SUDBURY AREA RISK ASSESSMENT

VOLUME II – CHAPTER 8: CONCLUSIONS AND RECOMMENDATIONS

Table of Contents

Page

List of Tables

Page

This page is left blank intentionally

8.0 CONCLUSIONS AND RECOMMENDATIONS

8.1 Conclusions

8.1.1 Overview of Risk Assessment Results

The results of the assessment of non-cancer endpoints for each of the COC *via* the oral/dermal and inhalation exposure pathways are summarized in Table 8.1.

Table 8.1 Summary of Assessment Results for Non-Cancer Endpoints (Female Preschool Child)

COC	Oral/Dermal	Inhalation [a]
Arsenic	HQ_{avg} = 1.0 – 1.7 HQ_{max} = 1.4	Not calculated [b]
Cobalt	HQ_{avg} < 1.0 HQ_{max} < 1.0	HQ < 1.0
Copper	HQ_{avg} < 1.0 HQ_{max} < 1.0	HQ < 1.0
Lead	HQ_{avg} < 1.0 HQ_{max} = <1.0 - 1.3	Not calculated [c]
Nickel	HQ_{avg} < 1.0 HQ_{max} < 1.0	HQ = < 1.0 to 13
Selenium	HQ_{avg} = 1.1 - 1.6 HQ_{max} = 1.6	HQ < 1.0

[a] Inhalation HQ for average conditions only as air values are area-wide, and not individual properties.
[b] Not calculated because there is no arsenic inhalation non-cancer regulatory value.
[c] TRV for lead includes inhalation and oral, therefore addressed by oral HQ

The results of the assessment of carcinogenic endpoint for arsenic are presented in Table 8.2. No carcinogenic endpoints were evaluated for cobalt, copper, lead, and selenium for the current assessment. Therefore, these are not considered in this discussion. 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 (refer to Chapter 5).

Table 8.2 Summary of Assessment Results for Carcinogenic Endpoints (Lifetime Receptor)

COC	Assessment Location	Estimated Risk Values
Arsenic	All COI (including TOR)	9.6×10^{-5} to 2.6×10^{-4}

Note: TOR = Typical Ontario Resident

8.1.2 Summary Discussion of Results

Arsenic: Both non-cancer and cancer numerical 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: In addition to using the U.S. EPA IEUBK model to assess blood-lead levels in children, the SARA-specific HHRA model was used to assess the hazards associated with lead exposure, as per other non-carcinogenic compounds. All HQ_{avg} estimates for the general population were below a value of 1.0 for lead. The highest HQ_{avg} estimate for lead was 0.94 for a female preschool child living in Copper Cliff under a 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 = 1.3), Coniston, (HQ = 1.1), Sudbury Centre (HQ = 1.1) and Falconbridge (HQ = 1.1). As a result of these HQ_{max} values, it was considered appropriate to undertake a more detailed weight of evidence approach for lead 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.

For the current assessment, potential risks from inhaling airborne COC were assessed by comparing annual average air concentrations in the GSA with the TRV from various agencies and sources. For nickel, these comparisons can be done for both non-cancer and cancer endpoints. 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 the inhalation TRV, based upon a non-cancer endpoint, established by the European Union 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.

As part of an overall weight-of-evidence approach, potential risks were also evaluated based upon the specific nickel species identified in the year-long monitoring program. The form of airborne nickel in the GSA is very site-specific and dependent on a number of factors, such as proximity to sources, wind direction, and other meteorological conditions (*e.g.*, wind speed, precipitation, snow cover, *etc*.). Results of the speciation analysis conducted on the air filters demonstrated a fairly consistent nickel species "fingerprint" across the entire GSA, with the exception of one localized area. Fugitive dust from the Vale Inco Copper Cliff facility appears to have a unique nickel species fingerprint which includes the presence of a small amount of nickel subsulphide. When the wind blew from a westerly directly, ambient air monitors located at the Sudbury Centre West station showed a speciation fingerprint impacted by fugitive dusts from the Vale Inco Copper Cliff facility. Similarly, when winds originated from an easterly direction, Copper Cliff air monitors showed a similar fingerprint. When wind is blowing from the opposite direction in each of these locations and is apparently not affected by fugitive dusts from the Copper Cliff facility, the more typical nickel species fingerprint (*i.e.*, absent any nickel subsulphide) is observed. It should be noted that there is a considerable amount of uncertainty associated with these nickel chemical fingerprints, as they are based upon a limited dataset of air monitoring samples, and an even more limited number of speciation analyses.

Some inhalation TRVs are available for the evaluation of nickel species-specific risks. The sources of these TRVs include the U.S EPA, WHO, and Health Canada. While, all agencies have based their TRVs on similar occupational data sets, these TRVs differ due to how each agency interprets the cancer mortality data, as well as the mathematical models used to conduct low-dose extrapolation of the dose-response information. The occupational cohorts utilized by the U.S. EPA, WHO and Health Canada to derive their unit risk factors were developed for nickel refinery dust which contains varying percentages of oxidic, sulphidic, and soluble forms of nickel, as well as concurrent exposures to a myriad of other chemicals. Unit risks have also been based on controlled animal studies, which subjects groups of rats and mice to varying levels of oxidic or sulphidic forms of nickel. The SARA Group believes many of these alternate IURs are overly conservative and unrealistic. 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: Based on a weight of evidence approach, no unacceptable risks or health effects are predicted with selenium concentrations in the Sudbury area. Non-cancer numerical risk estimates for selenium did exceed acceptable risk benchmarks for oral/dermal exposures. However, a significant proportion (approximately 75%) of the estimated total daily intake (ETDI) of selenium (and hence risk) was a result of consuming general market basket (or supermarket) foods. The ETDI from market basket foods alone exceeded the recommended selenium reference dose (RfD) under the RME scenario. The assumed facility-related risks are low and it can be concluded that the facility-related risks are within acceptable levels. Therefore, no further evaluation or consideration of selenium in the study area is considered necessary as part of this HHRA.

8.1.3 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_{max} estimates exceeded 1.0 in four of the COI 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 COI-specific soil risk management level (SRML) for lead to ensure the protection of receptors in locally impacted zones.

A preliminary remediation goal (PRG) or, in the case of the current assessment, SRML can be defined as the average COC soil concentration within an exposure unit (EU) that corresponds to an acceptable level of risk. In other words, the SRML is the exposure point concentration (EPC) in soil within a given EU (*i.e.,* a community of interest), which would yield an acceptable level of risk.

Based on the information available from this and 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.

8.1.4 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 soil concentrations at various soil lead levels 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 empirical approach generates a slope factor (µg/ Pb/dl blood/µg Pb/g soil) based on the correlation between measured soil lead concentrations and the blood lead concentrations in children assumed to be exposed to the soil. Empirical slopes reflect site-specific and study-specific exposure scenarios but provide insight into general trends. The available literature generally shows that a blood lead level of approximately 5 µg/dl results from exposure to soil containing lead concentrations ranging from 500 to 1,500 µg/g. Concentrations of lead in soil less than 500 µg/g were found to result in blood level concentrations of approximately 5 µg/dl in children living in urban areas and near mine waste, inactive smelter sites. The acceptable blood lead level in most jurisdictions is generally considered to be 10 µg/dL in children. However, it is important to note that recent literature suggests that a level approaching 5 µg/dL may be more appropriate. In fact, the MOE now uses a 5% exceedance of a blood lead level of concern of 5 µg/dL as the policy basis of their recently published new regulatory lead air standard.

Blood lead is a true marker of exposure, eliminating many of the assumptions and uncertainties inherent in the HHRA. Blood lead data is not available for the Greater Sudbury area, and all indications suggest that this HHRA model is conservative (refer to detailed discussions provided in Sections 5.4 and 7.0). Collection of blood lead data in the future would aid in minimizing many of the uncertainties inherent in the assessment.

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 SRML for children's play areas of 400 µg Pb/g soil), and the relative strength-of-evidence associated with each of these elements, it is 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.

8.2 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 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.

This page left blank intentionally

Document Sign-Off

The SARA Group has provided this report to the Sudbury Soils Study Technical Committee ("TC"), and Vale Inco Limited and Xstrata Nickel Limited (the "Companies"), solely for the purpose stated in the report. The information contained in this report was prepared and interpreted exclusively for the TC and Companies, and may not be used in any manner by any other party. The SARA Group and its member companies (including, but not limited to, Intrinsik Environmental Sciences Inc. and Gartner Lee Ltd.) do not accept any responsibility for the use of this report for any purpose other than as specifically intended by the TC and the Companies. The SARA Group does not have, and does not accept, any responsibility or duty of care whether based in negligence or otherwise, in relation to the use of this report in whole or in part by any third party. Any alternate use, including that by a third party, or any reliance on or decision made based on this report, are the sole responsibility of the alternative user or third party. The SARA Group does not accept responsibility for damages, if any, suffered by any third party as a result of decisions made or actions based on this report.

The HHRA has been performed in accordance with accepted practice and usual standards of thoroughness and competence for the profession of toxicology and human health risk assessment. Any information or facts provided by others, and referred to or utilized in the preparation of this report, is believed to be accurate without any independent verification or confirmation by the SARA Group. The information, opinions and recommendations provided within the aforementioned report have been developed using reasonable and responsible practices, and the report was completed to the best of our knowledge and ability.

The SARA Group

Elliot Sigal, QP_{RA}
Executive Vice President
Intrinsik Environmental Sciences Inc.

Glenn Ferguson, Ph.D., QP_{RA}
Senior Scientist
Intrinsik Environmental Sciences Inc.

Christopher Wren, Ph.D.
Senior Environmental Scientist
Gartner Lee Ltd.