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May 19, 2016

MEMORANDUM

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RE: Comments on Vale's Responses to previous MOECC comments on the Port
Colborne Community Based Risk Assessment

At the request of the Niagara District Office, we have reviewed the most recent submission from Vale Canada Limited (Vale) on the Port Colborne Community Based Risk Assessment (CBRA). This report titled "Port Colborne Community-Based Risk Assessment 2014 Update Report" dated September 12, 2014 was prepared by Stantec Consulting Limited (Stantec) to revise the CBRA to address previous comments provided by the Ministry of the Environment and Climate Change (MOECC or the ministry, and formerly MOE). However, a complete submission was not provided to the ministry for review until March 3, 2015. Review comments on the revised Port Colborne Community Based Risk Assessment report are provided in a separate memorandum dated May 17, 2016.

The purpose of this memorandum is to provide comments to Vale's responses to our previous comments provided by the ministry to Vale in May 2011 (letter to Mrs. Maria Bellantino Perco, Senior Specialist, Environment, Vale from Camilo Marinez, Coordinator, Community Based Risk Assessment, MOECC). To avoid duplication, only comments that require a response from the ministry are provided. We do not repeat, or only provide a brief summary of, comments provided by the ministry under separate cover on the Port Colborne Community-Based Risk Assessment 2014 Update Report. We also follow the original comment numbering that was used when comments were originally provided on the previous CBRA reports. Our May 2011 comments and responses from Vale are included as part of the CBRA 2014 Update Report (Appendix 1A).

Section I. MOECC Review Comments on CBRA ERA-Crops Studies

Global Comments

1. **Global Comment 1. Calculation of assessment endpoints from the 2000 Greenhouse Study data.** The Ministry acknowledges that there were shortcomings to the JW 2000 studies, but also recognizes these studies were included in the Port Colborne CBRA Crops report and that the results from these studies have some validity.
2. **Global Comment 2. Were the objectives of the Crop Studies met?** The Ministry does not regard the CBRA Crop studies as definitive studies and does not agree that information from other Port Colborne crop studies was to be used simply as a way of validating the Site Specific Threshold Levels (SSTL's) developed through the CBRA Crop Studies. The Ministry expected new SSTLs to be developed based on "the body of literature spanning 20 years" and the CBRA studies.
3. **Global Comment 4. Appropriateness of the soils used in the studies.** The response does not address the question of whether the use of woodlot or railway right-of-way soil is valid in an agricultural soil study.
4. **Global Comment 8. Structure of the Report.** The ministry accepts that there are different ways of structuring reports.
5. **Comment 11. Volume I – Page 1-3.** The ministry was not suggesting that the purpose of the study had not been given anywhere in the report, but rather that the purpose of the study should be included in the section entitled "Study Purpose".
6. **Comment 14. Volume I – Page 1-14.** The response is accepted. Here and elsewhere, the ministry notes that in many of the responses, such as this one, the statement is made that since the report was issued as "final" it cannot be changed. The ministry acknowledges that it may not be necessary to reissue a report for minor changes, but it may be necessary to issue errata sheets that highlight major changes/errors in the Crops reports (and the Ecological Risk Assessment for the Natural Environment (ERA-NE) and Human Health Risk Assessment (HHRA) reports). It should not be necessary to review the comment/response section in order to be made aware of errors in the original reports.
7. **Comment 16. Volume I – Page 1-16.** This section is titled Agricultural Setting and one would expect a table like Table 1-2 to show the percent of the region in agricultural production and also show that "x" percent of Niagara Region cropland is in corn, "y" percent to be in soybean and perhaps "z" percent in oats, which would back up the visual

survey. It is not clear why the variation in yield from year to year is given in this table when this is never related to the results of the crop studies.

8. **Comment 18. Volume I – Page 1-18.** The response is partially accepted. In the CBRA Crop Report, the MOE criteria for nickel in soil should not have been portrayed as unrealistic for Port Colborne soils but rather the emphasis should have been on the factors in Port Colborne soils that may make the nickel less available or less toxic to agricultural crops.
9. **Comment 21. Volume I – Page 2-2.** The response is accepted in that the determination of site-specific toxicological thresholds for the various COCs was one of the key objectives of the Year 2000 work.
10. **Comment 26. Volume I – Page 2-19.** The response is partially accepted. The volume of soil is 6.5 L for the Treepot versus 11.4 L for the Classic 1200 pot.
11. **Comment 27. Volume I – Page 2-21.** The response is accepted. However, it would have been preferable to have the low, medium and high designations consistent among soil types.
12. **Comment 34. Volume I – Page 2-53.** The response is accepted in that soil pH has an impact on metal and nutrient bioavailability. However, it is not clear that, in this situation, soil pH was the most crucial soil characteristic.
13. **Comment 36. Volume I – Page 3-11.** The response is accepted. It is understood that varieties change and that the same variety is not always available. The important point is not that both varieties are recommended for the area but whether the response to metals differs among varieties.
14. **Comment 42. Volume I – Page 3-33.** As stated in the CBRA, the objective of the crop studies 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. As stated previously, yield is critical to anyone growing a crop, whether in Port Colborne or not, and a reduction of yield is an unacceptable risk. While dose-response relationships are of interest, of key importance is that the research and conclusions are relevant to the agricultural community in the Port Colborne area. Therefore, these studies were not simply to look at dose-response relationships under specified growth conditions. If this were the case, there would be no need to conduct Port Colborne based studies and the CBRA could have simply referred to the scientific literature.
15. **Comment 43. Volume I – Page 3-40.** The response is accepted in that Mn deficiency may be a factor affecting growth and that Mn deficiency is not more important than COC toxicity.
16. **Comment 47. Volume I – Page 3-50.** The response is partially accepted. While “increased susceptibility” to increasing COC concentrations in the Engineered Field Plot (EFP) plants may be a valid interpretation of the data, there is little evidence that the EFP plants were more stressed than the greenhouse plants.

17. **Comment 52. Volume I – Page 4-4 to 4-6.** The correct OTR98 are as follows: copper = 41 ug/g (rural) and 65 ug/g (urban), cobalt = 16 ug/g (rural) and 17 ug/g (urban), and arsenic = 11 ug/g (rural) and 17 ug/g (urban).
18. **Comment 53. Volume I – Page 4-19.** If the Year 2000 experiments were to “provide insights to improve the experimental design of the Year 2001 Field and Greenhouse Trials”, it is difficult to understand why for the Year 2001 studies there was a complete change in researchers, location, soils used, and overall experimental approach.
19. **Comment 54. Volume I – Page 4-27.** The response is accepted but as a difference of opinion.
20. **Comment 55. Volume I – Page 4-34.** The ministry considers the lack of root data as a weakness in this research.
21. **Comment 58. Volume I – Page 5-4.** To clarify, the ministry did not think that goldenrod was randomly selected, but the reason given in the CBRA Crops Report for the selection of this plant was that it was the conspicuous floral element common to the chosen sites. This is likely true in the late summer and early autumn but it does not make it necessarily the best species to choose nor does it make it the most appropriate species to compare with crop plants (perennial versus annual, dicot versus monocot, metal tolerant versus metal sensitive). Also, the analysis of the whole plant means the metal uptake/tissue concentration data is of limited value when assessing plant tissue metal concentrations and uptake into crop plants.
22. **Comment 68. Volume II – Section 1 Page 11.** Roots are an important endpoint in plant toxicity assessment and if the emphasis was on plant parts of economic importance, why was yield not an endpoint.
23. **Comment 69. Volume II – Section 4 Page 6.** The response is not accepted. The ministry does not consider the EC25 and PNEC values derived from oats grown in the 2001 Greenhouse Trial to be protective of crops grown in the field in Port Colborne COC-impacted organic soils.
24. **Comment 70. Volume II – Section 4 Page 10.** The response is not accepted. Without supporting data it cannot be assumed that insect infestations will affect the outcome of a study in a certain way.

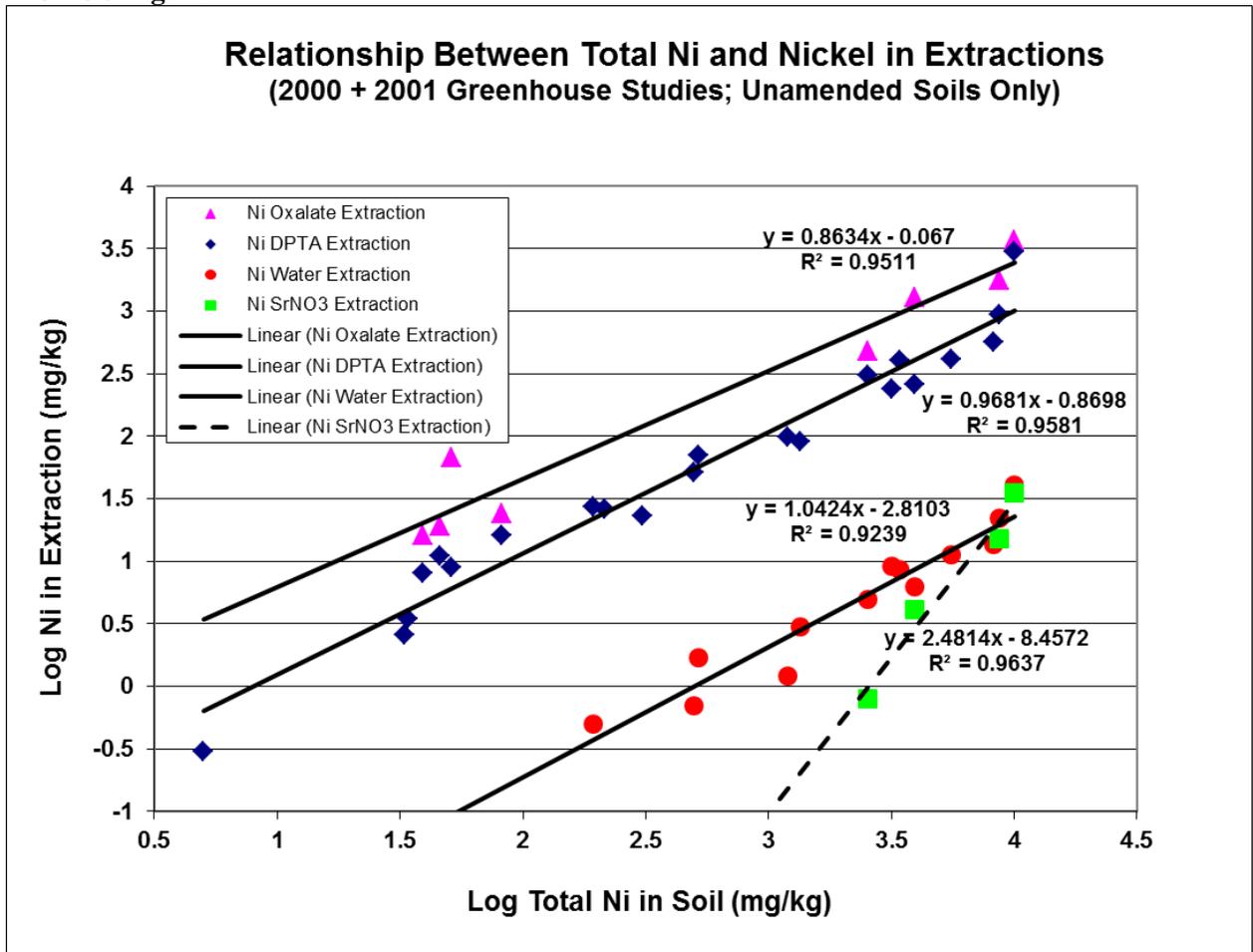
Section II. MOECC Review Comments on CBRA ERA-Natural Environment

25. **Summary of Review Comments.** The original comment provided a summary overview of ministry concerns with the ERA-NE report. The response provided is relevant for all 3 risk assessment reports and provides a summary from Vale and their consultant’s point of view on the CBRA process for this site and the reason for a CBRA Update report instead of a revised CBRA report. A few clarifying comments:
 - a. Ministry staff participated as members of the Technical subcommittee of the Public Liaison Committee (PLC) as a scientific resource only.
 - b. The final CBRA report should be able to withstand scientific scrutiny from anyone qualified to review risk assessments; not just those involved in the report preparation.

- c. It should be noted that the ministry did not receive a complete submission from Vale of this 2014 CBRA update report until March 3, 2015.
26. **Major Comment 1.** Overall, information provided in Chapter 2 - Site characterization and Section 4.2.2 has significantly improved the presentation of the sampling design and site characterization. The ministry agrees that focusing on the primary study area will address those areas where elevated risks are expected. However, the response provided only addresses uneven sampling in the woodlots. Information provided in Figures 4.B-1a to 4.B-7b (provided separately as hardcopy with the CBRA update report) graphically illustrates where samples were collected and provides information on if the sample was collected from a field or woodlot and if the soil was clay, organic, or unknown. These figures clearly illustrate when the number of sample sites in the primary area were well characterized (e.g., 25 sites for earthworms), adequately characterized (e.g., 7 sites for frogs and tadpoles, 6 sites for maple sap, 6 sites for maple leaf, 11 sites for insects) or poorly characterized (1 site for maple keys, 2 sites for meadow voles). Please ensure that the CBRA update report includes copies of these 14 figures.
27. **Major Comment 2.** The integration report may require additional soil samples collected from woodlots #1 and #2 to ensure proper site characterization. Currently only 2 woodlots have been adequately characterized (#3 and #7).
28. **Major Comment 5.** The new surface water data is limited to the Wignell and Beaverdams drains and from one sampling event (Oct 2013). It is not acceptable to ignore the previous water quality information when evaluating risks especially since the concentrations of COCs from the 2013 water quality samples are much lower than previous samples.
29. **Major Comment 7.** Earthworms have not been properly assessed in this revised CBRA. The site-specific data has been replaced by generic models used to assess plants and invertebrates as part of the Brownfields model.
30. **Major Comment 8.** Reviewer agrees that the analysis of deviance approach used in the previous version of this CBRA report was unconventional and not useful for developing a dose-response relationship.
31. **Major Comment 9.** The response is not accepted as it does not address the original comment. Even with the revised approach used in the CBRA update report; this information could have been presented as requested.
32. **Major Comment 10.** Section 4.2.6.1. The revised approach no longer addresses risks from Ni exposure to earthworms separately so no TRV is provided in the update report. This is also a clear example of how errors made in the previous “final” CBRA report remain uncorrected unless an errata sheet is prepared (since the previous report is considered final and will not be revised).
33. **Major Comment 24.** The lack of toxicity and/or field data on these plants is a major limitation of the ERA-NE report and reviewer agrees with Vale that the results from the crop bioassays are an adequate surrogate for herbaceous vegetation. Note that the ministry has concerns with the goldenrod assessment as described in the comments on the Crops ERA.

34. **Major Comment 27.** The predictive power of the oxalate, DPTA, or water soil extractions are the same (r^2 ranges from 0.92 to 0.96) between log total Ni in the soil and log total Ni in the extraction (Figure MOECC 1). Higher amounts of Ni were measured in the oxalate and DPTA extractions (higher intercept value) but the slopes are similar so it really doesn't matter what soil extract was used; the relationship between the extracts and the tissue Ni concentration for these extractions will all have similar predictive power. This would likely be apparent in Figure 5-6 if the data was shown as a log-log plot.

MOECC Figure 1



35. **Major Comment 31.** As noted in our comments on the CBRA update report, additional information is required to support the TRVs used in the risk assessment.
36. **Major Comment 32.** It is not clear what bioavailability estimates were used in the updated assessment. Several bioavailability examples are provided in subsequent comments (20%, 34.5%, and 100%) but only one was apparently used in the risk calculations.
37. **Comment 34.** Since these are environmentally sensitive areas, some comment on expected risk (or lack of risk) from COCs in soil for these areas should be provided.

38. **Comment 35.** The limitations raised in this comment are still valid. See ministry comments on the updated CBRA ERA-NE that address remaining concerns.
39. **Comment 73.** It is not apparent that an uncertainty factor of 3 was applied to the TRV for evaluating risks to rare and/or endangered species in the updated risk assessment.
40. **Comment 87.** It is not apparent that risk calculations were also calculated using the maximum soil and tissue COC concentrations in the revised risk assessment.
41. **Comment 176.** No concern with clarification that the acceptable concentration of soil Ni for earthworms is 3,000 mg/kg. This value is the same as what would have been calculated from an HQ of 1 and is consistent with the approach that was used for copper and arsenic.
42. **Comment 179.** The revised Table 8-9 shows significant effects at 50% soil dilution and frank toxic effects at 80% and 100% soil. Total COC concentrations for these treatments (% contaminated soil) should be provided as well (see comment 235 below).
43. **Comment 189.** It is apparent that there were limitations in data quality and/or data gaps as a result of the aggressive timeline and that this did influence the overall conclusions of the risk assessment. However, sufficient information is available to address some of these limitations (e.g., use of crops studies to assess herbaceous plants in woodlots). Otherwise, they remain a source of uncertainty that needs to be properly considered when establishing SSTL's (e.g., lack of robust information on decomposition processes in soil).
44. **Comments 223 to 234.** These responses are acceptable and highlight that there is uncertainty in the leaf litter studies estimating decomposition processes and that slower decomposition was observed in the Reuter Road woodlots (woodlots #16-18 from the numbering system used in the consultant's report).
45. **Comment 235.** The requested concentration data can be calculated and should be included in the update report as part of the recommended re-analysis of the earthworm information.

Section III. MOECC Review Comments on Vale CBRA HHRA

The ministry has numerous concerns with the human health risk assessment report of the updated CBRA report (2014) that are expected to affect the risk characterization of the compounds of concern (COCs) in Port Colborne soils and the overall conclusions of the risk assessment. As noted in our comments on the updated CBRA report provided separately, we have focused our comments on Ni since Ni levels in residential areas are the most significantly elevated above background levels and human health based soil criteria. Comments for other COCs namely Copper (Cu), Cobalt (Co) and Arsenic (As) may not be fully addressed as part of this review. Any risk management activities required to address elevated Ni contamination in soil are anticipated to also address the other metals of concern.

The following represents the MOECC comments on the Stantec/Vale responses presented in Appendix 3A: COMMENTS FROM THE MOE AND RESPONSES (dated September 12, 2014) of the updated report in 3 Sections:

- Section A: Response to MOE Comments on Original HHRA (PART A) (Comments issued May 11, 2011).
- Section B: Response to MOE Comments on Original HHRA (PART B) (Comments issued September 26, 2007 and May 11, 2011).
- Section C: Response to MOE Summary Comments on the Original HHRA (Comments issued June 22, 2011).

Section A: Response to MOE Comments on Original HHRA (MOE comments issued May 11, 2011)

46. **Comment 1.** For increased transparency, a table indicating the difference between the original MOE Table 'A' Guidelines (1996) and the updated MOE Table 2 Standards (O. Reg. 153/04, 2011) should be added to the CBRA update report. For example the Table 'A' guideline for Ni was 200 mg/kg and has been revised to 100 mg/kg.
47. **Comment 2.** The newly provided information has added clarity to the source and traceability of the soil data. The number of HHRA zones has also been reduced from 6 to 2 zones that would result in an increase in the sample size for some land use categories. Although land use and soil concentrations were not independently verified by the reviewer, it is noted that the response indicated that maximum measured values within each zone were selected. The response also indicated that this was considered a conservative measure, but this assumption has not been substantiated. The use of a maximum concentration is recommended by the ministry when there is insufficient site-specific information, thus it is not necessarily a conservative assumption. As originally requested, a data gap analysis would serve as a means to provide some reassurance of this assumption and increase confidence that risk were not underestimated.
48. **Comment 3.** The response indicated that toxicity reference values (TRVs) are used instead of ambient air quality criteria (AAQC) in the updated report. Although this addresses the interpretation of the chronic data, the staged farming activities are still being compared to AAQCs (Section 2.9.2). As indicated in the original comment, TRVs are preferentially recommended for use in risk assessments than AAQCs. As a consequence, the conclusions of the farming activity assessment should be placed within this context. In addition, the potential for short-term effects should be evaluated for farming activities based on available acute based TRVs.

In order to understand the potential risks associated with acute Ni exposure from farming activities, the following analysis was conducted by the reviewer.

- a. The acute based TRV from the Texas Commission on Environmental Quality (TCEQ, 2011) was used¹. TCEQ has set an acute reference value (ReV) of 1.1 $\mu\text{g}/\text{m}^3$ for Ni and inorganic Ni compounds. This TRV is based on the study by Cirila et al. (1985)² that observed respiratory effects in 12 metal plating factory workers with occupational asthma. Subjects were exposed for 30 minutes in a chamber to 300 $\mu\text{g}/\text{m}^3$ of Ni sulphate hexahydrate (equivalent to 67 $\mu\text{g}/\text{m}^3$). Exposure resulted in >15% decrease in the forced expiratory volume (FEV_1). The effect was considered to be significant bronchial constriction, and was considered as the Lowest Observed Adverse Effect Level (LOAEL). The air concentration of 67 $\mu\text{g}/\text{m}^3$ was then extrapolated to 1 hour (33.5 $\mu\text{g}/\text{m}^3$), and a total Uncertainty Factor (UF) of 30 (10 for using a LOAEL, and 3 for using an incomplete database) was included in the derivation of Texas' ReV of 1.1 $\mu\text{g}/\text{m}^3$.
- b. The acute exposure assumptions/data were as follows:
 - i. The reported data is based on 24 hour sampling regime of particulate matter (i.e., TSP, PM10 or PM2.5); however, it is reasonable to assume that the majority of the soil re-entrainment would occur primarily during the duration of farming activity. Depending on the activity (ploughing, disking or harrowing), this could vary between 5 to 6 hours. As a consequence, the potential health effects associated with short-term exposures duration akin to the farming activity length can be directly compared to the acute TRV as a reasonable worst case scenario. Ideally, shorter term exposure data of 1 hour or less would be preferential for interpretation.
 - ii. As the adverse effect is associated with a change in lung function, the respirable fraction (particle size less than 10 micrometer (<10 μm)) are used in the calculation of Hazard Quotients (HQ).
 - iii. Reported maximum Ni air concentrations based on a 24 hour monitor sampling regime were obtained from Table 17: Summary of the Ambient Air Monitoring Results in the Vicinity of Farming Activities (Volume IV, Appendix 11 pp. 27).
 - iv. Duration of agriculture activities ($\mu\text{g}/\text{m}^3$) were obtained from Table 2: Schedule for the Ambient Air Monitoring Program in the Vicinity of Farming (Volume IV, Appendix 11 pp. 11).

¹ Texas Commission on Environmental Quality (TCEQ), Toxicology Division. 2011. Development support document, final: Nickel and inorganic nickel compounds. CAS registry numbers: Nickel: 7440-02-0, nickel sulfate: 7786-81-4, nickel subsulfide: 12035-72-2, nickel oxide: 1313-99-1, nickel chloride: 7718-54-9)

² Cirila, A.M., F Bernabeo, and F Ottoboni. 1985. Nickel induced occupational asthma: Immunological and clinical aspects. In *Progress in Nickel Toxicology*, edited by S. S. Brown and F. W. Sunderman. Boston Blackwell Scientific Publications

- c. Based on the above exposure assumptions, the following Hazard Quotients were determined:

Activity	Size Fraction	Reported Max 24 hour Ni air concentration ($\mu\text{g}/\text{m}^3$)	Duration of agriculture activity ($\mu\text{g}/\text{m}^3$)	Hazard Quotient (HQ)
Ploughing	TSP*	0.11	5 hrs, 15 min	-
	PM ₁₀	0.04		0.04
	PM _{2.5}	0.04		0.04
Disking	TSP*	0.55	5 hrs, 50 min	-
	PM ₁₀	0.16		0.15
	PM _{2.5}	0.11		0.10
Harrowing	TSP*	1.38	6 hrs	-
	PM ₁₀	0.89		0.81
	PM _{2.5}	0.30		0.27

*TSP values were not calculated.

$$\text{HQ} = [\text{Max Ni}] / [\text{TRV } (1.1 \mu\text{g}/\text{m}^3)]$$

Therefore, based on these assumptions, and using the available monitored air concentrations, it appears that there are no concerns for acute inhalation exposure from farming activities with the following caveats:

- i. The reported air concentrations are representative of reasonable worst case scenario, inclusive of monitoring locations and site conditions (e.g. dry summer).
- ii. The analysis is limited to the potential for off-site impact and has not assessed the potential exposure to the farmer.

Furthermore, as the data is not representative of long term air concentrations that may occur as a result of soil re-entrainment especially during bare soil conditions (without green cover), no conclusions were made about the potential for long term effects to off-site receptors in the vicinity of the field. However, it is noted that CCME 2015³ has recently developed soil criteria guidelines for commercial (310 mg/kg) and industrial (1000 mg/kg) land uses that considers soil particle inhalation at a 1×10^{-6} cancer risk level based on generic assumptions. It is noted that the agricultural test plot soil Ni concentrations reported in Table 7 by depth at 5,920 mg/kg (0-5 cm), 2,260 mg/kg (5-10 cm), 3,170 mg/kg (10-15 cm), 2,550 mg/kg (15-20 cm), 91 mg/kg (20-25 cm) (Volume IV, Appendix 11 pp. 17) are all above these generic guidelines. In the absence of longer term monitoring in proximity to agriculture land with elevated soil Ni, and in consideration of generic non-site-specific CCME soil criteria based on soil re-entrainment, best practices should be considered to minimize soil re-entrainment.

49. **Comment 4.** The rationale explaining the inconsistency between the MOE data and Jacques Whitford (JW) data (presented in the report Appendix 3A, pp1.7) in the air Ni speciation information is accepted. However, the number of air samples is limited to a few samples obtained by the MOE from late summer and winter, to those obtained from JW during late dry summer. These few samples are not representative of a time-course study that represents multi-seasons or environmental conditions to fully characterize Ni

³ Canadian Council of Minister of the Environment. 2015. Scientific Supporting Document for Canadian Soil Quality Guidelines for Nickel: Environmental and Human Health

speciation in air over an annual period. However, the need to fully characterize Ni speciation in air is diminished by the use of an acceptable cancer inhalation unit risk based on the predominance of nickel oxide species (see response to comment #15). No further action is anticipated.

50. **Comment 5.** Response is reasonable. However, the exposure point concentrations associated with drinking water concentrations have not been independently confirmed by the reviewer.
51. **Comment 7.** Responses are not accepted. The following comments consider both the estimated ratio of outdoor soil to indoor dust and the lack of information on dust bioaccessibility pertaining to the assessment of Ni.

As noted in our comments on the update CBRA report, the ministry has concerns with the Ni soil to indoor dust ratio of 0.2 used to estimate the contribution of outdoor soil to indoor dust. A summary of our concerns are as follows: (1) it was based on a limited number of paired samples with high Ni soil concentrations (n=6); (2) approximately 65% of the data has a soil to indoor dust ratio higher than the ratio of 0.2; and (3) it does not account for the variability across the distribution of the data. Overall, the ministry recommends a ratio of 0.2 could be considered an acceptable qualitative value for characterizing soil with Ni concentrations greater than 2,000 mg/kg. For soil concentrations less than 2,000 mg/kg, a re-calculated ratio of [Ni] indoor dust to [Ni] outdoor soil of 0.56 is supported. See Appendix D of the ministry's comments on the updated CBRA report for additional details.

The bioaccessibility estimate for dust in Appendix 3E (Section 1.4 ROB/Bioaccessibility in soil versus Bioaccessibility in Dust) addresses the lack of bioaccessibility or ROB data for dust. Herein, a discussion is presented to support the use of the soil bioaccessibility/ROB in the absence of bioaccessibility information of dust samples. In absence of dust bioaccessibility information, the use of soil bioaccessibility to approximate dust is reasonable. However, the assumption by Stantec (page 1.20) that this is a conservative assumption has not been substantiated. For example, a greater bioaccessibility is reported for As, Co and Cu and a lower bioaccessibility is reported for Ni dust in the Sudbury Soils Study (2008). However, the ministry notes that the bioaccessibility estimates in the Sudbury Soils Study (2008) were based on the 95th UCLM of 44 soil samples and 27 dust samples to support their conclusions. The lack of dust bioaccessibility information remains a significant data gap for the Port Colborne CBRA.

Finally, a change in the Oral TRV for Ni (See Appendix A of the ministry's comments on the update CBRA report) will change the HQs associated with this response.

52. **Comment 8.** Ministry agrees that it is reasonable that the maximum soil concentration remains the same for zone B (as the property with the maximum Ni concentrations was not remediated). The expected community exposure for zone B would be less than the maximum concentration as individuals would not be exposed to the maximum soil concentration all the time. For increased transparency, the potential impact on the soil exposure point concentration for residential properties (zone B) that underwent soil clean-up should be mentioned in the report as well. As noted previously, a change in the Oral TRV for Ni (see Appendix A of the ministry's comments on the update CBRA report) will change the HQs associated with this response.

53. **Comment 9.** Since the school was closed, the response is reasonable. However, as noted, a change in the Oral TRV for Ni (see Appendix A of the ministry's comments on the update CBRA report) will change the HQs associated with this response.
54. **Comment 10.** Response is not accepted. The responses indicates that only the 2 week period considered in the CBRA as vacation time outside of Port Colborne has been changed from the 98th percentile to a mean estimate. Whereas, the estimates for Ontario background zone E (local) and F (Ontario) have not been updated as requested. Without this information, the incremental increase in soil exposure and associated risks between someone living in Port Colborne versus background exposure for someone living elsewhere in Ontario has been inappropriately characterized, as outlined in the initial comment. The recommended change to the oral Ni TRV makes this comparison more important. As noted, a change in the Oral TRV for Ni (see Appendix A of the ministry's comments on the update CBRA report) will change the HQs associated with this response.
55. **Comment 11.** The use of the Arsenic Inhalation non-cancer TRV of 0.03 $\mu\text{g}/\text{m}^3$ is accepted.
56. **Comment 12.** The ministry has not conducted a review of the cobalt oral non-cancer TRV at this time. However, because nickel is the key metal of concern in the risk assessment, addressing MOECC comments and developing appropriate risk management actions with regard to nickel are anticipated to also address concerns with other metals including cobalt.
57. **Comment 13.** The ministry is reviewing the copper oral non-cancer TRV at this time and notes that other scientifically defensible oral TRVs for copper are available and may be better supported. However, because nickel is the key metal of concern in the risk assessment, addressing MOECC comments and developing appropriate risk management actions with regard to nickel are anticipated to also address concerns with other metals including copper.
58. **Comment 14.** Response is not accepted. The Ni Oral TRV of 20 $\mu\text{g}/\text{kg}\text{-bw}/\text{day}$ based on body weight changes is not supported by the ministry as the most sensitive endpoint to use in assessing oral Ni exposure. Instead, the MOECC supports a TRV of 11 $\mu\text{g}/\text{kg}\text{-bw}/\text{day}$ based on adverse reproductive and developmental effects applicable to the toddler life stage (see Appendix A of the ministry's comments on the update CBRA report).
59. **Comment 15.** Response is accepted. The Ni inhalation cancer TRV now only includes the cancer risk approach II based on Conard and Seilkop (2011)⁴. This approach considers that nickel oxide is the predominant nickel species in Port Colborne air (related to soil). The cancer unit risk of 0.51 ($\mu\text{g}/\text{m}^3$)⁻¹ is acceptable for the Port Colborne CBRA.
60. **Comment 16.** Response is accepted. The Ni inhalation non-cancer TRV of 0.06 $\mu\text{g}/\text{m}^3$ is accepted.

⁴ Conard, B.R. and S. K. Seilkop, 2011. Estimation of Incremental Unit Risks for Inhaled Nickel Subulfide and Nickel Oxide, Based on a Combination of Human and Animal Data. Human and Ecological Risk Assessment, 17: 892-905.

61. **Comments 17 & 18.** Responses are not accepted. The new bioaccessibility and bioavailability information and analysis has contributed greatly to our understanding of this important component of the CBRA. For Ni, the *in-vitro* bioaccessibility information is support by the ministry but not the *in-vivo* rat bioavailability data. Using *in-vitro* bioaccessibility estimates does not require assumptions to be made on absorption of Ni in humans or rats, or on adult versus children absorption rates. Rather *in-vitro* bioaccessibility provides an estimate of the soluble Ni that can be liberated from Port Colborne soils and it can be compared directly to the soluble form of Ni used in the oral Ni TRV. See Appendix C of the ministry's comments on the updated CBRA report for additional details.
62. **Comment 19.** New bioaccessibility estimates have been provided for As, Cu, and Co in the updated CBRA report. Since the focus of our review was on Ni, the ministry has not conducted a thorough review of the revised estimates and additional justification for their use may be required in the future. Given that the limited number of soil samples tested for Ni bioaccessibility ranged from 8 to 16 (depending on the soil type and COC), the 95th upper confidence limit of the mean (95th UCLM) is recommended as the central tendency estimate by the ministry instead of the mean value as currently used in the CBRA. Data should also be re-analyzed based on sample location as done by the ministry for Ni (see Appendix C of the ministry's comments on the updated CBRA report). However, as Ni is the key metal of concern in the risk assessment, addressing MOECC comments and developing appropriate risk management actions with regard to nickel are anticipated to also address concerns with these other COCs.
63. **Comment 20.** The incidental soil ingestion rate (SIR) is a key parameter used in the CBRA and in the determination of RBSCs. The report presents a rationale to support an alternative soil ingestion rate of 110 mg/day for the toddler (Appendix 3B: Changes in Input Assumptions and Data). In recognition of the uncertainty associated with this exposure characteristic, the SIR of 110 mg/day is considered reasonable as a Central Tendency Exposure (CTE) estimate whereas, the SIR of 200 mg/day is still considered as a Reasonable Maximum Exposure (RME) estimate. The ministry recommends that the RBSCs should be calculated with both the CTE and RME estimates to bracket risk management considerations where soil exposure should be limited. See Appendix E of the ministry's comments on the updated CBRA report for additional detail.
64. **Comment 21.** Response is not accepted. The report's overall conclusion "that residents of Port Colborne are not expected to be at greater risk of health effects due to exposure to arsenic than typical Ontario residents" appears to be taken from a total arsenic risk perspective and has not differentiated between organic vs inorganic As forms. Inorganic As, which is found in drinking water sources, is used for developing TRVs; it is considered as the toxic form of As in comparison to the organic species (predominately present in food) that are considered relatively non-toxic. It is recognized that estimates based on total As would tend to over-estimate risk, especially for dietary As exposures. This additional context to the potential risks from incremental arsenic exposure from As in soil should also be included in the analysis to increase the transparency of the report. The use of this approach also tends to minimize the added risk from soil As exposure and is an insufficient rationale for not developing a RBSC for As.

For example, the report indicates a minimal change in overall risk when soil is or is not accounted for in the risk predictions. For example, the ingestion/dermal contact HQ's can

be as high as 6.2 (with soil) to 6.1 (without soil) (Table 3-17 Non-carcinogenic risk estimates for ingestion/dermal contact with arsenic-toddler receptor) and the cancer risk can be as high as 1.3×10^{-3} (with soil) to 1.2×10^{-3} (without soil) (Table 3-18 Carcinogenic risk estimates for ingestion/dermal contact with arsenic). The report concludes that “no amount of soil remediation could reduce risk estimates to regulatory levels” i.e. either $HQ = 1$ or $ILCR = 1 \times 10^{-6}$, and is used as part of the rationale for not developing RBSCs for As (Section 3.12.4 Arsenic). While it is appropriate to characterize risk from soil within the context of total risk, this diminishes the added risk from soil exposure.

The report should clearly differentiate the incremental risks from soil exposure in Port Colborne to background soil zone E (local) and F (Ontario). Additional consideration of As and background soil exposure maybe required, however; as nickel is the key metal of concern in the risk assessment, addressing MOECC comments and developing appropriate risk management actions with regard to nickel are anticipated to also address concerns with other metals including arsenic. Additional verification pending identification of an acceptable RBSC for Ni may be required.

Please note that in the response to this comment, the proponent’s statement that “...no health effects for arsenic exposure are expected for residents of Port Colborne” is not supported. This should be clarified and more appropriately placed in context to total risk and risks from soil exposure, as done within the other sections of the report.

65. **Comment 25.** The comparison of air concentrations to the TRV is accepted. For As inhalation risk, the report relies on a more conservative cancer assessment by using a cancer based TRV [US EPA, 1998, $4.3 \text{ (mg/m}^3\text{)}^{-1}$] that is more stringent than used by the MOECC 2011 [WHO, 2000, $1.5 \text{ (mg/m}^3\text{)}^{-1}$].
66. **Comment 27.** The revised context for the urinary As studies in Chapter 3 of the updated report (2014) is accepted.
67. **Comment 28.** The use of “unrealistic” has been dropped when discussing the risks at the maximum residential soil level in the revised report (2014).
68. **Comment 29.** Based on a limited review of the air concentrations used in the CBRA (Section 7.5 Maximum Ambient Air Concentrations) the ministry has the following comments:
 - a. It is noted that the updated CBRA uses both measured and modelled air concentrations (from the previous 2007 HHRA) depending on the zone and COC (Section 3.5.5). For Zone B, the long term measured ambient air is used for Ni, Co and As, while modelled data is used for Cu. For Zone D, only modelled results were used.
 - b. Some air concentrations could not be independently verified by the ministry as there were differences between the CBRA report and the HHRA excel-based model that was provided to the Ministry for review. However, the difference in final risk estimates using these different values appear to be small and insignificant.
 - c. No response has been provided to the ministry’s request for clarification on the modelled air concentrations. As a consequence, we are unable to conduct a technical review of the modelled data. However, this should not impact the overall risk assessment as the updated CBRA used measured ambient air levels

for zone B. Use of this measured air data suggests that exposures to COCs in air are being appropriately accounted for and have not been underestimated given the nearby proximity of the monitoring station to this zone.

- d. For Ni, the CBRA has used a measured ambient air concentration of $20.4 \mu\text{g}/\text{m}^3$. This is reasonable from a community exposure perspective and has been characterized appropriately (see comments 15 and 16).
- e. For As, the CBRA used a predicted ambient air concentration of $0.002 \mu\text{g}/\text{m}^3$ [from the HHRA model] and carcinogenic risks were assessed using a cancer based TRV [US EPA, 1998, $4.3 (\text{mg}/\text{m}^3)^{-1}$] that is more stringent than the TRV used in the MOECC 2011 [WHO, 2000, $1.5 (\text{mg}/\text{m}^3)^{-1}$].
- f. For Cu and Co, the reported air concentrations are well below appropriate health benchmarks and are not considered further.

69. **Comment 30.** The ministry supports characterizing risks using the Ni inhalation cancer unit risk of $0.51 (\mu\text{g}/\text{m}^3)^{-1}$ by Conard and Seilkop (2011) for this CBRA. In the absence of additional information, the indoor air sample IAS 102 should remain as a sample for risk characterization, even though the report indicates that it is “unresolved”.
70. **Comment 31.** According to the response, the agriculture land use scenario has already considered the residential receptors; therefore, the original statement by the proponent that “exposure” and “potential risks” would not be expected to increase is correct. However, the ministry is concerned that this statement is potentially misleading as land use may change in the future (e.g., from agriculture to residential land use) resulting in higher exposure and potential risks. The statements by the proponent should be modified to reflect this consideration.
71. **Comment 32.** Response is not accepted. The ministry’s concern that site characterization is limited for some of the woodlots has not been addressed. In addition, changes to the proposed RBSCs are expected to change the perspective of this response. A recreational and/or trespasser scenario should also be considered for the woodlot areas.
72. **Comment 34.** The revised report now includes an expanded discussion which addresses: (1) soil Ni contact with skin and the fraction of Ni that is bioavailable and able to interact with the skin; (2) the permeability of Ni into and across skin layers; and (3) a toxicity threshold identifying the amount of Ni in soil that is predicted to result in an adverse dermatological reaction from direct contact with soil. This additional information has improved the discussion and overall understanding of Ni dermal toxicity for this CBRA. However, the ministry continues to have concerns with how Ni contact dermatitis was assessed in this CBRA, and with the calculated HQ presented in Table 3H.2. (Hazard Quotients Estimates for Nickel Contact Dermatitis Scenarios). As a result of these concerns and the inherent challenges in assessing the direct soil Ni contact dermatitis pathway, risks can only be roughly evaluated at the present time. Predicted risks from this pathway should be considered as part of the sensitivity analysis.

The analysis of the Ni direct soil contact assessment conducted by Stantec resulted in a $\text{HQ} < 1$ for most scenarios considered; only 2 scenarios had a $\text{HQ} = 1$ or greater (i.e., $\text{HQ} = 3$) and these were limited to the toddler playing in mud. The analysis of dermatitis in the CBRA follows the approach by Horowitz and Finley 1994⁵ and relies upon the weighted

⁵ Horowitz, S. B. and B.L. Finley, 1994. Setting health-protective soil concentrations for dermal contact allergens: a proposed methodology. *Regulatory Toxicology and Pharmacology* 19:31-47.

soil adherence factors developed in US EPA RAGS Part E (Supplemental Guidance for Dermal Risk Assessment, 2004)⁶ for various soil contact activities.

While the ministry doesn't have any concerns with the general approach used in the CBRA update report; there are limitations in the assessment of this pathway as follows:

- Stantec used a value of 0.835 $\mu\text{g}/\text{cm}^2$ to represent the direct contact elicitation threshold (i.e., the toxicity threshold for Ni in soil that results in a dermatological response, from Fischer et al., 2011⁷). This value represents an effects level equivalent to a 10% response rate of the tested Ni-sensitive subpopulation. In other words, 1 in 10 exposed individuals from this Ni-sensitive population had an adverse dermatological response at this Ni skin loading concentration. The ministry does not have any concerns with selecting this value as a point of departure based on the dose-response relationship identified in this study, but notes that standard risk assessment practices would include the incorporation of uncertainty factors to account for extrapolating from a LOEAL to a NOAEL and for intra-individual variability. Given the available information, a total uncertainty factor of at least 10 (3x for LOAEL to NOAEL and 3x for intra-individual variability) is suggested by the ministry as appropriate uncertainty factors. This would result in a direct contact elicitation threshold of 0.0835 $\mu\text{g}/\text{cm}^2$ for Ni-sensitized individuals. Given the uncertainty associated with extrapolating the results of this study to the general population, the examination of soil Ni contact dermatitis should consider the range of 0.0835 to 0.835 $\mu\text{g}/\text{cm}^2$ as lower and upper bound estimates.
- The lack of soil Ni dermal bioaccessibility data limits the reliable use of dermal absorption versus soil leachability (or dermal bioaccessibility) estimates. It appears that Stantec double counted the contribution of Ni from soil for this pathway. In their assessment, both an estimate of the leachability of Ni from soil (of 10.9%) as well as a dermal absorption rate (of 2.8%) was used (Appendix 3D: Changes in Approach for Derma Exposure). However, the assessment of this pathway only requires an estimate of Ni leaching from soil into sweat. As no Port Colborne soil samples have been tested using a sweat model to determine the leachability of Ni from soil, Stantec used the results from the limited intestinal phase bioaccessibility data (performed by ESG, 2002) as a conservative surrogate. Since this data is based on the average of only three soil samples representing each of the Fill, Clay and Organic soil types, the ministry believes they are limited as a conservative estimate of dermal bioaccessibility. However, in the absence of Port Colborne data using a more appropriate sweat model, the estimate of 10.9% is supported as an approximate value to use, and incorporates the considerations presented in Appendix 3D Section 1.1.2 Leachability of Nickel in Sweat.

⁶ US EPA, 2004. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human health evaluation manual, (part E: Supplemental guidance for dermal risk assessment): Final. (EPA/540/R/99/005). Washington, DC

⁷ Fischer, LA, T Menne, A Voelund, JD Johansen, 2011. "Can exposure limitations for well-known contact allergens be simplified? An analysis of dose-response patch test data." In: Contact Dermatitis, 64, 337-342.

In addition to the above, there is an inherent inability to accurately estimate the potential for direct soil contact as a result of variability in activity-specific soil adherence factors (AF). These area weight factors have been developed by US EPA (2004; see Exhibit 3-3) and selected examples were presented in Table 3H.1 of the CBRA report. However, it is important to recognize that for a given activity scenario, the soil AF can be quite variable and encompass a broad range of values. In fact, the difference between the geometric mean and the 95th percentile AFs for any one activity-specific soil AF can range up to 2 orders of magnitude. This presents a significant limitation in the ability to select and interpret scenarios representative of community exposures in any risk assessment; not just this CBRA. A further review of AFs is warranted.

In order to facilitate our review of the risk characterization for this exposure pathway, the following AFs have been selected by the ministry (using best professional judgment to represent typical and high-end (atypical) soil conditions and exposure scenarios) for the purpose of estimating and characterizing risk.

- For the typical scenario, 0.2 mg/cm² was selected as the loading concentration since it is slightly less than the 95th percentile AF for children playing at a day care center (0.3 mg/cm²) and similar to the 50th percentile AF for children playing in wet soil (0.2 mg/cm²) as recommended for a child resident (<1 to < 6 years old) and is consistent with a high-end mean contact rate (US EPA, 2004).
- For the high end or atypical scenario, 1.0 mg/cm² was selected as the loading concentration since it falls between the 95th percentile AF for children playing in dry soil (0.4 mg/cm²) and the 95th percentile AF for children playing in wet soil (3.3 mg/cm²) and is consistent with a high-end of activity contact rate (US EPA, 2004).

Based on the above considerations, the following soil Ni concentrations were determined for the lower and upper bound range for the dermatitis elicitation threshold (0.0835 and 0.0835 µg/cm²).

Sample Calculation (e.g. Typical Scenario upper bound):

$$\begin{aligned} \text{Soil } \left(\frac{mg_{Ni}}{kg_{Soil}} \right) &= \frac{TRV \left(\frac{\mu g_{Ni}}{cm^2} \right) \times \frac{1}{1000} \left(\frac{mg_{Ni}}{\mu g_{Ni}} \right)}{AF \frac{mg_{soil}}{cm^2} \times \frac{1}{1000000} \left(\frac{kg_{soil}}{mg_{soil}} \right) \times FRAC \text{ (unitless)}} \\ \text{Soil } \left(\frac{mg_{Ni}}{kg_{Soil}} \right) &= \frac{0.0000835 \left(\frac{mg_{Ni}}{cm^2} \right)}{0.2 \frac{mg_{soil}}{cm^2} \times \frac{1}{1000000} \left(\frac{kg_{soil}}{mg_{soil}} \right) \times 0.109} \\ &= 3830 \frac{mg_{Ni}}{kg_{soil}} \\ &= 4000 \frac{mg_{Ni}}{kg_{soil}} \text{ (rounded to 1 significant figure)} \end{aligned}$$

Where:

Soil = Soil concentration (mg_{Ni}/kg_{Soil})

TRV = Dermal Elicitation Threshold (Range 0.0835 and 0.835 µg/cm²)

AF = Soil Adherence Factor (Range 0.2 -1.0 mg/cm²)

CF = Conversion Factor 1/1,000,000 (kg_{soil}/mg_{soil})

FRAC = Fraction of Available Ni (Dermal Bioaccessibility- 10.9%)

The following range of soil concentrations were determined:

	Exposure Scenario	
	Typical	High End (Atypical)
Soil Nickel Concentration	4,000 – 40,000 mg/kg	800 – 8,000 mg/kg

Based on this assessment, and in specific context to Port Colborne soil conditions, soil Ni concentrations between 4,000 and 40,000 mg/kg encompass the range where there would be a low concern of Ni induced contact dermatitis for the Ni-sensitized subpopulation residing in Port Colborne. This is based on a general understanding that a Ni-sensitive subpopulation are not likely to react to Ni in soil under typical exposure conditions at concentrations below 4,000 mg/kg. However, risk is not entirely discounted since soil Ni concentrations between 800 and 8,000 mg/kg encompass the range where there would be a low concern of Ni induced contact dermatitis for high end estimates (under the atypical exposure scenario). Hence Ni concentrations greater than 800 mg/kg may elicit a reaction from direct contact to soil containing elevated levels of Ni.

73. **Comment 35.** Soil Pica: A revised approach for evaluating soil pica exposure is presented in Table 3-51: Selection of Scenarios for Further Evaluation in the Sensitivity Analysis. The CBRA report indicates that HQs of 0.81 and >1 were determined for Zone B and D respectively. However, it is not apparent what soil concentrations were evaluated for each zone and no sample calculation is provided to support the results. According to the response provided by Stantec for this comment, the following key assumptions rates were used: pica soil intake rate of 1,000 mg/day (per event, US EPA 2011⁸) and chronic Ni ingestion intake rate of 20 µg/kg-bw/day (from Ambrose et al., 1976⁹). However, for the assessment of acute toxicity, the TRVs based on the dermatological endpoint are typically dependent on single dose treatments; thus they may also be considered for acute exposure scenarios and are more justifiable than a chronic TRV of 20 µg/kg-bw/day. Therefore, the assessment of soil pica in this CBRA and the calculated HQs as presented in the sensitivity analysis are not supported by the ministry.

In order to facilitate our review of the risk characterization for soil pica, the following points of departure (POD) have been considered by the ministry to reflect the range of response rates for dermatitis in the Ni-sensitive population, from the low end of 1.1 µg/kg-bw/day, based on the BMDL₁₀ analysis by EFSA 2015¹⁰ to the high end of 12

⁸ US EPA, 2011. Exposure Factors Handbook, Office of Research and Development, National Center for Environmental Assessment. United States Environmental Protection Agency. September, 2011.

⁹ Ambrose AM, Larson PS, Borzelleca JF, Hennigar Jr GR. 1976. Long Term Toxicologic Assessment of Nickel in Rats and Dogs. J Food Sci Technol 13:181-187.

¹⁰ EFSA. 2015. Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water. EFSA Panel on Contaminants in the Food Chain (CONTAM), European Food and Safety Authority (EFSA), Parma, Italy. EFSA Journal 2015;13(2):4002.

µg/kg-bw/day based on Nielsen (1999)¹¹ wherein 9 out of 20 individuals experiences a flare-up of dermatitis (used by WHO 2005¹², see Appendix A of the ministry's comments on the updated CBRA report for additional details). Given the uncertainty associated with extrapolating the results of these studies to the general population, the potential of soil pica behaviour to elicit dermatitis could consider the range of 1.1 to 12 µg/ kg-bw/day, representing a lower and upper bound range.

Sample Calculation: (e.g. Upper bound for Fill Soil)

$$\begin{aligned} \text{Soil } \left(\frac{mgNi}{kg_{soil}} \right) &= \frac{TRV \left(\frac{\mu g Ni}{kg-bw/day} \right) \times \frac{1}{1000} \left(\frac{mgNi}{\mu gNi} \right) \times BW \text{ (toddler)}}{ROB \times SIR_{Pica} \left(\frac{kg_{soil}}{day} \right)} \\ \text{Soil } \left(\frac{mgNi}{kg_{soil}} \right) &= \frac{12 \left(\frac{\mu g Ni}{kg-bw/day} \right) \times \frac{1}{1000} \left(\frac{mgNi}{\mu gNi} \right) \times 16.5 \text{ kg-bw}}{0.21 \times 1 \times 10^{-2} \left(\frac{kg_{soil}}{day} \right)} \\ &= 943 \frac{mgNi}{kg_{soil}} \\ &= 900 \frac{mgNi}{kg_{soil}} \text{ (rounded to 1 significant figure)} \end{aligned}$$

Assuming:

Soil = Soil concentration ($mgNi/kg_{soil}$)

TRV = Dermatological TRVs (Range from 12 µg/kg-bw/day – POD Nielsen 1999, to 1.1 µg/kg-bw/day, POD based on EFSA 2015 analysis)

SIR_{pica} = Pica Soil Intake Rate (1.0 mg (per event) per day, US EPA 2011)

ROB = Bioaccessibility (Soil Type Dependent: Fill 0.21, Clay 0.15, Organic 0.32, See Appendix C of the ministry's comments on the updated CBRA report for additional details)

BW = Toddler Body Weight (16.5 kg)

¹¹ Nielsen GD, S oderberg U, J rgensen PJ, Templeton DM, Rasmussen SN, Andersen KE, Grandjean P. 1999. Absorption and Retention of Nickel from Drinking Water in Relation to Food Intake and Nickel Sensitivity. *Toxicol Appl Pharmacol* 154:67-75.

¹² WHO DW. 2005. Nickel in Drinking-Water – Background Document for Development of WHO Guidelines for Drinking Water Quality. World Health Organization. Geneva, Switzerland. WHO/SDE/WSH/05.08/55.

The following range of soil concentrations were determined based on the 3 soil types:

Soil Type	Range [Ni soil]
Fill	90 -900 mg/kg
Clay	100 -1,000 mg/kg
Organic	60 - 600 mg/kg

Based on this assessment of soil pica and in specific context to Port Colborne soil conditions, soil Ni concentrations between 60-1,000 mg/kg encompass the range where there would be a low concern of Ni induced dermatitis for the Ni-sensitized subpopulation that exhibit soil pica behaviour.

74. **Comment 36.** The response is acknowledged. However, the comment is still valid as the ministry was unable to reproduce the assessment verification exercise. Regardless, addressing the comment is no longer relevant in the revised CBRA. Furthermore, it is recognized that the proponent is not obligated to follow the Brownfield assumptions, especially when supported by an updated science approach. Overall, we continue to recommend that when parameters differ significantly from the Brownfield generic assumptions, that these differences be highlighted and justified to strengthen the CBRA report. No additional follow-up is required.
75. **Comment 37.** The responses are not accepted. The RBSCs for Ni have been reviewed and are not supported by the ministry. As Ni is the key metal of concern in the risk assessment, addressing MOECC comments and developing appropriate risk management actions with regard to nickel are anticipated to also address concerns with other COCs.

Response to MOE Comments on Original HHRA (PART B) (MOE original comments dated September 26, 2007)

Responses to these comments have been either reasonably addressed or are now being addressed through Section A comments, with the exception of 2 comments pertaining to dietary exposure estimates as follows:

76. **Comments 29 and 30.** For the dietary exposure estimate, the revised CBRA report contains a new analysis using both supermarket and/or backyard garden produce exposure. Based on the ministry's review of the CBRA report, the Ni dietary estimate is not supported (See Appendix C of the ministry's comments on the updated CBRA report for additional details).

Response to MOE Summary Comments on the Original HHRA (MOE comments dated June 22, 2011).

Responses to these comments have been addressed in Section A comments.