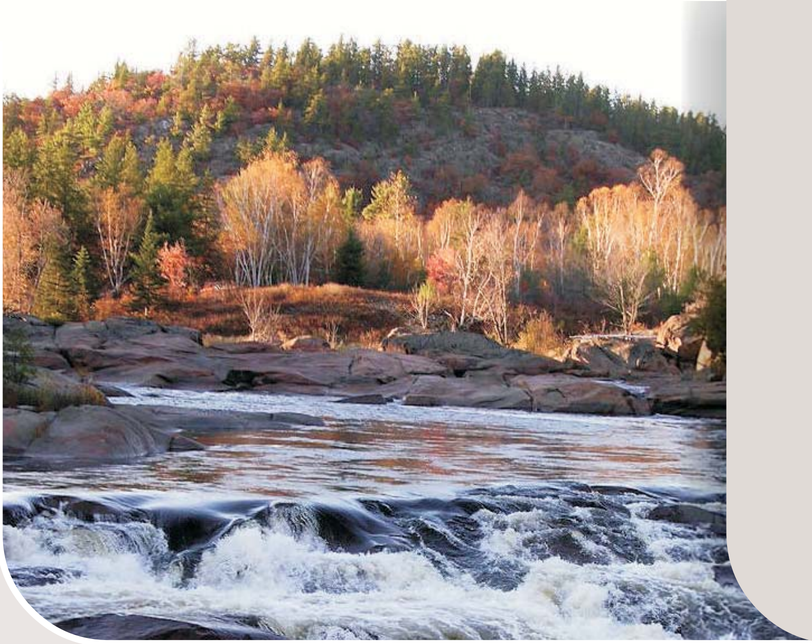

Sudbury Soils Study | Étude des sols sudburois

metals • health • environment
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# Summary of Volume II: Human Health Risk Assessment

May 2008

Prepared by:

SARA GROUP

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# Table of Contents

# Preface

The Sudbury Soils Study was conducted over a seven-year period from 2001 to 2008 and encompassed a 40,000 square kilometre study area. The purpose of this comprehensive scientific study was to determine whether the levels of metals in the study area environment pose a risk to humans, plants, or animals. The first two years of the study were devoted to developing and carrying out an extensive soil sampling and analysis program. The last five years focused on assessing the risks of historic and current airborne emissions from metal production operations on the health of area residents and on the local environment.

The complete *Sudbury Soils Study* will be comprised of three volumes:

*Volume I:* ............................*Background, Study Organization and 2001 Soils Survey;*

*Volume II:* ..............................................*Human Health Risk Assessment (HHRA);* and,

*Volume III:* ....................................................................*Ecological Risk Assessment (ERA)*.

This document provides a summary of the information in *Volume II: Human Health Risk Assessment* (HHRA). The Sudbury area HHRA was conducted over the five-year period from 2003 to 2008 by the Sudbury Area Risk Assessment (SARA) Group. The purpose of the HHRA was to evaluate current health risks to area residents from exposure to metals present in soil, air, drinking water, and food originating from air emissions from past and present local mining, smelting and refining operations. The intent of this document is to provide a summary report of the study process and conclusions of the HHRA. A list of acronyms and a glossary of terms can be found at the end of this report.

This document does not deal with risk management or remediation. These issues will be addressed in a *Risk Management Report* that is being prepared by Vale Inco and Xstrata Nickel, and will be made available to the public. Likewise, neither the HHRA nor this document addresses workplace exposures. Worker health and safety is addressed through ongoing programs at both mining companies and the Ontario Ministry of Labour.

The complete technical report (HHRA) including scientific approaches, technical information and detailed results is available for viewing at the offices of the Ontario Ministry of the Environment at 199 Larch Street in Sudbury, and at the public libraries in Greater Sudbury. Volume I has been released concurrently with Volume II. Volume III (ERA) will be released later in 2008, completing the Sudbury Soils Study. Electronic copies of the entire technical HHRA report and additional information are available online at **www.sudburysoilsstudy.com.**

# 1. Executive Summary

The purpose of this HHRA was to evaluate the potential for health risks to residents of the Sudbury area from exposure to metals in soil, air, drinking water and food that may be related to mining and smelting operations. The study was conducted between 2003 and 2008, and covered an area of 40,000 square kilometres, making it one of the largest and most comprehensive studies of its kind in North America.

Upon recommendation of the Ontario Ministry of the Environment (MOE), the HHRA was commissioned by Vale Inco and Xstrata Nickel and was administered by a multi-stakeholder Technical Committee. The Technical Committee was comprised of members from the MOE, the Sudbury & District Health Unit, the City of Greater Sudbury, Vale Inco, Xstrata Nickel, and the First Nations & Inuit Health Branch of Health Canada. An Independent Process Observer ensured that all stakeholders were given equal access and input to the process and that public interests were protected. A Public Advisory Committee facilitated community involvement and promoted the flow of information between the Technical Committee and the public. An Independent Scientific Advisor provided input to the Technical Committee to ensure that reliable scientific principles and methodologies were used to conduct the study.

More than 14,000 samples of soil, dust, water, air, vegetables, fish and blueberries were collected from the study area and analyzed for six chemicals of concern (COC): arsenic, cobalt, copper, lead, nickel, and selenium. The study was conducted by a group of scientists and independent consultants who joined together to form the Sudbury Area Risk Assessment (SARA) Group. The SARA Group used data collected from the study area to evaluate potential health risks to area residents.

A draft of the HHRA report was thoroughly reviewed by an Independent Expert Review Panel (IERP) comprised of six leading North American scientists who specialize in human health, toxicology, metal speciation, and risk assessment. The IERP agreed with the approach and assumptions used in the Sudbury HHRA.

**The main conclusions from the detailed human health risk assessment for the Greater Sudbury study area are as follows:**

1. Based on current conditions in the Sudbury area, the study predicted little risk of health effects on Sudbury area residents associated with metals in the environment.
2. There were no unacceptable health risks predicted for exposure to four of the six Chemicals of Concern studied: arsenic, copper, cobalt, and selenium.
3. The risk calculated for typical exposures to lead in the environment throughout the Greater Sudbury area are within acceptable benchmarks for protection of human health. However, levels of lead in some soil samples indicate a potential risk of health effects for young children in Copper Cliff, Coniston, Falconbridge and Sudbury Centre.
    - Lead levels in soil and dust in the Sudbury area are similar to levels in other older urban communities in Ontario.
4. The study calculated a minimal risk of respiratory inflammation from lifetime exposures (70 years) to airborne nickel in two areas: Copper Cliff and the western portion of Sudbury Centre.
    - Respiratory inflammation has been linked to the promotion of respiratory cancer caused by other agents.
    - Based on the conservative assumptions and approaches used in this risk assessment, it is unlikely that any additional respiratory cancers will result from nickel exposure over the 70-year lifespan considered in the risk assessment.
    - Health risks related to nickel inhalation were not identified in the other communities of interest.
5. Anglers, hunters and First Nations people who may consume more local fish and wild game are at no greater risk of health effects due to metals in the environment than the general population.

The SARA Group is confident that the study did not underestimate risks to the population of Greater Sudbury. The results and conclusions from this risk assessment will be used as the basis for risk management decisions in the Greater Sudbury area.

# 2. Background

## 2.1 Why was the Sudbury Soils Study conducted?

The rich mineral deposits in and around the City of Greater Sudbury in northern Ontario (Figure 2.1) have drawn people to the area for well over a century. The Sudbury area encompasses one of the largest known nickel ore bodies on Earth. This, along with a mining history of more than 125 years, continues to earn Sudbury international recognition as "The Nickel Capital of the World". Nickel and copper production in the Sudbury area have provided tremendous social and economic benefits to the region and to all of Canada.

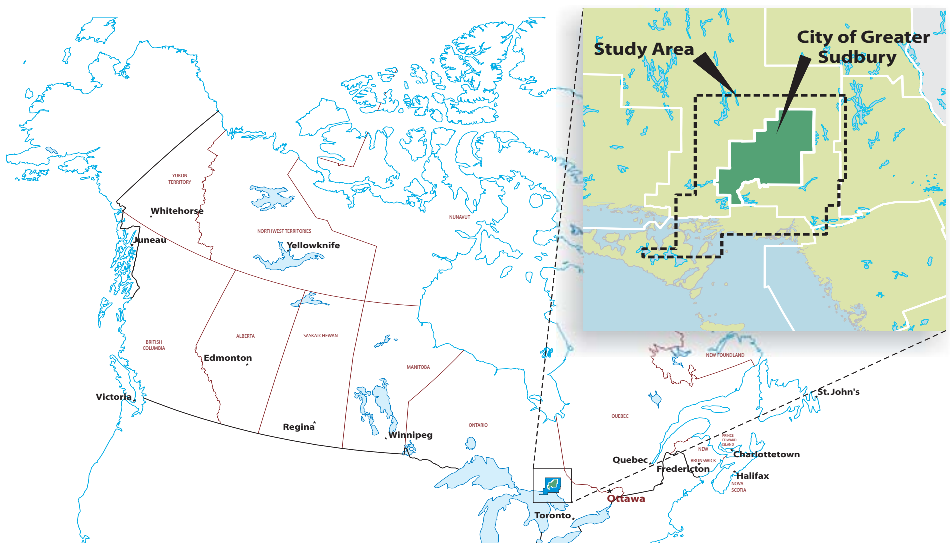


*Figure 2-1: The City of Greater Sudbury in Northern Ontario, Canada*

In addition to the benefits of mining, there are environmental consequences associated with smelting and refining operations over the past century. The Ontario Ministry of the Environment (MOE) and the two mining companies in the Sudbury area, Vale Inco (formerly Inco Ltd.) and Xstrata Nickel (formerly Falconbridge Ltd.), have conducted soil sampling programs across the region for more than 35 years. In 2001, the MOE published a report that reviewed and summarized the results of soil sampling programs conducted in the study area from 1971 to 2000. The MOE reported that in some areas of the region, levels of cobalt, copper, nickel, and arsenic did not meet provincial soil quality guidelines. These areas were generally near the historic metal production centres of Copper Cliff, Coniston, and Falconbridge. As a result of these findings, the MOE report recommended that:

1. A more detailed soil study be undertaken to fill information gaps from previous sampling programs; and,
2. Detailed human health and ecological risk assessments (HHRA and ERA) be conducted.

Both Vale Inco and Xstrata Nickel accepted these recommendations and, in 2001, the two companies voluntarily commissioned the Sudbury Soils Study (see Figure 2-2: Chronology of Events).

The first phase of the Sudbury Soils Study was a comprehensive soil sampling and analysis program that was undertaken in 2001 by the MOE and the mining companies. The data from this program provided up-to-date information on metal levels in study area soils and formed the basis of the risk assessment work to follow. The 2001 Soil Survey is summarized in Section 3.1.

The second phase of the study began in 2003 when comprehensive human health and ecological risk assessments were initiated. In particular, the HHRA was conducted to answer the question:

*Is there a health risk to people living in the study area from exposure to metals originating from air emissions from current and historic metal production operations in the region?*

In addition to air and soil, other possible sources of exposure were examined including fish, local fruit and vegetables, indoor dust and drinking water.

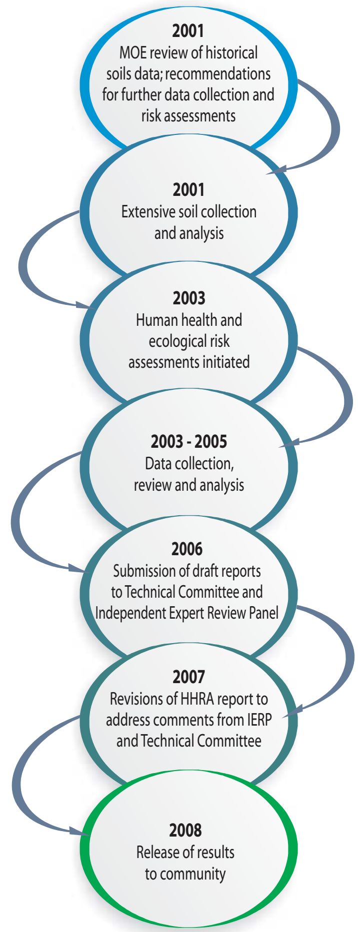


*Figure 2-2: Chronology of Events for the Sudbury Soils Study*

## 2.2 Who was involved in the Sudbury Soils Study?

The Sudbury Soils Study was initiated in the summer of 2001 following meetings between the MOE, the City of Greater Sudbury, the Sudbury & District Health Unit, and the two mining companies. It was important to the success of the study to involve all interested stakeholders, including local, regional, and provincial regulators, scientists, health experts, and members of the local community.

A **Technical Committee** (TC) was formed in 2001 to develop, guide, and implement all technical aspects of the Sudbury Soils Study. The TC includes members from the Ontario Ministry of the Environment, the Sudbury & District Health Unit, the City of Greater Sudbury, the First Nations and Inuit Health Branch of Health Canada, Vale Inco, and Xstrata Nickel.

The overall vision of the TC for the Sudbury Soils Study was to develop *"a transparent process that provides a thorough, scientifically sound assessment of environmental and health risks to the Sudbury community and effectively communicates the results so that future decisions are informed and valued."*

A number of measures and procedures were implemented to ensure that a transparent and scientifically rigorous study was conducted (See figure 2-3). These included the establishment of a Public Advisory Committee and a Communications Sub-committee, involvement of an Independent Process Observer, consultation with an independent Scientific Advisor, and review of a draft of the HHRA by an Independent Expert Review Panel (IERP). Each of these is discussed below.

Members of the PAC, the Canadian Auto Workers Union (representing Xstrata Nickel workers), and the United Steelworkers of America (representing Vale Inco workers) were also invited to attend and observe the TC meetings.

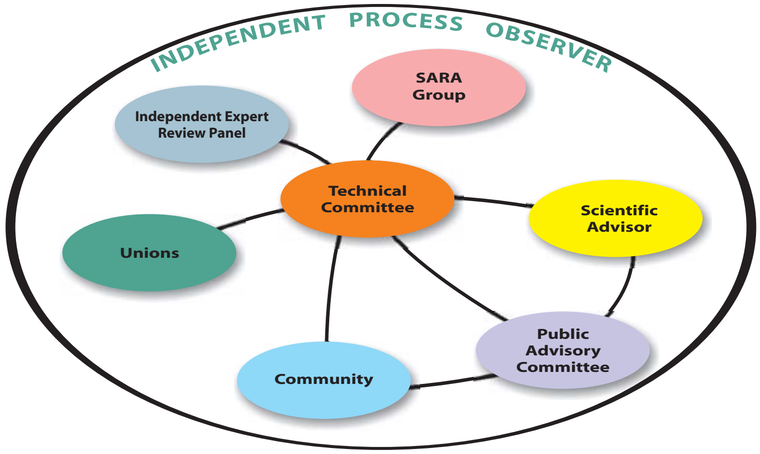


*Figure 2-3: Organization Linkages for the Sudbury Soils Study*

*As Independent Process Observer, Mr. Mariotti was given full autonomy to ensure that all TC members were given equal access and input to the process, and to represent the interests of the community.*

A **Public Advisory Committee** (PAC) was established in 2002 to facilitate community involvement and promote the flow of information between the TC and the public. The PAC was comprised of 10 to 15 volunteer citizens drawn from the study area.

A **Communications Sub-committee** (CSC) was formed in 2002 to help oversee communications and consultation initiatives for the Sudbury Soils Study. The CSC worked with the TC, the PAC, and the Independent Process Observer to ensure timely and effective public consultation. The CSC was comprised of communications professionals from the organizations represented on the TC, as well as members of the SARA Group and one member of the PAC. The mandate of the CSC was to foster community awareness and participation throughout the study process.

The **Independent Process Observer (IPO)** was retained to attend all TC and PAC meetings as well as any closed-door scientific meetings. The IPO was Mr. Franco Mariotti, a biologist and staff scientist at Science North and a respected member of the community. Mr. Mariotti observed all TC and sub-committee decisions. He published his observations in quarterly reports that were distributed to interested stakeholders and community members, and posted on the Sudbury Soils Study website.

The HHRA was conducted by the **Sudbury Area Risk Assessment (SARA) Group**. The SARA Group is an affiliation of several Ontario-based consulting firms specializing in the various scientific disciplines required to carry out a study of this broad scope. The main partners of the SARA Group are Gartner Lee Limited, Intrinsik Environmental Sciences Inc. (formerly Cantox Environmental Inc.), Rowan Williams Davies and Irwin Inc., SGS Lakefield, Goss Gilroy Inc., and Dr. Lesbia Smith, M.D.

The TC also enlisted a **Scientific Advisor** to independently review the development of the HHRA and to address questions and concerns from both the TC and the PAC. Dr. Ronald Brecher of GlobalTox International Consultants Inc. was chosen to provide support and guidance to the TC and PAC during the HHRA.

Given the TC's commitment to transparency and sound science in conducting the risk assessments, the draft HHRA report underwent a comprehensive review by an **Independent Expert Review Panel (IERP)**. The IERP was comprised of six leading North American scientists specializing in human health, toxicology, metal speciation, and risk assessment. The panel was formed and administered by *Toxicology Excellence for Risk Assessment (TERA)* an international not-for-profit organization located in Cincinnati, Ohio.

## 2.3 Public Consultation

Timely and effective public consultation was a priority for the Sudbury Soils Study partners. This was accomplished via several communication initiatives, including:

- Email and post mail updates to interested groups and individuals.
- The *Update* community newsletter, distributed periodically in local newsletters.
- Sudbury Soils Study website (*www.sudburysoilsstudy.com*).
- Toll-free phone line and email for interaction with the SARA Group.
- Quarterly IPO Reports.
- Public Question and Answer (*Q&A*) on the Sudbury Soils Study website.
- *Physician's Package* comprised of medical information on the chemicals of concern provided to Sudbury area physicians, nurses, and health care providers.
- Participation of the SARA Group in meetings of the TC, CSC, PAC, local interest groups, and local First Nations, namely Whitefish Lake First Nations and Wahnapitae First Nations.
- Media relations, including television, radio, and newspaper interviews with the SARA Group.
- *Have Your Say Workshops* held in Copper Cliff, Coniston, and Falconbridge to obtain detailed community input into the study and to ensure that community concerns were addressed.
- *Public Open Houses* to facilitate community updates and direct interaction of community members with the study partners.
- Telephone survey of a representative number of Sudbury area residents to evaluate the effectiveness of the communications initiatives and to assess public opinion of the Study.
- Recruiting Sudbury residents to participate in surveys and studies designed to collect Sudbury-specific data to be used in the HHRA. These included a food consumption survey, studies of metal levels in home garden vegetables, household dust, and drinking water in private wells.

*The Sudbury community made meaningful and significant contributions to the Sudbury Soils Study.*

Input provided by the community was invaluable in helping the SARA Group and the TC shape the study and the manner in which results were communicated to the public.

## 2.4 What is a Human Health Risk Assessment?

The term *risk* refers to the chance or likelihood that a particular event will occur. Human health risk assessment (HHRA) uses mathematical models to calculate the potential risk that a given population will experience adverse health effects from exposure to particular chemicals in the environment. The results of an HHRA are calculated risk predictions. Although they are based on real environmental data, the risk predictions are theoretical because they are calculated using models and assumptions about the population and their exposure to environmental chemicals. Human health risks are calculated based on three factors (Figure 2-4):

1. The known toxicity of the identified chemical(s);
2. The sensitivity of the exposed group of people (or *receptor*); and
3. The existence of a complete exposure pathway (through swallowing, breathing, or skin contact) for people to come in contact with the chemical, and the frequency and duration of exposure.

*The standard models and assumptions used in HHRA are designed to be conservative, or protective, of human health because they tend to overestimate rather than underestimate risks to the population.*

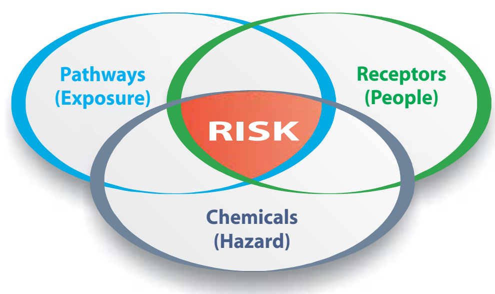


*Figure 2-4: Combination of Factors Contributing to Health Risk*

*Human health risk assessments do not measure health outcomes. An HHRA calculates potential risk to human health from exposure to substances in the environment.*

There is a potential for health risks if the amount of exposure or *dose* of a chemical received by a population is greater than a level that is considered 'safe' or permissible. Permissible levels of exposure are set by regulatory agencies to be protective of public health, based on a thorough review of current scientific evidence and existing regulatory policies.

HHRA combines knowledge of specific chemicals, exposure pathways, and receptors to make predictions about human health risks to populations living in (or visiting) a particular area. The relevance and accuracy of any risk prediction depends on the quantity and quality of available information for all three factors (chemicals, exposure pathways, and receptors). The more comprehensive and site-specific the information used in the HHRA, the more confident scientists can be that their predictions reflect actual risks to the population.

By design, the HHRA is a conservative process. The predicted risks using the HHRA process do not equate to actual human health outcomes. However, predicted risks indicate a need for further investigation and perhaps mitigation to reduce exposure.

## 2.5 How is a Human Health Risk Assessment Conducted?

Several federal, provincial, and state regulators provide guidance on conducting risk assessments, including Health Canada, the United States Environmental Protection Agency (U.S. EPA), and the MOE. The Sudbury area HHRA is geographically the largest study of its kind in Canada. The study area covered approximately 40,000 square kilometres (an area the size of Switzerland) and involved multiple stakeholders and property owners. Although there was no guidance available at the time for conducting area-wide studies of this size, the Sudbury area HHRA followed the risk assessment framework recognized by the MOE, Health Canada, and the U.S. EPA. The risk assessment framework includes the following four components as shown in Figure 2-5:

1. *Problem formulation*

   This is an information gathering and interpretation stage that focuses the scope of the risk assessment and characterizes the study area in detail. This component also identifies Chemicals of Concern (COC), people or *receptors* who may be exposed to the COC, the pathways by which people may come into contact with the COC, and any information gaps that may exist.

2. *Exposure assessment*

   This component involves using a precautionary and conservative approach to calculate the amount, or *dose,* of a COC that people may receive. All potential exposure pathways are considered. Site-specific data (samples of air, soil, dust, drinking water, local fruit and vegetables, and fish) were collected as part of this study, providing measured metal levels in the study area environment that were used to calculate exposures for each COC.

3. *Hazard assessment*

   This stage involves an evaluation of the COC and the adverse health effects that might occur under the exposure conditions that may be experienced by study area residents. This is also the point at which permissible doses (or toxicity reference values) are determined. These are levels of exposure or doses approved by regulatory agencies, which are protective of human health.

4. *Risk Characterization*

   At this stage of the HHRA, risks are predicted based on a comparison of calculated doses (from the exposure assessment) with permissible doses (from the hazard assessment) for each COC.

Where the HHRA predicts risk, risk managers must determine what can be done to reduce it. While the HHRA provides useful information for risk managers, risk management decisions are typically made separately from the HHRA process.

*HHRA is a tool that is used to rule out risks that are insignificant and to focus risk management efforts on the most important areas and issues of concern.*

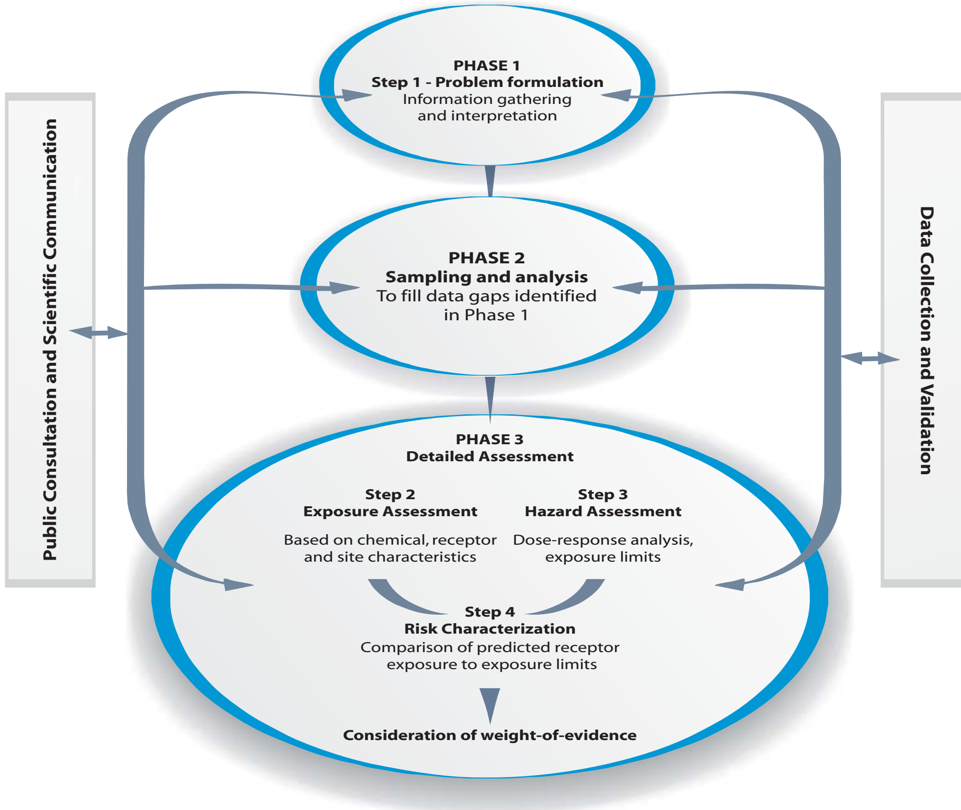


*Figure 2-5: Three Phases of the Sudbury Area HHRA*

## 2.6 Weight-of-Evidence Approach for Human Health Risks

In characterizing human health risks, information beyond the calculated risk predictions from the HHRA should also be carefully considered. Additional information or lines of evidence may help provide context for risk predictions calculated in the HHRA. Such information could include public health data on the prevalence of a particular health effect, community health surveys, biological monitoring studies, and published scientific information. The evaluation of these lines of evidence and their relative strengths and weaknesses can then be used to either support or refute the calculated risk predictions.

Both the quality and the quantity of evidence that is used to characterize calculated risk predictions should be taken into consideration. This process of scientifically evaluating and incorporating additional information into human health risk assessment is known as a *weight-of-evidence approach*.

## 2.7 Understanding the Results

The purpose of the Human Health Risk Assessment was to evaluate the health risks associated with exposure to six COC within the Sudbury area. This evaluation resulted in a series of numerical estimates of risk, calculated by a team of scientists using sophisticated equations, detailed exposure models and the latest information on the toxicity of each chemical.

Later in this report, we discuss the health risks associated with exposure to metals in the study area, which are expressed for two potential health outcomes or end-points: cancer and non-cancer health effects.

**Non-carcinogens**

The numerical risks calculated for non-cancer health effects are expressed as a Hazard Quotient (HQ). If the HQ value is less than 1, health effects are not expected and the risk is considered negligible. If the HQ value is greater than 1, risk cannot be ruled out and further study may be warranted (see Section 3.3.3 for further discussion of HQ).

**Carcinogens**

To provide a consistent framework of relative risks reported in this study, we have adopted the terminology suggested by recognized experts in the field of risk communication (Calman, 1996; Paling 2003). The terms associated with different levels of numerical risk are described below as defined by Calman (1996):

- **High:** risks may be fairly regular events and would occur at a rate greater than 1 in 100. They may also be described as *frequent, serious* or *significant*.

- **Moderate:** This term relates to a risk of between 1 in 1,000 and 1 in 100. This would apply to a wide range of medical procedures and environmental events.

- **Low.** This relates to a predicted increased risk of between 1 in 10,000 and 1 in 1,000. Again many risks of clinical procedures and environmental hazards fit into this broad category. Other words that might be used include *reasonable, tolerable* and *small*.

- **Very Low:** This describes a risk between 1 in 100,000 and 1 in 10,000; many healthcare interventions have adverse effects that are in this range.

- **Minimal:** This refers to a risk that is in the range of 1 in 1 million to 1 in 100,000 and that the conduct of normal life is not generally affected as long as reasonable precautions are taken to minimize exposure. Some policy makers consider a probability of anything less than 1 in 100,000 as *acceptable*.

- **Negligible:** This describes an adverse event occurring in less than 1 per 1 million episodes. While still important to identify and monitor, such a risk would be of little concern for normal living. Other words that could be used in this context are *remote* or *insignificant*.

These definitions may be useful in understanding the relative risks expressed in the conclusions of this report.

# 3. The Sudbury Area HHRA

The SARA Group used the risk assessment framework in conjunction with a weight-of-evidence approach to assess risks of metals emitted from mine, smelter and refining facilities to people living in the study area.

The following sections of this report describe the activities and results associated with each of the three phases of the Sudbury area HHRA. The final sections provide the results of the HHRA.

## 3.1 Phase 1: Problem Formulation

In this phase of the HHRA, scientists reviewed available background information, which helped to focus the approach of the study and lay the foundation for the HHRA. The following sections describe each of the problem formulation tasks (study area description, identification of receptors, chemicals of concern, exposure pathways, and information gaps) as completed for the Sudbury area HHRA.

*Refer to Volume I of the Sudbury Soils Study report for a more complete description of the history of mining in the area and effects of metal emissions on the landscape.*

### 3.1.1 Study Area History and Description

The study area is defined by the bounds of the 2001 Soil Survey. It encompasses a large geographic region of approximately 40,000 square kilometres. The study area includes the City of Greater Sudbury and captures a diverse natural environment including over 300 lakes, wetlands, wildlife habitats, and vegetation communities.

Naturally occurring copper and nickel deposits were discovered in the Sudbury basin in 1883 as the railway was being built through the Murray area near Sudbury. The Canadian Copper Company started mining at Copper Cliff in 1886 and began operating the region's first smelter in 1888. Since that time, mining activities continued to expand in the area and significantly influenced the local economy.

Initially, open roast yards were constructed for recovering nickel and copper from the mined ores. In the early 1900s, nearly all woody vegetation had been removed from the vicinity of the roast yards to provide fuel for the roasting process. It is estimated that more than 3.3 million cubic metres of wood were burned in the roast yards (equivalent to 17 football fields stacked 100 feet high). Over the 40-year history of the roast yards, researchers estimate that 10 million tons of sulphur dioxide were released from the ores.

Extensive logging and ore roasting activities dramatically changed the Sudbury landscape. The loss of vegetation resulted in extensive soil erosion that, combined with ongoing metal production facility emissions, prevented the natural regeneration of the forests that once covered the Sudbury bedrock. Early facility emissions consisted of larger and heavier particles that settled more rapidly and closer to the emission sources, compared with later emissions containing smaller and lighter particles that settled more slowly, drifting further from the production sites. The impact of historic facility emissions is therefore greater closer to the production sites. Inco Ltd. closed the smelter operation at Coniston in 1971. Vale Inco and Xstrata Nickel still operate facilities in the towns of Copper Cliff and Falconbridge, respectively.

### 3.1.2 Communities of Interest

The TC identified Copper Cliff, Coniston and Falconbridge as communities of interest because they are the locations of current and/or historic metal production. Sudbury Centre was chosen as an additional community of interest because it has the most concentrated residential population within the study area, and it is central to the three metal production facilities. Finally, Hanmer was included because it represents a local community that is not directly impacted by COC emissions from the mining facilities. Therefore, Hanmer can be used as a local background reference for comparison with the other communities of interest.

The populations of two First Nations communities (Whitefish Lake and Wanapitei) were also included in the HHRA as anglers/hunters living in the communities of interest.

### 3.1.3 The 2001 Soil Survey

*Over 8,400 soil samples from 1,190 locations were collected throughout the study area during the 2001 Soil Survey. Each sample was analyzed for 20 different metals/chemicals.*

The three studies (two funded by the mining companies and one by the MOE) that comprised the 2001 Soil Survey are discussed briefly below.

The *regional soil survey* completed by Laurentian University focused on collecting soil samples to determine the extent of the metal production facilities *footprint* (ground area that may have been affected by facility emissions). Remote and undisturbed areas were also sampled to determine background levels of metals naturally occurring in the local soils. The results of this sampling program defined the boundaries of the study area.

The *urban soil survey* was conducted by the MOE and focused on sampling soils from schools, daycare centres, parks and beaches throughout the study area, as well as from 439 residential properties.

The *Falconbridge soil survey*, completed by Golder Associates Ltd., focused on collecting soil samples from the Town of Falconbridge and some surrounding municipal and crown lands.

The results of the 2001 survey are summarized in Table 3-1. The values in Table 3-1 combine data for samples collected at different depths. The detailed metal concentration data collected for the Soil Survey provided the basis for the risk assessment studies that followed.

The data show localized areas containing elevated levels of some metals in soil. These areas are generally centered on the City of Greater Sudbury in the vicinity of the three metal production centres of Copper Cliff, Coniston, and Falconbridge. Concentrations of the elements are generally higher in surface soils (0 to 5 cm) than deeper soil layers, indicating that atmospheric deposition from the production facilities is a source of metals to the soils. Further details of the 2001 Soil Survey are available in separate reports (SARA Group, 2007 -Volume I, Chapters 7, 9, and 10; CEM, 2004; MOE, 2001).

**Table 3-1: Summary of 2001 Soil Survey Results for 20 Elements**

| N = 8148 [1] | Concentration in Soil (mg/kg) [2] | | | |
|---|---|---|---|---|
| | **Minimum** | **Average** | **Maximum** | **MOE Guideline [4]** |
| Aluminum | 2100 | 10400 | 39000 | NC [4] |
| Antimony | 0.4 | 0.48 | 8.1 | 13 |
| **Arsenic** | 2.5 | 16 | 620 | 20 |
| Barium | 9.8 | 56 | 720 | 750 |
| Beryllium | 0.25 | 0.61 | 2 | 1.2 |
| Cadmium | 0.4 | 1 | 6.7 | 12 |
| Calcium | 470 | 5165 | 250000 | NC[4] |
| Chromium | 9 | 34 | 1100 | 750 |
| **Cobalt** | 1 | 14 | 190 | 40 |
| **Copper** | 2.7 | 260 | 5600 | 150 |
| Iron | 4400 | 16327 | 110000 | NC |
| **Lead** | 1 | 35 | 790 | 200 |
| Magnesium | 350 | 3065 | 26000 | NC |
| Manganese | 33 | 211 | 3300 | NC |
| Molybdenum | 0.75 | 1 | 21 | 40 |
| **Nickel** | 7 | 264 | 3700 | 150 |
| **Selenium** | 0.5 | 2 | 49 | 10 |
| Strontium | 5 | 35 | 340 | NC |
| Vanadium | 8 | 31 | 130 | 200 |
| Zinc | 1.25 | 44 | 340 | 600 |

[1] N = number of samples analyzed
[2] mg/kg = milligrams per kilogram or parts per million
[3] MOEE (1997) Table A criteria. Guidelines are set "to protect against adverse effects to human health, ecological health and the natural environment".
[4] NC = no criterion
**Bold font indicates Chemical of Concern (see next section)**

## Selecting Chemicals of Concern

Since not all of the chemicals detected in a given area will pose a risk to human health or the environment, it is not necessary to conduct a detailed risk assessment for each one present. The process of selecting the chemicals that have the greatest potential health or environmental impacts is known as *screening*. During the screening process, levels of chemicals measured in the study area are usually compared with regulatory guidelines.

To identify the chemicals of concern (COC) for the study area, metal levels in the soil samples were compared with soil quality guidelines published by the MOE in their *Guideline for Use at Contaminated Sites in Ontario* (MOEE, 1997). Soil quality guidelines are set by the MOE "to protect against adverse effects to human health, ecological health and the natural environment" (MOEE 1997).

Only the chemicals present in soils at levels higher than the soil quality guidelines were selected as COC. Exceedance of the guidelines does not necessarily mean there is an actual risk to human health, and does not imply the need for remediation or cleanup. Three criteria were established by the Technical Committee for COC screening:

1. The chemical must be present at levels higher than the MOE soil quality guideline;

2. The chemical must be present across the study area; and,

3. The chemical must be associated with the mining companies' operations.

Screening of the data collected in the 2001 Soil Survey identified six COC for the HHRA: arsenic, cobalt, copper, lead, nickel and selenium. The COC screening process is illustrated in Figure 3-1.

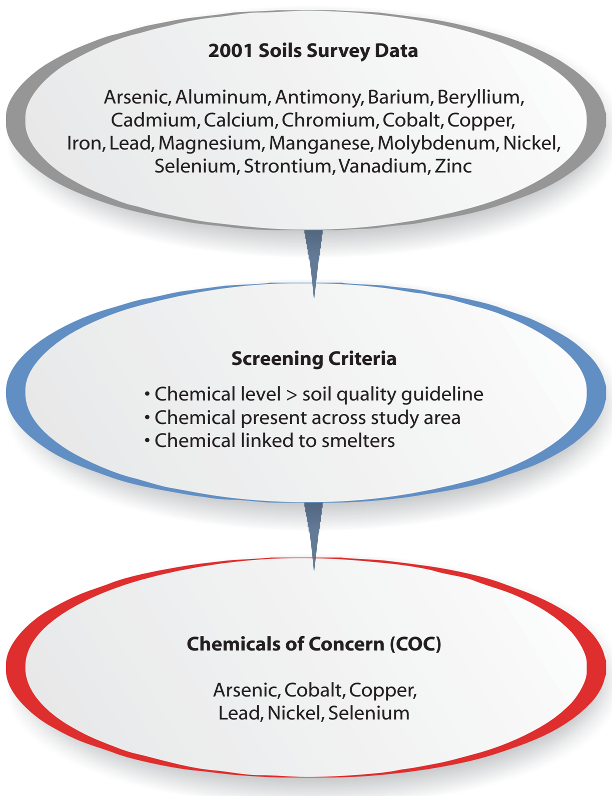


*Figure 3-1: COC Screening Process*

### 3.1.4 Health Effects Associated with COC Exposure

The six COC are naturally present in small amounts in food, drinking water, air and soil. Therefore, people are exposed to low levels of these COC in their everyday lives. The health effects of exposure to any chemical may vary depending on the level and duration of exposure, how one is exposed, individual traits and habits, and whether there is exposure to other chemicals at the same time. Detailed fact sheets produced by the MOE are available for most COC.

It is important to note that the current information on health effects of COC exposure comes primarily from animal studies (mice, rats, rabbits) and studies on workers who have been exposed in the workplace. In both cases, the doses causing the noted effects are much higher than those that would typically occur in the environment. Furthermore, in cases where only animal studies are available, toxic effects observed in animals are often presumed to occur in humans, even when these effects have not been observed in humans. This assumption is made as a precautionary measure in the interests of protecting public health.

***Arsenic***

*Exceedance of the MOE soil quality guidelines identifies the need for further study in the form of a risk assessment.*

Food is normally the largest source of exposure to arsenic. Most of the arsenic absorbed into the bloodstream is converted to a relatively non-toxic form and released in the urine. Some studies show that long-term exposure to *inorganic* arsenic may increase risks of certain cancers.

A detailed profile of arsenic and its health effects is provided as a detailed appendix in the Sudbury Soils Study Volume II: Human Health Risk Assessment. Fact sheets are also available on the MOE website at: http://www.ene.gov.on.ca/cons/3792e.htm

***Cobalt***

Food and drinking water are the largest sources of background exposure to cobalt. Cobalt is required for the production of vitamin B12 and is therefore necessary in small amounts for good health. Exposure to very high levels of cobalt can cause effects on the heart and lungs as well as skin irritation. Based on animal studies, cobalt has the potential to cause cancer, but this has not been demonstrated in humans.

A detailed profile of cobalt and its health effects is provided as a detailed appendix in the Sudbury Soils Study Volume II: Human Health Risk Assessment. Fact sheets are also available on the MOE website at: http://www.ene.gov.on.ca/cons/3793e.htm

***Copper***

Drinking water may contain copper if the water is acidic and travels through copper pipes or brass fittings. Skin contact with copper or copper-containing materials is also a source of exposure. Copper is an essential element that is required in small amounts for good health. However, exposure to very high levels of copper may cause damage to the liver and kidneys.

A detailed profile of copper and its health effects is provided as a detailed appendix in the Sudbury Soils Study Volume II: Human Health Risk Assessment. Fact sheets are also available on the MOE website at: http://www.ene.gov.on.ca/cons/4141e/htm

***Lead***

In addition to industrial activities, sources of lead in the environment may include old plumbing, leaded gasoline, lead-based paints, window blinds, toys, batteries, and other household consumer products. The main target for lead toxicity is the nervous system. Children are more susceptible to effects from lead exposure than adults. Children exposed to lead can experience nervous system effects such as reduced muscle-coordination and intellectual development. Some of the health effects associated with lead have been found at levels observed in many older urban areas.

A detailed profile of lead and its health effects is provided as a detailed appendix in the Sudbury Soils Study Volume II: Human Health Risk Assessment.

***Nickel***

Food is the major source of background exposure to nickel. Skin contact with nickel-containing soil, water or metals (such as coins and jewellery) is also a source of exposure. Most people are not sensitive to typical levels of nickel found in the environment. However, some individuals can become sensitive to nickel after long periods of constant contact with objects (usually jewellery) that contain nickel. The most common effect of this sensitization is a skin rash. Potential health effects of nickel differ depending on the route of exposure (inhalation, ingestion or skin contact). Historically, some workers who inhaled high levels of nickel over time developed lung inflammation, fibrosis, and respiratory cancers. In all of these cases, effects were observed at nickel exposures far higher than those normally found in the environment.

A detailed profile of nickel and its health effects is provided as a detailed appendix in the Sudbury Soils Study Volume II: Human Health Risk Assessment. Fact sheets are also available on the MOE website at: http://www.ene.gov.on.ca/cons/4017e.htm

***Selenium***

The most important source of background selenium exposure is food, followed by drinking water. Selenium is an essential element that is required in small amounts for good health. However, high exposures to selenium can cause hair loss, brittle nails, and effects to the heart, lungs, and nervous system. Selenium exposures that would cause these effects are higher than those typically found in the environment.

A detailed profile of selenium and its health effects is provided as a detailed appendix in the Sudbury Soils Study Volume II: Human Health Risk Assessment.

### 3.1.5 Human Receptor Groups Within the Communities of Interest

Risks from COC exposure may differ depending on general physical and behavioural characteristics of the receptor being evaluated. Several characteristics influence exposure, including body weight, breathing rate, food and drinking water consumption rate, amount of time spent outdoors, and others. These factors vary depending on the life stage (age) of the receptor. For example, toddlers tend to have more direct contact with soil and dust due to behavioural characteristics such as crawling and playing on the ground, and their tendency for hand-to-mouth activity. Potentially higher COC exposures, combined with the toddler receptor's small body size, tend to result in toddler receptors being the most highly exposed life stage in human health risk assessments.

Aside from differences due to life stage, people living in the same area may have different exposures to COC based on differences in their lifestyle and activities. For example, anglers, hunters, and First Nations people tend to consume more local fish and game than other members of the community. Therefore, if local fish and game contain higher levels of COC than those from outside the study area, these groups might be expected to experience higher COC exposures. To account for this possibility, risks to anglers, hunters, and First Nations people living within each community of interest were assessed using higher rates of local fish and game consumption.

In addition to evaluating risks for residents within the five communities of interest, a *Typical Ontario Resident* was also evaluated for comparison purposes. In this case, available regulatory and scientific information was used to evaluate background risks to Ontario residents living outside of the study area.

*Seafood contains significant amounts of arsenic, but most of this is in a relatively non-toxic form (arsenobetaine).*

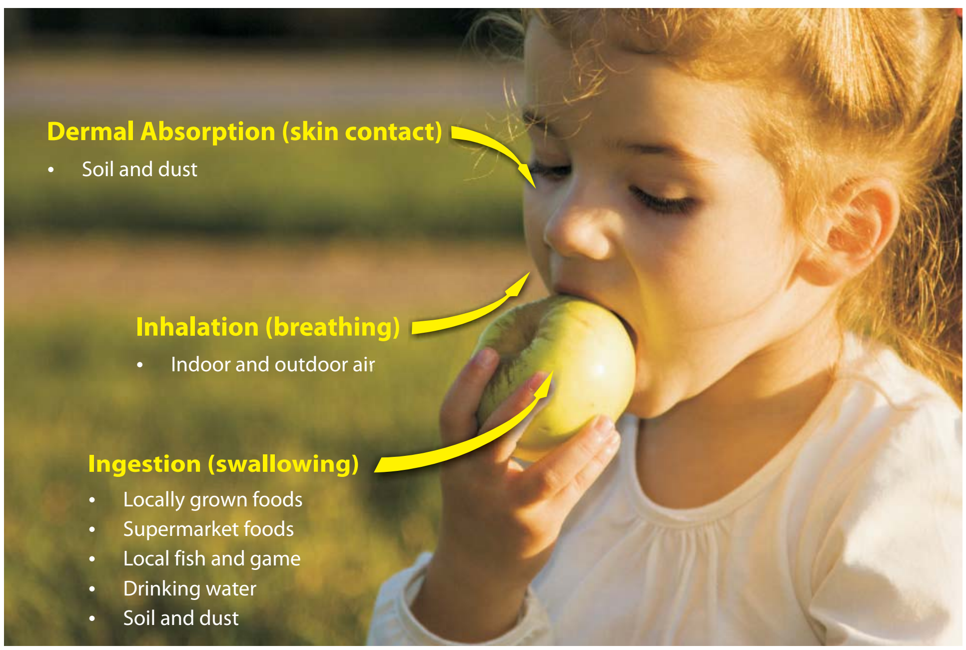


*Figure 3-2: Exposure Pathways Assessed in the HHRA*

### 3.1.6 Exposure Routes and Pathways

Although the initial trigger for conducting the HHRA was elevated COC levels in soil, all exposure routes and sources were considered in assessing risk to area residents. There are three primary routes by which people may come in contact with chemicals:

- Inhalation (breathing);
- Ingestion (swallowing); and
- Dermal (skin contact).

Within the three main exposure routes, several different sources of exposure to COC were evaluated for the Sudbury area HHRA. The various combinations of routes and sources of exposure comprise the *exposure pathways* by which people may be exposed to COC. These are illustrated in Figure 3-2.

### 3.1.7 Information Gaps

As a result of the 2001 Soil Survey, the SARA Group had access to extensive data for COC levels in soil within the study area. However, information was lacking for COC concentrations in other media such as local food items, drinking water, and air. These were identified as information gaps that needed to be filled in order to make the most accurate risk predictions possible. In particular, the SARA Group recommended that more information be collected on levels of COC in:

- Outdoor air;
- Homegrown fruits and vegetables;
- Wild blueberries and mushrooms;
- Local fish;
- Indoor dust; and
- Drinking water from private wells and local lakes.

In addition, information was collected on the different chemical forms of the metals (*speciation*) present and on how much might be able to enter into the bloodstream to have an effect (*bioaccessibility*).

*The five different life stages were considered in the Sudbury area HHRA:*
*- Infant (0 to < 6 months);*
*- Toddler (6 months to <5 years);*
*- Child (5 to <12 years);*
*- Adolescent (12 to 20 years); and,*
*- Adult (>20 years).*

## 3.2 Phase 2: Sudbury-specific Sampling and Analyses

Extensive survey and sampling programs were undertaken from 2003 through 2005 to gather the Sudbury-specific data information needed to complete the HHRA. The collection of this information was necessary to ensure that the final risk predictions were as accurate as possible. The following sections outline the sampling and survey programs that were carried out for the HHRA.

### 3.2.1 Air Monitoring Program

Metals are emitted from the smelting and refining facilities as small particles that are then transported in air currents. It is these particles, or *particulate matter (PM),* that must be collected and analyzed to measure the levels of COC in air. Particulate matter filtered from the air and samples was analyzed for a variety of metals, including each COC. Different particle sizes were analyzed separately for metals since the size of the particle determines how far it can travel into the respiratory tract and lungs.

### 3.2.2 Food Consumption Survey

A food consumption survey was conducted to collect detailed information on the types and amounts of local foods consumed by Sudbury residents. In addition to the general population of residents, this information was also collected for smaller *subpopulations* that might be more exposed to COC due to higher consumption of local foods (such as First Nations people, hunters and anglers, and gardeners).

The results of this survey were used in combination with data from larger national surveys (such as Health Canada, 2006) to determine how much of the total food consumption comes from local sources. These local food consumption rates were then used in the HHRA to calculate COC doses received from eating supermarket and locally produced food.

*A total of 1,200 air samples were collected from 10 locations (Figure 3-3) within the study area over a one-year period (October 2003 to September 2004).*

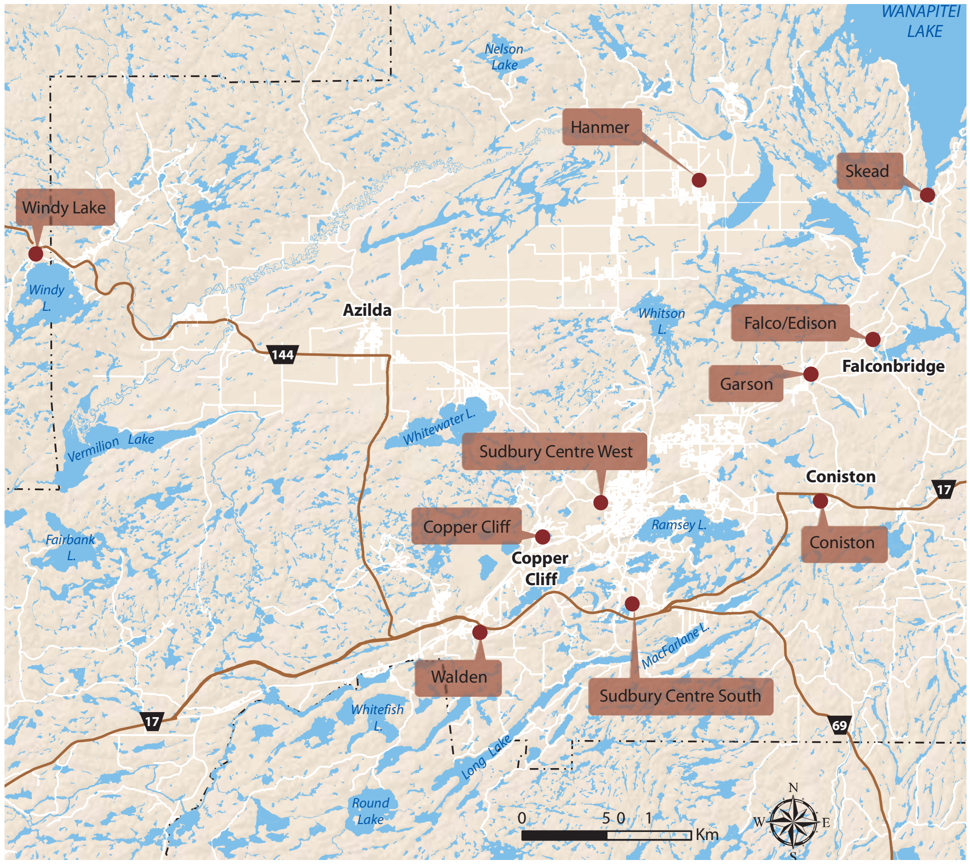


Figure 3-3: Air Monitoring Sites

*Information on consumption of local fish, game and home-grown vegetables was collected through telephone and personal interviews of 497 households (a total of 1,444 individuals) in the study area.*

### 3.2.3 Vegetable Garden Survey

The vegetable garden survey was conducted from May through October 2003 to determine the range of COC levels found in locally grown vegetables and fruit. Below-ground vegetables (such as potatoes, carrots), above-ground vegetables (such as lettuce, tomatoes), wild blueberries and mushrooms were collected for analysis.

### 3.2.4 Local Fish and Livestock Survey

The fish and livestock surveys were conducted to calculate doses of COC from consumption of fish from local lakes and locally raised livestock. A total of 145 fish (perch and walleye) were collected from eight lakes within the study area. Samples were also collected from 10 beef cattle that were raised in the study area for private consumption. The results of these two surveys were used, along with the information from the food consumption survey, to estimate doses of COC from consuming local fish and livestock.

### 3.2.5 Drinking Water Survey

Most of the households in the Study area receive their water from municipal water supplies that are regularly monitored for a variety of metals, including the COC. Therefore, exposures to COC from municipal water supplies could be estimated from existing data. However, levels of COC in private wells and surface water supplies were not known. Therefore, drinking water was sampled at 94 residences with private water supplies, including 76 wells and 18 lake water sources.

### 3.2.6 Indoor Dust Survey

Indoor dust represents an important exposure pathway, particularly for toddlers who tend to spend time in contact with floors and carpets. The purpose of the indoor dust survey was to measure levels of COC that may be contained in dust in area homes and schools. Soil samples were also taken from areas outside the buildings to see whether there was any relationship between levels of COC in indoor dust and outdoor soil. The results of the indoor dust survey were used in the HHRA to determine COC doses from ingestion and dermal contact with indoor dust.

*Dust samples were analyzed from 91 homes in the five communities of interest and eight schools in the Rainbow District School Board.*

### 3.2.7 Falconbridge Arsenic Exposure Study

The arsenic exposure study was conducted to address community health concerns related to elevated levels of arsenic in soil at some residential properties in Falconbridge. This study was funded by Xstrata Nickel and conducted separately from the Sudbury Soils Study. However, the results were considered in the weight-of-evidence for characterizing arsenic risks in the HHRA.

The study was designed to answer two questions:

1. Do Falconbridge residents have higher levels of arsenic in their bodies than residents living in a similar area with lower levels of arsenic in their soil?

2. Are arsenic levels in Falconbridge residents associated with human health risks?

*Residents of Falconbridge are not at any greater risk for arsenic-related health effects than other residents of the province.*

Arsenic exposure can be evaluated by measuring arsenic levels in urine. More than 700 residents of Falconbridge and Hanmer (the comparison community) provided urine samples and information on lifestyle and behaviours that might affect arsenic exposure. The arsenic study showed that Falconbridge residents did not have higher urinary arsenic levels than residents in the comparison community, despite higher arsenic levels in soil. These results indicate that health risks for arsenic are no different for Falconbridge residents compared to Hanmer or typical Ontario residents.

### 3.2.8 Bioaccessibility Studies

The term *bioaccessibility* refers to the portion of the total amount of a chemical that is available to be absorbed into the bloodstream. Whether a COC is able to be absorbed into the bloodstream depends on its chemical form. Once in the bloodstream, the chemical can be circulated to other areas of the body where it can cause a biological effect.

It was important to account for bioaccessibility in the Sudbury HHRA because each COC contained in soil and dust particles may be present in a variety of different chemical forms. Some of these forms can be absorbed into the bloodstream while others can not. In this study, laboratory analyses of soil and dust particles were conducted to determine the levels of COC that were available for human exposure.

### 3.2.9 Speciation Studies

Metals are found in different forms in the environment. *Speciation* is the process of determining the proportions of actual chemical forms of a metal found in a sample. It is important to *speciate* metals in samples because the chemical form of the metal can affect the bioavailability and relative toxicity of the metal. For example, two forms of nickel found in air - nickel oxide and nickel subsulphide - are associated with respiratory cancers, but with different potencies. Therefore, it was important to determine how much of each of these forms was present in air when evaluating cancer risks from nickel.

*The detailed assessment examined over 200 combinations of exposure and receptors.*

Speciation studies were also used to determine whether certain metal species originated from mine facility emissions. This is because metals from different sources are present in the environment in different characteristic forms, reflective of their source.

The numerous surveys, sampling programs and studies conducted for this HHRA provided a wealth of detailed Sudbury-specific information. Incorporation of these data into the HHRA significantly increased the accuracy of, and confidence in, health risk predictions for study area residents.

## 3.3 Phase 3: Detailed Assessment

The third and final phase of the HHRA involved combining all of the information collected in the previous two phases to predict health risks to study area residents from COC exposure. The HHRA evaluated human health risks for:

- All forms of six chemicals of concern (arsenic, cobalt, copper, lead, nickel, and selenium);
- Three exposure routes (oral, dermal, inhalation);
- Multiple sources of exposure (soil, dust, air, drinking water, diet);
- Both cancer and non-cancer health effects;
- Two exposure levels (average and maximum);
- Two genders (males and females);
- Five life stages (infant, toddler, child, adolescent, adult) and entire lifetimes;
- Two groups, (general study area population and subpopulation of hunters/ anglers/First Nations), in each of
- Five communities of interest (Coniston, Copper Cliff, Falconbridge, Sudbury Centre, and Hanmer).

The three components of the detailed assessment – exposure assessment, hazard assessment, and risk characterization - are described in the following sections.

### 3.3.1 Exposure Assessment

The exposure assessment uses all of the available information collected about people and COC levels to estimate the total dose of each COC received by each type of receptor (male and female infants, toddlers, children, adolescent, and adults).

Exposures from each potential source (soil, water, air, food) and each potential pathway were calculated for each route of exposure (swallowing, breathing, skin contact) to determine the dose of each COC received by each type of receptor. The exposure pathways assessed in the Sudbury area HHRA are shown in Figure 3-4, along with the source of information used to evaluate each pathway.

*Actual exposures to COC are lower than the total amount of COC measured in soil and dust, because not all forms can be absorbed into the bloodstream.*

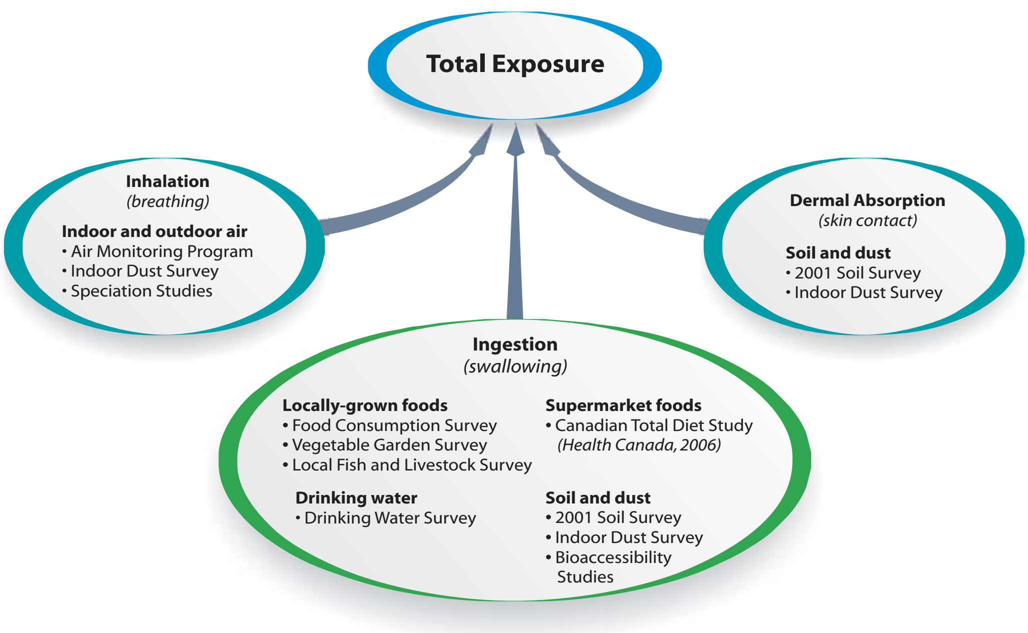


*Figure 3-4: Exposure Pathways Assessed and Sudbury-specific Data Used in the HHRA*

The physical and behavioural characteristics of different receptor groups directly affect their exposures to COC. Extensive population studies from the literature provide well-defined ranges of values for each of these characteristics (such as body weight, breathing rate, skin surface area, food consumption rates, *etc.*) for each life stage (infant, toddler, child, adolescent, adult) evaluated in the HHRA. Most of this information has been collected through census responses and similar surveys and is available from government sources, including Health Canada and the U.S. EPA.

The exposure assessment used this information, in combination with the Sudbury-specific data on COC levels in air, food, water and soil, to estimate doses for each receptor life stage within each community of interest. Both an *average* and a *maximum dose* were calculated for each receptor group and each COC in each community of interest. Average doses were calculated to estimate typical exposures of the general population to each COC. Maximum doses were calculated to represent a *worst-case scenario* that would ensure that the HHRA accounted for receptor groups who may be more highly exposed to the COC than the general population because of specific behavioural patterns.

For health effects other than cancer, the pre-school toddler (six months to five years of age) is typically the receptor group with greatest potential exposure to the COC. This is because of the small body size of the toddler receptor and typical young child behaviours (such as playing in soil, hand-to-mouth activities, *etc.*) that can result in higher COC exposure.

### 3.3.2 Hazard Assessment

The term *toxicity* refers to the ability of a chemical to cause temporary or permanent adverse effects to any part of the body. The toxicity of a chemical depends on many factors, including the properties of the chemical, the *dose* recieved, and the duration of the exposure. For some chemicals, there is an upper permissible or *threshold* dose. Any doses at or below this threshold are not expected to cause adverse health effects. This is true for chemicals that do not cause cancer, or *non-carcinogens*. Permissible doses for these chemicals are set by regulatory agencies such as Health Canada, the U.S. EPA, and the MOE based on toxicological studies. Permissible doses are usually reported as the *amount of chemical per unit body weight per unit time* that a person may be exposed to every day of their entire life that will not cause adverse health effects. For example, the oral (ingestion/swallowing) permissible dose for nickel used in this study was 20 micrograms per kilogram of body weight per day.

*The Sudbury area HHRA is one of the largest and most comprehensive of its kind in North America.*

There are some chemicals that are assumed in HHRA to carry some level of risk at any level of exposure. This is a precautionary assumption that is generally used for chemicals, thought to cause cancer, or *carcinogens*. For carcinogens, total exposure over an entire lifespan is calculated using a *lifetime receptor,* which represents a combination of all life stages (infant, toddler, child, adolescent, and adult). This accounts for the fact that cancer development is a long-term process that generally results from exposures to carcinogens over long periods of time. The exposure calculated for the lifetime receptor is known as the *lifetime average daily dose*.

*The use of Sudbury-specific information is critical at this stage to make the most accurate dose calculations possible.*

The potency, or cancer-causing power, of a carcinogen is represented by its *cancer slope factor*. These are values set by regulatory agencies such as Health Canada and the U.S. EPA. based on specially designed cancer studies. Cancer slope factors are used in combination with the average lifetime exposure estimates for carcinogens to estimate cancer risks.

During the hazard assessment, toxicological profiles were prepared for each COC using detailed reviews completed by regulatory agencies, toxicological databases, and the most up-to-date scientific literature.

### 3.3.3 Risk Characterization

The risk characterization component combines the exposure assessment (calculated dose) and the hazard assessment (permissible dose) to estimate risk. The process is different for carcinogens and non-carcinogens. Some chemicals can cause both cancer and other health effects, depending on the exposure pathway. All of the COC identified in the Sudbury area HHRA were evaluated for their potential to cause non-cancer health effects. Since some forms of three of the COC - arsenic, cobalt, and nickel - are considered to have the potential to cause cancer, these three COC were also evaluated as carcinogens.

**Non-carcinogens**

For non-carcinogens, risk is calculated by comparing the calculated dose of a chemical (to which the population has been exposed) to the permissible dose for that chemical. This comparison provides a *Hazard Quotient*, as follows:

$$\textit{Hazard Quotient} = \frac{\textit{Calculated Dose}}{\textit{Permissible Dose}}$$

When the calculated dose from all exposure sources is less than or equal to the permissible dose (Hazard Quotient $\leq 1$), adverse health effects are not expected. Risks may be considered insignificant or *negligible* and no further study is warranted. When the calculated dose exceeds the permissible dose (Hazard Quotient $> 1$), the risk of adverse health effects cannot be ruled out and should be investigated further.

*Permissible doses and cancer slope factors were selected from those published by reputable regulatory agencies such as Health Canada, MOE, and the U.S. EPA.*

**Carcinogens**

Since any level of exposure to carcinogens is conservatively assumed to be associated with some level of risk in HHRA, a tolerable or *acceptable* level of risk must be set for these compounds. Acceptable risks are set by regulators in the form of *incremental lifetime cancer risk*s. Acceptable incremental cancer risk levels differ depending on the agency responsible for setting them. For example, Health Canada's acceptable incremental lifetime cancer risk level is one-in-one hundred thousand people (1 in 100,000), while the MOE has set an acceptable incremental lifetime cancer risk level of one-in-one million people (1 in 1,000,000). Regardless of the jurisdiction, regulators set acceptable incremental lifetime cancer guidelines at risk levels considered to be negligible.

In reality, it is difficult to separate incremental risk from *total* risk. Total cancer risk is calculated by adding all exposures to a particular chemical, including background exposures. For carcinogens, risk is calculated by multiplying the *lifetime average daily dose* estimated for all life stages combined (lifetime receptor) by the *cancer slope factor* to estimate the incremental lifetime cancer risk*:*

$$\textit{Incremental Lifetime Cancer Risk} = \textit{Lifetime Average Daily Dose} \times \textit{Cancer Slope Factor}$$

An incremental lifetime cancer risk lower than the prescribed acceptable level indicates negligible cancer risk that does not require further study. An incremental lifetime cancer risk greater than the acceptable level indicates the need for further investigation.

# 4. Results and Discussion

## 4.1 Important Notes

As described previously, HHRA is a conservative process because the models and assumptions used to calculate risk predictions tend to over-estimate risk in the interest of protecting public health. As an example of this conservative approach, the SARA Group used the human receptors with the highest potential exposure (and therefore highest risk) to assess risks to the entire population. In general, the receptor group with the highest calculated exposure to metals in soil is the toddler, due to lower body weight and behaviour patterns. Using the toddler and lifetime receptors to assess risks to the entire population provides an additional layer of safety to the risk predictions. In cases where risks are predicted for toddlers or lifetime receptors, actual risk cannot be ruled out and further investigation may be required. Once again, this is a result of the protective models and assumptions used in HHRA and the use of the most sensitive receptors to represent risks to the entire population. In these cases, it is important to consider additional information in a weight-of-evidence approach (see Section 2.6) to validate the results of the risk calculations.

*Incremental lifetime cancer risk is the chance that one person in a given population will develop cancer during a 70-year lifetime, over and above the expected incidence of cancer, as a result of exposure to a carcinogen from a particular source.*

No significant differences were observed between risk predictions calculated for the general population and the hunter/angler/First Nations subpopulations. These results showed that the consumption of food from hunting and fishing activities did not significantly increase exposures to COC. Therefore, the results presented are for the general population in each community of interest.

For all health effects, risks were calculated based on both *average*, and *maximum exposures* to COC. This was done to ensure that exposures and risks were calculated for both the overall general population (average), and for receptor groups who may be exposed to higher than average levels of COC (maximum). In cases where risks could not be ruled out, further investigation using a weight-of-evidence approach was conducted.

## 4.2 Results by COC and Community of Interest

Risk predictions for oral/dermal exposures to each COC are presented in Table 4-1. The risk predictions for inhalation exposure are shown in Table 4-2. These predictions are discussed in detail in the following sections. Risk predictions calculated for typical Ontario residents living outside of the study area are also provided for comparison purposes.

Note that the type and severity of health effects from exposure to COC often depend on the route of exposure (inhalation, ingestion, or skin contact). Therefore, risks have been calculated and presented based on all routes of exposure.

The results summarized in Table 4-1 show that little or *negligible* risk is predicted for most combinations of COC in the communities of interest. This includes lead under average soil concentrations. However, when maximum soil concentrations are used for exposure conditions, lead was identified as a concern for toddlers in some areas within four of the communities. This issue is discussed in more detail in Section 4.2.4.

**Table 4-1: Summary of Health Risks for Oral/Dermal Exposure**

| Community of Interest | Ingestion and Dermal Absorption | | | | | |
|---|---|---|---|---|---|---|
| | *Arsenic* | *Lead* | *Cobalt* | *Copper* | *Nickel* | *Selenium* |
| *Copper Cliff* | O | ● | O | O | O | O |
| *Coniston* | O | ● | O | O | O | O |
| *Falconbridge* | O | ● | O | O | O | O |
| *Sudbury Centre* | O | ● | O | O | O | O |
| *Hanmer* | O | O | O | O | O | O |
| *Typical Ontario* | O | O | O | O | O | O |

O Negligible risk – no further investigation required
● Potential risk – risk management may be required in localized areas
Health risks for the Typical Ontario resident were based on average soil centrations, not maximum soil levels in a particular neighbourhood.

*If risks can be ruled out for toddlers and lifetime receptors, then risks to the rest of the population can also be confidently ruled out.*

Potential health risks due to nickel in air were identified in Copper Cliff and parts of Sudbury Centre (Table 4.2). These results are discussed in more detail in section 4.2.5.

**Table 4-2: Summary of Health Risks from Inhalation Exposure**

| Community of Interest | Inhalation | | | | | |
|---|---|---|---|---|---|---|
| | *Arsenic* | *Lead* | *Cobalt* | *Copper* | *Nickel* | *Selenium* |
| *Copper Cliff* | O | O | O | O | ● | O |
| *Coniston* | O | O | O | O | O | O |
| *Falconbridge* | O | O | O | O | O | O |
| *Sudbury Centre* | O | O | O | O | ● | O |
| *Hanmer* | O | O | O | O | O | O |
| *Typical Ontario* | O | O | O | O | O | O |

O Negligible risk – no further investigation required
● Potential risk – risk management may be required in localized areas

### 4.2.1 Arsenic

The full weight of evidence strongly indicates that Sudbury area residents are at no greater risk to arsenic than other Ontario or Canadian residents. Initially, the numerical calculations indicated some potential risks for individuals in all communities of interest. Therefore, risks could not be ruled out for arsenic in the study area, including Hanmer (the comparison community) or for typical Ontario residents outside of the study area. This is due to the low permissible dose levels (toxicity reference values) for arsenic recommended by health and environmental regulators. Therefore, other lines of evidence were evaluated to put these risks into perspective.

The prediction of some risks is typical for any human health risk assessment evaluating oral (ingestion) exposures to arsenic. This is because the major source of arsenic exposure is supermarket foods (or *market basket contribution*). Figure 4-1 shows that between 58 - 76 % of the arsenic exposure in the study area is derived from supermarket foods. Ranges are provided for each exposure route since the actual proportion differs between communites. Since Ontario supermarket foods come from common sources, these exposures are similar for all residents across the province. Therefore, even if arsenic levels in other exposure media (such as soil) were reduced to natural background levels, the calculated risk predictions would not decline substantially.

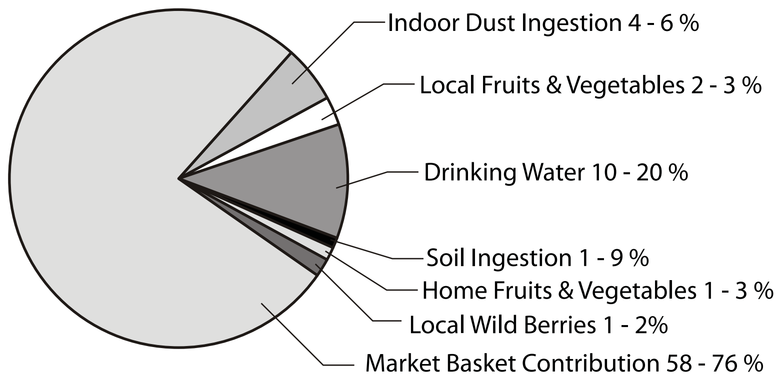


*Figure 4-1: Sources of Oral/Dermal Arsenic Exposure to Toddlers in the study area.*

*Consideration of all of the lines of evidence clearly show that residents of the study area are not at any greater risk for arsenic-related health effects than any other Ontario or Canadian residents.*

The Falconbridge Arsenic Exposure Study provided a second line of evidence for evaluating arsenic risks. Despite higher levels of arsenic in soil, urinary arsenic levels for Falconbridge residents were very similar to those of Hanmer residents, who were exposed to significantly lower arsenic concentrations in soils. This study showed that even though some people in Falconbridge may be exposed to higher concentrations of arsenic in soils, arsenic is not being absorbed into their bodies at these higher soil levels. Therefore, the actual risks of arsenic exposure are lower than predicted by the HHRA risk calculations. Based on this study, it was concluded that residents of Falconbridge are not at any increased risk from arsenic exposure compared to the rest of the Ontario population. These results can also be applied to residents in all other communities of interest in this HHRA, where levels of arsenic were lower than those found in some Falconbridge soil samples.

### 4.2.2 Cobalt

Hazard quotients for ingestion/dermal absorption of cobalt were less than 1.0 for all receptor groups in all communities of interest. Therefore, risks are considered negligible for cobalt in all of the communities of interest. No further action is required.

### 4.2.3 Copper

Hazard quotients for inhalation and ingestion/dermal absorption of copper were less than 1.0 for all receptor groups in all communities of interest. Therefore, risks are considered negligible for copper in all of the communities of interest. No further action is required.

### 4.2.4 Lead

Based on the calculated risk predictions (HQ < 1.0), health risks were negligible for exposure to average lead soil levels throughout the study area. When risk was calculated using the maximum soil concentrations measured in each of these communities, the hazard quotients (HQ) for oral/dermal exposures to lead marginally exceeded 1.0, as follows:

- Copper Cliff (HQ =1.3)
- Falconbridge (HQ = 1.1)
- Sudbury Centre (HQ = 1.1)
- Coniston (HQ = 1.1)

Although the estimated HQ is not much higher than in the reference community of Hanmer (HQ = 0.9), risk of health effects to toddlers under some soil and dust concentrations could not be ruled out at properties where higher soil lead levels were recorded.

Figure 4-2 shows the relative proportion of sources of lead exposure for residents in the study area.

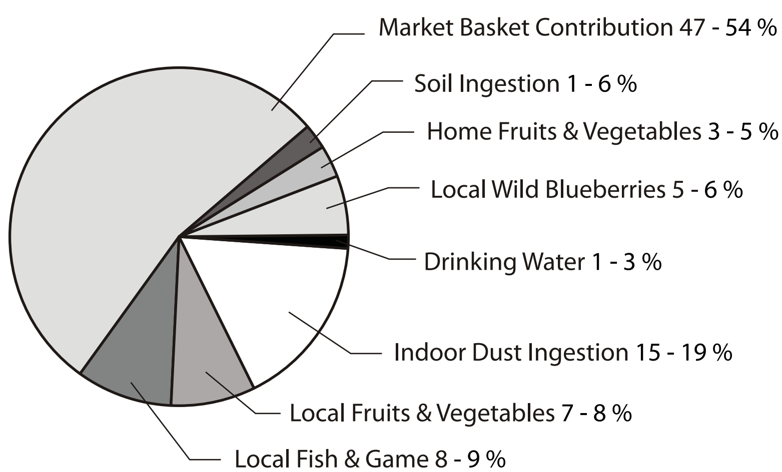


*Figure 4-2: Sources of Oral/Dermal Lead Exposure to Toddlers in Sudbury Centre*

### 4.2.5 Nickel

Two routes of exposure for nickel (oral/dermal and inhalation) are discussed in the following text to address different potential health outcomes.

*Oral/Dermal exposure:* The calculated risks are negligible for oral/dermal exposures to nickel for all receptor groups in all of the communities of interest (hazard quotients less than one). These risks are within acceptable benchmarks, and no further action is considered necessary.

_Inhalation exposure_: Two potential health outcomes related to breathing nickel in air were considered in this assessment: non-cancer (respiratory inflammation) and respiratory cancer. While respiratory inflammation was considered the primary outcome, risk for respiratory cancer was also considered.

No unacceptable risks related to inhalation of nickel were identified for Coniston, Falconbridge, Hanmer (the comparison community), or for the typical Ontario resident scenario. These risks are within acceptable benchmarks, and no further action is considered necessary.

***Identified risks related to nickel inhalation:***

- Respiratory inflammation: Using conservative assumptions, the study calculated risk of respiratory inflammation from lifetime exposures to airborne nickel in the areas of Copper Cliff (HQ=3) and the western portion of Sudbury Centre (HQ=13). These risks are based on nickel levels measured at two air monitoring stations immediately surrounding Vale Inco's Copper Cliff complex.

- Respiratory cancer: Respiratory inflammation has the potential to develop into respiratory cancer in the presence of other substances. The established toxicity reference value used in this assessment (European Union) is protective of the respiratory inflammation endpoint and is consistent with the aim of limiting excess lifetime cancer risk to not more than 1 in a million. Since the HQ for respiratory inflammation is greater than one, risk of respiratory cancer cannot be ruled out.

### 4.2.6 Selenium

Based on a weight of evidence, the results indicate that study area residents are not at any greater risk from selenium exposure than residents in other areas of the province. As with arsenic, the permissible doses for selenium are very low. Therefore, the numerical risk predictions indicated some risk from oral/dermal exposures to selenium in all communities of interest, including Hanmer (the comparison community), and in the typical Ontario scenario. Similar to arsenic, the study results showed that the major source (approximately 80%) of selenium exposure and, therefore, risk, comes from consuming supermarket foods.

Since Ontario supermarket foods originate from common sources, these exposures are similar for all residents across the province. Therefore, even if selenium levels in other exposure media (such as soil) were reduced to natural background levels, the risk predictions would not decline substantially. These results indicate that study area residents are not at any greater risk from selenium exposure than residents in other areas of the province.

# 5. Results Summary and Risk Context

The final results of the HHRA indicate that risks to the study area population are negligible for arsenic, cobalt, copper and selenium. However, there is a need for risk management consideration to address the following:

- Total exposure to lead in a few localized areas of Copper Cliff, Coniston, Falconbridge and Sudbury Centre, and
- Exposure to airborne nickel in Copper Cliff and the western portion of Sudbury Centre.

These two issues are discussed further in the following sections.

## 5.1 Lead

In most areas of Greater Sudbury, there were no unacceptable risks associated with lead in the environment. Therefore, for most areas, no additional action or consideration is required.

Minimal risks were identified in very localized areas of Coniston, Copper Cliff, Falconbridge, and Sudbury Centre, due to levels of lead found in some samples of soil and indoor dust. These risks are primarily a concern for young children, who are considered the most sensitive to lead exposure.

It is important to note that there are several sources of lead in the Sudbury environment. The major source of lead exposure (about 54%) for residents is supermarket foods, while soil accounts for 10% (or less) of total exposure. In older homes, lead levels can be elevated in household dust and soil due to historic use of lead-based paints, and in drinking water as a result of leaching from lead pipes and solder. Therefore, when considering options for reducing lead exposure and risks, it is important to consider all possible sources of lead in the environment.

Lead levels detected in soil and dust in the Sudbury area are similar to levels found in other older urban communities in Ontario that have no industrial sources. For information on how to reduce lead exposure, study area residents can contact the Sudbury & District Health Unit, the Ontario Ministry of the Environment, and Health Canada.

## 5.2 Nickel

Both respiratory inflammation and respiratory cancer were considered as possible health outcomes for lifetime exposure to nickel through inhalation. Respiratory inflammation was the primary endpoint (health outcome) associated with nickel inhalation in this study, and the risk is expressed as an HQ value (non-cancer effects). This led us to identify potential health risks in the areas of Copper Cliff and the western portion of Sudbury Centre.

Evidence of respiratory cancer associated with nickel inhalation comes from animal studies and occupational exposures. The exposures in these studies are typically much higher than normally found in the environment. The HQ value (non-cancer) cannot be translated into a cancer risk estimate. However, the established toxicity reference value used in this assessment (European Union) is protective of the respiratory inflammation endpoint and is consistent with the aim of limiting excess lifetime cancer risk to not more than 1 in a million. The acceptable total risk benchmark set by Health Canada is 1 in 100,000, while the MOE value is 1 in one million for each exposure source. Since the HQ for respiratory inflammation was greater than one, the risk for respiratory cancer could not be ruled out.

Based on the analysis conducted for this risk assessment, and the actual small populations within the communities of interest, it is unlikely that any additional respiratory cancers will result from nickel exposure over the 70-year lifespan considered in the risk assessment.

However, these results identify the need for risk management to reduce exposure to airborne nickel in these localized areas.

# 6. Conclusions

**The main conclusions from the detailed human health risk assessment for the Greater Sudbury study area are as follows:**

1. Based on current conditions in the Sudbury area, the study predicted little risk of health effects on Sudbury area residents associated with metals in the environment.
2. There were no unacceptable health risks predicted for exposure to four of the six Chemicals of Concern studied: arsenic, copper, cobalt, and selenium.
3. The risk calculated for typical exposures to lead in the environment throughout the Greater Sudbury area are within acceptable benchmarks for protection of human health. However, levels of lead in some soil samples indicate a potential risk of health effects for young children in Copper Cliff, Coniston, Falconbridge and Sudbury Centre.
   - Lead levels in soils and dust in the Sudbury area are similar to levels in other older urban communities in Ontario.
4. The study calculated a risk of respiratory inflammation from lifetime exposures (70 years) to airborne nickel in two areas: Copper Cliff and the western portion of Sudbury Centre.
   - Respiratory inflammation has been linked to the promotion of cancer caused by other agents;
   - Based on the conservative assumptions and approaches used in this risk assessment, it is unlikely that any additional respiratory cancers will result from nickel exposure over the 70-year lifespan considered in the risk assessment;
   - Health risks related to nickel inhalation were not identified in the other communities of interest.
5. Anglers, hunters and First Nations people who may consume more local and wild game are at no greater risk of health effects due to metals in the environment than the general population.

The results and conclusions from this risk assessment will be used as the basis for risk management decisions in the Greater Sudbury area.

# 7. Next Steps

In response to the results of the HHRA, Vale Inco and Xstrata Nickel are preparing a separate Risk Management Report outlining strategies to reduce the potential risks from lead in soil and nickel in air, where these risks are identified in the HHRA. This document will be available to the public at local libraries, the Ontario Ministry of the Environment and online at www.sudburysoilsstudy.com. The mining companies have indicated their commitment to the community of Sudbury and are continuing discussions with the City of Greater Sudbury, the Ontario Ministry of the Environment, and the Sudbury & District Health Unit.

After the release of the HHRA results, there will be a review period for public comments. Comments will be accepted in writing by mail , fax email or online at **www.sudburysoilsstudy.com.**

Further information on the public review period and comments will be provided in the local media and on the Sudbury Soils Study website.

# 8. Additional Information

Copies of the full technical report *(Volume II Sudbury Area Human Health Risk Assessment)* are available for viewing at the offices of the Ontario Ministry of the Environment at 199 Larch Street, Sudbury, and at the public libraries in Sudbury. Electronic copies of the entire technical report and other information regarding the Study are available on the Sudbury Soils Study website at **www.sudburysoilsstudy.com.**

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# 10. List of Acronyms

| | |
|---|---|
| **CEM** | Centre for Environmental Monitoring at Laurentian University, Sudbury, Ontario |
| **COC** | chemical(s) of concern |
| **COI** | Community of Interest |
| **CSC** | Communications Sub-committee |
| **ERA** | ecological risk assessment |
| **HHRA** | human health risk assessment |
| **HQ** | hazard quotient |
| **IERP** | Independent Expert Review Panel |
| **MOE/MOEE** | Ontario Ministry of the Environment (and Energy) |
| **PAC** | Public Advisory Committee |
| **PM** | particulate matter |
| **SARA** | Sudbury Area Risk Assessment |
| **SDHU** | Sudbury & District Health Unit |
| **TC** | Technical Committee |
| **TERA** | Toxicology Excellence for Risk Assessment |
| **Q&A** | question and answer |
| **U.S. EPA** | United States Environmental Protection Agency |

# 11. Glossary of Terms

***Absorption***
In general, absorption refers to the movement of one substance into another. In this document, absorption refers to movement of chemicals from outside of the body into the bloodstream.

***Acceptable Risk Level (Acceptable Level of Risk)***
A risk management term used to indicate the amount of cancer risk, *over and above* background cancer prevalence, that is tolerated in a given population (see *Incremental Lifetime Cancer Risk Level*). Acceptable risk levels are set based on the assumption that any exposure to carcinogens results in some hypothetical cancer risk. Since some level of exposure to carcinogens is inevitable over one's lifetime, a tolerable or acceptable level of risk must be determined for exposures to carcinogens from particular sources (such as Sudbury area metal production operations) that may result in greater than background exposures. Acceptable risk levels are arbitrary values set by regulatory agencies based on scientific data and social, political, and economic political factors. Therefore, different agencies have different acceptable risk levels. For example, Health Canada's acceptable risk level for increased cancer prevalence from carcinogen exposure is one person in 100,000 people, while the MOE's benchmark is one person in 1,000,000. This translates into the chance that an additional one-in-one hundred thousand (Health Canada) or one-in-one million people (MOE) will develop cancer over a 70-year lifespan, *over and above* the number of natural (background) occurrences of cancer.

***Adverse Health Effect/Health Effect***
A change in body function or cell structure that may lead to illnesses, including the development of cancer or non-cancer health problems such as skin irritations, nausea, dizziness, breathing difficulty, heart problems, and others. See also *Cancer* and *Non-cancer Health Effect*.

***Background Level***
The typical level of a chemical present in the environment. The term often refers to naturally-occurring or uncontaminated conditions, which vary from one location to another. For example, background concentrations of metals are generally greater in northern Ontario due to the geology of the area, which is rich in mineral deposits.

***Bioavailability***
The portion (or fraction) of the total amount of a chemical in a particular medium (such as soil or dust) to which one is exposed that is absorbed into the bloodstream.

***Bioaccessibility***
The mass fraction of a substance that is converted to a soluble form, and is, therefore, potentially available for uptake. If one is evaluating bioaccessibility via the oral route, it is the fraction of a substance that becomes solubilized within the gastrointestinal tract (i.e., stomach and small intestine). In the case of dermal exposures, it is the fraction solubilized on the outside of the skin (i.e., in sweat).

***Biological Monitoring***

***The measurement of chemicals in biological materials (such as blood, urine, breath,*** *etc.*__*) to evaluate the actual dose received by humans (or animals or plants).*__

***Cancer***
Any one of a group of diseases that occur when particular types of cells in the body begin to grow or multiply out of control.

***Cancer Risk Level***
A general term used to refer to the likelihood that an individual will develop cancer over a 70-year lifetime. See *Incremental Lifetime Cancer Risk*, *Total Lifetime Cancer Risk*, and *Acceptable Risk Level*.

***Cancer Slope Factor***
A numeric value that indicates the potency (ability or strength) of a chemical to cause cancer. The cancer slope factor is used to estimate incremental lifetime cancer risk (see *Incremental Lifetime Cancer Risk*) from exposure to a carcinogen from a particular source.

***Carcinogen / Carcinogenic***
*Carcinogens* are chemicals that can cause cancer. *Carcinogenic* refers to the ability to cause cancer. It should be noted that knowledge that a chemical can cause cancer is most often obtained from laboratory studies on animals. Therefore, it is often not known definitively whether a chemical causes cancer in humans. See also *Cancer*.

***Centre for Environmental Monitoring (CEM)***
A group formed by scientists in 2000 at Laurentian University in Sudbury, Ontario that uses the "natural laboratories" of the region to study the effects of metal production emissions and abatement technologies on the environment and human health.

***Chemical(s) of Concern (COC)***
In the case of the Sudbury area HHRA, a chemical or chemicals that is/are present in soil at levels greater than Ontario Ministry of the Environment guidelines. Chemicals of concern may pose a risk to human health and/or the environment and are therefore evaluated further in a risk assessment.

***Communications Sub-committee (CSC)***
Group formed in 2002 to help oversee communications and consultation initiatives for the Sudbury Soils Study and to ensure timely and effective public consultation. The Communications Sub-committee was comprised of communications professionals from the organizations represented on the Technical Committee, as well as members of the SARA Group. The mandate of the Communications Sub-committee was to foster community awareness and participation throughout the study process.

***Community of Interest***
A group of people or a geographical community identified at the beginning of a risk assessment that may be exposed to the chemicals of concern. Residents of the communities of interest are therefore subjects in the human health risk assessment process.

***Comparison Community***
In the case of this study, a comparison community is one that has not been affected by contaminants of concern originating from metal production activities in the Sudbury region. The comparison community for the Sudbury area HHRA is Hanmer. Levels of the chemicals of concern in the comparison community reflect those that are naturally present in the area. Comparison of other communities of interest with Hanmer (comparison community) helps risk assessors to evaluate the contaminant levels and health effects that might be attributed to Sudbury area metal production activities.

***Concentration***
The proportion of one substance contained in a given amount of another. The concentration unit has two components: the numerator (quantity of substance contained) and the denominator (quantity of the material in which the first substance is contained). For example, a lead soil concentration of 4 mg/kg represents 4 milligrams of lead present within one kilogram of soil, or 4 parts of lead within every million parts of soil.

***Contaminant***
A substance that is either present in an environment where it does not naturally occur or is present at levels that are greater than background levels.

***Dermal***
Referring to the skin.

***Dose***
The amount of a chemical to which a person is exposed over a given period of time. Dose is a measure or estimate of exposure and is often expressed as an amount of chemical per unit of body weight per unit of time (such as milligrams of chemical per kilogram of body weight per day). In risk assessment, estimated doses are calculated using exposure scenarios. See also *Exposure* and *Exposure Scenario*.

***Ecological Risk Assessment (ERA)***
A risk assessment that evaluates risks to plants and animals from exposure to a particular chemical or chemicals. See also *Risk Assessment*.

***Effect***
Change in the state or dynamics of an organism, system, or population caused by exposure to some agent or chemical.

***Emissions***
Materials that are released to the environment from a particular source or activity.

***Environmental Quality Guidelines***
Regulatory science-based limits for a variety of substances and environmental quality parameters that are set to protect human health and/or the environment.

***Exposure***
Refers to contact of a chemical with the outer boundaries of the body (skin, lungs, digestive tract). See also *Dose*.

***Exposure Assessment***
The part of the risk assessment process where chemical doses received by human receptors are either calculated or measured directly. The exposure assessment also takes into consideration the length of time and the nature of a population exposed to a chemical.

***Exposure Pathway***
The means by which a chemical moves from its source (such as soil, food, water, or air) into the body of a human receptor. Pathways link the source of a chemical to receptors.

***Exposure Route***
Refers to one of the three specific ways in which a chemical enters into the body of a human receptor: Ingestion (swallowing), inhalation (breathing in), or dermal absorption (through the skin).

***Exposure Scenario***
The circumstances and conditions under which exposures to chemicals may occur. These may include the source, timeframe, duration, and location of the exposure, and a description of the population and their activities that lead to exposure. Scenarios are often created to help risk assessors to calculate chemical doses under a variety of conditions.

***Guidelines***
General recommended limits on the level of a particular substance in a specific medium or environment that are set to protect against adverse effects to humans and/or the natural environment. Exceedances of guidelines trigger the need for further study. An example is the Ontario Ministry of the Environment soil quality guidelines.

***Hazard***
Refers to the inherent properties of a chemical that enable it to cause adverse effects when an organism, system or population is exposed to it.

***Hazard Assessment***
Phase of the risk assessment that describes the relationship between levels of chemicals of concern and human health effects.

***Hazard Quotient (HQ)***
Ratio of a calculated dose to a permissible dose for a particular chemical of concern. A hazard quotient less than or equal to 1.0 indicates that the calculated dose is lower than the permissible dose and that no adverse health effects are expected. A hazard quotient greater than one indicates that the calculated dose is higher than the permissible dose and that the risk of adverse health effects should be investigated further.

***Health Canada***
The Canadian federal department responsible for helping Canadians maintain and improve their health. Health Canada is responsible for researching and setting national guidelines and standards for the protection of human health.

***Health Risk***
Health risk refers to the chance that a particular population will experience an adverse health effect from exposure to a particular chemical. Health effects include both cancer and non-cancer effects such as skin irritations, nausea, dizziness, breathing difficulty, heart problems, and others.

***Human Health Risk Assessment (HHRA)***
A risk assessment that evaluates potential health risks to hypothetical human populations from exposure to a particular chemical or chemicals. See also *Risk Assessment*.

***Incremental Lifetime Cancer Risk***
Incremental lifetime cancer risk is the chance that an individual will develop cancer during a 70-year lifetime, *over and above natural or background cancer prevalence*, as a result of exposure to a carcinogen from a particular source. Incremental lifetime cancer risk is calculated by multiplying the estimated lifetime average daily dose (see *Lifetime Average Daily Dose*) of a particular carcinogen by the cancer slope factor (see *Cancer Slope Factor*). Incremental lifetime cancer risk is often expressed as the additional number of people in a population of a given size that are predicted to develop cancer over a lifetime (that is, *n* people in *x* people) in excess of background cancer prevalence. Agencies such as Health Canada, the U.S. EPA, and the MOE set acceptable levels (see *Acceptable Risk Level*) for incremental lifetime cancer risks. These values vary depending on the agency. Incremental lifetime cancer risk differs from *total lifetime cancer risk,* which accounts all sources of exposure, including background exposures. Incremental lifetime cancer risks tend to be extremely small relative to total cancer risks. See also *Total Lifetime Cancer Risk*.

***Independent Expert Review Panel (IERP)***
An international group of scientists chosen by the Toxicology Excellence for Risk Assessment (TERA) group (who were retained by the Technical Committee) to peer review the Human Health Risk Assessment.

***Independent Process Observer***
Position established to ensure that all stakeholders were given equal access and input into the Sudbury Soils Study and to represent the interests of the community. This position was filled by Mr. Franco Mariotti, a biologist and staff scientist at Science North in Sudbury and a resident of the community.

***Ingestion***
Refers to swallowing.

***Information Gap***
Information that is either unavailable or limited, and that would likely reduce uncertainty in the risk assessment if it were available or if the data set was more complete.

***Inhalation***
Breathing air and the substances it contains into the respiratory tract.

***Lifetime average daily dose***
The calculated average daily dose of a hypothetical human receptor group to a particular chemical throughout their entire lifetime (over all life stages, including infant, toddler, child, adolescent, and adult). Used to calculate cancer risks (see also *Incremental Lifetime Cancer Risk*).

***Lifetime Receptor***
A theoretical human receptor representing all life stages (infant, toddler, child, adolescent, and adult) used to assess cancer risks. Exposures to cancer-causing chemicals are calculated for each life stage and added together to produce a total lifetime dose. The lifetime receptor accounts for the fact that cancer development is often a long-term process that can take years to cause obvious symptoms.

***Market basket contribution***
The amount of exposure to a chemical of concern that comes from consuming supermarket foods.

***Media / Medium***
Soil, water, air, plants, animals, or any other parts of the environment that can contain chemicals. Body tissues or fluids such as bone, blood, or urine may also be considered media. *Medium* is the singular form of media.

***Negligible***
In a risk assessment context, the term negligible refers to levels of risks that are not expected to be associated with adverse health effects. Risks in this case are considered insignificant.

***Non-cancer health risk/ non-cancer health effect***
Non-cancer health risk refers to the chance of experiencing an adverse health effect *other than cancer* from exposure to a particular environmental contaminant. Non-cancer health effects are those other than cancer and may include anything from nausea, dizziness, and skin rashes to delayed neurological development and cardiopulmonary disease. See also *Adverse (Health) Effect* and *Cancer*.

***Non-negligible***
In a risk assessment context, the term non-negligible refers to levels of risks that are greater than acceptable levels set by regulators or that potentially could be associated with adverse health effects. Non-negligible risk predictions do not imply *actual* risks, but rather a need for further investigation.

***Ontario Ministry of the Environment (and Energy) (MOE / MOEE)***
Provincial agency responsible for developing, implementing, and enforcing regulations and various programs that address environmental issues. Formerly known as the Ontario Ministry of the Environment and Energy. The Ontario Ministry of the Environment is a member of the Sudbury Soils Study Technical Committee.

***Oral***
By mouth. Oral exposure to a substance occurs when that substance is swallowed. See also *Ingestion*.

***Particulate Matter (PM)***
A general term that refers to tiny particles of dust, soot, and/or smoke.

***Permissible Dose***
The amount of a particular chemical that one may be exposed to over a lifetime that is below the level at which adverse health effects are expected to occur. The permissible dose is therefore considered a 'safe' level of exposure. Also referred to as the *Toxicity Reference Value*.

***Population***
A group of people living within a given location in space and time or sharing similar characteristics (such as occupation or age).

***Prevalence***
The number of existing disease cases in a defined group of people during a specific time period.

***Problem Formulation***
Initial stage of risk assessment where information is gathered and interpreted to plan and focus the assessment.

***Public Advisory Committee***
A group of Sudbury area residents established in 2002 to facilitate community involvement in the Sudbury Soils Study and to promote the flow of information between the Technical Committee and the public.

***Receptor***
A specific group of people (such as female toddlers), plants, or animals that could come into contact with chemicals of concern.

***Remediation/Remedial***
Correction or improvement of a problem, such as work that is done to clean up or stop the release of chemicals from a contaminated site.

***Risk***
In human health risk assessment, risk refers to the likelihood of experiencing adverse health effects caused by exposure to chemicals of concern.

***Risk Assessment***
A process that estimates the likelihood that receptors (people, plants, or animals) may experience adverse effects from a particular series of events or circumstances, such as exposure to chemicals. The four components of a risk assessment are:

1. Problem formulation;
2. Hazard assessment;
3. Exposure assessment; and
4. Risk characterization.

***Risk Characterization***
Final phase of the risk assessment, where the exposure and effects information are combined to evaluate potential impacts of exposures to chemicals of concern.

***Risk Management***
The process of deciding whether, how, and how much to reduce or eliminate possible adverse effects on people and the environment. Risk management takes into consideration the results of the risk assessment, engineering capabilities (what can physically be done and how effective it will be), and social, economic, and political concerns.

***Route of Exposure***
See *Exposure Route*.

***Safe***
In the context of risk assessment, safe implies very low or negligible risk.

***SARA Group***
The affiliation of several Ontario-based consulting firms specializing in the various scientific disciplines responsible for conducting the Human Health and Ecological Sudbury Area Risk Assessments. The main partners of the SARA Group are Gartner Lee Limited (formerly C. Wren and Associates), Intrinsik Science Inc. (formerly Cantox Environmental Inc.), Rowan Williams Davies and Irwin Inc., SGS Lakefield, and Goss Gilroy Inc.

***Scenario***
See *Exposure Scenario*.

***Screening***
The process of comparing chemical concentrations found in the environment with environmental quality guidelines in order to identify chemicals of concern for a risk assessment (See also *Chemicals of Concern*).

***Speciation***
A process used to identify and quantify the different forms, or "species", of a metal present in a particular medium. Metals can exist in elemental form on their own, or in combination with other chemicals as compounds. This is important in HHRA because the form of the metal influences its toxicity. Speciation allows risk assessors to consider the different toxicities of the different forms of a metal when estimating risks to human health.

***Stakeholder***
Any person or organization with an interest, or "stake" in the outcome of a particular process.

***Study Area***
The particular geographical area(s) being examined in a risk assessment. In this case, the study area is the *Sudbury Area* as defined below.

***Subpopulation***
A smaller group of people within the general population that is distinguished by specific traits, activities, or behaviours. For example, hunters and anglers are a subpopulation who generally consume more wild game and fish than the majority of the general population.

***Sudbury Area***
The study area for the human health risk assessment, centred on the City of Greater Sudbury and radiating to the surrounding regions (approximately 40,000 square kilometres), in the core of the Canadian Shield in Northern Ontario. The study area includes the five communities of interest: Coniston, Copper Cliff, Falconbridge, Hanmer, and Sudbury Centre.

***Sudbury & District Health Unit (SDHU)***
A public health agency that delivers provincially legislated public health programs and services to the residents of the Sudbury and Manitoulin districts. The health unit works with individuals, families, and the community to promote and protect health and prevent disease. The health unit is a member of the Sudbury Soils Study Technical Committee.

***Sudbury Soils Study***
The name given to the group of comprehensive studies initiated in 2001 that identified elevated levels of metals in Sudbury area soils and then evaluated whether these metals pose a risk to people, plants, or animals in the region. The three main studies completed under the umbrella of the Sudbury Soils Study are the *2001 Soil Survey*, the *Sudbury Area Human Health Risk Assessment*, and the *Sudbury Area Ecological Risk Assessment*.

***Technical Committee (TC)***
The six organizations with the responsibility of overseeing the Sudbury Soils Study: Ontario Ministry of the Environment, Sudbury & District Health Unit, City of Greater Sudbury, Vale Inco, Xstrata Nickel (formerly Falconbridge Limited) and the First Nations Inuit Health Branch of Health Canada. All of these organizations are identified as major stakeholders in maintaining a healthy environment in and around Sudbury.

***Threshold***
A dose (or level of exposure) below which no adverse effects are expected.

***Total Lifetime Cancer Risk***
The chance that an individual will develop cancer during a 70-year lifetime from *all* exposures to carcinogens in the environment (including background *and* particular sources of exposure, such as the Sudbury metal production facilities). Total lifetime cancer risk is calculated by adding background cancer risks (or cancer prevalence) and incremental lifetime cancer risks. Total lifetime cancer risk is often expressed as a percent chance or as the number of people in a population of a given size that are expected to develop cancer over a lifetime (that is, *n* people in *x* people). See also *Incremental Lifetime Cancer Risk*.

***Toxicity***
Refers to the nature and severity of adverse health effect(s) caused by a chemical on the biological system of an exposed organism over a given period of time.

***Toxicity Reference Value***
See *Permissible Dose*.

***Typical Ontario Resident / Typical Ontario Scenario***
A hypothetical receptor used in the Sudbury Area Human Health Risk Assessment to evaluate exposures and health risks experienced by Ontario residents living outside of the study area. Exposures were calculated based on background concentrations of chemicals of concern in soil, water, air, dust, and food sources. This typical Ontario scenario of exposure can then be compared with exposures of residents living in and around Sudbury near metal production activities to see whether the predicted health risks differ.

***United States Environmental Protection Agency (U.S. EPA)***
Federal agency in the United States responsible for developing and enforcing environmental regulations. U.S. EPA is responsible for researching and setting national guidelines and standards for a variety of environmental programs.

***Weight-of-Evidence***
An approach to interpreting and integrating scientific information from different lines of investigation. Literally, the taking of evidence from different disciplines to make a judgement about the cause of a particular outcome.

*Sudbury Soils Study*

*Summary of Volume II:*
***Human Health Risk Assessment***

Sudbury Soils Study | Étude des sols sudburois

metals • health • environment
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