Appendix A

List of Attendees

Sudbury Soils Human Health Risk Assessment
Peer Review
September 20-21, 2006
List of Attendees

Ms. Kelly Anderson
Frontline Corporate Communications Inc.
(SARA Group)

Mr. Chris Bacigalupo
Cantox Environmental Inc.

Dr. Brendan Birmingham
Ministry of the Environment

Mr. Patrick Bolger
Bolger and Associates Ltd

Mr. Kevin Boyd
Union observer

Dr. Ronald W. Brecher
GLOBALTOX

Mr. Marc Butler
Xstrata Nickel (formerly Falconbridge Limited)

Mr. Brian Cameron
Ontario Ministry of the Environment

Dr. Bruce Conard
Inco Limited

Mr. Richard DeStefano
Sudbury Soils Study

Mr. Trevor Smith Diggins
Frontline Corporate Communications Inc.
(SARA Group)

Dr. Mike Dutton
Inco Limited

Dr. Glenn Ferguson
Cantox Environmental Inc.

Mr. Bruce Fortin
Sudbury & District Health Unit
Dr. Dr. Gordon W. Hall
Xstrata

Mr. Rick Grylls
Mine Mill 598/CAW

Mr. Ian Hamilton
Xstrata Nickel

Mr. John Hogenbirk
Centre for Rural and Northern Health Research

Mr. Gary Hrytsak
Independent

Mr. Franco Mariotti
Independent

Ms. Kerri Jones
Xstrata Nickel

Ms. Minnie de Jong
Ministry of the Environment

Mr. Denis Kemp
Denis Kemp Consulting

Ms. Aino Laamanen
Sudbury Soils Study

Dr. Evert Nieboer
McMaster University

Mrs. Julie Sabourin
Sudbury Soils Study

Mr. Elliot Sigal
Cantox Environmental Inc.

Dr. Penny Sutcliffe
Sudbury & District Health Unit

Mr. Glen Watson
Inco Limited

Dr. Christopher Wren
Gartner Lee Limited

Mr. Ido Vettoretti
Sudbury &District Health Unit

Appendix B

Meeting Materials

Agenda, Overview, Panel Charge, Panelist Biographical Sketches and Conflict of Interest/Bias Disclosures, and Presenter Biographical Sketches

Sudbury Human Health Risk Assessment Independent Expert Review Panel

Meeting Materials

September 20-21, 2006

Collège Boréal
Sudbury, Ontario

Table of Contents

Agenda

Sudbury Soils Study Human Health Risk Assessment
Independent Expert Review Panel (IERP)
Jean-Watters Auditorium, Collège Boréal • Sudbury, Ontario

Tuesday, September 19, 2006

7:30 **Public Briefing**

Welcome
Description of Peer Review Process
Introduction of IERP members
Questions and Answers on Review Process

Wednesday, September 20, 2006

7:30 **Registration and Continental Breakfast**

8:00 **Meeting Convenes**[1]
Welcome, Ms. Jacqueline Patterson, *TERA*
Panel Introductions and Conflict of Interest/Bias Disclosures, Panel
Meeting Process and Ground Rules, Dr. Michael Dourson, Chair

8:30 **Sudbury Soils Study – Human Health Risk Assessment**

Data Collection and Site Characterization
SARA Presentation (15 minutes)
Discussion

10:30 **Exposure Assessment**
SARA Presentation (15 minutes)
Discussion

12:00` **Lunch**

12:45 **Complete Exposure Discussion**

3:00 **Hazard Assessment**
SARA Presentation (15 minutes)
Discussion

4:30` **Conclusions from Day 1**

5:00` **Meeting Adjourns for the Day**

5:00 **Brief Tour of Site for Panel**

[1] The Chair will call a break mid-morning and mid-afternoon.

7:30 **Panel Dinner**

Thursday, September 21, 2006

7:45 **Continental Breakfast**

8:15 **Meeting Reconvenes**[2]
Chair's summary of Day 1 and plan for Day 2

8:30 **Complete Hazard Assessment Discussion**

9:30 **Risk Characterization and Site-Specific Remediation Goals**
SARA Presentation (15 minutes)
Discussion

12:00` **Lunch**

12:45 **Complete Risk Characterization Discussion**

3:00 **Conclusions and Recommendations**
Panel drafts bulleted list of conclusions and recommendations

5:00 **Meeting Adjourns**

[2] The Chair will call a break mid-morning and mid-afternoon each day.

Overview of the Peer Review Process

Background

This peer review meeting has been organized by Toxicology Excellence for Risk Assessment (*TERA)*. *TERA* is an independent non-profit organization with a mission to protect public health through the best use of toxicity and exposure information in the development of human health risk assessments. *TERA* has organized and conducted peer review and consultation meetings for private and public sponsors since 1996 (see www.tera.org/peer for information about the program and reports from meetings).

The purpose of this peer review is to have a panel of experts carefully evaluate the science and conclusions of the human health risk assessment. The Sudbury Soils Study and human health and ecological risk assessments have been undertaken to determine if there are unacceptable human health or ecological risks associated with metal and arsenic levels present in the Sudbury area. Based on the available information for Sudbury, the study will provide a measure of the risk level from metals and arsenic in soils, and may determine site-specific soil guidelines for the Sudbury area.

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

This meeting and the process is not open to the general public and the assessment results are not yet final; therefore, the panel and observers are asked to keep the assessment and panel discussions confidential and not discuss them with others, including the media.

Independent Expert Review Panel

The independent peer review panel includes seven scientists who have expertise in the key disciplines and areas of concern. Each panelist is a well-respected scientist in his or her field. Collectively, the panel has expertise in multimedia and site assessments, toxicology of metals and arsenic, bioavailability, environmental geochemistry, metal (loid) speciation in soils and mine waste, and mineralogical analysis, probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dust, and the calculation of soil clean up goals. *TERA* was solely responsible for the selection of the panel members.

Each panel member has disclosed information regarding potential conflicts of interest and biases related to the Sudbury Soils Study and its sponsors. *TERA* carefully evaluated these disclosures

when selecting panel members. Short biographical sketches and disclosure statements for panel members are provided in this package (see page 14).

Review Package and Charge to Peer Reviewers

The panel received the review package approximately two months prior to the meeting to ensure adequate time to carefully review the document and prepare for the meeting discussions. Materials sent included Volume I– Background, Study Organization and 2001 Soils Survey and Volume II – Human Health Risk Assessment (Parts A and B). Review materials also included compact discs, including data and reports from the soil surveys, and sub appendices for Part B (appendices). *TERA* developed a "charge to peer reviewers" document that outlined the key questions and scientific issues that need to be discussed by the panel in order to evaluate the quality and completeness of the risk assessment. A copy of the charge is found beginning on page 7.

Meeting Procedures

The meeting will be organized to make the best use of the time available to hear and discuss the opinions of the panelists regarding the charge questions and the human health risk assessment. The meeting will begin with brief panel introductions and a discussion of conflict of interest and bias issues. The discussion will then address the four broad areas of the assessment: data collection and site characterization, exposure assessment, hazard assessment, and risk characterization. To start each discussion section, the authors of the assessment document will make a short presentation. These presentations will highlight the salient points and focus on important issues. There will be a brief period for panel member clarifying questions and then the panel will discuss the relevant charge questions. At the end of the second day, the panel members will compile their major recommendations and conclusions into a bulleted list that will be included in the meeting report.

Observers

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

Meeting Report

TERA will draft a meeting report that briefly summarizes the panel's discussions and recommendations. The meeting report will serve as a record of the peer review and will assist the authors in making revisions to the assessment. The report will be reviewed by the panel members for accuracy before it is finalized.

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 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 Technical Committee 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?[3]
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)

[3] 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?[4] (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)

[4] 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?

Conflict of Interest

TERA was selected by the Technical Committee to independently organize and conduct this expert panel review. The Working Group of the Technical Committee has directed *TERA*'s work to organize the expert review. Inco, Ltd. and Falconbridge, Ltd. are paying for the expenses related to this review. *TERA* has not participated in the development or preparation of the human health and ecological risk assessments that are the subject of these reviews. *TERA* is not contracted to do any other work for Inco or Falconbridge, nor for the SARA Group and its member companies. *TERA* has past experience in risk assessment and toxicity of metals. This work has been done for a variety of public and private sponsors, but none of it is related to the Sudbury assessments.

TERA has conducted reviews and worked on projects involving some of the contaminants considered at the Sudbury site, including arsenic, nickel, copper, lead, cadmium, and selenium for a variety of sponsors. These projects were sponsored by the U.S. EPA, Health Canada, the Metal Finishing Association of Southern California, the International Copper Association, the U.S. Bureau of Land Management, Elf AtoChem North America Inc., the U.S. National Institutes of Occupational Safety and Health, and a metal refiner in South Africa. . Dr. Lynne Haber of *TERA* served as a peer reviewer for the Ontario MOE on the Rodney Street risk assessment and has been asked by MOE to be a peer reviewer for a community risk assessment currently being prepared.

TERA follows the U.S. National Academy of Sciences (NAS) guidance on selection of panel members to create panels that have a balance of scientific viewpoints on the issues to be discussed. As a result, the expert panels have a broad and diverse range of knowledge, experience, and perspective, including diversity of scientific expertise and affiliation. Panel members serve as *individuals*, representing their own personal scientific opinions. They do not serve as representatives of 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.

An essential part of panel selection is the identification and disclosure of conflicts of interest and biases. Prior to selecting the panelists, each candidate completes a questionnaire to determine whether their activities, financial holdings, or affiliations could pose a real or perceived conflict of interest or bias. The completed questionnaires were reviewed by *TERA* staff and discussed further with panel candidates as needed. (See www.tera.org/peer/COI.html for *TERA's* conflict of interest and bias policy and procedures for panelist selection).

TERA has determined the each panel member has no conflicts of interest and is able to objectively participate in this peer consultation. None of the panel members has a financial or other interest that would interfere with his or her abilities to carry out their duties objectively. None of the panel members works for Inco, Falconbridge, the other companies or agencies represented on the Sudbury Soils Study Technical Committee, or the companies comprising the SARA Group. Nor do the panel members have financial interests in the two mining companies. None of the panel members was involved in the preparation of the human health or ecological risk assessments.

A brief biographical sketch of each panel member is provided below. To promote transparency, as appropriate, a short disclosure statement describing potential conflict of interest or bias issues that were disclosed and evaluated is also included.

Biographical Sketches of Panel Members

Dr. Gary Diamond

Dr. Gary Diamond is a Senior Research Fellow in the Environmental Science Center of Syracuse Research Center (SRC) and has more than 20 years of experience in experimental research and applications of toxicological and epidemiological research to human health risk assessment related to heavy metals. Dr. Diamond has participated and/or led numerous research projects that have focused on developing improved methods for assessing risks and reducing uncertainty of estimates of health risks related to exposures to metals. He currently leads research projects to develop exposure-toxicokinetics models for cadmium, lead, and zinc compounds for use in risk assessment and to develop methods for the consistent integration of bioavailability information into quantitative risk assessment of metals. He has served as SRC Program Manager on numerous contracts and the SRC Principal Investigator on two cooperative agreements to support risk assessment programs of the U.S. Public Health Service Agency of Toxic Substances and Disease Registry (ATSDR), the U.S. Environmental Protection Agency (EPA), the U.S. Department of the Interior, and the U.S. Department of Transportation. Prior to joining SRC, as a member of the faculty of the Departments of Pharmacology and Environmental Medicine at the University of Rochester, he conducted research on the transport of heavy metals in the kidney. He served as a consultant to the Metals Subcommittee of the Environmental Health Committee of the U.S. EPA Science Advisory Board (SAB) for 5 years and also served on the SAB Dermal Risk Assessment Workgroup, as well as the International Life Science Institute Working Group on Bioavailability. He currently holds an adjunct faculty professorship at the State University of New York College of Environmental Science and Forestry (SUNY ESF), where he teaches and participates in collaborative research on exposure and risk modeling of metals. Dr. Diamond received a B.S. in Zoology from the University of Maryland and his Ph.D. in Pharmacology from the University of Minnesota.

Dr. Diamond was selected for the panel for his extensive expertise in metals toxicology, bioavailability, toxicokinetics, multimedia risk assessment, evaluation of human health hazards of soils and dusts, calculation of soil clean up goals, and familiarity with various agency risk assessment methodologies.

Disclosures: None

Dr. Michael L. Dourson

Dr. Dourson is the Director of Toxicology Excellence for Risk Assessment (*TERA*), a nonprofit corporation with a mission to protect public health. *TERA* develops partnerships among government, industry and other interested groups to address risk assessments of high visibility, such as soluble nickel, formaldehyde, perchlorate, and chloroform; as well as cooperative ventures such as the Voluntary Children's Chemical Exposure Program (VCCEP) and the International Toxicity Estimates for Risk (*ITER*) database available at the U.S. National Library of Medicine's TOXNET. Prior to founding *TERA*, Dr. Dourson worked 15 years for the U.S. Environmental Protection Agency (EPA), holding several leadership roles and winning four bronze medals for joint efforts on specific key projects, such as the creation of EPA's Integrated Risk Information System (IRIS). In 2003, Dr. Dourson was awarded the Arnold J. Lehman award for major contributions that improve the scientific basis of risk assessment by the Society of Toxicology (SOT). Dr. Dourson has published more than 100 papers on risk assessment methods, use of animal and human data in the assessment of risk, or assessments for specific chemicals. He has also co-authored well over 100 government risk assessment documents, made numerous invited presentations, and chaired many sessions at scientific meetings and independent peer reviews. Some of these papers and presentations dealt with toxicology and risk assessment of chromium, arsenic, copper, and nickel. Dr. Dourson has organized numerous symposia on a variety of topics, including: risk communication; chromium; information resources for toxicology and environmental health; risk assessment of essential trace elements; risk characterization; EPA's IRIS; uncertainty in risk assessment techniques; statistical and dose response models in risk assessment; workshop on benchmark dose methodology; basics of risk assessment; improvements in quantitative noncancer risk assessment; and neurotoxicity risk assessment. He has been elected to multiple officer positions in the American Board of Toxicology, SOT, and the Society for Risk Analysis. He is also a media resource specialist in risk assessment for the SOT, member of the editorial board of three journals, and vice chair of the NSF International Health Advisory Board.

Dr. Dourson received a B.A. in Biology from Wittenberg University and his Ph.D. in Toxicology from the University of Cincinnati. He is a Diplomate of the American Board of Toxicologists (DABT).

Dr. Dourson was selected for this panel for his expertise in metals toxicology, multimedia and probabilistic risk assessment, evaluation of human health hazards from soils and dusts, calculation of soil clean up goals, and familiarity with various agency risk assessment methodologies. In addition, Dr. Dourson has extensive experience effectively chairing panels of expert scientists in review of risk assessments.

Disclosure: Dr. Dourson is the Director of *TERA*, which is under contract with Inco and Falconbridge to organize and conduct this peer review. Dr. Dourson and *TERA* have not had any other previous involvement in the Sudbury Soils Study or risk assessment. *TERA*'s work to organize this independent peer review has been directed by the Working Group of the Technical Committee and interactions and communications with the companies has been limited to invoicing and budget. *TERA* has held numerous contracts with Health Canada (past and present) to provide risk assessment and scientific support, but none of these have involved the Branch that is part of this study, nor has

the work related to Sudbury. Dr. Lynne Haber of *TERA* served as a peer reviewer for the Ontario MOE on the Rodney Street risk assessment, a site at which Inco is a responsible party. In addition, she has been asked by MOE to be a peer reviewer for a community risk assessment currently being prepared by the responsible parties for the same site. These activities are being disclosed to promote transparency. *TERA* has determined that these activities are not conflicts of interest as they do not involve the Sudbury risk assessment, nor will they impair Dr. Dourson's scientific objectivity as a panel member.

Dr. Andrew P. Gilman

Dr. Gilman is President of a small international consulting firm, Sustainable Solutions International and a Research Fellow with the University of Ottawa Population Health Institute. In these positions, he applies his 31 years of experience in Government (health and environmental sciences, policy development, management and evaluation, sustainable development) and his academic and research background in toxicology and epidemiology to develop and implement projects for clients in Canada and abroad. Previously he served in various capacities for the Canadian government, including as the Executive Director of the Office of Sustainable Development and Director of the Bureau of Chemical Hazards, Health Canada. He has been actively involved in chemicals and metals management both domestically and internationally for 25 years. Chemicals-related activities have involved risk assessment and developing regional and global initiatives to control the long-range transport of environmental contaminants that can affect human health and the environment. He also has a focus on metals such as mercury, lead, cadmium, and uranium. Dr. Gilman has been involved in numerous public consultations, the negotiation of several international agreements including the recent Stockholm Convention, and in capacity building projects in Russia, the Philippines, Kenya, China, Mexico, and Thailand. He has been responsible for developing new programs related to population health in the Arctic, the Great Lakes Basin, and the St Lawrence River Basin and under the Canadian Government's program to embrace Sustainable Development. He received numerous awards for his public service, including the *Public Service of Canada's Award of Distinction* in 2002 and the *Queen's Golden Jubilee Award* for community and public service in 2003. Dr. Gilman has published and presented numerous scientific and policy papers and book chapters, and given guest lectures at Canadian and European universities and international agencies such as the World Bank and the UN Environment Program.

Dr. Gilman received his Honors Bachelor of Science degree in Zoology and his Master of Science degree in Toxicology from the University of Western Ontario. His Ph.D. was completed at the University of Guelph's Ontario Veterinary College, Department of Pathology, in 1975.

Dr. Gilman was selected for this panel for his expertise in metals toxicology, multi-media and exposure assessment, evaluating human health hazards of soils, and familiarity with risk assessment methods.

Disclosure: Dr. Gilman recently completed contracts with the First Nations and Inuit Health Branch of Health Canada to prepare a report on children's health in the Arctic and to develop a symposium for new scientists on Arctic Health issues. This relationship is being disclosed to promote transparency. *TERA* has determined that this is not a conflict of interest as it does not involve the Sudbury risk assessment, nor will it impair Dr. Gilman's scientific objectivity as a panel member.

Dr. D. Susan Griffin

Dr. Griffin is a Senior Toxicologist with the Superfund Program at the U.S. Environmental Protection Agency (EPA) in Denver, Colorado. She received her doctorate in Veterinary Toxicology and Pharmacology at the University of California, Davis and is board certified by the American Board of Toxicology. Dr. Griffin has worked for the U.S. Environmental Protection Agency for 19 years and has extensive experience in assessing human health risks from mining and smelting sites in the Western U.S. She has completed several hundred human health baseline risk assessments for hazardous waste sites and endangerment assessments for emergency response actions. At the Regional level, she has been involved in conducting site-specific bioavailability studies in swine and *in vitro* bioaccessibility studies to determine the amounts of lead and arsenic, which are bioavailable from soil. At the national level, she chaired the workgroup that developed the Integrated Exposure Biokinetic Uptake Model for Lead for the U.S. Superfund Program as well as the accompanying guidance documents. She was actively involved in writing and developing U.S. Superfund guidance documents, such as the Probabilistic Risk Assessment Guidance for Superfund and developing chemical toxicity values for EPA's Integrated Risk Information System (IRIS) data base. Dr. Griffin has also worked with U.S. Agency for International Development in Romania to instruct environmental agencies and citizen groups in assessing lead exposures and risks from smelters. In 2000, she was asked to consult with the Chilean Ministry of Mines on arsenic exposures and health effects at the Chuquicamata Mine.

Dr. Griffin has a B.S. in Genetics from the University of California, Davis and received her Ph.D. in Veterinary Toxicology and Pharmacology from University of California; Davis. She is a Diplomate of the American Board of Toxicology (DABT).

Dr. Griffin was selected for this panel for her extensive experience in multimedia and site assessments, toxicology of metals, bioavailability, probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dust, calculation of soil clean up goals and familiarity with risk assessment methods.

Disclosure: Dr. Griffin is participating in this review on her own time and outside of her duties with her employer, the U.S. Environmental Protection Agency.

Dr. Heather E. Jamieson

Dr. Jamieson is a professor at Queen's University, Kingston, Ontario with faculty appointments in Geological Sciences and Geological Engineering as well as the School of Environmental Studies. She teaches courses in aqueous geochemistry, mine waste geochemistry and global water issues. She is a Research Director of the GeoEngineering Centre at Queen's-RMC. Dr. Jamieson was awarded the Queen's Chancellor's Research Award ($50,000) in 2003 designed to provide a junior researcher with demonstrated high research potential the means to achieve significant impact on their discipline. Dr. Jamieson's current and recent research support includes grants from Queen's University, the Canadian and Ontario governments (National Sciences and Engineering Research Council of Canada (NSERC), including the Research Network Metals in the Human Environment, which is a collaboration of academia, government, and industry; Center for Research in Earth and Space Technology – Ontario Centers of Excellence; the Department of Indian Affairs and Northern Development; the International Development Research Center; Natural Resources Canada Synchrotron Research Program; and the Canadian Foundation for Innovation); Golder Associates; and BHP Billiton Diamonds.

Dr. Jamieson's expertise is in the area of environmental geochemistry applied to understanding rock-water interaction and the mechanisms that control metal release and attenuation from mine waste and contaminated soils. Her research program has a particular emphasis on the speciation of metals and metalloids in the solid form and the implication of element speciation for human health risk assessment. Dr. Jamieson and her graduate students have applied advanced microanalytical techniques such as synchrotron-generated X-ray analysis and proton-induced X-ray emission analysis to mine tailings and contaminated soils. Her research group has conducted field studies at operating and abandoned mine sites in Nova Scotia, Northwest Territories, Ontario, California, and Spain. These projects include sites of extreme acid mine drainage, gold mine tailings where pH is neutral but arsenic and antimony are mobile and diamond mine tailings stored in arctic lakes. Other projects include the potential for sequestration of carbon dioxide in kimberlite tailings and testing the use of geosynthetic clay liners to contain mine waste leachate.

Dr. Jamieson holds a B.Sc. in Geology from the University of Toronto and a Ph.D. in Geology from Queen's University.

Dr. Jamieson was selected for the panel for her expertise in environmental geochemistry, metal(loid) speciation in soils and mine waste, and mineralogical analysis.

Disclosure: None of Dr. Jamieson's research support comes from Inco or Falconbridge. Dr. Jamieson's, husband's brother-in-law currently works for Inco. *TERA* determined that this is not a conflict of interest as Dr. Jamieson has no financial relationship with her husband's brother-in-law and he is not involved in the Sudbury Soils Study project. This information is being disclosed to promote transparency. *TERA* and Dr. Jamieson do not think that this relationship would impair her scientific objectivity as a panel member.

Dr. Rosalind A. Schoof

Dr. Schoof is a consultant in toxicology and risk assessment with Integral Consulting, Inc. located in Mercer Island, Washington. She has conducted evaluations of chemical toxicity, health risk assessments for cancer and noncancer end points, and multimedia assessments of exposure to chemicals for diverse mining and mineral processing sites, manufacturing sites, landfills, incinerators, and other sources of exposure. Dr. Schoof's particular research interests include the bioavailability of arsenic and metals present in soils and dietary exposures to arsenic and metals. She has served on numerous peer review panels for U.S. agencies and Canadian ministries, and has been a member of several U.S. National Research Council Committees. Currently she is serving as a member of the British Columbia Contaminated Sites Science Advisory Board and the Expert Advisory Panel for the Canadian Metals in the Human Environment – Research Network.

Dr. Schoof received her B.A. in Molecular Biology fro Wellesley College and her Ph.D. in toxicology from the University of Cincinnati. She is a Diplomate of the American Board of Toxicology.

Dr. Schoof was selected for the panel because of her expertise in toxicology of metals, bioavailability, multimedia and probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dusts, calculation of soil clean up goals, and familiarity with various risk assessment methodologies.

Disclosure: Dr. Schoof served as a peer reviewer for the Ontario MOE on the Rodney Street risk assessment, a site at which Inco is a responsible party. In addition, she has been asked by MOE to be a peer reviewer for a community risk assessment currently being prepared by the responsible parties for the same site. Integral Consulting has a master contract to provide risk assessment support to the Ontario MOE, but there are no currently active projects, nor does MOE intend to ask Integral to do any work related to Sudbury. In the past Integral provided a metal bioavailability guide to the MOE. These activities are being disclosed to promote transparency. *TERA* has determined that these activities are not conflicts of interest as they do not involve the Sudbury risk assessment, nor will they impair Dr. Schoof's scientific objectivity as a panel member.

Dr. Joyce S. Tsuji

Dr. Tsuji is a Principal in Exponent's Health Sciences practice and is located in the firm's Bellevue, Washington office. She is a board-certified toxicologist with 19 years of experience in toxicology and risk assessment on projects in the United States, Canada, South America, Africa, Australia, and Asia for private clients, EPA, the U.S. Department of Justice, the Australian EPA, and state and local municipalities. Particular areas of interest include exposure assessment and toxicology of a variety of chemicals including those from industrial releases and in consumer products and nanomaterials. Dr. Tsuji has specialized experience with mining and smelting sites and the toxicology, bioavailability, and exposure to metals such as arsenic, lead, cadmium, mercury, manganese, and chromium. She has conducted risk assessments of mining and smelting sites, and has designed and directed exposure studies involving health education, environmental sampling, and biomonitoring of populations potentially exposed to metals in soil, water, and the food chain. Her consulting work has been done for public and private companies, including mining companies and state and federal agencies. Dr. Tsuji has served on expert committees for the National Academy of Sciences/National Research Council, including serving as a peer reviewer for the report on the Coeur d'Alene Basin mining site and risk assessment. she also serves on committees for the U.S. EPA, U.S. Army, and the State of Washington (including the Area Wide Soil Contamination group of experts convened by the State of Washington to evaluate arsenic and lead in soil). Dr. Tsuji has served as an expert witness on several legal cases involving metals and mines and has published a number of papers on risk assessment issues, including arsenic and lead in soils.

Dr. Tsuji received a B.S. in biological sciences from Stanford University with honors and distinction, Phi Beta Kappa, and a Ph.D. focused in physiology and ecology from the Department of Zoology, University of Washington. She is a Diplomate of the American Board of Toxicology.

Dr. Tsuji was selected for the panel because of her expertise in toxicology of metals, bioavailability, urinary arsenic monitoring studies, multimedia and probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dusts, calculation of soil clean up goals, and familiarity with various risk assessment methodologies.

Disclosure: Dr. Tsuji has performed work for a number of mining companies, but not Inco or Falconbridge, nor on any project related to Sudbury. However, she did work on a project for Noranda Mining (merged with Falconbridge in 2005) in the late 1990s/early 2000s commenting on an EPA risk assessment of Noranda's Blackbird Mine site in Idaho. She also was asked to discuss soil action levels for temporary worker housing on site with EPA in late December 2004 to early January 2005. As the Record of Decision has been issued for this site she has no expectation of any future work on it. Other professionals in her company have been involved in the past in litigation cases with multiple defendants (e.g., 30+) in which Falconbridge and Inco were defendants. Exponent was not hired by Falconbridge or Inco except in one case in which all defendants were noted as beneficial parties. Exponent has also consulted to Health Canada in the past. Dr. Tsuji did not participate in any of these cases herself, nor does she work regularly with the individuals on these projects. None of these past cases or projects appears to be

currently active and she does not think any of this work related to Sudbury. These activities are being disclosed to promote transparency. *TERA* has does not consider these activities to be conflicts of interest as they do not involve the Sudbury risk assessment, nor has she been directly involved in any Exponent cases that involved Inco or Falconbridge.

SARA Group Presenters' Biographical Sketches

Chris Bacigalupo, M.Sc., QEP

Scientist II/ Risk Modeling Specialist, Cantox Environmental

For over 10 years Chris Bacigalupo has been providing technical scientific support and advice to private and government sector clients in the areas of human health and ecological risk assessment. During this time, he has become one of the primary contributor in the development of deterministic and probabilistic models, focusing on methods used to predict chemical exposures and related human health risks. During his time with Cantox, Chris has managed, prepared and participated in numerous human health and ecological risk assessments throughout Canada and abroad. He has developed extensive knowledge of the methods used by regulatory agencies to develop human health-based soil and groundwater criteria.

Mr. Bacigalupo received a Masters of Science (M.Sc.) degree (2006) in Toxicology and Land Resource Sciences at the University of Guelph, Ontario. His graduate work involved exploring the human health risks of lead and inorganic arsenic exposure from the consumption of home produced vegetables. His Thesis also involved an investigation into the relationships between basic soil properties (*e.g.*, metal content, soil pH, organic carbon, iron content, *etc.*) and metal-specific vegetable concentrations, using multi-variable linear regression models. He graduated with an Honours B.Sc. in Environmental Science and Biology minor from the University of Waterloo, Waterloo Ontario, in 1995 and received his Qualified Environmental Professional (QEP) designation from the Institute of Professional Environmental Practice (IPEP) in 2002.

Glenn M. Ferguson, Ph.D.

Program Director / Senior Scientist, Cantox Environmental

Dr. Glenn Ferguson is a Senior Scientist with Cantox Environmental Inc. and the Program Director for Brownfield Risk Management. Dr. Ferguson has completed M.Sc. and Ph.D. degrees in Health Studies at the University of Waterloo, specializing in the validation of environmental and toxicological risk assessment models and techniques. His doctoral research was particularly focused on the development and utilization of physiologically-based pharmacokinetic (PBPK) model systems for the evaluation of potential health risk related to environmental exposures to persistent organic pollutants (POPs), such as polychlorinated biphenyls (PCBs) and polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/Fs). Dr. Ferguson also holds a BSc. in Biology and a Graduate Diploma in Ecotoxicology and Environmental Chemistry.

Dr. Ferguson has more than 12 years of experience in the fields of toxicology, human health and ecological risk assessment, and risk communication. In this time at Cantox, his duties have involved project management, public consultation and technical scientific lead on large variety of environmental and human health projects. These include managing and technical lead for all phases of risk assessment projects related to electrical power generation facilities, contaminated

industrial and residential sites, smelter and incinerator emissions, landfills, highways, major airports, abandoned mine sites, fuel oil spills, and drinking water contamination. For example, Dr. Ferguson is currently the technical project manager for the SARA Group, a consortium of companies conducting a large-scale human health and ecological risk assessment in the Sudbury Basin of Ontario, as part of the multi-stakeholder Sudbury Soils Study.

Dr. Ferguson brings senior toxicological expertise in a variety of environmental contaminants, and specifically with persistent organic pollutants (POPs) such as PCBs and dioxins and furans. He is a key contributor to the development of computer models used to predict the potential chemical exposure and health risks in human and environmental impact assessments, and previously completed a full redesign and implementation of the probabilistic environmental exposure model systems used by Cantox Environmental for risk assessment and management projects. Dr. Ferguson also provides risk communications services to clients on a variety of issues at public open houses and workshops, and has been a faculty instructor in the graduate department of Environmental Applied Science and Management at Ryerson University.

Elliot A. Sigal

Vice President, Eastern Region, Cantox Environmental

Elliot Sigal is a Senior Scientist and Vice President of Cantox Environmental Inc. Mr. Sigal graduated with an Honours B.Sc. in Toxicology from the University of Toronto in 1988. Since joining Cantox in 1989, he has gained over 15 years of experience in human health and ecological risk assessment, and toxicology. Mr. Sigal is responsible for supervising over 15 employees in our Mississauga office, as well as managing both small (a few thousand dollars) and large projects (over a million dollars).

Mr. Sigal has extensive experience in all aspects of toxicology and risk assessment with specific expertise in computer exposure modeling for human and ecological receptors. Elliot has been responsible for leading risk assessment teams in determination of potential for exposure of and risk to receptors associated with complex contaminated sites, military base closures, underground storage tanks, incinerator emissions, landfill sites and industrial processes. Mr. Sigal has been involved in the use of toxicological principles to facilitate the risk assessment process, such as the development of a health-based method for the evaluation of total petroleum hydrocarbons (TPH), and provision of a benchmark comparison of remediation alternatives, in order to determine economically feasible and scientifically sound solutions to risk management problems. Mr. Sigal was also integrally involved in development and implementation of deterministic (point estimate) and probabilistic (stochastic) exposure and hazard assessment modeling techniques

Elliot has conducted interpretive reviews of toxicology and mechanistic databases for a variety of chemicals including metals (i.e., arsenic, lead, nickel), chlorinated organics (i.e., vinyl chloride, PCBs, dioxins and furans), volatile organic compounds (i.e., benzene, toluene), combustion gases (NO_X, SO_X), and PAHs (i.e., benzo[a]pyrene). Mr. Sigal has conducted peer

reviews on many risk assessments in jurisdictions across Canada and the U.S., and has conducted reviews of risk assessments on behalf of the Ontario Ministry of the Environment.

Christopher D. Wren, Ph.D.

Senior Environmental Scientist, Gartner Lee Limited

Dr. Wren is a Senior Environmental Scientist with Gartner Lee Limited, in Guelph, Ontario. Prior to joining Gartner Lee early in 2006 he managed his own environmental consulting practice. Chris has the role of Director of the SARA (Sudbury Area Risk Assessment) Group that is conducting the Sudbury Soils Study and risk assessment. In this capacity he is the primary contact between the study team and Technical Committee that oversees the study. He is also the primary spokesperson for the study with the public and media.

Chris completed his Ph.D. in Aquatic Sciences in 1983 at the University of Guelph. He subsequently completed postdoctoral research at the University of Toronto where he examined metal accumulation in piscivorous wildlife (mink, otter) across Ontario including Sudbury. He also conducted experiments to examine interactions of methylmercury and PCBs on mink reproduction. He then conducted further studies on wildlife toxicology at the University of Trondheim, Norway. Dr. Wren has published over 40 scientific papers in peer-reviewed journals and frequently lectures on risk assessment and environmental toxicology at the University of Guelph, Queens University and University of Waterloo and other scientific forums.

During the past 20 years as an environmental consultant in Ontario Dr. Wren has continued to focus on the fate, behaviour and effects of metals in the environment. For the past decade much of his work has been directed at the mining industry. He routinely acts as a senior advisor to industry and various levels of government, and has peer reviewed many human and ecological risk assessment reports for various clients. Dr. Wren was intricately involved in revising the metal mining effluent regulations for the mining sector and development of guidance for environmental monitoring methods. He has also been involved with development of many environmental quality guidelines (water, soil) for both the Ontario Ministry of the Environment and Environment Canada. In particular he directed revision of Provincial Water Quality Objectives for zinc, copper, nickel, lead and arsenic to name a few substances.

Dr. Wren has also been involved with international mining projects including a review role in the Natural Resources Damage Assessment (NRDA) for the Anaconda smelter in Montana; investigation of a fish kill near a smelter in the Dominican Republic, and overseeing baseline environmental monitoring programs in Brazil and Indonesia. In 2001, Dr. Wren was selected by the World Bank (Washington) to participate in an investigation and assessment of a mercury spill from a gold mine in Peru, that resulted in mercury exposure and poisoning to several hundred country people.

Appendix C

Sponsors' Presentation Slides

The Sudbury Soils Study:

A Community Based Human Health and Ecological Risk Assessment

C. Wren, G. Ferguson, E. Sigal, C. Bacigalupo

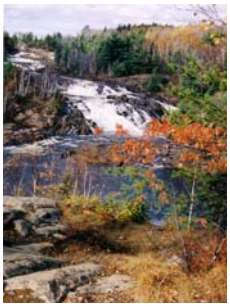
SARA GROUP

Presentation Overview

C. Wren and G. Ferguson

- Background and Overview
- Site Characterization
- COC Selection
- Data Collection

Questions?



Study Location

Mining is a way of life in Sudbury

A century of mining and smelting in Sudbury has resulted in elevated metal levels in the soil

Copper Cliff Roast Yards, circa 1890

Background

- In 2001, the Ontario Ministry of Environment and Energy (MOE) released a report that reviewed historic metal levels in Sudbury soils
- The report identified that concentrations of some metals in the Sudbury area exceeded the MOE generic soil quality guidelines (As, Cu, Co, Ni identified as COCs)

As a result, the MOE made two recommendations

- That a comprehensive soil survey be conducted to fill data gaps (Part I)
- That a human health and ecological risk assessment be conducted (Part II)

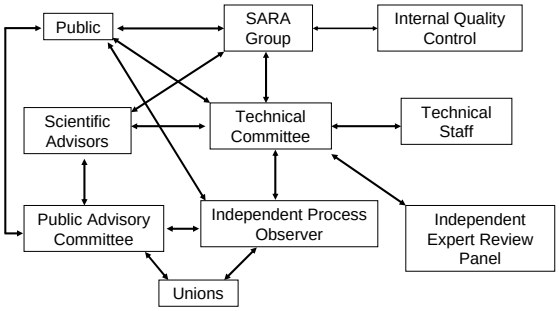
The companies accepted these recommendations and initiated the Sudbury Soils Study

Study Objectives

1: Soil Survey
- To clearly define soil metal levels in the Greater Sudbury area as a result of smelter emissions

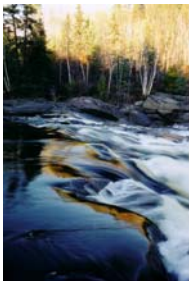
2: Risk Assessment
- Identify potential risks to human and ecological receptors associated with elevated metal levels
- Develop site-specific soil criteria to protect Sudbury human receptors

Sudbury Soils Study Organization



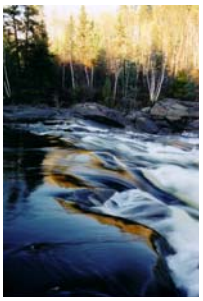
Members of the Technical Committee

- Ontario Ministry of the Environment
- Sudbury & District Health Unit
- City of Greater Sudbury
- First Nations and Inuit Health Branch of Health Canada
- Xstrata Nickel (formerly Falconbridge Ltd.)
- Inco Ltd.

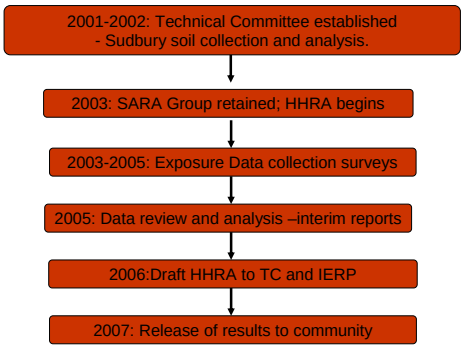


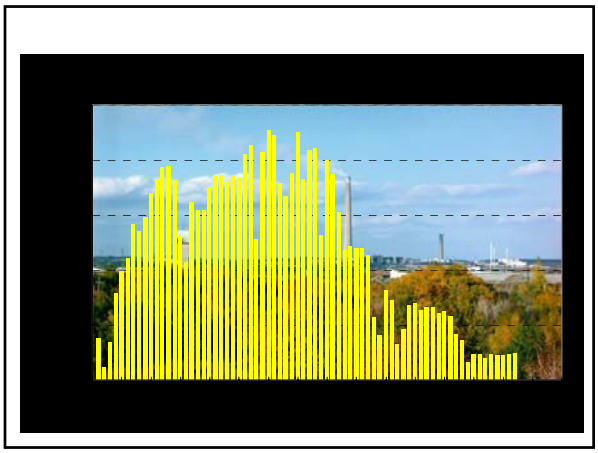
SARA Group (Sudbury Area Risk Assessment)

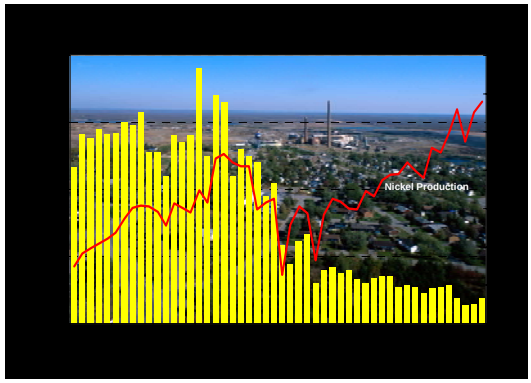
- Gartner Lee Limited
- Cantox Environmental Inc.
- RWDI
- Goss Gilroy Inc.
- 4DM
- Frontline Communications
- McLeod Wood Associates



Sudbury Soils Study Overview





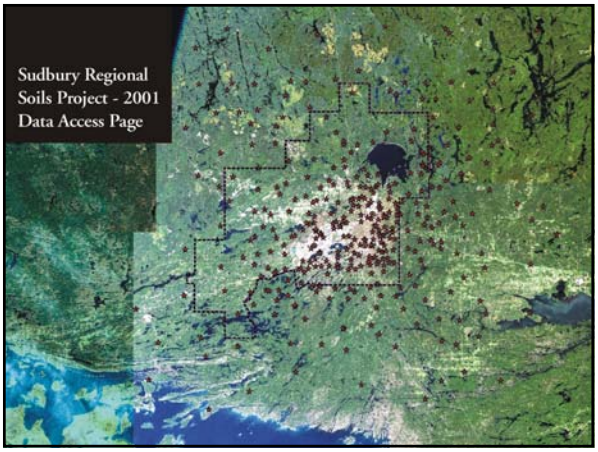


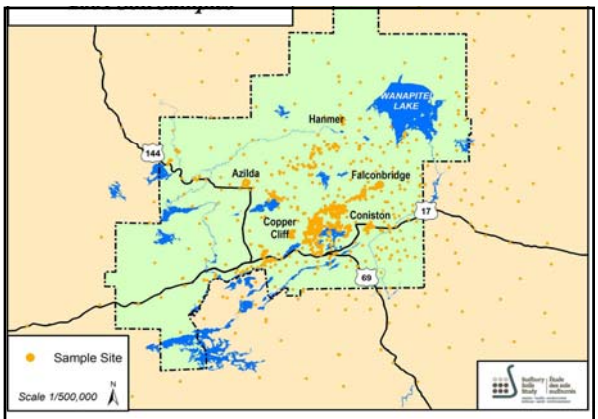
2001 Soil Survey

- Almost 8,500 soil samples were collected and analyzed for 20 inorganic parameters

As, Al, Sb, Ba, Be, Cd, Ca, Cr, Co, Cu, Fe, Pb, Mg, Mn, Mo, Ni, Se, Sr, V, Zn

These data form the basis for this study.





Two different sampling strategies employed

COC Selection Criteria

1: Parameter must be above Table A of the provincial soil quality guideline (MOE 1997)

2: Parameter must be present across the study area, and

3: Parameter must scientifically show origin from the companies operations

Soil Data Screening

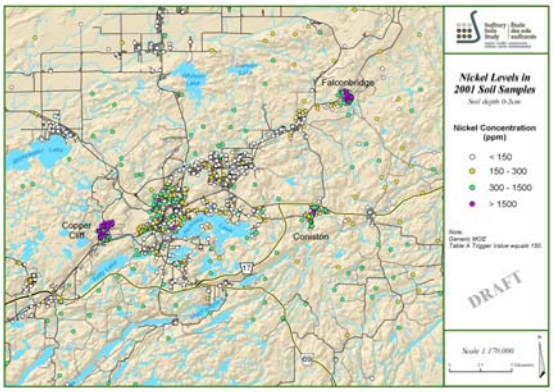
2001 Soils Data

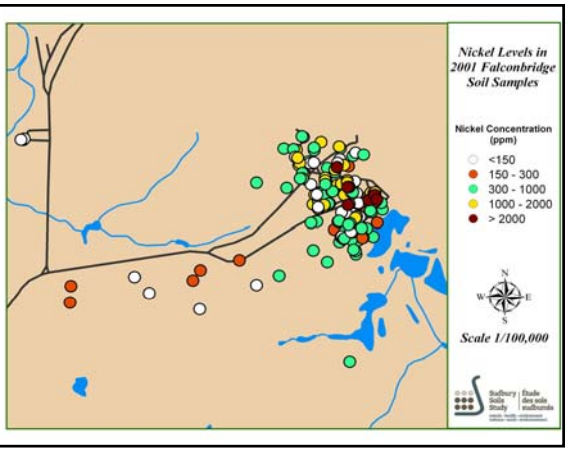
↓

Apply Screening Criteria

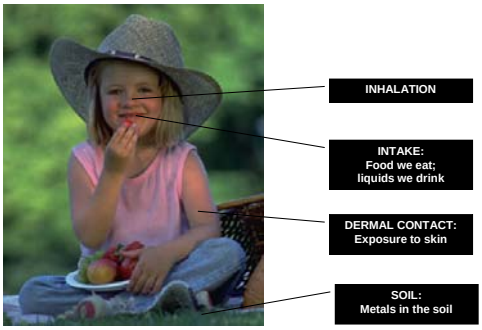
↓

Chemicals of Concern (COCs)
As, Cu, Co, Ni, Pb, Se



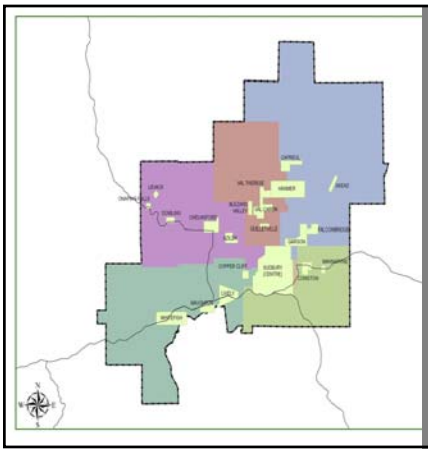


Human Health Risk Assessment



Technical Guidance

1. Ontario Ministry of the Environment
2. Health Canada
3. CCME (Canadian Councils of the Ministers of the Environment)
4. Other jurisdictions: eg. USEPA, WHO



Communities of Interest (COIs)

- Copper Cliff
- Coniston
- Falconbridge
- Hanmer
- Sudbury Centre

SOIL SAMPLES USED IN THE HHRA

- Not all soils samples in the SSS soils database were relevant to the HHRA.
- Samples taken from the surficial layer of soil at each sampling location (*i.e.*, 0 to 5 cm, 0 to 10 cm, or 0 to 15 cm, depending on the survey methodology) were included in the screening as they represent soils most available for human exposure.
- Of these samples, a large number were replicate samples and therefore were used to calculate a geometric mean for each specific sample location.
- The following samples were excluded:
  - Soil samples collected outside of the COIs or from non-residential locations
  - Samples from gravelled areas
  - Commercial gardens
  - Wild soils (*i.e.*, soil collected from areas outside of the urban and suburban areas of the GSA, likely during the wild blueberry and mushroom sampling program)

HHRA Studies 2003-2005

- Medicinal Plant Survey
  - Whitefish Lake First Nation
  - 5 sites, 25 species of plants
- Food Consumption Survey
  - 3,500 households
  - Patterns of consumption for 'local foods'
- Livestock Sampling
  - 10 beef cattle from local farms

HHRA Studies 2003-2005

- Drinking Water Survey
  - 80-100 private residential wells and lake water surveyed
- Municipal potable water data

Indoor Dust Survey

(Fall 2004)

- Samples of indoor dust samples from 'high traffic' areas in homes and outdoor soil samples collected
- 70 residences and 10 schools across Sudbury
- Important exposure pathway

Falconbridge Residents Arsenic Exposure Study

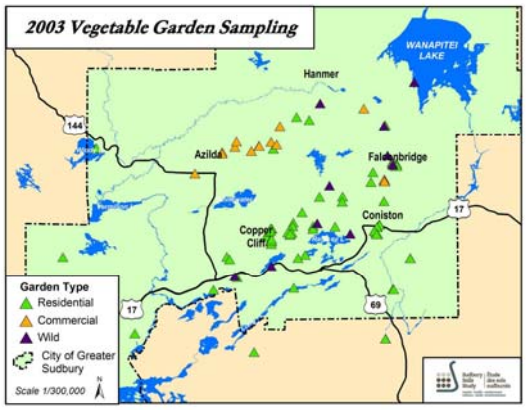
- Elevated As levels in soil
- Medical Officer of Health issued advisory to residents
- Resulted in a urinary arsenic exposure study over 700 residents
- Results used in HHRA as Weight of Evidence for As

Vegetable Garden Survey

Purpose:

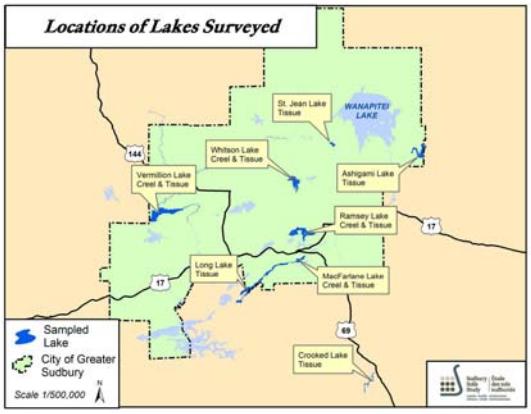
To measure metal concentrations in:

- home-grown vegetables
- commercial produce
- wild blueberries
- co-located soil samples



Survey of Sudbury Urban Lakes

- Sudbury area lakes are important for local sport fishing enthusiasts
- Tissues sampled in sport fish from 8 local lakes

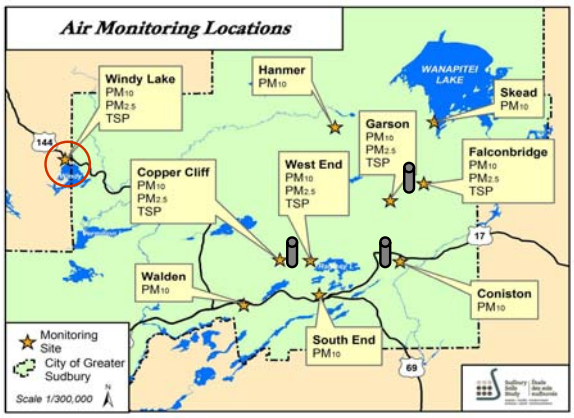


Extensive Sudbury Air Monitoring Program

Purpose:

To provide inhalation concentration values for the HHRA exposure model.

Hi-volume samplers collected air samples every 6 days for 52 weeks



Human Health Risk Assessment

Large amount of Exposure data collected:

- Soil samples – 8,500
- Air samples- 1,200
- Drinking water - 95
- Indoor dust - 95
- Local vegetables - 235
- Fish and beef – 165
- Each sample analyzed for min. 20 parameters

Total Metal levels are just part of the story: toxicity is influenced by chemical form of the metal and bioavailability

- Examined speciation of nickel in air, dust and soil
- Measured bioaccessibility of all COCs in soil and dust

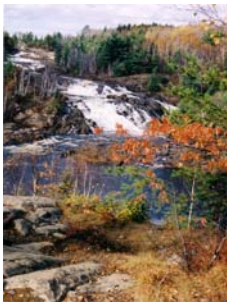
Public Involvement and Community Relations

- To provide information to the public
- Obtain input from the stakeholders
- Communicate results in understandable language
- Many different tools used to reach the public

Study Objectives/End Product

- Identify if humans are at risk from metals in the environment due to emissions from the smelters
- If risk is determined
  - What soil levels?
  - Where?
  - Establish soil remediation goals

Any Questions?



The Sudbury Soils Study:

EXPOSURE ASSESSMENT

SARA GROUP

OVERVIEW

- Exposure Point Concentrations (EPC)
  - how EPC values were generated for each community of interest
- Receptor Selection and Characteristics
  - receptor life stage selection (*i.e.,* infant, toddler, child, youth and, adult; male versus female)
  - receptor characteristics (*e.g.,* soil ingestion, exposed skin surface area, etc.)
- Exposure Pathway Selection and Assumptions
  - inclusion of background (*i.e.,* non-smelter related) sources of exposure
  - market basket EDI rates and local food consumption

EXPOSURE POINT CONCENTRATION DATA

- An EPC (for any given community of interest and environmental media) had to reflect the concentration in which an individual would be expected to come into contact with over some exposure duration (*e.g.,* 25 yrs, 50 yrs, 70yrs, *etc*.);
- The 95% upper confidence limit for the arithmetic sample mean (95% UCL) was used to characterize all EPCs used in chronic exposure assessment (U.S. EPA, 2001).

EXPOSURE POINT CONCENTRATION DATA

- EPC terms specific to each community of interest, metal, and environmental media (*e.g.,* air, drinking water, home garden produce) were developed;
- EPC terms for commercial produce, fish and wild game were not community specific but rather specific to the Greater Sudbury Area (GSA);
- The statistical software package ProUCL (Version 3.0) and corresponding guidance provided by the U.S. EPA (2004) was used to calculate the 95% UCL on the arithmetic sample mean;

EXPOSURE POINT CONCENTRATION DATA

Env Media	Metal	Region	Units	N	Min	Max	Mean (arithmetic)	95% UCL
soil	As	coniston	ug/g	203	2.5	55.7	9.5	12.1
soil	As	Copper Cliff	ug/g	197	2.5	72.0	17.4	19.0
soil	As	falconbridge	ug/g	188	2.5	400.0	69.4	78.6
soil	As	hanmer (bkg)	ug/g	80	1.5	22.4	3.7	4.3
soil	As	sudbury (core)	ug/g	597	2.2	59.0	6.0	7.2
soil	As	Typical Ontario	ug/g					17.0
soil	Co	coniston	ug/g	203	3.5	66.5	14.8	18.4
soil	Co	Copper Cliff	ug/g	197	6.0	150.0	30.6	33.4
soil	Co	falconbridge	ug/g	188	4.5	159.0	46.0	56.5
soil	Co	hanmer (bkg)	ug/g	80	2.7	11.0	6.2	6.5
soil	Co	sudbury (core)	ug/g	597	3.0	100.0	10.7	11.3
soil	Co	Typical Ontario	ug/g					21.0
soil	Cu	coniston	ug/g	203	8.6	1200.0	215.0	315.5
soil	Cu	Copper Cliff	ug/g	197	31.4	5291.5	1236.9	1370.0
soil	Cu	falconbridge	ug/g	188	11.0	2898.3	733.9	1005.5
soil	Cu	hanmer (bkg)	ug/g	80	9.3	330.0	42.7	67.0
soil	Cu	sudbury (core)	ug/g	597	6.2	1643.2	149.4	204.0
soil	Cu	Typical Ontario	ug/g					85.0
soil	Pb	coniston	ug/g	203	2.0	309.8	45.0	52.0
soil	Pb	Copper Cliff	ug/g	197	3.0	582.4	88.3	97.9
soil	Pb	falconbridge	ug/g	188	2.0	335.0	73.9	82.3
soil	Pb	hanmer (bkg)	ug/g	80	2.0	78.5	12.2	19.2
soil	Pb	sudbury (core)	ug/g	597	1.0	309.8	26.8	35.9
soil	Pb	Typical Ontario	ug/g					120.0
soil	Ni	coniston	ug/g	203	16.0	1797.2	290.4	432.8
soil	Ni	Copper Cliff	ug/g	197	28.5	3256.4	886.7	976.1

← EPC

RECEPTOR SELECTION

Health Canada (2004) recommends that:

- Exposure calculations may be completed for all potential receptors/receptor goups or only for those critical receptors that are confirmed to have the greatest exposure per unit body weight
- Age groups to be addressed are those specified by Health Canada (1994) and the CCME (1996):
  - infants (0 to 6 months of age);
  - toddlers (7 months to 4 years of age);
  - children (5 to 11 years);
  - teens (12 to 19 years); and,
  - adults (20+ years of age).

Health Canada 2004. Federal Contaminated Site Risk Assessment in Canada. Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA).
Health Canada. 1994. Human Health Risk Assessment for Priority Substances: Canadian Environmental Protection Act Assessment Report. The Canadian Council of Ministers of the Environment (CCME). 1996. A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines. Report CCME EPC-101E, CCME. March 1996.

RECEPTOR SELECTION

Health Canada (2004)

TABLE 3: Recommended Human Receptors and Their Characteristics for Preliminary Quantitative Risk Assessments

Canadian General Population							
Receptor Characteristic	Infant	Toddler	Child	Teen	Adult	Construction Worker	Source
Age	0 – 6 mo.	7 mo.– 4 yr	5 – 11 yr	12 – 19 yr	> 20 yr	>20 yr	Health Canada, 1994
Body weight (kg)	8.2	16.5	32.9	59.7	70.7	70.7	Richardson, 1997
Soil ingestion rate (g/d)	0.02	0.08	0.02	0.02	0.02	0.1	CCME, 1996 MADEP, 2002
Inhalation rate (m^3/d)	2.1	9.3	14.5	15.8	15.8	15.8	Richardson, 1997; Allen and Richardson,1998
Water ingestion rate (L/d)	0.3	0.6	0.8	1.0	1.5	1.5	Richardson, 1997
Time spent outdoors (hr/d)	--- [1]	--- [1]	--- [1]	1.5	1.5	8	Richardson, 1997
Skin surface area (cm^2) Hands: Arms (upper and lower): Legs (upper and lower): TOTAL:	 320 550 910 1780	 430 890 1690 3010	 590 1480 3070 5140	 800 2230 4970 8000	 890 2500 5720 9110	 890 2500 5720 9110	Richardson, 1997
Soil loading to exposed skin (g/cm^2/event Hands: Surfaces other than hands:	 1×10^{-4} 1×10^{-5}	 1×10^{-4} 1×10^{-5}	 1×10^{-4} 1×10^{-5}	 1×10^{-4} 1×10^{-5}	 1×10^{-4} 1×10^{-5}	 1×10^{-3} 1×10^{-4}	Kissel et al., 1996, 1998
Food ingestion[2] (g/day) Root vegetables: Other vegetables: Fish:	 83 72 0	 105 67 56	 161 98 90	 227 120 104	 188 137 111	NA	Richardson, 1997
Canadian Native Populations (characteristics not listed should be assumed to be equivalent to those for the general population)							
Receptor characteristic	Infant	Toddler	Child	Teen	Adult		Source
Age	0 – 6 mo.	7 mo.– 4 yr	5 – 11 yr	12 – 19 yr	> 20 yr		Health Canada, 1994
Food ingestion[2] (g/day) Fish: Wild goose:	 0 0	 95 85	 170 125	 200 175	 220 270		Richardson, 1997

RECEPTOR CHARACTERIZATION

Health Canada (2004) recommends that:

- Additional receptor characterization assumptions should be drawn from the *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson,1997);
- The Compendium (Richardson, 1997) contains recommended lognormal PDF describing receptor-specific (i.e., age class and male/female) Canadian exposure factors such as: body weights, food intake rates, body weights, inhalation rates, water intake rates.
- When Canadian data are lacking – alternative sources should be used (e.g., 1997 U.S. EPA Exposure Factors Handbook)

RECEPTOR CHARACTERIZATION

The *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson, 1997) and Health Canada were used to characterize the following input parameters for each age group male and female:

Receptor Name	Variable	Exposure Variable	Abbreviation	Units	Mean (arithmetic)	Std. Dev	CTE Estimate	RME Estimate	PDFs	Reference/Comments
Toddler	meat and eggs	BIR	F_Toddler_BIR	g/kg/d	6.2	5.1	5.7	6.5	6.5	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	breathing rate	BR	F_Toddler_BR	m^3/day	8.8	2.4	8.5	12.0	12.0	Richardson et al., 1997
Toddler	body weight	BW	F_Toddler_BW	kg	16.4	4.5	16.4	16.4	16.4	Richardson et al., 1997
Toddler	cereals and grains	CIR	F_Toddler_CIR	g/kg/d	11.7	8.7	9.6	13.5	13.5	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	milk and dairy	DIR	F_Toddler_DIR	g/kg/d	44.5	38.8	28.7	46.7	46.7	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	fish and shell fish	FIR	F_Toddler_FIR	g/kg/d	3.0	2.6	2.5	3.8	3.8	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	fats and oils	FNIR	F_Toddler_FNIR	g/kg/d	1.8	1.1	2.1	2.4	2.4	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	fruits & Juices	FVIR	F_Toddler_FVIR	g/kg/d	17.8	13.6	14.5	20.8	20.8	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	other vegetables	LVR	F_Toddler_LVR	g/kg/d	4.7	2.9	5.3	6.3	6.3	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	nuts and seeds	NSIR	F_Toddler_NSIR	g/kg/d	1.0	0.7	0.9	1.4	1.4	Based on Richardson et al., 1997 raw data (File organized by individual food items)
Toddler	root vegetables	RVIR	F_Toddler_RVIR	g/kg/d	7.4	5.3	7.1	9.6	9.6	Based on Richardson et al., 1997 raw data (File organized by individual food items)
Toddler	sugars & sweets	SSIR	F_Toddler_SSIR	g/kg/d	4.0	1.8	4.6	6.7	6.7	Based on Richardson et al., 1997 raw data (File organized by food group)
Toddler	time spent outdoors	TSO	F_Toddler_TSO	mins/day	91.0	83.0	67.2	182.2	182.2	Richardson et al., 1997
Toddler	water intake rate	WIR	F_Toddler_WIR	L/day	0.6	0.4	0.5	1.1	1.1	Richardson et al., 1997 (females and males combined data used)

RECEPTOR CHARACTERIZATION

Dermal Exposure Factors

Several sources were reviewed including:

- U.S. EPA, 2002. Child-Specific Exposure Factors Handbook;
- U.S. EPA, 1997. Exposure Factors Handbook, Volume I;
- U.S. EPA, 2004. Exposure Scenarios. National Center for Environmental Assessment;
- Compendium of Canadian Human Exposure Values (Richardson, 1997); and,
- Burmaster et al., 1998. Journal of Risk Analysis 18(1), 1998.

Correlation between body weight and total body surface area during Monte Carlo simulations was addressed by using the method provided by Burmaster et al., 1998 which expresses total body surface area as a function of body weight;

The total body surface area was not assumed to be in direct contact with soil and/or indoor dust

RECEPTOR CHARACTERIZATION

Child-specific EFH (U.S. EPA, 2002) presents various clothing scenarios in which 10 to 25% of skin surface area is estimated to be exposed. Suggested that the fraction of exposed skin could be refined based on seasonal conditions.

Seasonally-adjusted estimate of exposed skin was developed by dividing the year into four seasons including spring (61 days), summer (92 days), fall (91 days) and winter (121 days)

Refer to pages 4-57 and 4-58

Fraction of Exposed Skin					
Units	Spring	Summer	Fall	Winter	Prorated
Fraction	0.150	0.250	0.150	0.050	0.142
Days	61.0	92.0	91.0	121.0	365.0

Area-weighted soil adherence values were derived using the percentage of total surface area for each body part (hands, arms, legs and feet) in conjunction with body-part specific adherence values for a given activity (page 4-57; Table B.8)

RECEPTOR CHARACTERIZATION

Incidental soil and dust ingestion rates:

• chapter 6 (Section 6.5) contains a literature review of soil ingestion rates among children and pica behavior. Approximately 25 references were reviewed on this topic.

• U.S. EPA (1994;1999) IEUBK model presents total "soil and indoor dust" ingestion rates for 7 different age classes of children (0 to 7 years of age) ranging from 85 to 135 mg/d;

• soil and dust ingestion rates of infants (age 0 to 6 months) and children (aged 5 to 11 years) were characterized using intake rates from IEUBK (1994;1999);

• data from Stanek et al. (2001) were used to characterize soil intake rates among preschool children (7 months to 4years);

•soil and dust ingestion of teens (12 to 19 years) and adults were characterized using data from Health Canada (2004) - total soil and dust intake of 20 mg/day;

• the winter covering factor was applied to the outdoor soil ingestion pathway only (*i.e.,* indoor dust ingestion was assumed to continue throughout the winter months)

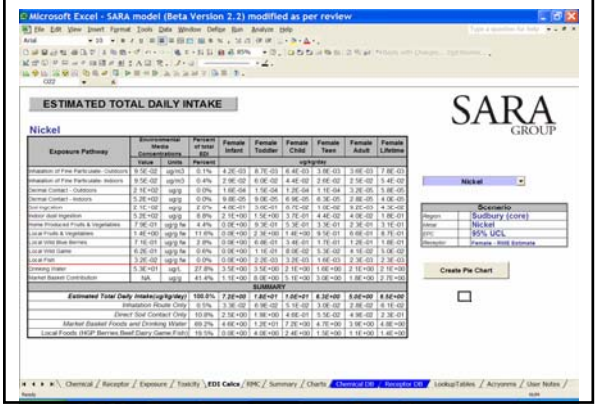
• 45% of the "soil and indoor dust" ingestion rate was assumed to be soil ingestion, the remaining 55% indoor dust (IEUBK, 1994)

RECEPTOR CHARACTERIZATION

Incidental soil and dust ingestion rates:

Toddler	dust intake rate	g/day	0.038	0.038	0.029	0.111	0.111	IEUBK - based on the 45/55 split between soil and dust intake using Stanek data
Toddler	soil intake rate	g/day	0.031	0.031	0.024	0.091	0.091	E. Stanek III et al., 2001
Child	dust intake rate	g/day			0.047	0.055	0.055	IEUBK - 55% of total soil and dust intake for children 4 to 5 year fo CTE, 6-7 yrs for RME
Child	soil intake rate	g/day			0.038	0.045	0.045	IEUBK - 45% of total soil and dust intake for children 4 to 5 year fo CTE, 6-7 yrs for RME
Teen	dust intake rate	g/day	0.011		0.011	0.011	0.011	HC, 2004 default value of 20 mg/day, Assuming a 45/55 split between soil and dust as per IEUBK
Teen	soil intake rate	g/day	0.009		0.009	0.009	0.009	HC, 2004 default value of 20 mg/day, Assuming a 45/55 split between soil and dust as per IEUBK
Adult	dust intake rate	g/day	0.011		0.011	0.011	0.011	HC, 2004 default value of 20 mg/day, Assuming a 45/55 split between soil and dust as per IEUBK
Adult	soil intake rate	g/day	0.009		0.009	0.009	0.009	HC, 2004 default value of 20 mg/day, Assuming a 45/55 split between soil and dust as per IEUBK

EXPOSURE PATHWAYS AND ASSUMPTIONS



EXPOSURE PATHWAYS AND ASSUMPTIONS

- for metals assumed to act by a threshold mechanism of toxicity, background sources of exposure (*i.e.,* non-smelter related sources) were included in the total estimated daily intake (EDI);
- although an individual's EDI to smelter-related sources maybe below the chronic daily dose considered being without harm (i.e., the RfD), it is possible that the same individual's total exposure (i.e. smelter plus background) could exceed the RfD;
- the Federal Government's (CCME, 1997) derivation of health-based soil quality criteria for threshold contaminants includes the subtraction of the EDI (i.e., background exposures) from the tolerable daily intake (TDI)
- background sources of exposure (*i.e.,* market basket) are not considered when calculating ILCR estimates;
- it is the incremental increase in exposure to a chemical (above and beyond existing non-site related exposures) which is of interest.

EXPOSURE PATHWAYS AND ASSUMPTIONS

- Market Basket EDI – the estimated daily intake of a chemical resulting from the consumption of typical supermarket foods across Canada;
- Market Basket Exposures – were classified as background exposures (*i.e.,* typical of Canadian supermarket foods);
- Appendix D provides the complete Market Basket Intake Report

EXPOSURE PATHWAYS AND ASSUMPTIONS

Market Basket EDIs:

•Canadian data were used to develop metal-specific EPC (*i.e.,* 95% UCL) for 11 different food groups (Appendix D);

•Corresponding food group intake rates were provided by the Compendium of Canadian Human Exposure Factors (Richardson, 1997) and Mark Richardson from Health Canada;

•The Richardson (1997) data were based on a 24-hr recall study – the lognormal PDF representing food consumption do NOT reflect long-term food consumption patterns but rather the variability in recall consumption rates over a 24-hr period;

•It was not considered realistic nor was it recommended by Richardson (1997) to use the lognormal PDFs (describing variability in consumption rates over a 24-hr period) during a chronic exposure assessment.

EXPOSURE PATHWAYS AND ASSUMPTIONS

Market Basket EDIs:

•The raw data used to develop the lognormal PDF presented within the Compendium (Richardson, 1997) were obtained from Mark Richardson of Health Canada;

•From the raw data, the arithmetic sample mean, standard deviation, 50th percentile and 95% UCL (on the arithmetic sample mean) were calculated for each food group-specific intake rate and receptor age class;

• For the central tendency exposure scenario (CTE), the 50th percentile food intake rates were used. The reasonable maximum exposure scenario (RME) employed the use of the 95% UCL food intake rates.

•For the PRA – the error surrounding the arithmetic mean intake rate was considered normally distributed and, therefore, a normal PDF was used in the Monte Carlo simulation to characterize uncertainty in the population mean food intake rates.

EXPOSURE PATHWAYS AND ASSUMPTIONS

Local Food Intake Rates:

- Local Foods – food either grown or caught within the GSA including garden vegetables, fruits, wild berries, fish and wild game;
- All local food group-specific intake rates were expressed as a fraction of the corresponding arithmetic mean food group intake derived from data provided by Mark Richardson of Health Canada;
- Expressing local foods as a fraction of the total corresponding food group intake was completed for two reasons:
  1. A background exposure assessment was completed including consumption of supermarket foods – it was important that food intake was not 'double counted'. That total food intake (local plus supermarket) remain constant;
  2. PRA – When local food intakes are expressed a fraction of the total corresponding (food group specific) intake rate, correlation issues between different PDF describing food intake are automatic.

EXPOSURE PATHWAYS AND ASSUMPTIONS

Local Food Intake Rates:

• Refer to Appendix B and the Local Food Intake Rate Table (the hand-out)

• Whenever possible, information from the Local Food Consumption Survey (Appendix K) and the EFH (U.S. EPA, 1997) were used to derived local food intake rates;

• To approximate consumption rates of local produce (i.e., root and exposed vegetables), the fractions of home produced root and exposed vegetables reported by the EFH (U.S. EPA, 1997 – Table 13-71) were multiplied by the corresponding mean root and leafy intake rates provided by Mark Richardson of Health Canada;

• The fraction of fruit, fish, game and wild berries caught or grown locally were derived using data from the Site-Specific food Survey and the corresponding arithmetic mean food group intake rate derived from data provided by Mark Richardson of Health Canada.

EXPOSURE PATHWAYS AND ASSUMPTIONS

Receptor Name	Variable Description	Exposure Variable	Units	CTE Estimate	RME Estimate	PDFs	Reference/Comments
All	Fraction of root vegetable grown locally	FRVL	unitless	1.8E-02	1.1E-01	1.1E-01	U.S. EPA, 1997 EFH; Table 13-71 (triangular at 0, NE per capita, houses that garden)
All	Fraction of other vegetable grown locally	FOVL	unitless	6.2E-02	2.3E-01	2.3E-01	U.S. EPA, 1997 EFH; Table 13-71 (triangular at 0, NE per capita, houses that garden)
All	Fraction of fruit grown locally	FFL	unitless	3.0E-02	5.3E-02	5.3E-02	Data from Survey; median value used for CTE, doubled for RME
All	Fraction of fish caught locally	FFCL	unitless	9.0E-02	2.2E-01	2.2E-01	Corresponds to a CTE of 12.4 g/day and an RME of 36 g/day; refer to pg 4-66
All	Fraction of meat which is local wild game	FMFWG	unitless	2.9E-02	3.1E-02	3.1E-02	General GSA population CTE of 7.2 g/d and an RME of 12 g/day refer to pg 4-68
All	Fraction of fruit which is local wild berries	FFWB	unitless	3.9E-02	6.0E-02	6.0E-02	CTE of 0.12g/kg/d (12 cups/year); RME was doubled at 0.24 g/kg/year

Exposure data collected

- Soil samples – 8,500
- Air samples- 1,200
- Drinking water - 95
- Indoor dust - 95
- Local vegetables - 235
- Fish and beef – 165
- Each sample analyzed for minimum 20 parameters

Additional Studies Conducted

- Vegetable garden survey
- Indoor dust survey
- Food consumption survey
- Metal levels in Fish
- Potable water survey
- Livestock survey
- Falconbridge urinary arsenic study
- Speciation
- Bioaccessibility

Bioaccessibility Study

- Protocol developed and vetted through technical committee
  - After a thorough review of the literature, a modified version of the Solubility/Bioavailability Research Consortium (SBRC) method was selected RFP issued and sent to four contractors
- Proposals reviewed
- Golder Associates in Mississauga selected to conduct study
  - Method modified as per Golder's proposal

Bioaccessibility Study

- ~100 soil samples subjected to 2-phase (gastric and intestinal) simulated stomach assay
- 20 dust samples analyzed using same protocol
- BA assay and analytical lab subjected to rigorous QA/QC proceedures (including blanks, CRM and duplicates)
- Gastric extraction fluid prepared as per SBRC specifications (HCl, glycine, pepsin)
- Bile and pancreatine added in intestinal phase in addition to NaOH
- 1 gram soil per 100 mL of extraction fluid dilution ratio
- 10,000g centrifuge for 10 minutes

Key Issues

- GIE vs. GE
  - 10 soil samples analyzed for both GIE and GE
  - Decision to use GIE only study based on several factors:
    - Primarily physiology
    - Results of scoping study
- Validation
- Dilution ratio
- Dust results

Table 3.8 Summary of Bioaccessibility Results

	Bioaccessibility (%)	
Chemical	**Soil**	**Dust**
Arsenic	41	3.7
Cobalt	26	2.4
Copper	64	4.6
Lead	16	3.4
Nickel	42	2
Selenium	27	100

Indoor Dust Survey

- Measure concentrations of COCs in indoor dust in the Greater Sudbury area (GSA);
- Measure concentrations of the COCs in co-located outdoor soil samples to identify a relationship (if any) between indoor dust and outdoor soil concentrations;
- Compare the data collected in Sudbury with other information and relationships reported in the literature;
- If a relationship exists between COC concentrations in outdoor soil and indoor dust, use this relationship to predict indoor dust levels in indoor living spaces over the range of COC levels reported in the 2001 soil survey; and,
- Generate data that can be utilized to estimate human exposure to COCs in indoor environments in the HHRA.

Table 3.28 Summary of Best Fit Linear Regression Equations for Each COC

COC	Equation ($\ln[\text{indoor dust}] = \beta_0 \pm SE \times \ln[\text{soil}] + C \pm SE$)	R^2	P model fit	N
Arsenic	ln[indoor dust] = 0.22±0.06 × ln[soil] + 2.27±0.15	0.148	0.0004	79
Cobalt	ln[indoor dust] = 0.57±0.07 × ln[soil] + 2.09±0.21	0.441	<0.0001	81
Copper	ln[indoor dust] = 0.21±0.05 × ln[soil] + 5.22±0.26	0.203	<0.0001	81
Lead	ln[indoor dust] = 0.26±0.06 × ln[soil] + 3.82±0.23	0.182	<0.0001	80
Nickel	ln[indoor dust] = 0.36±0.06 × ln[soil] + 4.32±0.33	0.317	<0.0001	82

Local Food Consumption Rate Table

Note: All local food group-specific intake rates were expressed as a fraction of the corresponding arithmetic mean food group intake derived from data provided by Mark Richarson of Health Canada

Input Parameter Description	Acronym	Units	Value		PDF$_v$				Reference/Comments/Notes
			CTE	RME	Shape	min	most likely	max	
Fraction of root vegetables grown locally	FRVL	unitless	0.018	0.106	triangular	0	0.018	0.11	EFH (U.S. EPA, 1997); Table 13-71 (Root vegetables). CTE - Northeast region of U.S (0.018).; RME - Individuals who reported gardening (0.106). The PDF attempts to characterize variability using a triangular PDF (0 for non-consumer,CTE,RME for high end consumer). Pg. 4-63 through 4-65
Fraction of other vegetables grown locally	FOVL	unitless	0.062	0.23	triangular	0	0.062	0.23	EFH (U.S. EPA, 1997); Table 13-71 (Exposed Vegetables). CTE - Northeast region of U.S (0.062).; RME - Individuals who reported gardening (0.23). The PDF attempts to characterize variability using a triangular PDF (0,CTE,RME). Pg. 4-63 through 4-65
Fraction of fruit grown locally	FFL	unitless	0.030	0.053	uniform	0.03	NA	0.053	Site-Specific Food Survey. Strawberries were the main source of local fruit. Median intake of local strawberries reported to be 10 cups/yr - approximately 2.3 kg per year (assuming 1 cup = 240 grams @ a density of 1 g/cm3) equal to 0.1 g/kg/day. The RME intake was assumed to be double the CTE. Pg. 4-65. These consumption rates were expressed as a fraction corresponding arithmetic mean food group intake derived from data provided by Mark Richardson of Health Canada
Fraction of fish caught locally	FFCL	unitless	0.09	0.22	triangular	0	0.09	0.22	Site-Specific Food Survey. Refer to Pg 4-65 through 4-66 and Table 4.25. Survey reported fish intake on a 'meals/yr' basis. The Great Lakes Sport Fish Consumption Advisory Task Force (GLSFATF, 1993) defined a typical meal size as 227grams of fish. Combining the consumption frequencies as per the survey (meals/yr) with 227 g/meal - a consumption rate on a g/day basis was derived. This was expressed a fraction of the corresponding arithmetic mean food group intake derived from data provided by Mark Richardson of Health Canada. Producing CTE and RME fractions of total fish that are locally consumed of 0.09 and 0.22 of the general population, respectively. CTE and RME fractions for 'angler and hunters' were 0.39 and 0.55, respectively.
Fraction of meat which is local wild game	FMFWG	unitless	0.029	0.031	triangular	0	0.029	0.031	Site-Specific Food Survey. Refer to Pg 4-67 through 4-68 and Table 4.26. Survey reported five type of game consumption on a 'meals/yr' basis. Using a meal size as 227grams of meat and Combing the consumption frequencies as per the survey (meals/yr) with 227 g/meal - a consumption rate on a g/day basis was derived. These were expressed as a fraction of the corresponding arithmetic mean total meat intake derived from data provided by Mark Richardson of Health Canada. This produced CTE and RME fractions of total meat consumed which is wild game of 0.029 and 0.031 for the general population, respectively. CTE and RME fractions of 0.122 and 0.14 were derived for anglers and hunters, respectively.
Fraction of fruit which is local wild berries	FFWB	unitless	0.039	0.06	triangular	0	0.039	0.06	Site-Specific Food Survey. Refer to Pg 4-61. Survey reported a mean and median blueberry intake rates of 173 and 12 cups/yr, respectively. 173 cups/yr was assumed to equal approximately 40 kg per year (assuming 1 cup is equal to 240 grams). Relative to EPA data (refer to Pg4-61) this reported mean was extremely high. 12 cups/yr (or 2.8 kg per year or 0.12 g/kg/day) was used for the CTE intake rate. The RME value was doubled to 0.24 g/kg/day (or about 5.5 kg/yr for an adult). These were expressed as a fraction corresponding arithmetic mean food group intake derived from data provided by Mark Richardson of Health Canada. This produced CTE and RME fractions of total fruit consumed which are local berries of 0.039 and 0.06 for the general population, respectively.

Food Intake Rates for Specific Food Groups (derived using data from Health Canada) - these food group-specific intakes were combined with the above fractions to derive intake rates of local foods

Intake Description	Acronym	Units	Value		PDFu			References/Comments/Notes
			CTE	RME	shape	mean	Std	
root vegetables - female adult	RVIR	g/kg/d	1.8	2.2	normal	2.2	1.6	Developed using the raw data provided by Richardson, 2005. The data provided by Richardson (2005) was used to develop lognormal PDFs describing the variability in short-term intake rates of specific food groups presented in the Compendium of Canadian Exposure Values for Risk Assessment (Richardson, 1997). The PDFu describes the uncertainty in the arithmetic mean intake rate of specific food groups. Refer to Pg. 4-62
other vegetables - female adult	LVR	g/kg/d	1.6	2.2	normal	2.1	2.0	
fruits & Juices - female adult	FVIR	g/kg/d	3.1	4.2	normal	3.9	3.3	
fish and shell fish - female adult	FIR	g/kg/d	1.3	2.1	normal	1.7	1.8	
meat and eggs - female adult	BIR	g/kg/d	1.8	2.2	normal	2.2	1.6	

CTE - represents 50th percentile intake
RME - represents 95% UCL on the arimethic mean

Local Food Consumption Rates (g/kg/day)

Local Food Group							Value CTE	Value RME	PDFu x PDFv
Local 'root vegetable' consumption rate	=	FRVL	x	RVIR	=		0.033	0.235	
Local 'other vegetable' vegetable consumption rate	=	FOVL	x	LVR	=		0.096	0.500	
Local fruit consumption rate	=	FFL	x	FVIR	=		0.092	0.221	
local fish consumption rate	=	FFCL	x	FIR	=		0.113	0.470	
local wild game consumption rate	=	FMFWG	x	BIR	=		0.053	0.069	
local wild blue berry consumption rate	=	FFWB	x	FVIR	=		0.120	0.250	

EFH (U.S. EPA, 1997). U.S. EPA Exposure Factors Handbook
Richardson 1997. Compendium of Canadian Human Exposure Factors for use in Risk Assessment

The Sudbury Soils Study:

Hazard Assessment

SARA GROUP

Development of TRVs

- The Toxicological Reference Values (TRVs) obtained from regulatory agencies including the MOE, Health Canada, the Canadian Council of Ministers of the Environment (CCME), the World Health Organization (WHO) and the U.S. EPA.
- A detailed toxicological assessment was conducted for each COC, involving identification of mechanism of action and relevant toxic endpoints, and determination of receptor- and route-specific toxicological criteria.
- Toxicological profiles based primarily on secondary information sources, such as ATSDR toxicological profiles and other detailed regulatory agency reviews, and supplemented with recent relevant scientific literature.
- The TRVs represent long-term exposure levels below which adverse health effects are not expected to occur.

Arsenic

- 615 references identified
- Key review documents:
  - ATSDR. 2005. Toxicological Profile for Arsenic. Agency for Toxic Substances and Disease Registry (ATSDR), Atlanta, GA.
  - NRC. 2001. Arsenic in Drinking Water, 2001 Update. National Research Council, Subcommittee to update the 1999 Arsenic in Drinking Water Report, Washington, DC. National Academy Press.
  - WHO-IPCS. 2001. Environmental Health Criteria 224. Arsenic and arsenic compounds. United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organization (WHO).

Summary Table of Exposure Limits for Arsenic Selected for the HHRA

Route of Exposure	Exposure Limit	Type of Limit	Toxicological Basis	Reference	
				Study	Regulatory
Cancer (Non-threshold) Effects					
Oral	0.0015 $(\mu g/kg/day)^{-1}$	SFo	skin cancer	Tseng *et al.*, 1968; Tseng, 1977	U.S. EPA (1998)
Inhalation	0.0043 $(\mu g/m^3)^{-1}$	IUR	lung cancer	Brown and Chu (1983a,b,c); Lee-Feldstein (1983); Higgins *et al.* (1982); Enterline and Marsh (1982)	U.S. EPA (1998)
	0.015 $(\mu g/kg/day)^{-1}$	SFi			
Dermal	NA		NA	NA	NA
Non-cancer (Threshold) Effects					
Oral	0.3 µg/kg/day	RfD	hyperpigmentation, keratosis, and possible vascular complications	Tseng *et al.*, 1968; Tseng, 1977	U.S. EPA (1993)
Inhalation	0.03 $\mu g/m^3$	Chronic REL	increased fetal malformations	Nagymajtenyi *et al.* (1985)	OEHHA (2000)
Dermal	NA		NA	NA	NA

NOTES:
NA = not available; SFo = oral slope factor; IUR = inhalation unit risk; SFi = inhalation slope factor; RfD = reference dose; REL = reference exposure level.

Arsenic Slope Factors

- Oral slope factor based on Tiawanese data sets
- Many problems with this data set and the slope factor derived from this data
  - Exposure to arsenic impacted drinking water
  - Nutritional status of exposed population poor compared to NA population
  - Concomitant exposure (food preparation, locally grown foods)
- US EPA update on-going
- Complicates assessment since background risk in Ontario often exceed 10^{-6} acceptable risk level

Cobalt

- 120 references identified
- Key review documents:
  - ATSDR. 2001. Toxicological profile for cobalt. Draft for public comment. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.
  - U.S. EPA. 2002. PPRTV Derivation Support Document for Cobalt and Compounds (CASRN 7440-48-4). U.S. Environmental Protection Agency, Office of Superfund Remediation and Technology Innovation. 00-122/1-15-02.

Summary of Toxicological Criteria Selected For Cobalt in the HHRA

Route of Exposure	Exposure Limit	Type of Limit	Toxicological Basis	Reference	
				Study	Regulatory
Non-cancer (Threshold) Effects					
Oral	20 µg/kg/day	RfD	Significant rise in hemoglobin	Duckham and Lee (1976)	PPRTV, as provided by U.S. EPA, 2002
Inhalation	0.02 $\mu g/m^3$	RfC	decreases in FVC, FEV1, MMEF, and PEF	Nemery *et al.* (1992)	PPRTV, as provided by U.S. EPA, 2002
Dermal[a]	NA		NA	NA	NA
Cancer (Non-threshold) Effects					
Oral	NA		NA	NA	NA
Inhalation	0.0098 $(\mu g/kg/day)^{-1}$	SFi	alveolar and bronchiolar tumours in rats and mice	NTP, 1998; Bucher *et al.*, 1999	PPRTV, as provided by U.S. EPA, 2002
	0.0028 $(\mu g/m^3)^{-1}$]	IUR			
Dermal	NA		NA	NA	NA

NOTES:
NA = not available; RfD = reference dose; RfC = reference concentration; SFi = inhalation slope factor; IUR = inhalation unit risk;
PPRTV = Provisional Peer Reviewed Toxicity Values.
[a] No regulatory dermal exposure limits were identified in the literature reviewed for the current assessment.

Copper

- 114 references identified
- Key review documents:
  - ATSDR. 2002. Toxicological profile for copper - draft for public comment. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Agency for Toxic Substances and Disease Registry.
  - WHO (International Programme on Chemical Safety). 1998. Environmental Health Criteria 200: Copper. Published jointly by the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization.

Summary of Toxicological Criteria Selected For The HHRA

Route of Exposure	Exposure Limit	Type of Limit	Toxicological Basis	Reference	
				Study	Regulatory
Non-cancer (Threshold) Effects					
Oral	140 µg/kg/day	UL	liver damage	Pratt *et al.*, 1985	IOM, 2000; Health Canada, 2005
Inhalation	1 $\mu g/m^3$	TCA	subchronic NOAEC (respiratory and immunological effects) in rabbits	Johansson *et al.*, 1984	RIVM (Baars *et al.*, 2001)
Dermal[a]	NA		NA	NA	NA
Cancer (Non-threshold) Effects					
Oral	NA		NA	NA	NA
Inhalation	NA		NA	NA	NA
Dermal	NA		NA	NA	NA

NOTES:
NA = not available
TCA = tolerable concentration in air; UL = Upper Intake Level.
[a] No regulatory dermal exposure limits were identified in the literature reviewed for the current assessment.

Lead

- 218 references identified
- Key review documents:
  - ATSDR. 2005. Draft Toxicological Profile for Lead. Agency for Toxic Substance and Disease Registry. U.S. Department of Human and Health Services.
  - CDC. 2004. Childhood Lead Poisoning Prevention Program, National Center for Environmental Health. Why not change the blood lead level of concern at this time? Center for Disease Control and Prevention
  - WHO. 1995. International Programme on Chemical Safety. Environmental Health Criteria 165. Inorganic Lead. World Health Organization, Geneva.
- Key References
  - MOE. 1994. Soil, Drinking Water, and Air Quality Criteria for Lead: Recommendations to the Minister of the Environment and Energy. Ontario. Ministry of the Environment and Energy (MOE), Advisory Committee on Environmental Standards (ACES), Toronto, Ontario. ACES Report No. 94-02.

Exposure Limits Selected for Lead in the HHRA

Route of Exposure	Exposure Limit	Toxicological Basis	Reference	
			Study	Regulatory
Non-cancer (Threshold) Effects (IOC_{POP})				
Oral	1.85 µg/kg/day	Neurological effects in children	Weight-of-evidence, numerous studies	MOE, 1994; MOE, 1996
Inhalation				
Dermal				
Cancer (Non-threshold) Effects				
Oral	NA	NA	NA	NA
Inhalation[1]	NA	NA	NA	NA
Dermal	NA	NA	NA	NA

NOTES:
NA = not available; IOC_{POP} = intake of concern (population).
[1] While OEHHA considers lead to be a carcinogen via the inhalation route, no other identified regulatory agency shares this opinion. As such, lead is not considered a carcinogen in the current HHRA.

Derivation of the Lead TRV

- MOE established an Intake of Concern (IOC_{pop}) of 1.85 ug/kg/day
- Based on 10 ug/dL blood level; intended to ensure that blood lead level of children (6 months to 4 years) remain < 10 ug/dL in 95% of population
- 10 ug/dL established as LOAEL (no threshold to establish NOAEL)
- Total intake of 3.7 ug/kg/day corresponds with blood lead level of 10 ug/dL
- Uncertainty factor of 2 applied to derive IOC_{pop}
- Recent literature reviewed with focus on epidemiological evidence for effects below 10 ug/dL
- Lead also assessed with IEUBK model vs. an acceptable blood lead level of 10 ug/dL

Nickel

- 177 references identified
- Key review documents:
  - ATSDR. 2003. Toxicological profile for Nickel. Draft for public comment (Update). Department of Health and Human Services. Public Health Service. Agency for Toxic Substances and Disease registry.
  - OEHHA. 2005. Chronic Toxicity Summary. Nickel and Nickel Compounds. Nickel Oxide.
  - TERA. 2004. Toxicological review of soluble nickel salts. Toxicology Excellence for Risk Assessment.
- Key References
  - Seilkop, S.K.,and Oller, A.R. 2003. Respiratory cancer risks associated with low-level nickel exposure: an integrated assessment based on animal, epidemiological and mechanistic data. Reg Toxicol and Pharma 37:173-190. plus corrigendum (correction) published in 2005 (Reg Tox Pharm 41:92-93).
  - Seilkop, S.K. 2004. Estimation of Respiratory Cancer Risks Associated with Exposure to Small Airborne Concentrations of Nickel-Containing Substances. Presention to the Ontario Ministry of the Environment and INCO. February 10th, 2004.

Summary Table of Exposure Limits Selected for Nickel

Route of Exposure	Exposure Limit	Type of Limit	Toxicological Basis	Reference	
				Study	Regulatory
Non-cancer (Threshold) Effects					
Oral	20 µg/kg/day	RfD	Decreased body and organ weight (fats)	Ambrose *et al.*, 1976	U.S. EPA, 1991a
Inhalation	0.05 µg/m^3 (for Ni compounds except nickel oxide)	Chronic REL	pathological inflammatory, hyperplastic, and fibrotic changes in lung, lymph nodes, and nasal epithelium	NTP (1996b)	OEHHA, 2003a
	0.1 µg/m^3 (nickel oxide)	Chronic REL	pathological changes in lung and lymph nodes, including active pulmonary inflammation, lymph node hyperplasia, and adrenal medullary hyperplasia	NTP (1996c)	OEHHA, 2003b
Dermal [a]	NA		NA	NA	NA

NOTES:
NA = not available; RfD = reference dose; REL = reference exposure level ; IUR = inhalation unit risk.
[a] No regulatory dermal exposure limits were identified in the literature reviewed for the current assessment.
[b] Health Canada (2004) converts the TCO5 of 0.04 mg/m^3 to an IUR of 0.0013 (µg/m^3)$^{-1}$by dividing the 0.05/TC05.

Summary Table of Exposure Limits Selected for Nickel

Route of Exposure	Exposure Limit	Type of Limit	Toxicological Basis	Reference	
				Study	Regulatory
Cancer (Non-threshold) Effects					
Oral	NA		NA	NA	NA
Inhalation	nickel oxide 2.3×10^{-7} (µg/m^3)$^{-1}$ nickel subsulphide 6.3×10^{-4} (µg/m^3)$^{-1}$	IUR	Lung cancer	Seilkop, 2004	none
	nickel refinery dusts 2.4×10^{-4} (µg/m^3)$^{-1}$ nickel subsulphide 4.8×10^{-4} (µg/m^3)$^{-1}$	IUR	Lung cancer	Extrapolations from epidemiologic datasets from Enterline and Marsh, 1982; Chovil *et al.*, 1981; Peto *et al.*, 1984; and Magnus *et al.*, 1982	U.S.EPA, 1991
	nickel compounds 3.8×10^{-4} (µg/m^3)$^{-1}$	IUR	Lung cancer	Andersen, 1992; Andersen *et al.*, 1996	WHO, 2000
	combined oxidic, sulphidic and soluble nickel 0.04 mg/m^3	TC05[b]	Lung cancer	Doll *et al.*, 1990	Health Canada, 1996
Dermal	NA		NA	NA	NA

NOTES:
NA = not available; RfD = reference dose; REL = reference exposure level ; IUR = inhalation unit risk.
[a] No regulatory dermal exposure limits were identified in the literature reviewed for the current assessment.
[b] Health Canada (2004) converts the TCO5 of 0.04 mg/m^3 to an IUR of 0.0013 (µg/m^3)$^{-1}$by dividing the 0.05/TC05.

Nickel Inhalation Unit Risks

- Species specific
- Regulatory guidance lacking
  - EPA – refinery dust and subsulphide
  - No regulatory IUR for NiO (predominant form)
- Inappropriate to apply Ni_3S_2 or refinery dust IUR to Total Ni or NiO
- Primary data reviewed including NTP studies and Seilkop which allow for distinct IURs for Ni_3S_2 and NiO

Selenium

- 148 references identified
- Key review documents:
  - ATSDR 2003. Toxicological profile for Selenium. U.S. Department of Health and Human Services, Public Health Service, Atlanta, GA. Agency for Toxic Substances and Disease Registry. September 2001.
  - NAS. 2000. Selenium. In: NAS. Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids. National Academy of Sciences (NAS). pp. 284-324.

Summary of Toxicological Criteria Selected For The HHRA

Route of Exposure	Exposure Limit	Type of Limit	Toxicological Basis	Reference	
				Study	Regulatory
Non-cancer (Threshold) Effects					
Oral	5.0 µg/kg/day	RfD/TRV	selenosis: hair loss and nail sloughing Clinical selenosis	Yang and Zhou (1994) Yang *et al.*, 1989a,b	IOM, 2000; Health Canada, 2005 U.S. EPA, 1991
Inhalation	20 µg/m^3	Chronic REL	Hepatic, cardiovascular, neurological	Yang *et al.*, 1989a,b	OEHHA, 2001
Dermal[a]	NA		NA	NA	NA
Cancer (Non-threshold) Effects					
Oral	NA		NA	NA	NA
Inhalation	NA		NA	NA	NA
Dermal	NA		NA	NA	NA

NOTES:
NA = not available; RfD = reference dose; REL = reference exposure level; TRV = toxicity reference value.
[a] No regulatory dermal exposure limits were identified in the literature reviewed for the current assessment.

Bioaccessibility Study

- Protocol developed and vetted through technical committee
  - After a thorough review of the literature, a modified version of the Solubility/Bioavailability Research Consortium (SBRC) method was selected RFP issued and sent to four contractors
- Proposals reviewed
- Golder Associates in Mississauga selected to conduct study
  - Method modified as per Golder's proposal

Bioaccessibility Study

- ~100 soil samples subjected to 2-phase (gastric and intestinal) simulated stomach assay
- 20 dust samples analyzed using same protocol
- BA assay and analytical lab subjected to rigorous QA/QC proceedures (including blanks, CRM and duplicates)
- Gastric extraction fluid prepared as per SBRC specifications (HCl, glycine, pepsin)
- Bile and pancreatine added in intestinal phase in addition to NaOH
- 1 gram soil per 100 mL of extraction fluid dilution ratio
- 10,000g centrifuge for 10 minutes

Key Issues

- GIE vs. GE
  - 10 soil samples analyzed for both GIE and GE
  - Decision to use GIE only study based on several factors:
    - Primarily physiology
    - Results of scoping study
- Validation
- Dilution ratio
- Dust results

Table 3.8 Summary of Bioaccessibility Results

Chemical	Bioaccessibility (%)	
	Soil	Dust
Arsenic	41	3.7
Cobalt	26	2.4
Copper	64	4.6
Lead	16	3.4
Nickel	42	2
Selenium	27	100

Metal Speciation

- A variety of approaches were undertaken to evaluate the specific speciation of the COCs:
  - Tessier leach extraction
  - SEM/QemSCAN microscopy
  - XAFS analyses conducted by two different sets of researchers

Results of Speciation Analyses

- Species present in dust samples are similar to those observed in air filters, indicating that the metals present within the dust likely originated from airborne emission sources, rather than being tracked in from outdoor soil sources.
- Much of the species present in the air filters appears to be coated by an organic carbonatious layer.
- Nickel subsulphide (Ni_3S_2) was detected in a number of air filter and indoor dust samples.
- Further investigations indicated that Ni_3S_2 was only detected in air samples taken around Inco's Copper Cliff facility, depending on wind direction.

The Sudbury Soils Study:

Risk Characterization

SARA GROUP

Details of Risk Characterization Approach

Conduct Deterministic Risk Analysis
•Oral/dermal path
•Inhalation path

↓

If HQ <1.0 : STOP
If HQ >1.0 : CONTINUE

↓

Interpret Results
Does Weight of Evidence minimize risk?
If Yes : STOP
If No : CONTINUE

↓

Conduct Probabilistic Risk Analysis

↓

Develop Preliminary Remediation Goals for soil

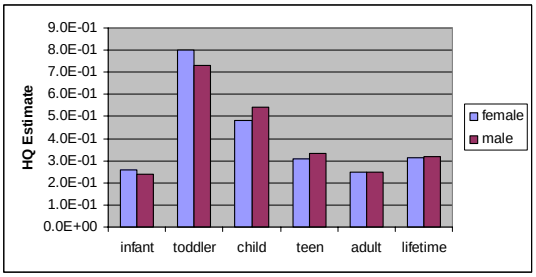
Acceptable Risk Levels (Ontario Policy)

- ILCR – 10^{-6} (1-in-one-million) for each environmental medium
- Total cancer risk – no clear policy
  - SARA proposes 10^{-5}
- Non-cancer – acceptable HQ < 0.2 (20% source allocation factor per environmental medium); however, a higher HQ may be proposed if accompanied with a multi-media exposure assessment
  - Since all significant media considered SARA proposes use of an acceptable HQ < 1.0
  - Non cancer risks calculated on the lifestage by lifestage comparison not on a lifetime basis

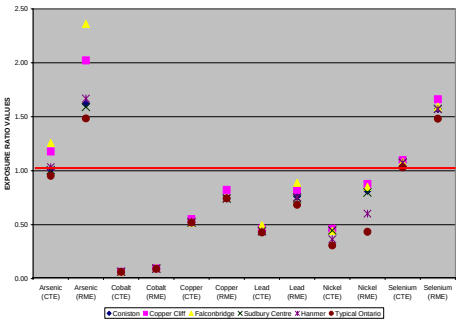
Risk Estimate Calculations

- Non-Cancer (HQ)
  - Sensitive life-stages and sexes considered (comparison to lifetime provided)
  - COCs considered independent based on mode, mechanism and site of action
- Cancer (ILCR)
  - Incremental vs. total risk
  - Composite receptor (composite of individual life-stages → lifetime risk
  - Adjustment made to more sensitive life-stages (infants, toddlers, children)

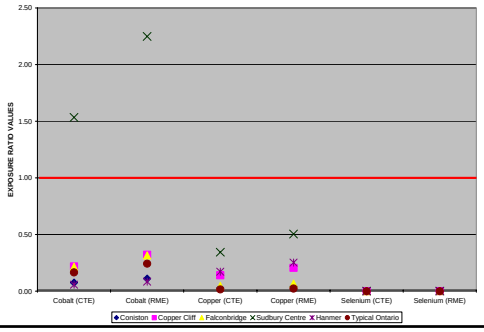
Lifetime HQ Estimates for Nickel (RME) - Sudbury (Centre)



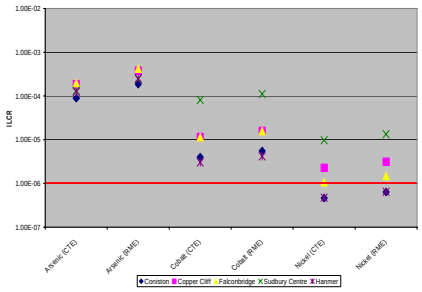
Mean Deterministic Oral Hazard Quotient (HQavg) Estimates for the Female Preschool Child - General Sudbury Population



Deterministic Inhalation Hazard Quotient (HQ) Estimates for the Female Preschool Child - General Sudbury Population



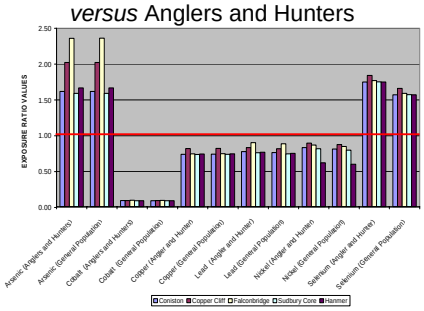
Female Incremental Lifetime Cancer Risk Level Estimates - General Sudbury Population



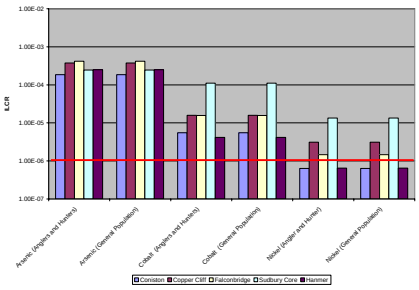
Comparison of Average and Upper-Bound Oral/Dermal Risk Estimates in Copper Cliff

Risk Metric	Arsenic	Cobalt	Copper	Lead	Nickel	Selenium
HQ_{avg}	**2.16**	0.0955	0.823	0.821	0.868	**1.66**
$HQ_{95\%ile}$	**2.27**	0.0980	0.854	0.880	0.989	**1.69**
HQ_{max}	**2.43**	0.102	0.895	**1.00**	**1.05**	**1.77**

Deterministic Reasonable Maximum Exposure Oral Hazard Quotient Estimates –Female Preschool Child - General Sudbury Population *versus* Anglers and Hunters



Female Incremental Lifetime Cancer Risk Level Estimates - General Sudbury Population *versus* Anglers and Hunters



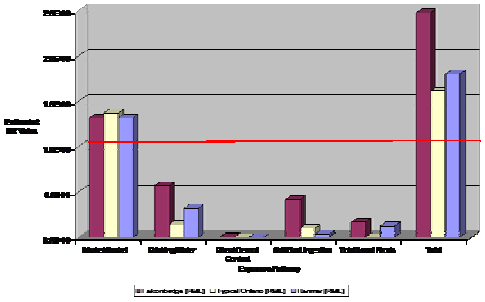
Summary of Results

- Potentially elevated risk related to inhalation of airborne nickel and cobalt;
- Average soil related risks acceptable for all COCs in all COIs;
- The deterministic assessment indicates some potential for localized areas of elevated risks related to soil-borne nickel and lead;
- Results of the probabilistic assessment indicate no predicted risks at the 95th percentile statistic (95% chance that the risks are within acceptable levels); and,
- SSRGs developed for Nickel and Lead to ensure no localized exceedances of safe levels.

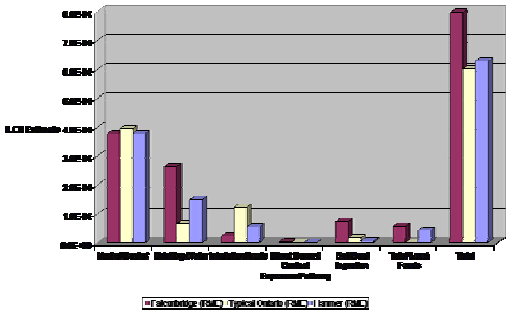
HHRA RESULTS
Arsenic

- Results typical of HHRA in Ontario and elsewhere in North America (*i.e.*, Port Hope, Deloro, Balmertown, Wawa, Anaconda).
- Risk level from all pathways is between 1- and 10-per-10,000.
- A weight of evidence evaluation is necessary to put arsenic related risks in Sudbury into perspective.

Arsenic HQs per Exposure Pathway
Female Toddler in RME Scenario



Arsenic CRLs per Exposure Pathway
Lifetime Receptor for RME Scenario



Arsenic Weight-of-Evidence

- No statistical difference in levels of arsenic in urine between Falconbridge and the comparison (unexposed) community;
- The levels of arsenic in urine in Falconbridge residents were not indicative of any excess levels of illness;
- Overall predicted exposures and risks for arsenic in all GSA communities were only slightly greater when compared to estimates for the typical Ontario resident;
- Market basket foods were the main contributor to arsenic related risks for both the typical Ontario resident and the typical GSA resident;
- The epidemiological review of cancer incidence and mortality data in the GSA found that, for many potential arsenic related cancers, no incidence or mortality rate was high enough to warrant more detailed analysis of the statistics; and,
- The results of the speciation analysis indicated that the forms of arsenic in the soil, dust and air are consistent between the various communities within the GSA.

HHRA RESULTS
Cobalt

- No unacceptable risks related to oral pathways.
- Elevated inhalation non-cancer and cancer risk levels at the Sudbury Centre air monitor (*i.e.*, Travers street).
- Analysis of results and wind patterns point to a potential source South West of the Sudbury Centre air monitor.
- Cancer risks at other air monitors are slightly elevated in the 1-in-100,000 range.

HHRA RESULTS
Copper

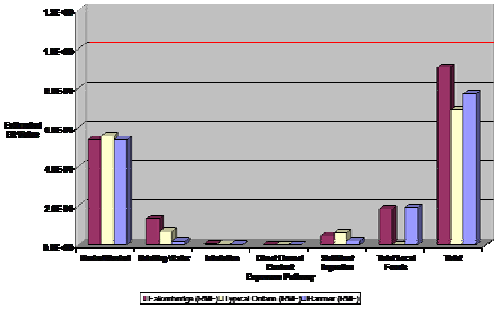
- All risk estimates (non-cancer) were within acceptable ranges for copper.

HHRA RESULTS
Lead

- SARA-developed HHRA model and U.S. EPA IEUBK model used to evaluate lead COC risks.
- Average risks levels within acceptable ranges.
- Risks marginally higher in Falconbridge due to historic levels in water well.
- Upper end risk estimates marginally elevated due to potentially localized areas of higher lead soil/dust levels.
- **PRA CONDUCTED**

Lead RME HQs for a Female Toddler

Angling and Hunting Population

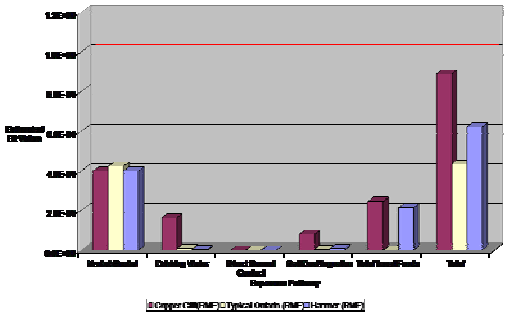


HHRA RESULTS
Nickel

- Average risks levels within acceptable ranges following oral exposures.
- Upper end risk estimates marginally elevated due to potentially localized areas of higher nickel soil/dust levels.
- Significant uncertainty related to the form of airborne nickel.
- Inhalation cancer risks range between 0.0273 and 5.97 per 100,000 depending on the form of airborne nickel.
- **PRA CONDUCTED**

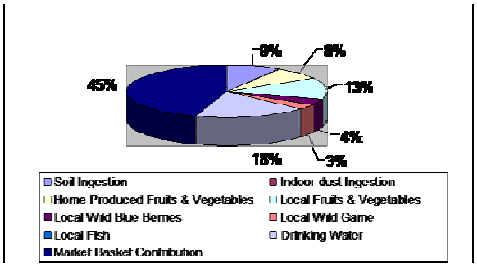
Nickel RME HQs for a Female Toddler

Angling and Hunting Population



Nickel RME Estimate Exposure Pathway Contribution

Female Toddler in Copper Cliff

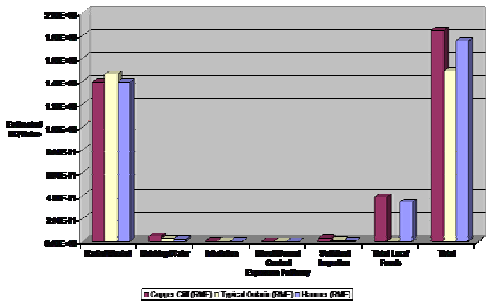


HHRA RESULTS
Selenium

- Non-cancer risk levels elevated in all communities of interest including typical Ontario and Hanmer;
- 75% of exposure as a result of the market basket (supermarket foods);
- Contribution of the facilities to the total risk estimate is <20% of the RfD; and,
- Selenium not considered to be a GSA concern.

Selenium RME Exposure Ratio for a Female Toddler

Angler and Hunter Sub-Population



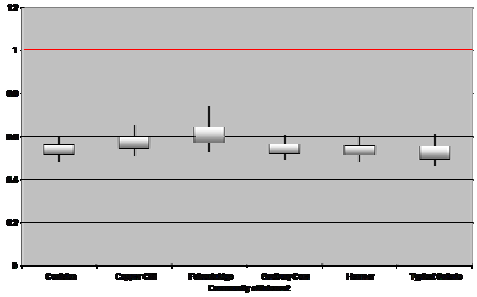
HHRA RESULTS

Probabilistic Analyses

- In cases where risks to human health are clearly not negligible or obviously unacceptable, a PRA is useful to better characterize risk.
- With the exception of nickel and lead, all COCs (*i.e.,* arsenic, cobalt, copper and selenium) did not fall into above mentioned category and were therefore not considered for further probabilistic analysis.
- A PRA was conducted for lead and nickel (*i.e.*, for oral exposure pathways).

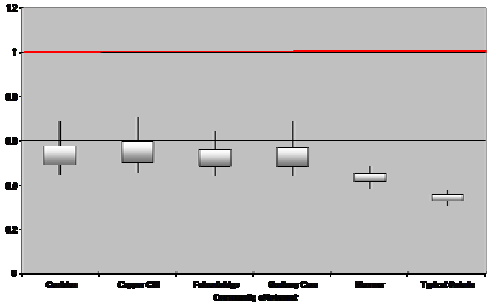
Probabilistic Lead HQ_{avg} Estimates

Female Toddler



Probabilistic Nickel HQ_{avg} Estimates

Female Toddler



DEVELOPING PRELIMINARY REMEDIATION GOALS (PRGs)

- A site-specific preliminary remediation goal (PRG_{soil}) can be defined as the average soil concentration within an exposure unit (EU) that corresponds to an acceptable level of risk (following US EPA guidance);
- The soil concentrations used to facilitate the long-term exposure assessment were defined as the upper 95th percent confidence limit on the arithmetic mean (95 UCLM) from a specific EU (or community of interest); and,
- PRGs are developed to be protective of both average soil levels (*i.e.,* community) and localized areas (i.e., individual properties) of elevated soil concentrations.

Nickel SSRGs

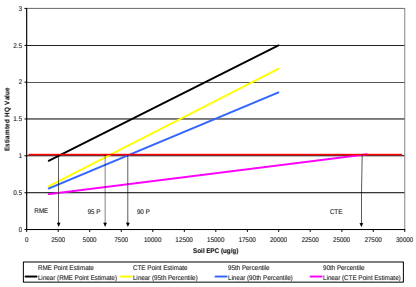


Table 5.11 Sensitivity Analysis – Impact of Key Input Parameters to Variance in SSRGs

Parameter Change	Original Value	Revised Value	Percent Change in SSRG (Δ%)	
			Nickel	Lead
Soil bioaccessibility estimate[1] (2-fold increase) [%]	16 (Pb) 42 (Ni)	32 84	 -56%	-47%
Dust bioaccessibility estimates[2] (dust BA = soil BA) [%]	3.4 (Pb) 2 (Ni)	16 42	 -63%	-22%
Gastric *vs.* gastro-intestinal bioaccessibility [%] (see comparison below)[3]	16/3.4 (Pb) 42/2 (Ni)	59/12.5 39/1.9	 0%	-61%
selected statistic for bioaccessibility (student t (UCLM) *vs.* Chebyshev (UCLM) *vs.* 95th%ile) [%][4]	16/3.4 (Pb) 42/2 (Ni)	19/5.5 42/2.3	 -4%	-13%
soil/dust ingestion rate[5] (selected value *vs.* U.S. EPA value *vs.* MOE/HC value) [mg/day]	202	100 80	+104% +174%	+103% +306%
Home garden/local produce ingestion rate [% of locally derived produce][6]	25% HG	100% HG	-15%	+28%
local fish/game consumption rates (% for fish/meat consumed)[7]	22%/3%	0/0	0%	+31%
soil to indoor dust relationship[8]	regression line	1:0.7 1:5.5 (Pb) 1:3.4 (Ni)	-11% -7%	+22% -53%
Market Basket estimated daily intake (EDI) [µg/kg/day][9]	8.4 (Ni)	6.2 (Ni) 3.9 (Ni)	+37% +74%	-

Appendix D

Summary of Observer Questions

Appendix D – Summary of Observer Questions

Observers for the IERP HHRA Peer Review meeting did not participate in the panel discussions. They were provided the opportunity to submit questions during the meeting. The observer questions were reviewed by the chair and prior to several meeting breaks, the chair read the collected questions to the panel members, who then offered individual responses. For several questions, the chair noted that the question had been addressed during previous discussions, while some of the other questions prompted additional discussion that is covered in the body of the meeting report. The following is a brief summary of observer questions and responses.

1. *How to address possibility of early exposures having late effects?*

   A. The panel noted that this issue is considered in deriving reference toxicity values; if not addressed by the experimental studies themselves (study design, age of dosed animals, and length and level of exposure) then addressed through the use of uncertainty factors. For example, the epidemiology studies for arsenic involved lifetime exposure and a dose from only early life exposure is encompassed in those studies; short-term exposure has been covered by the study population with the chronic exposure.

2. *How relevant is the indoor/outdoor ratio to other papers using different dust sampling methods? (Sudbury indoor dust obtained by vacuuming carpets versus dust settling on flat surfaces)*

   A. See discussion under Exposure Question 7.

3. *How should brief episodic dust exposures be related to daily intakes over a lifetime (RfD) or to lifetime cancer risk estimates? (Discussion of home remodeling and suggestion that this exposure to dust be included)*

   A. The Chair concluded that the IERP had already addressed this issue during discussion. In brief, exceedences of a Hazard Index (HI) or Hazard Quotient (HQ) for a brief period do not endanger a sensitive population (and therefore the whole population) as long as the lifetime average HI or HQ is not exceeded and any short-term health benchmark is not exceeded.

4. *Ontario Typical Range for soil is the 98th percentile, the Ontario report has the percentiles including the 50th percentile. So using a 98th percentile value for central tendency is inappropriate?*

   A. The Chair noted that if one used the 50% for central tendency for soil, it would lower overall intake by only a small amount because of the high proportion of overall exposure is due to the predominance of diet.

5. *Regarding lead bioaccessibility in dust and preference (by IERP) for gastric (acid) phase, the Golder data are based on a combined acid and neutral pH extraction, which will underestimate an acid only extraction. This may explain the low value for bioaccessibility of lead in dust.*

   A. The Chair concluded that the IERP had already addressed this issue during discussion. See discussion under Hazard Question 2.

6. *Why not use the reported nickel bioavailability data for humans? This is available for water-soluble nickel salts under non-fasting conditions. Fasting: 20-30%; non-fasting: 1-2%*

   A. A panel member clarified that information on absolute bioavailability is taken into account in deriving the toxicity values. What is being done in the HHRA is an attempt to determine relative bioavailability, between the soluble forms and what is present in the soil, to account for differences in the exposure medium.

7. *Since the fetus is as sensitive to lead as the child, should women of reproductive age not be considered as a sensitive receptor as well?*

   A. Panel members noted that for lead, children under seven have higher exposures than corresponding adults in similar environments, and therefore, if one protects for the child, one protects for the adult. This is not the case for methyl mercury, where the critical effect is on the fetus and the mother is protected to protect the fetus. Unlike for lead, exposure to methyl mercury (the form of concern for fetal exposure), environmental exposure is typically from food (e.g., fish) not from soil. Women eat more fish than do children, whereas children eat more soil than women.

8. *Are the potential health risks created by SO_2 and off-site slag deposits properly accounted for by the risk assessment?*

   A. The panel thought they had been properly accounted for, i.e., the media of exposure were measured, which included the contribution from the slag heaps. The SARA Group authors noted that SO_2 was evaluated as a modifying factor for pH changes and mobility of metals. Historical exposure to SO_2 as a gas was not considered in the study parameters.

9. *Are the historic effects of mining and smelting properly accounted for in the risk assessment? Does the risk assessment consider the impact on a middle-aged resident who has been living in the study area all his/her life? In other words, does the risk assessment properly account for any prior exposure for the middle-aged resident?*

   A. Panel members noted that risk assessment methods are designed to predict future risk (based on current levels) from the present forward. The risk assessment does not account for prior exposure. For past exposures, one would conduct a retrospective epidemiology study, which is very different from what the HHRA does. See also the discussion under Risk Characterization Question number 9.

10. *Are the potential health risks to miners properly accounted for by the risk assessment?*

    A. No they are not. The panel noted this was not the focus of the community assessment.

11. *Could SARA consider reducing critical HQ from 1 to something less (e.g. 0.8) to reflect the lack of explicit consideration of consumer products?*

    A. Panel members pointed out that this is a risk management decision and beyond the scope of the IERP.

12. *Suppose the HQ (non-soil) = 0.5 and the HQ (soil) = 0.6; is risk management needed if the HQs are added [and exceed] 1 and not needed if you look at HQ (soil) alone [which is only 0.6]? Isn't the public interested in the reduction of their total risks?*

    A. The authors indicated that they looked at all exposure pathways and compared the sum of the hazard quotients for all pathways to one. The authors did not back out other pathways to compare with a lower hazard quotient for risk management purposes. The default value in Ontario guidance is 0.2 unless a multimedia assessment such as this effort can replace the default with a more realistic value. They acknowledged that what they did is not clearly explained in the document. All soil uses were considered, except for home gardening uses due to altering of the soil for that specific purpose.

    The panel members recognized that it is useful for the risk managers to look at site-related (or soil) risks versus total risks, and that the risk managers must decide which to use in making remediation decisions. One panel member noted that the US EPA Superfund program does *not* consider all non-site related sources of a contaminant in the forward-going risk calculation or the development of cleanup levels. It was noted that to do so would drive most cleanup levels for inorganics down to (and below) background levels. The panel member recalled the soil cleanup standards developed by the State of New Jersey in the early 1990s, which included the contribution from essentiality, resulting in many soil cleanup standards being adjusted to zero from negative numbers. Another panel member thought that drinking water should not be backed out, as it is a local source.

13. *Is it justified to ignore recent epidemiologic assessments that support the earlier reports of lung cancer among workers exposed primarily to water-soluble nickel species?*

    A. Epidemiology studies up to about 2004 have been introduced into the draft soluble nickel EPA IRIS documents. These studies suggest promotional effects of soluble nickel on carcinogenicity of other nickel species, rather than direct cancer effects. Likewise, the author team thinks that these newer studies support promotion. The panel ask the authors to contact EPA for anything more recent than 2004 (contact Dr. A. Bathija at EPA). The authors may need to explore further the impact of these newer studies with an epidemiologist.

14. *Clarification regarding speciation discussion. Have a sufficient number of samples been analyzed to address quantitative aspects of the metal species (particularly Ni_3S_2) of concern in the various media (soil, air filters)?*

    A. A panel member noted that the numbers of samples are small, but useful information can still be gained. However, issues with speciation also exist with the methods used to obtain these samples, which were more fully discussed at the meeting.