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May 11, 2011

Mrs. Maria Bellantino Perco,
Senior Specialist, Environment
Vale, Port Colborne Refinery
187 Davis Street, Box 250
Port Colborne, ON L3K 5V2

Dear Mrs. Bellantino:

RE: Ministry Comments on Vale Port Colborne Community Based Risk Assessment (CBRA)

The ministry has completed the review of the following Vale Port Colborne CBRA reports submitted to us on August 2010:

- Port Colborne Community Based Risk Assessment - Crops Studies, prepared by Jacques Whitford Limited, dated December 2004.
- Community Based Risk Assessment, Port Colborne, Ontario – Ecological Risk Assessment Natural Environment, prepared by Jacques Whitford Limited, dated September 2004.
- Port Colborne Community Based Risk Assessment – Human Health, prepared by Jacques Whitford Limited, dated December, 2007.

Prior to reviewing the above noted documents, the Ministry review team met with representatives of Vale and Jacques Whitford Environmental Ltd. (JWEL) and received a detailed technical briefing of the CBRA studies. In addition, the Ministry has considered comments on the documents prepared by Watters Environmental Group (WEG) and the Public Liaison Committee, and JWEL`s response to those comments. The review team also participated in a two day field trip to Port Colborne to obtain a first hand understanding of the study area, which included a tour of the Vale refinery and Vale owned land.

The Ministry comments are presented in the attached document in three main sections: Ecological Risk Assessment -Crops, Ecological Risk Assessment - Natural Environment, and Human Health Risk Assessment. Please note that at this point the Ministry is not providing comments on the Integration Report (June 2008). The comments that follow are comprehensive and detailed. There are numerous comments, some of which are considered major because they may affect the report's conclusions. Other comments are provided to improve the transparency, organization, and clarity of the CBRA reports.

After Vale and your consultants have reviewed the comments, the Ministry is willing to meet with you to provide further context to our comments. It would be an opportunity for Vale to identify specific issues that wishes to discuss with the Ministry's reviewers. In addition, the Ministry is committed to work with you and your consultants to resolve the issues identified by our reviewers with the ultimate goal of endorsing the CBRA, the risk-based soil concentrations, and risk management measures.

If you have any questions about our review please feel free to contact me at (416) 327 8220.

Yours truly,

Camilo Martinez
Coordinator, Community Based Risk Assessment
MOE – Standards Development Branch

Comments by the Ministry of the Environment On Community Based Risk Assessment For Port Colborne Community

The following are Ministry comments on the following reports:

I. Port Colborne Community Based Risk Assessment - Crops Studies, prepared by Jacques Whitford Limited, dated December 2004.
II. Community Based Risk Assessment, Port Colborne, Ontario – Ecological Risk Assessment Natural Environment, prepared by Jacques Whitford Limited, dated September 2004. (see page 17)
III. Port Colborne Community Based Risk Assessment – Human Health, prepared by Jacques Whitford Limited, dated December, 2007. (see page 67)

I. MOE Review Comments on CBRA ERA- Crops Studies

The following comments are related to the Port Colborne Community Based Risk Assessment - Crops Studies prepared by Jacques Whitford Limited, dated December 2004. The report consists of the following volumes:

Volume I – Main Report
Volume I – Appendices
Volumes II – VI

There are major sections to this set of comments: global comments and specific comments. Global comments generally reflect overarching aspects of this risk assessment report and are usually not specific to any one section or specific part of the report. Specific comments are identified by volume, section and page number and typically reflect comments specific to the subject matter presented in these sections.

<u>Global Comments</u>

1. **Calculation of assessment endpoints from the 2000 Greenhouse Study data**

Assessment endpoints, such as EC25 or PNEC values, were not calculated from the 2000 Greenhouse Study data. As stated in the report "analysis of the [2000 Study] data revealed significant limitations in experimental design and execution that prevented development of dose-response relationships, and calculation of toxicity thresholds." However, data from the 2000 Greenhouse study was presented and limited statistical analyses were conducted, including the use of some of the data in the meta-analysis of oats. Therefore, EC25 and PNEC values should be calculated from the available 2000 Greenhouse data and included in the report.

2. Were the objectives of the Crop Studies met?

The main purpose of these studies, as stated in the report, was to determine the concentration of historically deposited [Chemicals of Concern] CoCs in soil that present an unacceptable risk to crops grown in the Port Colborne area. Although six main studies (2000 Greenhouse Study, 2000 Field Study, 2001 Greenhouse Study, 2001 Field Study, 2001 Engineered Plot Study and the Biomonitoring Study) were conducted as part of the CBRA, none of these studies provided assessment endpoints for field crops grown under field conditions in Port Colborne soils with a range of CoC concentrations. The following bullets provide the main deficiencies of each study.

- 2000 Greenhouse Study
  - high variability in soil parameters with confounding factors that made data interpretation difficult
  - missing data for biomass in clay soils and lack of germination in the organic control soil
  - no yield data or calculated assessment endpoints

- 2000 Field Study
  - Started too late in the season (late July)
  - Poor growth due to wet weather conditions and short growing time
  - No yield data, root data or calculated assessment endpoints
  - High variability in soil parameters in the organic soil
  - No replication of field plots

- 2001 Greenhouse Study
  - No yield data that could be related to yield of field crops in the Port Colborne area
  - No data on root growth
  - Soils used were often not agricultural soils (refer to Table 1)

Table 1: Soil collected for 2001 Greenhouse Study

Soil Type	**Treatment**	**Present Land Use**
Organic	Background	Rural farm, border between open field and woodlot
Organic	Contaminated	Abandon rural farm, woodlot
Heavy Clay	Background	Woodlot
Heavy Clay	Contaminated	Industrial – abandoned farmland
Sand	Background	Re-vegetation area
Sand	Contaminated	Wooded area
Till Clay	Background	Wooded area
Till Clay	Contaminated	Railway right of way, abandoned

- 2001 Field Study
    - No replication of field plots
    - No control field plots
    - No range of CoC concentrations within a plot
    - No yield data, root data or calculated assessment endpoints

- 2001 Engineered Field Plot
    - Pots bottoms were removed and so plants were exposed to soil within the pot and field soil below the pots, making interpretation of the results difficult
    - Pots started in the greenhouse and then moved to the field, with the reported potential of transplant stress
    - No yield data or root data
    - Planted in the field too late
    - Assessment endpoints only for heavy clay soil

- Biomonitoring Study
    - Only one species sampled
    - Plant parts were not separated before chemical analysis and age of the tissue and stage of development of the Goldenrod was not taken into consideration
    - No assessment of roots

Valuable information was gained by these studies, but there are many studies in the scientific literature on the effects of nickel in soil on the growth of plants and on the effects of liming in ameliorating these effects (refer to Volume 1 Part 3 Page 3-3). Several of these referenced studies were conducted on Port Colborne area soils (Freedman and Hutchinson (1980), Temple and Bisessar (1981), (Bisessar (1982), Frank et. al., (1982), Bisessar et. al. (1983), Bisessar (1989), McIlveen and Negusanti (1994), Kukier and Chaney (2000)). It is recommended that the determination of soil quality criteria for soils in the Port Colborne area not be based solely on the results of the CBRA Crop Studies but include the results all crop studies in the scientific literature that were conducted in the Port Colborne area where soil nickel concentrations are reported.

3. Use of soils from the Port Colborne area rather than standard soils spiked with metal salts

Using Port Colborne area soils and crops typically grown in this area was an appropriate approach to determine the concentration of historically deposited CoCs in soil that present an unacceptable risk to crops grown in the Port Colborne area. It is understood that the soils in the Port Colborne area are variable in terms of physico-chemical parameters, such as pH, texture, organic matter content, nutrient status, cation exchange capacity and concentrations of chemicals of concern. Also, it is understood that when conducting crop studies with these soils that it is not practical to match soil exactly or to find soils that are identical in all ways except CoC concentration. Finally, it is acknowledged that it would have been easier to have spiked a standard soil with metal salts to create a range of soil CoC treatments but the use of spiked soils would not have met the study's objectives.

4. Appropriateness of the soils used in the studies

It is recognized that the researchers took considerable effort to assemble information on Port Colborne soils from several sources and to properly analyze the soils before starting the studies. The soils selected were representative of the major soil groupings of the Port Colborne area. However, very limited data was available from the 2000 Field Study and the 2001 Field Study plots were restricted to heavy clay soil.

Many of the soils used in the 2001 Greenhouse Study, upon which the EC25 and PNEC values are based, were not from agricultural land, as can be seen in Table 1. The use of woodlot or railway right-of-way soil does not negate the value of this study but the use of agricultural soils would have been preferable.

5. Use of blended soils in the 2001 Greenhouse Study

The mixing of a control soil with a highly contaminated soil in various ratios in order to create a range of CoC concentrations in the study soils is acceptable. It is understood that the blended soil will not represent a particular soil that can be found in the field and it is acknowledged that drying, sieving, and mixing of the soil will alter the soil structure and severely affect the microfauna in the soil. However, there are limited options when conducting this type of research. The alternative of selecting soils with different CoC concentrations was attempted in 2000 but the problems of confounding factors made the interpretation of the data problematic. This latter approach can be successful but it would have required more soils and much higher replication.

6. Statistical analysis of the data

Appropriate statistical tests were used to analyse the data in the report, although there are a few points that require clarification, as outlined in the Specific Comments section.

7. Assessment endpoints

Although it is recognized that various assessment endpoints could have been used (NOEC, LOEC, PNEC, ECx), the EC25 and PNEC assessment endpoint are acceptable to the Ministry.

8. Structure of the Report

The Crop Studies component of the Port Colborne CBRA consists of six main studies, as given in Comment 2. In the main report, these studies are grouped according to study type (Greenhouse versus Field Studies), rather than in chronological order. This makes it difficult to follow the experimental approach, especially since the 2001 studies were designed in response to the 2000 results. It would be much easier to follow the studies in chronological order, which would follow the thought processes of the researchers. If a summary document is created, it is recommended that the chronological approach to presenting the studies be used.

Specific Comments

9. Volume I – vi

Part 6 – General Study Conclusions – General is spelt incorrectly

10. Volume I – Page 1-1

The third paragraph needs a graph showing emissions over time or at least a reference.

11. Volume I – Page 1-3

Section 1.2 is labelled Study Purpose but it is really how the crop study component of the CBRA fits into the CBRA. A statement of the purpose of the Crop Studies is required.

12. Volume I – Page 1-4

In the first paragraph the term "safe concentrations of chemicals is used. Consider revising to acceptable concentrations of chemicals or concentrations of chemicals at a low risk.

13. Volume I – Page 1-12

Only three components of the CBRA process are shown in Figure 1-1, yet on Volume I – Page 1-3, five components are identified.

It is not clear why the arrows point away from the overall CBRA process, when the various components feed into the CBRA process. Finally, it is not clear why there is not an arrow between the Field Studies and Biomonitoring Study since both are assessing the impact of CoCs in the soil under field conditions. Consider revising the diagram.

14. Volume I – Page 1-14

In the paragraph under Section 3.2, it is not clear why the authors mention that the organic soil are more permeable than the clays in the context of CoC concentration. Either expand on this idea or remove the statement.

15. Volume I – Page 1-15

In the first paragraph, the number of soil pits should be given. Also, it is not clear whether CoCs are evenly distributed in the top 20 cm of only clay and organic soils that have been historically ploughed or whether some soils that have not been ploughed also show this pattern.

In the final paragraph it would be helpful if the percentage area of woodlots were given.

16. Volume I – Page 1-16

In the second paragraph, there is mention of a visual survey of crops growing in the Port Colborne area that was conducted in 2001. It is not clear why this survey was only conducted in 2001. Also, why was the crop harvest data given in Table 1-2 not related to the percent of Niagara Region harvested land rather than Southern Ontario harvested land.

17. Volume I – Page 1-17

It would be helpful if the Study Objectives were stated earlier in the report in the Purpose section.

18. Volume I – Page 1-18

Reference is made to the MOE generic criteria. MOE criteria Tables A through E are effects-based and are set to protect against the potential for adverse effects to human health, ecological health, and the natural environment, whichever is the most sensitive. By protecting the most sensitive parameter the rest of the environment is protected by default. Criteria were developed only if there were sufficient, defensible, effects-based data on the potential to cause an adverse effect. These criteria are conservative and protective of the environment.

Throughout the Crop Studies report the authors use language that infers the MOE criteria for nickel in soil is unrealistic; such as "MOE generic guidelines were conducted using experimental designs that are likely to maximize nickel solubility and availability in plants"(Volume I – Page 1-18), the listing of factors that may result in overestimating phytotoxicity "(Volume I – Page 1-18), stating that "the existing guideline is based on total nickel concentrations in soils, and not on its bioavailable fraction, a more meaningful indicator or phytotoxicity (Volume II – Page 5-12) and referring to one of the studies the Ministry used to develop the guidelines as a "contentious study" (Volume II, Section 8, Page 1).

It is understood that the MOE site specific risk assessment approach allows the incorporation of considerations, which are specific to the site, in the development of soil and groundwater criteria. However, it is expected that those conducting research for the development of site-specific criteria (or community specific) will approach the research in a scientifically detached manner and not assume, a priori, that a soil nickel concentration of 200 mg/kg could not be toxic to plants under field conditions.

19. Volume I – Page 1-19

The last sentence of the first paragraph under Section 4.3 begins by stating “To counter this [meaning that greenhouse studies are not reflective of natural growing conditions] field experiments were conducted …. It is my understanding that the field studies were conducted as a check on or to verify the greenhouse results rather than to counter a perception that greenhouse studies are artificial or not reflective of field conditions. Consider rewording.

20. Volume I – Page 2-1

In the forth paragraph, the last sentence reads “ Because of the consistent correlation found between nickel and CoCs …. It is not clear why a consistent correlation is of importance. Should this read either consistent ratio or high correlation?

21. Volume I – Page 2-2

With regard to the first bullet, was the objective of the Year 2000 Greenhouse and Field Trials really “to select and characterise soil types typical of the Port Colborne area containing varying concentrations of CoCs for use in Greenhouse and parallel Field Trials”?

22. Volume I – Page 2-10

The report says that sand soils were not being included in the 2000 Field Trials because they make up only a small portion of the impacted lands in Port Colborne. However, since the focus of this study is on growing crops on contaminated land, the reason to include or exclude sand soil from the study should be based on the portion of the impacted lands that are both sand and potentially used for agricultural purposes.

23. Volume I – Page 2-15

The second to last paragraph states that “Soils were collected mostly from farmed (or formerly farmed) agricultural fields and a variety of other sources (agricultural fields, woodlots, and beaches) [It is assumed that agricultural fields were mistakenly included in the other sources category].

Tables similar to Table GH-16 (Volume I – Part 3 – Page GH-1B-2) should be included in the main report for both the 2000 and 2001 studies. For the 2000 studies, the Table should also include a column for pH and a column identifying where the soil was collected (e.g., agricultural field, woodlot, sand dune or from one of the field plots). This type of table in the main report would make it much easier to interpret the results.

In addition, it would be helpful to know the status of the agricultural field that were sampled (i.e., were the fields fallow, abandoned, actively farmed and if so, with what crops). This type of information would help identify confounding variables such as levels of soil pathogens (e.g., nematodes) or levels of rhizobium in the soil or the likelihood of herbicide residues being in the soil.

24. Volume I – Page 2-16

Following the list of five soil-metal concentrations, the MOE Table F value of 43 mg/kg nickel is referenced with Ontario Typical Range in brackets. The Ontario Typical Range is the range of concentrations for the element or compound of interest in Ontario soils for a specified land-use category. The OTR98 is a value that represents the 97.5 percentile of the sample population. The Table F background-based guidelines are based on the OTR98 and reflect the upper limit of typical background concentrations. Therefore, 43 mg/kg nickel in soil is not a typical background soil nickel concentration in Ontario, but the upper limit of background nickel concentrations in Ontario. A control soil should be well below this value.

25. Volume I – Page 2-17

The first sentence reads, "Field Trials in year 2000 paralleled the Preliminary Greenhouse Trials …". It is not clear what is meant by the term "paralleled" as usually, in a parallel trial, a subject is randomly assigned to a treatment group, such as potted plants being randomly assigned either to the field or to the greenhouse. In the Crop Studies it appears that the only thing that might have been paralleled between the field and greenhouse studies is the seed used.

In paragraph four, it is mentioned that the three test sites chosen had been used by other researchers in previous studies. These studies should be referenced.

26. Volume I – Page 2-19

The second paragraph in Section 2.4.2 reads "In order to establish a possible link between greenhouse and field trials, a set of pots with blended Heavy Clay (Welland Clay) soils identical to those used in the 2001 Greenhouse trials was prepared". While it may be true the soil was identical, the volume of the pots and the type of pot used were different (6.5 L Treepots versus Classic 1200 pots).

27. Volume I – Page 2-21

It is understood that it is not easy to match soils for a study of this type and that it is difficult to obtain soil CoC (or nickel) concentrations at the desired levels. However, it is not clear how the Soil CoC levels were chosen and why such a wide range of concentrations was considered reasonable for a set Soil CoC level. For example, the nickel concentrations in the three soils at the Medium Soil CoC level are 1200, 517 and 307 mg/kg.

28. Volume I – Page 2-22

In Table 2-4, the average given is the average of the numbers not the average of the pH values. Correct.

29. Volume I – Page 2-33

Table 2-18 give P, K, and Mg concentrations in the soils used to make the blends for the 2001 Greenhouse experiment. Although the concentrations given may be adequate for the growth of crops, this does not mean that crop growth will not be greater in soils with higher nutrient levels. Although it may not be practical to get an exact match in nutrient levels between the control and very high CoC level, differences in nutrient levels of up five times are likely to influence plant growth.

30. Volume I – Page 2-36

In Table 2-19, the nickel concentration in Plot #3 unamended soil is 7360 mg/kg and in Plot #3 1X soil it is 2800 mg/kg. With this difference in nickel concentrations, it is not clear how the effect of liming can be assessed.

31. Volume I – Page 2-23

In the notes below Table 2-23, when using acronyms like EQL it would be more helpful to the reader to explain the term such as "lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions" rather than "estimated quantification limit for analytical method".

32. Volume I – Page 2-45

In section 6.4, a greater explanation of why Plot 2A has such a high CEC is required.

33. Volume I – Page 2-51

The fourth paragraph reads "Jacques Whitford and staff of the University of Guelph Greenhouse measured soil pH and some other physical properties (e.g., density). The other physical properties should be listed.

34. Volume I – Page 2-53

In the fourth bullet, it is not clear why pH is the most crucial soil characteristic.

35. Volume I – Page 3-3

A review of pertinent studies is appropriate, but it is not clear why more studies were not included and why no reference was made to review papers on nickel phytotoxicity.

36. Volume I – Page 3-11

In Section 2.2, it is stated that the 2000 testing used soybean and corn, which are agricultural crops in the Port Colborne area. This statement could be strengthened considerably by including crop statistics from the Port Colborne area.

The final sentence reads "Continuity in the plant species selected for use in both Greenhouse and Field Trials in Years 2000 and 2001…". This statement is correct in that oats were used in both years, but the variety was different. At some point in the report the reason for changing varieties and the implications of this change on the results should be discussed.

37. Volume I – Page 3-15

In Volume I – Page 2-16, the concentration of the control is given as approximately 43 mg/kg nickel yet in the table on page 3-15 the control is given as < 100 mg/kg nickel. Why was the value for the control changed?

38. Volume I – Page 3-22

It is understood that there were problems with the 2000 Greenhouse study, but in spite of these problems, the soybean data shows drastic declines in biomass, particularly in the clay soil, which can be attributed to soil nickel concentrations. Although EC25 values were not given for soybean in this study, the data suggests that growth effects are occurring well below the EC25 values of 1888 mg/kg Ni for clay and 1350 mg/kg Ni for sand, which were determined in the 2001 Greenhouse study. Unfortunately, the oat biomass data for clay was not available, since the nickel uptake data shows a similar trend to that of the soybeans.

39. Volume I – Page 3-28

The second conclusion states, "there are environmentally safe (non-phytotoxic) CoC concentration levels that are higher than the current MOE generic effects-based guideline values". While it may be true that no measurable effects were documented on plants growing in some of the soils with nickel concentrations above the MOE generic effects-based guideline value, the primary objective of the Crop Studies was to determine the concentration of historically deposited CoCs in soil that present an unacceptable risk to crops grown in the Port Colborne area. The soybean data from the Greenhouse 2000 sand soil suggests that reductions in biomass may occur at soil nickel concentrations as low as the MOE effects-based guideline value. A similar trend can be seen in the soybean in clay soil data, although due to the lack of clay control data it is not possible to determine at what soil nickel concentration effects start to occur. Although it is acknowledged that there were problems with the 2000 Greenhouse Study, nevertheless EC25 and PNEC values should be calculated from the available data.

40. Volume I – Page 3-29

The focus on oats for the 2001 studies is reasonable; although the 2000 soybean data also showed sensitivity to nickel uptake and soybean may be a more economically important crop in the Port Colborne area.

41. Volume I – Page 3-31

In the fourth paragraph, it is not clear where the data analysis is that identifies which soil variable are confounded with total soil nickel concentrations.

42. Volume I – Page 3-33

In Section 4.3.1, it was noted that the plants were harvested after 28 days due to severe toxicity symptoms. It is understood that this was an extreme case but typically, oats take 90 to 100 days to reach maturity. In Table 5 on page 11 (Volume II, Section 4) the maximum growth duration was 77 days. It is possible that the oats matured more rapidly under greenhouse conditions. However, oats is a cool weather crop and it is known that the higher air temperature adversely affect yield. There should be some discussion of how the greenhouse conditions (temperature, humidity and natural light levels) may have affected crop maturation and yield.

43. Volume I – Page 3-40

In the report, decreases in biomass are often attributed in part to manganese deficiency. Although it is understood that a deficiency of manganese can affect plant growth, perhaps more emphasis is put on manganese than is warranted. For example, Figure 3-7 shows growth in most pots in the 1081 mg/kg nickel treatment to be comparable to the control, yet the tissue manganese concentrations are below the tissue manganese threshold value. In contrast, growth is poor in the 188 mg/kg nickel treatment, yet tissue manganese concentrations appear to be adequate. It would appear that other factors are more important in affecting growth than manganese concentrations.

Manganese deficiency is not necessarily a separate issue from CoC concentrations in the soil, since metals such as nickel and copper are known to displace manganese in soils.

44. Volume I – Page 3-42

It was worthwhile to investigate whether DTPA-extractable and Water-extractable nickel were better predictors of toxicity than total soil nickel. It is interesting that they were not.

45. Volume I – Page 3-46

In the 2000 Greenhouse study, the biomass of oats grown in clay soil was comparable to the biomass of oats grown in organic soil (with the exception of higher growth in the organic soil from the Grotelaar farm, which was attributed to higher nutrient (phosphorus) levels). In the 2001 Greenhouse study, oat biomass in the organic soil (Table GH-25) was much less than oat biomass in the clay soil (Table GH-30).

Discussion would be helpful regarding the relatively poor growth of oats on the 2001 organic soil and may shed some light on why the limestone amendments decreased growth of oats in this soil.

46. Volume I – Page 3-47

It is not clear why there was an apparent increase in growth at the highest soil nickel concentrations relative to oat growth around 1000 mg/kg nickel.

47. Volume I – Page 3-50

The idea of conducting a parallel experiment (Engineered Field Plot (EFP)) with pots in the greenhouse and field is sound. However, there were several aspects in the experimental design that precluded making a direct comparison between the field and greenhouse results. The pot size differed between the field and greenhouse, the field pots were started in the greenhouse and then moved to the field rather than being seeded in the field, and the bottoms of the EFP pots were cut off in the field so the plant roots were contacting two soil types.

According to the report, the plants in the EFP were more sensitive to soil nickel concentrations, which was attributed to greater stress under field conditions or transplant shock. However, oat biomass in the Greenhouse grown plants ranged from 22.93 to 31.42 g DW/pot and the oat biomass in the Engineered Field plot ranged from 26.8 to 43.6 g DW/pot. These data suggest the plants in the field plot had better growth than the plants in the Greenhouse, which would suggest they are not more stressed.

48. Volume I – Page 3-51

The lack of manganese deficiency in the Engineered Field plot may be because the roots of these plants penetrated the underlying soil and took up nutrients including manganese. Further discussion is required.

49. Volume I – Page 3-57

In Figure 3-24, it is not clear why tissue nickel concentrations were not also in a log scale.

50. Volume I – Page 3-62

It is not clear what is meant by the statement that variation in soil parameters that were confounded with soil Ni, do not have a large influence on plant accumulation of Ni, thus are not likely to have a large influence on the determination of EC25. How is this known?

51. Volume I – Page 4-3

In the second paragraph, the land use for the OTR98 value quoted should be included.

52. Volume I – Page 4-4 to 4-6

OTR98 values should be included.

53. Volume I – Page 4-19

In is understood that the 2000 field trials did not get underway until late July and the "data were too sparse to provide for a comprehensive analysis". According to OMAFRA, the target date for planting spring cereals is April 10, and for corn and soybeans is about May 7. As planting date has a great effect on yield, it is questionable how the growth and yield of the 2000 field crops can be related to the normal growth of field crops in the Port Colborne area.

54. Volume I – Page 4-27

It is not clear why agronomic tissue samples are being used to look at CoC uptake, since in Volume II Section 5 – Page 8, it states that agronomic sampling best describes the relationship between the concentration of essential nutrients and final grain yield, whereas toxicologic sampling best describes the relationship between the concentration of CoCs in the soil and the aboveground yield. Should the toxicologic data have been used?

55. Volume I – Page 4-34

In the fourth paragraph, the report states, "In no tissue did concentrations of cobalt or arsenic even approach levels thought to cause phytotoxic effects in plants". However, the greatest effect of arsenic is on the roots of plants. Why were the crop roots not examined?

56. Volume I – Page 4-37

The conclusions start by saying, "Within the field trials, there were few cases where plant nickel or copper concentrations approached or exceeded tissue concentrations reported in the literature to cause phytotoxic effects". However, on Page 4-32 we are told that in the C3 plot, symptoms of phytotoxicity are evident. Also, germination was affected and approximately 50% of the leaves [of oats] were necrotic and plants were stunted and slender with less foliage. In Figures 4-3 and 4-4 on Page 4-30, nickel concentrations in tissues of oat and soybean are very high in the C3 unamended treatment. Clearly, there is evidence of phytotoxicity due to nickel under field conditions where soil nickel concentrations may be as low as 2860 mg/kg. Unfortunately, due to the limitations in the number of field plots and soil nickel concentrations, the soil nickel concentration at which significant phytotoxic effects and reductions in crop yield occur could not be determined.

57. Volume I – Page 4-36

It is not clear why nickel induced iron deficiency is mentioned in the field report yet it is not mentioned in the Greenhouse studies and is not mentioned in the overall conclusions.

58. Volume I – Page 5-4

There are better reasons for using Goldenrod as the species of choice than because it was the conspicuous floral element common to the chosen sites.

In any uptake study, it is important to separate the various plant parts before chemical analysis, as uptake can be, and usually is, quite different among plant parts. Why this was not done is unknown. Also, the age of the tissue and stage of development are important factors when conducting any biomonitoring study. Again, why these factors were not taken into consideration while conducting this study is unknown.

Since many of the biomonitoring plots were adjacent to the Year 2000 sampling locations, it is not clear why the natural vegetation samples were not taken from all the Year 2000 sites so the uptake data could be compared to the 2000 Greenhouse data?

Since the Spearman Rank Correlation was used, which does not require normality in the data, it is not clear why the data was trimmed. The trimming of the data could affect the correlations.

59. Volume I – Page 5-7

Why was the arcsine-square root transformation used?

Stating “glm” was used is not sufficient; the actual model should be given.

60. Volume I – Page 5-10

Table 5-3 shows data for two sand sites (reference and medium), yet the Biomonitoring study table in Appendix B-1 shows three sand sites (reference, medium and high). Why is the high sand site not included in the table? Also, the mean and standard deviations given in the organic high treatment in Table 5-3 does not match the mean and standard deviations given in Appendix B-1.

61. Volume I – Page 5-17

Reporting correlations for two data points is of questionable value.

62. Volume I – Page 5-24

The second paragraph reads, “generally nickel is readily and rapidly taken up by plants and is mobile in plants; therefore, the nickel content in plants …” This should read nickel concentration in plants not nickel content in plants.

63. Volume I – Appendix Page 7-4

CEC levels in the organic soil are surprisingly low, as well as in clay soil (given on the following page).

64. Volume I – Appendix F-5

The layouts shown are strip plot designs rather than the conventional split plot designs. Presumably, this design was chosen because liming the soil in strips is easier than liming sub-plots in a split plot design. Discussion is required regarding the effect this design has on the precision of the main effects and interaction and the implications in interpreting the experimental results.

65. Volume II – Section 1 Page 4

In Table 1, for the sandy soils the nickel values for the medium and low CoC levels are both technically at the “low” level. It is understood that due to analytical challenges that the medium value is slightly lower than the low value. Nevertheless, there should have been a larger difference in nickel concentrations between the medium and low levels.

66. Volume II – Section 1 Page 5

In 2000, the variety of oats was Avena sativa L. cv. Stewart but in 2001 the oats variety was Avena sativa L. cv. Rigadoon)(Section 4 Page 4). Why was the variety of oats changed?

Is the 2001 oat variety Rigadoon or Rigodon? Also, why was the oat variety “Ogle” used in the 2001 organic soil?

67. Volume II– Section 1 Page 10

Each pot had two plastic liners closed at the bottom to prevent leachate from escaping. This means that the soil would not drain and it is likely that the soil at the bottom of the pot became anaerobic. Was there evidence (reduced sulphur smell) that the soil had become anaerobic? Was the redox potential of the soil measured? The redox potential of the soil will have an effect on arsenic speciation (and other metals) and could affect arsenic availability and phytotoxicity.

68. Volume II– Section 1 Page 11

In the first paragraph it is stated that “intact root systems of plants removed from each pot experiment were initially separated by shaking soil from them. Broken roots were removed from the loose soil using a combination of tweezers and dry sieving. Roots were discarded". With all this work done to remove the roots, it is not clear why the condition of the roots was not noted and why the roots were not washed, weighed and chemically analyzed.

69. Volume II – Section 4 Page 6

A greenhouse temperature of 27 degrees Celsius is high for oats.

70. Volume II – Section 4 Page 10

Insect and pathogen problems are commonly encountered in greenhouse and field experiments and it was appropriate to apply common agricultural pesticides in order to control the thrip and other insects. However, the percentage crop loss due to insect or other pathogen damage should have been calculated and the results included in the Main Report.

II. MOE Comments of Vale CBRA ERA-Natural Environment

The following comments pertain to the Community Based Risk Assessment, Port Colborne, Ontario – Ecological Risk Assessment Natural Environment dated September 2004 and which was prepared by Jacques Whitford Ltd. on behalf of INCO Ltd. The ERA report consists of the following volumes:

Volume I:	Main Report (including Appendices A to D)
Volume II:	Field Data Collection and Analysis Protocols
Volume III:	Supporting Data
Volume IV:	Consultants Report
Volume V:	Bio-Physical Data

Additional reports have also been provided and were reviewed along with the ERA report. These reports are:

- Addendum Report – March 2005
- Community-Based Risk Assessment Integration Report – June 1, 2008

Summary of Review Comments

Overall, potential risks to the natural environment have been underestimated for this site, particularly at locations close to the refinery. Below we provide extensive comments for the proponent to consider. The vast majority of our review comments address scientific or transparency issues or requests for further clarification. Pending satisfactory resolution of these comments, this ERA appears to provide sufficient information to characterize most ecological risks at this site and support the majority of the reports conclusions. However, there remain some limitations with this ERA. There are some concluding statements that will need to be revised due to a recommended reanalysis of the data. In addition, due to limitations in sampling data and time constraints with this study, some revisions are warranted for a number of concluding statements to more appropriately characterize the results of this ERA.

The ERA concludes that ecological impacts from Ni, Cu, Co and As are not significant in the Study Area. This conclusion is based on inappropriately averaging data and biological response information across the entire study area. Data are presented in these reports that suggest adverse impacts to vegetation, soil organisms and wildlife (e.g. amphibians) in close proximity to the refinery boundaries. Using Ni as an example, this risk assessment found that Ni is elevated in environmental media (soil, surface water, sediments) and exposure is occurring to aquatic and terrestrial biota (as demonstrated by elevated concentrations in exposed organisms such as grasses, maple leaves, insects, tadpoles, frogs, earthworms and voles). Evidence of toxicity in areas with high COCs (i.e., the primary study area) include: earthworm toxicity measured in laboratory toxicity tests, visible Ni damage observed to terrestrial vegetation (maple leaves), potential toxicity to amphibians (e.g., American Toad), evidence of impaired leaf litter decomposition, and toxicity observed in maple seedlings (from reference areas that were grown on contaminated soils). Some evidence is presented in the report of limited or no adverse effects as well but it is difficult to assess the significance of this information due to concerns with the overall report. Based on the experience at similar sites, distance from the refinery is a major factor that needs to be considered. However, there was only a limited attempt in this report to evaluate the potential relationship that might exist between potential adverse effects and distance from the refinery. Reference or control samples collected west and generally upwind of the refinery appear to be appropriate (based on chemistry – COC levels in soil, water, sediment). However, "Control" samples collected downwind may not be as it appears COC concentrations are elevated in these samples but at lower concentrations than those found in the primary and secondary study areas. Hence, the downwind "controls" were exposed to COCs and may not be suitable reference sites. Overall, it appears that adverse impacts are occurring as a result of exposure to COCs in soil but that the scope of these impacts is limited with respect to the entire study area.

MAJOR COMMENTS

1. The overall sampling design and site characterization is not well described in this report. It took a lot of effort by the reviewers to determine what data was collected and used in this Risk Assessment report. The sampling design is often uneven between the primary and secondary study areas (with respect to soil and biological samples). For example, a total of 127 soil samples were collected from the Primary Study Area, 112 from the control area but only 36 soil samples from Secondary Study Area. Twice as many soil samples were collected from woodlots in the Primary Area (34) than from woodlots in Secondary Study Area (17). The opposite was often observed for some of the biological data where more samples were collected from the secondary area (e.g., earthworm data, frog survey data). Site characterization and specific sample sites need to be more clearly presented in this report and where unequal sampling occurs, a rationale should be provided to justify that site characterization is adequate and that subsequent statistical analysis is not biased.

2. The soil sampling conducted for the woodlots was highly variable. In numerous cases, only one soil sample was collected and chemically characterized for COC levels. For Woodlots where additional soil samples were collected, the number of soil samples was usually low (i.e., 4 or 5 samples from Woodlots 4, 5, 11, and 14). In fact, only two woodlots appear to have been adequately characterized: woodlot 3 (11 samples) and woodlot 7 (9 soil samples). It is difficult to interpret the COC concentrations for those woodlots with only one soil sample given the relationship identified in the report between soil COC levels within Woodlots (and elevated concentrations on the windward site). Additional information should be provided to identify where within the woodlot these soil samples were collected and how representative they may be of expected conditions across the woodlot.

3. At present, there is no serious attempt to relate COC levels in soils (and potential for adverse effects) with distance from the refinery. Often the entire study area is lumped together resulting in an inappropriate averaging of areas with extremely elevated COC concentrations with areas with lower levels of COCs. For demonstration purposes, we have selected woodlots 2, 3, 7, 8, 11, and 12 as they fall more or less along an easterly transect downwind of the refinery out to approximately 4 km. The average (or typically the only soil Ni) concentrations for these woodlots are: 22,700 ppm, 15,257 ppm, 2,498 ppm, 2,025 ppm, 642 ppm, and 288 ppm. Even with the low sample sizes (number of soil samples are 1, 11, 9, 1, 4, and 1 respectively), a clear relationship between decreasing Ni concentration and increasing distance from the refinery is apparent (see Figure 1 below).

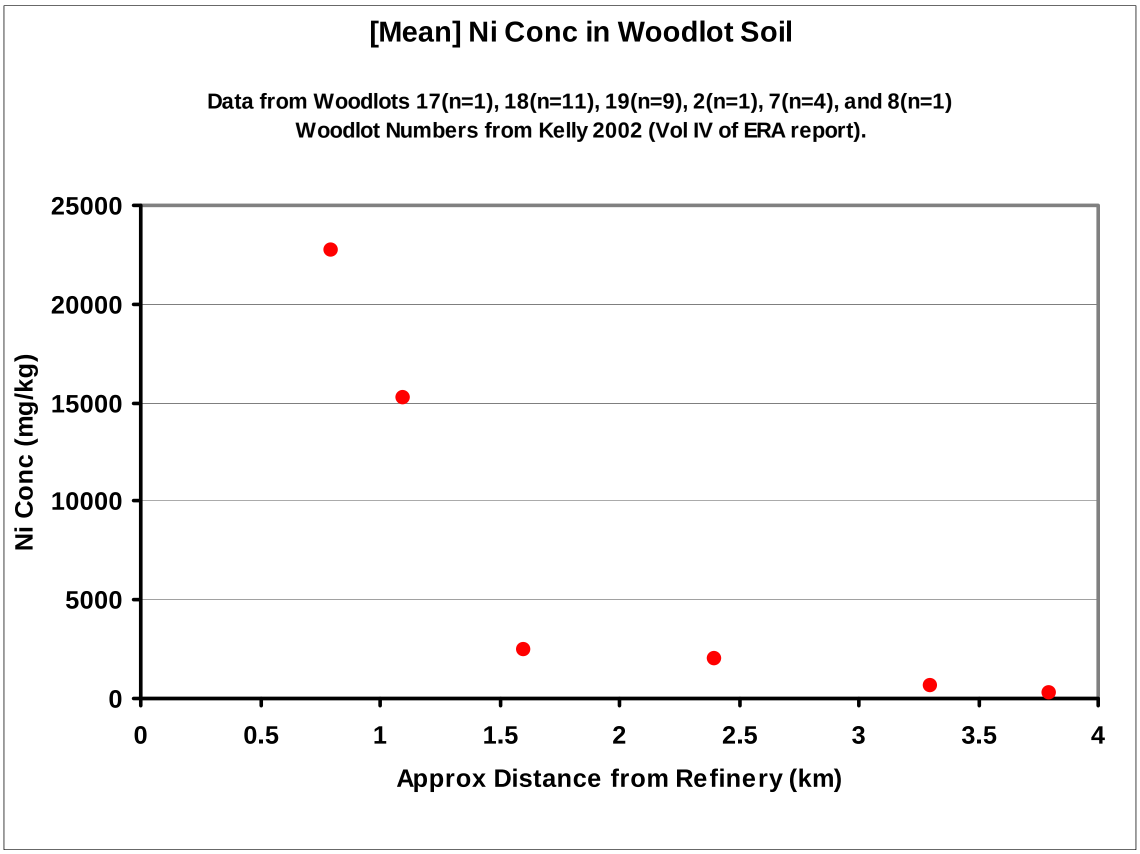

Figure 1.

4. No or very limited biological samples were collected from the main plume area north east of the refinery. A concentration gradient downwind of the refinery was observed with soils collected along the main plume area (see Comment #26; Figure 2 below). The lack of biological samples from these areas limits the ability to conduct a proper analysis of distance to the refinery along the concentration gradient in the soil. Please provide a rationale supporting why biological samples

were not collected from this area and include a discussion on the limitations of not having this data on interpreting the conclusions of the report.

5. Potential for adverse effects to Amphibians. Amphibian calling sites are unequal between the primary (n=10) and the secondary study area (n=20). Two sites within the primary study area are located in the Rodney Street community that should not be flagged based on poor habitat suitability (since urban environment). Hence, frog calling sites within the Primary study area are limited to Sites 17 to 22 and 26 (n=8). Based on the information provided in the amphibian survey field data, chorus frogs, spring peepers, and the American toad appear to be common across the entire study area. However, it is stated in the report that the expected high densities of spring peeper and chorus frog at quality breeding sites were not encountered. It is also stated that there may be some suppression in population numbers but not at levels that affect long term persistence of frog and toad populations in Study Area. In addition, the American Toad was not found at sites 17 or 26 on any of the 4 visits. Since the American Toad was found at every other site from across the study area, the absence of the toad at these sites within the primary study area should be noted and discussed. The authors conclude that the potential risk of soil COCs to the maintenance of frog and toad populations in the Study Area are low despite a hazard quotient (HQ) of 18 for Ni (based on toxicity data for tadpoles from the literature). The low densities observed at the breeding sites may suggest that an adverse impact is in fact occurring resulting in reduced peeper and chorus frog numbers. Based on the observations in the breeding call survey, the conclusion that potential risk to frog and toad populations are not at risk is not fully supported.

6. Overall, the authors conclude that they are highly confident that the ERA has shown potential risks to VECs in the Study Area are not underestimated. The rational given for this conclusion is that it is based on the use of site specific data (scientifically credible sampling) as well as scientifically defensible data from the literature. Generally, we agree that site-specific data is very useful in determining actual risks at a site. However, the author's conclusions rely heavily on site-specific data sets which are relatively small considering the size of the Study Area being assessed. Overall, this report does not provide enough information (as currently written) to support the authors claim that they are "highly confident" in the ERA results. Additional rationale is required to support these concluding statements (as discussed below in our specific comments). In addition, there should be a discussion of the uncertainty associated with such small data sets in the uncertainty analysis.

7. The goal of a risk assessment report is to evaluate the potential risk to the natural environment; not to determine if there is an immediate need to mitigate or manage risk to the natural environment. If the results of the risk assessment identifies that adverse impacts are occurring, then potential risk management measures may be considered. This should be clearly noted in the report. In addition, the executive summary should clearly note that adverse effects were identified for some soils

that have Ni concentrations in excess of the soil intervention levels and these specific adverse effects should be noted.

8. The report should provide additional information on the generalized linear model procedure and how to interpret these results. How do these models account for unequal sampling between Primary and Secondary study areas? What are the underlying assumptions for these models?

9. Presentation of data is often limited to means or tables of simple summary statistics. Often Figures are more effective for interpreting these statistics. In general, the use of Box plots or other graphical plots with data grouped by primary, secondary and reference areas (and by soil or habitat type as appropriate) should be provided when summarizing chemical and biological data. In addition, full data summary statistics and information on the underlying data distribution are often not provided or summary statistics are missing or incomplete. This information should be provided.

10. The application of the earthworm Ni TRV is troubling as it appears estimated Ni bioavailability is being double counted; once in developing the Ni TRV (where a high TRV is selected based on minimal bioavailability of Ni oxides) and again where the total Ni concentration in the soil is modified to estimate the bioavailable fraction based on a water extract or acid ammonium oxalate extraction (see Section 8.3.3.1). Total Ni in soil should be compared to the Ni oxide TRV and a bioavailable estimate of Ni (water and acid ammonium oxalate extract) should be compared to a bioavailable Ni TRV (e.g. 100-200 mg/kg as soluble Ni salt). It is not appropriate to compare Ni oxide effects (based on total Ni) to exposures modified to estimate a bioavailable fraction.

11. Additional clarification is required to support the statement that the 20% effect level should be considered a No Observable Effect Concentration (NOEC). Clearly, if 20% of the test species are affected, then an effect has been detected. A No Observed Adverse Effect Level (NOAEL) would be the highest concentration tested that was not statistically different from the control. In a properly conducted toxicity test, a NOAEL is often found at concentrations less than 20%. Please note that the use of the 20% effect level in this risk assessment is generally acceptable. The only concern would be for species of special concern where a lower effect level may be required. Overall, the 20% effect level should not be referred to as a no-effect level; rather it represents an acceptable effect level for most VEC species.

12. Greenhouse and field bioassays were conducted with Pt. Colborne soils and crops (oat, soybean, radish, corn). A field program was also conducted using golden rod (the reviewer assumes it is the common *Solidago canadensis*, an old field colonizer). This one field herb species is used to represent over a hundred herbaceous species, many of which are woodlot plants. No rationale is provided as to why one or two woodlot species were not included in the study. It is not

clear how these bioassays results are applicable to herbaceous plants expected in the under-story of woodlots; some of which may be more sensitive to Ni and/or other COCs. For example, there is no information on the relative toxicity of Ni (and other COCs) to various natural herb plants in the Study Area with respect to the test plants from the ERA Crop Study report. At a minimum, the relative toxicity of goldenrod to other herbaceous plants needs to be provided to put the bioassay results into context. These species may be more (or less) sensitive than the test species used in the Crop Study bioassays. The conclusions of the ERA-Crop Study report and their applicability to the natural environment should be summarized in this report. A rationale should be provided to support using the bioassay results from the Crops Study to predict potential adverse impacts to herbaceous plants.

13. The Niagara Region has 38 tree species and 46 shrub specie but this ERA only addressed one tree species (a soft maple) in any detail. The report notes that there are four provincially rare species in the Pt. Colborne area (i.e. Hop tree, Pignut Hickory, Pin Oak, Swamp White Oak). However, there is no discussion concerning potential impacts to these provincially rare tree and shrub species. Additional rationale is required that compares the relative toxicity of COCs to maples, and demonstrates that these rare and/or sensitive species are not being adversely impacted.

14. This ERA looked at flora and fauna in all fields and woodlots (a total of 21) in the Study Area as a single population and concluded that there are no adverse effects to these populations. We do not agree with this approach as it inappropriately averages the COC concentrations over too large an area and reduces the likelihood of observing adverse impacts to VEC species. For example, a meadow vole in a woodlot is exposed to the COCs in the woodlot. It is not exposed to the average COCs from a "population of woodlots". This approach can also potentially mask real impacts on a local scale. Measurable impacts were observed in a small number of woodlots but may not appear significant when the data is included in a data set for a much larger group of woodlots. For instance, trends that may exist with increased distance from the refinery can become obscured when averaged over a large distance. This issue needs to be addressed in this ERA.

15. Specific objectives were proposed by the authors in this ERA with the intention of determining if there is a relationship between effects and soil type/habitat type. One obvious objective that appears to be missing is determining whether a relationship exists between effects vs. distance from the refinery. This relationship needs to be evaluated in this ERA.

16. The overall study design is never clearly presented in this report. It is evident that the study design was grouped based primary on COC levels in soil (primary and secondary study area), but also by soil type (clay vs. organic) and by habitat type (field vs. woodlot). The location of actual sampling sites within these categories is

not clear. For example, the information presented in Table 1 of Volume II, Section 18 needs to be grouped by these major categories and illustrated in a series of Figures. It is also very difficult to determine what data was used in this report. Additional maps, figures, and tables are required that clearly summarize sample locations, data sources, and data results. If this information is available in other reports, then the specific locations in these reports should be identified. The large inset maps (map #1 and #2) have too many different types of data/samples included on them to be useful. Instead they are simply confusing and very difficult to interpret. Please provide Figures grouped by different types of sample data so it can be readily understood.

17. It is stated in the report that risk characterization was done for the entire Study Area including both the Primary and Secondary Study Areas. Populations representative of either the Primary or Secondary Areas were not assessed independently of each other. Therefore, it is not possible to determine if risks to populations in the Primary Study Area were higher than in the Secondary Study Area. This analysis needs to be conducted. Also, there is no mention of any evaluation (or discussion) of special areas considered significant (ANSIs, ESAs, PSWs).

18. Section 2.1.1. Overall, very little information is provided in this section to provide an historical overview of contamination. Instead, some information is provided to illustrate metal particulate emissions from the refinery over time.

19. Section 2.1.2. This section states that the list of selected contaminants of concern (Ni, Cu, Co, As) resulted from meeting three conditions. No information is provided concerning the COC selection process; the section just refers to three independent JWEL reports that addressed these three conditions. A short summary of the COC selection process needs to be added to this section as the risk assessment should be a stand alone report (i.e., it should not be necessary to review other reports to understand what was done in this ERA).

20. Page 2-5. 1st paragraph. The text indicates that the soil data used to generate the isolines in Figures 2-2 to 2-5 is provided in Tab 9 of Volume III. However, only the location of the soil samples is provided; no information is provided on the actual measured soil concentrations for the 4 COCs or information on soil type (or the relative distance and direction from the refinery) in this section. This raw data should be provided as an Appendix to this report and electronically as an excel spreadsheet or Access database on a CD. The text should also include a discussion on the number of soil samples used to develop these isolines and where they were located. In addition, the actual soil sampling locations can be superimposed on these Figures to allow for comparison of soil sample locations and COC concentration isolines.

21. There appears to be a number of discrepancies between the concentrations of Ni in soil and the isoline plots. For instance:

a. Concentrations of Ni in soil were measured at concentrations much greater than the 4000 ppm isoline (e.g., In woodlot #3 located east of Reuters Road, the maximum Ni concentration was 33,000 ppm; mean was 15,300 ppm). Why are these elevated Ni concentrations not identified in Figure 2-2? Given these extremely elevated Ni concentrations, it is not acceptable to simply use the 4000 ppm isoline to indicate Ni concentrations greater than 4000 ppm fall within this area. Additional isolines should be added (e.g., 8000 ppm and 16,000 ppm).
b. Woodlot 7 had a maximum Ni concentration of 4,745 ppm (mean of 2,498 ppm) but appears to be located between the 1000 and 2000 ppm isoline.
c. Woodlot 8 has a Ni concentration of 2000 ppm based on a single soil sample but appears to be located between the 500 and 1000 ppm isolines.
d. No data was collected from Woodlots #1 and #2 west of Reuters Road (a few samples were collected from open spaces along the north-east corner of Reuters Road). The single soil samples collected from each of these woodlots east of Reuters Road indicate very high Ni levels (12,900 and 22,700 ppm respectively). Given these elevated concentrations east of Reuters Road based on limited soil sampling, the lack of data west of the road is troubling and raises significant concerns regarding the accuracy of the 4000 ppm isoline.

22. Tab 9, Volume III. What was the sampling design used to collect these soil samples. It is not apparent from this Figure how soil samples locations were determined or who collected them (JW, AMEC, or MOE).

23. Page 2-5 2nd paragraph. The statement is made that "for both clay and organic soils the zone of potential adverse effects of soil COCs on area's biota and ecological processes is from the soil surface to a lower depth of approximately 20cm" and that "the soil depth 0-5cm interval represents a zone where COC values are considered to be representative of higher concentrations". However, Table 2-2 indicates that the highest metal levels were often observed in the 5-10 and 10-15 cm depth, yet sampling throughout the study area was taken at the 0-5cm depth only. This raises concerns that the COC concentrations in surface soil in the Study Area may not have been properly characterized because the 5-10 and 10-15cm depth was not sampled throughout the Study Area (especially in heavy clay soil). This needs to be addressed in the ERA report.

24. This ERA concentrates on woody species (i.e. trees and shrubs) but the vegetation that may be most impacted by contaminants in surface soil (0-5cm depth) would be shallow-rooted herbaceous plants established on the forest floor as well as in old fields. Tree seedlings would also fall into this category. The "woodlot health study" targeted mature trees only. No "field health study" was conducted to assess field herbs and grasses. Justification should be provided for limiting the 'health studies' to only mature trees in woodlots. The lack of this information should be discussed in the uncertainty section.

25. Figure 2-6. Please note that that the numbering of these woodlots is inconsistent in the ERA report and the appendixes: these woodlots are numbered 2, 3, 7, 8, 11, and 12 in Figure 2-6 of this main report (Vol I) but are also numbered 17, 18, 19, 2, 7, and 8 in the Kelly 2002 report [see Figure 4 of Volume IV of the ERA report]). A clear Figure/Table is required to delineate Woodlots, soil characterization (including COC concentrations), and terrestrial data collected so information in the Kitty 2002 report can be properly compared to information in the main ERA report.

26. Page 2-13. Tables 2-5 and 2-6. Similarly, additional information on metal levels in soil in relation to the distance to the refinery should be provided in a Figure. For example, Figure 4 from Volume IV of the ERA-Crops Studies provides the location of the test pit locations. From this Figure, we have selected several test pits that fall along a NE transect at various locations downwind of the refinery (e.g., Test pits Tp5, Tp6, Tp7, Tp3, J, J1, J2, K, X2, L, and M). We plotted Ni concentration in soil at three soil depth profiles (0-5, 5-10, and 10-15 cm) with distance to the refinery along this "NE transect". This figure clearly illustrates that Ni levels decrease significantly with distance from the refinery and that Ni levels are not always highest in the 0-5 cm soil profile (as suggested by the authors on page 2-5). (see Figure 2 below)

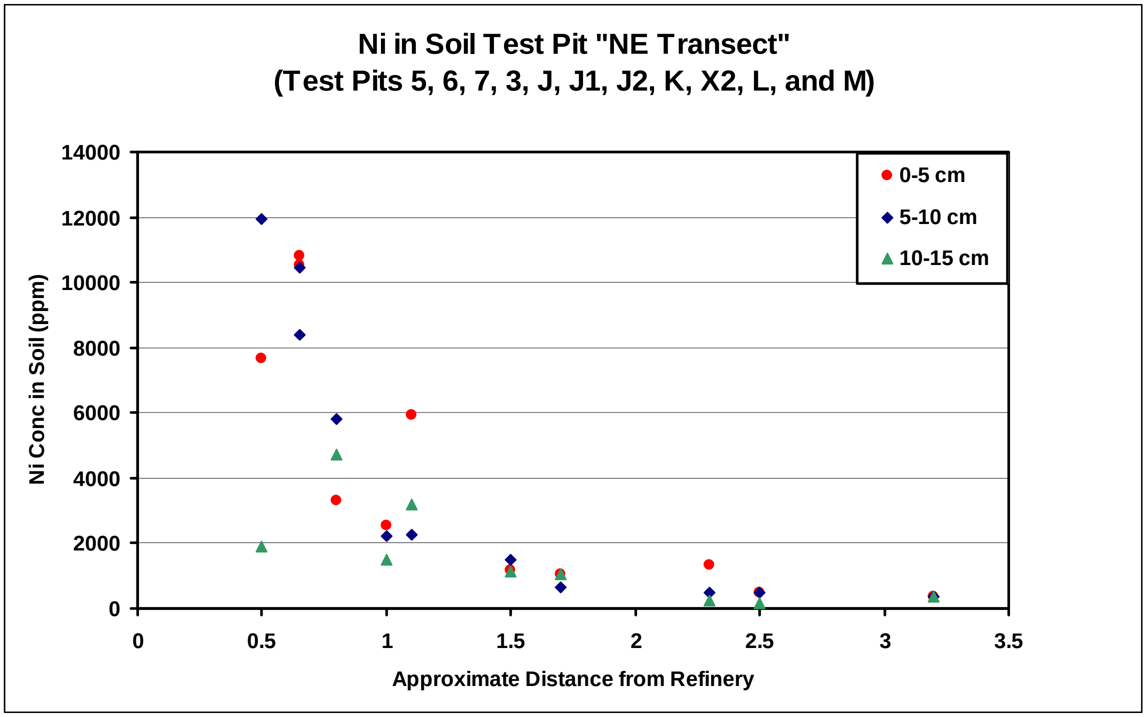

Figure 2

27. Page 2-15. Tables 2-8 and 2-9 illustrate that the % leaching of Ni and Cu was 100 fold higher in DTPA extracts than aqueous extractions in organic soil and clay

soils. The authors state that when considering conditions in the Study Area, aqueous extraction are the closest representation of potential conditions (e.g. rain and snow). We disagree. DTPA is a better representation as it is likely closer to the extraction of COCs by root exudates in the rhizosphere. Thus, Ni and Cu availability to plants may actually be much higher than suggested in this Section. The section should be revised to reflect this fact.

28. Table 2-10 illustrates that COC concentrations (Ni, Cu, Co) in sediment decrease with increased distance from refinery (primary versus secondary areas); however, As is the exception whereby sediments in the reference area were found to have higher As than sediments in the Primary Area. Some explanation as to why this might be occurring should be added to the report.

29. Page 2-16. The maximum and mean Ni concentrations measured in pond sediment exceed the Provincial Sediment Quality Guideline (PSQG) Severe Effect Level (SEL) in the primary and secondary study areas (the SEL is 75 mg/kg for Ni, 110 mg/kg for Cu, and 33 mg/kg for As; there is no PSQG for Co). In addition, the PSQG Lowest Effect Level (LEL) is exceeded for Cu in the primary and secondary study areas and the reference areas (LEL = 16 mg/kg). This should be addressed in the report.

30. Page 2-23. Concentrating on data from the Wignell and Beaverdam Drains, the higher Ni concentrations were observed in surface water in areas closer to the refinery and surface water Ni concentrations were greater in woodlots than in fields. The predation of aquatic invertebrates by terrestrial receptors is a potential ingestion pathway but aquatic invertebrates were not sampled from these drains. The authors should provide a rationale for excluding this exposure pathway from the ERA. Also, it appears that the units in Table 2-11 should be mg/L instead of mg/kg. The mean concentrations of Ni, Cu, and Co in the primary and secondary study areas exceed the Provincial Water Quality Objectives (PWQOs) to protect aquatic life. The PWQOs are 25 ug/L for Ni, 5 ug/L for Cu, and 0.9 ug/L for Co. The PWQO for As is 100 ug/L and was not exceeded in these surface water samples. This should be addressed in the report.

31. Overall, the TRV selection is incomplete. In many cases, insufficient information is provided to summarize the critical studies or how the TRVs were selected.

32. Page 6-40. The report states that a bioavailability study in rats is described in the HHRA. The information reported in this ERA is vague and only notes that rats were fed organic and clay soil from the Pt. Colborne study area with known COC concentrations. No information is provided on the details of this study (e.g., number of soils tested, COC concentrations, study design, etc.). Ni concentration in blood was measured and Ni concentrations in blood, urine and tissue were calculated. Soil Ni concentrations were compared to blood Ni concentration and % bioavailability was estimated. This study concluded that the % bioavailability of Ni is 3.2% for organic soils and 3.9% for clay soils and these results were

applied to many of the receptors assessed in this ERA. For transparency reasons this study, including the data and the corresponding calculations, need to be summarized in the ERA report (rather than simply referring to the HHRA which is in a separate report). In addition, while we agree that an assumption of 100% bioavailability would likely overestimate the true fraction that is bioavailable, we have some concerns with relying solely on the in-vivo bioavailability data presented in the HHRA report. We have not reviewed the entire bioaccessibility report at this time. However, we understand that only 3 soil samples were tested (clay soil, organic soil, and fill from the Rodney Street area) and each had a Ni concentration of about 10,000 ppm. Rats were exposed to a single dose of contaminated soil and blood was collected over 72 hours. Since only the tests done with the clay and organic soil are appropriate for estimating Ni bioavailability for this ERA, the sample size is quite limited (n=2). In addition, there is no dose-response information on percent bioavailability at different soil Ni concentrations (e.g., does Ni bioavailability vary at different total Ni levels in soil?). There is also some uncertainty with regard to interpreting a single dose exposure with expected chronic exposures and if that would influence expected bioavailability estimates. Pending addition information, it may be acceptable to use this information in the ERA but not by itself. We understand that in-vitro information is also available that estimated the bioaccessible fraction. Both should be reported and used in subsequent data analysis; not just the in-vivo estimate.

SPECIFIC COMMENTS

VOLUME I – MAIN REPORT (including Appendices A to D)

EXECUTIVE SUMMARY

33. The concentration of soil Ni is highest in woodlots located nearest to the refinery with the highest soil Ni levels being observed on the windward edge of these woodlots. The Executive summary does not indicate whether similar comparisons were carried out in other woodlots sampled throughout the Study Area. Also, woodlot soil was shown to accumulate significantly more COCs than in adjacent fields near the refinery (e.g. the Ni ratio for woodlot soil to field soil is stated to be 7.7 at a distance of 1 km). Was this scenario evident across the Study Area? Given this relationship, the uncertainty associated with characterizing individual woodlots where only 1 soil sample was collected would be expected to be quite high. These single data points may (or may not) be reflective of the actual conditions found within the woodlot. The Executive Summary or main report should explain why such a difference in soil concentrations might occur (e.g. one possible explanation is that during the growing season, a much higher surface area of foliage up in the forest canopy may intercepts more particulates than grasses and shrubs growing at ground level in adjacent fields).

34. Four environmentally sensitive areas are recognized in the Niagara Region that fall within the Study area but no information is provided as to whether or not there were any adverse impacts observed or predicted for these specific significant areas:

- Nickel Beach Wetland (58ha) – PSW (in Primary Area)
- Nickel Beach Woodlot (47ha) – ESA (in Primary Area)
- Weaver Road Woodlot (82ha) – ESA (in Secondary Area
- Humberstone Swamp/Forest (82ha) – PSW, ESA, ANSI

35. The report concludes that based on the ERA results and data analyses; there is no unacceptable risk to the natural environment in the Study Area as a whole and that there is no immediate need to mitigate or manage risk to the natural environment. It is premature to make this concluding statement given the number of uncertainties with this ERA. For example, there are several caveats to consider which may add significant uncertainty to the ERA study results and conclusions:

a. decomposers (i.e. earthworms) were shown to be adversely impacted in woodlots with organic soil near the refinery
b. the leaf litter study did not use standard methods to determine decomposition rates; a proxy method was used which severely reduces the usefulness of this line of evidence,
c. risks to 36 tree species and 48 shrub species were only partially determined from toxicity tests based on one tree species,
d. due to time and resources limitations imposed early in the study, no data is available from a quantitative or a qualitative terrestrial survey to determine the health of herbaceous species in fields or woodlots.
e. The data characterizing the site is highly variable and limited given the size of the study area. This introduces considerable uncertainty as results are averaged across the entire area (apparently without considering the influence of uneven sampling).
f. The data was collected in the early 2000s. While it is unlikely that conditions have changed very much over the last 8+ years, the lack of current data should be identified as a limitation.
g. No analysis was conducted to examine the relationship with potential adverse impacts and distance from the refinery. Instead results are averaged for the whole study area; severely limiting the ability to identify adverse impacts in areas with elevated COC levels in the vicinity of the refinery.

36. Table ES-4 summarizes COC concentrations is surface water. However, the data is reported in mg/kg; not ug/L. Is this a typo? All aquatic concentrations should be reported as mass per unit volume; not mass per mass.

1.0 INTRODUCTION

1.2 Purpose of CBRA

37. Herbaceous plants were not covered under this ERA because the authors claim they are addressed in the Quantitative crop studies (phytotoxicity testing) ERA – Crop Studies. However, only one herbaceous plant was examined in the ERA Crops Study report: goldenrod. As mentioned previously, the conclusions of the ERA-Crop Study report and their applicability to native vegetation should be summarized in this report with additional detail provided on how the conclusions from that ERA can be extrapolated to the natural field and woodlot plant species which are not addressed in this ERA.

1.4.8 General Study Design and Approach

38. The study area does not represent all lands in Pt. Colborne where soil Ni concentrations exceed the 200 ppm MOE standard for Ni. The authors explain that for the ERA to be completed on schedule, the collection of biological data began before all soil data collected was analyzed. It is possible that this may have introduced bias or error in the results. It is unfortunate that the initial project schedule took precedence over ensuring that adequate, high quality scientific data was collected, especially given the extensive time period that has elapsed since the data was collected back in 2001-2003.

39. Page 1-8 – how are these earlier MOE reports used? Data clearly indicate injury was observed in maple trees closest to the refinery and that tissue levels dropped off 30 km away (Smith 1975). How does the data collected for this study compare to this historical data?

40. For this ERA, a sustainable level of ecological functioning was selected as the most appropriate level of environmental protection desired. Measuring sustainability, such as determining a decline in VEC population numbers over time (e.g. changes in birth rate and/or mortality rate, emigration and immigration), generally requires measurements and observations to be taken over a number of growing seasons/years. In this ERA, sampling was all done within a single season. The authors should clarify how population(s) ‘sustainability’ was determined, based on a single year’s data.

2.0 PROBLEM FORMATION

2.1.1 Historical Overview of Contamination

41. Page 2-1. This section should clearly state that “particulate emissions” included metals since this risk assessment is focused on elevated metals in soils; not elevated “particulates”.

42. Page 2-1 last paragraph. It is stated that the downwind area (to the northeast) has been exposed to the greatest deposition (of metals released from the refinery) from 1918-1960. Sampling for this ERA occurred 40 yrs after this period. This section should also discuss chemical speciation of the various COCs and any potential changes resulting from weathering processes and/or natural attenuation which may have occurred over this lengthy period.

43. Page 2-1. For completeness, please add information on non-particulate emissions from the refinery.

44. Page 2-1. 2nd last sentence. What is the basis for the statement that "potentially harmful environmental effects on local biota ... are considered to have been greatly reduced compared to past elevated soils". Is this simply that emissions have been reduced or is there data available on adverse environmental effects when emission levels were higher? If so, please summarize this information.

45. Page 2-1. Last sentence. Add summary details from McLaughlin and Bisessar (1994) of how levels have remained unchanged.

2.1.3 Drainage Characteristics and General Soil Types

46. Page 2-4. Please identify where in this risk assessment report the "COC plume" identified by JW is located. If not, please add this information to the report.

47. Page 2-4 last sentence: "For simplicity, field data collection efforts focus on three general soil types; clay, organic and sand." Additional rationale is required to justify lumping clay loam, heavy clay and shallow clay into one group as these clay soils can differ in drainage and aeration properties.

48. Page 2-5 2nd paragraph. Please provide summary details of the test-pitting program (how many test pits (n=44?), where collected, etc.) and specifically where this information can be found in the ERA-Crops Studies report.

49. Page 2-10. Table 2-2. The range of metal concentrations should be provided from low to high; not high to low. Add sample size for each soil type to this table.

50. Page 2-11. Table 2-4 only provides information for 3 soil samples at various distances from the refinery. A figure with data from additional sites would aid in identifying this relationship and providing context on the geographical area of elevated metal levels. For example, as noted in our major comments, we developed a transect due East of the refinery that crosses several woodlots to more fully examine this relationship (Figure 1 above). This Figure supports the relationship that Ni soil concentrations decrease significantly with distance from the refinery.

51. Table 2-5 shows soil COC concentrations for field sites. The maximum soil Ni was observed in the Primary Study Area (10,525ppm); the mean for fields in the Primary Area was 1,354ppm Ni. There is no information provided concerning the location of this field but it appears that it was not the field adjacent to the woodlot with the highest soil Ni concentration (33,000 ppm in woodlot; 1,860 ppm in the adjacent field). Locations of field sample sites need to be clearly illustrated. In addition, was there a field inventory carried out of the plant species established at this (and other) field sites to determine if there were any observable adverse effects (e.g., reduced species diversity)?

52. Table 2-6 shows soil COC concentrations in the woodlots. The maximum soil Ni concentration was much higher in the Primary Area (33,000 ppm soil Ni) than in the Secondary Area (2,110 ppm soil Ni). The woodlots in the Primary Area are in closer proximity to the refinery, and based on the soil data, appear to have higher soil Ni concentration (as shown in Table 2-10). However, data from the woodlots were not assessed as a function of distance from the refinery, which may identify significant trends (as noted in previous comments).

53. The maximum Ni concentration in surface water is 1,045 ug/L; not 429 ug/L as shown in this Table. For some reason, not all of the surface water data was used in the summary statistics. This is troubling as the report does not make any mention of why this data point was removed. If there are concerns with the data quality of any of the sample results and they were not used in subsequent analysis, then this needs to be clearly discussed in the report. In general, unless there is overwhelming evidence to the contrary, all data should be used in the subsequent analysis including apparent outlier values since that may in fact represent actual elevated concentrations in the environmental media.

2.1.3 Hydrological Parameters

54. Note: under Reg 153/04 as amended, the Ministry developed aquatic protection values for the groundwater to surface water pathway. These APVs are 39 ug/L for Ni, 6.9 ug/L for Cu, 5.2 ug/L for Co, and 150 ug/L for As. Groundwater results could be compared to these APV values. Note: Table 2-10. The maximum Ni concentration in surface water is 1,045; not 429 as shown in this Table.

55. Page 2-25. 1st sentence. Revise “historical dust deposition” to more accurately reflect RA is examining particulate metal emissions from the refinery.

3.0 ECOLOGICAL SITE CHARACTERIZATION

56. Please add a rationale supporting why no effort was made to conduct a semi-quantitative or quantitative assessment of the ecological risks of COCs within these urban areas of the City of Port Colborne. At present, there is no assessment of potential ecological risk in these urban areas.

3.1 Identification of Study Area

57. Page 3-1 Section 3.1. The ERA does not provide any explanation for (inappropriately) combining the Primary (>500 ppm Ni in soil) and Secondary (>200 ppm Ni in soil) Study Areas into a single study area for subsequent data analysis. Combining the data from the two study areas into a single study area, and treating the two separate data sets as one data set, confounds the ability to determine if receptors in the "Primary Area" are at greater risk than those in the "Secondary Area". In fact, the report provides several reasons why these areas should be kept separate (e.g., page 3-1: elevated concentrations of COCs in primary area "is assumed to represent an area where ecological receptors would have a higher potential risk" and page 3-2: primary study area focus of field investigations since area has "been identified as significant natural areas by the Regional Municipality of Niagara").

3.2 Assessment Methods for Site Characterization

58. Page 3-2. Several rare species and significant areas are identified here and a statement is made that field studies focused on natural habitats located in the Primary Study Area as they represent significant natural areas identified in the Regional Municipality of Niagara. The reader is referred to Section 3.4 for details but this Section deals with soil types; not significant areas. This discrepancy should be corrected.

59. Page 3-2. The winter surveys conducted between December 2001 and February 2002 provided an opportunity to document mammal tracks after snowfalls. We were unable to find any information in this report which summarizes the results of the winter surveys? Was this data collected?

60. Page 3-3. Four factors are provided for not including qualitative investigations into species richness of non-woody vascular plants in Study Area. It is very unfortunate that the opportunity was lost to investigate herbaceous species richness to determine if there was a change in species numbers, composition and absence/presence with increased distance from the refinery/COC levels in soil (e.g. species diversity could have been measured along several transect points). As no data is provided on the "inherent variability of plant species richness between sites", it is not possible to determine if this data would have been useful or not. Also, the argument of high variability in observations due to the presence of heavy clay soil, cattle grazing and micro-habitat conditions could also apply to the trees and shrubs which were surveyed (i.e. these factors would affect seedling establishment and growth). In fact, the study design could have been targeted to specifically address the importance of some of these potentially confounding factors. Finally, we note that some information is available in the Kitty 2002 report (Volume IV) on herbaceous species. This information should be evaluated and discussed in this RA.

61. Page 3-4. The authors state that most of the rare plants and animal species were recorded in the Wainfleet Bog wetlands, Mud Lake and The Clay Pits which are outside the Study Areas. Since these areas also have low concentrations of COCs, it is possible that rare plants and animals have not been recorded in similar habitats in the Study Area because of adverse effects resulting from the presence of elevated metal concentrations in the soil (or other factors may be involved). The ERA should address this issue. For example, is habitat present in the study area where these rare plants and animal species would be expected to occur? If so, what factors may be responsible for their absence?

3.4 Soil Types

62. Page 3-7. Five soil types are identified; heavy clay, shallow clay, clay loam, organic, and sandy. The organic soils (69-80% organic content) lay 40 to 160cm over silty to clayey mineral soil and have a soil pH 4.8 to 5.6. This soil is acidic compared to the clay soils, and is highly permeable with a high water holding capacity. Under these acidic conditions, it is possible that a relationship may exist between low pH in the organic soil and increased COC availability to plants and soil invertebrates. However, the elevated organic matter would act to reduce COC availability. The authors should discuss this relationship between soil pH, organic matter, and COC bioavailability in more detail in this report.

3.5 Known Significant Natural Features

63. Page 3-9. There are several significant natural areas located in the Primary and Secondary study area:

- 1) Nickel Beach Wetland –PSW (Primary Area)
- 2) Nickel Beach Woodlot – ESA (Primary Area)
- 3) Weaver Road Woodlot – ESA (Secondary Area)
- 4) Humberstone Swamp/Forest – PSW, ESA, ANSI (Secondary Area)

However, the ERA does not provide any meaningful discussion on how COC may impact rare species or these specific areas of significance. The presence or absence of potential impacts to these four significant areas should be discussed in the ERA.

64. In addition, based on the soil sample locations described in the Figure in Tab 9 Volume III, no soil samples were collected from the Nickel Beach Wetland or Woodlot West of Reuters Road. This is surprising given that these are significant natural features. It appears that only the Weaver Road Woodlot has been comprehensively sampled (soil, surface water, leaf litter, maple leaf, woodland insect, earthworm, tadpole and frog survey). Based on the information provided in Map 1 and Map 2, it appears that only 1 surface water sample was collected from the Nickel Beach Wetland and that 2 surface water samples were collected from the Nickel beach woodlot. One sample was also collected from the Nickel beach woodlot for maple leaf and woodland insect analysis. Samples from the Humberstone Swamp/Forest are limited to maple leaf, woodlot insects, and frog

survey and maybe one soil sample (see Tab 9 Volume III). Given that these are known significant areas and have elevated COC levels, the relevant chemical and biological data for all 4 of these significant natural areas should be discussed.

<u>3.7 Significant Vegetation Communities</u>

65. Page 3-12. The Nickel Beach Woodlot is an undisturbed Lake Erie shoreline dune complex supporting a number of rare Carolinian tree species. For this reason it is considered an environmentally sensitive area. In addition, the mature Red Maple swamp on the INCO site is part of a provincially significant area. Both features are located in the Study Area east of the refinery but potential impacts are not addressed in any detail in the ERA. Some discussion of potential impacts to these areas is warranted.

66. Page 3-13. How does the number of tree and shrub species identified in the primary study area compare to the numbers observed in the reference sites? These data indicate significant species richness for tree and shrub species but no data is provided to support the statements that over 90% of the tree species and 80% of the shrub species that should occur in the areas were recorded in the primary study area. In addition, please provide the data to evaluate the relationship between species richness and distance from the refinery within the primary study area to support the statement in the 3rd paragraph that “the vast majority of the tree and shrub species were found growing on the lands directly adjacent to the Inco refinery”. While COC levels are highest here, the type of organic soil is also likely to dramatically reduce the bioavailability of these COCs. Hence, the reason for this enhanced species richness may be due to the lack of disturbance associated with agricultural practices. Also, please provide the data on relative abundance of these species by habitat type (we assume this information is available given the statement that “Most of the species occur in general abundance where suitable habitat is present”).

67. Page 3-16. Several Carolinian zone tree and shrub species are present in the Study Area which lies at the extreme northern limit of the Carolinian vegetation zone. For this reason these species are provincially (and even nationally) rare. They are:

- Pignut Hickory – sand dune forest inland from Nickel Beach and dunes
- Pin Oak – wet forest around refinery
- Swamp White Oak – wet forest around refinery
- Hop tree – 5 individuals in SE corner of refinery site at sand dune forest interface.

There is no discussion to show whether any attempt was made to determine the status of populations of these rare trees/shrub species in the Study Area (e.g. tree health, recruitment measurements/seedling establishment). The ERA should provide some information concerning the status of these five species in the Study Area. Is any information available in the Kelly 2002 report?

3.8.2 Birds

68. Page 3-16 to 3-23. Information on breeding birds was collected over two breeding seasons, 2000 and 2001. These data indicate significant species richness in the Study Area; however, for clarity, the section should indicate where the raw survey data is located in the ERA (e.g. provide details/data in an appendix or supporting document).

3.8.3 Mammals

69. Page 3-24 A total of 20 mammal species were recorded in Study Area (Table 3-8). As with the bird data, this section should indicate where the raw survey data is located.

70. Page 3-25. 2nd paragraph and Table 3-9. Where is the data and appropriate comparisons to control/reference sites to support statements that small mammals were "very abundant" and "in good numbers" in woodlots and field edges? Where exactly were the traps set and which traps were successful? Table 3-9 provides trapping results data from 2001; please add the trapping data from 2000.

71. Page 3-25, last paragraph. Please provide data to support and put into context the statements of "particularly high density" for the Eastern Cottontail and Gray Squirrel and "high densities" for deer.

72. Page 3-28, 3rd paragraph. Add information on where in this report the tadpole and frog tissue analysis is provided. For a large report of this nature, clear internal "signposts" are required to allow the reader to find relevant information quickly and easily within the report.

3.8.4 Reptiles and Amphibians

73. Table 3-10 indicates that 9 species of amphibian and 5 species of reptile were recorded in the study area. The eastern milk snake is considered provincially rare. The eastern red-back salamander was found in leaf litter and under logs in woodlots near the refinery. In addition, the snapping turtle has recently been listed as a special concern species in Ontario and nationally. The ERA does not provide any discussion of any potential impacts of Ni and the other contaminants of concern to these significant species. Some discussion should be provided. As before, data needs to be provided/summarized to support statements in this section. For example, the text on page 3-27, 1st paragraph should include information on the actual density of calling frogs estimated during this survey and the expected density based on observations in other areas of Southern Ontario.

74. In the census, spring peepers and chorus frog densities of calling adults were lower than expected compared to other areas in southern Ontario. American toad and wood frog were widely distributed but numbers were low in the study area. A rationale should be provided addressing why these numbers are low for the above species; i.e. is it related to COC concentrations in sediments and water or could other factors be important? Also, tadpoles and frogs were collected for tissue analysis, and to note deformities and abnormalities. This section should indicate where this tissue information is summarized in detail.

3.8.4.1Fowler Toad

75. The report states that specific lakeshore surveys were carried out with a number of calling sites; one primary breeding pond with 50 males was located near Lorraine Road. In the May to July 2001 survey, an estimate of 2000 to 3000 tadpoles were observed with full metamorphosis to young adults and complete emigration from the pond was completed in July 17th. Were any observations made of the frequency of deformities and abnormalities in the young?

3.10 Summary

76. The authors did not measure plant diversity quantitatively in the Study Area (e.g. utilizing randomly located quadrants in woodlots and field locations). Therefore, for non-woody plant species, the statement that diversity appears typical of the region is not based on quantitative measurements or observations. This should be clarified in the ERA and the lack of a quantitative assessment discussed in the uncertainty section.

4.0 RECEPTOR CHARACTERIZATION

4.1 Criteria for VEC Selection

77. Detailed data collection of rare and significant species was not considered appropriate because of their low population density. On pg 4-4 the authors state that it is not known if the VECs selected for the Study are the “most sensitive”. This suggests that the proposed soil standards may not provide adequate protection to the species declared rare or significant for the Niagara region or other species that the VECs are surrogates for. The issue of providing (or not) providing protection to sensitive species should be addressed in the ERA. This can be done by providing toxicity information on the relative sensitivity of the VEC species to the COCs for this site. That way, the results obtained for these VEC species can be evaluated with respect to the larger groups the VEC species represent.

78. Page 4-4 1st paragraph. 1st sentence. The “basic trophic levels found in the … aquatic environment” are not well represented by the selected VECs. There is no

VEC species to represent phytoplankton, benthic invertebrates, aquatic plants, or fish.

79. Page 4-5, Table 4-2. Adult frogs would also be exposed to COCs from soil.

80. Page 4-6, last sentence is vague: “Some research has found measures of individual responses are not as sensitive as measures of population responses (CCME 1997)”. Please add details on what was measured and if it is relevant to the COCs and VEC species evaluated in this risk assessment.

81. Page 4-7. 1st paragraph. A sustainable level of ecosystem functioning implies that some adverse effects/changes to ecosystem structure is considered acceptable as long as ecosystem function is not adversely altered (e.g., unacceptable toxicity to a species population may occur without altering ecosystem function). This possibility should be clearly stated in the report.

82. Page 4-7. 2nd paragraph. In general, we have no concerns with using the 20% effects level as a toxicity threshold to evaluate potential adverse effects to most VEC species. However, as noted previously, this level should not be referred to as a NOEC. In general, the use of a 20% effect limit is preferred (except for rare or significant species) since a NOAEL and LOAEL are based on the results of a statistical analysis and are highly dependent on the study design, doses selected, etc., of each individual study.

83. Page 4-7, 3rd paragraph. Please add a citation to support that tadpole survival is a particular sensitive lifestage for amphibians.

<u>4.3 VEC Characteristics</u>

84. One of the objectives of this ERA is to determine ecological risk at the population level. However, the ERA fails to provide any estimates of mortality rates, or emigration and immigration dynamics for any of the VEC animal populations within or outside of the Study Area. The ERA should clearly state what population measurements were made.

5.0 DATA COLLECTION METHODS

85. Page 5-1, Table 5-1 indicates how many stations were sampled for each receptor; As noted previously, a Figure specific to each receptor is needed to show where these stations are located. Map 1 and 2 allows the reader to determine the overlap between the different receptors but is too confusing to be able to readily identify for each.

86. Page 5-2. It is troubling that “no rigorous selection criteria” was used to select sample sites. Overall, sampling needs to adequately characterize the spatial scale of the site and reflect potential confounding factors (clay vs. organic soil, woodlot

vs. open field, gradient of COCs based on distance to the refinery, etc.). It is not clear if these conditions were met.

5.2 Biological Field Data

87. Table 5-1 illustrates that at each station, a single composite sample was taken for tadpoles, arthropods, tent caterpillars, or wild grape; only two or three stations were sampled for tadpoles. Best practices usually dictate that one collects duplicate or triplicate samples from each given station to account for site/sample variability. A rationale should be provided for having only a single composite sample from each sampling site. The lack of an error estimate on these composite samples should also be discussed in the uncertainty section.

88. Table 5-1 Why are there limited number of stations for evaluating the meadow vole (n=1 to 3) and tent caterpillars (n=0 to 1)? This is inconsistent with the number of stations for frogs, earthworms, anthropods, maple leaves, and leaf litter where at least 5 stations were sampled from the reference, primary, and secondary areas. Why no bird survey from the reference areas?

89. Page 5-4. Please add a summary of the results of the Stantec oversight (e.g., data was collected as per protocols, duplicate samples collected by Stantec were typically within x%, etc). Since Jacques Whitford was purchased by Stantec, a footnote should be added here (or elsewhere) to indicate how the PLC consultant is not in a conflict of interest due to creation of WEG).

90. Table 5-5. It is our understanding that there is a lot of air monitoring data for this area. Why is air data limited to that collected between Aug and Sept (presumably in 2001)? How does this compare to the larger air dataset? Is it appropriate to use only this air data for this report?

91. Page 5-8. It is unclear why the composite samples for maple key soils, maple leaf soils, and vole soils are so small (n=1-2). Please provide supporting rationale.

92. Figure 5-1. Figure indicates that the analytical data was corrected for moisture content but is reported on a dry weight basis. Is this correct? Shouldn't the data be reported on a wet weight basis if corrected for moisture content? How was the data corrected for moisture content?

93. Page 5-10. Section 5.4.2. Add summary results of these SRM analysis (e.g., in general, SRM were within x% of nominal concentrations).

94. Page 5-11 Section 5.4.5. What type of plastic sample bottles was used (e.g., PE, PP, PET)? Where they cleaned and acid washed prior to water collection?

95. Page 5-12. Add a short summary of the results of the duplicate analysis.

6.0 EXPOSURE ASSESSMENT

96. Page 6-7, Section 6.3.1. Please add a brief summary of sources of contaminants. As currently written, the reader must consult other reports to find out even basic information on the source of COCs to the study area.

97. Page 6-7, Section 6.3.2. COCs from refinery emissions in receiving media should also include subsurface soils (via translocation from surface soils and new soil created after deposition occurred).

98. Page 6-7. Section 6.3.4. It may be appropriate to assume that exposure to COCs to a population of VEC species occurs through-out the entire Study Area for large home range species (e.g., deer). However, this assumption is not valid for small home range species or for ecosystem processes such as litter decomposition. For example, it is unreasonable to assume that the Meadow Vole (home range of between 300 and 900 m^2) is exposed to average conditions across the entire Study area. In addition, given the significant relationship between COC levels in soil and distance from the refinery, assuming exposure to average COCs levels (i.e., exposure from the entire study area) inappropriately reduces the exposure and potential risk for species living in close proximity to the refinery. Additional discussion is warranted on what constitutes a population in the report. For example, we do not have a population of Woodlots. For small home range species and terrestrial plant species living within a woodlot, the “population” or “subpopulation” may be limited to each woodlot (depending on species-specific opportunities for interaction between woodlots).

99. Page 6-8. end of 2nd paragraph. Exposure from soil and water can also be evaluated.

100. Page 6-8, end of 3rd paragraph. Should indicate in the uncertainty section that it is recognized that additional exposure can occur (but was not assessed quantitatively) and that should be considered when discussing predicted risk results.

101. Page 6-9, 3rd paragraph, last sentence. Even though meadow voles prefer field habitat, they should be considered a VEC species for woodlots. Otherwise, there is no assessment of small mammals in woodlots. The meadow vole could be used as a surrogate species for small mammals that would be expected to reside in the woodlot (e.g., mice).

<u>6.3.4 Whitetail deer</u>

102. Page 6-8. Exposure of deer to Ni, Cu, Co and As was assessed in both field and forest habitats for the Study Area in general. It has been reported in the literature that moose livers in various parts of northern Ontario have been shown to bio-

accumulate elevated levels of cadmium. Were livers in whitetail deer analyzed from the Study Area for Ni, Cu, Co, and As to assess whether or not these metals were accumulating in that organ?

6.3.5 Limitations of Predicted Exposure Routes

103. Page 6-9. Snakes were excluded from the Red-tail hawk diet. What percentage of their diet is made up of snakes? Overall, please provide details on what major components of the diet are missing and details on what food items were based on surrogate data.

104. Page 6-10. Red fox preys on rodents and birds. Bird COC tissue concentrations were not measured but were predicted using exposure and bioaccumulation factors from the literature. Without measured COC tissue values, the authors were unable to evaluate the accuracy of their predictions but expected that the actual COC concentrations in these birds would be lower than predicted using calculated exposure. No analytical evidence is provided to support this assumption. What if this is not the case? Some discussion should be provided on the uncertainty attached to this statement.

6.4 Assessment of Bioavailability

105. Page 6-10. Section 6.4.1 First paragraph. We agree that it is not necessary to provide illustrations of BAFs between different receptors for every location or study area. However, this information should be provided in a Table or in an Appendix. Specifically, information should be provided comparing BAF between primary, secondary, and control areas.

106. Page 6-10. Last paragraph. Information is presented to describe how the mean bioaccumulation factors (BAFs) were calculated as illustrated in Figure 6-6 and 6-7. No information is provided regarding the raw data used to calculate the mean concentration in surface water and sediments other that the sampling locations. This is insufficient, at a minimum; the relevant location in Volume V of the report should be identified so the actual data can be reviewed.

107. Page 6-16. Last paragraph. The fact that a BAF is low or not should not be used to conclude that “COCs are not accumulating to any appreciable degree in plant and animal tissues”. The important factor is what is the concentration in these tissues and if levels are significantly elevated over control tissue concentrations. As shown in the frog tissue example (and for other tissue data – see Figure 3 after comment 111), concentrations are elevated in tissue samples collected in the primary and secondary areas in relation to control areas. This information is important as it shows that COCs are bioavailable and elevated in tissues. The question of what is the significance of this exposure should be addressed in the risk characterization section. The BAFs values are useful for predicting tissue concentrations for those areas where only soil data is available. A spatial

assessment illustrating COC concentrations with distance to refinery is needed for all tissue samples (e.g., frogs, tadpoles, earthworms, voles, etc).

108. As currently presented, it is not clear how the BAF values were developed. For example, the text should indicate that the BAF is calculated from the weighted average concentration of COCs in whole frog tissue divided by the mean COC concentration in the sediment or the surface water. No information is provided to represent the uncertainty inherent in the BAF value. If we understand what was done correctly, the BAF was determined from collocated samples where data is available from the same sampling location for concentrations of COCs in the environmental media (i.e., water, soil, or sediment) and concentrations of COCs in the tissue levels in the selected VEC species. If that is the case, then BAF values can be determined for each collocated sample and the mean and standard deviation of BAF values can be provided (instead of just the mean). This information is important to evaluate the relative variability in the BAF values. We developed site-specific BAF values using all of the collocated sediment and frog tissue data to determine how variable the BAF values are using the raw data for sediment (Vol V, tab 27), and average frog total Ni concentration (Vol II, tab8) as an example (Table 1).

Table 1. Calculation of Area Specific Bioaccumulation Factors (BAFs)
(Sediment data from Vol V, tab 27; Frog Tissue data from Vol II, tab 8)

Area	[Ni] in Sediment (mean ± SD)	Total [Ni] in Frog Tissue (mean ± SD)	Mean BAF (mean ± SD)
Primary Area (from Fig 6-6 in report)	279 (n=4)[1]	4.56 (n=4)	0.02 (n=4)
Primary	432 ± 354 (n=5)	4.04 ± 2.97 (n=5)	0.015 ± 0.014 (n=5)
Secondary	76 ± 68 (n=5)	1.88 ± 1.43 (n=5)	0.035 ± 0.039 (n=5)
Control	27 ± 8 (n=5)	0.82 ± 0.53 (n=5)	0.029 ± 0.010 (n=5)

1. Note: it is not clear why data from site FH3 was not used in main report. Data for both provided here.

This analysis presented in Table 1 is quite informative. For example:

- A clear relationship is observed in mean Ni concentrations in sediment and frog tissue based on proximity to the refinery (primary, secondary, or control areas); Ni concentrations are higher in sediment and frog tissue indicating elevated exposure in these areas over control areas.
- BAF values are variable within each category (likely due to the large variation in the frog tissue data because it is confounded with body weight).
- BAF values are lower in areas of higher Ni concentration than in areas of lower Ni concentration. Hence, area-specific BAF values should be used in subsequent analysis.

109. The text indicates that the COC concentrations in tadpoles and frog tissue represent weighted averages calculated from component tissues that were analyzed. The reader is directed to Volume III, tab 3 for more information. However, Volume III, tab 3 only provides the statistical results from a series of generalized linear models (glm); not information on the measured tissue concentration in frogs and tadpoles. After some searching, the reviewer found the tissue data in Volume II, tab 8. We note that not all the data was used to calculate the BAF for frogs. For some reason, the data from site FH3 was not used. Also tissue data was collected from frogs that varied considerable with respect to total body weight (suggesting large variation in age of individual frogs). It does not appear that any attempt was made to evaluate the potential relationship between body weight and COC accumulation in various tissues of these frogs and if the varying age/sizes of frogs is a source of uncertainty in the subsequent analysis.

110. Page 6-13. 1st paragraph. Please provide details on the qualitative or quantitative analysis of the amount of material in the GI tract of these collected frogs and tadpoles.

111. Page 6-13. Text states that: Goldenrod contains 0.3% of Ni concentration found in soil. Ni concentrations in field vole tissue were found to be higher than in goldenrod which suggests a degree of bio-accumulation is occurring in the vole. It is possible that the voles are getting the Ni from soil/dust ingestion as well as from ingestion of food and grooming their fur? Also, this section should indicate where the Bioaccumulation factor (BAF) calculations are located in the ERA. The reviewer could not find this information.

112. Page 6-16 2nd paragraph. Please provide BAF values from the literature from other metal contaminated soil sites to put these values reported here into context.

6.4.2.1 Summary of Predictor Analysis

113. It is stated that soil type and habitat type are generally poor predictors. Did the authors look for correlations between soil pH to COC concentrations observed in biological receptors? Soil pH may be a significant predictor and should be considered in the statistical analysis.

114. Page 6-18, Section 6.4.2.1. Last sentence before Table. Volume III does not provide a discussion of the statistical analysis, just the output tables.

115. Page 6-18. Table 6-2. The fact that there are significant relationships between COCs in environmental media and biological tissue is very important since it demonstrates that COCs are bioavailable and exposure to VEC species is occurring in a dose-response fashion. In addition to soil type and habitat type, this analysis should also look at grouping the data by primary and secondary

study areas to determine if elevated COCs in biological tissues are related to distance from the refinery.

116. Page 6-19, 2nd paragraph. If soil type and habitat type are generally poor predictors, then that suggests that this data can be combined. Alternatively, these factors may be poor predictors because of high variability in the data because of merging the primary and secondary study areas. We don't agree that assessing bioavailability of COCs through a food chain is "well beyond the scope of this study".

117. Page 6-20. 1st paragraph. The high variability in the environment is also due to merging the data from the primary and secondary study areas and not controlling potential confounding factors (e.g., size/age of frogs).

6.4.3 Key Receptor Data Used in glms

118. Page 6-21. Amphibian COC tissue results are presented in Tables 6-3 and 6-4 with data for the primary and secondary study area combined. In general, Ni, Cu, and Co concentrations are higher in tadpole and frog tissue from the Study Area than from reference area. In most cases, the highest concentrations were observed in the GI tracts of both tadpoles and adult frogs compared to whole body tissue; however, Cu in the frog liver was higher than other tissue sampled. However, there is no discussion of the potential impacts of elevated Cu in the livers of frogs in the ERA. In addition, this trend may not be restricted to frogs only; Cu may be bio-accumulating in livers of birds and mammals in the Study Area as well. Sampling and analysis of Ni, Cu and Co in bird and mammal livers should also have been conducted to determine if the liver results were restricted to frogs only (e.g. whitetail deer, voles, woodcock, etc.).

119. Page 6-21. Table 6-3 and similar tables. Data should be presented for COC levels in tissue based on primary and secondary study area and not the entire study area. Often significant accumulation of COCs is measured in tissue when comparing the overall study area to the reference areas. The magnitude of this increase would be expected to be much higher in the primary study area than the secondary study area since that is the area of significantly elevated COCs. However, this information is not provided in this report. As an example, the following figure (Figure 3) shows total Ni, whole body Ni (minus GI tract and liver) and Ni in liver (data from Vol II, tab 8). There is a clear relationship between elevated Ni in tissue and proximity to the refinery with the highest levels observed in the primary study area. This figure also provides a measure of how variable this data is (potentially a result of the large range of age/sizes of frogs collected from the site). Interesting, elevated Ni levels in the frog liver from the primary area is not elevated with respect to the secondary area. However, a clear pattern of increased exposure with distance from the refinery is apparent when examining total Ni or body Ni.

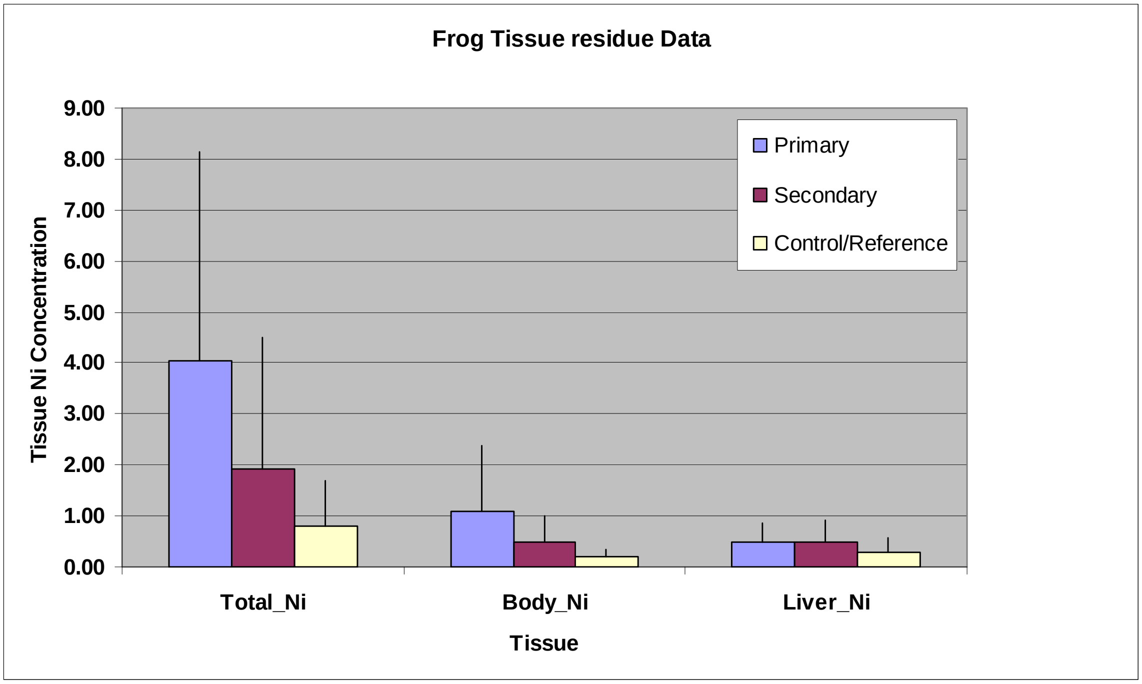

Figure 3

<u>6.4.3.2 Maple Tissue</u>

120. Table 6-5 shows that Ni and Cu concentrations were higher in leaves from the Study Area than the reference area although this was not the case for Co and As. Maple seeds were sampled from only 3 individual trees so the data set is very limited. Why was seed not collected and analyzed from as many woodlots as possible to build up a more robust data set. An opportunity was lost to determine possible trends in foliar concentration and distance for the refinery. How do these results compare to earlier MOE reports on Ni concentration in foliar tissue?

<u>6.4.3.4 Earthworm Tissue</u>

121. Page 6-27, Table 6-10 –The total COC concentrations of whole worm was considered bio-available to animals such as the robin. The authors state that this results in an over-estimation of the concentrations of COC actually available to the bird because the soil in the GI tract is expected to be less bioavailable than the tissue. A soil ingestion rate can be added to the exposure equation to account for the soil in the earthworm's GI tract.

122. Page 6-28, Table 6-10. Overall, these ratios have limited value given the low number of sample sites evaluated (between 1 to 4 depending on soil type), high variability in tissue concentrations for each COC for purged and non-purged earthworms, and the fact that the ratios reflect the overall study area and not the primary and secondary study areas separately. In addition, no information is provided on the total metal concentrations in the soils at these individual sites and

if there is a relationship between COC soil concentrations and the ratio observed at individual sites. This analysis should be provided as it is needed to support using this ratio for other earthworm data. Overall, there is considerable uncertainty in using these ratios as correction factors for estimating tissue concentration in earthworms (minus soil/metal in GI tract) that are consumed by VEC species. In addition, it is worth mentioning that the ratio observed from reference sites (about 1.0) is as expected since the soil is not contaminated and the vast majority of the COCs are incorporated in the tissues.

123. Page 6-28. Please provide the earthworm tissue data. We were unable to finds it in the material submitted for review. In addition, please clarify what information is presented for earthworms in Vol III, tab 1? The title does not provide enough information and there is no text describing this data (Note: this comment applies to several data tables provided in Vol III were data is provided with no or minimal context).

124. Page 6-29 last paragraph. Ni and Co did not "appear to be higher in anthropods", they were higher (by approximately 10-fold for Ni). The high variability may be due to inappropriately merging the data from the primary and the secondary study areas.

6.4.3.6 Meadow Vole Tissue

125. Both Ni and Cu concentrations are much higher in carcass of voles from the Study Area compared to carcasses from the Reference Area; i.e. 14.8 ug/g Ni and 1.5 ug/g Ni, respectively. The ERA should state that based on these data, predators of these voles will be exposed to 10x more Ni than they would be exposed to preying on voles from outside the Study Area.

6.4.4 Summary

126. One of the key findings in this ERA is that increases in soil and sediment values are reflected in the increases in tissue Ni concentrations in ecological receptors. The study results also show that Cu is also increasing in receptor tissue (e.g. frog livers). The accumulation of Cu in tissue should be included in the summary statement.

127. Page 6-32 1st bullet. What data/analysis is being used to support this statement that there is a soil-plant barrier that greatly reduces exposure to COCs? Is this the BAF data? If so, are the BAFs estimated for this site that much different than observed at other meal contaminated sites? Tissue data provided clearly show uptake is occurring as COC levels are elevated in plants and organisms from within the study area (hence COCs are bioavailable and exposure is occurring).

128. Page 6-32. 2nd bullet. The COCs at this site do not biomagnify. However, they do bioaccumulate.

129. Page 6-32. 5th bullet. The fact that soil type and habitat-type do not have a strong predictive relationship suggests they may not be important (and don't need to be treated as grouping variables in the statistical analysis). However, it also may be that the merging the data from the primary and secondary study sites is confounding these relationships. More robust statistical analysis is required to determine if these factors are important or not.

130. Page 6-33. 1st paragraph. We disagree that the magnitude of the difference (in tissue COC concentrations between the study area and the reference areas) are generally small. In addition, this summary should also identify that there are some limitations to the site-specific data collected for this site. For example, sample sizes are unequal between the primary and secondary study areas and are often low for specific receptors once separated out by soil type (clay/organic), habitat type (field/woodlot) and spatially (primary/secondary).

6.5 Exposure Magnitudes

131. Page 6-33. 2nd paragraph. The woodcock can also be exposed dermally via a "soil bath". This should be mentioned even thought it is not quantified in this RA.

132. Page 6-33. Last sentence. It is not usually done, but it is possible to assess potential risks associated with inhalation of COCs.

133. In Section 6.5.1, the authors indicate that air-to-flesh transfer factors were not available for inorganic chemicals. For that reason they used ingestion transfer factors as approximations (i.e. it is assumed that all COCs in air inhaled eventually enter the digestive tract and are absorbed as part of the whole body dose). Earlier in the report, it states that the inhalation pathway was not addressed in the ERA; hence the use of this factor in the hazard calculations is not clear and should be clarified.

134. Page 6-36. Please provide the basis for these uptake factors. Were the exposure parameters and the metal species tested from the Napier 1988 study appropriate for this site?

6.5.3 Employed COC Concs.

135. The report states that data from sample sites within the Study Area, as well as sites within 2km to the east of the Study Area, were used to calculate the UCLM for each data set. The report states that this was done to capture areas with elevated soil COC concentrations noted by JWEL but which were not captured by MOE (2000a,b). This section should also include an assessment on the effect of including this additional data on the UCLM; i.e. did the value of the UCLM change as a result of this additional data? Given the unequal sample design where more sites are located in the secondary study area than the primary study area, it

seems likely that the mean, and the UCLM, is biased low and are not representative of conditions or potential environmental risks found in the areas of significant COC contamination (e.g., the primary study area).

Bioavailability of Ni

136. Page 6-31, Table 6-17. Please add UCLM or max values from the reference areas. Estimated exposure from reference areas should be calculated for all VECs as a measure of background exposure. In addition, the accompanying text should provide a brief summary of the data collected as part of the Crops Study. It is insufficient to simple cite the report.

137. Page 6-42. Table 6-18. It is surprising that COC concentrations in earthworms and anthropods are not influenced by soil type or by the very high COC concentrations from sites near the refinery. Please provide the earthworm tissue data and the UCLM analysis so we can examine this relationship further.

138. Page 6-42. Table 6-19. Please provide the raw bioaccessibility data (not just the mean) for each soil type and the results for with and without glycine added. The Table should also include the results for the experiments conducted with Ni.

139. Page 6-43. Bioavailability of Cu, Co: The report notes that other studies indicate similar results for birds (e.g. mallards) but because of uncertainty, the % Bioavailability for mammals was doubled (2X) for application to birds. A rationale should be provided to explain why a 2X factor was considered sufficient rather than a larger uncertainty factor of 5 or 10 which is usually used in interspecies extrapolation. The rationale should include a discussion on the digestion process in birds and how it is different from the digestive process in mammals. In addition, please provide the data from the Levengood and Skowron 2001 study to allow for a comparison with the data in Table 6-19.

6.5.4 Calculated Receptor Exposure

140. A rationale is required to support the use of the UCLM based on data from all surface water samples taken within Study Area. The decision to combine all the surface water data from across the study area rather than assessing individual populations/water bodies within the Study Area is not appropriate since aquatic receptors are not exposed to the "average water quality" across the entire study area but the water quality at their particular location.

141. Page 6-44. Section 6.5.4.1. Please provide a rational supporting why the frog/tadpole was selected as the only aquatic VEC species given that the toxicity data in the literature is limited to surface water exposure only

142. Comment 114: Page 6-44, Table 6-20. Check units (should be mass per volume – ug/L or mg/L).

6.5.4.2-Fowlers Toad

143. Based on the information provided in the ERA, TRVs are only available for eggs/tadpoles in freshwater. Exposure calculations were based on exposure to COCs in breeding pond water (assuming 100% exposure). It is noted that Ni concentrations were highest in sediments and dune sand; however, these exposures were not assessed. In Section 8.3.1.1 the authors state that it is reasonable to conclude that the Ni concentrations in the sand do not pose significant risk to adult Fowler toads but there is no discussion of exposures to the juveniles. The ERA should examine whether or not Ni exposure of juvenile Fowler toads to the Ni in the sand could have a significant impact on their development and health (as they spend almost all time on the sand).

6.5.4.3 Earthworms

144. Exposure to earthworms is assumed to be through ingestion of surface soil (0-5cm) and it is also assumed that only soluble components are available for ingestion. There is no mention of the potential for Ni to be leached from soil particles by the strong acids in the digestive tract of the worm. For this reason, the acid ammonium oxalate extractions may likely a better representation of bioavailability than aqueous extractions (refer to table 6-23). This issue should be addressed in the ERA.

145. Table 6-22 (and similar Tables). Separate data for the primary and secondary study areas. Also, these tables should include data from the reference sites.

146. Page 6-49. Section 6.5.4.7. The Meadow Vole should be assessed for woodlots as well (see previous comment). This is similar to using the red-eyed verio to assess field habitat as was done in this report.

6.5.4.8 Raccoon

147. Exposure for the raccoon was based on a diet of wild grape, corn, oats, earthworms, arthropods, voles and frogs. Incidental ingestion of soil and water was not included in the exposure assessment. A rationale should be provided as to why ingestion of soil and water is not included in the exposure calculations.

6.5.4.9 (Red Fox) and 6.5.4.10 (Redtail hawk)

148. A rationale should be given as to why ingestion of soil and water is not included in the exposure assessments for red fox and red-tail hawk.

6.5.4.11 Whitetail deer

149. The exposure assessment is based on maple leaves, goldenrod, oat seeds and corn seed. Deer love tree fruits and seeds (maple keys, acorns, etc.). It would have been more appropriate to include maple keys in the diet for calculating potential exposure. Again, a rationale should be provided for not including ingestion of soil and water in the exposure assessment.

7.0 HAZARD ASSESSMENT

150. Page 7-1. Risk is always present at some level – "safe" is a relative word and can be easily misinterpreted or misunderstood. It would be preferable to refer to "acceptable" levels instead of safe levels. Also, please update the references for the primary sources and verify the TRVs have not changed. Presumably, these documents are final now. Some of these reports are quite old (e.g., Toxicity summary for Arsenic (1993), Copper (1992) and Nickel (1995)). An examination of more recent toxicological information may be required to ensure that these TRVs are up to date and represent the most appropriate values to use in this risk assessment.

7.1.1 Arsenic to 7.1.4 Nickel

151. The references for all reported NOAELs, LOAELs, LC50s, LD50s and body burdens need to be provided in this report (currently, no citation information is available). These references should be included in sections 7.1.1 to 7.1.4.

7.1.3 Copper

152. In the published literature, it is shown that both eastern white pine and red maple are sensitive to Cu (i.e. injury can be observed when leaves contain more than 10 to 12 mg Cu/kg and extractable Cu in soil is greater than 60 mg/kg soil). The authors should compare maple leaf Cu concentrations and soil available Cu concentrations measured in the Study Area to these adverse effects limits from the literature.

7.1.4 Nickel

153. In this section it is stated that it has been shown in the literature that nickel can interact with other metals resulting in additive effects. As Ni is present with Co, Cu, and As in the soils within the Study Area, some discussion of the potential for additive effects is warranted.

154. Page 7-8 3rd paragraph. Please compare the plant tissue data collected at this site to this 50 mg/kg Ni level as an indication of potential toxicity.

155. Page 7-10. Please add the pH range measured in soil from this study. Is it similar to that found by OMAFRA in 1989?

156. Page 7-10, Table 7-1. Please provide a figure with measured soil Ni concentrations and measured CEC data to show this relationship. A Table of means by generic category of Ni concentrations (Reference, Very High) is not helpful.

<u>7.2 Bioavailability of COCs</u>

<u>7.2.1 Arsenic</u>

157. The authors state that the conditions in the Pt. Colborne area favour the oxidized state of arsenic (As+5) which is less available to plants and animals and conclude that based on the collection of plants (maple leaves, grapes and goldenrods) it would appear that only a small portion of soil arsenic is being translocated to above-ground biomass. This statement pertaining to the oxidation state of As should be substantiated with a summary table of the tissue concentrations and/or a reference to where this information is presented. In addition, a figure should be provided showing As uptake into plant tissues grouped by primary, secondary, and reference areas to clearly illustrate this relationship.

<u>7.2.2 Cobalt</u>

158. It is stated that organic chelates of Co are known to be easily mobilized and translocated in soils making them readily available. Clay soils have been cited in many studies as exhibiting a great sorption capacity, but can also readily release Co just as easily. Soil pH is also an important factor in Co availability. The organic soils in the Study Area are acidic (pH as low as 4.8); therefore based on pH levels, Co should be readily available in the Study Area. As Co availability could impact plants and soil organisms, additional discussion should be provided on the relative availability of Co in the organic soils in the Study area.

<u>7.2.3 Copper</u>

159. It has been demonstrated in the scientific literature that fish are more susceptible to soluble Cu cations in water than humans (e.g., Cu injury to gills). For this reason, the MOE ecological component value for Cu in the Brownfield Regulation is lower than the Ontario Drinking Water Objective value. ODWO values are not appropriate values to use when assessing potential risk to aquatic receptors. Environmental standards and/or toxicity values specific for aquatic receptors should be used instead. Additional discussion of the sensitivity of fish and other aquatic receptors to Cu in this section is needed.

<u>7.2.4 Nickel</u>

160. The MOE report (McLaughlin and Bisessar, 1994) indicated that chlorosis (yellowing of leaves) was observed in leaves of mature silver maples growing in the vicinity of the Pt. Colborne refinery. Therefore, the assertion that maple trees are not being exposed to quantities of Ni sufficient to cause phytotoxicity is incorrect. Unless evidence is available to suggest that this adverse effect is no longer occurring, then it is more appropriate to assume that trees in close proximity to the refinery have chlorotic leaves based on previous studies.

7.3 Toxicity Reference Values (TRVs)

161. Additional rational is required to support the Ni TRV for earthworms (3000 ppm).
   a. More detailed information should be provided on the Nickel speciation soil study (e.g., what soil type was evaluated, how many samples, total Ni concentrations, etc.) and the actual report or Appendix cited.
   b. Since earthworms burrow within the soil profile and not just in the top 5 cm, information on Ni speciation at depth is also needed to support exposure to only Ni oxide.
   c. A discussion is required to reconcile the assumption of Ni oxide (and minimal Ni bioavailability) with measured Ni accumulation in earthworm tissues (indicating that Ni is in fact bioavailable) and toxicity tests that measured COC toxicity in organic soils and clay soils.
   d. Additional information is required to summarize the critical studies used to develop this TRV (e.g., the Hartenstein paper and the two Malecki papers). For example, why was 12,000 ppm chosen from the Hartenstein et al. paper when it appears effects were also observed at lower concentrations?

162. The mammalian TRV for Copper needs to consider the study by Jenkins and Hidiroglou (1989). They fed calves milk replacer containing 10, 50, 200, 500 or 1000 ppm Cu from 3 to 45 days. Adverse effects were observed at 200 and 500 ppm Cu (reduced weight gain). Only 4 of 7 calves survived the 1000 ppm exposure. This experiment should be considered to ensure the selected Cu TRV is protective for cattle and other ruminants (deer) in the study area. Cite: Jenkin K.J. and M. Hidiroglou. Journal of Dairy Science. Vol. 72 Issue 1 pp 150-156. Tolerance of the Calf for excess copper in milk replacer.

163. Page 7-14, last paragraph. The EPA citation is readily available, so why cite it as “as cited in Suter and Tsao 1996”? In addition, the references to Cameco Corp 1994 and SENES 2001 are not appropriate since they are industry/consultant reports and not readily available, peer-reviewed, nor published in the primary literature.

164. Page 7-15. It is unclear whether references that observed adverse effects in frogs and/or tadpoles at concentrations less than background surface water levels are provided in this report? Please clarify.

7.3.1 Additive and Less than Additive Effects

165. This section indicates that few investigations have identified any additive or greater than additive effects between the four COCs. It is unclear from this statement if there were many investigations in the literature in which additive effects have been shown not to occur or that studies have shown an additive effect do occur but there have only been a few of these studies conducted. The intent of the statement should be made clear and supporting documentation cited.

Table 7-2 TRVs and Test Endpoints

166. This section will need to be revised based on our comments provided on TRVS in VOLUME III: Supporting Data (TAB 4): Determination of Toxicity Reference Values (TRVs) for additional comments on TRVs.

167. Rationales for the selected TRVs are provided in Table 7-2; however, the TRV selection process was not transparent in all cases. The TRV selection process should be made clear to the reader..

8.0 RISK CHARACTERIZATION

8.2.3 Combined Effects of Chemical Mixtures

168. This section discusses the fact that for similar effects, the summation of doses is considered appropriate (U.S. EPA 2000). The authors identify that similar effects were observed for arsenic and cobalt. Therefore, there is some justification for a mixture risk assessment where HQs are added for the two COCs As and Co. This analysis should be done or a rationale provided stating why it was not.

8.2.4 Safe Levels

169. The calculations shown here are used for determining ‘safe levels’ for birds and mammals only, not soil organisms or vegetation. In addition, the statement that these calculations were used to estimate COC concentrations that provide ‘a general level of safety to the natural populations or community’ is unspecific as to the level of protection. The targeted level of protection and the VECs targeted for this protection should be clarified.

8.3 Risk Characterization for Receptors

8.3.1.1 Calculated Quotient for Tadpole/ 8.3.1.4 Summary of Effects of COCs on Frogs

170. The EC20 hazard quotient for Ni and Cu is 18 and 2, respectively. These ratios are significantly higher than 1, especially the ratio for Ni. Considering that the “safe” Ni level in surface water is 100 ug/L, these results suggest that 80% of the

ponds and ditches within the Study Area may put tadpoles at potential risk. The health of the local frog population was estimated by means of an adult frog breeding call survey. The data from the breeding call survey suggested that the distribution of calling males is not related to soil Ni concentrations and frog populations are typical of the region. What is unclear is how the survey results demonstrate that surface water Ni concentrations are not adversely impacting tadpole health and survival. Is it possible that Ni, as well as Cu concentrations in surface water and sediments in the Study Area are having a negative impact on frog survival at the tadpole stage of development? The ERA should clarify this issue.

171. Table 8-3. Please indicate the specific data that was used to determine the water exposure concentrations.

8.3.2 Maples

8.3.2.1 Dose-Response Experiments with Maples

172. Table 8-4 shows that germination success, seedling height, and number of unhealthy leaves is significantly co-related with seed origin, soil Ni concentration and soil type (i.e. germination success of seeds from the reference area decreased with increased soil Ni concentration). These data also suggest that Maple seedlings, from seeds collected in the Study Area, may be more Ni tolerant than Maple seedlings from seeds collected in the reference area (since they grew better at higher Ni concentrations). These findings do not support the final statement (pg.8-12) "the Greenhouse study indicates that increased COC concentrations up to 3000 mg/kg Ni, do not negatively affect maple germination or growth". The growth of seedlings from the reference area was shown to be inhibited compared to growth of seedlings from the Study Area; therefore, the statement should be revised to more accurately reflect the results observed from these studies.

8.3.2.2 Maples in the Natural Environment / 8.3.2.3 Woodlot Health Assessment

173. This section indicates that only 12 individual leaves were sampled and evaluated from various trees. There is no indication where the leaves were sampled from (i.e. new growth or old growth). Stand structure, basal area, etc. was investigated but condition of the leaf canopy was not assessed. The condition of leaves in the canopies would have also been a good screening approach of overall tree health prior to investigating individual leaves. It is unclear if overall canopy health (e.g. % of green vs. chlorotic leaves) was assessed. This is a significant uncertainty in the assessment of the health status of these trees.

174. Page 8-16, 2nd paragraph. Based on the results presented in this paragraph, only about 10% of the leaves were considered healthy (category #1); all others had some injury (category 2, 3, or 4).

175. Page 8-19. 2nd paragraph. Some woodlots in the study area had only 3 species of trees. This seems low. Which woodlots had this low species richness? What would the expected number of tree species be (i.e., how many are observed in the reference woodlots)?

8.3.3 Decomposers

8.3.3.1 Earthworm Quotient Calculations

176. In Table 8-7 (exposure estimated using acid ammonium oxalate extraction), the hazard quotients for Cu and As were 30 and 4, respectively, in organic woodlot soil which contained 1,621ppm Cu and 83ppm As. The proposed 'safe levels' of 50 mg Cu/kg soil and 21 mg As/kg soil seem reasonable based on the observed results. However, a soil Ni concentration of 5,960 ppm in organic soil also produced a HQ of 2 in organic woodland soil yet the proposed 'safe level' (soil Ni value of 7,600 mg Ni/kg soil) is higher than the soil Ni concentration in the organic soil. There is no rationale provided for setting a 'safe level' for soil Ni that is higher than observed soil concentrations which gave a HQ >1. In contrast, the Cu and As 'safe levels' were set at much lower values relative to the corresponding woodlot organic soil Cu and As concentrations which gave a HQ>1.

8.3.3.2 Earthworm Dose-Response Experiment

177. The authors state that it is difficult to believe that COCs would be so much more bio-available in clay soils compared to organic soils considering the results of the chemical extractions (Section 6.5) and assessments of bioavailability (Section 6.4). There is no discussion provided to explain this phenomenon. It is possible that the digestive fluids of the worms are very efficient in removing metal cations from the clay particulates or that estimates of bioavailability are in error. Additional discussion of this issue is warranted including biogeochemical processes that may be influencing metal bioavailability in organic and clay soils (e.g., soil pH, metal binding to organic matter, cation exchange capacity, etc.) and/or a discussion of potential bias/confounding factors that may have occurred. Alternatively, this represents a data gap that needs to be addressed to resolve this apparent contradiction.

178. Table 8-8. It is unfortunate that the COC concentrations in the diluted test soils were not measured. Depending on the quality of the soil mixing, the actual COC concentrations may be different from the nominal values reported in this Table.

179. Page 8.26, Table 8-9. Please add statistics (e.g., from Dunnett's test) in order to determine which exposures were statistically significant different from controls.

8.3.3.3 Leaf Litter in the Natural Environment

180. This section will need to be revised based on our comments provided on the Leaf Litter Study in Vol. 4 Consultant Reports.

181. Page 8-33, 2nd paragraph. Why was the higher soil COC concentration considered an outlier and excluded from the statistical analysis?

182. Page 8-44. Table 8-19. Why no data from reference soils or soils from Secondary Study area? Biomass from Reuter Road woodlot appears to be quite low.

8.3.4 Birds

183. This section will need to be revised based on our comments provided on TRVS in Volume III: Supporting Data: TAB 4: Determination of Toxicity Reference Values (TRVs).

8.3.5 Mammals

184. This section will need to be revised based on our comments provided on TRVS in Volume III: Supporting Data: TAB 4: Determination of Toxicity Reference Values (TRVs).

9.0 INTEGRATION

9.1 Approach

185. Three general lines of evidence were developed that were used for the interpretation of potential risk to the natural environment. It appears that the authors have put more emphasis on field observations over the results of controlled laboratory experiments and the Quotient Method in determining the ecological risk to VECs such as the earthworm. This approach is acceptable as long as sufficient field data has been collected from properly conducted field studies. However, the results from laboratory experiments should still be considered in the weight of evidence approach. This should be addressed in the report identifying the strengths and limitations of the laboratory data and the field data.

9.2 Summary Discussion of Risk

Woodlots

186. It is stated in the report that the results of the greenhouse trials, which included seed germination success, sapling growth and assessment of leaf health, suggested that maple keys from the Study Area responded differently than maple keys taken from the Reference Area with the Study Area plants growing better in the more contaminated soil. The significance of this apparent metal tolerance could not be determined because of the extremely small size of the source population (i.e. seed

were collected from one reference tree and two adjacent trees in the study area). As the ability of plants to tolerate or adapt to high metal concentrations in the soil is important in ensuring long-term viability in the plant communities it is unclear why additional follow-up studies were not carried out to determine if there are significant differences in metal tolerance in the maple populations in the Pt Colborne area.

Inland Aquatic Environment

187. A number of concluding statements are made in the report indicating no adverse effect to aquatic receptors due to COC exposure. For example:

- 'the potential risk (HQ) to tadpoles as a result of Ni and Cu concentrations in pond water does not appear to be supported by general field observations or analysis of field data'
- 'may be adversely affecting local frog populations through small reduction in numbers of tadpoles surviving to adult stage'
- 'field data identifying that long term (50+ yrs) exposure to Ni concentrations in surface water in ponds and swamps has not reduced the Study Areas high level of species diversity.

The wording of the above statements is not consistent with the study results; analyses of the COC concentration in sediment, water, and tissue, and exposure to Ni and Cu appears to present potential risk to frogs and tadpoles. Using available TRVs resulted in a hazard quotient of 18 and 2 for nickel and copper, respectively, indicating a potential risk to tadpoles. In fact, it was determined that Ni concentrations in surface water values for 80% of the ponds in the Study Area may pose a risk to tadpoles.

It is also stated in the report that based on the experience of the field biologist who conducted the frog calling survey, it was noted that although species were well represented throughout the Study Area, densities of calling adult frogs at quality breeding sites nearest the refinery were not as high as expected which suggests that there may be some suppression in population numbers due to reduced recruitment of tadpoles to adults in areas with very high soil Ni concentrations (>10,000 mg/g). The data suggests that within the Study Area there is a gradient of Ni/Cu impact to tadpoles/frogs vs. distance from the refinery but the authors have not emphasized this trend in their discussion. This analysis needs to be done.

10.0 UNCERTAINTY ANALYSIS

10.1 Uncertainties in the Problem Formulation

188. Table 10-1 indicates that there is no likely change to the risk conclusions by selecting a Primary Study Area (>500 mg/kg soil Ni) and a Secondary Study Area

(200 to 500 mg/kg soil Ni). This analysis needs to be conducted to demonstrate this fact. When warranted for large home range species, the primary and secondary study areas can be merged.

10.4 Uncertainties in Data Collection Methods

189. Table 10-4 indicates the author's belief that the constraint on sampling time likely did not cause any overestimation/underestimation of risk. However, the justification provided in the table suggests that data sampling was compromised (e.g. arthropods, earthworms, seasonal limitations affected the number of sampling sites for several VECs). In addition, no quantitative analysis of the vegetation community was conducted and the decomposition studies were modified as a result of time constraints. Additional rationale is required to justify that uncertainty due to the sampling constraints had no impact on the risk conclusions.

11.0 SUMMARY AND RECOMMENDATION

11.1 Summary

190. The Chapter will need to be revised to address the previous comments and more accurately reflect potential ecological risk to aquatic and terrestrial biota in the Primary and Secondary study area. For example, additional discussion is needed to support the statement that field surveys found that the Study Area supported high diversity and typical abundance of adult frogs for the species present. The HQ suggested impacts to the tadpole stage, the American Toad was found at all sites except two within the primary study area, and the breeding call count concluded that call frequency was rather lower than would be expected. The authors state that soil COC concentrations decrease with distance from the source in a north-easterly direction but fail to discuss what appears to be a relationship between likelihood of adverse effects vs. distance from the refinery (e.g. impacts were observed in maple foliage, earthworms and micro-organisms in woodlots that were closer to the refinery).

11.2 Recommendations

191. A total of four rationales are provided for recommending that the safe soil COC values be based on the 'earthworm' for the purpose of assessing future management options. Some of the toxicity data and field data for other VECs (e.g. woodcock, tadpoles, decomposer) suggest that the fourth bullet may not apply in all parts of the Study Area; i.e. "a safe soil COC concentration for earthworms would be protective for other flora and fauna that inhabit these areas of high soil COCs". The authors should revise these recommendations to reflect this.

11.4 Conclusions

192. Table 11-5 lists the final ‘safe’ soil COC concentrations for earthworms. Rationales are given for the ‘safe values’ chosen for Ni, Co and As but no rationale is given for the Cu ‘safe’ value. This may be a simple error of omission which should be rectified.

12.0 CITED REFERENCES

193. The reference list appears to be comprehensive but needs to be updated. Several JW references refer to draft reports that have been finalized and have a new date (e.g., COC selection reports).

VOLUME II: FIELD DATA COLLECTION and ANALYSIS PROTOCOLS

9.0 Maple Seed Greenhouse Trials Protocols

194. Maple keys were collected from a single tree from one woodlot near the refinery and one residential tree in Welland (control). All greenhouse studies and analyses were carried out on seeds from only two trees. The study results suggest that these trees differ significantly in soil Ni tolerance. The objective of the ERA was to look at population effects; therefore, seeds should have been collected from several trees established in a number of woodlots across the Study Area. In this way the greenhouse trials may have been useful to demonstrate any given range of Ni tolerance in the tree populations across the Study area. An opportunity was lost here. A rationale should be provided to justify the seed collection procedure used.

9.0 Earthworm Toxicity Tests and Field Sampling Protocol

195. In Table 1 (pg.4), the highest soil Ni concentration in organic soil is shown as 1490 ug/g. This value is likely in error as much higher Ni concentrations were measured in organic soils from this site.

VOLUME III: SUPPORTING DATA

TAB 4: DETERMINATION OF TOXICITY REFERENCE VALUES (TRVS)

Allometric Dose Scaling

196. MOE no longer accepts the application of allometric scaling for estimating chronic effects data and recommends direct extrapolation of chronic TRVs from lab studies to wildlife species. All chronic exposure calculations should be re-calculated without applying allometric dose scaling. Please refer to the 2009 MOE Technical Memo to QPRAs concerning the use of Allometric Dose Scaling.

Ni TRVs

197. The TRV tables mix diet concentrations (mg/kg) and dose concentrations (mg/kg body wt/d). This is confusing to the reader and in many cases it is not possible to compare studies because of these inconsistencies. The TRV tables should be revised to provide both diet concentrations and dose concentrations for each contaminant of concern.

198. For the Fowler toad the selected TRV was based on LC10=0.4 mg/L from Birge et.al. 2000 which does not specify the chemical form of Ni, the stage of development of the toad, or the study duration (table 2). This information should be provided. The authors should also provide a rationale for not including other TRVs from other studies.

199. For frogs, the selected TRV is based on an embryo study of eastern narrow mouthed Toad even though a TRV (Birge et.al. 2000) was available for the leopard frog which resides in the Study Area. The authors should explain why preference was given to a TRV for a toad, rather than a TRV based on studies using leopard frogs.

200. Birds – Table 4 and the paragraph below the table are confusing. The table should indicate that the mallard study by Cain and Pafford 1981 is the same study used in Sample 1996. Also, the TRV selection process should be more clearly presented as the same TRV is used for all of the avian receptors. Also, Table 4 should provide corresponding LOEL and NOEL values (mg/kg/d) from each study along with the LOECs and NOECs. For example, as it is presented, it is not possible to determine why the other listed mallard study (12.5 mg/kg Ni in diet) or the Plymouth Rock Chicken study (300 mg/kg Ni in the diet) were rejected. A lower avian TRV may have been derived using the results from one of these other two studies (i.e. toxicity causing reduced growth and elevated kidney levels of Ni). This should be addressed.

201. Mammals – As in previous tables, Table 6 contains a mixture of LOECs (mg/kg in diet) and LOELs (mg/kg body wt/d) which is confusing to the reader. This should be rectified. The 30mg/kg/d LOEL for rat reproduction effects (Springborn 2000a) was selected as the TRV for all mammalian receptors but there is no rationale provided to support why this study was selected over the other studies. Also, why not use the LOEL for the 2 yr beagle study for red fox? The TRV selection process should be presented more clearly.

Cu TRVs

202. Earthworms – the benchmark used for TRV appears valid but there are several other studies shown in Table 7 which are not discussed. The TRV selection process should be presented more clearly.

203. Fowler Toad – determination of the TRV is based on a LC50 of 2.69 mg/L from Birge and Black 1979 (as shown in Table 8) but in the calculation of the EC20 of 5mg/L, the authors have used a value of 26.96 mg/L. Use of the reported LC50 value would result in EC20 of 0.5mg/L. This discrepancy should be clarified. Please check the units from this primary study carefully as these Cu concentrations are quite high and would be acutely lethal to most aquatic life.

204. Birds – One TRV is used for all the avian VECs. It should be noted that studies with copper oxide or copper metal may represent the Pt. Colborne situation better than studies using either Cu chloride or Cu sulphate. There are several studies listed in Table 10, for which the chemical form of Cu is unspecified but which resulted in reduced growth in chickens and turkeys at lower concentrations than the study used to calculate a Cu NOEL of 47 mg/kg/d. The authors should provide arguments as to why these studies were not considered for this risk assessment. Also, NOAELs and LOAELs (mg/kg/d) have not been presented (or calculated) for several other studies listed in Table 10. Thus, one cannot compare potential TRVs resulting from these studies to the TRV which was selected. The authors should provide a rationale as to why these other toxicity data were not considered.

205. Mammals – In Table 11, the TRV of 10 mg/kg/d, calculated from survival of mink kits (Aulerich et.al. 1982), appears to be an appropriately conservative value but may not be protective of sheep. In the literature it has been shown that sheep are very sensitive to Cu in diet (Adamson et al. 1969). Haemolytic crisis and jaundice was observed in lambs at a Cu dose of only 0.885 mg/kg/d Cu. Gopinath and Howell in Eisler 1998a demonstrated severe morphological changes at 7.5 mg/kg/d Cu sulphate in an 83 day study. The TRV selected for Cu (10 mg/kg/d) may not protect domestic sheep that graze in contaminated fields in the Study Area.

206. Lab rats and mice are more closely related to field voles and shrews than mink. The authors do not explain why the data from rat and mouse studies were not considered; no basis is provided for rejecting these studies. It is also unclear why a number of studies are included in Table 11 yet the results are not discussed or compared in any way to the chosen TRV. Justification for choosing the selected TRV should be provided.

<u>Cobalt TRVs</u>

207. Fowler toad – It is unclear why the LC10 of 0.2 mg/L (from Birge et.al. 2000) was selected as the TRV for the Fowler toad when the chemical form of Co and the duration of the test were not specified. Also, why was the EC20 not calculated as was done in the case of frog receptors? This should be discussed in the ERA.

208. Frogs - Table 13 – the selected TRV was based on a study for eastern narrow mouthed toad embryos (Birge et al. 1979) despite there being similar toxicity data available for the leopard frog (Birge et.al. 2000). The authors should provide a rationale for this decision.

209. Birds – a conservative TRV has been used, based on a sub-chronic effects level (mortality to broiler chicks), as well as an uncertainty factor of 10 and 2 (because Co is in the form of a soluble chloride). Other chronic studies are listed which produced much higher TRVs (e.g. 7.8 to 17 mg/kg/d) apparently without applying an uncertainty factor. There should be some discussion as to why these chronic effects studies were rejected.

210. Mammals – In Table 15, there are several other studies of similar duration as the study conducted with Norwegian rats (Mollenhauer et.al. 1985) which was selected for the TRV. Several other chronic effects studies, with lower LOAELs (4.2-5.7 mg/kg/d), are listed but have not been discussed. A rationale should be provided to justify the selected TRV (e.g. did the other studies utilize more soluble forms of cobalt which may not represent Co availability in Pt. Colborne soils?)

<u>Arsenic TRVs</u>

211. Frogs – Table 17 – “pickerel frog” (R. palustris) is misnamed “leopard frog” (R. pipiens) in the Table.

212. Why was the Leopard frog LC10 of 0.01 mg/L (Birge et.al. 2000) not cited as the basis for the frog TRV instead of the narrow mouthed toad? Although it results in a similar value for calculating the EC20, the TRV would be based on data derived for the leopard frog.

213. Birds – The selected TRV (5.14 mg/kg/d) was based on a NOEL value (100 mg/kg) for mallard duck (USWS 1964). A rationale should be provided to explain why the LOEL (7.38 mg/kg/d) from the copper acetoarsenate – catbird study (Sample et al. 1996) was not suitable to be the basis for the selected TRV.

TAB 5: EXPOSURE PARAMETERS for RISK CALCULATIONS:

<u>Meadow Vole (Table pg. 2 of Section)</u>

214. Soil – IR** (food ingestion rate on dry wt. basis calculated to be 8.876 kg/day) – this value seems very large for this small VEC. It should be revisited and corrected if necessary.

<u>Red-tail Hawk (Table pg.16 of Section)</u>

215. Diet – DFk is defined as 74% vole, 26% birds. It should be noted that 6 to 13% of the diet for red-tail hawks can be snakes which is not accounted for here. Also, the authors use the average COC concentration of the robin, vireo and woodcock in the calculations for red-tail hawk. A more conservative approach, would be to use the highest concentration of the three prey species rather than an average. This would have provided the maximum exposure risk to the red-tail hawk. The authors may wish to calculate both an average and a maximum exposure risk.

TAB 6 EXAMPLE CALCULATIONS

216. The reviewer reviewed the American Robin example (woodlot – organic soil). For ADD soil *, it is unclear how the bioavailability factor of 6.4% was determined. This factor has significant effect on the ADD total (it brings the total dose of 44.08 mg/kg/d down to 6.04 mg/kg/d. The reviewer was unable to find the calculations for this "bioavailability factor/bioaccessibility factor". As factor was applied in determining the exposure estimates for several of the VECs, how this factor was determined should be provided.

TAB 8 CALCULATIONS of COC CONCENTRATIONS for COMPOSITE TISSUE SAMPLES

217. It is difficult to follow the COC concentration equations as they are currently presented. It would be easier to interpret if the equations were provided with symbols representing the variables (a legend could be added to explain the symbols).

TAB 10 PREDICTORS FOR TISSUE COCS

<u>1.1 Amphibian tissue</u>

218. The concentration of Ni in sediment is shown to be a significant predictor of tadpole GI tract Ni concentration but the authors state that sparseness of data and high variability restricted their ability to draw a conclusion. This should have been flagged as a deficiency in the ERA and attempts should have been made to collect enough samples to determine if the relationship is a strong one or not. Also, the sediment Ni concentration is a strong predictor of Ni concentrations in adult frogs. It is unclear if this relationship is reflected in the discussions and conclusions provided in the main ERA report.

<u>1.2 Maple Tissue</u>

219. The authors state that more sampling may be needed to clarify whether or not there is a significant relationship between soil Ni, Cu, Co, and As concentrations and metal concentrations in leaves. Does the main ERA report provides any additional information from the literature or additional sampling to determine if the soil metal levels are predictors of foliar metal concentrations?

1.3 Earthworm Tissue

220. Although the sample size was small, the analytical data indicates that worms in woodlots (organic soil) may have higher As concentrations than worms from clay soils in the Study Area. Does the ERA indicate whether feeding on worms from organic soil result in an adverse As effect on woodcock in the Study Area? Soil concentrations for all of the COCs were significant predictors of metals in earthworms ($p<0.01$) for both clay and organic soils. Why were only field habitats sampled for worms in 2002 and not woodlot soils as well? This was a missed opportunity to see if trends observed in organic vs. clay soils in fields also existed in the woodlots as well.

1.4 Arthropod Tissue

221. In Table 8m, soil Ni, Cu, and Co concentrations were all significant predictors of levels in arthropod tissue but not As. The authors do not explain the reason why As is acting differently from the other COCs. Some discussion should be provided in the ERA.

1.5 Meadow Vole Tissue

222. Only one vole specimen was caught in the secondary area of the Study Area. There is no explanation provide as to why As accumulation in vole tissue is acting differently from that of the other three COCs. Also, it is difficult to determine if this vole is representative of the meadow vole population without replicate samples. Voles are quite common in grassy fields across southern Ontario and it is unclear why more specimens were not obtained for analysis. Why was more effort not put into obtaining additional voles for analysis?

VOLUME IV: CONSULTANTS REPORT

1. LEAF LITTER STUDY

223. The authors assume that the total amount of decomposition that occurs in any single year at any one woodlot equals the amount of litter entering the system at that site. This leads to the conclusion (based on general observations) that no unusual litter accumulation was occurring; net decomposition is constant and there is no net litter accumulation occurring on the ground. However, contrary to this, the section also concludes that the decomposition process might be slowed in woodlots within the highest soil Ni and Cu concentrations because the amount of litter was much higher in high soil Ni woodlots. This discrepancy should be addressed in the main ERA report.

224. The proxy method used to measure decomposition rates is not a quantitative measure of rate of decomposition. There is no way to determine if a comparable

amount of litter has fallen in each of the selected woodlots. The author of this report states that he needed two years to do a litter bag study but was unable to do so because of time constraints. However, the ERA was not completed until 2004 (more than three years later). A proper leaf litter bag study could have been conducted. Therefore an opportunity was lost to provide quantitative, conclusive data to support the conclusions of the ERA. This limitation should be noted in the main ERA report.

225. For a current year litter study, one would normally choose to use standard litter traps and measure all the bits of litter caught over that given year. In this study, the authors collected leaves off the ground after the autumn leaf drop (on Nov. 2, 2001). This is a rather imprecise measure compared to the litter trap method. Also, only one sample site (consisting of five 1-m^2 sample grids) was established for each soil type and COC zone. A rationale should be provided for not establishing leaf litter sampling sites in more of the 21 selected woodlot sites with different soil types and soil metal concentrations.

226. Litter buildup can result in reduced nutrient availability to forest trees and shrubs. Did the author compare the health (e.g. vigor and size) of various trees at the litter study sites in the woodlots? Also, factors such as temperature, moisture, soil pH, soil structure, shade, etc. all influence litter decomposition. Were these factors measured at the various sample sites?

227. Figure 15 shows the number and composition of wood stems within the study plots is quite variable from site to site (e.g. Site #2 consisted of 5 trees, 55 shrubs whereas Site #3 consisted of 30 trees, 6 shrubs). The objective of the study was to select sites which were as similar as possible. This high plot-to-plot variability between trees and shrubs should be addressed in the report.

228. A very detailed discussion is provided on the composition of litter and of plant species, as well as bird species observed in woodlot sites; however, none of this discussion addresses the question of soil metal impacts on the 'rate' of decomposition.

229. It is stated that the results demonstrate that significantly higher amounts of standing litter were present in woodlots on organic soil with high metal concentrations (386 g/m^2) compared to controls (138 g/m^2). After reading the previous statement, the following statements appear to be contradictory - "Even though this decomposition pattern relationship with soil metals can be demonstrated, the total amount of decomposition that occurs in any single year at any one woodlot equals the amount of litter entering the system at that site. This conclusion is based on general observations that suggest no unusual accumulations of litter on the ground. The rate of average annual fresh litter input is essentially at equilibrium with amount decomposing each year". This discrepancy should be addressed in the report. Also, these conclusions are based

on very limited data (only five individual plots, one per zone). Statistically, the plots may not be representative of the entire Study Area.

230. The concept of Figures 21 and 22 (conceptual litter decomposition processes under two level of soil metal loading) is not clear nor is the process used to create them. This should be clarified.

231. The reviewer was unable to locate the calculations for expected decomposition rates using lignin content in foliage (Meetemeyer, - ref 132) and potential evaporation using Thornthwaits [171]. This information should be provided with the report.

232. With the exception of the Reuter Rd. site, the average leaf weight loss was 43.3%, assuming weight of leaves in 2000 was the same as 2001, and no litter was older than one year. However, leaf litter weight losses vary considerably from site to site (3.2% to 81.5%) . This should be discussed and a rationale provided to explain the large site to site variability.

233. It is stated in the report that slower decomposition rates were observed at the Reuter Rd woodlot but these slower rates were not due to metal concentrations in the fresh foliage; it was some other agent. No discussion is provided to address what that agent might be or the agent's relationship to high metal concentrations in litter or soil, or both. It is possible that soil metal concentrations have reduced soil invertebrates, nematodes and fungi numbers which could result in slower decomposition rates. Additional rational is required to explain possible reasons for the observed slower decomposition rates.

234. The author of this consultants report states that the study is not 'best science' and that the study should have included the following:

- collection of fresh litter fall over at least one full year using formal litter collection devices
- exposure of leaf litter in mesh bags at selected study sites over a 2 yr+ period
- exposure of leaf litter to known metal concentrations under controlled but realistic conditions
- conducting bioassays (e.g. removal of large soil cores from different woodlot locations and relocating them together in other woodlots topped with fresh litter).

The reviewer concurs that the above mentioned procedures would have taken two to three years to complete but it would have likely provided a more complete picture of the impacts of historical emissions. It is unfortunate that this work was not carried out because of perceived time constraints. These limitations should be included in the main ERA report.

2. EARTHWORM TOXICITY STUDY (E. Andrei)

235. Phase 1 consisted of four undiluted site soils and a control. Tables are provided in the Appendices which show physiochemical data on the four soils; however, COC concentrations (Ni, Cu, Co, and As) are not shown. The COC concentrations should be provided in these tables for comparative purposes. Phase 2 involved dilution tests to derive effects concentrations. Again COC concentrations of the eight soil treatments (0-100% mixtures) are not provided. This information should be provided. Data for Phase 2 results (% soil mixtures) are shown but no discussion of results or statistics is provided.

3. WOODLOT HEALTH ASSESSMENT STUDY

SITE PRODUCTIVITY

236. There were no significant differences between mean maximum height for the PSAC and CTLC but on average the PSAC was 16 yrs younger than CTLC. The authors claim this is a reflection of the site selection process rather than a growth or age inhibitor. This is a limitation of this study. Why did the authors not attempt to select sites of similar age?

WILDLIFE HABITAT

237. The author's state that the COCs may have a role in the increased amount of wildlife habitat trees in SWD3-4 sites especially Ni, which has greater effect on sites with lower soil pH. More discussion should be provided here concerning changes to the forest as a result of the soil COCs, especially in acidic soils.

III. MOE Comments of Vale CBRA HHRA

The following comments pertain to the December 2007 Port Colborne Community Based Risk Assessment (Volumes *I* to *VI*). The review focussed on identifying if the risk for potential adverse effect to human health has been characterized appropriately in a scientific and defensible manner and that the conclusions of the human health risk assessment (HHRA) are supported by the data, information and interpretations included in the HHRA.

It was stated in the HHRA that the primary objective was to determine whether the soil concentrations of Chemicals of Concern (CoCs) in the Port Colborne area present an unacceptable risk to human health in the Port Colborne community. In addition to this, the HHRA has the second objective of estimating the environmental concentrations of CoCs in soil at which no adverse effects on human health are expected to occur. According to the HHRA these have been termed Risk Based Soil Concentrations (RBSCs) and are defined as "*an estimate of the concentration of that CoC in soil that is expected to be protective of human health for a worst case exposure of sensitive receptors*". The calculations of the RBSCs are dependant on the assumptions of the HHRA.

The proponent concluded in the report that "*The results of the assessment of conservative exposure scenarios indicate that the concentrations of nickel, copper, cobalt and arsenic in the Port Colborne environment do not pose an unacceptable risk to residents as defined by the MOE target risk levels*".

Furthermore, the proponent derives a site-specific RBSC for nickel of 20,000 mg/kg that it indicates would serve as a human health based soil remediation guideline. The proponent also indicated that RBSCs would not be required for copper or cobalt because "*the computed values were less than the maximum measured*" whereas, in the "*quantitative evaluation of uncertainties, arsenic oral/dermal exposures were found to have uncertainties too large to make the evaluation reliable*".

As a consequence of this review, MOE has identified concerns in this memo that must be satisfactorily resolved and are likely to influence the recommended RBSC's for the CoC's including nickel. As a result, MOE will not provide final comments on the derivation of the RBSC until the concerns identified have been resolved.

A key determinate of the proponent recommended RBSC of 20,000 mg/kg for nickel is based on the site-specific relative oral bioavailability (ROB) factor of 4%. While MOE believes that there is sufficient site-specific bioavailability information to deviate from the default 100% used for the Ontario generic based soil criteria[1], MOE does not share the proponent's confidence in the 4% ROB as determined by their weight of evidence analysis. Instead MOE recommends that an ROB of 19% as was previously relied upon

[1] The generic soil standards for Ontario use a 100% ROB (or relative bioavailability factor of 1 as in MOE 2009) in the absence of site-specific information.

by the Ministry for the Rodney Street risk assessment (MOE 2002) be used for the purpose of determination of a RBSC for nickel and in risk characterization for Port Colborne. The consequence is that the RBSC of nickel would result in a lower more stringent RBSC.

The following are MOE findings as they relate to the HHRA conclusions. Comments are provided as Part A specific comments, and Part B responses to previous comments made by MOE.

<u>Part A:</u> Specific Comments

<u>Site Characterization</u>

1) **Screening Process for Selection of CoCs:** According to Section 2.3 CBRA Chemicals of Concern of the HHRA: *"For the CBRA, the definition of a CoC is a chemical found in Port Colborne soils originating from the Inco Refinery where **all** of the following conditions are met:*

   > *Condition 1) Chemicals that were historically used or generated by the Inco Refinery or its processes, **and***
   > *Condition 2) Chemicals that are present at a community level at concentrations greater than MOE generic effects-based guidelines (MOE, 1997), **and***
   > *Condition 3) Chemicals whose presence in soil shows a scientific linkage to the historical operations of the Inco Refinery.*

   The CoCs considered in the HHRA are nickel, copper, cobalt and arsenic. The identification and selection of CoCs for the CBRA is reported elsewhere (Jacques Whitford, 2001a; 2001b; 2001d). This documentation was used by Jacques Whitford in the CoC selection process and although standard practice is to review CoC selection at the time of submission of the HHRA, the CoC selection was preformed in 2001. In order to facilitate the review of the current HHRA, CoC selection was not considered as apart of this review. Therefore, MOE's comments are limited to the identified CoC's - nickel, copper, cobalt and arsenic.

   MOE notes that in December 2009 Brownfields soil criteria (component values and revised soil standards) "Rationale for the development of soil and ground water standards for use at contaminated sites in Ontario" were updated. As such the proponent is encouraged to ensure that the submission would satisfy these criteria, first to help place the current assessment in the context of the current Ontario regulatory environment with best science practice, and second to increase the openness and transparency of the document such that it could be read as the contemporary accepted practice of risk assessment.

   It is important that appropriate relevant criteria be used to determine the study area (Section 2.2), and in CoC selection (Section 2.3). As indicated by the proponent in Section 1.2 CBRA process "*the components of the CBRA process include: An* *evaluation to confirm that all relevant CoCs have been considered;"* , the proponent should ensure that the submitted risk assessment satisfies these criteria.

2) **Section 2.7 Soil Parameters.** The reviewer was not able to fully evaluate the site soil characterisation information provided. The proponent has provided contour maps for CoC's (Figures 2-6 to 2-8) which present a good visual aid. However, the combined soil data used in the assessment as provided in Appendix 20, and soil sampling locations provided in map Figure 2-3, Soil Sampling Locations Port Colborne, are not clearly presented. Specific details are required to aid in the understanding of the rationale behind the soil EPCs selection process used by the proponent in the HHRA model, including a detailed spatial presentation of the information. It would be more appropriate if the following information is provided for each of the zones:
   - A map showing sampling locations of all the data used in the HHRA.
   - For each sample location, the soil land use (category) as a recreational (woodlot), commercial, residential, school yard or garden type etc. should be indicated.
   - For each sample location CoC concentrations including the max with an indication of the soil depth.

   This will enable the reviewer and future readers to gain a better understanding of the selected data and support the statistical representation of the data used in the HHRA. MOE also has concern due to insufficient data for the following zones:

Zone	Soil by Land Use	Sample Locations
A	Recreational	4
A	Commercial	2
A	Schools	2
C	Schools	7
D	Commercial	3

   Without sufficient sampling data the reviewer is not in a position to determine the adequacy of the exposure assessment. While there is some general guidance on sampling requirements for conducting a site-specific risk assessment, specifics for a CBRA are lacking. MOE recommends that a data gap analysis be conducted when less than 10 distinct sample locations are used and for residential properties especially when the sampling represents less than 10 % properties within each zone.

3) **Section 2.7 Air Quality.** The proponent indicated that the results of the ambient air monitoring program for Port Colborne were evaluated using the MOE 2001 Ambient Air Quality Criteria (AAQC) and that all the ambient air CoC concentrations obtained from Port Colborne were below the associated AAQC guidelines (Section 2.7.1 Ambient Air Monitoring). However, AAQCs are used in compliance assessment of a facility and are not necessarily TRVs, may not be human health risk-based, or may not reflect current knowledge. Therefore, the appropriateness of the AAQC in context of health protection within a HHRA as "*safe*" (e.g. Page 2-37) should be re-addressed by the proponent. It is noted that the MOE is currently reviewing and updating the respective AAQC's for Nickel (Ni), Arsenic (As) and Copper (Cu).

4) **Section 2.7.1.1 Nickel Speciation Scan of Ambient Air Samples.** The proponent indicates that according to ambient air filter samples, oxidic forms of nickel (about 80% of total) were found in particulate. This information is inconsistent with the MOE data (2001-2002) for Port Colborne, which indicated that up to 85% of the PM_{10} sample is nickel sulphate (MOE 2009, EBR posting # 010-7188). The proponent should review the evaluation to resolve the inconsistency and incorporate appropriate changes into the report. All information necessary to demonstrate that the assessment undertaken is appropriate for the HHRA should be included.

<u>Problem Formulation</u>

5) **Section 3.2.4.1 Concentrations in Drinking Water:** The proponent has used the MOE's Drinking Water Surveillance Program (DWSP) data (Appendix 15, Table 18) to estimate the drinking water exposure for HHRA Zones A, B, C, and E (Sections 2.6.3 and 3.2.4.1). According to the report the data set is based on water samples obtained from the distribution system and not the tap. Drinking water exposure from a community-based perspective is most applicable from the tap where water is obtained. This introduces a limitation to the HHRA, as relying on the distribution system water samples may not account for the exposure at the tap. This is potentially significant for the CoC Cu, where due to water-based corrosive activity Cu can be leach from copper piping. As such, the use of the distribution system versus tap water data is likely to underestimate Cu exposure from drinking water. The lack of this information should be discussed in the uncertainty section.

   In the determination of the drinking water exposure from the drilled well supply the proponent has combined the non-tap (Table 7) and tap (Table 8) collected data as they assert that the data sets are "*similar*". The combined data set (Table 9) was used as the EPC for Zone D and E. It is not apparent if a statistical analysis was performed to support this statement. Furthermore, specifically, Cu tap water samples are preferred (mean Cu concentration: non-tap = 0.0040 mg/L verses tap = 0.059 mg/L) for use in the HHRA. Data sets for dug wells were also combined, but due to low sample numbers combining of data might be required. A statistical analysis of these data should be provided.

   It is stated in this section that the MOE DWSP data from Dunnville, Fort Erie (Rosehill), Haldimand-Norfolk, Port Dover and Port Rowan water distribution systems were used for Zone F background EPC drinking water. However, according to Appendix 15, Section 5.6 data were taken from taps serviced by water treatment plants throughout the Niagara region, including treatment plants at Dunnville, Fort Erie, Grimsby, Hamilton, Nanticoke, Niagara Falls, Ohsweken, Port Colborne, Port Dover, Port Rowan, St. Catharines (De Cew), Simcoe, Waterford, and Welland. This inconsistency should be resolved and appropriate changes made to the report. Furthermore, the proponent should confirm that the water samples were obtained from the tap (preferred) as opposed to the distribution system as indicated elsewhere in the HHRA.

6) **Section 3.2.5.3 Concentrations in Indoor Air:** The proponent has selected 0.6 as the ratio of indoor air to outdoor (ambient) air (Appendix 13, Indoor Air and Dust Study). The selection of a 0.6 ratio was based on an analysis of 24 hour indoor air samples collected at 10 residences in each of the 3 air zones, totalling 30 residences as identified in Figure 2 (Samples Zones Used in the Indoor Air Sampling Study Port Colborne). The data was pooled from the 3 air zones (Table 3 Definition of the Three Sampling Zones used in the Indoor Air and Dust Study) to provide a comparison to monitoring data collected at the baseball diamond (Rodney and Davis Street). The monitoring data at the baseball diamond was the site used as the source for Zone B EPC for air and used to limit the maximum modelled air concentrations for other Zones.

   The reviewer is not confident that this ratio represents the Port Colborne area-wide and between-Zone ratios, as the sampling of indoor air is highly variable, and was not preformed with co-localized outdoor air sampling. Therefore, while the HHRA relies on the ratio of 0.6, MOE recommends that a ratio of 1.0 also be tested in the sensitivity analysis and in the assessment of the maximum exposed individual. (See also related Comment 29).

7) **Section 3.2.5.4 Concentrations in Indoor Settled Dust:** The indoor dust pathway can be a significant exposure pathway particularly for the toddler, which is likely to have greater time spent indoors and greater hand to mouth activity than adults. The proponent has adopted the US EPA equation (1997) for estimating dust ingestion for the toddler (Appendix 2, Section 2.2, Ingestion of General Household Dust). The reviewer has concerns about the assessment of the dust route of exposure in the HHRA because:
   - the data is based on a limited number of pooled residential homes (30 locations),
   - the data is highly variable, no background exposures for Zone F were determined (thus direct comparisons can not be made),
   - the soil relative bioavailability adjustment was used to approximate the dust specific relative bioavailability, and
   - there is a lack of assessment of the dust maxima found.

   Therefore, MOE recommends that the maximum dust concentration be used in the Risk Characterization for Maximally Exposed Individuals (Chapter 7) and that in the absence of a verified measurement, the relative oral bioavailability (ROB) of 1.0 be tested for dust as part of a sensitivity analysis (Chapter 8) to help improve the transparency of the report, and to provide a more complete risk characterization.

8) **Section 3.2.8 Table 3-8: Selected Exposure Point Concentration (EPC) for Zone B:** The proponent indicates in the report that an objective of the HHRA is to evaluate current risks to human health in Port Colborne. For the determination of the soil EPC for the residential Zone B receptor the proponent has relied on soil sampling data prior to 2002 (Appendix 20, Section 3.2.1 Zone B Residential Soils). Since Zone B includes the Rodney Street community and remediation has occurred it is not apparent how the soil-clean up has been incorporated into the HHRA. As the

proponent has indicated throughout the HHRA that the assessment is of "*current*" risks, the proponent should clarify how this objective is being met.

9) **Section 3.2.8 Tables 3-8 to 3-11: Selected Exposure Point Concentration (EPC) for Zone A, B, C and D:** As indicated by the proponent seven school soil samples were analyzed for Ni, Co, Cu, and four samples for As. Since the number of samples collected for Zone C schools was less than 10 the proponent used the maximum concentration measured for the RME EPC scenario for soil (Appendix 20, Section 3.3.3, Zone C School Soils). Given that zone delineation for HHRA is somewhat arbitrary, the school soil sampling is limited, and the close proximity of schools in zone D (across the street), the near schools within zone D should be incorporated with Zone C schools. Additionally, for the Zone D receptor it is not apparent why Zone C versus Zone D school soil was used in the assessment.

10) **Section 3.2.8 Table 3-13: Selected RME Exposure Point Concentration (EPC) for Zone F:** Ontario typical range (OTR_{98} from MOE, 1997), EPC for Zone F was used as the Niagara region background (e.g. Table 3-1: HHRA Zones and Rationale, Section 3.2.3, Appendix 20, Section 5.0, Derivation of Background Soil Concentrations) in order to compare receptors in Port Colborne zones. The use of the 98^{th} percentile of the Ontario data set is not the same as the RME (i.e. UCLM) EPC used for the Port Colborne selected soil EPC. Since the OTR_{98} is used throughout the HHRA (e.g. Section 5.3.1 Background Exposures, Tables 5-6 Zone F Background Doses of CoCs), comments and results pertaining to Zone F should be reviewed and revised where appropriate, to take into consideration a more appropriate soil concentration.

TRV Selection

Comments (11 through 16) refer to the Toxicity Assessment Appendix 7 and Tables 4-2 and 4-3 of the main report. In many cases, insufficient information is provided on the critical study or how the TRVs were selected.

11) **Arsenic Inhalation non-cancer TRV:** The proponent has not evaluated the inhalation non-cancer risks for arsenic (As) as it was reported that no TRV was found. MOE recommends that the proponent use the MOE (2009) chronic inhalation non-cancer Arsenic TRV of 0.03 $\mu g/m^3$ based on Cal EPA (2000). If the proponent elects to use a different value from another authoritative body, a scientific rationale should be provided.

12) **Cobalt Oral non-cancer TRV:** The proponent has relied on U.S. EPA's Region III (2001) oral Reference Dose (RfD) of 0.02 mg/kg-day for cobalt (Co) as it was considered the most appropriate by the proponent for use in the HHRA. MOE notes that U.S. EPA Region III no longer supports this value and has adopted a more conservative value of 0.3 µg/kg-day although a rationale is not apparent. MOE recommends that the proponent use the MOE (2009) oral TRV of 1.0 µg/kg bw – day based on the intermediate MRL of ATSDR (2004), with the application of an additional uncertainty factor of 10 times for subchronic to chronic extrapolation. The

TRV should be replaced and any estimations or calculations relying on this value reviewed and appropriate revisions incorporated into the report.

13) **Copper Oral non-cancer TRV:** The proponent has used the Institute of Medicine (IOM, 2001) oral copper (Cu) non-cancer TRV of 130 µg/kg bw –day. This TRV is less appropriate than the TRV value of 30 µg/kg bw –day derived by Health Canada (HC DWQ, 2004) and preferred by the MOE (2009). MOE recommends that the proponent consider the use of the MOE (2009) chronic oral non-cancer Copper TRV of 30 µg/kg bw –day based on Health Canada (HC DWQ 2004). If the proponent elects to use the IOM (2001) TRV a more fulsome scientific rationale to justify selecting this TRV values should be provided.

14) **Nickel Oral TRV:** The selection of the nickel (Ni) Oral TRV has been considerably debated as part of this risk assessment. Whereas, the Ministry has maintained a preference for using the US EPA RfD (1998) based on the analysis of Ambrose (1976) at 20 µg/kg bw –day to assess potential non-cancer effects from estimated intakes from all exposure routes, the proponent has maintained its preference of 20 µg/kg bw –day based on its analysis of the Springborn (2001) study.

In MOE's view, the limitations of the Springborn study (2001), particularly the lack of a dose response or identifiable LOAEL, renders it less reliable than the Ambrose (1976) study used by the US EPA. It should be noted that two credible agencies have considered the Springborn 2001 study as a supporting study for a lower RfD (11 µg/kg bw/ day (California OEHHA, 2005, 2010; WHO 2007)).

Furthermore, use of the US EPA RfD would be consistent with:

- Brownfield (2004) program and recently re-endorsed (2009).
- Rodney Street RA (2002) HHRA as recommended by an international expert panel for the Port Colborne RA
- Sudbury Soil Study as conducted by SARA 2008 and independently endorsed by its International Expert Review Panel.

In the context of the use of this value, as indicated by US EPA, the RfD is believed not to cause an individual to become sensitive to Ni but, those who already are hypersensitive to Ni "may not be fully protected". A similar statement (is not intended to protect hypersensitive individuals) was also made by the Working Group who supported a 20 µg/kg bw - day TRV based on the Springborn study (2001). As such, it is the expectation that the qualitative statement be brought forth in all communications on the findings of the report as a limitation in the quantitative assessment and in reference to the proponent's Ni RBSC. Note: oral elicitation of dermatitis in individuals who are already sensitized to nickel has been observed following oral Ni dosing which has resulted in lower, more stringent oral TRV's for Ni (WHO, 2007).

15) **Nickel Inhalation cancer TRV:** The proponent's assessment of the inhalation carcinogenic potential of Ni was performed by reviewing several (I to IV) approaches

(Appendix 7, Section 2.4.2.2.). The various approaches combined a cancer threshold and non-threshold (unit risk) analysis for comparative evaluation. According to the HHRA, "*the threshold approach was concluded to be more appropriate and the unit risks and resulting cancer risk estimates were concluded to over state actual risks*". The cancer threshold approach (proponent Approach III) employed a point of departure analysis of the Copper Cliff refinery worker cohort with the application of uncertainty factors to derive the 0.6 $\mu g/m^3$ value based on the analysis of the European Commission (EC, 2001) and Lewis and Caldwell (1999). However it is noted that, while the EC did develop a cancer threshold estimate for Ni, they also developed a threshold non-cancer and a non-threshold cancer estimate. Ultimately the EC developed an air limit of 0.02 $\mu g/m^3$, which was intended to be protective of both cancer and non-cancer effects. The Copper Cliff refinery worker cohort is also used by the US EPA IRIS to develop its unit risk estimate and the EC in its cancer non-threshold approach I (unit risk) (this report (0.24 $mg/m^3)^{-1}$). It was also endorsed by the Ministry in its update to the Brownfield Program (2009).

MOE has proposed an annual limit of 0.02 μg Ni/m^3 as part of consultation for the development of air standards for nickel and nickel compounds for Ontario (O. Reg. 419/05) consultation (EBR posting # 010-7188). The air standard review and rationale indicates that no regulatory agency reviewed has adopted the cancer threshold approach for establishment of a limit for nickel mixtures. Thus MOE recommends that for the quantitative risk assessment of inhalation in Port Colborne, Approach I (refinery dust) and II (oxidic nickel) should be used to bracket the potential range of risks in the quantitative assessment. Reference to approach III (cancer threshold approach) is not supported and should not be part of the assessment.

Note also: Appendix 7, page 108. Approach III. The 1.1 $\mu g/m^3$ EC (2001) value based on a cancer threshold approach represents the upper estimate of a range of values; a low end, middle and upper end of a range have also been developed (0.06, 0.6 and 1.1 $\mu g/m^3$). The text should clearly indicate and discuss the range of values, derived by the EC (2001).

16) **Nickel Inhalation non-cancer TRV:** The proponent has used the ATSDR (2005) chronic inhalation MRL for nickel sulphate TRV of 0.09 $\mu g/m^3$. MOE recommends that the proponent consider the MOE preferred (2009) TRV of 0.06 $\mu g/m^3$ TERA (1999) with the application of an additional uncertainty factor of 3 times for animal to human extrapolation, and the EU (2004) limit of 0.02 $\mu g/m^3$. If the proponent elects to use the ATSDR (2005) TRV a more fulsome scientific rationale to justify selecting this TRV values should be provided.

Relative Bioavailability Adjustments

The following comments (17, 18 and 19) refer to the proponent's selection of relative oral bioavailability (ROB) used in the HHRA, Appendix 8 and Tables 4-4 in the report:

17) **Weight of Evidence Criteria Evaluation Criteria Summary:**
For the purpose of determining a ROB adjustment factor, the proponent has outlined the evaluation criteria (Appendix 8, Table 13) used in its weight of evidence. Attributes were selected in order to evaluate the weighting that they believed should be placed on each measure of bioavailability or bioaccessibility. In general, the proponent ranked the attribute (importance – low, moderate or high), as well as the criteria in which to evaluate whether the attribute was satisfied or not (ranking – low, medium, or high). While this has aided MOE's review there are specific concerns with the evaluation criteria used by the proponent:

a) "*Site-specificity and spatial representation*" attribute was ranked to be of "*Moderate*" importance in the assessment of ROB; however, MOE recommends that this attribute be ranked as "*High*", as the confidence in the ROB estimate is intended to be site-specific. Furthermore, within the evaluation criteria of this attribute, the proponent has indicated the following ranking criteria, "*Low*" confidence be assigned to "*Artificial substances not site-specific*", "*Medium*" confidence assigned to "*Few samples or soils not including all of clay, organic and fill*" while assigning the "*High*" to "*10 or more soil samples including clay, organic and fill*". MOE recommends that since this is a community-based risk assessment, and that heterogeneity and distinct soil types are found throughout the subject community that a greater weighting should have been allotted to the use of statistically robust site-specific information. For example, the assignment of "*Low*" may be reserved for "*Few samples or soils not including all of clay, organic and fill*", "*Moderate*" for "*10 or more soil samples including clay, organic and fill*" and "*High*" for "*10 or more soil samples for each of the soil type including clay, organic and fill*".

b) "*Test Vehicle*" and "*Strength of Method*" attributes are both ranked "*High*" importance by the proponent, it is not apparent if some overlap exists in these attributes. In the absence of a more fulsome explanation, MOE recommends that they should not both be ranked as "*high*". Alternatively, the two attributes could be combined to form a single attribute for evaluation purposes and/or there should be a thorough explanation and selection rational provided.

c) Furthermore, it is noteworthy that while the importance of the "*Strength of Method*" is ranked "*High*" by the proponent, there is a difference between method validation, which means the method is only acceptable if it has adequately been evaluated, documented and undergone independent peer review, and regulatory acceptance.

As was previously noted by MOE (referred to in Part B), authoritative bodes have only accepted two methodologies for Arsenic (As) (State of Hawaii) and lead (Pb) (US EPA, 2007), both of which are highly dependant on the consideration of in vivo validation. As such, a high overall ranking does not necessarily dictate that the analysis as performed by the proponent be relied upon for the HHRA.

Overall confidence in the proponent's weight of evidence criteria is limited as it is not apparent how the ROB evaluation criteria have taken into account absorption of CoC`s for the toddler. As a consequence of this limitation, as well as the lack of assessment ROB for these CoC's in the primary literature, MOE feels that the certainty associated with the use in vivo and in vitro data to make a ROB adjustment dictates cautious interpretation and use in the HHRA.

18) **Summary: Ni TRV and ROB**

The ROB of Ni is a risk driver for both the estimated risks, as well as for the development of the risk based soil level (RBSL). There are no known validated procedures for the evaluation of Ni bioavailability in soil, although general guidance is available for the evaluation of methods to assess bioavailability of metals from soil.

In consideration of the available TRV's for Ni, and with the available information to make a ROB adjustment, MOE recommends that the US EPA (1996) RfD of 20 µg/kg bw /day be used (See Comment 14).

Two paths forward were considered by MOE regarding the ROB:

- in vitro bioaccessibility data underlying the 19% ROB used for the Rodney Street (2002) risk assessment, and
- the in vivo bioavailability data underlying the 4% used in the proponents weight of evidence analysis,

MOE continues to recommend a ROB of 19 %, as previously supported by the Ministry be used for the reasons discussed within, which includes accounting for exposure to toddlers and in consideration of the criteria for weight of evidence evaluation (Comment 17).

Previous MOE analysis: The Rodney Street (2002)

In the Rodney Street (2002) risk assessment the MOE used the ROB of 19 % (mean within range from 11.8 to 23.3 %) based on the in vitro determination of bioaccessiblity data of fill soil samples (n = 10). In general, bioaccessibility data as determined by the in vitro analysis of the fill soil likely represents an upper estimate of bioavailability and was previously relied upon in the development of the soil remediation level. While the ROB of 19% was developed to represent the Rodney Street area, the applicability of this parameter for the different soil types found in the greater community wide Port Colborne (e.g.,Welland Clay or Organic) was outside the scope of the 2002 assessment. Based on the additional data provided by the proponent, it is reasonable to interpret that of the soils tested, the fill soil may contain the least bioavailable Ni, as determined in both the in vivo (Fill = 2.5%, Welland Clay 4.5%, and Organic 4.1%) and in vitro (Fill = 6.9%, Welland Clay 14%, and Organic 26%) analyses. However, given the lack of descriptive nature of the fill soil it is more appropriate to conclude that the estimate of 19% bioaccessible as used by the MOE (2002) is within the range of the bioaccessible Ni as determined by the proponent.

MOE appreciates that there are constraints associated with the 19% estimate gleaned from in vitro data but notes that it is based on an established procedure, and is more statistically robust. Based on the information outlined above MOE does not share the proponent's interpretation that bioaccessibility determination of a ROB via in vitro data be ranked "*low*". Furthermore, the intent of a bioaccessibility data is only directed at providing an estimate of the available Ni from the soil under stomach physiological conditions. The use of a ROB based on bioaccessibility information enables the direct relative comparison to the TRV as an intake dose (an in vitro measurement), thus it does not require assumptions to be made on the absorption of Ni into blood (an in vivo measurement).

Additionally, in the absence of toddler specific absorption information, a sufficiently conservative estimate of bioaccessibility is deemed by MOE to be warranted from a regulatory perspective. Bioaccessibility data has previously been used by the MOE (2002) and was relied upon in the Sudbury Soils Study (SARA, 2008).

<u>Proponents Weight of Evidence Approach:</u>

In the current HHRA, the proponent has supported the use of a ROB factor of 4 % based on a weight of evidence approach. The approach considers site-specific in vivo and in vitro determination of bioavailability and bioaccessibility respectively, and includes an indirect analysis using soil Ni speciation information. The proponent considers the in vivo data as a "*high*" overall attribute in its weight of evidence evaluation to support the recommended 4 % ROB. However, in review of this material MOE does not share the proponent's confidence in reliance on the very limited in vivo data and, in turn, MOE lacks confidence in the derived ROB of 4% (Appendix 8, Table 14).

The following concerns are raised in regard to the in vivo bioavailability determination of a ROB of 4%, ranked "*high*" by the proponent:

1) Limited sampling

Only 3 soil samples representing Fill, Welland Clay and Organic soils were tested (i.e., n=1 for each soil type). The variability of the bioavailability of the Port Colborne soils introduced by this limited number of soil samples is a concern and may not truly represent area soil variability. A larger sample size is needed to ensure that the bioavailability assessment yields a more reliable estimate.

2) Single oral dose

The in vivo determination of bioavailability was based on rats administered a single oral gavage dose of test vehicle, Ni-sulphate, or test soil. This was undertaken in order to make a comparison of the bioavailability of the Ni from Port Colborne soils to the oral Ni TRV. A key assumption inherent to this approach is that the relative absorption comparison between the Ni-sulphate in water and Ni in soil by a single administered dose is representative of the long-term absorption of Ni in the development of the oral Ni TRV. While this would not preclude the use of the in vivo information submitted by the proponent, the dosage regimen of the in vivo study is considered to be a significant limitation to the reliance on this data for the determination of the ROB.

In the context of this HHRA, the intent of the ROB adjustment is to determine a relative factor that is site-specific and takes into consideration the Ni speciation and protocol utilized in the TRV. In this case, the preferred US EPA (1996) RfD of 20 µg/kg bw /day was based on Ni-sulphate fed (spiked rat chow) to rats for 2 years. In this report the proponent has used a single administered dose of Ni-sulphate in water by gavage to relate the Ni absorption into blood of Ni-sulphate to the test soil. This has introduced some uncertainties to the applicability of this surrogate approach.

It is important to note that ROB adjustment is not intended to directly account for the absorption of Ni, as the adjustment applied to the oral TRV as an intake dose not an uptake dose. In fact, the determination of absorption of Ni from soil requires the added considerations of an understanding of the fed versus fasted state, use of the rat model to mimic human absorption, and whether the absorption rate is sufficiently conservative to account for a toddler.

3) Overall data quality
MOE is concerned that the proponent has assigned greater quality to the in vivo data than may be warranted. For example, the proponent has developed a ROB by comparing the absolute bioavailability determined by blood Ni levels absorbed over a 72 hour period to the area under the curve (AUC) of Ni-sulphate for each of the three soil types. The blood Ni concentration - time curves based on mean data are presented (Appendix 8, Figures 7 and 8). MOE notes the following: (Appendix 8, Attachment A), the blood Ni levels are highly variable, with the Ni blood levels from the soil dosed animals within the variation of the vehicle treated group, thus making differences between the vehicle and soil treated group hard to differentiate.

Together, the proponent's overall ranking of this line of evidence as "*high*" is not shared by MOE, because of the use of a single oral gavage dosing regime to make a relative prediction to the long-term bioavailability of Ni in rats, a lack of soil samples tested, and data quality limitations.

MOE is further concerned that the proponent has considered the in vitro bioaccessibility data ranked "*low*" by the proponent, to support a ROB of 17-21 %.

Previously MOE has commented on the proponent's derived in vitro data as presented in earlier drafts. Those comments stated that the information provided was insufficient and unacceptable to support the interpretations and conclusion of the report because: 1) an insufficient number of samples, 2) ROB values did not meet standards for statistical acceptance, and 3) the lack of validation of the bioaccessiblity data. The proponent responded by combining its bioaccessibility data with the data obtained as part of the Rodney Street Risk Assessment (MOE,

2002) in this version of the report. This was done to account for the broad range of characteristics and indicated that it is suitable for analysis as a statistical pooled data set to cover the range of soil characteristics found in the area (Appendix 8, Section 5.3 Bioaccessibility – In vitro Study). It is not apparent if an analysis was undertaken to determine if data from two different labs could be pooled to generate the 21 % ROB estimate.

In the absence of an appropriate methodology to pool the data sets, the in vitro bioaccessibility data as used by the MOE (2002) is more robust (n = 10) and hence warrants further consideration. Given the more site-specific nature of the data, MOE does not share the proponent's assessment of a "*low*" overall ranking.

Data pertaining to the in vitro stage 2, as conducted by ESG, is not a generally accepted method for assessment of bioaccessibility and therefore, is not considered in MOE's analysis.

Lastly, the proponent has used soil Ni speciation information in an indirect assessment of a ROB of <5%, ranked from "*low*" to "*high*" by the proponent. MOE's concerns with this approach are:

The proponent indicates that, based on Ni speciation work of soil samples of the exchangeable Nickel (soluble), the bioavailability of Ni in soil "*would be less than 5 %*" (Appendix 8, Section 2.7 Expected Bioavailability Based on Soil Nickel Speciation Data). While the exchangeable Ni fraction provides (Table 5) an indication of the potential or readily available Ni in soil, reliance on this fraction only has not taken into consideration biologically relevant processes that contribute to the leaching of Ni from the soil matrix. The Ni bound to carbonates or subsequent to degradation /dissolution of carbonate, will also be a contributor of Ni bioavailability (Table 5 reported soil samples 4.0 and 5.3%). In addition, the Ni bound to organic matter may be leachable at lower pH conditions and thus, may also be a contributing source (Table 5 reported soil samples 41.3 and 12.6 %). As such, the proponent has not fully accounted for all the Ni that could leach from soil.   The result of this omission is that the bioaccessibility fraction is likely higher than the estimated < 5%. Furthermore, due to the limited number of soil samples analyzed, it is not apparent that there is adequate information to support the proponent's assertion.

In predicting the bioavailability of the Ni from soils based on Ni speciation information, combined with human literature reports, the proponent considered the human absolute bioavailability of 7.1% by Nielsen et al., 1999 as being the "*most applicable to a long term average exposure*". Using this human absolute bioavailability factor resulted in a calculated ROB of approximately 2.8% (Table 7). The use of 7.1% was based on the judgement of the proponent that the absorption rate, as determined in the pre-feed participants (eggs given 1.5 hours prior to dosing), as being the most appropriate of the scenario's preformed by Nielson et al., (1999) in reflecting the typical behaviour of a child (expected to eat prior to playing outside). Nielson et al., (1999) determined the human bioavailability ranged from 3.4 to 25.8 % depending on the fed or fasted conditions. While a rationale to support the selection of 7.1% is provided, it is not apparent how the absorption of the adults in the Nielson et al., (1999) paper can be used to represent a toddler's absorption rate. In lieu of specific child data, MOE recommends that the maximum human adult absorption rate of Nielsen et al., (1999) of 25.8% be used in this line of evidence.

The use of Ni speciation information combined with human and rat absorption rates from the literature are not a generally accepted methodology for making site-specific ROB adjustment. This indirect method in not preferred over the direct determination of in vivo bioavailability, nor the in vitro determination of bioaccessibility. As direct methods are preferred, MOE does not share in the proponent's confidence in assessing an overall ranking of "*high*".

MOE acknowledges the potential contribution of the in vivo data to refine the approach used by the MOE (i.e., 19% ROB based on in vitro data). However, the concerns detailed above lead to an overall lower confidence in the data and resulting 4% ROB, than attributed by the proponent. See additional Comment 17 on weight of evidence evaluation criteria.

Added Consideration – the exposure of toddlers

In deliberation of the proponent's weight of evidence assessed in this version of the report and in context of the Ni TRV, it is noted that OEHHA (2005) has developed a child specific Ni TRV (chRD) for non-cancer effects of 11 µg/kg bw /day based on Smith (1993) and Springborn (2000) studies. As part of the analysis, a deliberation of matrix effect and child specific differential absorption rates was considered. Using the assumption that the absorption of Ni from water is about 10 times greater than that from food, and that the matrix effect of soil and food are equivalent in retarding absorption, the water based TRV could have a 10 times greater absorption than that of soil. In consideration of an adult versus child's absorption, OEHHA concluded that children are likely to have an 11.8 times higher GI absorption rate of Ni. Thus, in consideration of the retardation of absorption by the soil matrix and the higher GI absorption in children in totality, OEHHA determined that a child specific absorption factor is not required. In addition, OEHHA has noted that since they had considered bioavailability of Ni in developing the chRD, that a further correction for oral bioavailability would not be required in conducting an exposure assessment.

While OEHHA uses a more conservative ROB of 100% than previously used to assess the risks of Port Colborne soils from Ni by either the Ministry (2002) or the proponent, the importance of a children perspective in consideration of absorption rates is noted and warrants a prudent health practice.

Conclusion

In evaluation of the bioavailability of the Port Colborne soils for the purpose of conducting a human health risk assessment, MOE believes that there is sufficient site-specific bioavailability information to deviate from the default 100% used for the Ontario generic based soil criteria[2].

Historically, by considering the data underlying the Ministry's (2002) previous use of 19% along with new data and the weight of evidence provided by the proponent, it is reasonable to suggest that the value of 19% is likely conservative and thus the predicted bioavailability of Ni from Port Colborne soils is likely less than 19%.

Nonetheless, while the provision of much needed in vivo data adds considerably to the site-specific information, MOE does not share the proponent's confidence in the 4% ROB, for key reasons discussed above, notably the single-dose regimen of the in vivo experiment, the minimal number of soil samples, and the ability to the rat model to account for child's absorption. Even so, the new analysis adds weight to the suggestion that the historical approach of the MOE (i.e., 19%) tends to be conservative, yet the information provided does not provide MOE with sufficient confidence to rely on the proponent's weight of evidence for the characterization of risk for Port Colborne or in the determination of the RBSL.

Finally, as the site-specific ROB is a risk driver for Ni, and that there exists uncertainty in the estimation of potential risk characterization of Ni in the Port Colborne soils, it is suggested that this uncertainty be reflected as part of the risk communication.

Final ROB recommendation: 19%

19) **Weight of Evidence evaluation for As, Cu and Co ROB`s**
In the assessment the ROB for the CoC's, As, Cu and Co, the proponent has relied on the in vitro bioaccessibility data determined by the Exponent Environmental Group as used by the MOE for the Rodney Street HHRA (2002). In the weight of evidence evaluation, the proponent (Appendix 8, Section 6.0 Weight of Evidence Criteria Evaluation Criteria) has assigned a "*Low*" confidence to Cu and Co and "*Medium*" confidence to As, thus the rationale for selecting the 95^{th} UCLM versus the maxima has not been sufficiently substantiated. MOE recommends that given the limited number of soil samples tested and the proponents weighting that the soil maximum ROB be considered and factored into the sensitivity analysis.

Clarification of Appendix 8, Table 19 Summary of Selected ROB values. According to Table 18 the UCLM (bolded) was used in the HHRA, yet summary Table 19 indicates that the mean ROBs were used. Spread sheets provided to the MOE (July, 24, 2010), indicate that the UCLM data was used. The proponent should ensure that

[2] The generic soil standards for Ontario use a 100% ROB (or relative bioavailability factor of 1 as in MOE 2009) in the absence of site-specific information.

the UCLM data was used in the HHRA as indicated and resulting appropriate changes to the table(s) be incorporated.

<u>Exposure Assessment</u>

20) **5.1.3 Literature Review**: The proponent has omitted the MOE's December 2009 updated Brownfields soil criteria (component values and revised soil standards) "Rationale for the development of soil and ground water standards for use at contaminated sites in Ontario" from its literature review. This document contains the MOE preferred receptor characteristics recommended to be used in HHRA's and in the development of site specific soil standards. The proponent should ensure that the current submission would satisfy/fulfill these criteria, especially when the proponent has used less conservative receptor characteristics. However, it is also noted that site-specific receptor characteristics have been incorporated into this HHRA and if sufficiently supported, may be acceptable. A comparison of receptor characteristic from the MOE preferred criteria (2009) to the characteristic used is the submitted HHRA should be incorporated into Appendix 3, Receptor Characterisation; this would increase the transparency of the report. Additionally, other citations should be updated, such as the US EPA Child-Specific Exposure Factors Handbook (2008, 2009). Where appropriate updated or MOE (2009) preferred receptor characteristics should be integrated into the exposure assessment of the HHRA.

21) **5.3.5.1 Uncertainty in Arsenic Exposures:** The proponent indicates that "*the arsenic oral and dermal exposures were concluded to have too great uncertainties associated with them for the valuation of exposure to be reliable*" (Page 5-32). Based on this assessment, risk estimates were not generated in the report, despite As being a CoC and TRVs being selected. The uncertainty in estimation of the exposure to As due to undetectable levels in samples of well water, municipal water, supermarket foods and garden produce is discussed in Section 5.3.5.1, Uncertainty in Arsenic Exposures of the HHRA. In Table 5-13, when the Estimated Quantification Limit (EQL), Method of Detection Limit (MDL), ½ MDL or zero for As was used in the exposure assessment, the reported variation between these default assumptions in exposure in comparison to the variation among zones was deemed by the proponent insignificant.

An uncertainty in the arsenic exposure estimate, due to samples being below the detection limit, is an insufficient reason to not complete the quantitative arsenic risk characterization (Section 6.2.4.2). It is important to note that only 1 of the soil samples (Appendix 20 Statistical Analysis of the Soils Database) was considered non-detect (ND). Thus, as the focus of this HHRA is a soil study, while the risk estimates for other media may introduce uncertainty in the overall risk estimate, the uncertainty of the soil exposure is reliable to make a risk prediction. Thus, a comparison of the arsenic exposure estimates to the arsenic TRVs is required.

Risk Characterization

As many of the MOE comments (including Part B) would influence the risk characterization, various statements made by the proponent in this section would require additional justification, and may also change once MOE comments are addressed or incorporated by the proponent. Comments are limited to concerns not identified by earlier comments.

22) **Section 6.1 Risk Estimation Equations (Page 6-3):** The proponent includes the following statement "*Where background doses are used, these are used for comparative purposes only; effects smaller than 10 to 20% above natural background cannot be reliably distinguished or quantified*". The statement is not supported. If the proponent elects to retain this statement in the document a rationale supporting it should be provided.

23) **Section 6.1 Risk Estimation Equations (Page 6-3):** The proponent includes the following statement "*For each non-threshold acting chemical, the incremental lifetime cancer risk (ILCR) was estimated for the incremental dose discernible from background (see Equation 6-3) or the incremental concentration in the case of inhalation risks (see Equation 6-4)*". The statement is not supported. The proponent has confused a compliance assessment wherein a facility's incremental contribution is assessed and a community based risk assessment for which background (total) exposures are to be taken into consideration. See also Part B Comment 34 where this has been previously commented on by MOE. The original comment remains valid, and the response by the proponent is not accepted.

For the purpose of evaluating the inhalation cancer risk in the CBRA, MOE considers the Total Lifetime Cancer Risk (TLCR) data as being relevant only to the characterization of inhalation risk for the community, provided that the background air concentrations are confirmed to be included in the risk estimation.

24) **Section 6.1 Risk Estimation Equations (Page 6-4):** The proponent has indicated that "*All estimated ILCRs and HQs in the following sections have been rounded to the number of significant digits in the selected TRVs*". The use of significant digits of a converted number in relationship to the selected TRV has resulted in a tendency to reduce the accuracy of the estimated reported data i.e. the measures or modelled exposure data used in the report. For example, as indicated in Table 7-22, for the zone B resident, the Max value HQ for the infant is reported as "*1*" (1 significant digit); however, due to rounding this could represent an HQ from 0.7 to 1.4. The result is that the rounding methodology used by the proponent has tended to loose information. Consequently the risk manager is not in a position to assess whether an HQ of 1.0 has been exceeded.

It should be noted that the HQ and ILCR designation are converted ratios, in that the analysis culminates in the expression of the report data as a ratio to the TRV. The precision of the report data should be retained such that the accuracy is neither sacrificed nor exaggerated. As a consequence of excess rounding based on the TRV, forming a converted number has resulted in the loss of useful information. Given that the HHRA consists of mixed data based on varying degrees of precision and accuracy, and with the intended use of this information, it is recommended that both hazard quotients and cancer risks be reported to 2 significant figures.

For the purpose of risk management, the significance of exceedance of an HQ of 1 or ILCR of 1 in a million, especially when small differences are identified, should also be taken into consideration in the overall error/uncertainty of the risk estimation. The risk assessment report should provide sufficient information to inform risk management decisions.

25) **Section 6.2.4.1:** In Section 6.2.4.1, Inhalation, the proponent concludes that "*All of the maximum measured air concentrations fall within the range of typical Ontario ambient air concentrations of arsenic and no incremental (i.e., above background) health risk is indicated*". This statement is not supported. In context to the HHRA, as mentioned in comment 3, this should be re-addressed by the proponent as health based statements should only be made in reference to a TRV and not an AAQC. Furthermore, it is noted that As compounds have been targeted for review by the Ministry as recent studies have identified new toxicological information since the previous guideline was set in 1981.

26) **Section 6.2.4.3:** The Section 6.2.4.3, Historical Use of Arsenic Trioxide, is more appropriately considered as part of a discussion of results versus within risk characterization, as it was not specifically investigated as part of this HHRA.

27) **Section 6.2.4.4 Findings from Studies Involving Bioassays:** The proponent has by "*extension*" and for comparative purposes suggested that residents of Port Colborne would not be expected to have adverse health effects from As exposure, by comparing three urinary health studies conducted in Ontario (Volume III, Appendix 7, Attachment B). These previous Ontario studies, while providing context to the Port Colborne scenario, should not be used to make declarations that there are *"no health effects from arsenic exposure are expected to residents of Port Colborne*", because the previous studies were not based on an urinary As exposure limit associated with a clinical effect, but were used to make comparisons to other As exposure sites. Furthermore, no urinary health-based study has been conducted in Port Colborne. Comments on As exposures should be limited to comparisons to other communities, and health claims should be removed.

28) **Section 7.2 Maximum Concentration in Soil at All Sample Depths.** In order to assess potential maximally exposed individuals, the maximum concentration in soil scenario was used. However, the proponent states *"the maximum concentrations in soil scenario is likely unrealistically conservative but provides an upper estimate of potential for exposures to soil"*. This statement is not supported. While on a community-based level the use of the maxima would not be representative of the typical or average exposure for most human receptors, a given toddler's exposure

may be limited too a residential property, thus the maximum soil concentration should be considered. Furthermore, limitations in the site characterization may also indicate that the use of the maxima is warranted, including depths below the 0-5 cm range, due to insufficient information (see Comment 2).

29) **Section 7.5 Maximum Ambient Air Concentrations:** As part of the risk characterization for the RME scenario and the maximally exposed individual, the ambient air exposure point concentrations for various Zones were assessed. The assessment relies on a combination of both measured and modelled air data. In general, it is difficult to readily understand how the air concentrations were derived for use in the exposure assessment and if they are reflective of the ambient air. For example, for Zone B, the maximum ambient air concentration, as measured at receptor location 25 referred to as the baseball diamond, was considered in the RME scenario. For Zones B, C, and D, the Zone B maximum ambient air concentration was used to assess the maxima at these Zones. However, it is noted that the estimated ambient air data was modelled for Zones A, C, and D, yet these predicted air concentrations were used as long as they were not higher than the Zone B highest year averages (Section 3.2.5.3 Concentrations in Indoor Air). The rationale for excluding the modelled predicted air concentrations for Zones A, C, and D requires additional justification in the assessment of maxima. Additional clarity in presentation of material is required.

Furthermore, since indoor air concentrations were evaluated as being proportional to ambient air at a ratio of 0.6 and, given MOE's hesitation for reliance on this estimate, it is recommended that the outdoor air concentration be compared directly too the TRV or a ratio of 1.0 be assessed. In accordance with comment 15**,** Table 7-17 using Ni approach III should also be omitted.

Overall, as a consequence of the above concerns, this report does not provide enough information to support the proponent's claim that "*the results of the assessment of maximum ambient air concentrations indicates that inhalation health risks associated with the highest evaluated maximum ambient air concentrations (i.e. highest location) are not expected*" (page 7-16). Additional rationale and justification is required to support this concluding statement.

30) **Section 7.6 Maximum Indoor Air Concentrations:** As part of the risk characterization for maximally exposed individuals, the indoor air exposure point concentrations for Zone B were assessed. Despite the reservations of the proponent to include home IAS 102 because it may be being a statistical outlier, the observed air concentration should be assessed as a maximum indoor air concentration (Appendix 13, Section 3.0 Sample Outliers). The inclusion of this observation is supported, given that the indoor air data was based on a limited number of residential homes tested in the most impacted air zone (n = 10), and that the data is highly variable. However, MOE acknowledges that the sample IAS 102 does not represent the community exposure.

In characterizing the Ni inhalation risks associated with the maximum;

- the proponent's cancer Ni approach I and II are noted to predict cancer risks above a one in a million benchmark,
- reference to the proponent's approach III (cancer threshold approach), is not supported (See Comment 15), and
- confidence in the risk characterization of inhalation non-cancer is hampered by rounding (See Comment 24).

The proponent's conclusion "*There is unlikely to be an elevated risk from nickel inhalation, even for residents of the home with the maximum measured indoor air nickel concentration*" (Page 7-19), is not supported because of the potential exceedances of cancer and non-cancer endpoints and, the insufficient site characterization information available. Additional rationale and indoor air sampling would be required to substantiate the supposition.

<u>Sensitivity Analysis</u>

It is anticipated that once MOE comments are addressed, this section would be expanded. Thus the following comments are reserved for information presented that has not been addressed through other comments.

31) **Table 8-1 Sensitivity Analysis for Site Characterization and Problem Formulation** For the risk analysis study factor "*Changes in future land use – agricultural*" the proponent indicates that a "*change of agricultural areas to other land uses would not be expected to increase potential exposures".* It is not apparent, how the proponent has arrived at this conclusion. A rationale to support the statement should be provided. It is noted that the agricultural land is located in the predominate down wind footprint from the facility. Thus the potential for increased exposure to CoC's is likely.

32) **Table 8-1 (continued)** The risk analysis study factor "*Changes in future land use-recreational"* the proponent has indicated that for the Reuter Road woodlot residential development would "*increase exposures and may lead to higher risks*"**.** This statement is supported. However, the proponent also indicates that concentrations in other woodlots are less than those found in the current residential location, thus the statement is limited to the Reuter Road woodlot. Given that higher CoC levels are detected in woodlots (Figure 2-4, CoC Concentrations in Selected Woodlot Soils (0-5 cm Deep) Port Colborne, ON) than the surrounding residential area, this too would be expected to increased exposures for the residential receptor. Consequently, the limiting of the comment to the Reuter road woodlot warrants additional elaboration and or justification. Due to some woodlots being characterized by a single soil sample, this limitation should also be discussed as part of the confidence in the proponent's response.

33) **Table 8-3 Sensitivity Analysis for Toxicity Assessment:** In this Table the proponent has indicated that through the incorporation of uncertainty factors (UF) the oral TRVs for Ni and Cu, and the inhalation TRVs for Ni and Co, inherently "*overestimate*" risk. MOE does not share the proponent's interpretation. UFs are intended to account for

deficiencies or gaps in the original study that they are derived from, therefore can not contribute to the risk overestimation. UF are not equivalent to "safety factors" although historically were referred to as such. In general, as the body of scientific information increases TRVs are more likely to become more stringent with time, not less. Thus the application of UF is deemed to be appropriate, when applied at the time of establishment of the TRV. Including the discussion on the uncertainties associated with the TRV in the sensitivity analysis is unconventional and is more appropriately included in the toxicological (hazard) assessment.

34) **Section 8.5.5 Nickel Contact Dermatitis.** The proponent has indicated, based on a "*extreme maximum estimate of potential soluble nickel loading to skin from soil exposure at the maximum concentration*" would yield an estimated 0.7 µg Ni/cm^2 dermal exposure. The HHRA compares this estimate to <0.1 to1 µg/cm^2 concentration range, a range identified by Menne (1994) as being unlikely for the elicitation of nickel dermatitis assumed for sensitized individuals, but not hypersensitized individuals (as low as 0.0075 µg/cm^2 estimate of Menne (1994) when exposed on inflamed skin under occlusion). From this, the proponent asserts that "*a dermatological response to nickel in Port Colborne soils was concluded to be highly improbable for nickel-sensitized individuals*". It is not apparent from the information provided how the proponent has calculated this estimate. Therefore, MOE can not substantiate the proponent's conclusion. A detailed calculation of the estimate, including a rationale supporting key assumptions used by the proponent is required. It is noted that MOE recommends the use of 0.2 mg soil/cm^2 skin soil adherence factor (MOE, 2009) versus 0.1 mg soil/cm^2 as was indicated (page 8-45).

Confidence in the proponent's conclusion is also limited as the toxicological assessment of Ni dermatitis is abbreviated (Sections 4.4.1 Nickel Contact Dermatitis and Appendix 7 Section 2.4.3 Dermal Toxicity). A more fulsome hazard assessment of Ni dermatitis is required. Furthermore, MOE notes that the most recent scientific paper cited was in 1994, an updated review of the science literature of Ni dermatitis is warranted.

35) **Section 8.5.7 Soil Pica Behaviour in Children:** As part of the sensitivity analysis, the proponent has attempted to account for pica behaviour of children (deliberate ingestion of soil) Section 8.5.7, Soil Pica Behaviour in Children. The proponent indicates that "*For the purpose of the Port Colborne HHRA, the US EPA (1997) upper percentile estimate of 400 mg/day was chosen as the representative soil ingestion rate relevant to soil pica behaviour*." The toddler for Zone B is used to demonstrate the influence of a more conservative SIR of 400 mg/day versus 100 mg/day on the calculated ingestion dose and hazard quotient (HQ). This is intended to account for the soil pica versus RME scenario (Table 8-11, Sensitivity of Inhalation Hazard Quotients to a Pica Toddler Scenario). MOE notes that the SIR of 400 mg/day is an upper percentile (95th) whereas, 100 mg/day SIR is considered by the US EPA (2007) to be the best estimate of the mean for children under 7 years of age. Thus the use of 400 mg/day is inappropriate to account for soil pica and instead would be appropriately used in a RME scenario. It is noted that MOE (2009) SIR of

200 mg/day is preferred as a conservative estimate of the average SIR (95 UCLM) for the toddler for use in HHRA's in Ontario and in the development of soil standards.

36) **Section 8.5.10 Assessment Verification.** The proponent has adopted some of the key assumptions of the MOE Rodney Street assessment (MOE, 2002) into its model as outlined in this section. The corresponding changes are reported in Table 8-14 Ingestion/Dermal Hazard Quotients for Nickel. Details of the changes adopted for use and additional model assumptions are required to indicate how each of the parameters was modified by the proponent. The analysis was not reproducible given the supplied information. Detailed model inputs and or modifications may also be required. Furthermore, confidence in the proponent's assessment is limited as multiple variables (12) were simultaneously modified. Preferably a percentage change in HQ should be indicated, first for each modified variable before combining of variables. Additionally, site-specific variables from the MOE 2002 report should be incorporated, whereas, the receptor characteristics should be obtained from the MOE 2009 Brownfields rationale document where available.

Risk-Based Soil Concentrations (RBSC)

37) **9.1 Derivation of RBSCs.** Many of the concerns outlined in this memo have not been satisfactorily resolved and are likely to influence the recommended RBSC's for the CoC's. As a result, MOE will not provide final comments on the derivation of the RBSC until the concerns appropriate to this issue have been resolved. The proponent requests a RBSC of 20,000 mg/kg for Ni; however, MOE is not confident that the proposed level will be protective of human health for the citizens of Port Colborne. Furthermore, many of the considerations of the RBSC rely upon risk management, thus a broader/general Ministry approach is warranted. MOE offers the following comments in the interim to facilitate this review:
- The proponent has not provided the Hazard Quotient or Cancer Risk associated with the determined RBSCs. This key information should be incorporated into the report and communicated in the executive summary.
- The proponent should indicate that not all exposures have been qualitatively accounted for in the HHRA; specifically, the omission of consumer products should be mentioned.
- The decision to not derive a RBSC for Co, Cu, and As has resulted in the stated objective of the report not being satisfied.

Additional discussion with the Ministry is anticipated.

Part B: Proponent's Responses to Previous Comments Made by MOE (September 26, 2007)

Part Two: Responses to Ontario Ministry of the Environment's Comments - for tracking of responses, blocks within tables have been sequentially numbered. Responses and clarifications are provided as groupings with additional sub- related comments made. Where appropriate, emphasis on the Part A new MOE comments are highlighted. For the most part, Part A of this review, above, addresses ongoing MOE concerns.

Comments 1 and 2 (Preamble)
Responses are acknowledged. While the application of O.Reg 153/04 as mentioned, to the Port Colborne community-based risk assessment process, is more of a legal issue and outside the context of this review, from a Human Health perspective the regulation, as mended (2009), provide the proponent with MOE's expectation of scientifically acceptable methodology and criteria (e.g. TRV's and receptor characteristics) that the Ministry prefers to be used in an HHRA or in the development of soil criteria. These criteria have been used in the assessment of the submitted HHRA.

Comments 3, through 12 (Soil and dust in vitro extraction issues)
The proponent has addressed the concerns by providing a weight of evidence evaluation for the determination of the oral bioavailability adjustment (ROB) factor, Part A Comment 17, 18 and 19 apply.

Additionally

> Comment 7
> Response is partially supported. There are many factors that may contribute to differences in oral bioavailability between soil and house hold dust that can be attributed to facility emission. Forefront in this consideration is the influence of particle size on bioavailability, that is the fraction which is likely to enter through aerial deposition in the house from outdoors and is likely a smaller size fraction then that which deposits outdoors. It is not uncommon to observe higher bioavailability adjustments for co-localized dust than soil, likely attributable to particle size differences. The lack of dust sampling remains an outstanding limitation of the HHRA, Part A Comment 7 applies.
>
> Comments 9 and 10
> The response does not address the statistical limitations or methodology used to assess the data.
>
> Comments 11
> Response is acknowledged. MOE's comment should have clarified that it is only when the in vitro data had been well supported by in vivo data it is considered a generally accepted and validated method. This would not preclude in vitro data in of its self invalid, but does highlight a significant limitation of the information provided.

Comments 13, 14, and 15 (Inhalation cancer risk factor for Nickel)
The proponent has made modifications to the inhalation cancer hazard assessment for Ni. Part A Comment 15 applies.

Comments 16, through 22 (Assessment of Soil and other media exposure point concentrations in the context of CBRA)
The proponent has addressed the concerns by providing an assessment of the maximally exposed individuals, however, MOE has identified concerns with the proponent's

analysis, and has recommended additional criteria to be assessed. Part A Comments 5, 6, 28, 29 and 30 apply.

Additionally,

Comment18

The response by the proponent is not supported. While extensive soil sampling has occurred in the highest impacted area, the uncertainties in other zones or in other media have introduced limitations and uncertainties in the assessment. Part A Comments 2, 5, 6, 7, 9, and 28 apply.

Comment 23 (Proposed SSTL exceed soil maximum for each zone)
The proponent has provided a risk based soil concentration for Nickel of 20,000 mg/kg. see Comment 37.

Comments 24 through 28 (Soil Dermal Absorption Adjustment)
The response is acknowledged, additional clarification is required see Part A Comment 34.

Comments 29 and 30 (Intake of nickel form supermarket food issues)
The proponent has provided additional rationale to support the use of daily dietary intake method 2 for use in the estimation of doses and risks for the HHRA. The use of method 2, by larger food category is assumed to be dependant on the combination of mean data for each food item. Given the lack of food items sampled by the proponent, the justification of using mean data is not warranted; the statistical procedure as outlined in Appendix 4, should be used for each food item. Additional clarity and justification is required.

Comment 31 (Oral Nickel RfD Issue)
See Part A Comment 14.

Comment 32 (Requirements for both CTE and RMA assessments)
The response is reasonable and no further response is required.

Comment 33 (Arsenic assessment issues)
The response is not supported, a quantitative assessment is requested see Part A Comment 21 and 25.

Comments 34 to 39 (Subtraction of background from lifetime risk calculation).
The response is not acceptable. Part A Comment 23 apply.
Additionally

Comments 35 and 37

The response is provisionally acceptable, contingent on the proponent clearly indicating the HQ or ILCR that the determined RBSC represents. Part A Comment 37 applies.

Comment 39

The response is not accepted.

Comment 40 (Surface soil depth issue)
The response is reasonable and no further response is required.

Comment 41 (Exclusion of woodlot soil data)
The response is accepted, clarification should be gained by addressing site characterization concerns Part A Comment 2.

Comment 42 (Soil ingestion rate)
The response is acknowledged, the soil ingestion rates of 100 mg/day and 400 mg/day published by the US EPA have been used in the final report. Part A Comment 20 and 37 apply.

Comment 43 (Soil and dust in vivo bioavailability issue)
The response is not acceptable. Part A Comment 17, 18 and 19 on the weight of evidence to support the ROB apply.

Comment 44 (Soil CoC speciation issues)
The response is acknowledged.

Comment 45
The response is accepted; however, the proponent should organize the material such that it can be readily located. The reviewer was forced to search all disks to find the attachment as referenced "*Attachment C Electronic copy of referenced reports*" does not indicate the location of the material.

Comment 46 (Model sensitivity)
The response is not acceptable. The proponent has been requested to conduct additional sensitivity and/or uncertainty analysis to address the MOE concerns; Part A Comments 5, 6, 7, 18 and 37 apply.

Comment 47 (Use of chronic TRV to calculate SSTL)
The response is reasonable and no further response is required.

Comment 48 (Adjustment of cancer risks in early life stages)
The response is reasonable and no further response is required.

Comment 49 (SSTL Calculation)
The response is provisionally acceptable contingent on the proponent including the "*Hand Calculation of RBSC for Nickel*" as an appendix of the main report versus an appendix of the Stantec Consulting Ltd. draft report "*Responses to PLC consultants report Human Health Risk Assessment Port Colborne, Ontario*" dated February 23, 2010.

Comment 50 (Clarity and errors/discrepancies)
The response is reasonable and no further response is required.

Comment 51 (Air data)
The response is acknowledged, additional clarification is requested (Part A Comment 29).

Comment 52 (use of adjusted air concentrations to assess inhalation risks)
The response is reasonable and no further response is required.

Comment 53
The response is reasonable and no further response is required.

Comment 54
The response is reasonable and no further response is required.

Comment 55 (Infant diet exposures)
The response is reasonable and no further response is required.

Comment 56 (Potential effects of mixtures and cumulative effects)
The response is reasonable and no further response is required.

Comment 57 (Attachment 1)
The comment and responses have been addressed above, and no further response is required.