SUDBURY AREA RISK ASSESSMENT

VOLUME II – EXECUTIVE SUMMARY

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EXECUTIVE SUMMARY

The Executive Summary follows the same order and chapter numbering system as the main body of the text for quick reference and orientation.

ES-1.0 INTRODUCTION

ES-1.1 Background

The Sudbury Basin is an area rich in mineral deposits, particularly nickel and copper ores. Recent studies have demonstrated there are areas in Sudbury with elevated metal levels in soil. These areas are generally close to the historic smelting sites of Coniston, Falconbridge and Copper Cliff. In 2001, the Ontario Ministry of the Environment (MOE) released a report that identified that the concentrations of nickel, cobalt, copper and arsenic exceeded the generic MOE soil quality guidelines. Under Ontario legislation, this triggers the need for more detailed study; therefore, the MOE recommended:

- That a more detailed soil study be undertaken to fill data gaps; and
- That a human health and ecological risk assessment be undertaken.

Inco Limited (now Vale Inco Limited) and Falconbridge Limited (now Xstrata Nickel Limited) voluntarily accepted the recommendations and commissioned "The Sudbury Soils Study". The full background and rationale for the Sudbury Soils Study is presented in Volume I of this report series.

A Technical Committee (TC), comprised of Vale Inco, Xstrata Nickel formerly Falconbridge Limited), the MOE, the Sudbury & District Health Unit (SDHU), the City of Greater Sudbury, and Health Canada First Nations and Inuit Health Branch, was formed to oversee the study.

The first part of the Sudbury Soils Study was a comprehensive soil sampling and analysis program. This was undertaken in 2001 by the MOE and the mining companies. The data from this program form the basis of the current study and is provided in Volume I.

Early in 2003, a consortium of professional environmental consulting firms (the Sudbury Area Risk Assessment, or SARA Group) was retained to undertake the risk assessment portion of the study. This document, Volume II of the Sudbury Soils Study, presents the methods, results and conclusions of the human health risk assessment (HHRA) conducted in the Sudbury Area.

ES-1.2 The Sudbury Human Health Risk Assessment

An HHRA is a scientific study that evaluates the potential for the occurrence of adverse health effects from exposure of people (receptors) to chemicals of concern (COC) present in surrounding environmental media (*e.g.*, air, soil, sediment, surface water, groundwater, food, biota, *etc.*). An HHRA is based on the fundamental dose-response principle of toxicology. The response of a receptor to a chemical exposure increases in proportion to the dose. The dose is determined by the degree of exposure, which is proportional to the chemical concentrations in the environment where the receptor lives, works or visits.

The Sudbury HHRA was conducted in the spirit of the regulatory guidance provided by the MOE (*O. Reg.* 153/04; MOEE, 1997 and related documents) and Health Canada (1993; 2004); and was primarily based on guidance developed by U.S. EPA for the Superfund program (U.S. EPA, 1989; 1992; 1997; 1999; 2001a,b; 2002; 2004). The Sudbury HHRA is an area-wide risk assessment, as it evaluates a large geographic area rather than an individual property. The framework and methodology used in the Sudbury HHRA are described in the following section.

The Technical Committee identified several guiding objectives for the HHRA, including the following key objectives outlined in the original request for proposals for the Sudbury Soils Study:

1. Identify any human health risks attributable to present environmental conditions and levels of COC in the Sudbury area;
2. Assess potential exposure pathways *via* all relevant media (*e.g.,* air, food, water, soil, *etc.*) and routes of entry (*e.g.,* dermal absorption, ingestion and inhalation) for individuals living in the Sudbury community;
3. Quantify the intake of each chemical of concern (COC) from each exposure pathway;
4. Compare each integrated COC intake with suitable acceptable or safe intakes (*i.e.*, with toxicity reference values);
5. Utilize results of the Sudbury-specific COC speciation and bioaccessibility analyses to better understand the toxicity and bioavailability of the COC; and,
6. Determine a range of soil intervention levels that may be used as a management option to reduce risk (if applicable).

Each of these objectives was integrated into the current HHRA, where possible, to respond to the specific concerns and issues raised as part of the Sudbury Soils Study.

ES-1.3 The Human Health Risk Assessment Framework

An HHRA evaluates the likelihood (or risk) of health effects following chemical exposures. It requires consideration of the toxic properties of the chemicals, the presence of receptors, and the existence of exposure pathways between the chemicals and the receptors. When all three factors are present (*i.e.*, chemicals, receptors and exposure pathways), there is a potential for adverse health effects to occur if exposures to the chemicals are elevated above acceptable levels (see Figure ES-1.1).

Figure ES-1.1 Factors Required for a Risk of Health Effects

The Sudbury HHRA follows the standard HHRA framework (see Figure ES-1.2), which consists of four steps:

- Problem Formulation:
- Exposure Assessment:
- Hazard Assessment:
- Risk Characterization:

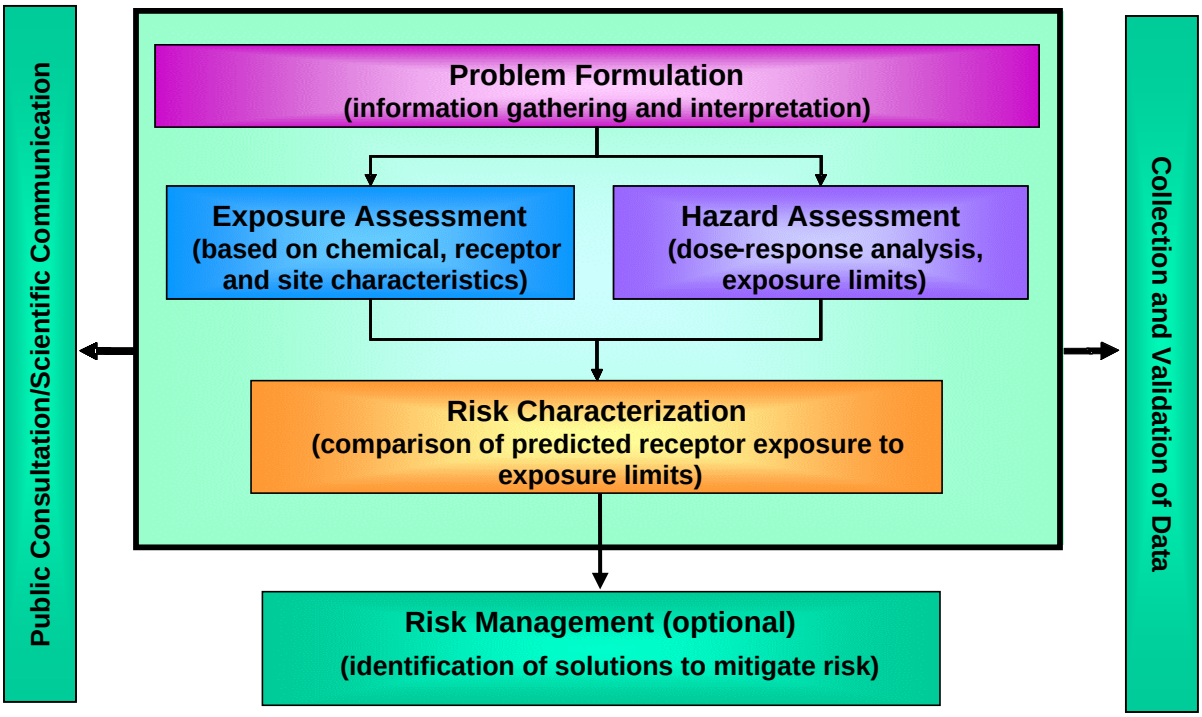

Figure ES-1.2 Overview of the Risk Assessment Framework

ES-1.4 A Phased Approach to Human Health Risk Assessment

The HHRA framework followed three phases (see Figure ES-1.3) that incorporate the steps outlined above:

Phase 1 **Problem Formulation and Screening Level Risk Assessment (SLRA)**

Phase 2 **Sampling and Analyses to Fill Identified Data Gaps**

Phase 3 **Detailed Human Health Risk Assessment**

The phased approach allowed for any issues and uncertainties to be addressed as they were identified. The activities and results associated with the three phases are described in more detail below.

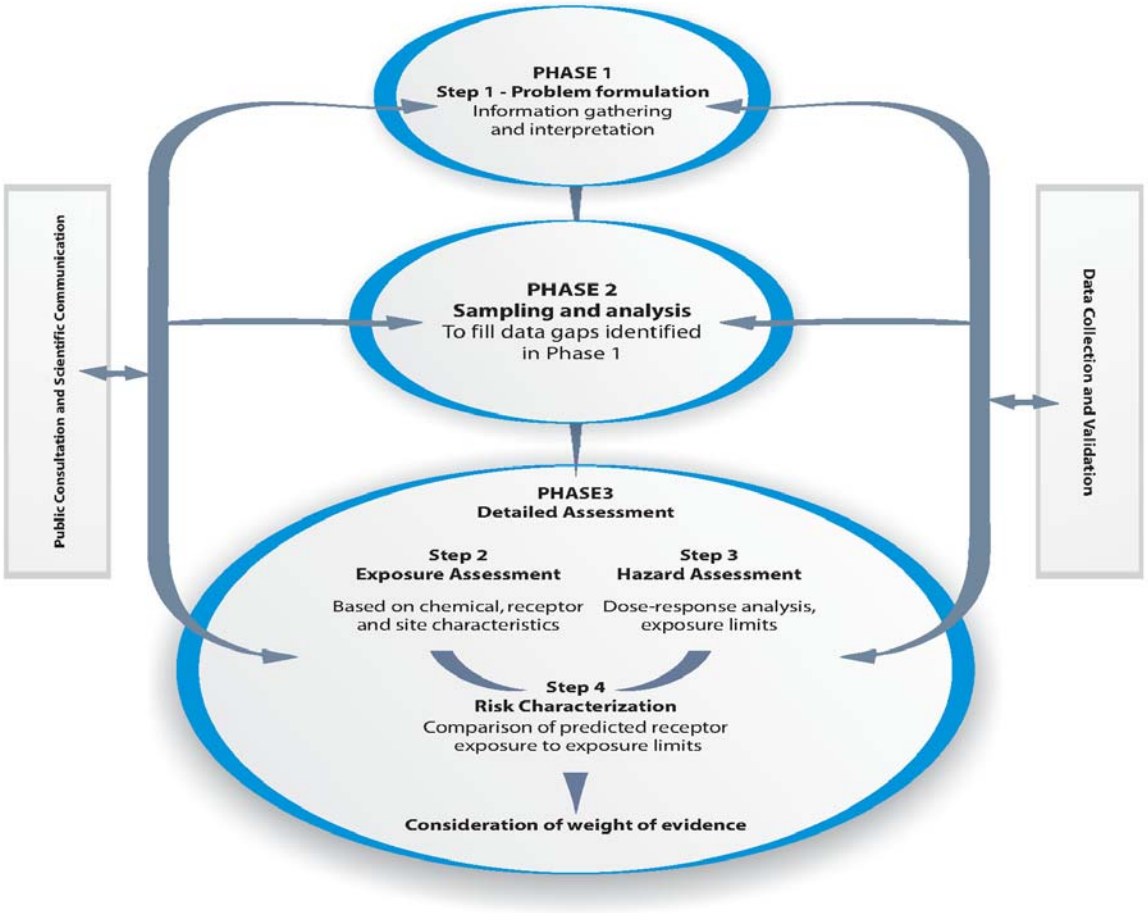

Figure ES-1.3 The Three Phases of the Sudbury HHRA project

ES-2.0 PHASE 1 - PROBLEM FORMULATION

Phase 1 of the HHRA laid the foundation for the entire risk assessment process, by outlining the key issues to be addressed, and the process to be followed to achieve the study objectives. The first phase of an HHRA typically consists of: i) Problem Formulation; ii) Screening Level Risk Assessment (SLRA), and iii) Identification of Data Gaps. These steps are outlined below.

ES-2.1 Problem Formulation

The Problem Formulation step of an HHRA characterizes the study site; identifies chemicals, receptors and exposure pathways of concern; and, identifies data gaps and uncertainties.

Study Area

The overall study area encompasses 40,000 km^2, as defined by the boundaries of the 2001 Sudbury soil sampling program. The smelting communities of Copper Cliff, Coniston and Falconbridge were originally identified for detailed evaluation (Figure ES-2.1). The study also considered Ontario as a whole for the evaluation of a typical Ontario resident (TOR).

Identification of Chemicals of Concern

The Terms of Reference for the HHRA provided three criteria to select COC using the 2001 soil survey database:

- Chemical concentration in soil must be above the MOE Table A soil remediation guideline for a residential/parkland use (MOEE, 1997);
- Chemical must be present at elevated levels in soils across the study areas; and,
- Chemical must be scientifically demonstrated to originate, at least in part, from the local mining/smelting operations.

Approximately 8,400 soil samples were collected as part of the 2001 survey and analyzed for 20 inorganic parameters. The SARA Group applied these criteria to results from the 2001 soil survey, and identified arsenic, cobalt, copper, lead, nickel and selenium as COC for the HHRA.

To ensure that any important potential COC were not missed, metal concentrations in additional media that were sampled as part of the HHRA (*i.e.*, air water, food, dust) were compared to regulatory screening criteria on an ongoing basis; however, no additional COC were identified.

Receptor Identification and Characterization

Communities of Interest (COI): Five Communities of Interest, or COI, were considered for the current HHRA. The towns of Copper Cliff, Coniston and Falconbridge were considered primary COI because they are the locations of current and/or historic smelting activity. The core region of the City of Greater Sudbury, called Sudbury Centre, was selected as an additional COI because it is the largest area of residential occupation within the GSA, and it is central to the three smelters. Finally, Hanmer was selected as a reference COI because it is nearby with similar geology and demographics, but it is not impacted by particulate deposition from the smelters, and thus is suitable for a baseline comparison with the other COI. For an additional background comparison, a typical Ontario resident (TOR) was also

evaluated. First Nations community members were addressed by considering the lifestyle and activities of First Nations peoples living within the established COI.

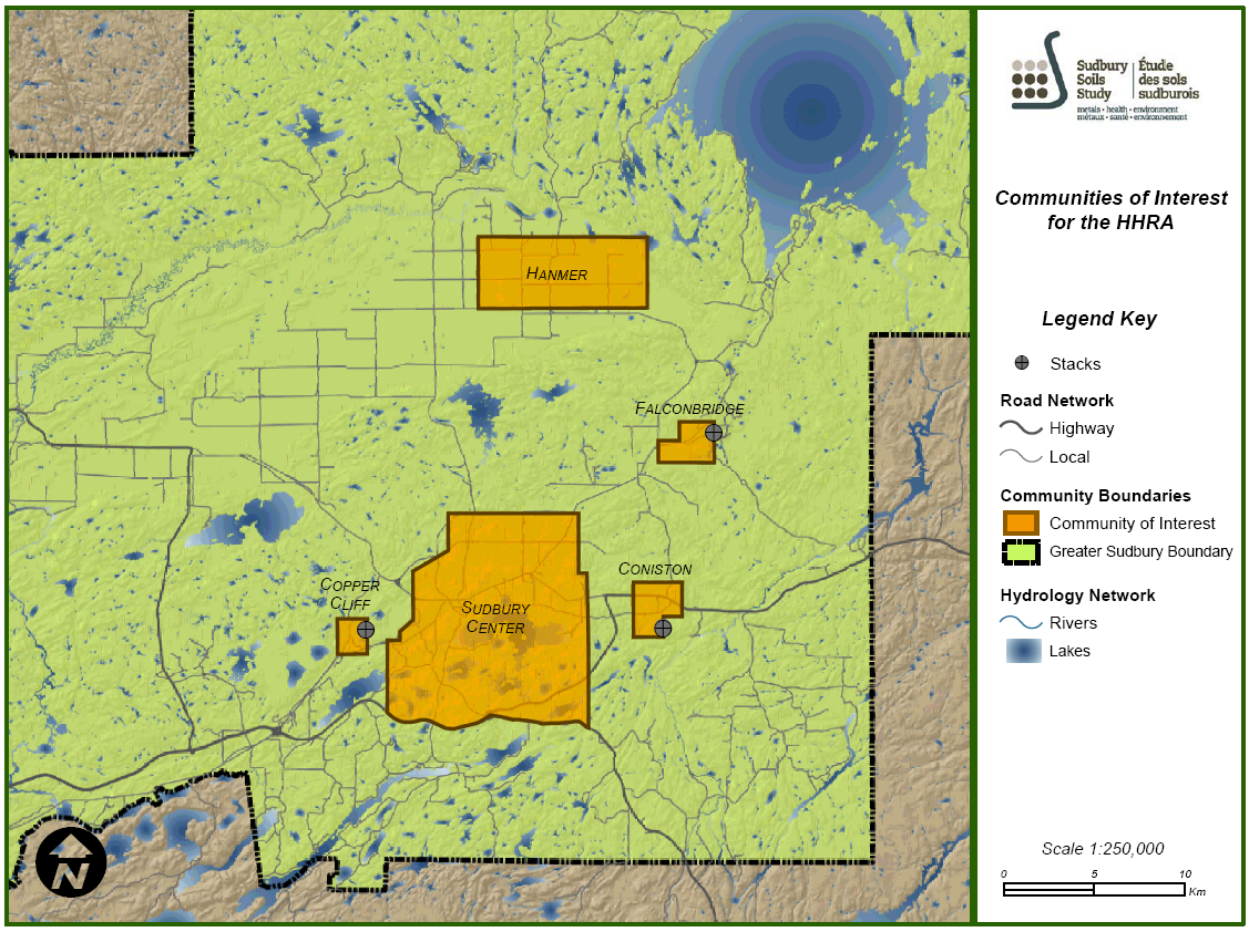

Figure ES-2.1 Map of the Communities of Interest (COI) for the Sudbury HHRA

Human Receptors within the COI: A human receptor is a hypothetical person (*e.g.*, infant, toddler, child, adolescent, or adult) who resides or works in the area being investigated and is, or could potentially be, exposed to the chemicals of potential concern. General physical and behavioural characteristics specific to the receptor type (*e.g.*, body weight, breathing rate, food consumption rate, *etc.*) were used to determine the amount of chemical exposure received by each receptor.

Five life stages were considered as part of the risk assessment to ensure that risks were predicted for all sensitive life stages and receptor characteristics:

- Infant (0 to < 6 months);
- Preschool child or toddler (6 months to <5 years);

- Child (5 to <12 years);
- Adolescent (12 to 20 years); and,
- Adult (>20 years).

To conservatively assess potential incremental lifetime cancer risks (ILCRs) from carcinogenic chemicals, a female composite receptor, which encompasses all five life stages from infant to adult, was used. A female receptor typically has higher potential exposures and risks than its male counterpart, largely due to their lower body weight-to-exposure ratio and longer life expectancy.

Identification of Exposure Pathways

People may come into contact with chemicals in their environment in a variety of ways, depending on their daily activities. Several exposure pathways were evaluated in the current risk assessment and illustrated in Figure E2.2 including:

- Inhalation of indoor and outdoor air;
- Incidental ingestion of soil and dust;
- Dermal contact with soil and dust;
- Consumption of potable water;
- Consumption of market basket (supermarket) foods;
- Consumption of locally-grown produce (*i.e.*, fruits and vegetables from local farms/gardens, wild berries);
- Consumption of local wildlife (*e.g.*, moose);
- Consumption of fish caught from local lakes; and,
- Consumption of baby formula by infants.

ES-2.1.6 Exposure Scenarios

Exposure scenarios describe the situations and conditions in which receptors may be exposed to COC. The following exposure scenarios were selected for the assessment:

- Typical GSA Resident: Exposure to COC occurs while living and working in the GSA, as well as exposure via consumption of market basket foods.

- Background – Typical Ontario Resident (TOR): Exposure to COC occurs at typical Ontario background (or ambient) levels.
- GSA Subpopulation – First Nations: Exposure includes wild games and fish consumption rates that were adjusted to reflect the behaviour and food consumption patterns of the First Nations community.
- GSA Subpopulation – Recreational Hunters/Anglers: Exposure includes wild game and fish consumption rates that were increased to reflect the consumption patterns of hunters and anglers.

The Sudbury Soils Study did not address health risks due to occupational exposure. Occupational health is addressed by both mining companies through their joint Occupational Health and Safety Committees.

ES-2.1.7 HHRA Conceptual Model

The conceptual model illustrates all potential receptors and the exposure pathways (see Figure ES-2.2).

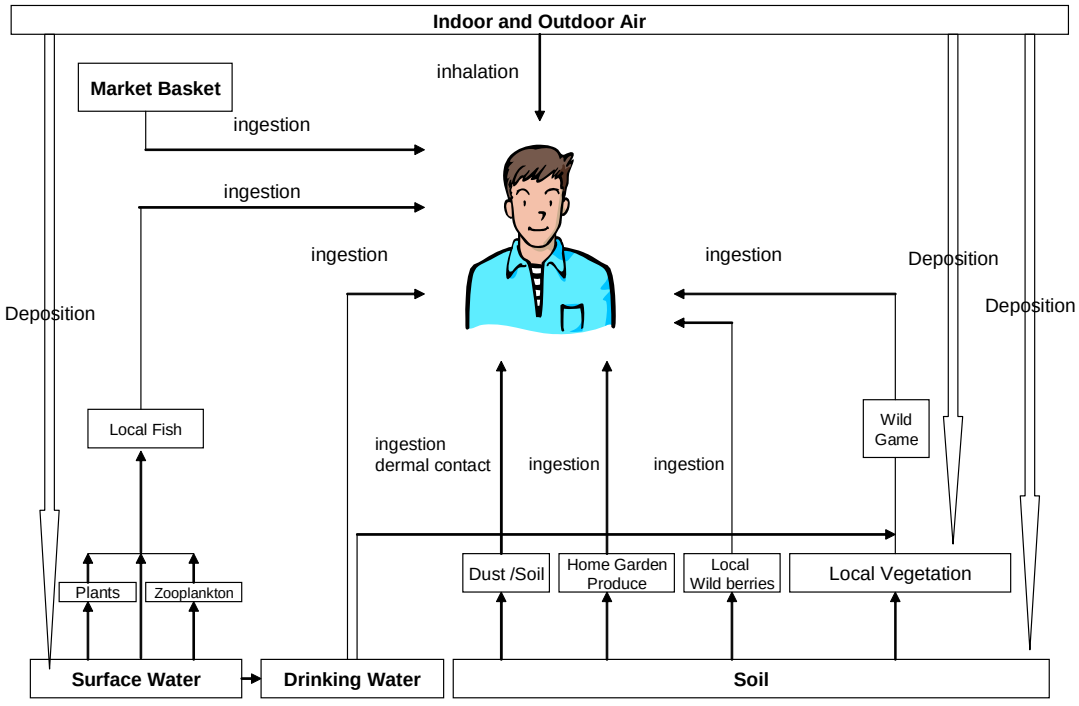

Figure ES-2.2 Conceptual Model for the Sudbury HHRA

ES-2.2 Screening Level Risk Assessment

A formal SLRA was not undertaken for this study because the Technical Committee requested that a full HHRA be conducted for each of the COC. Also, significant site-specific investigations had already been conducted as part of the Sudbury Soils Study; therefore, in many areas, the extremely conservative assumptions that characterize an SLRA were not needed.

ES-2.3 Identification of Data Gaps

Identification of data gaps that require further investigation is a key part of the problem formulation. Some of the data gaps or areas of uncertainty identified in conjunction with the Technical Committee include:

- Levels of COC in ambient outdoor air;
- Food consumption patterns of Sudbury residents;
- Levels of COC in drinking water from private residential wells or lakes;
- Bioavailability of COC in soil and dust;
- Speciation of COCs in soil and particulates;
- Levels of COC in indoor dust;
- Levels of COC in home-grown and wild fruits, vegetables and mushrooms;
- Levels of COC in wild game and fish from local lakes; and,
- Exposure of Falconbridge residents to arsenic in soil.

These issues were addressed in the HHRA as described below.

ES-3.0 PHASE 2 – SAMPLING AND ANALYSIS TO FILL DATA GAPS

Phase 2 of the HHRA was undertaken to collect the necessary data to fill identified data gaps and reduce uncertainties where possible.

Air Monitoring Program

An extensive air monitoring program was conducted to characterize the levels of COC in air inhaled by residents of the GSA. Ten monitoring sites in the GSA were selected to assess exposure in each for each of the COI. A six-day sampling schedule was established between October, 2003 and September, 2004. Three particulate matter (PM) size fractions were sampled:

- Respirable particulate matter less than 2.5 microns in diameter ($PM_{2.5}$);
- Respirable particulate matter less than 10 microns in diameter (PM_{10}); and,
- Total suspended particulate matter less than 44 microns in diameter (TSP).

Each size fraction has a different toxicological significance. Samples were weighed and analyzed for a suite of 20 metals, including the COC.

Sudbury Food Consumption Survey

To develop a profile of the various local foods consumed by residents of the GSA, a food consumption survey was conducted. The key research questions of the survey were:

1. What types of local foods do residents consume?
2. What approximate quantities of local foods do residents consume?
3. What are the sources of local foods consumed by residents?

COC in the Sudbury Area Potable Water Supply

Consumption of drinking water containing COC is one of the primary exposure pathways for GSA residents. The majority of households in the GSA are serviced by a municipal water supply. The municipal water supplies are routinely monitored for a suite of metals, including the COC. However, several thousand households obtain drinking water from private wells or lakes. The concentrations of COC in private wells and surface water supplies were unknown and potential exposures could not be quantified. Therefore, in the fall of 2004 drinking water was sampled at 94 residences with private water supplies. The results of the survey indicated that all concentrations of COC in drinking water samples were below their respective drinking water standards or guidelines (where available). Furthermore, COC levels were similar to concentrations reported in the municipal potable water supply.

Bioavailability/Bioaccessibility

Toxicity data (*e.g.*, reference doses [RfDs] and cancer slope factors [CSFs]) typically do not take the bioavailability of a chemical compound into account. It is, therefore, important in risk assessment to quantify the relative bioavailability. Bioaccessibility, which may be used to estimate relative bioavailability, is defined as "the fraction of a chemical solubilized from a [media] sample using *in vitro* test methods that simulate gastrointestinal conditions" (Kelly *et al.*, 2002).

A bioavailability/bioaccessibility study was conducted to determine the relative bioavailability factor (RAF) for each COC in soil and dust. An *in vitro* test method, which simulates gastric and intestinal phases of absorption was used. These data were then used in the HHRA to derive exposure estimates.

Speciation of the COC

Speciation is the process of determining the actual form of a metal within a sample matrix. It can be important to speciate metals in soil and particulate samples because the form of the metal may affect its bioavailability and toxicity to humans. For this study, the species of nickel in air samples was of primary interest, since one particular form (nickel subsulphide) is considered carcinogenic when inhaled.

Evaluation of COC Levels in Indoor Dust

Both airborne particulates and settled material may be transferred into homes as dust. Exposure to COC present in indoor dust is an important exposure pathway, especially for children. An indoor dust survey of 86 homes and eight schools was initiated to provide information for the HHRA on the concentrations of COC in indoor dust.

Levels of COC in Locally Grown Produce

A vegetable garden survey was conducted from May to October in 2003, to obtain site-specific data on the range of metal concentrations found in locally grown fruits and vegetables that might be a source of dietary exposure to COC. Produce and co-located soil were sampled at 89 sites, including 64 residential gardens, 15 commercial and 10 natural sites. Below-ground vegetables (*e.g.*, potatoes, carrots), above-ground vegetables (*e.g.*, lettuce, tomatoes), blueberries and wild mushrooms were collected, and prepared as for consumption before analysis. Soil samples were collected at depths of 0 to 15 cm, and 15 to 30 cm.

Levels of COC in Local Fish and Livestock

To measure metal concentrations in fish tissues being consumed by local anglers, fish were collected from 8 lakes in the study area. The lakes ranged in distance from only a few kilometres to over 45 km from the smelters. A total of 327 fish were collected. For the purpose of the HHRA, only species that are typically consumed by humans (*i.e.*, perch and walleye) were considered (n = 145 fish tissue samples). Tissue samples were also collected from ten cattle raised in the Sudbury area. Samples of kidney, liver and muscle were collected, and analyzed for a suite of metals and metalloids.

Falconbridge Arsenic Exposure Study

In response to community concerns over elevated levels of arsenic in soil on residential properties, an arsenic exposure study was initiated. Falconbridge Limited (now Xstrata Nickel) funded this study, which was not formally part of the Sudbury Soils Study. The study was designed to address two specific questions:

1. Do Falconbridge residents have higher urinary arsenic levels than residents living in a comparison area with lower levels of arsenic in their soil?
2. What health risks relative to other communities are associated with the urinary arsenic levels of Falconbridge residents?

The mean soil arsenic level in Falconbridge (69 mg/kg) was approximately 18 times higher than in the reference community of Hanmer (3.7 mg/kg). Sampling took place in September and October of 2004. Study participation was excellent, with large sample sizes from both Falconbridge (n=369) and Hanmer (n=321) making this one of the largest studies of its kind. The results of the study showed that Falconbridge residents' urinary arsenic levels were very similar to those of Hanmer residents. Residents of Falconbridge are, therefore, not at any increased risk from arsenic exposure compared to individuals living in areas with much lower arsenic soil concentrations. The survey results were incorporated into the weight-of evidence approach used to characterize overall health risks from arsenic exposure in the HHRA.

ES-4.0 DETAILED HHRA APPROACH AND METHODS

This chapter comprises the remaining three steps of the HHRA: exposure assessment, hazard assessment and risk characterization.

ES-4.1 Exposure Assessment

The primary objective of the exposure assessment is to predict, using site-specific data and a series of conservative assumptions, the rate of exposure of the receptors to the COC in each of the exposure scenarios. The degree of a receptor's exposure to the COC depends on the interactions of the following factors:

- Concentrations of COC in environmental media;
- Physical-chemical characteristics of the COC;
- Site-specific environmental characteristics; and,
- Physiological and behavioural characteristics of the receptors.

Media Concentration Data Selected for Use in the HHRA

Exposure point concentrations (EPCs) were used to characterize the concentrations of COC in each environmental medium. In each medium, the 95% upper confidence limit of the mean (95% UCLM) was used to characterize average concentrations. The EPC data used in assessment are summarized in Table ES-4.1. In addition to the 95% UCLM, the upper bound of COC concentrations in soil and indoor dust was also characterized (95^{th} percentile or maximum). The upper or maximum COC concentrations in soil were used to evaluate "worst case" exposure scenarios.

Table ES-4.1 Summary of 95% UCLM values for all Exposure Point Concentrations (EPCs) used in the HHRA

Community of Interest	As [a]	Co	Cu	Pb	Ni	Se
Soil Concentrations			**µg/g**			
Coniston	12	19	320	52	433	1.3
Copper Cliff	19	33	1370	98	976	7.5
Falconbridge	79	57	1010	82	1070	3.1
Hanmer	4.3	6.6	67	19	68	0.68
Sudbury Centre	7.2	11	204	36	210	1.3
Typical Ontario Resident	17	21	85	43	120	1.9
Dust Concentrations (calculated)[b]			**µg/g**			
Coniston	87	98	204	127	221	49
Copper Cliff	98	113	298	150	273	77
Falconbridge	142	130	276	143	280	61
Hanmer	67	74	136	98	137	41
Sudbury Centre	76	85	182	116	183	49
Typical Ontario Resident	95	101	145	121	158	54
Air Concentrations (outdoor and indoor)			**µg/m^3**			
Coniston	0.0024	0.00087	0.016	0.0080	0.012	0.0034
Copper Cliff	0.0050	0.0025	0.081	0.022	0.059	0.0055
Falconbridge	0.0024	0.0025	0.026	0.015	0.028	0.0034
Hanmer	0.0056	0.00066	0.099	0.0098	0.012	0.0040
Sudbury Centre						
Combined data (2 stations)	0.0061	0.0097	0.17	0.025	0.095	0.0092
Travers Street only	0.0090	0.018	0.20	0.031	0.26	0.014
Typical Ontario Resident	0.001	0.0019	0.0091	0.0080	0.0014	0.0019
Drinking Water			**µg/L**			
Coniston	1.1	0.2	45	0.31	53	1.3
Copper Cliff	2.5	0.05	170	1.4	49	3
Falconbridge	2.6	0.2	30	0.97	32	2.5
Hanmer	1.5	0.06	65	0.49	0.8	1.3
Sudbury Centre	1.1	0.2	45	0.31	53	1.3
Typical Ontario Resident	0.64	0.088	0.41	2.2	1.9	1.6
Home Garden – Below Ground Vegetables			**µg/g wet weight**			
Coniston	0.0069	0.024	0.81	0.26	0.56	0.029
Copper Cliff	0.0088	0.019	1.2	0.13	1.7	0.42
Falconbridge	0.025	0.13	1.2	0.23	3.7	0.016
Hanmer	0.042	0.10	1.1	0.25	0.31	0.10
Sudbury Centre	0.0075	0.017	1.1	0.075	0.79	0.040
Home Garden - Above Ground Vegetables			**µg/g wet weight**			
Coniston	0.0069	0.21	0.54	0.095	0.57	0.030
Copper Cliff	0.016	0.13	0.92	0.13	1.8	0.68
Falconbridge	0.052	0.11	0.75	0.038	2.0	0.02
Hanmer	0.0046	0.0074	0.46	0.089	0.28	0.0083

Table ES-4.1 Summary of 95% UCLM values for all Exposure Point Concentrations (EPCs) used in the HHRA

Community of Interest	As [a]	Co	Cu	Pb	Ni	Se
Sudbury Centre	0.0067	0.027	0.75	0.094	0.75	0.059
Home Garden – Fruits			**µg/g wet weight**			
All COI	0.0063	0.019	0.90	0.046	2.7	0.058
Wild Berries			**µg/g wet weight**			
All COI	0.0052	0.016	0.68	0.074	0.71	0.016
Local Commercial Produce			**µg/g wet weight**			
Root Vegetables	0.0086	0.037	1.0	0.11	0.91	0.13
Above Ground Vegetables	0.0079	0.038	0.71	0.078	1.1	0.10
Fruit	0.0061	0.035	0.65	0.042	1.5	0.024
Fish and Wild Game			**µg/g wet weight**			
Wild Game	0.00013	0.040	0.68	0.0040	0.62	1.4
Fish	0.00022	0.019	0.52	0.30	0.032	2.0
Market Basket Foods - TEDIs			**µg/g**			
Infant Formula	7.2×10^{-6}	0.0046	0.90	0.0023	0.011	0.020
Dairy	0.0032	0.010	0.36	0.0060	0.015	0.072
Meat and Eggs	0.00046	0.011	1.1	0.0066	0.022	0.25
Fish	0.00041	0.0093	1.3	0.0069	0.037	0.43
Root Vegetables	0.0043	0.033	1.1	0.0073	0.075	0.014
Other Vegetables	0.0093	0.013	1.2	0.0050	0.28	0.023
Fruits	0.0022	0.025	1.7	0.014	0.080	0.0092
Cereals and Grain	0.0059	0.025	1.8	0.012	0.17	0.13
Sugar and Sweets	0.0077	0.024	1.4	0.040	0.27	0.021
Fats and Oils	0.0091	0.022	0.25	0.00038	0.057	0.025
Nuts and Seeds	0.0073	0.063	14	0.014	2.0	0.32

[a] The arsenic exposure point concentration (see highlighted entries) for all food products (*i.e.*, home garden, local produce, fish and wild game, and market basket foods) were adjusted to represent only the inorganic arsenic fraction content of the food (on which the TRV is based), as follows: all vegetable produce: 0.42, fruits and berries: 0.33, wild game: 0.028, fish: 0.002, infant formula: 0.55 (based upon whole milk), dairy: 0.47, meat and eggs: 0.03, cereals and grains: 0.21, sugars and sweets: 0.34; fats and oils: 0.34, and nuts and seeds: 0.34.

[b] Indoor dust concentrations calculated based upon regression equation developed from paired soil and indoor dust data collected during the Sudbury indoor dust survey

Background Exposure Assessment

Background exposures are exposures to chemicals that are not related to the point source or area of impact under assessment. In the HHRA, it is important to consider background exposures and risks in the absence of the mining and smelting activities in the GSA. Background exposures were addressed by considering a Typical Ontario Resident (TOR) scenario. COC concentrations used in the background exposure assessment were derived from monitoring programs across Ontario and Canada.

Market Basket Estimated Daily Intakes

Market basket foods, that is, foods obtained from grocery stores, supermarkets, butchers, *etc.* are considered a background source of exposure for all receptors. This exposure is termed the *market basket estimated daily intake*, or EDI_{MB}. Background concentrations in market basket foods were obtained from the Canadian Total Diet Study, the Port Colborne assessment (JWEL, 2004a), and the U.S. FDA Total Diet Study. These concentration data were combined with food intake rates to obtain the EDI_{MB}.

Exposure Assessment of Carcinogens

For the assessment of carcinogenic chemicals, the endpoint of concern is the lifetime cancer risk, with an assessed exposure period of an entire lifetime (assumed to be 70 years). For exposures of less than 70 years, exposures must be amortized over the entire lifetime. In order to provide an evaluation of lifetime cancer risks in this assessment, all five receptor age classes were combined to produce a composite lifetime receptor.

Deterministic *versus* Probabilistic Exposure Analysis

The numerical values input into a risk assessment may be either point estimates (deterministic assessment) or probability distributions (probabilistic risk assessment or PRA). Deterministic risk assessments generally incorporate conservative assumptions. Therefore, if risk to a particular receptor is not predicted, the population can be removed from further consideration with confidence. A deterministic risk analysis was used for this HHRA, although some probabilistic modeling was initially undertaken to verify the predictions. As point values were selected, in consultation with the International Expert Review Panel (IERP) for many of the assumptions used in the assessment, a full PRA would not provide further useful information, and was ultimately not considered necessary for the HHRA.

Exposure Estimation Methods

The estimated rate of lifetime daily exposure to a given COC was evaluated through the estimation of an exposure point concentration (EPC) for each media type. Soil concentrations were based on the 95th percentile upper confidence level of the mean (95% UCLM) and maximum concentrations; all other media were characterized by 95% UCLM. Receptor characteristics were defined by central tendency estimate (CTE) and reasonable maximum exposure (RME) scenarios. However, the RME scenario, which used reasonable upper-bound receptor characteristics, was selected as the primary scenario for evaluating potential health risks arising from exposures to the COC in the GSA. Finally, two sets of

receptors were evaluated in the current assessment: i) the general population, and ii) the hunters and anglers sub-population (which includes First Nations members).

Development of the Risk Assessment Modelling Tool

Exposure estimation for the HHRA used an integrated multi-pathway environmental risk assessment model. This Excel-based model incorporates the latest techniques and procedures for exposure modelling from various regulatory agencies (*e.g.*, U.S. EPA, MOE, CCME, Cal/EPA, U.S. EPA Region VI, WHO, *etc*.), and the published, scientific literature. The model is capable of both deterministic and probabilistic analyses, and of modelling complex exposure scenarios with multiple exposure pathways.

ES-4.2 Hazard Assessment

Toxicity refers to the potential for a chemical to produce either permanent or temporary damage to the structure or functioning of any part of the body. The toxicity of a chemical depends, among other things, on the dose and the duration of exposure. The objectives of the hazard or toxicity assessment are to:

- Review the toxicological effects reported to be associated with exposure to the COC;
- Determine whether each COC is considered to cause carcinogenic (non-threshold) or non-carcinogenic (threshold) effects; and,
- Identify the most appropriate and scientifically valid intake or exposure limits, for each COC against which calculated intakes can be compared to provide estimates of potential health risks.

There are two main dose-response relationships for chemicals:

- Threshold Responses – For chemicals with a threshold response, it is thought that there is a dose below which no adverse effects are expected. This relationship applies to all chemicals that do not cause cancer by altering genetic materials. Intake limits for threshold-response chemicals are called reference doses (RfDs), acceptable daily intakes (ADIs), tolerable daily intakes (TDIs), or permissible daily intakes (PDIs). These intake (or exposure) limits are expressed in units of µg/kg body weight/day.
- Non-threshold Response – For chemicals with a non-threshold response, it is assumed that any dose greater than zero has a non-zero probability of causing some type of response. This response typically applies to genotoxic carcinogens. Accordingly, it is assumed that any exposure has some potential to cause damage, so it is necessary to define an "acceptable" level of risk. In risk assessment, "acceptable" risk is usually defined by governments and other public agencies as a

risk of 1-in-100,000 to 1-in-1,000,000. Exposure limits for non-threshold chemicals are typically expressed as "increased risk per unit of dose." These exposure limits are called cancer slope factors or cancer potency factors, and have units of $[\mu g/kg \text{ body weight/day}]^{-1}$.

Overview of Exposure Limits Selected for the HHRA

A detailed toxicological profile was prepared for each COC, detailing mechanisms of action, relevant toxic endpoints, and receptor-and route-specific toxicological criteria (see Appendix A). The purpose of the profiles was to:

- Summarize the most relevant toxicological and epidemiological information on the COC;
- Outline any recent information that may challenge previous findings; and,
- Provide supporting rationale for the exposure limits selected for the HHRA.

The profiles are mainly based on secondary sources, such as ATSDR toxicological profiles and detailed reviews by regulatory agencies. The secondary sources were supplemented by literature reviews from the date of the last major review to the present.

Selection of Toxicological Criteria for the HHRA

MOE guidance discourages the use of de novo toxicological criteria when health-based exposure limits from major health agencies are available. In keeping with the approach preferred by the MOE, the exposure limits used in the HHRA were selected from the limits published by various regulatory agencies (e.g. MOE, Health Canada, CCME, WHO, Cal/EPA, ATSDR, U.S. EPA).

The selected exposure limits are provided in Table ES-4.2.

Table ES-4.2 Summary of Toxicological Criteria chosen for the Sudbury Human Health Risk Assessment

Chemical	Route	Toxicological Criterion [a]		Regulatory Agency
Arsenic	Oral	RfD	0.3 µg/kg/day	U.S. EPA, 1993
		SF_o	$0.0015 (\mu g/kg/day)^{-1}$	U.S. EPA, 1998
	Inhalation	Chronic REL	0.03 $\mu g/m^3$	OEHHA, 2000
		SF_i (IUR)	$0.015 (\mu g/kg/day)^{-1}$ $[4.3x10^{-3} (\mu g/m^3)^{-1}]$	U.S. EPA, 1998
Cobalt	Oral	RfD	10 µg/kg/day	ATSDR (2001)
	Inhalation	RfC	0.5 $\mu g/m^3$	RIVM (Baar *et al*, 2001)
Copper	Oral	UL	140 µg/kg/day	IOM, 2001; Health Canada, 2005
	Inhalation	TCA	1 $\mu g/m^3$	RIVM (Baars *et al*., 2001)

Table ES-4.2 Summary of Toxicological Criteria chosen for the Sudbury Human Health Risk Assessment

Chemical	Route	Toxicological Criterion [a]		Regulatory Agency
Lead	Oral, Inhalation, Dermal	IOC_{POP}	1.85 µg/kg/day	MOE, 1996a; MOE, 1994
Nickel	Oral	RfD	20 µg/kg/day	U.S. EPA, 1996
	Inhalation	RfC	0.02 µg/m^3 (total nickel)	OJEU, 2005
Selenium	Oral	RfD/TRV	5.00 µg/kg/day	IOM, 2000; Health Canada, 2005; U.S. EPA, 1991a
	Inhalation	Chronic REL RfC	20 µg/m^3	OEHHA, 2001

[a] RfD = reference dose; SFo = oral slope factor; SFi = inhalation slope factor; IUR = inhalation unit risk; REL = reference exposure level; TCA = tolerable concentration in air; UL = upper intake level; IOC_{POP} = intake of concern (population) – unlike an RfD or RfC (or similar benchmark), there is no established threshold or 'acceptable' or 'safe' levels for critical health effects of lead, at or below which no adverse health effects would be expected to occur.; TRV = toxicity reference value.

Note: For chemicals with no identified inhalation toxicological criteria, it was assumed that inhalation bioavailability and toxic potency is equivalent to that which occurs *via* the oral exposure route.

Bioavailability/Bioaccessibility

Bioavailability is an important consideration in determining the exposure and response of target tissues to a COC. Bioavailability is the fraction of the total amount of a substance to which an organism has been exposed that enters the blood stream.

Bioaccessibility is a similar concept to relative bioavailability. It is the fraction of a chemical that is solubilized in body fluids and available for absorption. To better characterize this fraction, a detailed site-specific *in vitro* oral bioaccessibility study was conducted to estimate the bioaccessibility of each of the COC in soil and dust. The results of the study are summarized in Table ES-4.3.

Table ES-4.3 Summary of bioaccessibility results and relative absorption factors (RAFs)

COC	Bioaccessibility (%)		Relative Absorption Factors (RAFs)			
	Soil	Dust	Oral		Inhalation	Dermal
			Soil	Dust		
Arsenic	39	45	0.39	0.45	1[a]	0.03
Cobalt	28	30	0.28	0.30	1[a]	0.001
Copper	74	49	0.74	0.49	1[a]	0.003
Lead	78	95	0.66	0.83	1[a]	0.001
Nickel	44	31	0.42	0.30	1[a]	0.001
Selenium	26	67	0.26	0.67	1[a]	0.001

[a] Assumes that 100% of PM_{10} size fraction is available.

ES-4.3 Risk Characterization

The risk characterization integrates the exposure and hazard assessments to provide a conservative estimate of human health risk for the receptors in the various exposure scenarios. Risk is characterized by comparing the estimated exposures (from the exposure assessment) to the exposure limits (from the hazard assessment). For COC with threshold-type dose response (*i.e.*, for non-carcinogens), risk is characterized using the Hazard Quotient (HQ).

$$\text{Hazard Quotient (HQ)} = \frac{\text{Estimated Exposure (ug/kg/day)}}{\text{Exposure Limit (ug/kg/day)}}$$

The HQ value is used to identify scenarios where the total exposure received by receptors is greater than the exposure limit (*i.e.*, where HQ > 1), and to estimate the potential impact of such exposures.

For COC with non-threshold type dose response (*i.e.*, for genotoxic carcinogens), risk is characterized using the Cancer Risk Level (CRL).

$$\text{Cancer Risk Level (CRL)} = \text{Lifetime Average Daily Dose} \times \text{Cancer Slope Factor } (q_1^*)$$

The CRL can be compared to an acceptable level of cancer risk to determine if the exposures pose an unacceptable cancer risk. In many jurisdictions, including Ontario, an incremental cancer risk level of 1-in-1,000,000 (CRL $\leq 10^{-6}$) is considered acceptable; however, it is important to note that because a CRL includes risks from non-facility-related exposure (*i.e.*, not just incremental exposures), it is not strictly comparable to the benchmark for incremental cancer risk; an alternate acceptable risk level may be appropriate.

In the case of Sudbury, it is difficult to separate the incremental contribution made by the smelters from other urban and natural inputs; therefore, the cancer risk estimates are estimates of total risk, and are greater than the true incremental risk. Careful consideration needs to be given to selection of an appropriate benchmark for total cancer risk.

ES- 5.0 RESULTS AND DISCUSSION

When considering the results of the HHRA, the benchmark comparisons (*i.e.*, the HQs and CRLs), the strength-of-evidence and the weight-of-evidence must also be considered.

Results presented in this Chapter include:

- Results of the deterministic assessment for non-cancer endpoints for six COC, five COI, the general Sudbury population (using female toddlers as the most exposed receptor), and the hunters and anglers subpopulation (that also includes First Nations members). This assessment includes the oral/dermal and inhalation exposure pathways for the six COC. (Note that for arsenic and lead, all exposure routes were evaluated together under the oral/dermal pathway.)
- Results of the deterministic assessment for carcinogenic endpoints for three COC in five COI. Cancer risk estimates for cobalt and nickel represent the total lifetime cancer risk due to inhalation exposure (CRL). The arsenic results are based on lifetime exposure to inorganic arsenic via all exposure pathways (CRL).
- Development of a soil risk management level (SRML) for lead based on a weight of evidence evaluation.

ES-5.1 Overview of Results

ES-5.1.1 Non-Cancer Endpoints

Oral/Dermal Exposure

Hazard Quotients (HQs) were developed for average (HQ_{avg}) and maximum soil concentrations (HQ_{max}), in each COI. The HQs for the oral/dermal pathway were less than 1.0 for cobalt, copper, lead and nickel in all COI for all scenarios indicating no risks are predicted for these COC *via* oral/dermal exposure (Table ES-5.1). The oral/dermal HQs for arsenic and selenium were greater than 1.0 for all exposure scenarios (except arsenic in Sudbury Centre), indicating that further consideration of arsenic and selenium was required. It should be noted that, due to the nature of the selected TRVs for each, the predicted risk values reported for arsenic and lead represent total exposure (*i.e.*, oral/dermal, as well as inhalation, exposure).

Table ES-5.1 Summary of Oral/Dermal HQ_{avg} Results for the Female Toddler

COC	HQ_{avg} [a] Oral/Dermal Exposures					
	Coniston	**Copper Cliff**	**Falconbridge**	**Sudbury Centre**	**Hanmer**	**TOR**
Arsenic [b]	**1.3**	**1.5**	**1.7**	**1.3**	**1.3**	**1.2**
Cobalt	0.081	0.083	0.085	0.08	0.08	0.078
Copper	0.62	0.66	0.62	0.62	0.62	0.62
Lead [b]	0.86	0.93	0.91	0.83	0.81	0.75
Nickel	0.67	0.71	0.7	0.66	0.54	0.35
Selenium	**1.6**	**1.6**	**1.6**	**1.6**	**1.6**	**1.3**

[a] Any HQ > 1.0 is listed in **bold** text.
b Estimates provided for arsenic and lead represent total exposure and include oral/dermal exposures, as well as inhalation exposures.
Note: Assumes RME receptor exposure scenario.

When considering community-wide risks, it is prudent to consider exposures of individuals who may reside in areas that are associated with soil concentration greater than the COI average. When the maximum soil concentrations of lead were considered in each COI, the lead HQ_{max} estimate exceeded a value of 1.0 in Copper Cliff (HQ_{max} = 1.3), Coniston, (HQ_{max} = 1.1), Sudbury Centre (HQ_{max} = 1.1) and Falconbridge (HQ_{max} = 1.1).

Inhalation Exposure

The inhalation risk HQ values were less than 1.0 for cobalt, copper and selenium in all COI. The inhalation HQ values for nickel were greater than 1.0 at the Copper Cliff (HQ = 3), Falconbridge (HQ = 1.4), and Sudbury Centre West (HQ = 12) monitoring stations. As noted previously, due to the derivation of their respective selected TRVs, arsenic and lead are not considered in this section because the oral/dermal exposure estimates represent total exposure and include the inhalation pathway.

ES-5.1.2 Carcinogenic Endpoints

The results of the risk assessment for carcinogenic endpoints of arsenic are presented in Table ES-5.2. While the primary nickel endpoint of concern for the current assessment was based upon a non-carcinogenic health measure, carcinogenic endpoints related to the inhalation of nickel were evaluated as part of an overall weight-of-evidence approach. Cancer risk estimates for nickel inhalation are discussed in Section ES-5.2, and presented in Section 5.2.5.1. The other COC are not considered in this section.

The CRL estimates for the general Sudbury population resulting from inhalation exposure to arsenic exceed a risk of 1-in-1,000,000 (1.0×10^{-6}) at all COI.

Table ES-5.2 Summary of CRL Results for Arsenic for the Female Lifetime Receptor

COC	Cancer Risk Level (CRL) [a]					
	Coniston	Copper Cliff	Falconbridge	Sudbury Centre	Hanmer	TOR
Arsenic	**1.3×10^{-4}**	**2.4×10^{-4}**	**2.6×10^{-4}**	**1.5×10^{-4}**	**1.2×10^{-4}**	**6.3×10^{-5}**

[a] Any CRL > 1.0×10^{-6} is listed in **bold** text.

Hunting and Fishing Populations within the GSA

Members of the hunting and fishing subpopulation (including First Nations members), who consume local wild game and fish to a greater degree than the general population, were also considered when predicting HQ and ILCR values. There was no appreciable difference between the HQs and ILCRs predicted for this subpopulation and that predicted for the general population.

ES-5.2 Discussion of Results

Arsenic: Both non-cancer and cancer risk estimates for arsenic exceeded standard acceptable benchmarks for both oral/dermal and inhalation exposures. Results were compared with data from other studies, chemical speciation information, and the Falconbridge Arsenic exposure Study. The weight-of-evidence evaluation strongly indicates that there are no unsafe exposures or increased health effects associated with soil arsenic levels within the Greater Sudbury Area and the communities of interest. As such, no further consideration or actions related to arsenic in the study area are considered necessary.

Cobalt: Oral/dermal and inhalation exposures were within acceptable levels in all communities of interest. It was not considered necessary to undertake more detailed assessment or actions related to cobalt in the study area.

Copper: The estimated HQ values associated with copper exposures were less than 1.0 under all exposure and receptor scenarios. It was not considered necessary to undertake detailed assessment or actions related to copper in the study area.

Lead: The HQ values predicted for average lead soil concentrations did not exceed 1.0 in any of the COI. However, when the maximum soil concentrations of lead were considered in each COI, the HQ_{max} estimate exceeded a value of 1.0 in Copper Cliff (HQ = 1.3; max. soil concentration = 582 mg/kg), Coniston, (HQ = 1.1; max soil concentration = 310 mg/kg), Sudbury Centre (HQ = 1.1; max soil concentration = 310 mg/kg) and Falconbridge (HQ = 1.1; max soil concentration = 335 mg/kg). As a

result of these HQ_{max} values, it was considered appropriate to undertake a more detailed weight of evidence approach to develop a Soil Risk Management Level (SRML) for lead.

Nickel: Oral/dermal exposures were within acceptable levels in all communities of interest. Therefore, it was not deemed necessary to undertake further evaluation related to oral/dermal exposure to nickel in the study area.

While a variety of valid TRVs for both cancer and non-cancer endpoints were evaluated in the current assessment as part of a weight-of-evidence approach, ultimately an inhalation TRV established by the European Union, based on a non-cancer endpoint, was selected as the primary benchmark to evaluate risks related to the inhalation of airborne nickel particulate in the GSA. However, it is important to note that that this EU TRV is also considered compatible with the objective of limiting excess lifetime cancer risks to not more than one-in-a-million.

Based upon the European Union TRV, the HQ values were greater than 1.0 at the Copper Cliff (HQ = 3) Falconbridge (HQ = 1.4) and Sudbury Centre West (HQ = 12) monitoring stations. Further consideration should be given to airborne nickel concentrations in the areas surrounding the Copper Cliff and Sudbury Centre West monitoring stations. However, it is the opinion of the SARA Group that the potential risks related to airborne nickel exposures in Falconbridge are considered negligible given the degree of safety built into the assessment and no further evaluation or action is considered necessary.

Results of the weight-of-evidence assessment of the various cancer and non-cancer endpoint TRVs indicate potential inhalation health risks in the area immediately surrounding the Vale Inco Copper Cliff facility, which includes the Sudbury Centre West and Copper Cliff air monitors.

Selenium: The HQ values for selenium were greater than 1.0 for oral/dermal exposures. However, a significant proportion (approximately 75%) of the estimated total daily intake (and hence risk) of selenium was a result of consuming general market basket (or supermarket) foods. The intake from market basket foods alone exceeded the reference dose under the RME scenario. Based on a weight of evidence evaluation and comparison with a Typical Ontario Resident, it is concluded that selenium in the Sudbury environment does not pose an unacceptable human health risk.

ES-5.3 Development of Soil Risk Management Levels (SRML)

When considering community-wide risks, it is prudent to consider exposures of individuals who may reside in areas that are associated with soil concentration greater than the community average. As

discussed previously, the lead HQ estimates exceeded 1.0 in four of the COI (*i.e.*, Coniston, Copper Cliff, Falconbridge, and Sudbury Centre) when the maximum concentration of lead in soil was used in the estimate of risk. While the predicted risks are only marginally above the established HQ benchmark, it was considered appropriate to derive a soil risk management level (SRML) for lead. Based on the information available from the current risk assessment, as well as other studies pertaining to lead in the environment, a weight-of-evidence approach was used in the evaluation of health risk estimates and the development of a SRML for lead.

An SRML is the average COC concentration in soil within a given exposure unit (*i.e.*, a COI) that would yield an acceptable levels of risk (*i.e.*, the EPC value that corresponds to an HQ of 1.0). Because receptors do not move randomly around the COI (*i.e.*, because some receptors might spend more time on properties which exceed the EPC value) it is not appropriate to apply the SRMLs to a COI as a whole, but rather should be applied to individual residential properties.

ES-5.4 Weight of Evidence Evaluation for Lead

The following primary lines of evidence were evaluated to aid in the development of an appropriate lead SRML:

- Risk predictions from the Sudbury HHRA exposure model for each COI;
- A sensitivity analysis pertaining to input variables in the Sudbury exposure model;
- A detailed literature review of the empirical relationship between lead in soil and blood lead levels, and how this information has been used to derive soil lead criteria for other sites; and,
- An evaluation of the recommended SRML in the Sudbury exposure model and the U.S. EPA IEUBK model to evaluate the level of estimated risk posed by a variety of soil lead concentrations, including the recommended SRML.

Results of the detailed risk assessment indicate that the Sudbury-specific model-derived SRML (based on the assumptions inherent in the HHRA) were very conservative relative to soil lead values derived for screening purposes by Ontario Ministry of the Environment and U.S. EPA. The sensitivity analysis further demonstrated the conservative nature of the Sudbury exposure model and how changes in the input parameters could significantly alter the model outputs. The model was particularly sensitive to the bioaccessibility values used for soil and dust in the Sudbury HHRA.

The primary literature was reviewed to investigate the relationship between lead concentrations in soil and dust, and the corresponding blood lead levels in children. The literature and other expert opinion

reveal that a blood lead level of approximately 5 µg/dL results from exposure to soil containing lead levels of 500 to 1,500 µg/g.

Based on the weight-of-evidence (*i.e.*, the conservative risk assessment, the strong indication provided in the literature that 500 µg Pb/g soil is a safe level for residential properties, and the previously established regulatory screening level for children's play areas of 400 µg Pb/g soil), and the relative strength-of-evidence associated with each of these elements, it was concluded that an SRML of 400 µg Pb/g soil would be appropriate for the Greater Sudbury Area. As the U.S. EPA indicated in the derivation of their lead criteria, consideration of the uncertainty of the scientific evidence regarding environmental lead levels at which health effects would result, a SMRL of 400 µg Pb/g soil provides a sufficient level of protection to minimize the likelihood of harm to human health.

Ultimately, blood lead is a true marker of exposure, eliminating many of the assumptions and uncertainties inherent in the HHRA. While blood lead data is not currently available for the Greater Sudbury area, collection of blood lead data in the future would aid in minimizing many of the uncertainties inherent in the assessment.

ES-6.0 OTHER ISSUES

In the course of the HHRA, several issues were identified that required consideration during the risk assessment process. These issues are discussed in detail in Chapter 6 and identified below:

- Special Considerations for the Assessment for Children's Exposure and Toxicity
- Sulphur Dioxide (SO_2)
- Occupational Exposures
- Chemical Mixtures: Overview of Metal-Metal Interactions
- Soil Ingestion Rates in Children and Long-Term Pica Behaviour
- The IEUBK Model for Lead Exposure
- Dermal Sensitization to Nickel
- Epidemiology and Selected Community Health Indicators
- The Elderly and Lifetime Exposures in Risk Assessment
- COC Lifetime Body Burden

ES-7.0 LIMITATIONS AND UNCERTAINTIES

Each of the decisions and input variables contain some element of variability and uncertainty and can affect the outcome of the assessment to some degree. This leads to some amount of "uncertainty" with the final results and conclusions. Risk managers need to know the uncertainties surrounding the study conclusions so that they can make recommendations accordingly (*e.g.*, ask for more experimentation or monitoring, hedge decisions away from large losses). An uncertainty analysis can pinpoint the priorities for obtaining new information, so that uncertainty can be reduced, and the decision-maker can have increased confidence in the decision ultimately taken.

Chapter 7 describes the areas of uncertainty in the Sudbury HHRA. Sensitivity analysis was undertaken to examine the affect of varying input variables on the predicted risks. Other areas of uncertainty are evaluated qualitatively. A critical consideration when considering uncertainty in the HHRA is whether the approach has possibly underestimated risk. In the Sudbury HHRA, the approach has been conservative and there is confidence that risk has not been underestimated.

ES-8.0 CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Arsenic: The weight-of-evidence evaluation strongly indicates that there are no unsafe exposures or increased health effects associated with soil arsenic levels within the Greater Sudbury Area and the communities of interest. As such, no further consideration or actions related to arsenic in the study area are considered necessary.

Cobalt: Oral/dermal and inhalation exposures were within acceptable levels in all communities of interest. It was not considered necessary to undertake more detailed assessment or actions related to cobalt in the study area. No health risks are predicted for Sudbury residents from exposure to cobalt.

Copper: Oral/dermal and inhalation exposures were within acceptable levels in all communities of interest. It was not considered necessary to undertake more detailed assessment or actions related to copper in the study area. No health risks are predicted for Sudbury residents from exposure to copper.

Lead: All risk estimates for general population exposures to lead concentrations in each COI were below the established regulatory benchmark. However, due to special concerns with lead it was considered prudent to consider exposures of individuals who may reside in areas with soil concentration greater than the COI average. Predicted risk estimates for lead exposures exceeded the established regulatory

benchmark when the maximum worst-case concentrations of lead in soil were considered. As a result, a weight of evidence approach was used to develop a Soil Risk Management Level (SRML) for lead.

Based on this weight of evidence approach, a soil risk management level (SRML) of 400 µg Pb/g soil is recommended as appropriate and protective for soil concentrations of lead in the Greater Sudbury area.

Nickel: Oral/dermal exposures were within acceptable levels in all communities of interest. No health risks are predicted for Sudbury residents from oral or dermal exposures to nickel.

The assessment of inhalation risks in each COI indicated that the airborne concentrations of nickel detected by the Copper Cliff, Falconbridge, and Sudbury Centre West monitoring stations exceeded the selected regulatory benchmark. In addition to the non-cancer TRV selected to assess inhalation exposures to nickel, a variety of alternative TRVs for both cancer and non-cancer endpoints were evaluated in the current assessment, as part of a weight-of-evidence approach.

Based upon this approach, potential inhalation health risks were predicted for individuals living around the Copper Cliff and Sudbury Centre West monitoring stations. Fugitive dust from the Vale Inco Copper Cliff facility is considered a likely source of the elevated airborne nickel. However, it is the opinion of the SARA Group that the potential risks related to airborne nickel exposures in Falconbridge are considered negligible given the degree of safety built into the assessment and no further evaluation or action is considered necessary.

Selenium: Based upon a weight-of-evidence approach, it is concluded there are no unacceptable risks or health effects associated with selenium levels in the Greater Sudbury area.

Recommendations

There are a few areas of uncertainty in the exposure assessment that should be further investigated to provide greater confidence in the predictions of risk. These include:

- The exceedance of acceptable risk benchmarks for nickel at the Sudbury Centre West and Copper Cliff air monitoring locations for inhalation exposure requires further consideration. Fugitive dusts from the nearby Vale Inco Copper Cliff facility appear to be influencing particulate levels and air quality in the nearby communities, depending on local meteorological conditions. Further consideration and risk management activities should focus on fugitive dust from the Copper Cliff facility as a potential source of airborne nickel.

- The geographic area influenced by fugitive emissions from the Copper Cliff facility could be better defined.
- A limited amount of recent data is available on drinking water quality in Falconbridge since the new water supply was brought online. While data from the samples appear to indicate that COC concentrations have declined in the new water supply compared to the previous source, additional samples of drinking water should be collected from the water supply in Falconbridge and analyzed for all COC (lead in particular) to ensure concentrations have been reduced over the longer term.
- The Technical Committee (TC) should carefully review the SMRL for lead, the method of development, the supporting rationale and the sensitivity analysis provided in Chapter 5. The TC will then be in a position to determine if risk management is needed for lead in soil in any of the Communities of Interest in the Greater Sudbury Area.
- A blood lead survey should be considered as a viable option to address uncertainty in the predictions of risk related to lead in the Sudbury environment. A blood lead survey could be used to establish a baseline conditions in the study area prior to any risk management activities, if any are implemented, and could also be used to provide a comparison of conditions in Sudbury with other Ontario communities.

The above recommendations can be undertaken as follow-up to this risk assessment, as part of a transition to risk management.