

Review of the Flin Flon and Creighton Human Health Risk Assessment

Volume I

**Report of the Independent Expert Review Panel
(IERP) meeting
June 23-24, 2009
Winnipeg, Manitoba**

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

**Final Report
September 14, 2009
Amended June 8, 2010**

June 8, 2010

To the Residents of Flin Flon and Surrounding Areas:

On behalf of the Independent Expert Review Panel (IERP), **I am pleased to release this final report of the IERP for the Flin Flon Human Health Risk Assessment (HHRA)**. Colleagues and I have reviewed Intrinsic authors' responses to the IERP comments and the revised HHRA. The authors were responsive to the panel's concerns and recommendations and revised the HHRA accordingly.

Specifically, the IERP found that the HHRA followed commonly accepted human health risk assessment methods and that overall the input data and assumptions were valid and appropriate. The IERP offered numerous suggestions for improvement to the HHRA, most of which the authors accepted. While a few differences of scientific opinion remain between the IERP and the authors of the HHRA, these differences do not impact the conclusions of the HHRA or the protection of public health in Flin Flon and surrounding areas. The HHRA and results were found to be scientifically-sound and appropriately health protective. The HHRA has been revised to address the IERP recommendations and be responsive to the IERP issues and concerns.

My best wishes to your continuing efforts to protect your community's health.

Sincerely,

Michael L. Dourson, Ph.D, DABT, ATS
Chair, IERP

NOTE

This report was prepared by scientists of Toxicology Excellence for Risk Assessment (*TERA*) and reviewed by the panel members. The members of the panel served as individuals, 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) of scientists met June 23-24, 2009 to conduct an independent review of the draft human health risk assessment (HHRA) for Flin Flon, Manitoba, and Creighton, Saskatchewan. The draft HHRA was prepared by Intrinsic Environmental Sciences Inc. to address the potential human health risks associated with exposure to smelter-related metals in soils and other environmental media (such as air, water, dust, local foods, and fish) in the Flin Flon and Creighton area. A Technical Advisory Committee with representatives from national and provincial agencies provided technical guidance to Intrinsic on the draft document and attended the IERP meeting. Hudson Bay Mining and Smelting Co., Limited (HBMS) provided funding for the HHRA and the IERP.

The panel included eight well-respected scientists with relevant expertise. The panel carefully reviewed the draft HHRA and supporting documents prior to the meeting. At the meeting, the Intrinsic authors presented information on the data, analyses, and conclusions and the panel asked questions to better understand the authors' approach and results. The panel then discussed the data, assessment, and key questions and scientific issues to evaluate the quality and completeness of the risk assessment. The IERP report summarizes the panel's discussions, conclusions, and recommendations. This executive summary is intended to provide a brief overview of the IERP report for a non-technical audience.

Environmental Sampling and Laboratory Testing

Panelists thought that the supplemental sampling to measure the concentrations of the metals in soil, indoor dust, air, water, fish, and local foods was very comprehensive. Individual panel members suggested gathering some additional data that would strengthen the assessment including: more sampling in non-impacted areas for background metal concentrations to cross reference with the Flin Flon and Creighton sampling data and mineralogical analysis of mine tailings to better characterize the source of contamination; The panel also suggested that the authors return to locations where higher boron concentrations were found in soils and do additional analysis of samples using two analytical methods to confirm the accuracy of the concentrations measured.

The panel members suggested that the authors explain better how they decided which metals to address in the HHRA. The IERP agreed with the decision to include arsenic, lead, mercury, cadmium, and copper, but were not convinced that selenium should have been included.

Laboratory testing was conducted on sample soils to provide information to help determine how much of the metals would be absorbed by humans from ingesting contaminated soil. The percentage absorbed is important to determining how toxic the metals could be to humans. The panel thought that the absorption percentages used in the HHRA for cadmium, copper, mercury, lead, and selenium were appropriate. For arsenic in soils, not all of the panel agreed with the percentage used, and after some discussion the panel suggested the authors consider the panelists' individual suggestions and use their best scientific judgment to decide what to use for arsenic.

Exposure Assessment

The panel discussed the ways that people living in the Flin Flon area might come in contact with the metals of concern (for example, eating home grown foods, playing in contaminated soil, drinking water, breathing air) and the exposure characteristics of the populations (for example, breathing rates, blueberry consumption). The panel agreed that most of the population characteristics and exposure values used in the HHRA were appropriate. Some panel members suggested that the HHRA should also evaluate whether nursing infants may be exposed to the chemicals or if outdoor recreational activities might expose people to contaminated lake sediments. Panel members questioned whether the average amount of food consumed was a realistic estimate, particularly the amount that was assumed for toddlers.

The IERP discussed that there may be other sources of pollution (other than the mining and smelting operations) that are contributing to the levels of copper and lead found in drinking water. The IERP discussed if there was a contamination source within the water distribution system or at the household tap to explain the measured concentrations, which are significantly higher than the maximum copper and lead concentrations in the waters that are the source of local drinking water. The IERP also suggested some testing of homes for lead-based paint and water pipes for lead and copper. The IERP also found the indoor dust concentrations of lead unusual, in that they are higher than outdoor soil concentrations; and the IERP thought that there may be other sources of contamination for these metals. The IERP suggested investigating other sources of contamination, perhaps contaminated dust remains in seldom used parts of home (for example attics) from high smelter emissions in the past, and that this contaminated dust is contributing to current concentrations in living areas. The panel thought the discussion of exposure to lead from consumer products was helpful to understand the total picture and suggested that potential consumer product exposure for other metals be included.

The IERP discussed the concentrations in air, soil, indoor dust, water, local foods, and fish that were used in the HHRA and whether they were appropriate and scientifically sound. The panel discussed whether the use of the 95% upper confidence limit on the mean (95% UCLM) was conservative enough for estimating people's exposure to chemicals in the soil. Other options would have been to use the average (or mean) or the highest concentration measured. Some panel members thought that these upper confidence limits of the mean may not represent the level to which a child living on a property with high soil concentrations could be exposed. However, other panelists pointed out that because the toxicity for most of the metals of concern (with the exception perhaps of lead and methyl mercury) is based on long-term exposure over a lifetime, the 95% UCLM for soil is the appropriate value to use. Panel members did not all agree on which statistic to recommend and noted that preference for the 95% UCLM or maximum value varies among countries and agencies.

Hazard Assessment

The IERP agreed with the authors that most of these metals are well-studied compounds with excellent toxicological assessment documents available that can be reliably used for the HHRA. However, the panel noted that sufficient scientific disagreement exists with regard to oral arsenic

carcinogenicity that the HHRA should provide more discussion of recent arsenic toxicity evaluations and the scientific issues surrounding arsenic carcinogenicity. The panel thought that the authors should present the range of risk assessment values for arsenic rather than rely on a single value.

HHRA Results and Risk Characterization

The panel members generally agreed that overall the HHRA followed the commonly accepted human health risk assessment methods. Overall, the panel agreed that the input data and assumptions used in the assessment were valid and appropriate, they raised a number of issues and questions and made some recommendations for revisions.

The panel noted that estimating risk from short-term exposures to the chemicals is problematic, as is identifying human medical conditions or adverse effects from short-term exposures. The panel also noted that the only relevant short-term exposures to consider are from air. In contrast, lifetime exposure to contaminated soil, water and food should be assumed when calculating risk in a screening assessment. The IERP recommended that the HHRA not estimate risk for short-term exposures to metals in the air, but clearly explain that if short-term exposures are below the long-term risk benchmarks, then people will be protected from the effects of short-term exposures.

The HHRA calculated non-cancer hazard quotients (HQs) for five different age groupings, and found that the highest HQs were for the toddler group. Panel members questioned the appropriateness of the toddler results, and thought that the larger HQ for toddlers only reflects that this age group drinks more water on a per kilogram body weight basis than the other age groups. They also cautioned that the toddler's few years of exposure are being compared to toxicity values meant to be protective for a lifetime of exposure. For most of the chemicals of concern, particularly arsenic and cadmium, these toddler hazard quotients are not appropriate because the toxicity values are based on studies with whole life human exposures. For arsenic, the panel noted that there is no indication that children are more sensitive to arsenic than adults on a body weight basis, therefore calculating risk for different age groups for arsenic is not appropriate. An author agreed that the arsenic risk assessment results alone do not provide a realistic assessment and suggested that a urinary arsenic study in the population can provide additional information to better characterize risk. Panel members noted that other toxicity reference values (e.g., lead) are based on effects from shorter exposures and calculating HQs for smaller age categories may be appropriate for lead.

The panel suggested that the authors consider whether a particular local lake is a "favorite" and therefore give more weight to concentrations of chemicals from this preferred lake, rather than averaging all local lakes. The IERP also questioned whether the evaluating an outdoor worker exposure is necessary when the HHRA assumes indoor and outdoor air concentrations are the same, so workers inside or outside would have the same exposure. The panel suggested that the HHRA include a discussion of potential recreational exposure to contaminated sediments (for example accidentally ingesting sediment while swimming and playing near shore) because it is a common pathway considered in HHRAs. However, the panel did not think such a discussion would affect the quantitative results. The panel also suggested that the authors present the number of properties that have concentrations exceeding the level of concern for at least one of the COCs, to provide an indication of the magnitude of concern.

The panel discussed whether the U.S. EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model was appropriate to use for a community risk assessment. The panel recommended that the HHRA rely upon the risk characterization based upon exposure concentrations using the same Canadian and site-specific assumptions as the other metals. They suggested the IEUBK model be used to support the other results and that the details on the model be moved to an appendix. Some panel members questioned why preliminary remediation goals (PRGs) for soil were calculated, regardless of whether a chemical exceeded a safe level, or whether soil was a significant contribution to exposure. Typically, PRGs are not calculated unless it is determined there is a problem. Other panelists agreed with the authors that the PRGs are useful to help identify the metals or exposure to focus efforts.

HHRA Recommendations

The draft HHRA recommended a comprehensive biomonitoring program, including urinary arsenic, blood lead, and urinary inorganic mercury, to evaluate environmental contaminant exposure to children in Flin Flon and Creighton. The panel discussed the HHRA conclusions and recommendations and the support for the recommendations.

For arsenic biomonitoring, some panel members thought the recommendation was appropriate, while others voiced concerns. Panelists thought it would be difficult to distinguish between background levels to which all Canadians are exposed and local sources of arsenic exposures. The authors indicated that they do not expect to find elevated arsenic levels in the community, but hope that the biomonitoring results will allow them to compare people in the community exposed to different soil concentrations to see if soil is the driver of exposure. The panel cautioned that the authors must be careful interpreting the arsenic hazard quotients for toddlers because the toddler's few years of exposure is inappropriately being compared to chronic toxicity values that are based on lifetime human exposures, which already account for exposure to the infant, toddler and in the mother's womb. Some panelists thought that employee biomonitoring data should be evaluated before community biomonitoring is considered, and were concerned that the number of people in the community participating in the biomonitoring study may not be large enough to be able to determine that blood and urinary measurements are from local soil and air exposures. Half the panel agreed with the authors' recommendation for an arsenic biomonitoring program, while the other half either did not agree, or had significant reservations about such a program.

The draft HHRA recommended a blood lead survey be conducted for a sample population up to age 7. One panelist did not think the testing was justified based on the risk assessment and the relative contribution from the HBMS facility. The other panel members supported this recommendation for lead testing, although most of the supporters had some reservations and offered cautionary advice. One reviewer thought that the risk assessment did not support the recommendation, but agreed that a blood lead survey would be helpful to alleviate uncertainties in people's minds. Some thought that if the authors step away from using the IEUBK model, their conclusions may be somewhat different, with hazard screening resulting in identification of fewer problem properties. One panelist thought that a blood lead survey is a good idea for any community with an aged housing stock, near a source of lead emissions, and with some properties with high soil concentrations. Having these data will assist future risk assessment

efforts (particularly if the Health Canada toxicity benchmark for lead is reduced) and can provide data for measuring effectiveness of cleanup efforts. A panelist suggested the authors consider testing for lead up to age 16 to include older children who may have more opportunity for exposure. Panelists cautioned that the limitations and study design should be carefully explained to the community and there should be a plan for how to respond to any elevated levels found, including if the source is lead based paint.

The majority of the panel did not agree with the recommendation for a biomonitoring program for inorganic mercury, noting that it appears that duration of exposure is a factor involved for inorganic mercury's toxicity and that the hazard quotient for inorganic mercury averaged only 2. The panel agreed with the recommendation to consider a fish advisory for methyl mercury and suggested ongoing monitoring of methyl mercury in fish.

Final Panel Conclusions

The panel members generally agreed that overall the HHRA followed the commonly accepted human health risk assessment methods. Overall, the panel agreed that the input data and assumptions used in the assessment were valid and appropriate, except for those identified during discussion. The panel agreed that in general, the HHRA was presented clearly and completely, and that it was a very comprehensive effort. Panel members recognized the challenges in conducting such a comprehensive assessment and thought that the panel's suggestions and recommendations could be incorporated fairly readily into a revised HHRA.

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Technical Executive Summary

An independent expert review panel (IERP) of scientists met June 23-24, 2009 to conduct an independent review of a draft human health risk assessment (HHRA) for Flin Flon, Manitoba, and Creighton, Saskatchewan. The draft HHRA was prepared by Intrinsic Environmental Sciences Inc. to address the potential human health risks associated with exposure to smelter-related metals in soils and other environmental media in the Flin Flon and Creighton area. A Technical Advisory Committee with representatives from national and provincial agencies provided technical guidance to Intrinsic and attended the IERP meeting. Hudson Bay Mining and Smelting Co., Limited (HBMS) provided funding for the HHRA and the IERP review. The panel included eight well-respected scientists with expertise in multi-pathway risk assessment; environmental fate; toxicology and epidemiology; biomonitoring studies; exposure assessment; bioaccessibility of metals from soils; sampling and analysis for metals; derivation of clean up levels; and, uncertainty and sensitivity analyses. The panel carefully reviewed the draft HHRA prior to the meeting. At the meeting, the Intrinsic authors presented information on the data, analyses, and conclusions and the panel asked them many questions to better understand the authors' approach and results. The panel discussed the data, assessment, and key questions and scientific issues to evaluate the quality and completeness of the risk assessment. This report summarizes the panel discussions and conclusions.

Problem Formulation and Sampling

Panelists indicated that the supplemental sampling effort was very comprehensive. Individual panel members suggested some additional data and analysis to increase confidence in the assessment including: more sampling in un-impacted areas for background levels; analysis and speciation of tailings to characterize the source of contamination; and testing of homes for lead-based paint and lead and copper from water pipes. The panel also suggested that the authors return to locations where high boron concentrations were found and do split samples with the two analytical techniques to confirm the concentrations and determine whether boron should be a chemical of concern (COC).

The panel members discussed the selection of COCs and recommended that objective screening criteria be defined and applied systematically, and that the screening process be made more transparent in the assessment document. Several panel members questioned the inclusion of selenium as a COC because of the few samples where selenium exceeded the criterion for inclusion.

The conceptual model, scenarios, and receptor characteristics used for the exposure assessment were discussed. Some suggested further consideration of a nursing infant scenario and recreational exposure to sediments. The panel agreed that most of the receptor characteristics and values were appropriate. Panel members suggested other sources for the food consumption values that might be more realistic (particularly for the toddler).

In Vitro Bioaccessibility Testing

In vitro bioaccessibility testing was conducted to provide information for the soil ingestion pathway and relative absorption factors (RAFs) were calculated. The panel agreed with the RAFs selected for four of the COCs (cadmium, copper, mercury and selenium), and further

discussed the bioaccessibility testing results for lead and arsenic. For lead, panel members agreed that the *in vitro* results are reliable, and the RAF of 58% was appropriate. The panel discussed whether the RAF of 34% for arsenic was appropriate to use when the *in vitro* bioaccessibility method for arsenic has not been fully validated with an *in vivo* model. One panel member supported use of 34% as reasonable for this community assessment, based on the fairly good, but not perfect, correlation seen between *in vivo* and *in vitro* results, and the mineralogy data on house dust. Another reviewer questioned whether evidence is available to be confident that the community soils are more like those with the good correlations than those with poor correlations. The panel did not reach consensus on this, but recommended that the authors consider the suggestions, examine the data closely, and calculate an estimate for the soil levels of concern.

The panel also discussed the relationship between bioaccessibility and soil concentrations, noting that results may differ depending on the soil concentration, and therefore the soil concentrations used for the *in vitro* assays should be representative of the community soils. A panel member suggested that regression analysis could be used to evaluate the relationship between soil concentration and bioaccessibility. The panel discussed that the arsenic bioaccessibility results do not look reliable at lower soil concentrations and several panelists suggested dropping results from those arsenic samples below 50 ppm and recalculating the 95% upper confidence limit on the mean (95% UCLM) for arsenic bioaccessibility. The panel suggested the authors analyze whether the variance at low concentrations introduces bias in estimating the 95% UCLM .

Exposure Assessment

Exposure point concentrations (EPCs) were derived from the available exposure data and additional modeling for lead in children was done with the Integrated Exposure Uptake Biokinetic (IEUBK) model. EPCs under the residential scenario were derived for all media including outdoor soil, indoor dust, ambient air, drinking water, garden vegetables, local fish, wild game, and snow. Exposure estimates were derived for receptors in each of the five age classes for the residential exposure scenarios for each of the five communities of interest (COI).

Other potential sources for the contamination were discussed. Panel members questioned the EPCs for copper and lead in drinking water and wondered if there was a source within the distribution system or at the tap to explain these values, which are significantly higher than the maximum surface water concentrations. The indoor dust levels of lead are unusual in that they are higher than soil levels; potential other sources could be lead-based paint, high levels of emissions in the past; or attics serving as reservoirs of continuing contamination for the homes.

The panel also discussed the inclusion of non-smelter sources of exposure, such as consumer products, in calculating the exposure point concentrations. The authors accounted for consumer product exposure for lead quantitatively and the panel recommended that the consumer product pathway should be discussed qualitatively for the other five COCs.

The panel discussed whether the use of the 95% UCLM was sufficiently conservative for the soil EPCs. These upper confidence limits of the mean may not account for the child living on a property with high soil concentrations. Panelists pointed out that because the toxicity for most of the COCs (with the exception perhaps of lead and methyl mercury) is based on long-term

exposure over a lifetime, the 95% UCLM for soil is appropriate. Panel members did not reach agreement on which statistic to recommend and noted that preference for mean or maximum value varies among countries and agencies.

The assessment compared local results to national soil and water background levels for the COCs. Several reviewers questioned whether the national background levels are representative of background for a mining area.

Hazard Assessment

The authors explained that the COCs are well-studied compounds with excellent toxicological assessment documents available, but noted issues with use of the arsenic cancer risk value and the lead and copper TRVs. The panel discussed the problems with the acute TRVs and the arsenic oral carcinogenicity assessment and their use in the HHRA. The panel recommended that the authors address acute risks qualitatively (but not quantitatively) and clearly explain that the chronic values are protective of acute exposures. The panel noted that there is sufficient controversy with regard to oral arsenic carcinogenicity that the assessment should discuss more recent arsenic assessments, additional data, and the issues surrounding arsenic. The panel thought that the authors should qualitatively discuss the range of risk assessment values for arsenic.

Results and Risk Characterization

The HHRA found that there were some elevated concentrations of arsenic and mercury in the West Flin Flon area with soil identified as a significant pathway with respect to arsenic and inorganic mercury. Fish and some other foods drive the methyl mercury risk. The assessment evaluated lead exposures using a deterministic approach and the IEUBK model, but the authors noted that measurement of blood lead levels would be a definitive measurement of exposure.

Acute exposures apply only to the air pathways in this study and estimating acute exposures and risks is problematic. The panel recommended the authors reconsider the available acute TRVs and consider addressing acute risks qualitatively, but not quantitatively. The panel recommended the authors carefully describe acute exposures and risks so that members of the public do not respond inappropriately to the perceived magnitude of the risk.

The HHRA calculated non cancer hazard quotients (HQs) for five age groups, and the highest HQs were for the toddler group. Panel members questioned the appropriateness of using the toddler because this age group drinks more water per kilogram body weight than the other age groups and this is the cause for the larger HQ. Panel members noted that the arsenic TRV is based on populations exposed over an entire lifetime, including children and *in utero* exposures, and there is no indication that children are more sensitive to arsenic than adults on a body weight basis, therefore use of age groups for arsenic is not appropriate. Other TRVs (e.g., lead) are based on effects from shorter exposures and breakdown by the smaller age categories may be more appropriate. An author agreed that the arsenic risk assessment results alone do not provide a realistic assessment and suggested that a urinary arsenic study can provide additional information to better characterize risk.

The panel recommended that the authors recalculate the risk estimates for cadmium. They also noted that the statement regarding the cancer risk for cadmium being elevated should be evaluated closely, as the estimated risk is no greater than that for arsenic.

The panel identified a number of additional concerns with the chronic endpoints. For the residential scenario, the assessment added risks from different routes and then compared the sum to an oral TRV. Some panel members questioned this, while others agreed with the approach. The panel recommended that the authors calculate separate oral and inhalation HQs when toxicity values are available. These HQs should then be added together and presented with the authors' original approach.

After examining the results, panel members made a number of other recommendations. They suggested that the authors consider a "favorite lake" scenario or some use of a weighted average based on the data to reflect local fish consumption patterns; use a composite receptor for arsenic given the carcinogenicity endpoint; use a mean exposure value for the outdoor worker and reconsider whether the outdoor worker scenario is even necessary if one assumes indoor and outdoor concentrations are equivalent; address sediment exposure (e.g., oral exposure while swimming and playing near shore) qualitatively because it is a common pathway considered, although they did not think it would materially affect the quantitative results; and provide an indication of the magnitude of concern by communicating the number of properties that exceed a target level for at least one of the COCs.

The panel also discussed a number of issues with use of the IEUBK lead model, in particular that the model is meant to be applied to a homogenous exposure scenario, which is not the case here. A reviewer noted the variability in bioaccessibility of the lead samples, which leads this reviewer to think there are different sources of lead. The reviewer thought that the IEUBK model will indicate the problem is soil, when it is likely the lead is from house paint. The reviewer suggested looking for consistency in bioaccessibility by source or area and noted that mineralogical analysis will help understand which bioaccessibility estimates to apply to which soil concentrations. The panel agreed that the HHRA should use the hazard indices derived from the deterministic model for lead risk, noting that the deterministic approach used the same Canadian and site specific assumptions as the other COCs. However, they also suggested the authors use the IEUBK model to support the spreadsheet model results, harmonizing the parameters between the two as much as possible.

Panel members questioned why preliminary remediation goals (PRGs) and provisional trigger concentrations (PTCs) were calculated regardless of whether a COC exceeded the decision criteria or whether soil was a significant contribution to exposure. Some questioned why market basket foods and dental amalgams were included in intake calculations. In particular panel members questioned a PRG for selenium, where the soil accounted for just 2% of intake. Other panelists thought the PRGs are useful to identify which media and compounds to focus efforts.

Recommendations

The draft assessment recommended a comprehensive biomonitoring program to evaluate environmental contaminant exposure to children in Flin Flon and Creighton. Surveys of urinary arsenic, blood lead, and urinary inorganic mercury levels in a sample population were

recommended to help refine and validate the HHRA's exposure estimates. The assessment did not recommend further action for cadmium, noting that the smelter is closing in the next year and with its closing, the air concentrations will reduce dramatically. For methyl mercury, the authors recommended more evaluation to determine the best action for reducing exposures (including consideration of a fish consumption advisory), but noted that biomonitoring would not assist in decision making.

The authors noted that for lead, both the IEUBK and deterministic models predicted average lead related exposures to be within acceptable levels. However, because a significant number of residential properties in West Flin Flon have concentrations in outdoor soil greater than the residential PTC, and Health Canada is expected to lower the benchmark for lead, the authors recommended a blood lead survey focused on sampling children up to age 7 to reduce uncertainty in the exposure assessment.

The panel discussed the HHRA conclusions and recommendations. Panelists thought it would be difficult to distinguish between background levels and sources for arsenic and the authors indicated that they do not expect to find elevated arsenic levels in the community, but hope that the biomonitoring results will allow them to compare people in the community exposed to different soil concentrations to see if soil is the driver of exposure. Some panel members thought the recommendation for arsenic biomonitoring was appropriate, while others raised a number of concerns. The panel cautioned that the authors must be careful interpreting the arsenic hazard quotients for toddlers because the toddler's few years of exposure is inappropriately being compared to chronic toxicity values that are based on lifetime human exposures, which already include infants and *in utero* exposures. Additional panel concerns included that employee biomonitoring data should be evaluated before community biomonitoring is considered, the statistical power of a community biomonitoring study may not be sufficient to attribute an incremental exposure to soil and air exposures, and with the smelter closing postponing biomonitoring because current emissions are more relevant to exposure than soil concentrations. Half the panel agreed with the authors' recommendation for an arsenic biomonitoring program, while the other half either did not or had significant reservations about such a program.

The HHRA recommended a blood lead survey be conducted for a sample population up to age 7. All but one panel member supported this recommendation, although most of the supporters had some reservations and offered caveats. One reviewer thought that the risk assessment did not support the recommendation, but agreed that it would be helpful to alleviate uncertainties in people's minds. Some thought that if the authors step away from using the IEUBK model, their conclusions may be somewhat different, with hazard screening resulting in identification of fewer problem properties. One panelist thought that a blood lead survey is a good idea for any community with an aged housing stock, near a source of lead emissions, and with some properties with high soil concentrations. Having these data will assist future risk assessment efforts (particularly if the TRV for lead is reduced) and can provide data for measuring effectiveness of cleanup efforts. A panelist suggested the authors consider testing for lead up to age 16 to include older children who may have more opportunity for exposure. Panelists cautioned that the limitations and study design should be carefully explained to the community and there should be a plan for how to respond to any elevated levels found, including if the source is lead based paint. One panelist did not think the testing was justified based on the risk

assessment and the relative contribution from the HBMS facility. The panelist thought it would have been better to do such a survey prior to the HHRA and incorporate the results.

The majority of the panel did not agree with the recommendation for a biomonitoring program for inorganic mercury, noting that it appears that duration of exposure is a factor involved for inorganic mercury's toxicity. The TRV is based on a chronic study and an exposure slightly greater than the TRV for the toddler (HQ of 2), does not support biomonitoring. The panel agreed with the recommendation to consider a fish advisory for methyl mercury and suggested ongoing monitoring of methyl mercury in fish.

The panel members generally agreed that overall the assessment followed the commonly accepted human health risk assessment methods. Overall, the panel agreed that the input data and assumptions used in the assessment were valid and appropriate, except for those identified during discussion. The panel agreed that in general, the HHRA was presented clearly and completely, and that it was a very comprehensive effort. Panel members recognized the challenges in conducting such a comprehensive assessment and thought that their suggestions and recommendations could be incorporated fairly readily.

1. Participants

Authors/Presenters

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¹ Affiliations 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.

2. Overview of the Independent Expert Review Panel (IERP) Process

This meeting of an independent expert review panel (IERP) was 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* convened this panel to review the draft human health risk assessment (HHRA) of Flin Flon, Manitoba, and Creighton, Saskatchewan. The draft HHRA was prepared by Intrinsic Environmental Sciences Inc. to address the potential human health risks associated with exposure to smelter-related metals in soils and other environmental media in the Flin Flon and Creighton area. A Technical Advisory Committee (TAC) with representatives from national and provincial agencies provided technical guidance to Intrinsic. TAC members attended the IERP meeting. Hudson Bay Mining and Smelting Co., Limited (HBMS) provided funding for the HHRA and the IERP review.

The IERP included eight scientists with expertise in the key disciplines to review the assessment. Each panelist is a well-respected scientist in his or her field. Collectively, the panel has expertise in multi-pathway risk assessment; environmental fate, human toxicology and epidemiology; biomonitoring studies; exposure assessment and pathways modeling; bioavailability and bioaccessibility of metals from soils; sampling and analysis for metals in diverse media; evaluating human health hazards of soils and dust; derivation of Soil Trigger Concentrations (STC) and soil preliminary remediation goals (PRG); and uncertainty and sensitivity analyses. Panel members were very familiar with Canadian and United States (US) guidance and methodologies for multimedia risk assessments. Each panel member disclosed information pertinent to evaluating potential conflicts of interest and biases related to the HHRA and its sponsor. *TERA* carefully evaluated this information when selecting panel members. *TERA* was solely responsible for the selection of the panel members. Short biographical sketches and disclosure statements for panel members are provided in Appendix A.

The panel was sent the HHRA and review materials approximately six weeks prior to the meeting to ensure adequate time to carefully review the document and prepare for the meeting discussions. *TERA* developed a “charge to peer reviewers” document that outlined the key questions and scientific issues to evaluate the quality and completeness of the risk assessment. A copy of the charge is found in Appendix B, along with other meeting materials.

Members of the TAC were invited to observe the panel meeting process. The TAC members were provided some opportunities to ask questions of the panel. A list of attendees is found in Appendix B.

TERA prepared this meeting report. The report summarizes the authors’ presentations, the panel discussions, the authors’ comments during the discussions, and questions from the TAC attendees. The meeting report is a summary, not a transcript. Opinions and recommendations of the panel members are noted (although panelists are not identified by name). Panel members have reviewed the draft report, and their comments and corrections have been incorporated into this report.

3. Panel Introductions, Conflict of Interest, and Meeting Process

The meeting opened with a welcome by Ms. Jacqueline Patterson of *TERA*. She described the background and purpose of the peer consultation and the agenda for the meeting. Ms. Patterson noted that copies of panel members' biographical sketches and conflict of interest and bias statements were provided to all attendees (see Appendix A). The panel members then introduced themselves and noted whether they had additions or changes in their statements. None of the panel members had any substantive changes to their statements.

Dr. Dourson, the panel chair, then described how the meeting would be conducted. He explained that discussions would be organized around the charge questions and would follow the order in the agenda (see Appendix B). He noted that all panelists would have the opportunity to state their own positions on the charge items and panel members are encouraged to question one another to make sure that all the panel members and the authors understand the scientific basis for the panelist's opinion. The panel will seek agreement, but if agreement is not reached, areas where panelists' disagree will be noted. Authors will make brief presentations and answer clarifying questions from the panel members. The authors will also be permitted to ask clarifying questions of the panelists so that they fully understand what is being suggested or said.

4. Background

4.1 Presentation by Mr. Alan Hair, Hudson Bay Mining and Smelting Co., Limited (HBMS)

Mr. Alan Hair of HudBay Mineral Inc. presented background information on the Flin Flon/Creighton HHRA including maps of the area, pictures of the smelter, and a history of the smelter. Slides of his presentation are found in Appendix C. Mr. Hair noted that by 1993 major process upgrades for the zinc plant significantly reduced emissions. The copper smelter, however, uses standard technology and is slated to close in 2010. He explained that ore and materials from outside the area have been trucked in for processing on site, along with material from the Flin Flon mines. The mill tailings are currently stored directly next to the complex and Mr. Hair noted a large dust storm in 2002 spread contaminants from the mill tailings area throughout the community.

4.1.1 Clarifying Questions

Panel members asked a number of questions about the tailings impoundment and measures in place to control run-off and migration off-site. Mr. Hair explained that Flin Flon Lake was drained to store the tailings and it all drains to the lake bottom; therefore there is just one point of effluent discharge, and no issues with contamination of local waters. Tailings have been managed with sand and slag cover and soil cement to eliminate tailings migration from the management area. Major changes were implemented after the dust storm in 2002. Mr. Hair also noted that smelter slag has been widely used throughout the area. The slag passes all the leachate tests, and metals are locked up fairly well and levels are low. In response to a question about availability of a wind rose, Mr. Sigal (an author) explained that there is a wind rose in the CD of references provided to the reviewers.

In response to panel questions, Mr. Hair explained that the communities started as unplanned settlements directly adjacent to the HBMS mining and metallurgical complex when operations commenced in 1927. Flin Flon was not incorporated until 1933. In the uptown area next to the operations, part of West Flin Flon in the study, housing was built from the 1930s onwards with constant redevelopment. Farther out from the operations, in the area referred to as East Flin Flon, there would have been some original housing dating from the 1930s and 1940s, but the main expansion occurred after World War II, with subdivisions being progressively developed from the 1950s through to the 1990s. The town of Creighton was first incorporated in 1952, and most housing would also have been developed after World War II.

5. Problem Formulation and Sampling

5.1 Presentation by Mr. Adam Safruk, Intrinsic

Mr. Adam Safruk, one of the HHRA authors from Intrinsic, presented information on the problem formulation used in this risk assessment. Slides of his presentation are found in Appendix C. He described the site characterization and the communities of interest (COIs) and noted numerous studies have indicated elevated levels of metals in the area soils. It was noted that the predicted wind direction was towards the southeast. A residential soil sampling study was initiated in fall 2007 by Jacques Whitford (2008). A chemical of concern (COC) list that included 6 COCs was identified based on the comparison of concentrations in soil and health risk guidelines, as well as consideration of regional background concentrations. The authors identified human receptors as infant, toddler, child, adolescent, and adult. Exposure pathways included oral, inhalation, and dermal pathways from soil, dust, home garden vegetables, blueberries, fish, wild game, surface water, drinking water, and snow. Scenarios included residential (children and adults) and outdoor commercial workers, the latter at the request of the TAC. The worker scenario is meant to assess exposure to an outdoor worker in the area who does not also live in the area. The authors derived PRGs and provisional trigger concentrations (PTCs) to assess on a property-by-property basis because they thought it was not realistic to assume that most receptors will move randomly throughout the community.

5.1.2 Clarifying Questions

Panel members had no clarifying questions on the presentation itself, but asked a number of questions on information in the HHRA and in particular sought to understand some of the monitoring data presented. In response to their questions, Mr. Safruk reported that there are air monitoring data back to the 1990s, but that for the HHRA the 2007-2008 data were used. Chapter 4 of the HHRA includes a table of the timeline for the air data covering the last few years, but Mr. Safruk noted that the data prior to 2002 were not relied upon because technologies have greatly improved since then. The authors revised this table to include a longer time frame and provided the revised table to the panel later in the day (see Appendix D).

The authors did not know the reason for the substantial decrease in lead, copper, and zinc concentrations associated with particulate matter air sampling from 2002 to 2006, but thought that the data reflected normal variability in weather, wind and feed materials. They did not know why there was an apparent increase in copper and lead concentrations in drinking water from 2002 through 2006 collected as part of the ongoing HBMS monthly sampling program (as reported in Table 2-4). Mr. Safruk noted that the annual concentrations reported in Table 2-4

represent mean values of samples from multiple locations. This prompted panelists to question whether these values represent water in the distribution system, or the tap, or a mix of the two, and pointed out that if the source is not consistent between years, or treatment changed, this might explain the variations in the data. The authors noted that the historic data were used to identify additional sampling needs, and the subsequent sampling was of tap water. The authors stated that they would check to see if the surveys included questions about lead pipes. However, only one of the fifty tap water samples exceeded lead guidelines in the Jacques Whitford (2008) survey. Thus, the authors do not think that lead from pipes is a problem in these communities.

In response to other panel questions, Mr. Safruk noted that he was not aware of the area being naturally high in radioactive materials or radon; and that there are no fish advisories for Ross Lake, because there are no fish present due to poor water quality and sewage.

Panel members questioned the authors on what criteria were used for selection of COCs. Mr. Sigal stated that they used a criterion of 1% of samples exceeding the screening level.

Mr. Sigal clarified that the data for yard soils, indoor dust, and tap water were all from self selected volunteers. A panel member suggested that Tables 3-3 and 3-4 list local background concentrations, particularly for arsenic and cadmium. The screening criteria used for arsenic and cadmium are below background levels found in some parts of the world.

A panel member sought explanation for why arsenic concentrations were an order of magnitude higher for Ross Lake than Schist Lake, and why lead concentrations in sediment differ. The panelist asked if the Stantec (2008) data were included and explained that these questions relate to background and stack emissions and which lake to use for calculating risk from fish consumption. Mr. Safruk indicated he would have to look into this. The reviewer was also concerned that fish concentrations of arsenic from Schist Lake were lower than other lakes, and questioned the representativeness of Schist Lake for the greater community. Mr. Safruk responded that the reason for the fish survey was to have a consistent source of fish data to make comparisons among the lakes; it is difficult to do a comparison among all the studies due to the uncertainties in the historic data.

Panelists had a number of questions regarding the fish data. Mr. Safruk agreed that the percentage of surveyed residents who consumed the filet portion of fish was inconsistently reported and that they would have to go back to the original data to determine what is meant by the term “majority.” He did note that the proportion of fish eaters eating non-muscle was less than 5% and stated that the fish sampling data only included the filet. Panel members noted that metals accumulate in gills, bones, and organs, and this could be a concern if the whole fish with bones are eaten. A panel member was concerned that the authors better distinguish what is rare and what is common for the local area. Mr. Safruk also explained that the local food survey did not ask respondents whether they were First Nations or non-First Nations people. He noted that First Nations’ reserves are far from the Flin Flon and Creighton area, but there are some First Nations people living in the local area.

The panel sought clarification on how the exposure point concentrations for COCs in fish presented in Table 4-10 were calculated and whether consumption was species specific. Mr.

Safruk explained that they pooled the fish data over all lakes and used the 95% upper confidence limit on the mean (95% UCLM) for the exposure point concentration (EPC), unless the 95% UCLM for walleye exceeded the value. This is because the surveys show that many local people consume walleye exclusively. Table 4-8 shows the concentrations for each fish species. A panelist asked if the authors conducted a sensitivity analysis for how often the higher concentration fish are eaten. The authors indicated they had not. The panel suggested the authors more clearly explain how they derived these EPCs in the text.

Mr. Safruk also clarified that the mushroom data represent annual consumption and that there is a very short mushroom season.

Panel members also sought clarification on scenarios and pathways. Mr. Safruk reported that they considered the nursing infant scenario but could not find a validated approach for these COCs and that this is mentioned in the uncertainties section. A panelist asked whether the authors considered swallowing of airborne dust. Mr. Safruk responded that in their past work they found that swallowing of particles was much less than direct ingestion. Another panelist thought that the swallowed portion of inhaled particles would be accounted for in the toxicity factors as they are generally based on occupational studies and those workers would have swallowed and inhaled. In addition, Figure 3-2, the conceptual site model needs an arrow from surface water to the receptor to represent ingestion of water while swimming. In response to panel questions, Mr. Safruk also noted that they could add an assessment of ingestion of suspended or deposited sediments, but would have to determine whether surface water samples were filtered or unfiltered.

5.3 Panel Discussion

The panel members discussed Charge Questions 1-5, which covered issues on the problem formulation and supplemental sampling.

5.3.1 Charge Question 1

Charge Question 1: Comment on the adequacy of the data gap analysis and supplemental sampling. Were the appropriate types of data collected and analyses performed that are necessary to assess the extent of contamination? Did they adequately characterize the distribution and concentration of COCs in each of the media of interest? [¹ For example - 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 the communities? Do the study reports include a description of quality assurance and quality control measures for each study?

Panelists indicated that the overall sampling effort was very comprehensive and examined a multitude of media pathways. Individual panel members had some additional questions and comments. One panelist pointed out a few areas where additional sampling and analysis would be helpful to increase confidence in the assessment. The soil screening levels are close to background levels and it might be helpful to do more sampling in un-impacted areas; in particular, the Cranberry Portage area used for background levels. Since the tailings impoundment is a source of contamination in the recent past, it would be useful to analyze and speciate the tailings to characterize the source of contamination and determine what is from the

facility. In addition, given the age of much of the housing stock, it would be helpful to test more homes for lead-based paint and lead from water pipes.

Another panel member questioned the representativeness of the yard soil and dust measurements and suggested that the potential for selection bias should be addressed to help determine representativeness. The panelist asked whether data are available to quantify or to determine spatial variability and also noted that normally with self-identified subjects, one sees more participation from less impacted communities. An author explained that the Jacques Whitford (2008) study was not 100% volunteer participants. A predetermined number of houses were identified for each community and if they did not generate sufficient volunteers, the study workers went door-to-door to recruit participants. As a last resort they sampled vacant lots.

Addition of more information about the nature of the data, including sample size and variability was recommended for the tables in Chapter 2. Some tables provide more of the needed information than others, and it would be helpful to the reader if the authors provide sufficient data in all tables.

The analytical techniques used for the boron samples (hot water soluble boron and total acid digestion techniques) were discussed and the implications addressed. Panel members asked which technique was used to analyze the different samples, and which technique was the protocol for the screening levels to which the sampling concentrations were compared. One panel member noted that the Canadian Council of Ministers of the Environment (CCME) guideline is 2 micrograms per gram ($\mu\text{g/g}$) based on the hot water soluble boron technique, but the guideline is based on ecological effects. The reviewer did not know what protocol the US Environmental Protection Agency (EPA) Region 9 value used, but noted that the EPA value does not account for intake from plants and livestock and that boron accumulates in plants, so this is an important potential pathway for humans. He noted that they divided the EPA screening values by 5 to allocate just 20% of the reference dose (RfD) to soil.

An author explained that the Jacques Whitford (2008) study used the hot water technique, but he was not sure what the Manitoba study (Manitoba Conservation 2007) used. A reviewer questioned whether boron should be included as a COC and indicated that local background concentrations should also be examined to help make this determination. An author explained that they do not have measured concentrations that are comparable to the soil guidelines and a panelist suggested they could use a standard conversion between the hot water soluble concentrations and the total acid digestion concentrations. The reviewer explained that the relationship between hot water soluble and acid digestible boron analyses is that the acid digestion method can give results about five times greater than the hot water method and that the conversion is a function of soil texture. The panel suggested that the authors return to locations where high boron concentrations were found and do some split samples with the two techniques to confirm the ratio between results. This work would be helpful to have greater confidence that boron is not a COC.

5.3.2 Charge Question 2

Charge Question 2: Were the appropriate Chemicals of Concern (COC) selected for the communities?

The panel members discussed the screening criteria and recommended that the authors be more transparent in describing the screening of the sampling data to identify the chemicals of concern. The authors had explained that they used a cut-off of 1% of samples above the soil screening guidelines and noted that it was easier to include more COCs (selenium in particular) at this stage than have to add them later. One panel member thought the 1% seemed somewhat arbitrary and would have thought that persistence and toxicity should be considered, along with the distribution of the concentrations. Many reviewers found the rationales for individual COC selection less than transparent and identified seeming inconsistencies between COCs. For example, several reviewers were not convinced that selenium should be a COC, even if it is a component of the smelter emissions, noting that there were only 13 samples out of 1362 above the guideline. One of these reviewers suggested the authors include a table of background concentrations for selenium as had been done for other metals and was concerned that including selenium dilutes emphasis on other more important COCs. Another reviewer noted that 16% of the samples for manganese exceeded the soil criterion, but because there was no correlation with any known or suspected elements of smelter emissions and the concentrations were less than the local background, manganese was not selected as a COC. A third reviewer agreed with the decision not to include aluminum and zinc, but thought the decisions should be based on human health criteria. The panel recommended that objective screening criteria be explicitly stated and applied systematically and that the screening process be made more transparent in the assessment document.

A panel member asked whether the soil concentrations used for the screening were yard-by-yard measurements, a single point, or a composite of samples. An author explained that the concentrations used for the screening represent concentrations for individual samples which are a composite of multiple cores. Multiple samples from individual properties were included in the screening process. To derive EPCs for the HHRA, individual samples from a single property were averaged to represent a single property concentration.

5.3.3 Charge Question 3

Charge Question 3: Does the conceptual model adequately demonstrate the potential human receptors and the related exposure pathways? Do the selected exposure scenarios sufficiently cover the situations, behaviors, and conditions under which receptors are likely to be exposed?

The panel discussed the conceptual model, scenarios, and receptor characteristics used for the HHRA. A panel member asked for clarification on the commercial worker scenario. An author explained that the commercial worker was assumed to spend 50 hours /week working out of doors in the study area and to not live in the area (i.e., no exposure at home). A reviewer questioned whether seasonal differences should be considered when estimating the proportion of

time outdoors by different receptors. An author noted that because the indoor and outdoor air concentrations were assumed to be the same, allocating time to indoors and outdoors is not needed for air exposures. In addition, the authors had originally used a 45/55 split for soil and dust ingestion, based on the US EPA Integrated Exposure Uptake Biokinetic Model (IEUBK) default, but the TAC requested they assume 100% exposure to soil in the summer and 100% exposure to dust in the winter.

Food estimates were also discussed. A reviewer questioned the reasonableness of estimates of food consumption, particularly for the toddler, noting that the local and market basket foods added up to over three pounds of food per day, which seems unreasonable. There is little difference between child and adult consumption rates and alternate sources of data should be considered to generate more realistic estimates, particularly since the toddler is the receptor of interest and market basket foods are such a high proportion of intake. Using these unreasonably high consumption rates will overestimate risk. An author explained that they used the mean values from Richardson (1997), a commonly used reference for food consumption in Canada which is based on Nutrition Canada food consumption survey results (3 day self reported recall). The mean values were used in the HHRA.

Panel members suggested several other sources for food consumption data, particularly for the toddler. One noted that more recent Canadian fish consumption data are found in a methyl mercury report by Health Canada (2007). The Exposure Factors Handbook (EFH) of the US EPA was suggested by several panelists who noted that this reference uses recent USDA food survey data and so is based on US data, but it might be useful for comparison with the Canadian data. Another panel member thought that the EFH data may be broken down by region of the US and if so, a northern region might be most appropriate to compare with Canada. The inorganic fraction of arsenic in seafood is addressed in a paper by Schoof and Yaeger (2007) and includes more recent studies on arsenic. Another panel member asked whether the Schoof and Yaeger (2007) ratio of inorganic-to-organic arsenic would apply to a range of exposure levels. The first panelist noted that some of the studies used by Schoof and Yaeger (2007) were from contaminated mining/smelting sites. An author indicated that a fish sampling is planned for this summer and additional analysis could be done.

A panel member suggested the authors further consider a nursing infant exposure pathway and scenario for the HHRA and discuss the issue in the uncertainty section. The panelist thought there might be an appropriate approach for this pathway for methyl mercury. Another panel member suggested that the authors be careful in their use of qualitative terms to make sure they are appropriate and internally consistent. For example, on Page 2-40, 500 milliliters (ml) of blueberries is referred to as a small amount, but this is equivalent to about 2 cups, which does not seem small.

An author provided clarification on the wild game consumption estimates, indicating that they used an 8 ounce (oz) serving size based on the serving size for fish recommended by provincial and national agencies. Eight ounce serving size was used for wild game meat, and local fish. Up to 20% (32 grams (g)) of total meat consumed (market basket and wild game) was assumed to be wild game (percentage varied by age group) and it was also assumed that all age groups (excluding infants) ate wild game. A panel member thought that this sufficiently captures the

upper bound of exposure, but less so for the average, and suggested explaining this in the text. Another reviewer suggested that if local foods do not have different concentrations than market basket foods, then this breakdown is not necessary, and the breakdown does cause problems for use of the IEUBK model where one would be double counting. An author agreed that this would result in double counting in the IEUBK model runs, but that they wanted the community to see the wild game results. He indicated that they could compare market basket and local concentrations. A panel member suggested this be explained in the text or a footnote to it.

5.3.4 Charge Question 4

Charge Question 4: *In vitro* bioaccessibility testing was conducted to provide information for the soil ingestion pathway. Were the approach and results valid? Are the recommended relative absorption factors (RAFs) appropriately calculated?

The panel members agreed with the relative absorption factors selected for the COCs and discussed the use of bioaccessibility testing results for lead and arsenic. The panel agreed that the results for lead are reliable, but several questioned the use of results from arsenic bioaccessibility testing.

A reviewer noted that *in vitro* bioaccessibility method for lead was optimized and validated against *in vivo* animal bioavailability studies. In the US, EPA accepts the use of the *in vitro* bioaccessibility method for lead, by itself, to determine the bioavailability factor to apply to lead in soil. Therefore, this panel member can accept the *in vitro* bioaccessibility results for lead from the Flin Flon study with no reservations.

A reviewer questioned whether the RAF for arsenic (34%) is appropriate, when the bioaccessibility assay has not been validated with an *in vivo* model. Another reviewer explained that bioaccessibility for arsenic ranged from 5-60% in the *in vivo* animal models and therefore defaulting to 100% is clearly overly conservative. This reviewer thought that while there is some uncertainty using an unvalidated method, the weight of evidence leans toward 34%. The reviewer explained that the method has not been optimized and validated for arsenic, but it is thought to be pretty close and noted that in a regression analysis comparing over 35 *in vitro* and *in vivo* arsenic results from juvenile swine and monkeys they find a correlation coefficient of 0.8 for all but 7 samples. The reviewer noted that US EPA's Region 8 uses arsenic test results, but they back them up with speciation of the samples. This reviewer would not accept the *in vitro* bioaccessibility results *per se* without also looking at the mineralogy of the samples tested. While there was no mineralogical analysis of the soil samples at Flin Flon, in Sub-appendix H of the HHRA, a mineralogical analysis was conducted for a number of indoor dust samples. For the samples which appeared to be associated with smelter contamination, the arsenic was primarily associated with arsenopyrite and iron oxy hydroxides. These mineral forms are relatively insoluble and have been shown to have low bioavailability in *in vivo* swine and monkey studies. Based on the *in vitro* bioaccessibility results, the fairly good, but not perfect, correlation seen between *in vivo* and *in vitro* results, and the mineralogy this reviewer concluded that the use of a 34% bioavailability factor for arsenic in soil is reasonable for this site. Another reviewer provided a number of additional studies on comparison *in vitro* and *in vivo* results that the authors might find helpful (see list in Appendix E). The first reviewer questioned what evidence

is available to say that the community soil is not like the seven problem soils found in the bioaccessibility testing, and suggested some language to express this potential concern.

The panel discussed the relationship between bioaccessibility and soil concentrations. A reviewer suggested identifying the soil concentrations that were used in the bioaccessibility tests because one can get different results based on soil concentration, and the concentrations used should be representative of the site. Another panelist commented that for lead, bioaccessibility is higher at low concentrations, and asked if the same situation would apply to other metals. Other reviewers said they have seen the concentration differences at some sites and thought that it reflects source differences and geochemical speciation. This precludes one from generalizing from low and high concentrations. They also thought that the variability around detection limits for low concentrations might also give higher results. The reviewer asked if it is possible one might exclude taking action on a relatively low concentration property because the bioaccessibility factor was too low because it was based on a higher concentration test result. The other reviewers thought that if samples are representative of the variation in site concentrations, one can have confidence in the results. The authors confirmed that they looked at the range of concentrations and the bioaccessibility testing did represent the concentrations in the area. Panel members suggested the authors present soil concentrations and size fractions with the results and noted that Health Canada has some guidance on how to demonstrate independence of size fraction and bioaccessibility estimates.

One reviewer questioned the validity of the comparison of results from the different size fractions and solute:solid ratios in the bioaccessibility summary table (Table 2-16). The reviewer thought the authors were confounding the influence of the two variables by changing them both, and it is not clear which is changing the results. Another reviewer interpreted the table to show that Methods 1 and 2 indicate particle size does not make a difference and Methods 2 and 3 show that the solute ratio makes a large difference. An author explained that they did not intend to use eight different methods, but followed Health Canada guidance for different particle sizes and solute ratios. They tried to do a range finding study to see if one method was most reliable and then just run one method with 50 samples. The reviewers thought that this should be better explained in the report. The text needs to better describe the rationales for the method selections.

A reviewer asked other panel members which solute ratio they thought was more representative of the human digestive system. A reviewer thought that the 100:1 is much more representative, but that humans are highly variable. When soil first enters the system, it is thought that most of the contaminants will desorb from the soil in the first hour. The problem with the larger ratio is a detection problem and that the ability to detect small amounts in solution controls how finely one can detect the contaminant and accurately estimate bioaccessibility.

The panel agreed with use of the 100% bioaccessibility for the COCs other than lead and arsenic. The panel recommended that the authors move much of the bioaccessibility discussion to an appendix and focus the report text on the lead and arsenic testing and results used.

Later in the meeting, the authors provided a handout on relative absorption factors to assist the panel members in their review (see Appendix D). The panel discussed this new information. One panel member said that there does not appear to be a consistent pattern between soil

concentration and bioaccessibility and for most of the compounds there is a reasonable distribution of soil concentrations. This panelist suggested doing regression analysis to determine if there is a relationship between concentration and bioaccessibility. In response to panelist questions, an author said he thought they eliminated the non-detects, and a panel member agreed that would be the best approach rather than using half the detection limit. Another panel member entered the lead data into a spreadsheet and found there was no relationship between lead concentration and bioaccessibility; the arithmetic bioaccessibility mean was 0.69 compared to the 95% UCLM.

A panel member asked the authors about the quality control and assurance on the bioaccessibility testing and whether the data were evaluated to see if they met the data quality objectives (DQO). The panel member asked if detection limits and recovery percentages were specified prior to the work and pointed out that this needs to be discussed in the report. An author explained that they did not independently assess this, but deferred to the laboratory which said they met the DQOs.

The panel discussed that the arsenic bioaccessibility results do not look reliable at lower concentrations and discussed approaches to address this. Two panelists suggested dropping results from all the samples for arsenic that are below 50 parts per million (ppm) and recalculating the 95% UCLM for arsenic bioaccessibility. They explained that the results from the assay are highly variable and therefore uncertain at concentrations that are close to the detection limit; small differences are significant because the denominator is so small. These panelists suggested 50 ppm would be a good cut-off based on their personal experience that the method is very sensitive to perturbations at low concentrations. Another panel member pointed out that to use the 50 ppm cut-off, the authors should determine if the laboratory they used has the same detection limits as the laboratories with which these panel members have worked. If the laboratory used here has a lower detection limit, then a lower concentration should be considered. Several panelists did not entirely agree with discarding the lower concentration data and suggested the authors look at the data closely to see what the scatter is and analyze the data to see whether the variance at low concentrations introduces bias in estimating the 95% UCLM. Another thought that the scatter in bioaccessibility results at low soil concentrations will introduce bias in calculating the magnitude of variation in the bioaccessibility at the high end (i.e., 95% UCLM); uncertainty in the estimate at low concentrations will drive the 95% UCLM bioaccessibility higher. The panelist also pointed out that accuracy in the bioaccessibility estimate is most desirable at higher concentrations near where a cleanup level might be set, not at lower concentrations near background, which are less of a health concern. The panel did not reach consensus on this, but recommended that the authors consider the suggestions, examine the data closely, and calculate an estimate for the soil levels of concern.

For lead, the authors calculated a RAF of 58%. Panel members agreed that this was an appropriate RAF noting that the method is reliable. They discussed whether the lead concentrations below 50 ppm should be discarded in a fashion similar to arsenic. A panelist thought this was not likely an issue for lead as the lead concentrations were generally higher than arsenic concentrations, but that the authors should ask the laboratory for their level of confidence in the lead results. The panel concluded that the 58% RAF for lead was appropriate and suggested that the authors might consider plotting on a map the variation of bioaccessibility for

different areas of the communities, which may reflect manmade distribution of tailings used as fill.

5.3.5 Charge Question 5

Charge Question 5: Are there any concerns or limitations of these studies that affect the usefulness of the data in the HHRA? Do you have any further concerns or comments regarding the problem formulation or supplemental sampling?

Many panel members questioned whether the assessment assumed soil is the problem source for lead, and did not adequately address other potential sources, including potential contributions from lead based paint and lead pipes. The indoor dust levels of lead are unusual in that they are higher than soil levels, which would indicate that there must be some other source. An author clarified that they did dust wipes in homes and found no elevated lead levels, which gave them some indication that lead paint is not a problem. They could collect more data on paint in the future if necessary.

The author also noted that they do not have data on lead in pipes, but would look at the Jacques Whitford (2008) report to see if they included a question on lead in pipes. [The authors reported after the meeting that the Jacques Whitford (2008) report does not include information on lead in pipes of sampled homes]. There are also some data from residential taps in the HBMS data. A reviewer indicated that the raw data will be important for PRG calculations; if there is a water pathway driving exposure and it is related to pipes, this will affect risk management decisions.

A reviewer asked why the Jacques Whitford (2008) residential soil sampling was not combined with the Manitoba (2007) data to make larger data set. The authors clarified that the Manitoba (2007) study did not sample residential properties; it was limited to public areas, some of which (e.g., ditches and behind gas stations) were not representative of places people would generally be exposed to soils. The authors felt that they should use the residential data alone.

The reviewer questioned why different sieve sizes were used and thought they should be consistent between dust and soil. The authors explained that the soil was sieved the same between the Manitoba (2007) and the Jacques Whitford (2008) studies. They followed ASTM International protocols which recommend a smaller sieve size for dust than soil. In the bioaccessibility studies, the soil was sieved as per the individual method's protocols, and Health Canada requested use of different sieve sizes.

A reviewer asked about the dust sampling. An author clarified that the samples were collected with a special vacuum from carpeted areas away from the entrance and traffic (e.g., sitting areas) and virtually every home had carpet or area rugs. Houses ranged from old to new and spanned the economic range of the community. A reviewer questioned the use of 100% relative absorption for lead in house dust and noted that the IEUBK model default is 30%. An author clarified that the TAC asked them to use 100%.

The panel briefly discussed the study objectives of the HHRA as they are described in Chapter 1 of the HHRA report. One panel member expressed concern that the HHRA reads as if the

objective was to justify biomonitoring specifically. An author clarified that the HHRA was not done to set up a biomonitoring program, but from the start there were people asking for biomonitoring and it was in the authors' minds to use the HHRA results to help scope a biomonitoring program. From the authors' perspective, biomonitoring data may help characterize bioaccessibility and bioavailability uncertainties.

Other panel members agreed that the objectives were not clear; in particular they were concerned with Objective 2 – development of a risk management plan. One noted that this is a screening risk assessment without probabilistic and uncertainty analyses and so this HHRA could not determine specific properties to clean up. Mr. Sigal confirmed that they have not developed a risk management plan at this stage. An observer from Manitoba Conservation noted that they had found soils with levels of metals above the CCME guidelines. The goal of the HHRA is to determine whether metals in soils posed undue risk to humans in the long term, recognizing other exposures in the community, and to better define what the risks are. CCME screening levels are very conservative and the HHRA is the second step; the second objective is not addressed yet. An author and a Manitoba provincial representative explained that the plan is for the HHRA to be released in conjunction with any biomonitoring studies that may be done, and that risk management will be addressed at the same time (target early 2010).

6. Exposure Assessment

6.1 Author Presentation

Mr. Adam Safruk presented information on the exposure assessment portion of the risk assessment. Slides of his presentation are found in Appendix C. The exposure assessment included selection of exposure point concentrations (EPCs) from the available exposure data, and additional IEUBK modeling for lead in children. Under the commercial worker scenario, maximum concentrations were used for the soil EPCs, which reduced the need to derive PRGs for commercial land use. If there is no risk with exposure to the maximum concentration, then there would be no need to derive commercial PRGs. EPCs under the residential scenario were derived for all media including outdoor soil, indoor dust, ambient air, drinking water, garden vegetables, local fish, wild game, and snow. Exposure estimates were derived for receptors in each of the five age classes for the residential exposure scenarios for each of the five communities of interest (COI). The IEUBK model predicted blood lead concentrations for children that reflected the distribution of soil lead in the region.

6.1.1 Clarifying Questions

Mr. Safruk answered a number of clarifying questions regarding the exposure assessment. He clarified that indoor dust values were predicted using regression equations, based upon statistically significant relationship between outdoor soil and indoor dust. For lead there were no statistical significant relationships, and so they used the 95% upper confidence limit on the mean (95% UCLM) from the results of the indoor dust study for the communities of East Flin Flon, Channing, and Creighton. For the community of West Flin Flon, the multiple source analysis (MSA) methodology recommended within the IEUBK model accurately predicted indoor dust concentrations based on concentrations measured in outdoor soil and air. Therefore, the MSA methodology was used to predict indoor dust concentrations within West Flin Flon homes to allow for the coordinated adjustment of indoor dust concentrations when deriving soil PTCs.

A panelist asked whether the authors thought that assumption that indoor air concentrations would be the same as the outdoor concentrations was conservative (health protective), noting that some think that indoor air concentrations may be greater than outdoor, particularly for volatiles (e.g., mercury is volatile). The panelist noted that this is an area of uncertainty. Mr. Safruk responded that the TAC recommended they estimate indoor concentrations to be equivalent to outdoor.

One panel member noted that Shaw (1981) measured higher concentrations of lead at Lewis Lake, but this was not included in the UCLM values and asked why. An author said it was not included because it was older data and since 1981 there have been mitigation efforts that reduced emissions (emissions were reduced to 10% of previous levels since 1991). The panelist suggested returning to the Shaw sampling sites to determine if concentrations have been reduced from previous measurements. The same panelist also questioned the adjustment factor for inorganic to organic arsenic and wondered if contamination of the gardens is from aerial deposition, in which case the plant may not be transforming inorganic arsenic to organic arsenic. Mr. Safruk agreed it would be helpful to go back and determine the source of contamination in the study used to derive the inorganic arsenic adjustment factor.

A panel member questioned the use of the Student t-test rather than a parametric value for the fish data. The authors indicated that they would check this as it may be a software mistake and they generally choose what the statistical software recommends. They also recognized that reference to the inhalation of fine particulates in indoor air by the outdoor commercial worker is a typographical error in the title of equation 9.0 in Chapter 4 and should refer to the inhalation of fine particulates in outdoor air.

Mr. Sigal also reported on the snowfall data, noting that sampling was conducted in a typical year, and the protocol they used was the same as that used by Manitoba Conservation to estimate a concentration for the season. He recognized that deposition varies and so they had more samples taken and stated that the snow consumption assumption (one snowball per day) was his best professional judgment.

Panel members had a number of clarifying questions regarding the mercury exposure estimate. A panel member asked how the authors determined the organic fraction of mercury in air. Mr. Safruk replied that the fractions of organic mercury in drinking water and air were based on recommendations from the CCME, which he believes are measured mercury data, and that CCME says it is methyl mercury in the air, but he will confirm. He also said that the fraction was also applied to background exposures.

Mr. Safruk further clarified that current measurements of COCs in outdoor ambient air collected from the Provincial Building were used to derive EPCs for the community of West Flin Flon. However, since the air monitors on the Provincial Building currently only measure COC content associated with total suspended particulates (TSP), concentrations associated with the PM₁₀ component were approximated using the ratio for historic paired data for TSP and PM₁₀ concentrations within samples collected at the Provincial Building. These ratios were applied to

current TSP data from the Provincial Building to derive EPCs for PM₁₀ concentrations in West Flin Flon ambient air.

Mr. Safruk clarified that Table 4-5 includes data for drinking water from two studies which explains why some of the values are less than the one study's detection limit.

A panel member pointed out that a standard fish size was used, but that fish of different sizes and age will have different concentrations of mercury. Another panel member questioned dental amalgams assigned to toddlers, as generally baby teeth are not filled, and recommended reconsidering this. The estimate of the amount of blueberries consumed per day per child (4 g/day) was considered excessive by a panel member, but Mr. Safruk explained that this value was based on US EPA's Exposure Factors Handbook for those with berries in home gardens and noted that blueberries are widely available in the area and free for picking.

Panel members questioned the exposure point concentrations of copper and lead in drinking water and wondered if there was a source within the distribution system or at the tap to explain these values which are significantly higher than the maximum surface water concentrations. The authors were unable to get Manitoba or Saskatchewan background levels and noted that the Jacques Whitford (2008) study was flushed samples; they will check with HBMS regarding their water samples.

6.2 Panel Discussion

The panel discussed Charge Questions 6-12 on the Exposure Assessment.

6.2.1 Charge Question 6

Charge Question 6. The authors evaluated the sampling data, and calculated the exposure point concentrations (EPCs) for ambient air, indoor air, drinking water, garden produce, fish, indoor dust, wild game, blueberries, surface water, and snow. Are the selected exposure point concentrations appropriate for the risk assessment?

The panel discussed whether the use of the 95% UCLM was sufficiently conservative for the soil concentrations because of the assumption that people, particularly toddlers will not move randomly throughout the community, and the mean may not account for the child living on a property with high soil concentrations. For air and water concentrations the authors used the 95% UCLM as these are media in which contaminants would widely distribute. The authors compare values at individual properties to this 95% UCLM to determine how many properties exceed that number.

A panel member noted that if the authors want to estimate exposure then back calculations (e.g., PRGs) will determine the prevalence of exposure, but not the magnitude of exposure. Another noted that a forward risk calculation would probably identify an unacceptable risk at some properties, but these are population level statistics, and are not meant to be applied to individuals.

One panelist supported use of the 95% UCLM for soil (for all but lead, and maybe methyl mercury) because the toxicity is based on long-term exposure and people do not stay in one place but move around the community. The panelist explained that there are decades of biomonitoring

of arsenic and lead at multiple sites that show no relationship between levels in blood and yard soil. The exposure is coming from the larger community, and not the personal yard. For lead, children are the age group of interest and they are less mobile. If there are areas closer to the smelter with higher concentrations, one could divide these into subareas with higher concentrations. Others agreed when one averages all areas, this may be stretching the boundaries for the younger people, and so subareas may be helpful. However, another reviewer thought that some toxicity reference values are based on shorter periods of exposure that correspond with limited movement from individual properties. A reviewer noted that the Bunker Hill (Von Lindern et al., 2003) and Rochester studies (US EPA, 2007) have shown statistically significant correlations between blood lead and concentrations in neighborhood soils. But another reviewer thought that the Bunker Hill situation is unusual in that the average blood lead level was very high (70 micrograms per deciliter ($\mu\text{g}/\text{dL}$)), there had been lots of uncontrolled air emissions and a recently operating smelter in the community, there was high deposition on soil and high lead concentrations in soil, and there was old housing with lead paint and many years of accumulated emissions. Soil concentrations near the smelter site were also very high and the housing stock was also older and in poorer condition closer to the smelter. These factors tend to produce stronger apparent correlations between blood lead and soil lead. In addition, lead is often confounded by paint and consumer products, especially for soil samples taken from near foundations where lead paint can be found. Several studies in the literature that report correlations between blood lead and soil actually are between blood lead and soil near the foundation of the house which is highly influenced by eroding paint (e.g., Succop et al., 1998; Lanphear et al., 1998, 2002). Correlations are much weaker between blood lead level and average yard soil. For arsenic, until one reaches about 300 ppm of arsenic in soil, there is no correlation because these exposures are within the dietary noise (i.e., background inorganic arsenic exposure from diet). Another reviewer pointed out that studies of twins living in the same homes do not have the same blood lead levels, presumably because personal behaviors are more important determinants of exposure and uptake than simply residential lead contaminant concentrations.

Reviewers thought identification of the maximum concentrations would be helpful as well as seeing the distribution of hazard within a community by identifying how many properties exceed a certain concentration and the magnitude of the exceedence. Breaking up areas with higher levels into subareas may be useful. Some panel members questioned whether this level of work would be worth the effort and particularly for lead, biomonitoring seems most appropriate. Others thought it worth considering to aid risk managers in determining where to sample next.

An author clarified that he thinks they have accomplished what the panel is discussing in that they derived PRGs independent of soils concentration and then looked at how many properties exceeded the PRG. It would be reasonable to sample other houses in close proximity to those that had concentrations in excess of the PRG, but they did not make this recommendation, since they would like to see biomonitoring results first. They thought it best to use the 95% UCLM for forward calculations and back calculate on a property-by-property basis using US EPA methods. They clarified, however, that their conclusions are not based on EPCs, but on the percentage of properties that exceed the PRGs. Showing a distribution will not change the results as the PRGs are independent of soil concentration. A panel member noted that it would affect the prediction of risk if one used subareas. An author was not sure they have sufficient delineation to do

smaller subareas. An observer commented that the areas studied are very small in terms of geography and population, probably equivalent to a few blocks of a major city, and therefore equivalent to neighborhoods already. A panel member disagreed with the use of the back calculation (i.e., PRG) approach, noting that the purpose of the risk assessment is to determine if you have a risk and if so then decide what to do to manage it. If there is no risk in an area, then there is no need to develop PRGs or PTCs. If the authors do not think the four COIs are the appropriate exposure areas, they should revise them and redo the forward risk calculations.

A panel member pointed out that since the authors used mean values for some exposure parameters; the PRG is protective of the mean, not the 95% UCLM. Some exposure parameters, for example breathing rate, food consumption, water consumption are means. If one did the same back calculation based on 95th percentiles of these parameters, then the PRG would be lower, and one would be protecting 95% of the population. The panel member suggested using the 95% upper confidence limit on the mean for the parameters where they used mean values. The reviewer pointed out that the risk assessment is not necessarily conservative if they use means for some values. After some additional discussion, the panel recommended that the authors list beside each exposure factor, the statistic used (e.g., 95% of the distribution, 95% UCLM, mean value, or combination) so that it is clear to the reader what the number represents.

The panel did not reach resolution on which statistic to use. Panel members pointed out that selection of the mean or a maximum value varies among countries and agencies. In Ontario they prefer central tendency and a reasonable upper bound. In like fashion, soil concentrations at US EPA Superfund sites are based on the 95% UCLM for the central tendency and a high-end exposure estimate. The panel agreed that the concept of estimating an average concentration for an area is important. Panel members agreed that choosing the area to average must consider the receptors and their exposure patterns. For example, for lead, exposure is on a specific property basis; in contrast, the community average concentration does not have much meaning.

The panel discussed whether the 95th percentile of soil concentrations should be used to assess risk to the person who is on a high concentration property. Several panel members pointed out that on a single property one generally finds variable concentrations and so it would be most appropriate to use an average concentration term, given people move around the property and do not remain in just one place. Several panel members discouraged more sampling, pointing out that sampling yard by yard would not be practical given the relatively low concentrations found in the sampling. Rather, the panel suggested that the authors calculate the percentage of properties that exceed the PRGs and indicate the magnitude of the exceedence, to put the concentrations in perspective. In addition, the authors could show the hazard quotients in a frequency distribution and avoid identifying individual properties.

The panel was comfortable with using the 95% UCLM for a conservative central tendency for soil concentration. One panel member cautioned that if the authors choose to use the 95th percentile of an exposure value, they have to carefully explain this to the residents so that they understand the results; otherwise people may think everyone is in danger, when this is not the case.

6.2.2 Charge Question 7

Charge Question 7. Which size fraction of particulate matter and its associated metal constituents should be used to best estimate the risk associated with the ambient air exposure pathway? (Section 4.1.1.2)

Footnote: Recently, the US EPA revised its National Ambient Air Quality Standard (NAAQS) for lead and discusses use of TSP (see in particular page 66988, Federal Register, Vol. 73, NO. 219, November 12, 2008, <http://www.epa.gov/fedrgstr/EPA-AIR/2008/November/Day-12/a25654.pdf>)

In response to this charge question, a reviewer noted that it is best to try to match the particle sizes used with the data that were used to derive the toxicity criteria. However, this is difficult for these metals and most of the toxicity criteria are based on data from workers in refineries and smelters. These workers were exposed to a mixture of fumes and small and large particulates. For air exposures, there is no consistent guidance, although using fine particulates is conservative. This reviewer agreed with the authors' use of particulate matter less than 10 µm in diameter (PM₁₀) in the assessment. Another panel member noted that in the US EPA lead NAAQS expert review, there was much discussion on this issue with some panel members arguing strongly for smaller sizes (i.e., PM_{2.5} or PM₁), but for practical reasons the EPA decided to use PM₁₀ because PM₁₀ samplers are what is currently employed in EPA's ambient air sampling programs. The fraction of PM₁₀ to total arsenic was 0.8, meaning not much is missed by using the PM₁₀ fraction. A panel member referred to Figure I-22 in Appendix I and asked whether based on emissions from the facility, would one expect particle size fractions to be the same? Based on physical properties of the COCs, they may be different. Copper has a nice distribution of particle size but other metals do not, which makes the reviewer wonder if there are additional sources (besides the smelter) for the other constituents where there is a less uniform particle distribution. The reviewer asked whether any particle geochemists had looked at this and an author said no.

6.2.3 Charge Question 8

Charge Question 8. Were the best available data used to calculate appropriate background exposure values?

Several reviewers questioned whether the national background levels are representative of the local area, since this is a mining area it may be very different from what was used for national background. Are the geology and soil type of the background areas similar to the Flin Flon area? Sampling protocols for the national soil studies and local studies could also be different. Similarly, the arsenic water concentration is quite low compared to the national water providers, but higher than Ontario. The reviewer asked if there is a better measure of background of drinking water in an area away from the smelter. An author said they were unable to get provincial background values. Another reviewer thought that background levels on fish might be a data gap that could be filled.

A reviewer again noted that for arsenic, copper, and zinc, recent data 2005 and/or 2006 (Tables 2-5 and 2-12 of the HHRA) show that the concentrations were higher in the finished drinking water than the raw water, which indicates the potential of contamination by these metals from other sources. Another reviewer noted that the drinking water data seem to suggest that the

water distribution systems may contain lead and copper. For example, lead and copper concentrations from the Creighton Distribution System are <0.1 and 3 µg/L, respectively (Table 2-5). Yet the exposure point concentration terms for lead and copper in Creighton are 3.1 and 124 µg/L, respectively. If this holds true for the other COIs, it appears that a source of these inorganics (i.e., plumbing) has not been discussed in this report. Another reviewer thought it appropriate to discuss and calculate the contribution from other sources to provide perspective, and the authors should be careful about attributing chemicals in the drinking water to the municipal water source and be sure there is evidence that the source has contaminated the drinking water supplies. The panel cautioned the authors to not send mixed messages that a risk manager will find hard to interpret.

A panel member asked the authors to clarify why potential non-smelter exposures were included in the HHRA. An author explained that the federal guidance dictates that if background is not accounted for, then one apportions 20% of the safe dose to the soil medium. By calculating all exposure sources, the authors can determine a data-based apportionment from soil, rather than defaulting to 20%. A panel member pointed out that the HHRA does not consider consumer products (one of the five exposure media) and therefore, the HHRA should only use 80% of the RfD. The authors clarified that for the lead PRG the assessment allocated 20% of the residual RfD (i.e., RfD minus market basket exposure) for consumer products. However, for arsenic, because it is a carcinogen and a linear dose response assessment is presumed, the apportionment is not relevant. This reviewer thought that consumer products should be accounted for with the other COCs, while other reviewers thought that the consumer product pathway would not be that relevant for the others. However, all panelists agreed that the consumer product pathway should be discussed qualitatively for the other five COCs.

6.2.4 Charge Question 9

Charge Question 9. Are the selected receptor characteristics and values the most appropriate for use in this assessment? Were the assumptions and exposure input parameters appropriate and were the intake rates calculated correctly?

The panel agreed that most of the receptor characteristics and values were appropriate with the exception of some values discussed under Charge Question 3. Reviewers suggested improvements or revisions to the text. They recommended that the authors standardize the exposure equations; many are missing exposure duration or frequency components and some (e.g., indoor/outdoor air apportionment) are not needed. Concentration units should be used for the inhalation equations to be consistent with the toxicity values (US EPA Superfund guidance provides newer equations). Several reviewers commented on terminology, noting that labeling of parameters as RME (reasonable maximum exposure) was not accurate as the RME describes the individual who receives the highest amount of exposure that can be reasonably anticipated, not the individual parameters themselves. The equations and parameters used to develop an RME risk estimate combine both high-end and central tendency inputs. They suggested adding a column to the tables to indicate what each parameter represents (e.g., percentile of the distribution).

A reviewer expressed concern about the fairly high concentrations of lead measured in indoor dust, noting that blood lead and arsenic levels are more correlated with indoor dust than outdoor soil and that most people spend the largest time indoors. The dust was analyzed by four laboratories with differing results. The reviewer speculated that lead-based paint might be contributing and/or high levels of emissions in the past. The reviewer asked if it is possible that attics are serving as reservoirs of contamination for the homes, a situation that has been seen in a former smelter site in Montana.

The panel recommended that the authors add receptor characteristics and assumptions for the receptors to the relevant tables, as well as a column to indicate the type of parameter estimate for each.

6.2.5 Charge Question 10

Charge Question 10. The exposure assessment predicts the rate of exposure using site-specific data and conservative assumptions. Are the exposure estimates correctly calculated?

Two panel members independently spot checked the exposure calculations and found no problems with the equations or calculations. One panelist noted that some of the assumptions are conservative while others may not be as conservative. Another reviewer pointed out that the purpose of a risk assessment is not to provide a conservative estimate, rather to provide an accurate characterization of the exposure distribution, including the average and upper-end exposures. It is the risk manager's purview to decide what is conservative. The panel reiterated its recommendation to explicitly identify what each parameter represents within this distribution (particularly for Tables 3-7 to 3-11).

6.2.6 Charge Question 11

Charge Question 11. Was the US EPA Integrated Exposure Uptake Biokinetic Model (IEUBK) model for lead used appropriately in the HHRA?

Please see discussion under Charge Question 18.

6.2.7 Charge Question 12

Charge Question 12. Do you have any further concerns or comments regarding the exposure assessment?

The panel members had a number of remaining questions or suggestions on the exposure assessment. In response to a question an author said that the 99% UCLM was used for arsenic in above ground vegetables, rather than the 95% UCLM which was used for other COCs, based on the recommended value for the upper bound estimate of mean from the statistical software.

Several panel members provided editorial comments and suggestions.

- The authors should check the number of significant figures used throughout the document, for example the fraction of inorganic arsenic was reported to one figure and the organic arsenic fraction to two.
- Small errors in the text are distracting and reduce confidence in the assessment. For example, the number of samples for the West Flin Flon area is reported as 77 in some places and 76 in others. Table 5-15 lists different concentrations than reported in the text.
- Indicate in the text whether the household water data were first draw or flushed samples.
- Yost et al. (2004) corrects values for grapes and watermelon used by Schoof et al. (1999).
- Sieved soil samples are more indicative of what gets on children's hands. 100% is too conservative. Look at data for another estimate that can be derived.
- Including the non-detected samples in the averaging of bioaccessibility results is not reliable. One panel member suggested removing the bioaccessibility results from samples with low arsenic concentrations before calculating the average bioaccessibility of arsenic in soil.

7. Hazard Assessment

7.1 Author Presentation

Mr. Elliot Sigal, another of the Intrinsic HHRA authors, presented information regarding the selection of toxicity reference values (TRVs) for the COCs from those derived by various government and international agencies. Slides of his presentation are found in Appendix C. He noted that the COCs are well-studied compounds that have excellent toxicological assessment documents available, therefore it was not necessary for Intrinsic to review the literature data base on these compounds. They selected TRVs for acute (1-hour and 24-hour exposures) and chronic (lifetime) durations for cancer and non-cancer endpoints. Mr. Sigal noted that the chronic values selected are well-accepted for use by the risk assessment community; however, the acute values are less established. Mr. Sigal reviewed the selection of the TRVs for arsenic, cadmium, copper, lead, mercury, and selenium, noting some of the strengths and weaknesses for each. He noted that for arsenic the oral slope factor is based on Taiwanese data sets and that the use of this value results in background risk calculations in Canada often exceeding acceptable risk levels. For lead, he noted that Health Canada is currently revising its TRV and the new value is expected to be lower than the current provisional Tolerable Daily Intake (p-TDI) of 3.6 µg/kg-day. Because Health Canada has not released a revised value, they used the current value in this assessment. He noted that one reason to recommend biomonitoring for lead is to then have local data to compare to the new value when it is released. Mr. Sigal also described the bioaccessibility studies conducted by Dr. Ken Reimer at Royal Military College/Queens University. The author noted that Dr. Reimer is a well-regarded expert in the field and his methods are similar to Dr. John Drexler, another leader in the field.

7.1 Clarifying Questions

None.

7.2 Discussion

The panel discussed charge questions 13-15 on the hazard assessment.

7.2.1 Charge Question 13

Charge Question 13. Were the most appropriate exposure limits or toxicological criteria selected for each of the COCs, and are the rationales for the selections defensible?

The panel discussed the selected chronic and acute TRVs. The panel members had concerns with the selection of the acute toxicity values. They recognized that some of the regulatory agencies that set these values (e.g., Ontario MOE) are combining risk assessment and management objectives. Some of these acute values are lower than chronic values. This is counterintuitive, and it is sometimes difficult to determine the scientific rationale for the value. One panel member thought that the regulatory agencies are force fitting the chronic methods to acute situations and thought that it is more appropriate for these acute values to protect for endpoints such as allergic response, irritation and poisoning; such as the approach used in occupational settings.

A panelist pointed out that when the public reads the document and sees the inconsistencies between acute and chronic values, their confidence in the assessment and credibility of the process will be diminished. Another noted that if the focus of the document is on long-term protection, then a chronic assessment is most important. Others agreed and questioned the need for acute values. After some additional discussion, the panel agreed that the acute values are problematic and recommended that the authors use their best professional judgment whether such values were even needed. If they are needed, the authors should clearly present the reasoning for their choices. If no appropriate acute values are available, or determined not to be needed, then the authors should explain this and provide a qualitative discussion. The authors indicated that the TAC was interested in the acute assessment and that Manitoba relies on some of the Ontario numbers. The authors will have to discuss these issues with the TAC. Panel members also suggested the authors look for inconsistencies between acute and chronic values and also between oral and inhalation values for the same COC. The authors should explain that the chronic values are protective of acute exposures.

The panel discussed the oral carcinogenicity estimates for arsenic, noting that there is sufficient controversy with regard to arsenic carcinogenicity that the assessment should address some of the additional data and issues surrounding arsenic. For example, there are other cohorts with positive associations, such as those in Argentina and northern Chile despite sufficient nutrition unlike in SE Taiwan. However, other data from SE Taiwan, China, West Bengal, and Bangladesh have been evaluated and it has been shown that poor nutrition and certain nutrients or factors do affect the potency of arsenic. There are also low-level drinking water studies in the US and other countries (e.g., Finland, Argentina) with populations with good nutrition (Mink et al., 2007) and meta analyses of groups of studies showing no relationship between arsenical cancers (i.e., bladder) and arsenic, that should be considered. Several agencies and organizations

(e.g., Health Canada Biostatistics Units, US EPA, US NRC) have published more recent arsenic assessments than the US EPA IRIS (1998) used in the HHRA. The panel recommended that the other assessments and their differences should be presented.

A panelist pointed out that the selected TRV for copper is lower than the RDA for copper (IOM, 2003), which is based on an upper limit of the safe dose. The authors should look into this TRV further.

Panel members discussed whether the assessment might present a range of arsenic risk values based on different selections. Some thought that using a range of values is leading to probabilistic assessment and the methods are not good enough. The panel thought that the authors should qualitatively discuss the range of risk values for arsenic.

7.2.2 Charge Question 14

Charge Question 14. Was the approach used to account for bioavailability and bioaccessibility of the COCs in the various media appropriate and are the results incorporated into the HHRA appropriately?

See discussion under Charge Question 4.

7.2.3 Charge Question 15

Charge Question 15. Do you have any further concerns or comments regarding the hazard assessment?

Individual panel members suggested several editorial revisions or clarifications:

- The Ontario intake of concern for lead should be mentioned in the text. The value of 1.85 µg/kg-day is a population-based value.
- The definition of incremental lifetime cancer risk needs to be rewritten to make it clear that it refers to a population risk and not a prediction of risk for an individual. The upper bound lifetime cancer risk is an upper bound risk estimate. The true risk is likely to be lower and could even be zero. Health Canada's TD₀₅, however, is not an upper bound, but is a linear extrapolation from the TD₀₅ representing the best estimate. If one divides the TD₀₅ by 5000, the result is a dose with a best estimate risk of 1 in 100,000.
- The discussion on interactions between COCs could be put into a table. Most of the interaction data are on high doses where people would be expected to see effects, but what is really of interest for this assessment is interactions at low concentrations below the "safe" level, resulting in risk to those exposed. Panel members suggested using ATSDR toxicological profiles and the *Handbook of Metals Toxicology* (2007). Several other metals are elevated or present in site soils that might interact with the COCs, e.g., zinc antagonizes the absorption and effects of several metals such as cadmium.
- A panel member suggested mentioning limited sunlight and Vitamin D deficiency as a potential special consideration.
- For arsenic, a correction for early life exposure is not needed as arsenic is not mutagenic and the data are from full generation exposures.

- The community blood intervention level for Saskatchewan and Manitoba is not an absolute 10 µg/dL.
- There is a statement in the document regarding lead indicating that the assessment is conservative in respect to adverse health effects, but elsewhere the authors acknowledge the potential for effects at lower levels of lead.

8. Results, Risk Characterization, Uncertainties

8.1 Author Presentation

Mr. Elliot Sigal presented on the assessment results, risk characterization, and uncertainties. Slides of his presentation are found in Appendix C. For acute inhalation risk estimates he noted that some elevated risks reflect the use of TRVs that may not be reliable. He noted that the frequency of 24-hour exceedences in most cases is quite low. The TAC had requested that snow consumption be considered and the hazard quotients for acute snow exposure in toddlers were estimated based on consumption of one snowball per day. He noted a number of issues: the hazard quotients for acute soil exposure for toddlers have a number of uncertainties, the copper TRV is highly suspect, and there were some fairly elevated concentrations of arsenic and mercury in the West Flin Flon area. The pathway specific hazard quotients for toddlers with other COCs showed soil as a significant pathway with respect to arsenic. Inorganic mercury risk is driven by soil, and methyl mercury is driven by fish and some other foods. While the assessment evaluated lead exposures using a deterministic approach and the IEUBK model, Mr. Sigal noted that measurement of blood lead levels would be a definitive measurement and therefore they recommend biomonitoring for lead. While the contribution of air pathways to total arsenic exposure was significant, the authors stayed away from recommendations related to air because the focus of this study is on soils. In addition, it was recently announced that the smelter will close next year, which will cause emissions to drop dramatically. A sensitivity analysis was used to identify exposure variables that may be driving the risk values and to demonstrate the impact of variable selection on the risk assessment process. Mr. Sigal noted that Chapter 7 discusses many of the uncertainties and they will continue to add to that discussion.

8.1.1 Clarifying Questions

A panelist asked whether the authors looked at all parameters for the sensitivity analysis and wondered if there are other parameters not evaluated that could potentially influence the results more than others. Mr. Sigal indicated that they only looked at key exposure parameters, many of which were identified through community and technical advisory committee activities. They did not do a sensitivity analysis with the toxicology values.

8.2 Panel Discussion

The panel members discussed Charge Questions 16-22 on the risk characterization.

8.2.1 Charge Question 16

Charge Question 16. Was the approach used to estimate Concentration Ratios (CRs) and Hazard Quotients (HQs) for acute inhalation and ingestion risk, respectively, consistent with accepted risk assessment methods, and were the values calculated correctly?

The panel again discussed the problems quantifying acute risks – the lack of defensible acute TRVs and large uncertainties in the results led them to recommend that the authors characterize acute risks qualitatively, but not quantitatively (see also discussion under Charge Question 15). They indicated that this is appropriate for a screening assessment because the TRVs and hazard quotients (HQs) are not bright lines and should not be interpreted as such. Panelists voiced concerns that the acute results presented in the draft may be interpreted inappropriately causing people to be concerned when they should not. Panelists noted that if the authors do not have one-hour sampling data then they should not calculate one-hour hazard quotients. The characterization of chronic risk will protect for acute exposures. One panelist agreed with the others, but cautioned that if there are TRVs based on *in utero* developmental toxicity endpoints these should be explored and communicated carefully.

A panelist noted that most of the pathways (i.e., soil, drinking water, food) are chronic exposure situations, with the exception of the pica child behavior and so acute values are not important. But, the panelist pointed out that air is a relevant acute pathway, as there may be short term excursions. The assessment should focus the acute discussion on the air pathway. The panel asked HBMS if there are any warning systems for the community. A representative from HBMS noted that there are no methods for testing metals emissions in real time. A Level 1 and Level 2 warning system for sulfur dioxide emissions is used by the company and community, which would probably minimize metals exposures that track with sulfur dioxide stack emissions.

In summary, the panel agreed that estimating acute exposures is very problematic, as is identifying medical conditions or adverse effects from acute exposures. Acute exposure concerns apply only to the air pathways. Current air excursions are addressed through sulfur dioxide monitors and warnings. The assessment should characterize acute risks qualitatively. They cautioned the authors to be careful in characterizing acute hazards and risks so that the public does not misinterpret the true risk and take actions that are inappropriate to the magnitude of the risk.

8.2.2 Charge Question 17

Charge Question 17. Was the approach used to calculate the HQs and Incremental Lifetime Cancer Risks (ILCRs) for residential, outdoor workers, and recreational scenarios consistent with accepted risk assessment methods, and were these calculated correctly?

The panel members discussed several general issues with how the HQs and incremental lifetime cancer risks (ILCRs) were calculated. A panel member addressed the inclusion of other sources

in the risk calculations, noting that it is Canadian policy to do so, but other governments such as the US approach this differently. In the US Superfund program, they are looking at exposure from the source alone and therefore when a risk is given it reflects the additional risk above background. For example, a cancer risk of 1 in 10,000 indicates that the population risk of cancer from the source may be as high as 1 case in 10,000 exposed above the background cancer risk (1 in 2 for men and 1 in 3 for women). An author clarified that they followed the regulatory guidelines of Health Canada and the CCME and did not add risk from the background sources for cancer, but do include all the background sources in the noncancer calculations.

The panel again expressed concern with quantitative estimates of risk for acute exposures (see discussion above). They briefly discussed issues regarding interpretation of the hazard quotient with one panelist pointing out that one needs to look at the TRV behind the HQ to interpret the HQ and potential values around or exceeding 1. This panel member also suggested the authors review their use of significant figures for the HQs, pointing out that in Table 5-4 for example; a HQ of 1.2 for arsenic should be 1, as only one significant figure is appropriate.

A panelist suggested the authors consider some way to assess risk from fish consumption for specific lakes. The issue is that some lakes have elevated concentrations and if these are favorite lakes for some people, exposure may be higher than the average for all the lakes. The panelist suggested a “favorite lake” scenario or some use of a weighted average based on data collected. Another panelist suggested evaluating the impact of a fish advisory on the overall risk to determine if a fish advisory would be an appropriate risk management consideration. An author clarified that the risk assessment back-calculated the concentration of mercury in local fish that would result in an HQ of 1 using the assumed consumption rates and additional sources of exposure. This concentration (0.19 ppm) was lower than the provincial (Manitoba and Saskatchewan) and federal (Health Canada) guideline of 0.5 ppm, likely as a result of the higher local fish consumption rate assumed in the risk assessment. The risk assessment provided a comparison of the 0.5 ppm guideline to the 95% UCLM mercury concentrations for each fish species and for fish in each individual lake. A panel member pointed out that there is no pattern of elevated methyl mercury levels in fish with distance from the source.

A panel member questioned why the authors did not use a composite receptor for arsenic given its carcinogenicity. Others agreed the composite receptor would be appropriate and the panel recommended its use for arsenic.

The panel discussed the outdoor worker scenario and questioned use of the maximum value for exposure point concentrations for the outdoor worker, noting that the resulting cancer risk for arsenic does not look right as it indicates the worker has a risk when the public who lives in the community does not. A panelist suggesting that a mean exposure value would be more appropriate because the worker would be expected to move around the community and not stay in one location. An author noted that the cancer slope factor for arsenic is problematic because it indicates a cancer risk at the normal Canadian background levels. The author agreed that a mean value would be more appropriate. Another panelist questioned if the outdoor scenario is necessary in that if indoor and outdoor air concentrations are assumed equivalent, and the general public is not at risk, then anyone working outdoors and not living in the community would be protected as well.

The HHRA calculated non cancer hazard quotients for arsenic and cadmium for five age groups, and the results showed that toddlers have the highest risk. Panel members questioned the appropriateness of this – the toddler drinks more water per kilogram body weight than the other groups and this is the basis for the larger HQ. The authors should look closely at the data and endpoints that the TRVs are based upon to determine if smaller age categories are appropriate. For example, the arsenic TRV is based on populations exposed over an entire lifetime, including children and *in utero* exposures; much longer than the few toddler years would be needed to elicit effects from arsenic. There is no indication that children would be more sensitive to arsenic than adults on a body weight basis, therefore use of age groups for arsenic is not appropriate. However, for methyl mercury and lead, the TRVs are based on effects from shorter exposures and breakdown by age category may be more appropriate, although the methyl mercury TRV is based on an adult female intake per body weight and associated fetal exposure. A panelist explained that risk assessors try to keep the exposure metric equivalent to the toxicity metric. To look at chronic exposure greater than 7 years, one compares these exposures to chronic risk values. For exposures less than 7 years, one would use a subchronic value. The panelist noted that ATSDR has developed a shorter term arsenic value and the panelist will provide this to the authors. An author agreed that the arsenic results alone do not provide a realistic assessment and that was why they presented multiple lines of evidence for consideration. The authors think that a urinary arsenic study can provide additional information to better characterize risk.

Panel members recognized the sediment data are limited and will not materially affect the quantitative results, but recommended that sediment exposure (e.g., oral exposure while swimming and playing near shore) be addressed qualitatively because it is a common pathway considered.

A panel member sought clarification on why the CCME soil criteria used for screening are lower than the TRVs used for calculating risk and how this would be explained to a member of the public. An author explained that the CCME criteria are intentionally developed to be very conservative to protect all situations and people across Canada and are used to trigger further study. Site specific information is used for the risk assessment to reflect the site situation and populations.

Panel members recommended that the authors consider providing an indication of the magnitude of concern by communicating the number of properties that exceed a target level for at least one of the COCs. They should avoid double counting properties.

8.2.3 Charge Question 18

Charge Question 18. To assess lead exposure, the authors used the HHRA exposure model as well as the US EPA IEUBK model. Comment on the analysis and scientific defensibility of the results.

The panel members discussed the problems with presenting two different approaches (deterministic model and IEUBK model) for characterizing the risk from lead exposure. Panel

members noted that both are good tools, but the results cannot be compared quantitatively (apples and oranges comparison). The deterministic approach compares modeled lead intake to a tolerable lead intake (lead intake is the denominator in the hazard quotient). The IEUBK models a blood lead concentration and this output is compared to some benchmark of acceptable blood lead concentration (blood lead concentration is the denominator in the IEUBK approach). The authors of the report argued that the tolerable lead intake used in the deterministic approach (3.6 µg/kg-day) was equivalent to the benchmark of acceptable blood lead concentration used in the IEUBK approach (10 µg/dL). However, the report does not provide any evidence to support this assumption. From first principles, a lead intake of 3.6 µg/kg-day could produce a wide variety of blood lead concentrations because the relationship between intake and blood lead is dependent on the bioavailability of the source of lead.

Panel members raised issues with use of the IEUBK model; in particular one noted that the model is meant to be applied to a homogenous exposure scenario. The authors took the UCLM of a variable exposure scenario and used it as an input; the distribution that comes out of the IEUBK is meant to reflect individual behaviors and physiology, not variability in the population's exposures. The exposure concentrations from the Manitoba soils study and the Jacques Whitford (2008) study are not homogenous; the coefficient of variance is about 0.8.

The panel discussed comparing results of the deterministic model with the IEUBK outputs. Several panel members suggested ways that might make the two results more comparable. One panel member suggested that using the same parameter values would make the comparison of results a little better, but there is still the issue of bioavailability to contend with. Another panel member noted that even with the same assumptions, the two models use different toxicity benchmarks. A third agreed and noted that the two models are fundamentally different in that the deterministic approach uses conservative estimates and the IEUBK model uses central tendency estimates and then using an assumed geometric standard deviation, calculates the 95th percentile blood lead level, which is then compared to 10 µg/dL. The authors stated that they did not intend to compare the two approaches and added that the deterministic approach used Canadian parameter values, while the IEUBK model uses US values.

One panel member thought that using the IEUBK model results in inappropriate comparisons between the two methods. This reviewer noted that the US CDC does not recommend that their lowest blood lead intervention level (10 µg/dL) be used as a toxicity reference value for setting allowable concentrations of lead in the environment (Brown and Rhoads, 2008; Brown and Meehan, 2004; CDC, 1991). The blood lead intervention levels are derived to guide secondary prevention (after exposure has already occurred), not establish acceptable levels for primary prevention (defining acceptable levels of exposure). This reviewer did not think the model adds to the HHRA or should be used, stating that the IEUBK model is most appropriately used for interventions, not for prevention activities, which should be based on the TRVs. Another agreed saying the deterministic model reflects the concept of a community blood level and the two should be kept in separate contexts. A third panelist thought that there is uncertainty with all models, but the results of the two models are within the same range. Other panel members agreed that the two results generally support each other, but were concerned about making an explicit or quantitative comparison. A panelist pointed out that if the authors do not use the IEUBK model they will be subject to criticism from those who know it is an available tool which

is used widely. The authors agreed that they would be considered remiss if they did not use the IEUBK model but they understand and agree with the panel's concerns and comments. They clarified that they used the IEUBK defaults for the most part, but used some site specific parameters as they were justified.

One panel member noted that there is a large difference in the contribution from different media in the IEUBK and deterministic approaches for market basket foods. IEUBK says 80% of lead from soil, while the spreadsheet model says 50%, and it looks like diet is the difference. An author pointed the panel to the brief discussion above Table 5-24 and stated that the IEUBK model uses a higher soil ingestion rate than the deterministic approach, and for market basket the IEUBK model uses updated recommended values by EPA, which are significantly lower than the spreadsheet model using Canadian data (Dabeka 1993, 1995, 2003). The authors considered using IEUBK market basket food values, but sufficient details were not available.

The panel was comfortable with the lead hazard indices from the deterministic modeling and noted that the authors used the same Canadian and site specific assumptions as the other COCs. The panel recommended that the authors mention the IEUBK model and results very briefly in the text, but move all the details to an appendix where they can explain how the results of the IEUBK model support those of the HHRA. The primary reasons for moving the IEUBK to the appendix is the homogeneity issue and that the two models are not directly comparable. Moving the details to an appendix will also improve the readability of the chapter. The authors should attempt to harmonize the input parameters so that the results are even more comparable. The final paragraph in section 5.2.4 recommending blood lead monitoring should be retained (except for comparison to 10 µg/dL, see below). A panel member noted that it is useful to compare different models, but they need to use the same exposure inputs, and thought that if the authors used the same inputs as the spreadsheet model, the IEUBK results will be lower. An author noted that one difficulty is that the spreadsheet model does not have parameter values for all the different age groups evaluated within the IEUBK model.

A panel member questioned the accuracy of calling 10 µg/dL the Canadian community blood lead intervention level, noting that the appropriate guidance is CEOH (1994). That guidance does not identify 10 µg/dL as a standalone value, but recommends community intervention be considered when the mean blood lead levels of a sample from the community exceeds a reference mean plus three standard deviations from the reference mean, or when the percentage of children in a community with values above 10 µg/dL is double that seen in the general population.

Another panel member asked the authors how they calculated the TDI and equated it to the 10 µg/dL blood lead level. An author indicated that the TDI was based on studies of formula fed infants, breast milk, and infant food and that 58% absorption factor is used. The panel member thought this absorption factor seemed high given that the absolute gastrointestinal absorption of soluble lead in water is 50%.

A panel member suggested that when calculating the contribution of lead exposure from each medium that soil and dust contributions be separated. This reviewer also cautioned presenting absolute values and predictions from the model and that it is more appropriate to use the results

in a relative comparison of two scenarios. Several reviewers suggested rewording some of the conclusions in section 5.2.5, in particular the inappropriately predictive statements regarding the percentage of properties containing levels of lead that may have adverse effects on young children.

A reviewer noted the variability in bioaccessibility of the samples, which leads this reviewer to think there are different sources of lead. The reviewer suggested looking for consistency in bioaccessibility by source or area and noted that mineralogical analysis will help understand which bioaccessibility estimates to apply to which soil concentrations. Plotting these as contour lines on a map would be helpful. This reviewer also thought that the risk at most sites is not from soil, but from the house (e.g., paint). The information on the relationship between concentrations of lead in soil and blood lead levels from different North American populations and sites (Table 5-27) does not convey a straight story. In the well-controlled studies, the relationship of soil to blood lead is not very strong. The reviewer thought that the IEUBK model will indicate the problem is soil, when it is likely the lead is from house paint. Another reviewer suggested adding two more studies – the Rochester cohort (US EPA, 2007) and Succop (1998), and provided these references to the authors. The first panelist clarified that Succop found correlations of blood lead with perimeter soil, which is influenced by eroding house paint but not yard soil.

An author asked if the panel members thought they should adjust inhalation rates for the IEUBK model to put on scale with body weights, a parameter which cannot be changed in the model. A panelist suggested scaling for body weight as appropriate, and to leave the other parameters that cannot be changed. Another noted that the soil pathway is 85% of the risk and so uncertainty in inhalation will not matter much.

In summary, the panel agreed that the HHRA should use the hazard indices derived from the deterministic model for lead risk. However, they also suggested the authors use the IEUBK model to support the spreadsheet model results, harmonizing the parameters between the two as much as possible. The authors should move the detailed discussion of the IEUBK to an appendix.

8.2.4 Charge Question 19

Charge Question 19. Soil Preliminary Remediation Goals (PRGs) and Provisional Trigger Concentrations (PTCs) were derived in Chapter 5 for the COCs. Was the approach consistent with accepted risk assessment methods and were the values calculated correctly?

A panel member again reiterated that inclusion of market basket foods and dental amalgams has to be clearly communicated to the risk managers, noting that in the US PRGs are derived for contaminants when risk decision criteria are exceeded (i.e., an unacceptable risk occurs). In this assessment, PRGs and PTCs were derived regardless of whether the risk assessment results were above or below decision criteria. This approach seems to be counterproductive and begs the question of why the risk assessment was even done. A particularly egregious example is that of selenium. All calculated non-cancer risks were below a hazard index of 1.0. The market basket

dietary intake accounted for 73% of that risk, whereas soil accounted for only 2%. Yet a PRG was developed for selenium. Cadmium and copper were also below non-cancer decision criteria with market basket dietary intakes accounting for the majority of the estimated risk. Yet PRGs were developed for these inorganics. In the case of copper this could result in unnecessary and expensive soil cleanups, while completely ignoring what appears to be a significant contribution of copper from the water distribution systems in homes.

Another reviewer noted that the market basket foods are not an adjustable factor and therefore PRGs should not be derived for this pathway. That leaves just air and soil because if one predicts a risk from a pathway, then one needs to look at where something can be done to reduce exposure. Unfortunately, only 10% of properties were sampled for soils and nothing is known about the other 90%. Another reviewer suggested the author set the air levels to background to calculate a PRG because the smelter will be shut down.

A panelist questioned why the authors calculated PRGs for compounds where soils are small contributors to exposure. Another panelist thought the PRGs are useful to identify which media and compounds to focus efforts to reduce exposure and prioritize use of resources.

8.2.5 Charge Question 20

Charge Question 20. Chapter 6 identifies and evaluates other risk issues relevant to the HHRA. Are the analyses and conclusions for these issues scientifically sound? Have the issues been appropriately considered in the overall HHRA and recommendations? Have potentially sensitive populations been adequately addressed?

Several panelists thought that the discussions in Chapter 6 were very good. Panel members had specific comments on several items.

- A panel member suggested that the discussion of mixtures found on page 6-14 would benefit from inclusion of some newer publications from the US EPA and referred the authors to www.epa/ncea for these publications (publications listed in Appendix E).
- In Section 6.8 and discussions of lead body burden, panelists questioned statements that lead is partitioned to bone. The panel members pointed out that lead in bones is a dynamic process, with ossification and de-ossification over time. Panelists also noted that cadmium accumulates in the kidney, another organ that accumulates metals over a lifetime.
- A panelist sought clarification from the authors whether they applied age-dependent uncertainty factors to increase the cancer dose response assessment slopes. An author indicated they did not and will clarify this in the text.
- Referring to the body burden discussion in Section 6.8.1, a panel member noted that there are *in vitro* studies that suggest that methylated daughter products of arsenic may be more toxic than the inorganic form. Another panel member noted that ingested methylated arsenical compounds have been determined by the US EPA's Science Advisory Board to be threshold carcinogens, and that more extensive methylation capacity results in more

efficient excretion and less *in vivo* exposure to inorganic arsenic and certain more toxic metabolic intermediates (e.g., trivalent monomethyl forms).

- Under the discussion of arsenic uptake, distribution, storage, and elimination, a panel member questioned how one could have inhalation exposure to arsenobetaine as it is a non-toxic, water-based compound that is excreted unchanged from the body. An author indicated they would check on this.
- A panelist clarified that the discussion at the bottom of page 6-5 regarding the NAS (1993) recommendations on a child protective uncertainty factor. Discussions related to children's exposure and risk, for example, as found on page 63, should include some additional publications for a more balanced presentation. On the bottom of page 6-5, the NRC statement that EPA uses an uncertainty factor when developmental toxicity data are available is not correct; rather EPA uses a database uncertainty factor when such data are missing. Several publications were suggested and are listed in Appendix E.

8.2.6 Charge Question 21

Charge Question 21. Are there additional issues or concerns that the authors should have addressed regarding the hazard assessment, the selection of exposure limits and the appropriate use of the values in the risk assessment? Do you have additional comments regarding aspects of the risk characterization and results?

Several panel members asked about the biomonitoring study plans. An author explained that the biomonitoring is on a parallel process as the HHRA due to timing issues. They would like to conduct biomonitoring in the fall of this year and a team of experienced medical practitioners and others experienced with biomonitoring studies is working on this. The biomonitoring plan is being peer reviewed separately from the HHRA. The TAC plan is to release the HHRA and the biomonitoring results at the same time, so that the individual evaluations are independent.

Other panel members discussed the community health assessment with Dr. James Irvine, an observer from Saskatchewan Ministry of Health during a break and asked him if there were key disease endpoints missing from the community assessment. Dr. Irvine told them that the assessment could not address skin cancer due to differences in nomenclature between the two provinces. Dr. Irvine explained to the panel that community assessment combined data from the two provinces. It was meant to be an overall approach to a community health assessment to compare demographics, non-medical health determinants, cancer incidence, and the common causes of death for Flin Flon and Creighton with their corresponding health regions and provinces but it was not specifically related to the COCs. Unfortunately, they could not get accurate data for skin cancer. He also explained that the health endpoints were not standardized for economic status, although they did compare non-medical health determinant statistics (including economic indicators) for Flin Flon and Creighton with the comparison groups. They compared the Creighton – Flin Flon data to the general population of Manitoba and Saskatchewan in addition to NOR-MAN and Mamawetan Churchill River Health Regions to provide a more comparable socioeconomic status. An author noted that Flin Flon has a relatively high standard of living, about three times the Canadian average. A panel member commented that when the report indicates that the health status of Flin Flon is better than the province, the results were not corrected for socioeconomic differences and one would expect Flin Flon with a

higher standard of living to have a better health status than the province. The panel recommended that the authors more fully discuss the community assessment and the strengths and weaknesses of the study and conclusions, particularly that the most likely cancer from arsenic exposure would be skin cancer and the community assessment did not evaluate skin cancer.

8.2.7 Charge Question 22

Charge Question 22. Chapter 7 presents uncertainty and sensitivity analyses. Were all the significant sources of uncertainty identified and characterized? Were quantitative uncertainty and sensitivity analyses done correctly? Are the conclusions regarding the significance and impact of the uncertainties on the resulting assessment correct?

A panel member noted that normally with a sensitivity analysis, one changes each parameter by a certain amount (e.g., 5%). But since linear regression was used, all the parameters will be the same. In this assessment, the authors evaluated different choices and so it is hard to understand the true sensitivity in the model when you vary the parameter values. An author did not entirely agree and thought that changing a soil ingestion rate by two times does not necessarily change the other parameters by the same amount. A panelist noted that the authors had not done a sensitivity analyses on the changing soil concentrations as a function of the various slope factors for arsenic. He encouraged them to do so. Another panelist suggested adding a qualitative discussion about potential exposure from breast milk for each of the COC and whether breast milk would be a pathway of concern for any of the COC. The panelist suggested a number of papers on concentration of constituents in breast milk and blood, and thought that breast milk exposure will be important for methyl mercury, less so for lead (see Appendix E for list of recommended papers). Another panel member noted that the arsenic TRV is based on a population with exposure to drinking water throughout all life stages and therefore breast milk exposure would have been included. Exposures to arsenic in soil and dust for the Flin Flon population for pregnant and nursing women would be considerably lower than for children compared to in a population exposed by drinking water. Thus, the Flin Flon population would not receive much exposure *in utero* or through breast milk as the population that forms the basis for the arsenic TRV. Information on fish consumption for the child receptor is mentioned in Chapter 7, but was not described in earlier chapters and should.

9. Conclusions and Recommendations

9.1 Author Presentation

Mr. Elliot Sigal presented the conclusions of the risk assessment for each of the COC, along with the authors' recommendations. Slides of his presentation are found in Appendix C. He noted that the utility of the findings of the community health status assessment are fairly limited, given the small population size. For arsenic, one needs to look at more than just the results and consider the overall weight-of-evidence. The authors recommend a urinary arsenic study, focusing on homes in West Flin Flon and Creighton, where a significant number of homes in the residential sampling program had concentrations in excess of the PTC. They recommended

comparison with a control community or control values found in the literature, as the literature has enough control information to rely upon.

The authors did not recommend further action for cadmium; they reported that the predicted cancer risk for cadmium from the ambient air was elevated, but noted that the smelter is closing in the next year and with its closing, the air concentrations (and corresponding risks) will reduce dramatically.

For lead, both the IEUBK and HHRA models predicted average lead related exposures to be within acceptable levels. However, because a significant number of residential properties in West Flin Flon have concentrations in outdoor soil greater than the residential PTC, and Health Canada is expected to lower the benchmark for lead, they recommended a blood lead survey focused on children up to seven years to reduce uncertainty in the exposure assessment.

A significant number of residential soils in West Flin Flon exceeded acceptable levels for inorganic mercury for the toddler receptor and the authors recommended biomonitoring as an option to more accurately assess exposure. However for methyl mercury the authors noted that the primary route of exposure is from fish and they originally considered biomonitoring, but noted that this would require venous blood draws which would complicate sampling. The authors recommended more work to determine the best action for reducing methyl mercury exposures, but noted that biomonitoring would not assist in decision making.

Mr. Sigal concluded that they recommend a comprehensive biomonitoring program to evaluate environmental contaminant exposure to children in Flin Flon and Creighton. Urinary arsenic, blood lead, and urinary inorganic mercury studies are recommended to start in the fall of 2009. Assessing biomarkers of exposure will help refine and validate the HHRA's exposure estimates

9.1.1 Clarifying Questions

A panelist asked why the authors recommended biomonitoring for inorganic mercury and arsenic up to age 16, but only to age 7 for lead. Mr. Sigal said that they wanted a large enough population size, but before individuals may start working in the facility and potentially have occupational exposure. The panelist noted that given the levels of arsenic in the market basket it would be difficult to distinguish between background and source. The author agreed but thought that they will not likely find elevated arsenic levels in the community. They hope to be able to compare people in the community exposed to different soil concentrations to see if soil is the driver of exposure, but may have difficulty recruiting enough children and expect issues related to speciation and creatinine correction will complicate this goal. The panel member recommended a paper by Dana Barr (Barr, 2005) of the CDC regarding the pitfalls of using creatinine for correction of urinary biomonitoring data.

A panelist suggested the authors consider testing for lead up to age 16. In other studies it is found that boys who are not under continual adult supervision have the highest levels of lead and so older children should be included. The panelist asked how exposure will be confirmed. The author explained that they would use the results of biomonitoring, and look at population trends, and levels in urine and blood to determine if elevated exposures are occurring and if they are at levels of concern. The panelist noted that they are then using biomonitoring results for risk

assessment and asked what criteria will be used to compare with the findings, noting there are guidelines for lead, but not arsenic. The author noted that the biomonitoring study principals are developing the criteria.

Another panelist asked whether the referent population for blood lead levels for children under six has been identified as there are few studies on young children and recent data are needed. The author indicated they will use other Canadian studies. Panelists also questioned the basis of the statement in slide 8 that children under 7 are more sensitive to neurological effects of lead. They noted that children of different ages with the same blood lead levels are not more or less susceptible, but children under 7, for an equivalent amount of lead in the environment, will have higher exposure. The younger child will be exposed and take up more than an older child; however an older child with an elevated blood lead level is a concern.

9.2 Panel Discussion

The panel reviewed the recommendations and conclusions of the assessment and discussed charge questions 23-29.

9.2.1 Charge Questions 23 and 24

Charge Question 23. Are the conclusions for each COC valid and are they supported by the data and the risk assessment? What is the likelihood that actual health risks have been over or under estimated? Are the potential human health hazards of the COCs adequately addressed?

Charge Question 24. The authors discuss biomonitoring and make recommendations regarding arsenic, lead and mercury. Are these recommendations appropriate and adequately supported?

The panel reviewed the conclusions and recommendations as presented in Chapter 8. Below is a summary of the panel's recommendations.

- *Acute Endpoints (8.1.1)*

The panel reiterated their recommendation that the authors carefully consider the available acute toxicity reference values and consider addressing acute risks qualitatively, but not quantitatively.

- *Chronic Endpoints – Residential Scenario (8.1.2)*

Mr. Safruk clarified how the authors added risks from multiple routes. He explained that for systemic toxicity endpoints they added inhalation, dermal, and oral daily intakes (mg/kg-day) and then compared the total intake with the oral TRV. In addition, they compared the inhalation intake alone with the inhalation TRV. For arsenic carcinogenicity, the oral and dermal intakes were added and risk calculated with the oral slope factor. For inhalation they calculated risk with the inhalation unit risk. The inhalation and oral/dermal risks were then added for a total carcinogenic risk. For lead, a separate inhalation risk was not calculated. Exposure *via* inhalation was added to the oral and dermal exposures for comparison to the oral TRV.

A panel member disagreed with the approach for the systemic toxicity endpoints and recommended that the authors keep the intake metric consistent with the toxicity metric (for inhalation - $\mu\text{g}/\text{m}^3$). The inhalation and oral hazard quotients can then be added for a hazard index. This reviewer thought that the authors' approach was not correct in that they did not take into account absorption and distribution, and when there are systemic toxicity values for both routes, they should not convert the inhalation intake to a dose. Another panelist agreed with the authors' approach for assessing endpoints that are portal of entry effects in addition to systemic endpoints where doses from multiple routes were added by the authors and compared against a TRV for a systemic endpoint for one route. The panelist explained that one is concerned with the dose to the target tissue and the separate HQs (for portal of entry effects as well as systemic effects from multiple routes of exposure) is defensible. The approach taken by the authors is defensible and allows for assessing portal of entry effects against a portal of entry TRV as well as adding exposure from multiple portals of entry for evaluating risk based on a systemic endpoint. However, this reviewer thought that the approach would be limited in terms of adding HQs for different endpoints based on toxicokinetic considerations. Another reviewer agreed and thought that the oral and inhalation results should be added together for systemic toxicity endpoints because what gets absorbed and distributed systemically is then available. A fourth panel member agreed that systemic dose is what is important and that one needs to account for relative bioavailability by pathway.

Panel members also sought clarification on how the authors adjusted dermal concentrations to calculate intake noting that it should be based on gastrointestinal bioavailability from the oral toxicity study. An author indicated that they used relative dermal absorption factors provided by Health Canada (2006). The panel members suggested explaining this in the text and providing the reference for the Health Canada values. One panelist noted that the 3% dermal absorption for arsenic that the authors used is based on a study by Wester et al. (1993) that had some design issues and used soluble arsenic freshly added to soil rather than arsenic in soil from a site. Lowney et al. (2007) repeated the study with a breathable patch and aged soils. They found that they could not detect any dermal absorption of arsenic.

The panel recommended that in addition to what the authors have presented, they should calculate separate oral and inhalation HQs when toxicity values are available. These HQs should then be added together and presented with the authors' original approach. The alternative HI should be discussed with the results in Chapter 8 (e.g., Table 8-4).

The panel also cautioned that one must be careful interpreting the hazard quotients for toddlers. The toddler's few years of exposure is being compared to chronic toxicity values and for most of the COCs these hazard quotients are not appropriate because the toxicity values are based on lifetime exposure. For example, the arsenic and cadmium TRVs are calculated from studies with whole life human exposures.

- *Chronic Endpoints – Outdoor Commercial/Industrial Workers (8.1.3)*

The panel recommended the authors use the 95% UCLM rather than the maximum value.

- *Chronic Endpoints – Recreational Scenario (8.1.4)*

The panel recommended the authors qualitatively address the potential for exposure through sediments.

- *Summary of Discussion of Chronic Residential Results (8.2)*

- Arsenic

The panel discussed the recommendation for arsenic biomonitoring of a sample population of children up to 16 years of age. Some thought the recommendation appropriate, based on results of the HHRA. Others expressed concerns with the recommendation. One panelist did not think biomonitoring would be justified because the results of the HHRA were not elevated much above background and the panelist did not think that biomonitoring would show anything above background levels. Another expressed concern that the bulk of intake is from market basket foods and the panelist was not convinced that one would be able to distinguish site sources from food. A third thought that if the biomonitoring finds that levels are not above background, this would be a useful finding and one could conclude that exposure levels in the COIs are similar to other populations in Canada. This panel member thought that communicating risk on arsenic has always been difficult and if they do not do a urinary arsenic study, what other measures can they take? Others cautioned that the TAC must think about risk communication and identify beforehand what health screening benchmarks to use and what message to communicate about higher values and whether they will give individual their results.

An author clarified that the biomonitoring protocol is being developed. They have health benchmarks selected and plan to give individuals their results and follow up with the individuals. They will use community-wide results to feed into the risk assessment.

Several panel members cautioned the authors to be careful with using non-cancer endpoints for arsenic, particularly for toddlers. Cancer is driving the recommendation and the cancer toxicity value is based on populations with lifelong exposure. A panel member asked why the authors recommend testing only those under 16. An author explained that those over 16 may be working at the site and have additional occupational exposures. Several asked what levels are seen in the workers and suggested that the employee biomonitoring data be analyzed as a first step.

Panel members discussed what to use for a reference population. One thought that having a reference population was not always necessary. If the effect of soil concentrations is the question, then the authors could look at biomarker levels of children within the community exposed to different soil concentrations to see if a relationship exists. Another panel member suggested the authors use a nearby referent population; otherwise community members will see the study as deficient. Another suggestion was to use the population being testing for internal reference and the question is whether the individual's soil and biomonitoring results are correlated.

One thought that at best, biomonitoring could be useful to reassure people that their results are within expected ranges and the ranges of other communities. Biomonitoring may assist with risk

communication with the public, but the panelist did not think it would provide useful data to fine tune the risk assessment.

Several panel members questioned the value of biomonitoring at the present time if the smelter is closing next year and emissions will be reduced. Current emissions are more relevant than soil concentrations for contributions to exposure and the biomonitoring should be done after shut down. They cautioned that it would be unfortunate if the biomonitoring triggered soil cleanup, if the soil is not the source of exposure, and encouraged that the TAC plan for home visits by medical professionals and identification of sources before any remedial actions are taken. Another panelist, however, pointed out that biomonitoring at this point would provide a reference point for the future.

The authors noted that when they tried to determine which properties would benefit from biomonitoring they did not use the 95% UCLM values, rather they looked at the number of properties exceeding a back calculated value. A panelist again cautioned that they used values from oral exposures to toddlers and those risk statements need to include caveats as explained earlier.

The chair asked if the panel could definitively recommend biomonitoring if all the concerns they raised were addressed. Half the panel recommended that biomonitoring for arsenic be done. One of these suggested using a local population as reference and split properties below and above a trigger concentration to see if there is a difference between them. Others thought biomonitoring could provide the community with assurances regarding risk. One of these panelists did not think that the HHRA findings support biomonitoring, but thought it could be useful if people want it; however, the program would need to include surveys on activities and diets to help determine the sources of exposure and the relative contribution of non-site exposure.

The other half of the panel did not recommend biomonitoring for arsenic, or had significant reservations about such. One panelist did not see a medical or scientific rationale at this point that suggests the need for biomonitoring to assure the safety of the population, but noted that the HHRA has yet to be revised based on the panel's comments. The panelist was also concerned that by collecting this information on individuals, there is a responsibility to deal with the information and work with the individuals. Two panelists suggested first looking at employee biomonitoring data before community biomonitoring. One expressed concern about the power of a community biomonitoring study, the *a priori* sample size, and the variance. The panelist questioned how they would be able to attribute an incremental exposure to soil and air. This panelist's experience is that biomonitoring is hard on the communities being studied, and thought this should be considered carefully in making a decision. One panelist stated that based on the HHRA and the relative contribution of arsenic from the site sources, the panelist did not think biomonitoring was justified. This panelist would have conducted biomonitoring before the HHRA but thought that if they do it now and do it very well it can be useful to the risk assessment; however, if it is not done well, it could do more harm than good.

➤ Lead

The authors recommended a blood lead survey up to age 7. All but one panel member supported this recommendation, although most of the supporters had some reservations and offered caveats. One panelist noted that if the authors step away from the IEUBK model in the text, their conclusions may be somewhat different, with hazard screening resulting in fewer problem properties. Another panelist thought that blood lead survey is a good idea for any community with an aged housing stock, near a source of lead emissions, and with some properties with high soil concentrations. Blood lead can help identify the need for intervention sooner rather than later. Another thought that the recommendation is supportable, but that the community should be involved in the design, and the limitations and study design should be carefully explained to the community members. Another also cautioned that those conducting the blood lead testing will have to be very savvy with risk communication and what they tell people about risk.

One panel member supported biomonitoring for lead, particularly because the TRV for lead is expected to be reduced and when that happens, it may call into question the validity of this HHRA's conclusions. Having blood lead measurements will provide information to help assess risk with the expected lower value. This panelist also thought that soil is a large contributor to lead exposure and the biomonitoring data will provide information for measuring effectiveness of clean up.

A reviewer was of the opinion that the risk assessment did not support the recommendation, but agreed that it would be helpful to alleviate uncertainties in people's minds. The panelist recommended they plan in advance how to respond to elevated levels and if the source is lead based paint, they should have a plan to address it. Another panel member agreed with biomonitoring because the panelist could see no other feasible way to integrate uncertainty of individuals into the assessment.

One panelist did not think the testing was justified based on the risk assessment and the relative contribution from the site. The panelist thought it would have been better to do the testing prior to the HHRA and incorporate the results. The panelist thought that if the TAC goes forward with biomonitoring and it is done very well, it can be useful, but if it is not done well, it could do more harm than good.

The panel discussed a panelist's recommendation that pre-pregnant women be included because the prenatal influence of lead is very important. Occupational guidelines recommend considering blood lead levels prior to pregnancy. This panelist recommended using 10 µg/dL as an action guide for pre-pregnant women, and suggested seeking to reduce exposure if they were near that level. The panelist did not think bone lead measurements would be needed. Another panelist did not recommend initially including the elderly or pre-pregnant women because children will have the highest exposures. If there is a problem in children, then they can expand to other sub-populations. Other panel members cautioned that one would have to be very careful communicating risk to pregnant women.

➤ Cadmium

The panel noted that with the previous discussions, the authors need to recalculate and revise the text for cadmium. They noted that the statement regarding the ILCR being elevated should be

checked closely, as the risk is no greater than that for arsenic. The authors need to be careful to be consistent with these types of qualitative judgments and statements between COCs. They also noted that the reference to future smelter emissions should be revised.

➤ Methyl Mercury

An author clarified that they have revised this section and no longer recommend biomonitoring for methyl mercury. The authors did recommend that a fish consumption advisory be considered, particularly for sensitive populations, to reduce exposures to methyl mercury. One panelist thought that the levels were just marginally different from market foods and was not sure a fish advisory would do any good. The panel agreed with the recommendation to consider a fish advisory for methyl mercury and suggested ongoing monitoring of methyl mercury in fish.

➤ Inorganic Mercury

The panel discussed the authors' recommendation for biomonitoring for inorganic mercury. They discussed that the TRV for inorganic mercury is based on a NTP chronic rat study with renal effects (tubular necrosis). A 14-day study in rats has a no effect level at the same critical dose and so it appears that duration of exposure is a factor involved for inorganic mercury's toxicity. A panel member pointed out that the only receptor with a hazard quotient over 1 was the toddler and asked who they would suggest for biomonitoring. Another panelist asked what would be used for the trigger level and pointed out that the hazard quotient for inorganic mercury averaged only 2. Panelists objected to biomonitoring for inorganic mercury because the TRV is based on a chronic study, whereas the HQ for toddlers is 2, and there is a large uncertainty factor associated with the TRV; therefore, exposures slightly greater than the TRV may not be associated with any appreciable risk of adverse effects. Another reviewer noted that the HHRA authors used 100% bioavailability in their calculations and in this panelist's opinion, 50% would be more appropriate.

All but one panel member thought that the data did not demonstrate a need for biomonitoring given the concerns discussed above. The one panel member who disagreed thought that if arsenic biomonitoring in urine was being conducted, they might as well include urinary mercury; they can both readily be done at the same time.

➤ Selenium

Panel members questioned selenium's inclusion as a COC, no one on the panel disagreed with the HHRA conclusion that there are no risks from selenium in the COIs.

9.2.2 Charge Question 25

Charge Question 25. Have the key objectives of the HHRA been addressed by this assessment? (Section 1.3)

Objective 1: To assess risks to human receptors residing in Flin Flon, Manitoba and Creighton, Saskatchewan as a result of exposure to metals in soil and other environmental media impacted by the activities of the HBMS complex. The HHRA will estimate the contribution from individual exposure pathways and environmental media to assist in the development of risk management objectives; and,

Objective 2: Develop risk management objectives and/or mitigation plans if unacceptable risk levels are identified in the HHRA. These risk management plans will be based on scientific approaches in consultation with the Technical Advisory Committee and the community.

The panel discussed the objectives earlier under Charge Question 5. For the most part, they thought the HHRA had met Objective 1, but pointed out difficulties posed by some of the wording. One panel member noted that Objective 1 (as written in Section 1.3 of the HHRA) is to assess risks to human receptors as a result of exposure to metals in soil and other environmental media impacted by the activities of the HBMS complex. Inclusion of the market basket dietary intake into the risk estimates is not consistent with this objective and makes sound risk decision making more difficult. Another countered that this type of approach is valuable because it provides a picture of total exposure from all sources for the people of the community.

The panel recognized that Objective 2 was not intended to be met by the HHRA document that they were charged with reviewing. However, one noted that if they intend to meet Objective 2, they will have to identify what is an acceptable risk for each COC.

9.2.3 Charge Question 26

Charge Question 26. 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 US EPA)?

The panel members generally agreed that overall the assessment followed the commonly accepted methods. However, there are some instances where the commonly accepted methods differ from one another or with the current scientific literature.

9.2.4 Charge Question 27

Charge Question 27. Overall, were the input data and assumptions valid and appropriate for the Flin Flon and Creighton communities?

Overall the panel agreed that the input data and assumptions were valid and appropriate, except for those that were discussed at the meeting.

9.2.5 Charge Question 28

Charge Question 28. Is the Human Health Risk Assessment presented clearly and completely?

The panel agreed that in general, the HHRA was presented clearly and completely, and that it was a very comprehensive effort. One panelist thought the authors did a good job organizing the document and the panelist was able to quickly find everything. Panel members recognized the challenges in conducting such a comprehensive assessment and thought that their suggestions and recommendations could be incorporated fairly readily.

9.2.6 Charge Question 29

Charge Question 29. Are there additional important issues that should have been addressed?

None.

10. Post Meeting Review of Revised HHRA

In late December 2009, Intrinsik forwarded to *TERA* a copy of the revised HHRA and a 39-page “Response to IERP Comments on the Human Health Risk Assessment”. In their response, Intrinsik authors identified each of the IERP recommendations and explained how they revised the HHRA to be responsive. *TERA* forwarded the Intrinsik response document to the IERP committee. The IERP agreed that *TERA* and Dr. Dourson, as Chair of the IERP, should review the revised HHRA and Intrinsik responses for consistency with the IERP recommendations and consult with IERP members as needed to make these determinations. Dr. Michael Dourson and scientific staff of *TERA* carefully reviewed the HHRA authors’ responses to the IERP recommendations. *TERA* staff checked the HHRA text to verify the revisions and their completeness. Dr. Dourson also read the revised HHRA to determine the authors’ overall responsiveness to the IERP recommendations.

Several of the Intrinsik responses to IERP recommendations were initially not clear to Dr. Dourson and the *TERA* staff and clarifying questions on these items were sent to Dr. Sigal, who provided responses. In addition, *TERA* reviewed the IERP report and identified several additional panel member recommendations that were not clearly addressed in the Intrinsik response document and forwarded this list to Dr. Sigal. Intrinsik staff provided written responses to each of the clarifying questions and the list of additional items. These email exchanges are documented in Appendix T of the final HHRA.

Overall, the *TERA* review found that the Intrinsik authors had revised the document appropriately to be consistent with the IERP recommendations. There were a few issues or recommendations for which the Intrinsik authors did not fully accept the IERP recommendations. Dr. Dourson and *TERA* reviewed Intrinsik’s explanations carefully and for several of these consulted with relevant IERP members to determine whether the Intrinsik positions and explanations were acceptable. In particular, panel members were consulted on issues related to the IEUBK model and Health Canada and CCME guidance on selection of TRVs to match exposure duration. While a few differences of scientific opinion remain between the IERP and the authors of the HHRA, these differences do not impact the conclusions of the HHRA or the protection of public health in Flin Flon and surrounding areas. The HHRA and results were found to be scientifically-sound and appropriately health protective. The HHRA has been revised to address the IERP recommendations and be responsive to the IERP issues and concerns.

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