

Charge to Peer Reviewers

Sudbury Soils Study: Human Health Risk Assessment

Background

The purpose of the Independent Expert Review Panel (IERP) is to provide expert review and evaluation of the Sudbury Soils Study Human Health Risk Assessment (HHRA). The panel members will review the provided documentation and will objectively discuss the materials charge questions at a panel meeting on September 20-21. Initial discussions on Volume 1 will be held during the orientation conference call currently scheduled for August 14. The panel will attempt to reach consensus on the conclusions. *TERA* will compile the panel discussions into a meeting report that will summarize the key points from the discussions, with a focus on the conclusions regarding the charge questions.

Sudbury is a nickel mining community in Northern Ontario. The soils are contaminated with nickel, arsenic, lead and some other chemicals. In 2001, the Ontario Ministry of the Environment (MOE) published the results of soil monitoring studies conducted in the Sudbury area and identified elevated levels of several elements in soils near the three historic smelting and refining centers of Copper Cliff, Coniston, and Falconbridge. The MOE recommended a more detailed soil study be conducted to fill data gaps and that human health and ecological risk assessments be conducted. The Sudbury Soils Study was then initiated, with the underlying objective to answer the question: “Do Sudbury soils containing metal and arsenic levels above the generic guidelines pose an unacceptable ecological or human health risk?” While elevated soil levels was the original impetus for the study, sampling and data collection on concentrates of metals in other environmental media was included.

The Study is overseen by a Technical Committee (TC), comprised of Inco and Falconbridge Ltd., the Ontario MOE, the Sudbury & District Health Unit, the City of Greater Sudbury, and the First Nations and Inuit Health Branch of Health Canada. The assessments were prepared by the SARA Group, a group of environmental consulting firms and consultants. The Study has included broad consultation with local communities and stakeholder groups. The two mining companies are providing funding for the study and this peer review. More information can be found at www.sudburysoilsstudy.com.

The package of materials for review includes Volume I– Background, Study Organization and 2001 Soils Survey and Volume II – Human Health Risk Assessment (Parts A and B). Additional reference materials and data are provided on compact discs.

Background Information from Volume II, Executive Summary:

“The purpose of the HHRA is to evaluate the potential for the occurrence of adverse human health effects from exposures to the chemicals of concern (COCs) currently present in surrounding environmental media (e.g., air, soil, sediment, surface water, groundwater, food and biota, etc.), under existing or future exposure conditions.

The HHRA was conducted using the risk assessment procedures endorsed by regulatory agencies, including Environment Canada, Health Canada, the Canadian Council of Ministers of the Environment, and the United States Environmental Protection Agency (U.S. EPA). Past experience with the policies and preferred approaches of the Ontario Ministry of the Environment (MOE) and the Sudbury Soils Technical Committee (TC) was considered during the methods development stage of this assessment, to ensure compliance with existing practices governing the use of risk assessment in Ontario.

The current study is considered an area-wide risk assessment (i.e., encompassing a large geographical area) rather than a site-specific risk assessment (i.e., generally involving an individual property owner). Conducting the Sudbury study on an area-wide basis was most appropriate for two main reasons:

- The extensive nature of the study area as delineated by elevated soil metal concentrations resulting from local smelting operations; and,
- The involvement of multiple stakeholders, communities, and property owners.

The size of the area of impact and involvement of multiple stakeholders necessitated the collection and use of large community-based data sets (e.g., lifestyle, diet) for the purpose of modeling risks. While many of the elements of an area-wide assessment have their roots in the approaches used to evaluate risk on a site-specific basis, it is important to note that there is no specific regulatory guidance available governing the application of risk assessment on an area-wide or community-based level in Canada.”

The HHRA results will be used to establish Sudbury-specific soil quality guidelines that will provide the basis for determining the need for and potential scope of any future risk management activities. The authors and TC will consider the panel’s recommendations and revise the HHRA. The final assessment will be released to the public.

Data Collection/Site Characterization

1. Have all appropriate Chemicals of Concern (COC) been included in the risk assessment?
2. Were the appropriate types of data and analyses necessary to assess the extent of contamination collected and performed, and did they adequately characterize the distribution and concentration of COCs in each of the media of interest?¹
3. The authors evaluated the available sampling data and for each media calculated the exposure point concentrations (Volume II, Section 4.1.1). Are the exposure point concentrations appropriate?
4. Are there any concerns or limitations of these studies that affect the usefulness of the data in the Human Health Risk Assessment (HHRA)?

Exposure Assessment

1. Does the conceptual model (Volume II, Section 2.1.7) adequately demonstrate the potential human receptors and the related exposure pathways?
 - The assessment identified five communities of interest (Copper Cliff, Coniston, Falconbridge, Sudbury Central or core, and Hanmer, as well as First Nations people living in these communities). Has the study area been adequately separated into unique exposure communities? Was the selection of communities of interest appropriate?
 - Were all appropriate potential exposure pathways evaluated and was the selection of pathways appropriate and defensible? Was the justification for excluding exposure pathways reasonable? (Volume II, Section 2.1.5)
2. Do the selected exposure scenarios (background, typical Greater Sudbury Area resident, First Nations resident, and recreational hunters/anglers) sufficiently cover the situations, behaviors, and conditions under which receptors are likely to be exposed?
3. The assessment identified receptors of interest (male and female receptors in five life stages, and lifetime). Do these receptor categories adequately characterize the population?
4. Are the selected receptor characteristics (Volume II, Tables 2.1 to 2.5; Appendix B; and Volume II, Section 6.5) and values the most appropriate for use in this assessment?
5. Background exposure was derived from monitoring programs in Ontario and across Canada. Were the values calculated for the Typical Ontario Resident (TOR) appropriate? (Volume II, Section 4.1.2)

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

6. Was the approach to developing the market basket estimated daily intakes reasonable and were they estimated appropriately? Is it appropriate to add these local exposures to local foods consumed? (Volume II, Section 4.1.3 and Appendix D).
7. Are the evaluation of indoor environmental exposures based upon indoor dust survey and use of soil-to-indoor dust regression relationships reasonable?
8. For each combination of pathway and receptor, were the assumptions and exposure input parameters appropriate and were the most appropriate intake rates calculated? (Volume II, Section 4.1.6, Chapter 2; Appendix B and O)
9. Have potentially highly exposed populations been identified and addressed adequately?
10. Do you have any further concerns or comments regarding the exposure assessment?

Hazard Assessment

1. Are the potential human health hazards of the COCs adequately addressed? (Appendix A and CD-1).
2. Were the most appropriate exposure limits identified and were the rationales for the selections defensible for each of the COCs?² (Volume II, Section 4.1.8)
3. Was bioavailability and bioaccessibility of the COCs in the various media addressed appropriately? Volume II, Section 3.4 and Appendix J describe the *in vitro* site-specific oral bioaccessibility studies conducted. Were the relative absorption factor (RAF) values selected appropriately (Volume II, Section 4.1.9)? Has the information been incorporated correctly in the assessment?
4. Have potentially sensitive populations been addressed adequately?
5. Are there additional issues or concerns that the authors should have addressed regarding the hazard assessment, the selection of these exposure limits, and the appropriate use of the selected values in the risk assessment?

Risk Characterization

Chemical –Specific Risks

1. Was the approach used to estimate Hazard Quotients (HQs), Incremental Lifetime Cancer Risks (ILCRs), and the soil specific oral reference doses consistent with accepted risk assessment methods, and are these calculated correctly? (Appendix O)
2. Deterministic analyses were used to initially characterize the exposures, and where elevated risks indicated, probabilistic analysis was conducted for exposure estimation to provide a more rigorous estimate of potential risk. Did the authors choose the appropriate methods and exposures to conduct probabilistic analyses (e.g., appropriate shapes for the parameter distributions)?
3. Was the probabilistic risk assessment reasonable based on the unique characterization of the Sudbury site? (Appendix P)

² For example - Is the use of the use of urinary arsenic study results and epidemiological data in the weight of evidence approach for evaluating arsenic health risks reasonable? Is the use of the IEUBK model and approach used for lead reasonable? Section 3.5 discusses metal speciation of the COCs and the weight of evidence approach used. Were the analyses appropriate to resolve the questions regarding speciation?

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

Site-Specific Remediation Goals

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

Uncertainty

6. Were all the significant sources of uncertainty identified and characterized? Are the authors' conclusions regarding the significance and impact of the uncertainties on the resulting assessment conclusions appropriate? (Volume II, Chapter 7)
7. Were quantitative uncertainty and sensitivity analyses done correctly? Could they have been done differently to improve the assessment of uncertainty? (Volume II, Chapter 7)
8. What is the likelihood that actual health risks have been over or under estimated?
9. Do you have any additional comments regarding aspects of the risk characterization, including estimating of chemical risks, SSRGs, or uncertainty?

Conclusions and Recommendations

1. Was the approach used for this community assessment consistent with commonly accepted methods and procedures by government agencies (such as Environment Canada, Health Canada, the Canadian Council of Ministers of the Environment, and the United States Environmental Protection Agency [U.S. EPA])?
2. Is the Human Health Risk Assessment presented clearly and completely?
3. Overall, are the input data and assumptions valid and appropriate for the Sudbury community?
4. Are the conclusions for each COC valid and defensible, and are they supported by the risk assessment? Are there additional points that should be made?
5. Have the important uncertainties been identified and their impact on the characterization of risk and overall conclusions been discussed?
6. Have the key objectives of the Sudbury Soils Study been addressed by this assessment? (Volume II, Page 1-6)
7. Are there additional important issues that should have been addressed?