SUMMARY REPORT OF THE INDEPENDENT CONSULTANT REVIEW OF THE COMMUNITY BASED RISK ASSESSMENT IN PORT COLBORNE, ONTARIO

Prepared for:

PUBLIC LIAISON COMMITTEE &
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1.0 PURPOSE OF THIS REPORT

For the past decade, Vale Inco (Inco) has undertaken a Community Based Risk Assessment (CBRA) covering a large portion of the City of Port Colborne (the City) in the Niagara Region of Ontario. The CBRA is intended to assess the environmental impact, and potential clean up required, related to approximately 60 years (1918 to 1985) of historical emissions from a nickel refinery formerly operated by Inco in the City.

Consultants for Inco, working within a public process and structure and generally following principles for conducting environmental risk assessments in the Province of Ontario, undertook analysis and produced a series of reports evaluating the environmental impact from Inco's emissions, the clean up "trigger" criteria, and the type/extent of clean up required to address the impacts identified.

Watters Environmental Group Inc., preceded by Beak International and Stantec Consulting, was retained by the City to work as scientific advisors and the "Independent Consultant" to a Public Liaison Committee (PLC) and the CBRA process. The role of the Independent Consultant was generally established by a Terms of Reference from the City and a Technical Scope of Work for the CBRA.

As part of the CBRA process, the Independent Consultant produced a series of reviews of Inco reports including the following (provided under separate cover):

- Independent Consultant Review of the Chemicals of Concern (CoC) and the Status of Lead as a CoC for the CBRA;
- Independent Consultant Review of the Ecological Risk Assessment (ERA) Report on the Natural Environment of Port Colborne;
- Independent Consultant Review of the ERA Report on the Agricultural Systems (Crops) of Port Colborne;
- Independent Consultant Review of the Human Health Risk Assessment (HHRA) Report for Port Colborne; and
- Independent Consultant Review of the Integration Report (i.e., the plan to implement the findings of the CBRA on a property-by-property basis).

The Independent Consultant also produced review reports related to Quality Control and Quality Assurance (QA/QC) for each component of the CBRA process.

This document is intended as compilation, summary and observations related to the CBRA process generally, and the Independent Consultant Review Reports specifically. This report is not intended to replace the "Review Reports"; rather, this report should be viewed as an "Executive Summary" intended for ease of review by any observer or interested party.

2.0 GENERAL BACKGROUND

Inco operated a nickel refinery in the City of Port Colborne from 1918 to 1985. During that time, the refinery emitted large amounts of different chemicals into the environment, including nickel, copper, cobalt, arsenic and lead. To assess the extent of the impact that these emissions have had on the natural environment, crops and human health within the City of Port Colborne, and to determine the nature and extent of cleanup (if required), Inco undertook a Community Based Risk Assessment (CBRA).

The CBRA includes a Human Health Risk Assessment (HHRA), and an Ecological Risk Assessment (ERA) that consists of an assessment of the impact on the natural environment (ERA-NE) and on crops grown in the Port Colborne area (ERA-Crops).

As part of the CBRA process, a Public Liaison Committee (PLC) was established comprising interested members of the Port Colborne community. The PLC was supported by an Independent Consultant that acted as scientific advisor to the Committee. The role of Independent Consultant is currently held by Watters Environmental Group Inc. (Watters Environmental). The Independent Consultant acted as Chair of a Technical Sub-Committee (TSC) that was established to ensure that sound scientific principles were applied throughout all phases of the CBRA and to provide advice on the conduct of the studies to Jacques Whitford (JW), Inco's consultant. The TSC was made up of representatives from the Ministry of the Environment (MOE), Niagara Regional Public Health Department, the City of Port Colborne, Inco and its consultants, in addition to the Independent Consultant.

The CBRA addressed impacts from four chemicals, namely nickel, copper, cobalt and arsenic. There remains ongoing debate about whether lead should be Chemical of Concern (CoC) for the CBRA. The proponent has not accepted lead as a CoC and, therefore, the impact of lead has not been as addressed as part of the CBRA process.

3.0 ROLE OF THE INDEPENDENT CONSULTANT

An Independent Consultant was appointed in June 2000 to assist the PLC. The original contract was awarded to Beak International Incorporated, which was acquired by Stantec Consulting. Subsequently, in 2004, this role was assumed by Watters Environmental.

From the outset, the expectation was that the Independent Consultant was to be "active" in the process having responsibilities for peer review, regular liaison with the PLC and City of Port Colborne, community consultation, and leadership of the TSC.

The Independent Consultant's role changed quite significantly over time, with much effort expended to first finalize the Technical Scope of Work (TSOW) document, and second to assist in the development of the detailed technical protocols for the studies to be undertaken as part of the CBRA. The Independent Consultant was heavily involved in ensuring the quality of the scientific process, and in ensuring that proper quality assurance/quality control (QA/QC) was established in each of the technical studies of the CBRA.

The Independent Consultant was also requested to lead the public involvement program, which involved ensuring that the community was regularly informed of the progress of the CBRA, and that the community was provided with an interpretation of the information relating to the project so that the public could provide informed comments. This involved writing regular weekly columns and articles for the local newspapers, and attending a large number of public meetings and Open Houses. At the outset, the Open Houses involved explaining the benefits of the CBRA and the process it would follow. Later, they included explanations of the detailed technical studies planned, and then sessions to explain the findings of those studies.

While the Independent Consultant's role was primarily to assist the City of Port Colborne and the PLC in understanding the science within the CBRA, an important additional responsibility was to help ensure that quality assurance / quality control (QA/QC) was included as an integral part of the sampling, analytical, assessment and reporting stages of the studies carried out for the CBRA. The Independent Consultant, with input from the PLC, critiqued the study elements of these projects to sharpen the focus of the project and to attempt to ensure that proper planning and sampling was carried out, as well as to ensure that QA/QC was in place and could be documented for the various projects.

The Independent Consultant coordinated the QA/QC program, and was requested by the PLC, City of Port Colborne and community to actively participate in all field activities. For this, the

Independent Consultant obtained agreement from the PLC to allow a representative of the Independent Consultant to work alongside a representative of JW.

While the CBRA process was extremely transparent, there were times when "closed door" meetings were required between the Independent Consultant and JW, to avoid technical "debates" in a public forum or to resolve a technical issue in a timely manner. Generally, the Independent Consultant provided summary of Consultant meetings at subsequent PLC meetings.

The Independent Consultant assisted with moving the various studies of the CBRA through the different stages of approval. In that respect, the Independent Consultant had regular liaison with the PLC, the City, the MOE, Niagara Region Public Health, Inco and Inco consultants. In addition, the Independent Consultant worked with the PLC members and with Port Colborne residents to provide understanding of the CBRA process.

In addition to the specific studies of the CBRA, the Independent Consultant was requested by the PLC and City of Port Colborne to assist with a health study (conducted by Ventana Clinical Research) and a Property Valuation Study (undertaken by Deloitte & Touche). The Independent Consultant was asked to participate in the scoping of these studies; coordinating TSC meetings and Open Houses, and reviewing public presentation materials and scope-of-work documents.

4.0 TECHNICAL SCOPE OF WORK

The TSOW is the document that outlines the overall study design for the CBRA. It sets out the process to be followed in conducting the assessment and describes the general scope of the technical studies comprising the CBRA. From the outset it was viewed by all parties as a critically important document and consequently it was given extensive public and technical scrutiny. The Independent Consultant's role during development of the TSOW focused on two main areas:

- Ensuring that the CBRA process and technical studies were designed to be comprehensive, science-based and credible, and

- Ensuring that the technical information would be presented to the community in a form that could be readily understood.

The TSOW took nearly eight months to complete (from April to November 2000). The review, editing and rewriting process was time-consuming because of the large number of technical issues that needed to be addressed, including:

- Lack of clarity on the understanding of the overall objectives of the CBRA.

- The schedule of activities required to complete the CBRA to ensure that critical periods were not missed such as growing seasons, breeding periods, etc.,

- Ensuring there was a common understanding of the review and approvals process for each step and each study component of the CBRA, including agreeing on the role of the key participants such as the TSC, the PLC, and consultants, and agreeing on the need for (and timing of) community engagement,

- Agreeing on the overall QA/QC process for the CBRA, including requirements at each step of sampling, analysis, assessment (including statistical approaches) and interpretation,

- Peer review QA/QC (i.e., how and when the Independent Consultant would peer review the studies and their conduct), and

- Requirements for documentation and approval of field and laboratory protocols for each study.

The Independent Consultant was particularly concerned that the schedule and review process be clearly established before each study commenced, and that there be written, approved protocols for each field study.

In the fall of 2000, and to avoid further "slippage" in finalizing the TSOW, the PLC requested that the Independent Consultant become directly involved in writing and completing the document. In late 2000, the TSOW was approved and received by the TSC and PLC respectively, and the formal CBRA could begin.

5.0 SELECTION OF THE CHEMICALS OF CONCERN

An early TSC task was consideration of the Chemicals of Concern for the CBRA. It was agreed that the "Conditions" for determining a CoC are as follows:

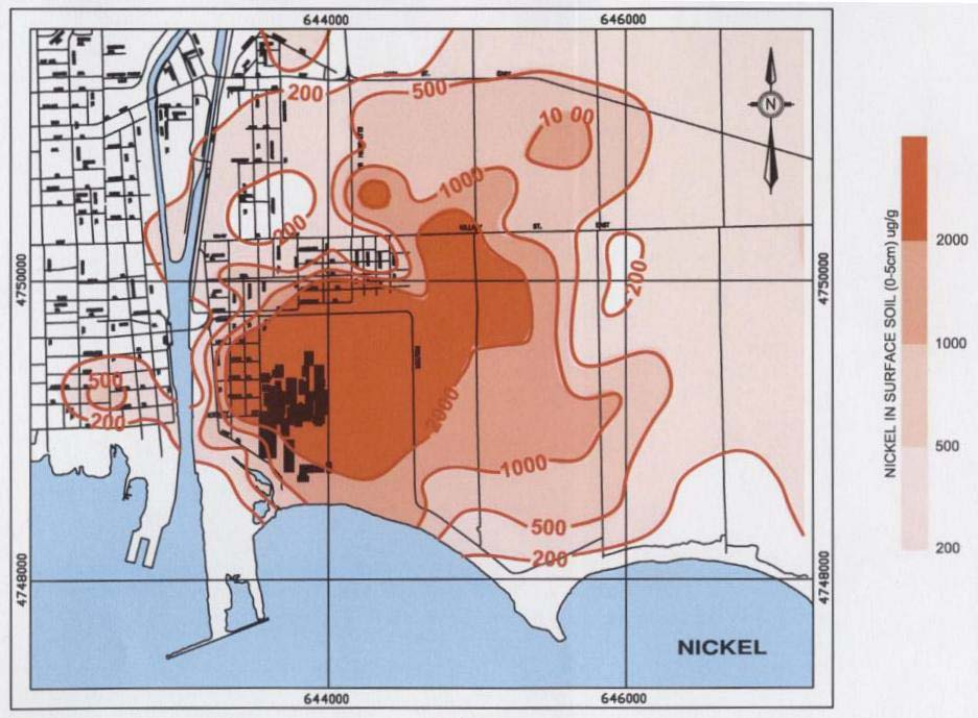
- Chemicals that were historically used or generated by the industrial source(s) or its processes, and
- Chemicals that are present at a community level at concentrations greater than the MOE generic effects-based guidelines (i.e. Table A Guidelines, MOE, 1998), and
- Chemicals whose presence in soil shows a scientific linkage to the historical operations of that industrial source(s).

JW produced reports considering the various chemicals as CoCs for the CBRA. As a result, Inco accepted nickel (Ni), copper (Co), cobalt (Cu) and arsenic (As) as CoCs for the CBRA (but not lead). Consequently, the CBRA studies analyzed those elements. The JW studies related to lead concluded, and Inco is of the position, that lead is not a CoC.

The Independent Consultant is of a different opinion, specifically that lead meets all three conditions for a CoC.

Sections 5.1 through 5.5 of this report summarize the position of the Independent Consultant relating to the CoCs. The detail of the Independent Consultant's review of CoCs is found in report entitled, "Independent Consultant Review of Chemicals of Concern and the Status of Lead" November 2010, provided under separate cover. A summary of this information is provided in the sections below:

5.1 NICKEL AS A CHEMICAL OF CONCERN

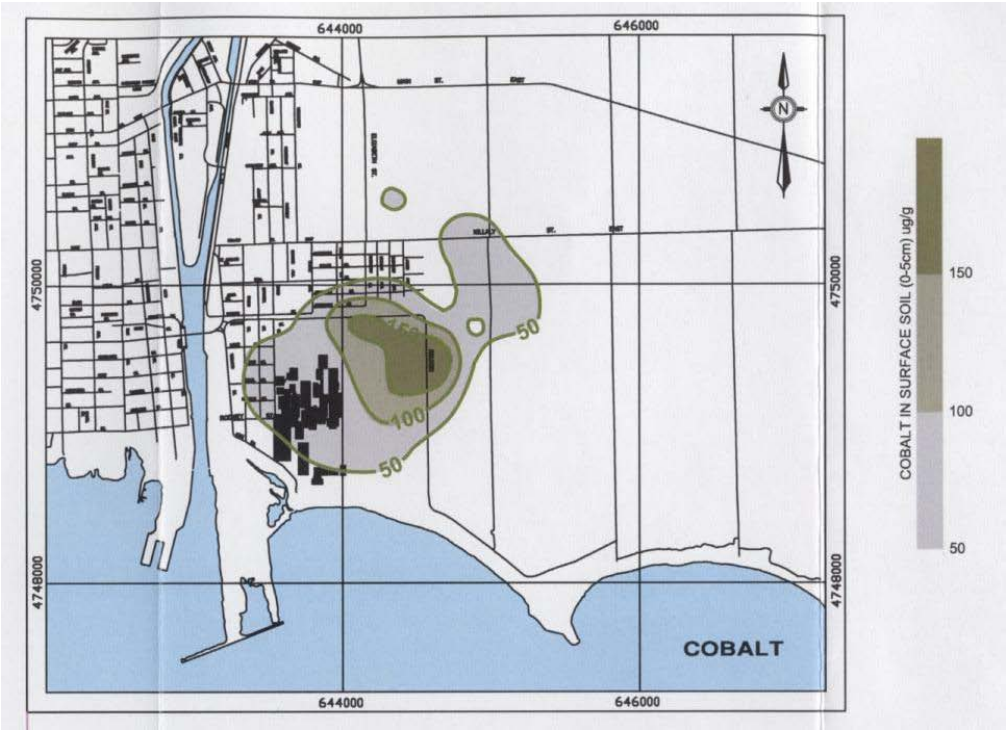


Criterion	Criterion Met?	Rationale
Chemicals that were historically used or generated by the industrial source(s) or its processes.	**Yes**	Nickel ore containing nickel was used in Inco's refinery operation from 1917 to 1984
Chemicals present at a community level at concentrations greater than the MOE generic effects-based guidelines.	**Yes**	Nickel concentrations are present in community soils at concentrations that far exceed the MOE Generic Standard of 200 mg/kg
Chemicals whose presence in soil shows a scientific linkage to the historical operations of that industrial source.	**Yes**	The prevailing wind in Port Colborne is from the SW quadrant. Primary deposition is to the NE, or downwind of the Inco refinery.

5.2 ARSENIC AS A CHEMICAL OF CONCERN

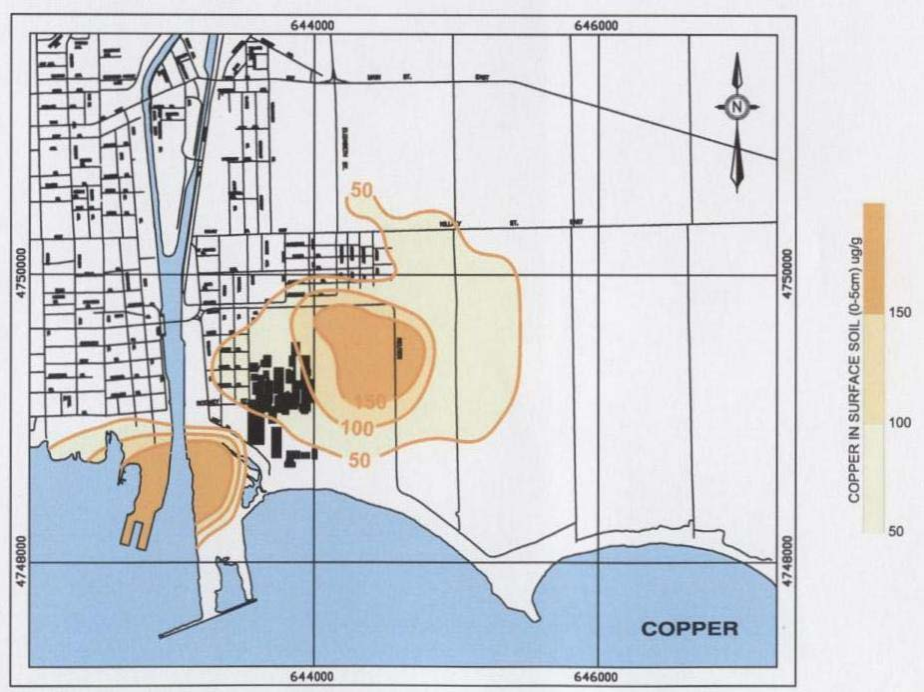
Criterion	Criterion Met?	Rationale
Chemicals that were historically used or generated by the industrial source(s) or its processes.	**Yes**	Arsenic is intrinsic to minerals commonly making up Ni, Co, Cu ores and associated gangue minerals.
Chemicals present at a community level at concentrations greater than the MOE generic effects-based guidelines.	**No**	The arsenic contamination does not extend into the community but is contained on Inco property.
Chemicals whose presence in soil shows a scientific linkage to the historical operations of that industrial source.	**Yes**	The prevailing wind in Port Colborne is from the SW quadrant. Primary deposition is to the NE, or downwind of the Inco refinery.

5.3 COBALT AS A CHEMICAL OF CONCERN



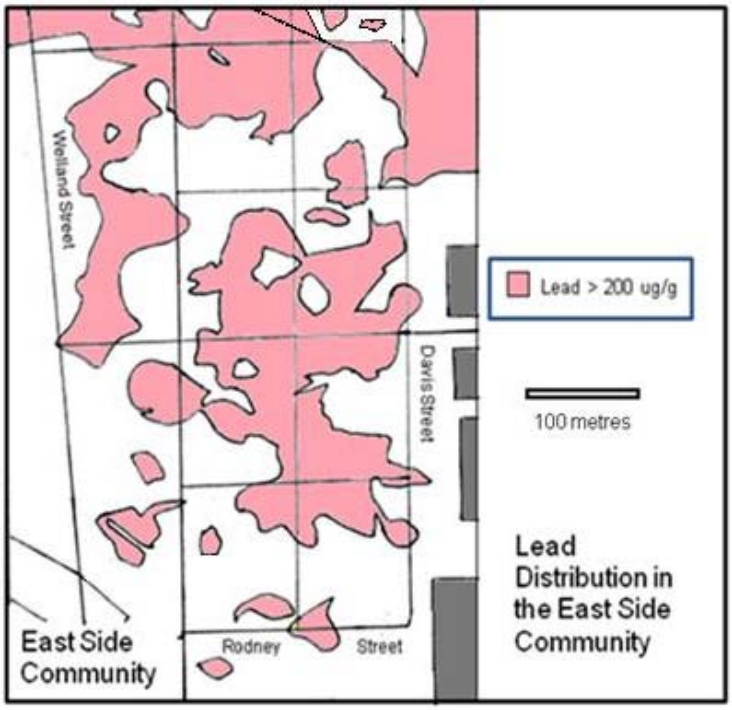
Criterion	Criterion Met?	Rationale
Chemicals that were historically used or generated by the industrial source(s) or its processes.	**Yes**	Nickel ore containing cobalt was used in Inco's refinery operation from 1917 to 1984
Chemicals present at a community level at concentrations greater than the MOE generic effects-based guidelines.	**Yes**	Concentrations of cobalt are present in community soils above the MOE Generic Standard of 50 mg/kg
Chemicals whose presence in soil shows a scientific linkage to the historical operations of that industrial source.	**Yes**	The prevailing wind in Port Colborne is from the SW quadrant. Primary deposition is to the NE, or downwind of the Inco refinery.

5.4 COPPER AS A CHEMICAL OF CONCERN



Criterion	Criterion Met?	Rationale
Chemicals that were historically used or generated by the industrial source(s) or its processes.	**Yes**	Nickel ore containing copper was used in Inco's refinery operation from 1917 to 1984
Chemicals present at a community level at concentrations greater than the MOE generic effects-based guidelines.	**No**	Concentrations of copper above the MOE Generic Effects Guideline of 200 mg/kg are not present in the community.
Chemicals whose presence in soil shows a scientific linkage to the historical operations of that industrial source.	**Yes**	The prevailing wind in Port Colborne is from the SW quadrant. Primary deposition is to the NE, or downwind of the Inco refinery.

5.5 LEAD AS A CHEMICAL OF CONCERN



Criterion	Criterion Met?	Rationale
Chemicals that were historically used or generated by the industrial source(s) or its processes.	**Yes**	Lead was emitted from the nickel refinery stack primarily between 1918 and 1930 and was also emitted from the lower stack associated with the Precious Metals Refinery, located south of the Nickel refinery stack, between 1987 and 1997.
Chemicals present at a community level at concentrations greater than the MOE generic effects-based guidelines.	**Yes**	Concentrations of lead are present in community soils above the MOE Generic Standard of 200 mg/kg
Chemicals whose presence in soil shows a scientific linkage to the historical operations of that industrial source.	**Yes**	Sampling conducted to the east of the refinery shows a plume of lead contamination downwind of the Precious Metals Refinery.

Generally, there are two ways by which lead has been introduced into soils in the community. Localized high concentrations or "hot spots" are likely the result of buried lead objects such as batteries or piping wheel balance weights. However, there is a general layer of lead soil concentrations in the 200-400 ug/g range near the Inco facility in the area known as the east side community and, east of the Inco facility. Evidence indicates that lead was an aerial deposition both from the nickel refinery and precious metals facility.

The exclusion of lead as a CoC, which is present in the community at concentrations exceeding the MOE generic effects based guidelines, presents significant issues for the community and, in the opinion of the Independent Consultant, is a shortcoming for the CBRA process.

6.0 NATURAL ENVIRONMENT

JW produced an Ecological Risk Assessment (ERA) Report analyzing the impacts of Inco's emissions on the Natural Environment. In this report, there is a confusing array of study objectives. The study objective for the CBRA as included in the Technical Scope of Work (TSOW) is to produce; "*an empirical model that predicts safe concentrations of CoC's based on relevant soil parameters, such as texture, pH and organic content, for Port Colborne soils*". However, the Natural Environment "Final Report" describes its primary objective as, "*to determine if CoCs in soils, as a result of* [Inco] *Refinery emissions, present a potentially unacceptable risk to the natural environment found in the Port Colborne area. For the ERA, an unacceptable risk is defined as an estimated risk linked to the occurrence of soil concentrations of CoCs that prevents sustainable population(s) of flora and fauna, or prevents a sustainable level of ecological functioning, within the defined Study Area*." (Final Report, page vi). JW does not explain the reason for changing the study objective.

The assessment involved data collection and field investigations in 2001 and 2002. The ERA-NE involved studies and assessments of several Valued Ecosystem Components (VECs), including decomposers (earthworms, woodlot litter), amphibians (frogs; tadpoles and adults and Fowler's Toad), plants (maples and woodlots), mammals (Meadow Voles, Raccoon, Red Fox and White-tailed Deer), and birds (Red-tailed Hawk, American Woodcock, American Robin, and Red-eyed Vireo).

Following technical review of previous "drafts" of the report, JW produced and released a "Draft" report for public and agency review in July of 2003. That "Draft" document was the subject of community and agency input, and was also reviewed by Inco's external (peer) review consultant (CH2MHill). The "Final" report (2004) was produced with the objective of attempting to address the concerns with the "Draft" report (2003) raised by the public, the MOE, the peer reviewer and the Independent Consultant.

In response to matters raised by the community and the Independent Consultants after the release of the "Final" Report in 2004, JW produced an "Addendum" to the Natural Environment Report dated March 2005. The "Final" Report (2004) and "Addendum" Report (2005) formed the basis of a submission from Inco to the MOE in early 2005.

Two, quite different, conclusions are presented in JW's Natural Environment Report:

1. In the Executive Summary of the Report, a very clear and strong statement is made that:

"*Following a number of lines of evidence to assess potential risk caused by soil CoCs, no unacceptable risk to elements of the natural environment in the Study Area as a whole was identified. As a result of these findings, no immediate need to mitigate or manage risk to the natural environment has been identified*."

2. However in Section 9 (Conclusions) of the Report, quite different and more equivocal conclusions are presented stating that:

"*Based on the results of the general field observations undertaken for this study, it is evident that existing CoC concentrations in the soil or other environmental media do not represent a toxicity level that is lethal to local flora and fauna. Quantitative assessment of the potential risks to VECs in the natural environment undertaken in this study support these qualitative observations*"

The Independent Consultant's review of the Natural Environment Report found that the data in the report does not support either of the alternative conclusions presented. The manner in which the data were analyzed and interpreted introduces significant uncertainties into the findings, and our own interpretation of the data leads us, in many instances, to come to conclusions opposite to those presented by JW. For example, while the JW report asserts there is no adverse effect on frogs and toads in the aquatic environment, the Independent Consultant concluded, based on the same information presented in the report, that there is evidence of adverse impacts on the amphibia populations. This is demonstrated in both the empirical modeling and the observational studies.

Further, sufficient scientific justification or rationale is not provided in the JW report to support the contention that there is no unacceptable risk to the natural environment of Port Colborne. As example, the study area(s) originally included a "primary study area", a "secondary study area" and a "reference area" based on reported soil levels of CoCs, with intent to characterize exposure and risk in each. However, the final report merged the data from the primary and secondary areas into one area, which significantly increases uncertainty in the study results because of the size of the standard deviation relative to the mean of the data. In simple terms, merging (or blending) of the data from the various study areas "averages away" potential risks. This results in standard deviations for the data sets that often exceed the reported mean values.

Other concerns with the study included the following:

- Within the Study Area(s), there are gaps in the general distribution of sampling points that exclude large areas of potentially important habitat (such as the wetland and wooded areas on Inco lands to the west of Reuter Road),

- The sample size for several of the VECs studied was insufficient to draw any reasonable conclusions on these components of the natural environment,

- The Study Area excluded the "urban" (residential) areas of Port Colborne, which contain important elements of the environment both in terms of flora and fauna. As a result of this exclusion, the impact of CoCs on domestic animals and other "urban" elements of the Natural Environment has not been fully addressed,

- There is no attempt to identify species that would be expected to be present in the habitats found in the Study Area but which are missing or are only present in reduced numbers and which could, therefore, provide an indicator of ecological stress,

- Seemingly arbitrary choices are made in selecting or rejecting lines of evidence for assessing risks, and there is selective weighting given to various study components when drawing conclusions,

- The impact of arsenic on the natural environment has not been assessed.

- As the study progressed, the risk quotients used for certain VECs (e.g., woodcock) were changed without adequate justification, and

- Notwithstanding the important sources of uncertainty described above, the "uncertainty analysis" contained in the final report does not provide sufficient analysis to address the concerns.

The combined result of the above issues, and particularly the blending of the data, is that the standard deviation for data sets is often greater than the mean value. As such the risks are most probably underestimated, particularly for species that are not mobile or which do not range widely.

7.0 CROPS

JW produced an Ecological Risk Assessment (ERA) Report concerning the impacts of the emissions from the Inco facility on agricultural crops.

The objective of the Crops Study was, *"to determine the concentrations of historically deposited CoCs in Port Colborne soil that present an unacceptable risk (phytotoxicity) to agricultural crops"*.

The Crops Study involved several greenhouse and field trial studies conducted in 2000 and 2001, using various crops and several soil types. A biomonitoring study was also completed in 2001, measuring nickel concentrations in field soils and in goldenrod, a wild plant common across the Port Colborne area. In the final Crops Report, only the 2001 Greenhouse Study was relied upon to develop the conclusions. JW made it clear to CBRA participants that the 2000 data were discarded as it was deemed to be unreliable. The field trial studies were also not used. As such, the conclusions for the Crops Study were developed based on the analysis of one CoC (nickel) and one crop (oat). The results of the biomonitoring study were used to attempt to provide validation of the findings of the greenhouse trial.

In the final Crops Report, JW proposed Port Colborne-specific soil nickel intervention levels that were significantly higher than the MOE generic standard for soil nickel of 200µg/g (or 200 ppm). Different "safe levels" are proposed for each soil type found in Port Colborne. The proposed safe levels range from 750 µg Ni/g soil for sand soils to 2,350 µg Ni/g for organics. Till clay was determined to have a safe level of 1,650 µg Ni/g and the Welland Clay, the predominant agricultural soil in the area a level of 1,400 µg Ni/g.

In its review of the Crops Report, the Independent Consultant concluded that there were too many uncertainties to justify the JW proposed Port Colborne-specific soil nickel intervention levels and found that the conclusions of the Crops Report were not supported by the data.

The sources of uncertainty within the Crops Report and the proposed Port Colborne-specific soil nickel "standards" that lead to this view are as follows:

- Oat is the primary study species. It is asserted by JW that oat is the most sensitive species, but this is not supported by their data. The establishment of a dose-response curve for oat introduces uncertainty in the calculated predicted no effect concentration (PNEC) for other more sensitive crops species grown in the Port Colborne area. The

result is that the suggested "safe" soil concentration is too high to be sufficiently protective;

- Conclusions are based only on results from the nickel studies when other CoCs, especially copper, are known to be toxic to plants;

- Findings are based on studies involving manufactured soils blended from soil taken from a limited number of locations. The Independent Consultant review of the ERA – Crops Report demonstrates that the "low-nickel blended soils" and "high-nickel soils" have significantly different soil characteristics, including particle size distribution and nutrient levels;

- Lime (calcium carbonate) was added to adjust the pH of all soils used in the greenhouse study. Liming of soils has been shown to reduce the uptake of nickel and thus there is an unknown influence on the soil concentration of nickel that will cause phytotoxicity under different pH conditions;

- The study relied on assessing impacts to plants based on biomass, rather than crop yield (which is the parameter of importance to a farmer). Also the study did not address potential aesthetic (discolouration) effects, which occur at an earlier stage of plant development than do impacts on plant biomass. Additional safety factors need to be included to address these issues;

- Inconsistent statistical treatment of data was applied in order to get a "best-fit" and there was insufficient data available in the important mid-range of nickel concentrations in order to establish a dose-response curve and to extrapolate to no-effect levels; and

- The biomonitoring study was relied on as a reason to obviate the need for further analysis of the impact of confounding variables.

As a result of these issues, and the lack of "safety factors" to address the known (and unknown) uncertainties and variability, the Independent Consultant came to the conclusion that the JW proposed Port Colborne-specific soil nickel "standards" cannot be supported based on the data available, and do not offer an equivalent level of protection to the specific site conditions of Port Colborne as the MOE's generic standard offers to crops throughout the remainder of the province.

8.0 HUMAN HEALTH RISK ASSESSMENT

JW produced a Human Health Risk Assessment (HHRA) Report analyzing the impacts of emissions from the Inco facility on the health of residents.

In JW's HHRA Report, it is concluded that the "safe" risk-based soil concentration (RBSC) limit for nickel in Port Colborne soil is 20,000 milligrams of Ni per kilogram of soil (mg/kg). For reference, the corresponding regulatory standard for the protection of human health in Ontario for safe levels of nickel in soils is 300 mg/kg.

The existing "generic" Ontario regulatory soil standards established by the MOE in Ontario are designed to provide protection for a range of environmental components, including the natural environment and human health. It is for this reason that the law in Ontario allows for risk assessors to calculate intervention levels to guide site-specific risk management options, at higher concentrations than the generic standards, by taking into consideration the local specific characteristics and exposure conditions of an individual contaminated property.

The TSOW for the CBRA sets out the general objective of "… *finding out what risks exist, if any, and determining how to remove such risks in a scientifically acceptable and practical manner."*

The HHRA component of the CBRA is described in the TSOW as, "*the evaluation of the probability of adverse health consequences (i.e. health risks), and the accompanying uncertainties, to humans caused by exposure to each of the chemicals of concern (CoCs)."*

To achieve the overall objective of the HHRA, the study was required to:

(i) address media that were affected by contamination (i.e., soils, water, air, and other environmental media),

(ii) provide information regarding whether the elevated CoC concentrations present have the potential to cause adverse health effects, and

(iii) establish safe, risk-based criteria for each CoC for different land use areas within Port Colborne.

The Independent Consultant is of the opinion that there is insufficient scientific evidence to support the view that the proposed soil nickel concentration of 20,000 mg/kg offers an equivalent

safe-level of protection to Port Colborne residents, as the existing MOE regulatory soil standard for nickel provides.

In the opinion of the Independent Consultant, it is unreasonable for a "site specific" intervention number to be several orders of magnitude higher than the generic standard when applied across an entire community such as Port Colborne. The JW report achieves the high intervention number by application of large adjustment factors primarily to account for bioavailability of the CoCs. In the opinion of the Independent Consultant, the proposed soil intervention value of 20,000 mg/kg for the Port Colborne community is found to be inappropriate and is not supported by the information or analyses presented in the JW report.

In that respect, the Independent Consultant identified significant technical concerns with the analysis and interpretation of the studies within the HHRA Report, which appreciably affected the reliability and the confidence in the findings. There are also concerns with the validity of the methods used to develop the HHRA model. The more notable of the concerns are as follows:

- The HHRA did not follow the established requirements of relevant regulatory guidance documents, despite its commitment to do so.

- The transparency and public disclosure of the exact methods and information used in the derivation of the RBSC, a requirement for Environmental and Human Health Risk Assessments in Ontario, did not match the commitments made by Inco at the outset of the CBRA. Transparency is essential to a study such as the CBRA so that it is abundantly clear to stakeholders and reviewers how the proposed soil intervention numbers are derived and what the numbers mean for public health protection. This is particularly the case when a proposed RBSC is presented that is orders of magnitude higher than current regulatory standard. Examples of insufficient transparency include:

  - Inco would not make the HHRA model available to the Independent Consultant for review and assessment.

  - The HHRA Report does not show what specific values were used to calculate proposed "safe" soil nickel concentration of 20,000 mg/kg.

  - The HHRA Report provides no analysis of the potential for immediate health threats (i.e. acute toxicity) in children and others in the population from soil ingestion, for respiratory and/or skin sensitization from contact with nickel in soil at concentrations

above the existing regulatory health-effects standard, including at the proposed value of 20,000 mg Ni per kg soil.

- There is inadequate evidence to provide assurance that the additional lung cancer risk from nickel-contaminated soils at 20,000 mg/kg (and other levels significantly above the current MOE soil standard) would meet an acceptable cancer risk of one-in-one million from environmental sources as required under the Ontario *Environmental Protection Act* (OEPA).

- The HHRA Report did not contain an analysis of possible impact to public health from the chance of error such that health impacts might occur at a soil nickel concentration at 20,000 mg/kg.

- The estimated total daily intake of nickel and metals used in the HHRA were not reliable representations of daily exposures for the general population in a lifetime, and would have underestimated the range in total daily exposures and possible risks to public health.

- Established regulatory methods for estimating total cumulative daily exposures to contaminants in food were not followed and, therefore, the MOE regulatory requirements for deriving reliable source allocation factors for contaminants in soil were not followed.

- The reliance on only a few grab samples of some local food items collected over a short time period meant that the study did not take fully into account the amount of variation in metal concentrations in the wide range of food items consumed in a lifetime. This would have underestimated the nickel and other metal intakes from dietary sources.

- The daily lifetime exposure to nickel and other metals from consumer products was not included in the calculation of cumulative exposures.

- The soil intervention value would actually have been much less than 20,000 mg/kg if reliable estimates of the daily nickel intake from food and consumer products were used in the calculation.

- A significant adjustment factor was applied to the calculation of the “safe” soil nickel concentration to account for differences in how much nickel in food becomes released for uptake (i.e., is “bioavailable”) compared with the total amount of nickel in soil.

- Following a lengthy review of the literature and a statistical analysis of the data provided in the HHRA Report, the best available science supports that there should be no appreciable difference in bioavailability from nickel in soil compared with food. As such, an adjustment for bioavailability is inappropriate according to MOE and United States EPA HHRA guidance documents. Therefore, the regulatory guidance requires that for the protection of public health no adjustment should be made for bioavailability when differences in media influences are minor. The MOE guidance states that, "*Conversions for bioavailability should only be undertaken on the basis of strong observational data from human and/or animal studies, and not on model prediction or assumption*". The removal of this inappropriate correction to the soil intervention calculation reduces the proposed 20,000 mg/kg safe concentration value by several orders of magnitude.

- Reasonable maximum exposures for different areas of the community were inconsistently determined, thus making comparisons between the areas inappropriate and statistically invalid.

- Significant uncertainties associated with the various technical studies, as well as cumulative impacts from exposure to several CoCs, media and other stressors, were not adequately considered in the calculation of the 20,000 mg/kg soil intervention value.

- Inco offered insufficient public consultation on this final version of the HHRA Report. Although the required meetings and Open Houses were held, only superficial responses were provided to comments and questions from TSC members and the community.

- Three residential homes in the City of Port Colborne were identified with calculated cancer risks exceeding the OEPA requirement of one-in-one-million additional lifetime cancer risk level for inhalation exposure to nickel. The level of inhalation cancer risk was not addressed in the calculation of the RBSC for soil nickel.

9.0 INTEGRATION REPORT

An Integration Report was prepared by Inco (dated June 1, 2008) to provide guidance on how the findings of the CBRA would be applied to individual properties located within the City of Port Colborne. In the opinion of the Independent Consultant there are some significant shortcomings with the approach advocated in the report.

The general approach used by Inco to integrate the three CBRA studies appears sound, and generally involves considering the most sensitive receptor for a property and then remediating to the level deemed to be safe by the CBRA studies.

However, there are specific issues of concern as follows:

- The current structure of the Integration Report assumes that the findings of each of the three study reports are correct. In the opinion of the Independent Consultant, this is not a reasonable assumption. As aforementioned, the Independent consultant has identified significant issues with the data analysis and interpretation of results. As such, and in our opinion, credence cannot be given to the conclusions in the ERA and Crops Reports and, the structure of the Integration Report would likely be much different if the results of the three studies are confirmed to be incorrect.

- The currently proposed "integration" by Inco does not allow for unrestricted land use for properties with the City. As Inco notes in its Report, *"...in order to protect vegetables being grown, specific conditions will be instituted for risk management..."* (page 16). Backyard vegetable gardens need to be sampled and tested by Inco before use, and it appears that the homeowner is responsible for contacting Inco when this testing is required. Under Ontario Regulation 153/04 (as amended), all Ontario residents (including those residing in Port Colborne) have unrestricted use of their land (i.e., they don't need to contact anyone to have soils tested before use, and there are no special conditions applied to their land).

- The discussion of options for remediation is insufficient, providing scant information on approaches that might be effective and no information on their likely effectiveness, time to complete, adverse side-effects and the sustainability of the proposed interventions over time.

- Lead has not been included for discussion in the Report, despite the fact that the community has raised lead as a significant concern and, in the opinion of the Independent Consultant, lead meets the conditions for inclusion as a CoC for the CBRA.

- There is scarcity of information on the specific logistics for sampling, testing, remediation and reporting that would affect the homeowner. Of particular importance to a homeowner is what documentation is provided at the end of the process, and this remains unclear. It is also unclear what happens if a homeowner isn't supportive of Inco's proposed actions, and what opportunities there are for mediation.

- There are inferences made to the likely risks for pets and domestic animals, but no supporting information provided. The concern for pets has been raised repeatedly by residents, with no serious review of assessment made by Inco/JW.

- There is little information on how Inco will ensure that all future homeowners are made aware of the CBRA and Inco's responsibilities and commitments. This is particularly relevant for future owners that may want to change or add new backyard vegetable gardens.

- Inco has proposed an advisory role for the MOE and a diminished opportunity for community input and oversight for the second phase of the CBRA. The MOE must advise on whether its role of regulator of the CBRA process can include being an advisor to the proponent. The history of the CBRA process to date underlines the importance of community oversight of the process. The PLC, in some form or other, must continue to ensure that the needs of the community are understood and acted upon.

- Inco has presented no proven approaches to remediating highly contaminated agricultural land and it is extremely uncertain whether it will ever be able to return cropland to conditions that would meet the objective of establishing, "*concentrations that would present no risk to any agricultural crops being grown or reasonably expected to be grown within the Study Area.*" Consequently the company is encouraged to consider the application of biodiversity offsets in the Port Colborne area in order to establish a net biodiversity gain for the area rather than more narrowly focusing on remediation. Instead of investing in uncertain remediation, Inco could consider purchasing highly contaminated land, at fair market value, and reverting this to Carolinian woodland, ponds and other wetland habitat. This would provide fair compensation to affected landowners while boosting biodiversity in the Port Colborne area. The approach would have

additional social benefits by providing educational and research opportunities, employment opportunity and attractions for visitors to the area.

10.0 QUALITY ASSURANCE / QUALITY CONTROL

From the onset, the CBRA had to meet some very high demands. First, the CBRA was required to be comprehensive – it had to be a true and proper risk assessment from a community perspective. This means it had to meet all of the scientific requirements of an ERA and HHRA, and also provide guidance and answers from an economic and social aspect; and it must be acceptable to the public at large, to the MOE, and to Inco.

Second, the science of the CBRA had to be unquestionable and the results unequivocal. The studies comprising the technical backbone of the CBRA needed to be well planned, properly documented, flawlessly executed, and capable of demonstrating internal quality and reproducible outcomes verifiable by the harshest critics.

Third, the goals of the studies, and the databases, methodologies, quality assurance and conclusions were required to be credible and easily understood by the community. To achieve this, they needed to be described in such a manner that scientists, civil servants and the general public could understand them, and the process had to be open and transparent.

These three demands could only be met through rigorous commitment to sound science and the application of an effective QA/QC program. **Quality control** (QC) is a planned system of activities whose purpose is to provide a quality product. **Quality assurance** (QA) is a planned system of activities whose purpose is to provide assurance that the quality control program is effective. There was a considerable amount of QA/QC applied to the Port Colborne CBRA.

The Independent Consultant was insistent throughout the process that there should be a strong QA/QC program. This involved ensuring that there were written protocols for each field study, and that these protocols outline, in detail, the rationale for the study; the technical procedures for collecting and sampling; the procedures for analyzing the data (including statistics); the procedure(s) for interpreting the data; and the program for QA/QC.

The Independent Consultant outlined the process for review and “approval” for each study, with concurrence from all parties. At the request of the PLC, the Independent Consultant was required to participate in all field studies (alongside JW). The Independent Consultant shared all of its technical experience to establish the best science for the project and to provide a better product (i.e., the Independent Consultant worked collaboratively with JW to prepare sound protocols and reports rather than simply commenting on deficiencies).

10.1 NATURAL ENVIRONMENT

The QA/QC for the laboratory analysis of Port Colborne ERA samples is extensive, and the data demonstrates that the ERA dataset is of good quality. The ERA database had a significant amount of QA/QC applied to it and the laboratory confirmed that the ERA project followed established laboratory sample preparation and analytical protocols. Agreement between certified values and observed values in the laboratory analysis is good and there is good agreement between replicate samples.

The problem with QA/QC in the ERA-NE study lies with the sampling strategy employed. Data quality objectives were not developed at the outset, so it was not known how many samples would be required to obtain reliable, precise CoC values for the various sample types.

Most (but not all) of the ERA-NE sampling protocols were subject to the agreed approval process and consequently there was proper documentation of the study methodologies. However, some studies were done without the benefit of a final protocol that had undergone the agreed approval process and which had been peer-reviewed.

Data averaging across the entire Study Area of 22 km^2 contributed to considerable data variability and even the seven hundred samples taken for the ERA-NE were insufficient to properly characterize the large number of organisms, habitats and soil types in the study area (e.g., only three tadpoles were sampled from the Primary Area, three from the Secondary Area and there were two controls). The low numbers of biological samples contributed to the very high variability in the database.

There were problems with the manner in which the data was aggregated. For example, the CoC concentrations in frogs and tadpoles were determined by dissecting the animals, measuring the CoCs in various body parts, then arithmetically adding up the various concentrations to obtain a CoC value for the entire animal. This consistently underestimated body burden compared with whole body analyses conducted by the Independent Consultant. The arthropod dataset averaged CoC values for spiders and various insects including grasshoppers, caterpillars, etc. Not surprisingly, the “plus or minus” values for the mean CoC concentrations were very large and it was not possible to differentiate between CoC concentrations in predatory and vegetarian arthropods.

The sparse sampling for most of the VECs and other organisms, and the generally very large variability of the data, renders it incapable of supporting scientifically meaningful conclusions.

The overall conclusion that can be drawn from examination of the ERA-NE database is the database has such sparse geographic coverage and large variability that little confidence can be accorded to conclusions drawn from it.

10.2 CROPS

There are no substantive concerns with the laboratory analytical work carried out for the Crops Study. There is a high level of agreement between replicate soil samples taken and analyzed by JW with those of the Independent Consultant.

All soil samples were split and shared with the Independent Consultant and 20% of the field soils were analyzed at the analytical laboratory for comparison with JW results. Results of vegetation samples were sent by the laboratory to both consulting firms.

Low mean percent differences and fairly strong linear relationships between the JW soil data and the Independent Consultant soil data meant that no systematic error with the data was observed and the variability between the JW and the Independent Consultant soil results was reasonable for this study.

However, a central problem with the Crops Studies is that they were undertaken with protocols of insufficient quality and detail to clearly describe the objectives of the study, including data quality objectives. The protocols lacked specific information with regards to how the studies would be conducted and how the data generated would be treated. This had significant adverse effects on the later conduct of the Crops Study and its ability to provide meaningful information. For example, the protocols failed to specify acceptable ranges for the concentrations of nickel in soil blends in the Greenhouse Study. This resulted in a large gap between high and very high Ni soil concentrations used to construct the dose-response curve in the critical zone where the change in slope is expected to occur. This led to additional uncertainty in the derived predicted no effect concentration (PNEC).

The lack of specificity in the protocols presented a major and insurmountable problem for the Crops Study. Unknown inconsistencies in methodology and the influence of decisions made in the field, mid-study, have an unquantifiable influence on the results derived from the studies.

10.3 HUMAN HEALTH RISK ASSESSMENT

Protocols were in place for the various study components and sufficient notice was given to the Independent Consultant to allow observation of field work.

With some minor deviations, which are addressed in the QA/QC comments on each study, the protocols were generally followed.

There are no significant concerns with the analytical work carried out for the HHRA. There is a high level of agreement between replicate samples taken and analyzed by JW with those of the Independent Consultant.

10.4 SUMMARY

QA/QC on the component studies of the CBRA shows that studies were conducted in a manner generally consistent with the study objectives, and the quality of the data collected is high.

11.0 INDEPENDENT CONSULTANT REVIEW REPORTS

- Independent Consultant Review of the chemicals of Concern and the Status of Lead; Watters Environmental Group Inc.; November 2010

- Independent Consultant Review of the Ecological Risk Assessment Report on the Natural Environment of Port Colborne; Watters Environmental Group Inc.; November 2010

- Independent Consultant QAQC Review of the Natural Environment, ERA; Watters Environmental Group Inc.; Revised November 2010

- Independent Consultant Review of the Ecological Risk Assessment Report on the Agricultural Systems of Port Colborne; Watters Environmental Group Inc.; November 2010

- Independant Consultant QAQC Review of the Crops ERA; Watters Environmental Group Inc.; Revised November 2010

- Independent Consultant Review of the Human Health Risk Assessment Report for Port Colborne; Watters Environmental Group Inc.; November 2010

- Independent Consultant Peer Review Report for the Community Based Risk Assessment (CBRA), Quality Assurance Review on the Human Health Risk Assessment Port Colborne, Ontario; Watters Environmental Group Inc.; Revised December 2010

- Independent Consultant Review of the Integration Report, City of Port Colborne Community Based Risk Assessment; Watters Environmental Group Inc.; November 2010