metals other than lead.

4. Have potentially sensitive populations been addressed adequately?

- The panel agreed that the potential sensitive subpopulations have been adequately addressed.

The panel thought the potential subpopulations were adequately addressed. They noted that discussions regarding children's sensitivity need to be chemical specific. Panel members pointed out that it is the cumulative dose that matters for the majority of the chemicals of concern and for these the critical effects are from long-term exposure. For arsenic, a panel member pointed out that potential sensitivity is covered adequately by applying findings from the Taiwanese study. It was noted that the studies upon which the risk values are based, were very large (tens of thousands of individuals, including exposures at all life stages from *in utero*, childhood, through adulthood). In addition, the Taiwanese populations were already sensitive in that they were malnourished, exposed *in utero* to high drinking water levels, had nutritional deficiencies and potentiation of carcinogenicity (see the paper by Tsuji et al. (2004) for a discussion on children's sensitivity and arsenic).

After the meeting, a panel member provided some additional thoughts on this topic. The panelist explained that the additional safety factors for arsenic risk to protect children do not seem necessary given the scientific basis of the arsenic slope factor (malnourished population exposed for a lifetime including *in utero*) and the many conservative assumptions involved. Mechanisms for arsenic carcinogenicity involve oxidative stress and cancer promotion by interference with DNA repair mechanisms. Such effects would not be expected to render early life stages more sensitive. Evidence from epidemiological data also indicates that children were not more sensitive to the toxicological effects of arsenic (e.g., skin lesions) than adults in a population that was exposed to arsenic for 5 years (Tsuda et al., 1995). The 33 years of follow up also noted a relationship between signs of arsenic toxicity (e.g., skin signs) and later development of lung and urinary cancer. This study does not report that those who were exposed as children were at higher risk of later contracting cancer. Clinical dosing of leukemia patients with a drug containing arsenic trioxide, likewise has not shown that children are more sensitive than adults to acute effects of arsenic toxicity (reviewed by Tsuji et al., 2004).

The assessment of greater sensitivity to children also does not take into account the greater arsenic dose per body weight that children received relative to adults in populations exposed to arsenic in drinking water. Thus, if children did show a greater sensitivity to effects (which is not apparent), such sensitivity could also be attributed to a greater dose per body weight.

The panel also discussed a statement in the report that indicated one might be concerned about young people being more sensitive than the reference values indicate, because animal studies only look at mature animals. Panel members pointed out this is incorrect. Many chronic animal studies segregate animals shortly after they are weaned (e.g., 6 to 8 weeks old for rodents), and after two weeks of acclimatization begin dosing. Dosing begins at an age that is roughly equivalent to human teenagers. In addition, if chronic data are not available, the reference dose or safe dose approach for non-carcinogens accounts for this in the assignment of uncertainty factors. For genotoxic carcinogens, the US EPA recommends the consideration of an additional adjustment to the cancer dose-response assessment slope. This adjustment is equivalent to an uncertainty factor, and the net effect is to only increase the lifetime cancer risk by 1.6. This modest increase is well within the imprecision of such risk values and is of little consequence.

5. **Are there additional issues or concerns that the authors should have addressed regarding the hazard assessment, the selection of these exposure limits, and the appropriate use of the selected values in the risk assessment?**

The panel did not have additional issues that were not covered elsewhere.

4.4 Risk Characterization

1. **Was the approach used to estimate Hazard Quotients (HQs), Incremental Lifetime Cancer Risks (ILCRs), and the soil specific oral reference doses consistent with accepted risk assessment methods, and are these calculated correctly? (Appendix O)**

- The panel agreed with the general approach and found it generally consistent with accepted risk methods for the most part, but thought the presentation of information needed to be improved for this section and recommended a number of specific changes.
- The Panel was concerned that the assessment and particularly the Executive Summary presents total risk, without clearly noting that the total risk is driven by the market basket foods. The panel recommended that the exposure and risk be clearly differentiated between what is site-related (from the mining and smelting operations) and what is from background and non-site local sources.
- Summary tables of intakes of nickel, arsenic, and lead for each community should be presented, and site-specific intakes should be distinguished from total intakes.

The panel found that the equations and algorithms used were generally consistent with standard risk assessment practice. They were concerned with how some of the results were presented. In particular, there was concern that the Executive Summary did not distinguish the risk resulting from the mining and smelting operations from sources of exposure that could be considered background and not related to the site.

Panel members were very concerned that the public and readers of the HHRA understand that the total risk levels found in Sudbury appear to be dominated by sources that are <u>not</u> related to the mining and smelting operations, but rather are from background sources, primarily market basket foods. They suggested that when the total hazard quotients (HQs) and inhalation cancer risk levels (ICRLs) estimates are presented (e.g., Table 5.1 and Figure 5-7), that the site-related portion should be clearly indicated as well. Risk from all exposure sources should be provided as a total risk, but the site-specific risk should be clearly identified. In addition, when intakes of specific metals are summarized, the source of exposure should be clearly distinguished.

A panel member noted that Figure 5-12 illustrate the contribution of each exposure pathway for the reasonable maximum exposure. It was suggested that a table be presented with the hazard quotient values by each source, divided by background and local sources. These could be summed to indicate the contribution from background and the contribution from the local and

site related sources. The local and site related portion could then be used for calculating the site specific remediation goal. The panel member thought this was consistent with MOE guidance.

- The exposure point concentration presented should be the average exposure (i.e., 95% UCLM) and the 95% and maximum values should not be presented in the risk characterization.
- The same term should be consistently used to describe the average (i.e., 95% UCLM).
- If there are higher exposure levels for a community, consider further subdivision of the community of interest to determine if there are portions of the community with higher exposures and higher risks

The panel members were concerned with the use of three different descriptors for the exposure concentration term in the risk characterization stage. One panel member noted that if the authors do not have a good understanding of the contaminant variability in exposure at this stage, they should go back and examine this again. The exposure point concentration term should be represented by the 95% UCLM. Other statistical descriptors such as the maximum concentration or 95^{th} percentile should not be used to represent the exposure point concentration. The authors noted that they used the maximum values to help identify concerns regarding localized areas with higher concentrations. A panel member pointed out that if the authors can define separate areas with lower or higher exposures, then they should subdivide the communities further. The need to clean up individual properties can be determined by comparison with clean up goal. Another panel member noted that the authors need some way to address if a portion of a community of interest with higher exposure is being diluted by averaging the community as a whole. The results from the maximum soil values are only presented in the combined hazard quotient, which makes it difficult to tell what impact the maximum soil concentrations have on the total.

- The panel questioned calculating risk for separate life stages. While they agree that estimating exposures for each life stage is appropriate and the HHRA should present life stage exposure estimates by community, the life stage distinctions cannot always be carried forward to the risk characterization. If the critical effect is from chronic exposure, then the hazard quotient should be based on a comparison with lifetime exposures. They recommended that the authors base the hazard quotients on lifetime amortized exposure estimates if the critical effect is chronic, or use child specific health values if appropriate and available.
- Separate tables should be presented for oral and inhalation cancer risk by community, as well as oral and inhalation hazard quotients by community.

Panel members noted that the risk assessment information is not generally developed for specific life stages and therefore chronic risk values cannot generally be used with different life stages with accuracy. A panel member noted that one can use the chronic toxicity values with less-than-lifetime exposures in a conservative screening exercise, but not for more definitive risk judgments. Rather, in such cases a specific risk value for the life stage of concern, such as for children, would be preferred. For example, use of the chosen risk value for lead is acceptable for children because this value is based on a risk to children and based on extensive neurological findings. For the other metals, the use of the chronic risk values is likely to overestimate childhood risks based on the life stage exposure table and chronic exposure data. The hazard quotients greater than 1 shown for the toddler probably are not real, because the toxicity values (chronic exposure) are not appropriate. The authors should then present only the appropriate life stage results (e.g., for arsenic the RfD is based on chronic exposure and should be used to develop a single hazard quotient based on comparison with lifetime average daily exposures). The authors should derive weighted lifetime average daily exposures based on the exposures for each life stage and then use the lifetime average daily exposure to calculate the hazard quotient and inhalation cancer risk level. Subchronic or child specific RfDs could also be applied to the child exposures if there is concern about higher intakes during that life stage.

The panel members pointed out that the risk values (e.g., RfDs) are intended to be protective of lifetime exposure including *in utero*, infancy, childhood, adolescence, and adulthood. Several of the criteria for the metals are based on human populations with such exposures. Where there is uncertainty, uncertainty factors have been included to make the criteria more protective. At the lowest exposure levels associated with health effects, cumulative exposure over time is typically more of a concern than short-term exposure. Thus, a daily dose that is safe for a lifetime should also be highly protective of low dose, short-term exposures. In addition, for the RfD, the lifetime daily dose is based on a larger lifetime average body weight relative to the chemical intake rate (e.g., arsenic in water) and thus is lower (more protective) than the actual dose on a body weight basis experienced by the children in the population studied. If one multiplies an RfD by a child weight (e.g., 10 kg), the result is a much smaller daily intake. Comparing this smaller intake level to a daily exposure for a specific life stage (less than a lifetime of 70 years)' will often overstate the risk. The panel thought that the authors should discuss in the uncertainty section whether there are concerns regarding subchronic risk. The panel also recommended that the cancer and non-cancer risks be presented in separate tables, that the cancer risks be divided by oral and inhalation routes, and that tables be developed for each community.

Panel members pointed out that it is inaccurate in most cases to distinguish risk between males and females, unless there are data from an animal or human study, which specifically identifies gender differences in response to exposure duration and dose. The only difference in parameters between males and females used in the report appears to be body weight. The authors noted that they will check to confirm that body weight is the only factor. The panel suggested that this should be discussed in the uncertainty section, rather than presented as separate results for males and females. The tables can footnote on which human receptor category the results are based to provide transparency.

- The document needs a summary table for each algorithm that clearly presents all of the exposure assumptions for that particular pathway.
- The IEUBK model has had some values updated, based on US Food and Drug Administration total diet and levels of lead in food. These more current values are available on US EPA's website and should be used in the HHRA.

Panel members suggested a number of other improvements. They thought that all the general exposure parameters as well as the media exposure parameters for each pathway need to be listed together so that the reader might readily see what is being used. The IEUBK model has updated values that should be used and a panel member also suggested adding age specific exposure parameters used in the simulations to the tables as these data are needed to reproduce the model runs.

2. **Deterministic analyses were used to initially characterize the exposures, and where elevated risks indicated, probabilistic analysis was conducted for exposure estimation to provide a more rigorous estimate of potential risk. Did the authors choose the appropriate methods and exposures to conduct probabilistic analyses (e.g., appropriate shapes for the parameter distributions)?**

AND

3. **Was the probabilistic risk assessment reasonable based on the unique characterization of the Sudbury site? (Appendix P)**

- The panel questioned the logic for conducting a probabilistic risk assessment for lead and nickel, given that the deterministic results did not indicate a problem. They asked the authors to more clearly explain this in the document and if a probabilistic assessment is conducted, then the authors should conduct a sensitivity analysis, prior to the probabilistic risk assessment, to identify the most sensitive parameters. The panel recognized that for complicated sites, probabilistic risk assessment can be helpful as one can use the full range of data to better characterize and communicate risk.
- The documentation for the probabilistic risk assessment needs to be improved to clearly identify the selection of distributions used, explain why they were selected, and clearly identify the sources of the various parameters.
- The key information needs to be brought forward from the appendix to the main report.

Although the panel agreed with the SARA Group that for complicated sites probabilistic risk assessment can be helpful (as one can use the full range of data rather than picking single values, thereby providing a fuller characterization of the risk and more confidence in the results) the panel suggested that the authors more clearly explain their logic for proceeding from the deterministic results to the probabilistic risk assessment. A panel member noted that conducting a probabilistic risk assessment takes a lot of time and resources. Within the US EPA, the deterministic assessment is a conservative approach that generates health protective results and more sophisticated and detailed probabilistic risk assessment is only done when a pathway or contaminant exceeds the acceptable level in the deterministic analysis. The logic used in the HHRA is unclear as contaminants with a hazard index of less than one are carried forward, and others greater than one, are not. If a probabilistic risk assessment is warranted, the authors should first conduct a sensitivity analysis to determine which variables are the major contributors and then focus on those. The authors should explain why they are conducting a probabilistic risk assessment and what information they intend to get from it. This goal will determine how best to design the probabilistic assessment.

Another panel member was impressed with the thoroughness of the model, but had to undertake considerable searching through the document to find most of the input information to verify the adequacy of the approach and results. Another panel member noted agreement with the general approach and supported using the 95^{th} percentile of the distribution to represent the reasonable maximum exposure. However, not enough information was presented to review the critical distributions and insure that these are sufficiently conservative to derive appropriately conservative risk distributions. Panel members suggested that the description and presentation of the probabilistic assessment needs to be improved. Information should be provided on the variables chosen, the literature examined, the distribution functions developed and the statistical descriptors. These need to be fully explained and a table with the key information should be provided. The authors could also connect the algorithms to the probabilistic risk assessment by footnoting the parameters that are represented in the assessment as probability density functions, and provide the distributions in Appendix P.

- The authors need to separate out variability from uncertainty, and run these separately to allow for clear interpretation of the results. The panel suggested that variability be looked at in the first run, and then uncertainty.
- The authors need to discuss more completely the uncertainties associated with the probabilistic risk assessment model in the uncertainty discussion.

The panel recommended that the authors address variability and uncertainty separately in the probabilistic risk assessment. If a sensitivity analysis is performed prior to the probabilistic assessment and the exposure pathways or input parameters are not likely to be influential, then the use of point estimates is warranted. A panel member noted that the uncertainties in the probabilistic assessment should be discussed in the uncertainty section, for example, limitations and methodologies, how correlations may or may not have been handled, and the implications of these decisions.

4. Are the conclusions regarding the potential for toxicological interactions amongst the COCs reasonable/defensible? (Volume II, Section 6.4)

- The panel thought that the discussion in Section 6.4 was complete and they agreed with the authors' conclusion that toxicological interactions cannot be quantitatively included in the risk assessment. The panel suggested that the conclusions from Chapter 6 be discussed in the Risk Characterization.

The panel members discussed the possibility of interactions amongst the chemicals of concern. One panel member thought the generic discussion on chemical and metal interactions in Chapter 6 was fair and complete and that the authors' conclusions for this specific HHRA were probably acceptable. Another panel member noted that the common approach for site assessments is to be prudent and add risks for chemicals with similar modes of action (or carcinogenicity). Other panel members did not think that was necessary, that most of what is known about chemical interactions is at much higher doses than present here, and that the rationale presented was reasonable. Panel members pointed out that in considering metal interactions, the relevant interactions to consider for risk assessment and for guiding risk management decisions (i.e., cleanup level determination) is not whether metals will interact when they are present at toxic doses, but whether they would interact at low doses when each is present at levels that would otherwise be considered safe with individual exposure to each metal. Consequently, the conservative policy from US EPA is to add hazard quotients together; however, if the total exceeds unity, then an evaluation should be conducted of whether the individual metals act on similar endpoints or target organs by similar mechanisms. It was also noted that conservative assumptions had been applied in evaluating risks for several of the individual metals, which might also be adequate for addressing any possible additivity of effects from exposure to mixtures of these same metals.

A panel member also noted that it should be recognized that interactions among metals can also be antagonistic (e.g., selenium and arsenic; zinc and cadmium or copper; iron and manganese) because they compete for absorption or metal carriers within the body, or affect the detoxification of the other metal. In addition, Table 6.2 should note the possibly beneficial effects of arsenic. Studies on multiples species of animals from chickens to rodents to goats and pigs have shown that low arsenic diets result in growth deformities and other signs of deficiency. Although, the exact mechanism has not been worked out, it likely involves a role as a metal cofactor for enzymatic reactions (e.g., in methionine metabolism; Uthus and Kang, 1998). Low doses of arsenic are also associated with up-regulation of DNA repair mechanisms (Snow et al., 2005) and adds to evidence of beneficial effects of arsenic at low doses that has resulted in discussion in the literature of arsenic demonstrating hormesis (Calabrese and Baldwin, 2003). Arsenic deficiency has not been shown in any human populations, and background exposures are likely above the nutritional requirement level.

5. **The authors calculated site-specific remediation goals (SSRGs) for lead and nickel in soil, using both deterministic and probabilistic assessment results. Were the $SSRG_{soil}$ values calculated correctly? Should additional SSRGs have been calculated? (Volume 2, Section 8.1.4)**

- Panel members questioned whether site-specific remediation goals were needed; given the deterministic and probabilistic results were below the decision criteria. If goals are calculated, they recommended that the justification for calculating them be included in the text.

The panel discussed the calculation of site-specific remediation goals, but questioned the rationale for deriving these values given the deterministic and probabilistic results were below the decision criteria. Panel members clarified with the authors that in deriving the site-specific remediation goals the authors first subtracted air from the acceptable risk allotment, then estimated goals for soil, assuming soil was the only portion of intake that could be modified (p. 40 RS). They also noted that the hazard quotients are average values and that central tendency estimates and reasonable maximum exposure values were only used for receptor characteristics. Panel members suggested that the nickel intakes and exposure point concentration summaries and intakes for each receptor be presented in the site-specific remediation goals discussion. This would provide useful information for risk managers to make decisions that are more informed. If goals are derived in the revised document, the panel recommended that the authors clearly explain the rationale for deriving them.

6. **Were all the significant sources of uncertainty identified and characterized? Are the authors' conclusions regarding the significance and impact of the uncertainties on the resulting assessment conclusions appropriate? (Volume II, Chapter 7)**

AND

7. **Were quantitative uncertainty and sensitivity analyses done correctly? Could they have been done differently to improve the assessment of uncertainty? (Volume II, Chapter 7)**

- Panel members generally agreed that the significant sources of uncertainty were identified in Chapter 7, but made a number of comments and corrections for some of the statements.

Panel members discussed the need to include or improve discussions regarding uncertainty in a number of areas (see other parts of this report). Regarding the information presented in Chapter 7, the panel thought that the key sources of uncertainty had been identified and adequately discussed, but took exception to a number of statements in the HHRA:

- Page 7-7, line 200 - in reference to the statement that 10% of properties sampled with a focus on areas of particular concern would tend to mitigate risk of missing local areas of higher concentrations. A panel member said this rationale is not correct because focusing on high use areas (e.g., schools and parks) has nothing to do with mitigating the risk of missing local areas of high concentrations. Focusing on areas near the source of contamination or downwind from sources would help ensure that areas of high concentrations are not missed in the sampling.
- Page 7-9, line 254 "As formula exposures were estimated to be greater than mother's milk exposure using simple exposure comparison, the potential contribution of COCs in mother's milk was not considered." A panel member thought this was overstated and should say that the difference between mother's milk and formula were very small and for this assessment, it was decided not to consider them a significant factor. Another panel member thought the report could mention that the chemicals of concern based on exposed human populations would have included exposure *in utero* and from mother's milk.
- Page 7-10, line 303 in reference to the bioaccessibility studies - "Since the results of the study are used in a relative manner, these uncertainties are not expected to affect the results of conclusions of the HHRA." A panel member disagreed with this statement and noted that the uncertainty is mostly a lack of validation of the bioavailability assays, and there is no greater confidence with relative bioaccumulation. Another panel member wanted to see whether the uncertainties with bioaccumulation affect results
- Page 6-67, section 6.10 last two sentences of first paragraph: "This is largely because the COCs in question do not bioaccumulate, resulting in very little body burden over time. In fact, three of the six COCs are actually essential elements needed by the

body for proper health." These two sentences have no clear relationship. A discussion of body burden and whether or not a chemical bioaccumulates has nothing to do with essentiality, which is a nutrient component.

- Page 7-3, line 78. Regarding the use of uncertainty factors blurring the distinction between science and decision-making, a panel member noted that there has been significant work done to incorporate science into the uncertainty factors.

- The panel noted that the use of Monte Carlo to do a sensitivity analysis is commendable and excellent. The appropriate methods were used, not withstanding concerns about the design of the Monte Carlo simulation.

A panel member noted that appropriate methods were used and use of Monte Carlo for sensitivity analysis is excellent. However, the mixing of uncertainty and variability needs to be addressed (see discussion under questions 2 and 3 above).

8. What is the likelihood that actual health risks have been over or under estimated?

- The panel thought that the likelihood of the community-wide risks being underestimated are small given the thoroughness of the authors to make the HHRA complete. They agreed that the authors used appropriate and accepted procedures that make it more likely that they overestimated risk, rather than underestimated risk, and the result should be a fairly reliable estimation of the reasonable maximum exposed individual. However, panel members felt that their other recommendations and revisions will likely change the results, which will need to be further studied.

Panel members pointed out that because soil does not contribute much to the overall exposure and risk; it is not likely this HHRA underestimates risk even for potential local areas with higher than average exposure concentrations. While the panel agreed that the authors tended to make conservative (health protective) choices, several panel members pointed out that there are key uncertainties, such as indoor dust and relative bioavailability.

9. Do you have any additional comments regarding aspects of the risk characterization, including estimating of chemical risks, SSRGs, or uncertainty?

The panel discussed the other risk assessment issues covered in Chapter 6 and offered a few additional comments that have not been covered in other discussions. A panel member noted that discussion on children was appropriate and offered to send several supporting citations and enhancements. Regarding sulphur dioxide, a panel member suggested discussing what lime will

do to element solubility and bioavailability. Regarding occupational exposure, the panel members recognized this was not the focus of the HHRA, but suggested the authors might consider occupational data if they are available. A panel member complimented the authors regarding the text on soil ingestion rates for children and pica behavior, and noted that the rationale in the HHRA for excluding the 'pica' child is correct. A panel member suggested there may be other local cancer incidence data available that could be included and discussed in section 6.8. A panel member suggested moving the essential element discussion out of the body burden section, as they are not related.

Panel members noted that traditionally a site risk assessment uses an assumption of 30 years living near the site, but that this HHRA used 70 years, to protect those who live their entire life in the community. One panel member said this is appropriate and makes the results more conservative (health protective). Another panel member noted that the elderly in Sudbury may have been exposed to higher concentrations when younger and those in their 50s and 60s may have lifetime exposure levels that are greater than what is estimated in the HHRA based upon current conditions. Other panel members noted that the purpose of a risk assessment is to determine if one needs to take action based upon the current and future risk and this HHRA provides the structure to do that. The HHRA is not a community health assessment that would evaluate past exposures.

A panel member suggested that the authors distinguish between individuals who are more exposed versus those who are more sensitive, since they are often two different groups.

One panel member suggested the authors be careful when they adjust urine measurement for creatinine (consider lean body mass potential and first morning void) and should look at results for both adjusting and not adjusting. The member also suggested if there are dust and soil samples from residences of individuals in the urinary arsenic study, that consideration be given to evaluating if there are meaningful correlations. Another panel member noted that section 3-67 would benefit from a summary table of the results from the appendix.

4.5 Conclusions and Recommendations

The following are the panel's overall conclusions and recommendations (in addition to the specific recommendations above).

1. **Was the approach used for this community assessment consistent with commonly accepted methods and procedures by government agencies (such as Environment Canada, Health Canada, the Canadian Council of Ministers of the Environment, and the United States Environmental Protection Agency [U.S. EPA])?**

- The panel reached consensus that the overall approach used for the Sudbury HHRA was generally consistent with common practice. The HHRA was not limited to a single agency's approach, but considered the circumstances and science to draw upon the best and most appropriate procedures from various jurisdictions.
- The paradigm and the algorithms used are consistent with common methods for risk assessment, focusing on the current and future risk.

2. **Is the Human Health Risk Assessment presented clearly and completely?**

- The panel found this to be a very comprehensive assessment. They were especially pleased to see the extent of sampling done in the community, including the soil, air, dust, market basket and local foods, as well as the urinary arsenic study, bioaccessibility testing, and speciation. However, the panel members also agreed that the authors need to better organize and present the information. Important information was not always included in the necessary chapters, nor were complete details of the data and assumptions presented alongside the algorithms. This made it difficult for the panel to recreate the calculations and check the conclusions.
- The panel recommended that a technical editor read and edit the entire HHRA for flow and to insure internal consistency.
- Panel members noted that a more clear and understandable Executive Summary is very important, as this may be all that many people read.

3. Overall, are the input data and assumptions valid and appropriate for the Sudbury community?

- The panel agreed that the environmental data collection was extensive and provided community-specific data to use instead of defaults.
- The panel thought that most of the data and assumptions were appropriate for the stated objective of the study – to look at health effects currently present for future and existing exposure conditions. They also noted that the assumptions and data selections were appropriately conservative selections.
- The panel had significant discussions regarding some of the input data and assumptions, the source of the data and the strength of the support for their use. The panel provided a number of suggestions for alternatives and recommended further investigation to determine the best data and assumptions to use.

4. Are the conclusions for each COC valid and defensible, and are they supported by the risk assessment? Are there additional points that should be made?

- Panel members agreed that it was premature to say if the conclusions for some of the chemicals of concern are valid and supported. If the recommendations of the panel are implemented, the assessment will be revised and some conclusions may change.
- The panel thought that overall the calculations of exposure and risk associated with metals from sources of concern (i.e., smelting and mining) are health protective and likely overestimate risk (that is they err on the side of more health protection, rather than less).
- If the panel recommendations are followed, the accuracy and usefulness of the study for making risk management decisions will be improved.

5. Have the important uncertainties been identified and their impact on the characterization of risk and overall conclusions been discussed?

- The panel thought that Section 6 of the HHRA covered the important issues that affect uncertainty and the overall conclusions.

6. **Have the key objectives of the Sudbury Soils Study been addressed by this assessment? (Volume II, Page 1-6)**

- The panel thought that the objectives have been addressed but that some topics need further study and consideration to respond to the panel recommendations. They pointed out the inconsistency between objective 1, 2 and 3, where risk from metals in the environment (Objective 1), was expanded to quantify exposure from all sources. This creates some difficulties in communicating risk to the public, for example, when the market basket foods contribute far more to total risk than the local contamination.

7. **Are there additional important issues that should have been addressed?**

See above.

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