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MEMORANDUM

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RE: Review Comments on the Revised Port Colborne Community Based Risk Assessment

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As requested by 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.

Our involvement with this file started in August 2010 when Vale submitted a series of “final” CBRA reports and Addenda Reports on the Human Health Risk Assessment, the Crops Study, and the Ecological Risk Assessment for the Natural Environment. These reports were prepared by Jacques Whitford Limited or Stantec and ranged in date from September 2004 to February 2010 (list of reports provided below). Even though the CBRA started in 2000, the ministry reviewers were intentionally held “in reserve” in order to conduct an independent review. The overall goal of our review is to ensure that the CBRA has been conducted in accordance with appropriate risk assessment methodologies and practices, that risk has been properly characterized, and that any proposed risk based soil concentrations are appropriate.

We previously provided detailed and comprehensive comments to Vale on the previous CBRA reports in a May 2011 letter to Mrs. Maria Bellantino Perco (Senior Specialist, Environment, Vale) from Camilo Marinez (Coordinator, Community Based Risk Assessment, MOECC). Because of the nature and extent of our comments, and the extensive public review and consultation process that had already occurred, we met with Vale and their consultants on numerous occasions between June 2011 and November 2013 to help Vale understand our comments and resolve outstanding concerns. Our May 2011 comments and responses from Vale are included as part of the CBRA 2014 Update Report (Appendix 1A).

Overall, we reviewed the following Port Colborne CBRA Reports (most of these reports have been included as Appendixes in the CBRA 2014 Update Report but the HHRA Addendum report #1 and the ERA Crops Addendum Report #2 were missing from the update report):

- Port Colborne Community-Based Risk Assessment 2014 Update Report.
- Human Health Risk Assessment “Final Report” dated December 2007.
- HHRA Addendum Report #1 – Response to PLC Consultant Report Human Health Risk Assessment Port Colborne, Ontario dated February 2010. Responds to comments received on Sept 2009 from Watters Environmental Group Inc. (Watters Environmental); the Public Liaison Committee’s (PLC) Consultant.
- Crop Studies Report “Final Report” dated December 2004.
- Crops Studies – Addendum Report #1 dated September 2006. Responds to comments received following a public review and comment period on the final Crop Studies Report.
- Crops Studies – Addendum Report #2 dated April 2009. Responds to comments received on Oct 2008 from Watters Environmental.
- ERA Natural Environment “Final Report” dated September 2004.
- ERA-NE – Addendum Report #1 dated March 2005. Responds to comments received following a public review and comment period on the final report and documents the CBRA public review process.
- ERA-NE – Addendum Report #2 dated January 2009. Responds to comments received on Oct 2008 from Watters Environmental.

It addition, we also considered comments on the CBRA reports provided to the ministry on November 2013 by Ms. Diana Wiggins.

We recognize that Vale has spent considerable effort to update the CBRA to address our previous comments. However, despite these revisions, the ministry continues to have numerous concerns with the Port Colborne CBRA reports and the proposed Risk-Based Soil Concentrations (RBSC) (also referred to as site-specific threshold levels, SSTLs). Overall, we are unable to endorse the current CBRA or support the proposed RBSC’s. Below, we have provided our comments on the CBRA Update report for each chapter. Comments on Vale’s responses to our previous comments from May 2011 will be provided in a separate memorandum. In general, we have focused on Nickel (Ni) as the primary contaminant of concern (COC) for our review. Any risk management activities required to address elevated Ni contamination in soil are anticipated to also address the other metals of concern (i.e., Arsenic, Copper and Cobalt).

Comments on Chapter 1 – Introduction

1. **Section 1.0.** This section provides background information on the overall CBRA, various challenges in conducting the assessment, and subsequent discussions that were held to address ministry review comments from May 2011. To be clear, the fact that independent ministry reviewers were involved in the technical review is not a limitation of the review process and should not be seen as the reason for the extensive concerns that the ministry raised. The final CBRA report should be able to withstand scientific scrutiny from anyone qualified to review risk assessments; not just those involved in conducting the CBRA.

2. **Section 1.1, page 1.7.** The 2^{nd} paragraph should indicate that in addition to the additional soil investigation, the MOE 2002 report also contains the results of the Human Health Risk Assessment that was conducted by the ministry for the Rodney Street Community. A brief summary of the Rodney Street HHRA could also be added at the end of Section 1.2.1.

3. **Section 1.3.3.** While the two large farms were not sampled as part of the CBRA, the risk based soil concentrations developed from the crops study should still apply to them; hence they are not excluded from the CBRA.

4. **Section 1.6.** The CBRA does not provide any information on ecological risks for "human-influenced environments such as parks, playgrounds, gardens, and residential yards". Given the absence of a formal risk assessment for these areas, information from the ERA natural environment and the crops study should be used to establish appropriate risk based soil concentrations for these areas to allow for reasonable use that is not impacted by elevated COCs in soil.

5. **Section 1.8.** The CBRA reports and addenda reports were not formally reviewed by the ministry until August 2010.

6. **Section 1.9.** The HHRA Addendum Report #1 should be included in this section (Response to PLC Consultant Report, Human Health Risk Assessment Port Colborne, Ontario dated February 2010).

Comments on Chapter 2 – Site Characterization

7. **Section 2.5, page 2-12.** While excluded from the CBRA, these industrial lands (i.e., the refinery property) should be identified in future risk management plans as a potential source of COCs to the surrounding area if the soil is disturbed. Measures to minimize this pathway may already be in place and should be summarized in the planned Implementation Report.

8. **Section 2.6., page 2.12.** Presumably, this section is referring to Table 2-2 since there is no Table 2-4 in Appendix 2A. The focus of these comparisons is to show that Ni levels are much higher in woodlot soils than in nearby field soils. That is not in dispute. However, given the extensive data collection summarized in Section 2.1, it is surprising that only 3 comparisons are made and that two of the locations are over 4 km away from the refinery (e.g., only one comparison occurs within the original primary study area).

9. **Section 2.8.3.** This section should note that while fish may not be present, these intermittent drains and ditches still provide habitat for aquatic organisms when water is present and that organisms may be exposed to elevated COCs from water and sediment. This is one of the reasons that amphibians were evaluated in the risk assessment. Also, information should be provided on the sediment and surface water samples collected and summarized in Table B-3 (Primary and Secondary Study Areas, and Control Area Sediment Concentrations Used in Revised Risk Calculations) and Table B-4 (Primary, Secondary, and Control Area Surface Water Concentrations Used in Revised Risk Calculations).

Comments on Chapter 3 – Human Health Risk Assessment

The following provides a brief summary of the ministry's review of the Human Health Risk Assessment component of the Port Colborne CBRA Updated Report 2014. As soil Ni is the most significantly elevated COC in the community above background levels and human health based soil criteria, the review focuses on the toxicity, and potential exposure to Ni. This review considers the information within the revised CBRA report, as well as additional information from other regulatory agencies and current scientific literature, in order to better characterize the risks from Ni exposure and identify appropriate Ni Risk Based Soil Concentrations (RBSCs). RBSCs were developed for the toddler receptor as they have higher contact rates with soil and are still developing into adults.

Overall, the ministry has numerous major concerns with the revised CBRA that are provided in detailed Appendixes at the end of this memorandum. These concerns include:

- The oral Ni Toxicity Reference Value (TRV) that was used as the toxicity benchmark
- How dietary background exposure was estimated
- The bioavailability and bioaccessibility of Ni in soil
- How outdoor soil was used to estimate indoor dust concentrations
- The Ni soil ingestion rate that was used to estimate exposure to the Toddler

As these concerns are significant in nature and have not been resolved, specific comments on Chapter 3 are not provided.

Overall Conclusions on the Oral Ni TRV (Appendix A): The ministry does not support the Ni TRV used in the revised CBRA for assessing oral Ni exposure. A TRV is the benchmark used in risk assessment as an indicator of the maximum acceptable daily dose to which a person may be exposed without adverse effects. The oral Ni TRV of 20 micrograms per kilogram body weight per day (µg/kg-bw/day) used in the CBRA is based on adverse changes in body weight and organ weight observed in exposed test animals (rodents). This TRV was originally supported by the MOECC as noted in previous ministry comments (MOE 2011). However, based on the most up-to-date scientific information, changes in weight are no longer the most sensitive endpoint to use in assessing oral Ni exposure. Instead, the MOECC supports a TRV of 11 µg/kg-bw/day based on adverse reproductive and developmental effects observed in rodents.

Overall, the TRV of 11 µg/kg-bw/day is considered by the MOECC to be appropriate for the protection of Ni-associated reproductive and developmental adverse effects, including the potential toxicity of Ni in developing male reproductive organs. However, it must be noted that this TRV may not be fully protective of Ni-sensitized individuals from the development of dermatitis. Finally, this TRV of 11 µg/kg-bw/day is supported by Health Canada (2010), the

World Health Organization (WHO, 2007) and the Office of the Environmental Health Hazard Assessment, California Environmental Protection Agency (OEHHA, 2012) and the analysis by the European Food and Safety Authority (EFSA , 2015). This TRV represents the most up-to-date value to use in risk assessment as an indicator of the maximum acceptable daily dose to which a person may be exposed without adverse effects.

Overall Conclusions on Dietary Exposure (Appendix B): The ministry does not support using the estimated Ni concentrations in garden produce and supermarket foods that were developed for evaluating dietary Ni exposure in this CBRA, despite the extensive work that was done by Vale in attempting to develop a Port Colborne specific estimate for this exposure pathway. Deficiencies in sampling of both garden produce and supermarket food significantly limit the interpretation of these results and the final CBRA estimates for the Port Colborne diet fall within the low range of the expected community exposure of Ni through the diet. Instead of the estimates proposed in this CBRA, the ministry recommends that the overall average estimate from Health Canada's Total Diet Survey's between 2000 and 2007 should be used instead. Supermarket exposure should be similar throughout Canada and given that the available data from the CBRA update report clearly indicate that Ni is elevated in local garden produce (i.e., locally grown fruits and vegetables), dietary exposure to residents of Port Colborne should be higher than the Canadian average; not lower as indicated in the report.

Overall Conclusions on Bioaccessibility (Appendix C): The ministry supports the general argument that not all of the Ni in soil is biologically available. That is, if a person consumes soil containing Ni, not all the Ni would be available for absorption from the soil in the gastrointestinal tract (i.e., bioaccessible) and the resulting absorption of Ni into the bloodstream would be less than 100% (i.e., bioavailable). However, the ministry does not support the approach used in the risk assessment to estimate the bioaccessibility of Ni. Specifically, the ministry believes that the estimates are too low and, for the purpose of this risk assessment, underestimate Ni exposure from soil and the risk resulting from incidental ingestion.

Overall Conclusions on the Outdoor Soil to Indoor Dust Ratio (Appendix D): Based on a limited number of samples, the ratio between Ni in indoor dust and Ni in soil was estimated in this CBRA to be 0.2 (i.e., dust contains 20% of the total Ni that is found in soil from the Port Colborne community). This ratio was used in the CBRA to estimate the Ni concentration of indoor dust from measured Ni concentrations in soil as part of developing the RBSC. The ministry has concerns with this ratio primarily because the dataset is too small to develop a robust estimate and also because the ratio of Ni in indoor dust to Ni in soil is often much higher than 0.2 when soil Ni concentration is less than 2,000 mg/kg.

Overall Conclusions on Soil Ingestion Rate (Appendix E): The ministry has considered the alternative incidental soil ingestion rate (SIR) of 110 mg/day for the toddler receptor and finds that it is reasonable for use in the CBRA. However, this represents a Central Tendency Exposure (CTE) estimate in the calculation of exposure from the soil and dust pathways. The ministry also considers the SIR of 200 mg/day to be valid for use in the CBRA as a Reasonable Maximum Exposure (RME) estimate. The SIR of 200 mg/day has been identified as a conservative assumption (MOE, 2011) and MOECC maintains its use in the development of Brownfields (O. Reg. 153/04) soil standard setting. The incidental SIR is the key exposure assumption used in the CBRA in estimating exposure from the combined soil and dust pathways. As the SIR does not distinguish between soil and dust it may be assumed for both the soil and dust exposure pathways by using the 45:55 ratio as assumed in the US EPA's Integrated Exposure and Uptake Biokinetic (IEUBK) model for lead in children (US EPA, 2002). In addition, as done in the CBRA, the soil pathway may also be pro-rated for winter snow cover, where exposure to soil outdoors is considered negligible or zero.

Overall, based on our review, the ministry has determined that the most appropriate oral TRV for Ni is 11 µg/kg-bw/day. This TRV is based on both reproductive and developmental effects observed in animals. However, background dietary exposure to Ni makes up the majority of the exposure to the toddler and is also estimated to be 11 µg/kg-bw/day. Thus, background dietary exposure to Ni – irrespective of any elevated soil Ni exposure for conditions in Port Colborne – is similar to the health based toxicity benchmark. Given this fact, an alternative approach will need to be considered that allocates an appropriate amount of overall Ni exposure to soil. Because of these concerns, the ministry believes that the revised CBRA currently underestimates the potential risk from Ni exposure in Port Colborne soils to toddlers in some areas of Port Colborne with elevated Ni levels in soil.

Comments on Chapter 4 – Natural Environment Environmental Risk Assessment

Based on comments the ministry provided in May 2011, Stantec has substantially revised the format and approach of this ecological risk assessment for the natural environment. Instead of estimating risks based on averaging soil concentrations across the entire study area, the revised approach now focuses on the most contaminated lands that are closest and downwind of the refinery to determine potential risks to ecological receptors. However, the revised approach incorrectly uses the Modified Ecological Protection (MEP) option under O. Reg. 153/04 to characterize the risk for the entire Port Colborne natural environment (i.e., non-residential woodlots and non-agricultural fields). This MEP option is specific for individual properties being evaluated under O. Reg. 153/04 if certain conditions are met and requires a certificate of property use to inform future land owners that adverse effects may occur to some plants, soil organisms, and wildlife that might reside in or frequent the site. The MEP approach is not appropriate for identifying and characterizing risks for large scale ecological risk assessments as it uses less stringent eco-toxicity values to develop site-specific soil standards. No information is provided on potential risks without the MEP option. Additional site characterization information has been provided which addresses many of our previous comments relating to site characterization. In addition, the ERA now includes some new water surface water quality data for the Wignell and Beaverdams drains for use in further characterizing risks to amphibians. However, there remain significant concerns with this risk assessment and the ministry is not in a position to accept the proposed site-specific soil intervention values as appropriate for the Port Colborne natural environment.

Specific Comments on ERA-NE Report

10. **Page 4-2. Ecological Risk Assessment Objectives and Scope.** As noted, the “ERA focused on the natural environment: human-influenced environments such as parks, playgrounds, gardens, and residential yards were not considered”. However, these human-influence environments are not addressed elsewhere in the various CBRA reports and represent a limitation in the CBRA report that will need to be addressed. While this may have been an acceptable approach when the CBRA was started, it is no longer the case that these human-influenced environments can be overlooked. However, information is available from the Crops ERA and this ERA-NE to develop appropriate soil thresholds for the protection of soil invertebrates, residential gardens, and grasses, shrubs, and trees that would be expected in these environments.

11. **Page 4-4, Section 4.2.2.1. Site Description.** As noted in previous ministry comments, some woodlots have too few samples to properly characterize the variability in the patchiness of COC concentrations. As a result, additional data collection may be needed for some woodlots to determine if they have acceptable COC concentrations or not.

12. **Page 4-5, Section 4.2.2.3 Data Used in the ERA.** This section should include the detailed maps illustrating sample location by receptor and environmental media that were provided separately as hardcopy to the ministry.

13. **Page 4-6. 1st paragraph.** In general, the MOECC agrees with the approach of using the 95% UCLM as a reasonable worse-case woodlot and adjacent field scenario (although, see comments #17 and 18 below). However, using the 95% UCLM will not result in an overly conservative prediction of potential exposure and subsequent risk as noted in the report. Instead, the risk-based estimate for this woodlot and nearby field area will be appropriate for predicting potential impacts across the entire site as they can be adjusted to determine the risk threshold where soil concentrations are equal to a HQ of 1.0. Also, there was not a "perceived influence of unequal distribution of sampling"; this was a fact as described in previous Ministry comments.

14. **Page 4-7.** Table 4-1 shows a very limited dataset and only includes 1 example of data close to the refinery; the other 2 are over 4km away. Using the data provided in Tables B1 and B2, the average COC concentrations from the worse-case scenario woodlot and field scenario are likely a better example for conditions close to the refinery (e.g., mean Ni in woodlot = 18,000 mg/kg; mean Ni in nearby fields = 1,870 mg/kg). Similarly, using data from the woodlot 1 km to the East of this area provides a better example of the decrease in COC levels (e.g., using woodlot data from LL19, SSH1 to SSH3 and field data from CSH7, CSH8, OSH27 and OSH28 results in average Ni concentrations of 2,700 mg/kg in woodlots and 930 mg/kg in nearby fields). It is also important to note that the difference in COC concentrations between the woodlots and the fields are less at woodlots and fields farther away from the refinery.

15. **Page 4-8.** Even though the aquatic features are intermittent in nature (ponding in woodland swamps; ephemeral conditions in Wignell and Beaverdams drains), aquatic receptors may be exposed to elevated COCs when these features are present and risks associated with this exposure should be characterized.

16. **Page 4.11. Section 4.2.3.2. Identification of Receptors.** Table 4.2. No major concerns with using MOECC VECs from the generic model in the revised risk assessment except for evaluating plants, soil invertebrates and decomposers. These receptors should continue to be assessed separately and not as a group (especially since site-specific data is available from the Crops ERA (e.g., for herbaceous plants) and the Natural Environment ERA (e.g., site-specific information for maple trees, soil invertebrates and decomposers).

17. **Page 4.13, Section 4.2 4.1. Exposure Point Concentration.** The revised CBRA uses the 95% UCLM as the exposure point concentration based on the rationale that this upper estimate of the central tendency is appropriate for evaluating the "population" of non-mobile soil invertebrates and plants. However, we recognize that exposure will exceed these values in some places and that risks will be higher for organisms exposed to concentrations above the 95% UCLM. Areas in excess of the 95% UCLM should be identified and if discrete contiguous areas in excess of the 95% UCLM are present (e.g.,

contaminated hot spots), then it may be necessary to evaluate risks at the maximum concentration for those areas as well. Overall, the areas potentially impacted by elevated COC concentrations in soils needs to be clearly delineated.

18. **Page 4.13. Table 4-5.** No concern that the 95% UCLM for woodlot #3 is an appropriate upper estimate of central tendency exposure that would be expected in any woodlot in the Port Colborne area. However, some concerns with the corresponding "worse-case" field scenario as several relevant soil samples are not considered (e.g., data from IH2 and IH4 are not used yet they have elevated Ni concentrations of 3,790 and 2,600 mg/kg respectively). Hence, the 95% UCLM may be too low to characterize the field habitat.

19. **Page 4.14.** BLM modelling has been conducted on a very limited dataset (n=3 for Beaverdams; n=6 for Wignell) from water samples collected from only one sampling event on Oct 3, 2013. No rationale is provided on if parameter values (e.g., for pH, DOC and hardness) would be expected to vary over the course of the year and if modelling water quality conditions in October are appropriate. In addition, total concentrations of COCs collected in 2013 from these drains are much lower than the concentrations measured from the intermittent ponds and used in the risk modelling of other receptors (see Table B-4). For example, the EPC for Ni from the primary areas is 1,063 ug/L whereas the EPC for Ni from the Wignell drain is 8.3 ug/L (reduced to a BLM EPC of 3.5 ug/L) and the EPC for Ni from the Beaverdams drain is 19 ug/L (reduced to a BLM EPC of 1.4 ug/L). In fact, except for Co, the maximum concentrations are less than the applicable PWQO (max Cu = 1.9 ug/L; max Ni = 19 ug/L), hence, there would be no need to model bioavailability as total concentrations in these drains on this date were acceptable.

20. **Page 4.15.** No information is provided for the EPC for sediment. Table B-3 provides data but it is not clear if it is used in the risk assessment.

21. **Page 4.15. Section 4.2.4.2. Calculation of Tissue Residues for Food and Forage.** No information has been provided on what site-specific uptake factors were used in this assessment and if they are appropriate to use at the soil Ni concentrations found under the "worse-case scenarios" tested. The update report simply cites the previous 2004 risk assessment. A comparison between the site-specific uptake factors used in this risk assessment and the generic BAFs provided in the generic model (MOE 2011) should also be provided. As an example, the reviewer was unable to duplicate the estimated Ni uptake into terrestrial plants provided in Table 4.7.

22. **Page 4.16 Section 4.2.4.3. Calculation of Average Daily Dose for Birds and Mammals.** No information has been provided on what site-specific absorption factors were used in this assessment and if they are appropriate to use at the soil Ni concentrations found under the "worse-case scenarios" tested for the receptor evaluated. The report refers to information in Appendix 3.E of Chapter 3 of this update report but no specific information is provided here. For consistency, a comparison between the site-specific absorption factors used in this risk assessment and the factors provided in the generic model (MOE 2011) should also be provided.

23. **Table 4.8 and 4.9.** It is difficult to determine how the total average daily dose (ADD) was calculated for mammals and birds in the woodlots and adjacent field. The information provided in Appendix C is difficult to review and insufficient as no rationale is provided for any of the inputs. Additional rationale is needed to support why the ADD

for some receptors in the woodlot are so low when compared to the adjacent field given the much higher soil EPC for the woodlot. For example, the estimated total ADD for the short-tailed shrew (90 vs 165 mg/kg-day) and woodcock (98 versus 207 mg/kg-day) are all lower in the woodlot than the adjacent field even though Ni concentrations are 10 times higher in the woodlot.

24. **Page 4.17. Section 4.2.5.** In this revised CBRA, Stantec changed their TRVs from the TRV's used in the previous version of this CBRA to the default MOE TRVs from O. Reg. 153/04 (MOE 2011). However, they did not consider if the default MOE TRVs are appropriate for this site or if they are based on the most up to date science. This is a requirement for all risk assessments submitted under the regulation and is especially relevant for a site-specific assessment within a CBRA. For example, for mammals, the original Ni TRV used by JWEL (2004) was based on a LOAEL of 30 mg/kg-day from a two-generation study with rats (Springborn 2000a). However, a re-analysis of this study conducted by the WHO (2005) results in a LOAEL of 2.2 mg/kg-day (based on post-implantation loss and perinatal mortality). CCME (2015) selected this analysis for deriving the human health based soil quality guideline. However, for mammals and birds, CCME used a TRV of 14.6 mg/kg-day based on a 44% reduction in growth in Holstein calves over an 8 week period. These lower values are based on more up-to-date science and are lower than the TRV used previously (30 mg/kg-day), the TRV used in the generic model (80 mg/kg-day) or the TRV used in this risk assessment under the Modified Ecological Protection option (152 mg/kg-day). A rationale is required for all TRVs to support their use in this risk assessment.

25. **Page 4.18. Section 4.2.5.1. Modified Ecological Protection.** It is highly unusual to apply the modified ecological protection option for a large geographic area as done in this revised CBRA. The MEP approach was developed under O. Reg. 153/04 to minimize inappropriate risk management on a local scale (i.e., on individual properties); it was never intended to be used for a CBRA over a large geographic scale. It also has several conditions that need to be met and requires a certificate of property use to inform future land owners that adverse effects may occur to some plants, soil organisms, and wildlife that might reside in or frequent the site. This option essentially treats the land as zoned industrial and uses less stringent eco-toxicity values to develop site-specific soil standards. In addition, risks need to be calculated with and without modified ecological protection. Overall, it is not acceptable to only use this approach for estimating risks to ecological receptors in this CBRA.

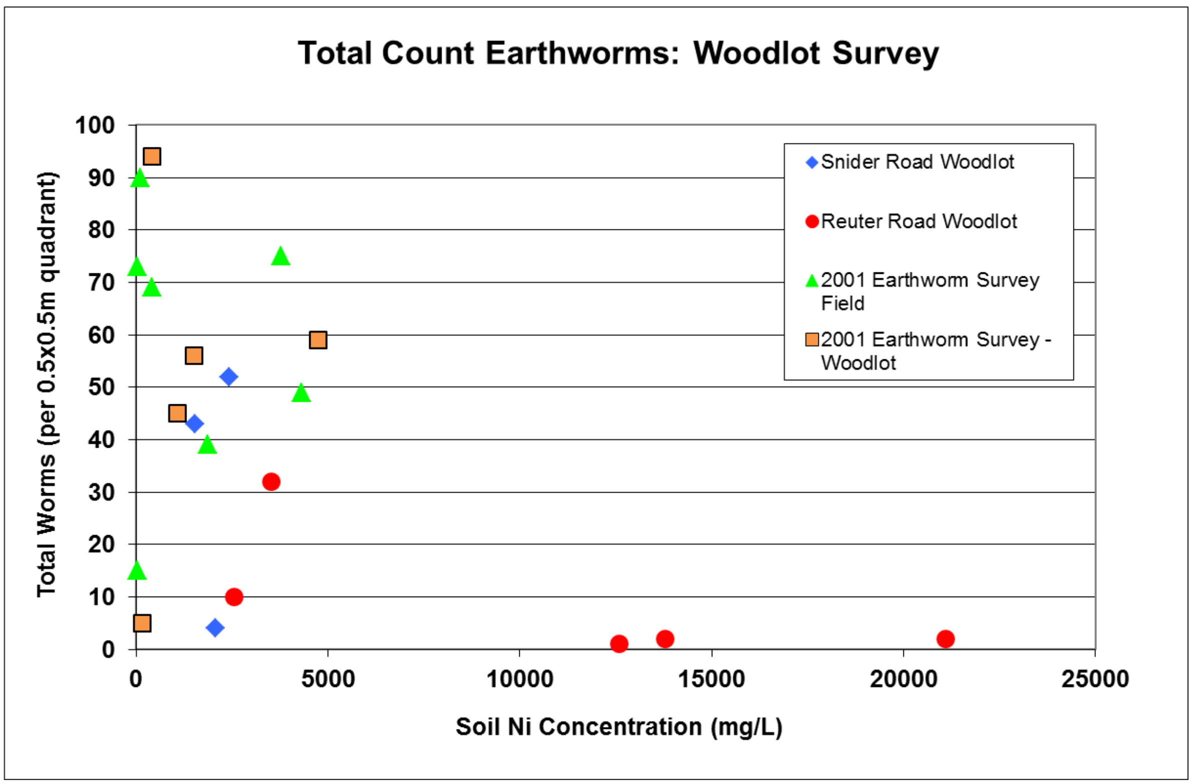
26. **Page 4.18, second paragraph.** The objective of the risk assessment was not to identify those areas where remediation was or was not required.

27. **Page 4.18, third paragraph.** Using the MEP approach is not a reflection of the "conservatism inherent in the standards". As noted, the main purpose of the MEP is to avoid inappropriate risk management activities that result in net environmental damage (e.g., removing terrestrial habitat by paving an area to limit exposure).

28. **Page 4.19. Section 4.2.5.2 Surface Water.** Aquatic Protection Values (APVs) have not replaced Provincial Water Quality Objectives (PWQOs). APVs can be used to better understand potential risks of elevated COCs in surface water but they should be used in conjunction with PWQOs.

29. **Page 4.21. Section 4.2.6.1. Assessment of Risks to Plants and Invertebrates**. Since these HQ were developed using the MEP option, a HQ of 4.7 does not represents a "marginal risk" to plants and invertebrates. Since limited site-specific information is available for herbaceous plants in woodlots and non-agricultural fields (other than the goldenrod data), information from the Crops ERA would be more appropriate for assessing risks to plants in woodlots and non-agricultural fields. Risks to invertebrates should be addressed separately. In addition, instead of a qualitative statement defining potential areas at risk, a spatial analysis should be provided that clearly identifies those areas where soil COC concentrations exceed a HQ of 1.

30. **Page 4.22, 3rd and 4th paragraph.** The presence of a few adult and/or juvenile earthworms at soil concentrations greater than 20,000 mg/kg does not indicate a "healthy earthworm population". While there is variability in total number of earthworms at lower concentrations, there are clearly adverse impacts to earthworms at elevated Ni concentrations (see MOECC Figure 1). The field results support the site-specific earthworm toxicity data of adverse impacts occurring at much lower soil Ni concentrations.



MOECC Figure 1: Relationship between Total Number of Earthworms and Soil Ni Concentration

31. **Page 4.23, 3rd paragraph.** A well conducted field survey with the ability to detect differences is needed to support the approach discussed in Chapman 2005.

32. **Page 4.24. Section 4.2.6.2. Assessment of Risks to Birds and Mammals.** MOECC does not consider the potential risk to mammals and birds to be irrelevant. Given the uncertainty over the estimated Average Daily Dose (from Section 4.2.4.3), and the use of inappropriately high TRVs using the MEP option, it is clear that many of the Hazard Quotients calculated for most of these VECs will exceed 1.0 under the worse-case scenario.

33. **Page 4.25. Table 4-14.** Risks to sheep in the adjacent field scenario will need to be based on an agricultural setting; not industrial as assumed under the MEP option.

34. **Page 4.26. Section 4.2.6.3. Assessment of Risks to Amphibians.** The assessment of risks to amphibians are only appropriate for the Wignell and Beaverdam drains but are limited by the fact that they are based on only one water quality sampling event from October 2013 and that the hazard quotients are calculated based on comparisons to APVs instead of PWQOs. As noted previously, total concentrations of COCs collected from these drains are much lower than the concentrations measured from the intermittent ponds found in the primary and secondary area that were used in the risk modelling of other receptors (see Table B-4). Overall, despite the discussion provided on the frog calling survey, the CBRA is unable to discount that adverse impacts may be occurring to amphibians in some intermittent aquatic habitats. However, it is likely that the potentially impacted areas overlap with areas already identified as having an adverse impact based on elevated COC levels in soils and impacts to other ecological receptors.

35. **Page 4.27. Section 4.3. Conclusions.** There is no rationale provided to support the conclusion that the previous SSTLs developed by JWEL are valid. No analysis has been conducted to determine what the soil COC concentration would be at an HQ of 1.0 based on this revised assessment under the worse-case scenario for the woodlot and adjacent field habitat. Areas greater than the recommended soil thresholds should be identified to inform potential risk management measures.

36. **Appendix B of Chapter 4**.
    a. **Table B-1**: It is not clear why the soil sample from LL17 was not included in this dataset. Regardless, the risk estimates based on the currently 95% UCLM is unlikely to change if this data is added.
    b. **Table B-2:** It is not clear why the soil samples from IH2 (Ni = 3,790 mg/kg) and IH4 (Ni = 2,600 mg/kg) are not included in this dataset while data collected nearby these samples are. As noted, the absence of these 2 datapoints may influence the 95% UCLM for the “worse-case” field environment.
    c. **Table B-3 and B-4.** A few sediment and surface water samples in the primary study area have much higher COC concentrations than the rest (e.g., sediment site FH3; surface water sites S2 and S3). These samples may be more representative of the worse-case scenario analysis since they appear to be located in or around Woodlot #3 (at least for sediment; not clear for surface water where samples are from).

Comments on Chapter 5 – Ecological Risk Assessment - Crops

The following review comments are for the report titled *Port Colborne Community-Based Risk Assessment (CBRA) 2014 Update Report, Chapter 5 – Ecological Risk Assessment –Crops, prepared for Vale Canada Limited by Stantec Consulting Limited, Guelph, Ontario, File number 122210662, September 12, 2014* (Update Report). The update refers to updating the Crops Studies section of the CBRA conducted in the early 2000s (Jacques Whitford, 2004)[1]. Crop studies were conducted on Port Colborne soils in the field and in greenhouses in 2000 (referred to as JW 2000) and in 2001 (referred to as JW 2001). These studies were designed to determine the effects of arsenic, cobalt, copper and nickel in Port Colborne soils on selected crops. Nickel was targeted as the primary toxicant. The consulting firm Jacques Whitford Limited conducted these studies for Inco Limited. Although Vale (then CVRD) took over Inco in 2006 and Jacques Whitford became Stantec Consulting Limited in 2010, the primary authors of this chapter of the Update Report have been involved with the CBRA review and response process for years and one of the authors was lead scientist for the JW 2001 crop studies.

The following comments on the Update Report follow the sections given in Chapter 5 of the Update Report.

37. **Section 5.1** of the Update Report provides background information and states the purpose of the Crop risk assessment, which was to determine "*the concentrations in historically deposited COC in Port Colborne soil that represent an unacceptable risk (phytotoxicity) to agricultural crops*". The authors go on to give the purpose of the Update Report "B*ased on the multiple rounds of review and response, there were areas of disagreement between reviewers [of the CBRA Crop Studies] and the authors of the report. To this discussion, the MOE review is added, and this chapter of the 2014 Update Report is primarily a response to the MOE's review comments. It is hoped that the discussion below provides the necessary clarity to finalize the Crop risk assessment fourteen years after its initiation."* The MOECC understands that this has been a very long process, with multiple rounds of review and responses and considerable discussions on how best to move forward to address our concerns. While the update report has considered additional information from other crop studies conducted in the Port Colborne environment, the new analysis does not adequately reflect our previous concerns. As a result, the proposed SSTL's are exactly the same as the SSTL's in the original 2004 Crop Studies report (Jacques Whitford, 2004).

    Although the 2004 Crops Report includes several studies, the SSTL values are based only on the JW 2001 greenhouse studies. As has been stated previously by the Ministry (MOE 2011)[2], these studies are not considered definitive for several reasons including the lack of yield data, the growing of plants in a mix of soils other than agricultural soils (soils were collected from woodlot and railroad right of way), the growing of plants in pots, the growing of plants in a greenhouse rather than under field conditions, and the focus on only one crop (oats). The ministry recognizes that Vale has put considerable time and

[1] Jacques Whitford, 2004. Port Colborne Community Based Risk Assessment – Ecological Risk Assessment, Crops Studies, Project No. ONT34663. Prepared for Inco Limited by Jacques Whitford, December.

[2] MOE 2011. Letter to Mrs. Maria Bellantino Perco (Senior Specialist, Environment, Vale) from Camilo Marinez (Coordinator, Community Based Risk Assessment, MOECC) providing ministry comments on Vale Port Colborne Community Based Risk Assessment.

resources into conducting these studies, with the likely expectation that these studies would be definitive. Also, we acknowledge that when the JW 2000 study did not work out as expected, Vale was willing to fund a new upgraded study for the JW 2001 studies. The ministry understands that the development of SSTLs by Vale is a voluntary process and that conducting additional crop studies may not address limitations in the JW 2000 and 2001 studies. However, the ministry is also very aware of the historic concerns expressed by the Port Colborne agricultural community regarding adverse effects to crops attributed to emissions from the nickel refinery and high nickel and other metal concentrations in the area soils. The Ministry is also very familiar with many of the studies conducted in the Port Colborne area on the effect of nickel and other COCs on crops. In fact, several of these studies, as well as complaint investigations, were conducted by Ministry scientists. Consequently, the Ministry suggested in discussions with Vale after our comments were provided in May 2011 that it might be possible to develop more appropriate SSTL's incorporating not only the CBRA studies but also studies conducted on crops in soils from the Port Colborne area. We note that although the ministry has not recently received complaints regarding nickel toxicity in Port Colborne crops, this should not be interpreted as meaning that there is no longer a problem with soil nickel toxicity to agricultural crops in the Port Colborne area.

38. **Section 5.3** gives an overview of the JW 2000 and JW 2001 crop studies. For the JW 2000 study, the Update Report states *"Data generated from the 2000 Greenhouse Trials proved unsuitable for derivation of phytotoxicity thresholds due to confounding soil variables, analytical difficulties and (in some cases) an inappropriate range in soil CoC exposure concentrations* (Section 5.3.1, pg. 5). It is understood that Dr. Jim Warren was in charge of the JW 2000 studies and that while these studies were less than ideal, it is not clear whether Dr. Warren, the person in the best position to judge the merits of the studies, considered the 2000 data unsuitable. In the Crops Report and the Update Report, evidence of suppressed growth of corn, oats and soybeans from the JW 2000 studies at nickel concentrations at or close to 200 ug/g nickel (Tables GH-1, GH-2, GH-5, and GH-9) is largely ignored (Jacques Whitford, 2004) yet the Update Report uses the JW 2000 results to support conclusions regarding the suitability of the Port Colborne soils for crop growth, such as "*The result of the field trials conducted in 2000 were equivocal; however, they generally supported the tenet that crops could successfully be grown in soils greatly exceeding the MOE generic soil criteria for nickel*" (pg. 5.4). The Ministry acknowledges that there were shortcomings to the JW 2000 studies, but also recognizes that the results from these studies have some validity.

39. As stated previously, a major shortcoming of the JW 2001 studies was the lack of yield data. This issue was never directly addressed in the Vale/Stantec responses to our previous comments on the crops study. However, this issue was also raised by the independent consultant peer reviewer (Watters, 2008[3]) and at that time, a response was provided (Jacques Whitford, 2009[4]). Although this response went into considerable detail explaining how there can be a relationship between biomass and grain production, using terms such as harvest index and mentioning that "plant biomass is a standard measurement used in phytotoxicity studies" and that "the results obtained by using plant biomass data are reliable and comparable with other well documented scientific studies" (Jacques Whitford, 2009), it failed to address the key issue, which is that for the agricultural community, yield is critically important and yield of oats means the quantity of grain produced. It is understood that for some farmers, oat straw may be of interest and that oats may be used as a forage crop, but including a measure of the amount of grain produced is critical in any agricultural study looking at oat crops. Furthermore, Stantec has often used the term yield when referring to biomass of oats; this is not acceptable and should be changed in the reports. Trying to redefine the term "yield" does not change the fact that for an agricultural study with oats, the lack of any information on the amount of grain produced is a major shortcoming and a major source of uncertainly in the development of SSTLs from the JW 2001 greenhouse studies.

40. **Section 5.3.2**. The relationship between soil and plant tissue concentrations of COCs in the greenhouse crops and the goldenrod collected as part of the Biomonitoring Study was considered to be similar and the report authors state that the Biomonitoring Study "greatly reduced the uncertainty regarding the legitimacy of the toxicity thresholds as calculated." This is similar to the wording used in the conclusions of the Biomonitoring Section of the CBRA Crop Studies report; yet in the results section of the Crop Studies report (3.0 Results) it is stated "the limitations of the experimental protocol, particularly the low replication of samples and lack of replication of sample sites within each treatment, restrict our ability to make generalizations regarding the COC uptake of goldenrods on different soils." (Jacques Whitford, 2004 – pg. 5-8). Viewing the data given in Appendix B-2 of the Crops Report, the latter appraisal is far more accurate than the former (i.e., there are significant limitations in the experimental protocol of the Biomonitoring Study and that the results do not "greatly reduce" the uncertainty as suggested). As can be seen in the data for the high sand plot (Plot 3) and the high clay plot (Plot 4), there is poor agreement between replicates of soil and plant tissue nickel concentrations (MOECC Table 1). Also, higher soil nickel concentrations do not necessarily mean higher plant tissue nickel concentrations (MOECC Table 1).

[3] Watters, 2008. Independent Consultant Peer Review Report for the Community Based Risk Assessment (CBRA) Ecological Risk Assessment on Agricultural Crops in Port Colborne, Ontario. Prepared for the Public Liaison Committee and City of Port Colborne by Watters Environmental Group Inc., Reference No. 04-0007, October 2008.

[4] Jacques Whitford, 2009. Commentary on Watters Environmental Group Inc. October 2008 Document – CBRA Crops Studies in Port Colborne, Ontario, Project No. ONT34657, Prepared for Vale Inco Limited, April 2009.

MOECC Table 1: Selected soil and goldenrod nickel concentrations from a sand and a clay site as given in Appendix B-1 Data for Biomonitoring Study (Jacques Whitford, 2004)

Site	Plot	Replicate	Soil Ni (mg/kg)	Goldenrod Ni (mg/kg)
Sand	3	1	600	28.4
Sand	3	2	3440	28.1
Sand	3	3	4690	15.0
Sand	3	4	462	5.9
Clay	4	1	7267	8.8
Clay	4	2	6397	12.7
Clay	4	3	3583	12.4
Clay	4	4	3200	17.1

There are other weaknesses with the Biomonitoring Study which were pointed out in the Ministry's 2011 comments, including the assessment of only one plant species, the lack of separation of plant parts before chemical analysis, the differing ages and stages of development of the plant samples, and the lack of root data. Furthermore, the goldenrod is referred to as Solidago spp., which suggests that more than one species of goldenrod may have been sampled. It is possible that metal uptake and metal tolerance could vary by species. Also, goldenrod is a weedy species that is known to colonize well in heavy metal polluted areas (Dong et al., 2006[5]) and this plant can be considered a metal tolerant species rather than a good representative of Port Colborne flora. In summary, given the lack of replication, the uncertainty in what plant parts were sampled, the uncertainty as to the age and developmental stage of the sampled tissue, the lack of clarity on what species was sampled, the often high variability in uptake results, and the selection of a species known to tolerate highly metal contaminated sites, the argument that the Biomonitoring Study reduces the uncertainty of the calculated toxicity thresholds is not supported.

The MOECC understands that the contaminated organic muck soils in the vicinity of the refinery are currently owned by Vale and no longer in agricultural production. However, if these lands were sold, it is possible that they could be put back into agricultural production. Since it is not known what a farmer might try to grow on these lands or how a farmer might alter the soil chemistry though tillage practices, fertilization, liming, acidification or pesticide applications, it is important not to underestimate the phytotoxic potential of the nickel in these soils. It is important to remember that nickel toxicity in these soils is not a theoretical problem, since historically muck farmers have reported serious issues in growing crops on these lands that were attributed to soil nickel contamination.

41. **Sections 5.4 and 5.5 (including the various subsections).** Stantec identifies the MOECC concerns, outlines a strategy to resolve the issues and provides a meta-analysis of the data. It is important to note that the MOECC, Stantec and Vale were initially working through this process together but that Vale ended the consultative process and the MOECC was not involved in the final meta-analysis of these studies. As with any meta-analysis, the decisions to include or exclude data are critical to the outcome and the ministry was involved with and agreed with the inclusion/exclusion decisions and score assigned to each study. Our concern rests with how the meta-analysis was used to

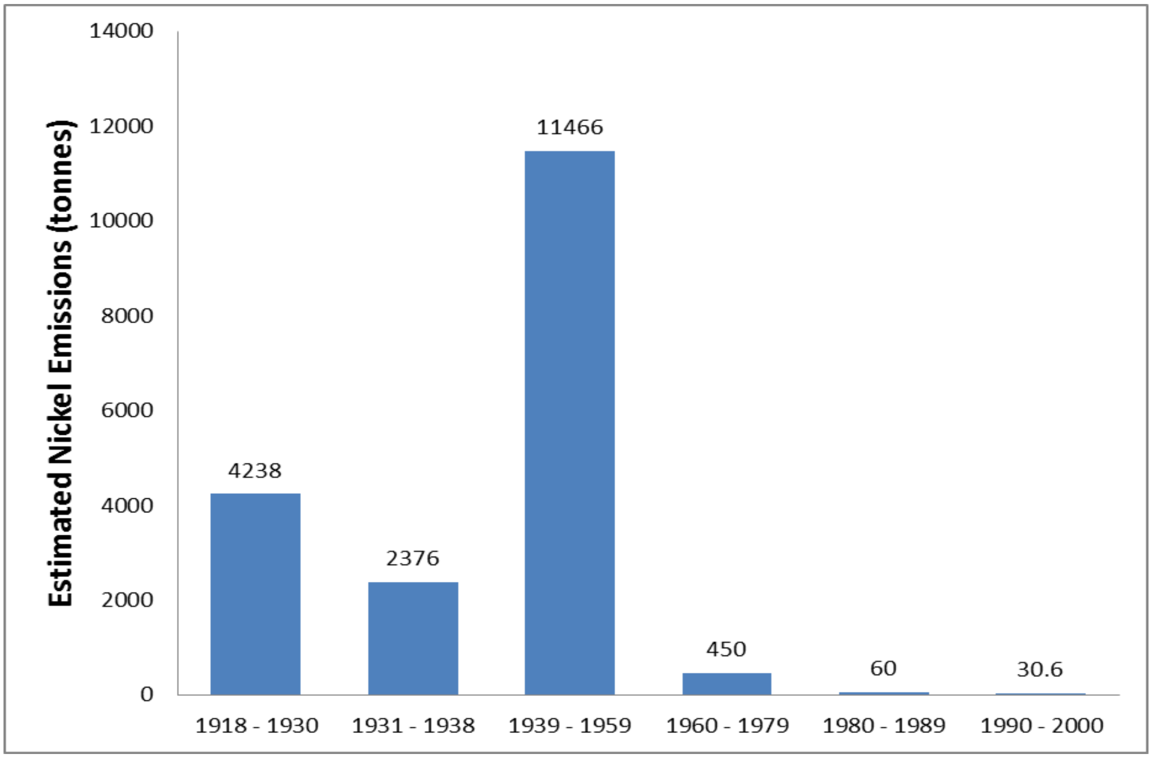
[5] Dong et al., 2006

support the SSTLs developed in the JW2001 document rather than as the basis for the development of new SSTLs based on all Port Colborne crop studies.

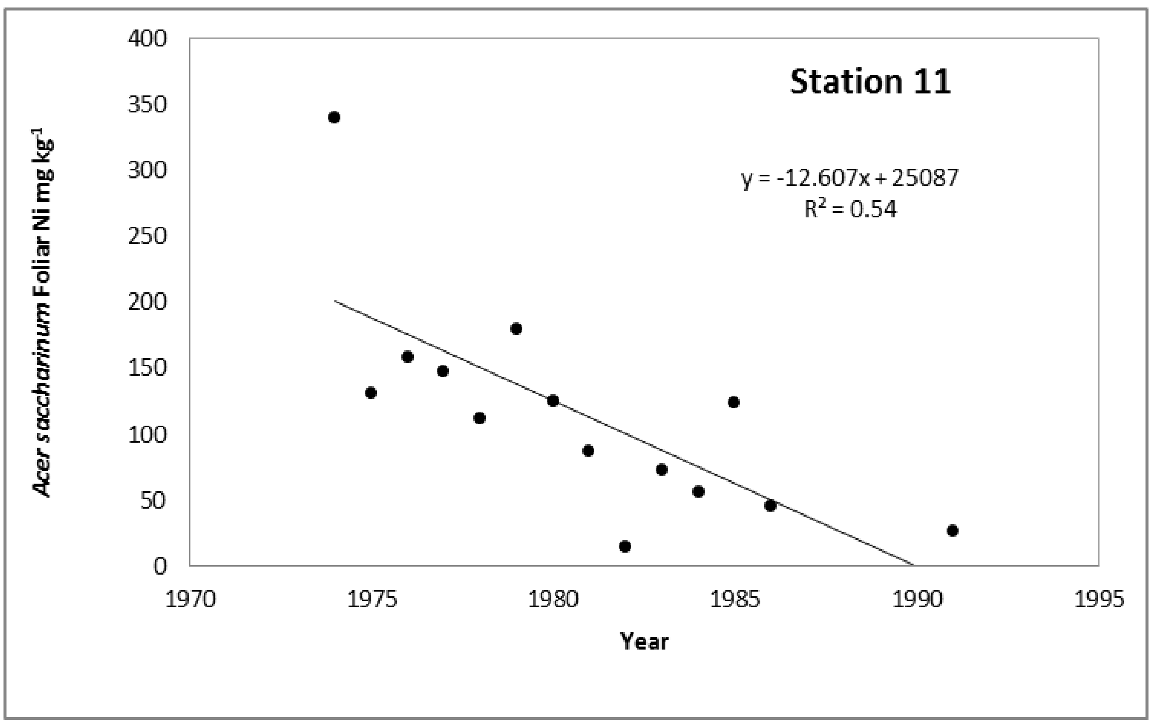
In Section 5.5, the Update Report mentions studies dating back to the 1950s, and points out that when the nickel refinery was in full production that there was a significant amount of nickel, possibly water soluble, deposited on local vegetation and soils, which resulted in phytotoxicity. It is important to note that the amount of nickel emitted and the composition of refinery emissions changed dramatically after an electrostatic precipitator was installed at this refinery in 1961. Prior to this installation, the refinery operated largely without pollution controls and approximately 97% of the nickel emitted from the refinery from 1918 to 2000, occurred prior to 1960 (MOECC Figure 2). Given the drastically different levels of pollution in the Port Colborne area from the 1950s to late 1970s, the ministry does not consider it appropriate to refer to studies conducted on the 1950 in order to downplay the importance of nickel uptake from the soil in studies conducted from the late 1970s to early 2000s.

The Update report also makes the argument that the refinery was still in operation when many of the complaints were made by local farmers and that nickel concentrations in local vegetation were much higher when the refinery was in operation than after it shut down in 1984. The authors show a graph of nickel in unwashed silver maple foliage from the late 1950s to 2001 (Figure 5-1), which shows a steep decline in nickel concentrations with time. The authors state that this “points to the importance of active emissions to nickel accumulation and toxicity of silver maples” and that “The same trend would apply to agricultural plants” (page 5.11). While this may seem reasonable, the argument is not supported when stations closer to affected farms are considered. The data given in Figure 5-1 is for MOE Station 11, yet it is MOE Station 14 that is adjacent to two muck farms where many of complaints and MOE investigations and studies were conducted (MOE, 1979).

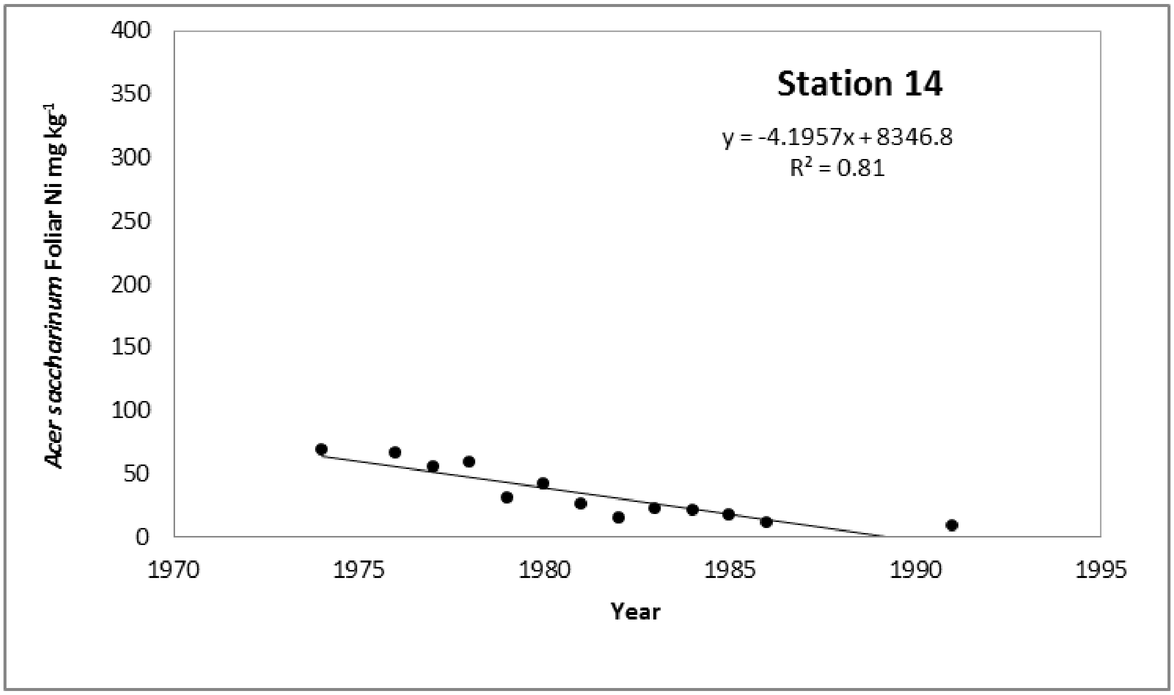
When comparing nickel concentrations in unwashed silver maple foliage collected by the MOE at Stations 11 with Station 14 from 1974 to 1991, it is clear that Station 11 has much higher foliar nickel concentrations and that the decrease in foliar nickel concentrations is much more pronounced at Station 11 than at Station 14 (MOECC Figures 3 and 4).



MOECC Figure 2: Estimated nickel emissions (tonnes) from the Port Colborne refinery from 1918 to 2000 (JWEL, 2001c)



MOECC Figure 3: Nickel concentrations in silver maple foliage (ug/g dry weight) from MOE Station 11 in the vicinity of the Port Colborne nickel refinery – 1974 to 1991



MOECC Figure 4: Nickel concentrations in silver maple foliage (ug/g dry weight) from MOE Station 14 in the vicinity of the Port Colborne nickel refinery – 1974 to 1991

It is acknowledged that aerial deposition of nickel onto tree leaves can cause injury to leaves, but this should not be over-stated. In the late 1970s when injury to silver maples leaves was noted in the vicinity of Christmas and Killaly Streets (850 m northeast of the refinery), nickel concentrations in unwashed maple foliage at these sites were as high as 309 ug/g (MOE, 1977). This concentration is approximately double the foliar nickel concentration observed at Station 11 (MOECC Figure 3) and over four times higher than the foliar nickel concentration at Station 14 (MOECC Figure 4) over the same time period. Also, nickel in particulate on the leaf surfaces may not be available for plant uptake and the particulate can be washed or blown from the leaves by precipitation and high winds before it affects the foliage. Furthermore, the nickel toxicity was noted in plants grown in the Port Colborne muck soils even when there was no particulate on the leaf surfaces from Inco emissions. The "bioassay experiments" conducted on muck soils from the farms around Station 14 by the Ministry in the 1970s were conducted in greenhouses in Toronto, well away from any influence from the Port Colborne refinery emissions. This means the phytotoxicity documented in this study was from soil uptake of nickel and not from aerial deposition of nickel (MOE, 1978)[6]. Although the Update Report downplays the relevance of studies conducted before 1984, with statements such as "some caution is required when comparing the toxicity of nickel in Port Colborne soils from the period before 1984 with the toxicity of the nickel in soil today" (pg. 5.13), the Ministry considers these studies still relevant today and that less caution in accepting the relevance of these studies is required than suggested. Again, it should be noted that the

[6] Although root-knot nematodes were found to cause significant growth reductions in lettuce and celery grown in these muck soils, metals in these soils were calculated to reduce lettuce growth by 20-35% and celery growth by 30-35% (MOE, 1978)

vast majority of the nickel in these soils was deposited prior to 1960 and that this nickel had at least 15 years to equilibrate with the soil before the earliest of these MOECC bioassay studies were conducted.

42. **Section 5.6.2.** This section considers other studies that have been conducted since 2004. Studies were conducted from 2005 to 2007 by growing oats and soybean on clay soils by a master's student under the supervision of Dr. Bev Hale of the University of Guelph. Yields of oats were poor and the Ministry agrees with the authors of the Update Report that it is difficult to make "specific conclusions as to the impact of the soil metal contamination on oat growth and yield" (pg. 5.17). Soybean yield was better, but variable from year to year. The Ministry agrees that it is not clear to what extent soybean grown in the Port Colborne clay soils are being affected by soil nickel concentrations. In August 2010, Vale arranged for a site visit for the MOECC to a farm northeast of the refinery where there appeared to be a good soybean crop growing, in spite of elevated soil nickel concentrations. It should be noted that this site visit was not an assessment of a field study but simply the observation of a soybean crop grown on contaminated land by an area farmer. From this brief visit it was not clear how the soil chemistry had been altered by the farmer through liming and fertilization or how soybean yield had been affected by the various soil nickel concentrations across the field.

43. **Section 5.6.2.** There is considerable discussion regarding various soil extracts in this section, with the conclusion that strontium nitrate, calcium chloride, or aqueous extractants offer the most information. The use of various soil extractants can help to determine the availability of nickel to plants growing in these soils and possibly other organisms. The authors conclude that "*the long-term management of the agricultural lands affected by nickel contamination at Port Colborne will need to balance production and nickel translocation into crops"* (pg. 5.20). The Ministry agrees with this statement and no specific comments are warranted for this section. In terms of the availability of nickel in the Port Colborne soils and the translocation of nickel into crops, it should be noted that Vale put considerable resources into investigating the potential of plants, such as Alyssum murale and Alyssum corsicum, to extract nickel from these soils (Chaney et. al., 2003). This research showed that some plants can hyperaccumulate nickel from Port Colborne soils even in the 2000s, which is direct evidence of nickel translocation into plants.

Comments on Chapter 6 – Summary of Conclusions in CBRA

44. We recognize that Vale has spent considerable effort to update the CBRA to address our previous comments. However, despite these revisions, the ministry continues to have numerous concerns with the Port Colborne CBRA reports and the proposed Risk-Based Soil Concentrations (RBSC) (also referred to as site-specific threshold levels, SSTLs). Overall, we are unable to endorse the current CBRA or support the proposed RBSC's.

Appendixes Providing Detailed Comments on the Human Health Risk Assessment Component of the Revised CBRA

Appendix A: Toxicity Reference Value (TRV) for Nickel

Overall Conclusions on Oral Ni TRV:

The ministry does not support the Nickel (Ni) toxicity reference value (TRV) used in the revised CBRA for assessing oral Ni exposure. A TRV is the benchmark used in risk assessment as an indicator of the maximum acceptable daily dose to which a person may be exposed without adverse effects. The oral Ni TRV of 20 micrograms per kilogram body weight per day (µg/kg-bw/day) used in the CBRA is based on adverse changes in body weight and organ weight observed in exposed test animals (rodents). This TRV was originally supported by the MOECC as noted in previous ministry comments (MOE 2011). However, based on the most up-to-date scientific information, changes in weight are no longer the most sensitive endpoint to use in assessing oral Ni exposure. Instead, the MOECC supports a TRV of 11 µg/kg-bw/day based on adverse reproductive and developmental effects observed in rodents.

A number of considerations support the ministry's decision that 11 µg/kg-bw/day is the appropriate Ni TRV to use. This TRV was derived from studies where oral exposure to Ni was associated with increased post-implantation and perinatal lethality (i.e., effects on the developing fetus). In addition, this TRV is also appropriate for protecting adverse effects of Ni exposure on the male developing reproductive tract (i.e., effects in both toddler and adult males). Although this TRV of 11 µg/kg-bw/day was used in the CBRA in the sensitivity analysis, its application was limited to the adult receptor of reproductive age. In contrast, because of the concerns associated with Ni and adverse effects to the developing fetus and reproductive system in males, the MOECC supports using this TRV for both the adult and toddler receptor.

Nickel is also associated with oral provocation of dermatitis in humans. This effect has been observed in a study where Ni sensitized individual's experienced systemic dermatitis after ingesting a single oral Ni dose of 12 µg/kg-bw (Nielsen et al., 1999). This effect has also been observed at lower doses as well. Given the fact that this adverse effect of Ni exposure was observed in a human study, the MOECC considers (at the very least) an exposure dose of 12 µg/kg-bw/day as an upper limit for establishing an oral Ni TRV.

Overall, the TRV of 11 µg/kg-bw/day is considered by the MOECC to be appropriate for the protection of Ni-associated reproductive and developmental adverse effects including the potential toxicity of Ni in developing male reproductive organs in toddler and adult males. However, it is noted that this oral TRV may not be fully protective of Ni-sensitized individuals from provoking dermatitis. Finally, this TRV of 11 µg/kg-bw/day is supported by Health Canada (2010), the World Health Organization (WHO, 2007), the Office of the Environmental Health Hazard Assessment, California Environmental Protection Agency (OEHHA, 2012) and the analysis by EFSA (2015). This TRV represents the most up-to-date value to use in risk assessment as an indicator of the maximum acceptable daily dose to which a person may be exposed without adverse effects.

As described in more detail below, the recommended TRV of 11 µg/kg-bw/day is based on the following:

1. The previous TRV of 20 µg/kg-bw/day based on changes in body and organ weight is no longer appropriate.

2. The TRV of 11 µg/kg-bw/day, based on developmental and reproductive effects, represents the most up-to-date science and uses the most appropriate endpoints.
    - It is supported by Health Canada (2010), WHO (2007), OEHHA (2012) and the analysis by EFSA (2015),
    - and is protective of effects on the male reproductive system for both adult males and toddlers
3. Oral provocation of Ni dermatitis in humans has been measured at a dose of 12 µg/kg-bw.
    - The TRV of 12 µg/kg-bw/day should be applied as an intake dose; not an uptake dose.

Detailed Comments on Oral Ni TRV Selection:

1) The previous TRV of 20 µg/kg-bw/day based on changes in body and organ weight is no longer appropriate

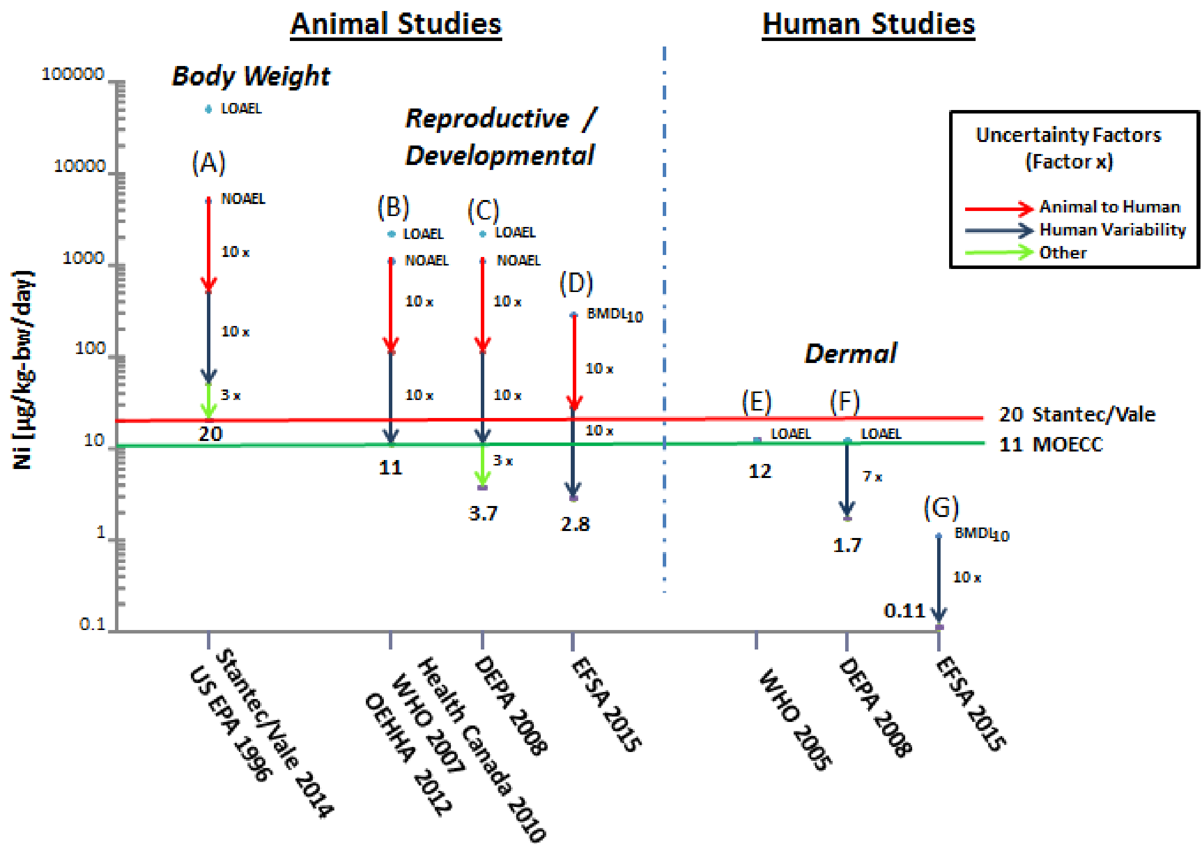
Stantec used a TRV of 20 µg/kg-bw/day from Ambrose et al. (1976) to evaluate oral exposure to Ni as part of developing risk based soil concentrations (RBSC) for the Port Colborne CBRA (see TRV "A" in MOECC Figure A1). This TRV was originally supported by the ministry at the onset of the CBRA review (2011). However, during the extensive consultation process (over several years) since our original comments were prepared, new toxicological assessments of Ni and Ni TRVs have been published. Consequently, the MOECC conducted a thorough review of all the new information on Ni toxicology and concluded that the TRV of 20 µg/kg-bw/day can no longer be supported.

The TRV used in the Port Colborne CBRA is the 1996 US EPA reference dose (RfD) for Ni based on a two year study in which rats were exposed to Ni sulfate (a water soluble form of Ni) spiked in their feed. From this study, a No Observable Adverse Effect Level (NOAEL) of 5 mg/kg/day was identified as the Point of Departure (POD) based on decreased organ and body weight (Ambrose et al., 1976). The TRV was derived by the application of a combined uncertainty factor of 300: 10 to account for intraspecies variability, 10 for interspecies variability, and 3 for inadequacies in reproductive studies to the NOAEL. At higher Ni doses, Ambrose et al. (1976) observed changes in body and organ weight but also observed increased lethality rates in the exposed animals. The low survival rate in the study, particularly in the control group, was criticized by both the California EPA (Cal EPA chRD, 2005; OEHHA 2012) and WHO (WHO DW, 2011) as a source of uncertainty in relying on this study to derive a TRV.

Although an uncertainty factor of 3 for inadequate reproductive studies was incorporated into the TRV derived from the Ambrose et al. (1976) study, there are other reproductive studies (e.g. Springborn, 2000a,b and Smith 1993) that were either not available or not considered by US EPA at the time of establishing its RfD. These reproductive studies have observed adverse effects at levels lower than the NOAEL of 5 mg/kg-bw/day reported in the Ambrose et al. (1976) study. The Lowest Observable Adverse Effect Level (LOAEL) from these studies is plotted in MOECC Figure A1

MOECC Figure A1 illustrates the different TRVs considered in this review; the points of departure (PODs; LOAEL, NOAEL or $BMDL_{10}$) as well as the uncertainty factors applied to the POD (x = times) are included.

MOECC Figure A1 Ni Oral TRVs



In summary, adverse reproductive and developmental effects may occur at lower levels of oral exposure to Ni than adverse changes to body and organ weight. Therefore, changes in body and organ weight cannot be considered as the most representative toxicological endpoint for establishing a TRV for oral Ni exposure. As a result, the TRV of 20 µg/kg-bw/day that was used in the Port Colborne CBRA is out-of-date and no longer supported.

2) The TRV of 11 µg/kg-bw/day based on developmental and reproductive effects represents the most up-to-date science and uses the most appropriate endpoints.

In the CBRA update report, the TRV of 11 µg/kg-bw/day was considered in the sensitivity analysis for assessing exposure to an adult of reproductive age. However, the MOECC supports using this TRV for the main analysis as it is based on the most up-to-date science and appropriate endpoints (reproductive and developmental effects), and is applicable to the toddler receptor.

TRV of 11 µg/kg-bw/day is supported by Health Canada (2010), WHO (2007), OEHHA (2012), and analysis by EFSA (2015).

The TRV of 11 µg/kg-bw/day (see TRV "B" in MOECC Figure A1) is supported by Health Canada (2010), WHO (2007), OEHHA (2012) and the analysis conducted by EFSA (2015). This TRV is based primarily on the Springborn (2000 a,b) studies that identified an increased rate of post-implementation loss and perinatal lethality in rats treated by gavage with nickel sulfate (hexahydrate) in drinking water. The TRV was derived from a NOAEL of 1.1 mg/kg-bw/day and the application of a combined uncertainty factor of 100: 10 to account for intraspecies variability, and 10 for interspecies variability.

The NOAEL of 1.1 mg/kg-bw/day was identified based in part on the fact that an unbounded LOAEL of 2.2 mg/kg-bw/day was observed from the first generation range finding study (Springborn 2000a) (i.e., no NOAEL could be developed from this study alone). The analysis conducted by OEHHA (2012) supported the NOAEL of 1.1 mg/kg-bw/day from the Springborn studies, and considered the Smith et al. (1993) study that independently identified a LOAEL of 1.3 mg/kg-bw day as supporting evidence. In addition, the CBRA report identifies the dose of 2.2 mg/kg-bw/day as a LOAEL for reproductive effects, relying on an independent analysis conducted by Seilkop (2013).

DEPA (2011) also considered the NOAEL of 1.1 mg/kg-bw/day based on the identification of a LOAEL of 2.2 mg/kg-bw/day from the combined post-implantation loss and perinatal lethality from the Springborn (2000b) study. DEPA's re-analysis considered that there was a mechanistic basis to assume that the effects on the developing fetus appear to be the same. This POD for reproductive and developmental effects was supported by WHO (2007) and Health Canada (2010). However, DEPA determined a TRV range of 3.7 to 5.5 µg/kg-bw/day after applying a combined uncertainty factor of 200-300: 10 to account for intraspecies variability, 10 for interspecies variability, and 2-3 for severity of effects observed at only twice the dose level of the NOAEL (see TRV "C" in MOECC Figure A1). Upon considering the rationale provided by DEPA (2011), the MOECC does not support the use of an additional uncertainty factor of 2-3 for severity of effects.

Recently, the European Food and Safety Authority (EFSA, 2015) reanalyzed the first generation range finding study (Springborn 2000a) and the subsequent full 2-generation study in rats (Springborn 2000b), combining the results from the two studies. EFSA identified reproductive and developmental toxicity as the critical effects for the risk characterization of chronic oral exposure to Ni, and derived a benchmark response at 10% extra risk (BMD_{10}) of 0.76 mg/kg-bw/day) with a lower 95^{th} confidence limit ($BMDL_{10}$) of 0.28 mg/kg-bw/day), based on post-implantation loss of the combined single data set. Using the derived $BMDL_{10}$, EFSA estimated a tolerable daily intake (TDI) of 2.8 µg/kg-bw/day upon the application of a combined uncertainty factor of 100: 10 to account for interspecies differences, and 10 for human variability (see TRV "D" in MOECC Figure A1).

The MOECC agrees with the approach used by EFSA 2015 of combining the two Springborn rodent studies (2000a,b) and using of benchmark dose response analysis for deriving a TRV. However, the MOECC considers that the application of a total uncertainty factor of 100 to a $BMDL_{10}$ is tending towards an overly conservative consideration for use in the Port Colborne CBRA. For example, the use of BMD_{10} instead of $BMDL_{10}$ would yield a TRV of 7.6 µg/kg-bw/day instead of 2.8 µg/kg-bw/day.

Within these ranges of TRVs and considering the variability and uncertainty inherent in TRV derivation, the MOECC considers that the TRV of 11 µg/kg-bw/day is an appropriate and reasonable estimate for assessing oral Ni exposure and protecting against reproductive and developmental Ni toxicity.

TRV of 11 µg/kg-bw/day is also protective of effects on the male reproductive system for both adult males and toddlers

Several studies have provided evidence of an association between Ni exposure at low doses and the male reproductive system. EFSA (2015) used the potential toxicological effects on male fertility to support its selection of a POD of 0.28 mg/kg-bw/day for assessing post-implantation loss in rats. EFSA (2015) cited two studies conducted by Pandey et al. (1999, 2000) which indicated adverse effects of Ni on sperm (decreased sperm count and motility and an increase in abnormal sperm) and on accessory sexual organs (decreased weight of seminal vesicle and prostate gland) in mice at oral doses as low as 1.1 mg/kg-bw/day. While these studies were not considered adequate for the hazard characterization by EFSA (2015), a preliminary dose response analysis on sperm motility and sperm count conducted by EFSA (2015) estimated a BMD_{05} and $BMDL_{05}$ varying from 0.42 to 0.38 mg Ni/kg-bw/day for sperm motility, and from 0.62 to 0.46 mg Ni/kg-bw/day for sperm count.

Study limitations such as poor documentation and data inconsistencies and potential confounding effects of feed restriction, were cited in the CBRA by Stantec in their rationale for considering the evidence on the toxicity of Ni in the male reproductive tract and function. Even though these confounding factors cannot be ruled out, these studies provide supportive evidence on the adverse impact of Ni on the male reproductive system, particularly since these effects were observed at concentrations lower than the NOAEL of 5 mg/kg-bw/day for body and organ weight changes reported by Ambrose et al. (1976) and the NOEAL of 1.1 mg/kg-bw/day from the Springborn studies, and were used by EFSA to support the POD based on post-implantation loss (EFSA 2015).

Pandey et al. (1999) also observed an increase in pre- and post- implantation loss at 2.2 mg/kg-bw/day when only male mice were treated with Ni. This suggests that the reproductive and developmental effects reported in the Springborn (2000a,b) studies may not necessarily be limited to parturition (as suggested by NiPERA in a separate briefing to the MOECC provided on May 17, 2012 (Oller, 2012). In addition, in a reproductive study conducted by Toman et al. (2012), a time-dependent degradation of the seminiferous tubes of the testis was observed in Ni exposed mice. The effects were observed at 3, 6, 9, and 12 weeks in male mice treated at puberty with 2.5 mg/kg-bw/day Ni in feed (Ni spiked chow). The study by Toman et al. (2012) was considered by the MOECC to support the observations made by Pandey et al. (1999) of adverse effects of Ni on sperm and on accessory sexual organs in mice. In contrast, in the CBRA, Stantec suggests that restricted feed in this study was a potential confounding factor on the observations. Although the confounding effects of diet cannot be ruled out, the finding from this study that the intake of Ni caused serious damage on spermatogenesis and the developing testicular structure was considered by the MOECC as valuable information in understanding the overall toxicity of Ni.

Taking in consideration all the published evidence on this toxicological endpoint, the MOECC considered that a TRV of 11 µg/kg-bw/day based on developmental and reproductive effects also confers protection against Ni toxicity to the male reproductive system. Therefore, the MOECC concurs with the application of the TRV of 11 µg/kg-bw/day to the toddler stage to ensure that potential adverse impacts to the developing male reproductive system are included in this CBRA.

3) *Oral provocation of Ni dermatitis in humans has been measured at a dose of 12 µg/kg-bw; a TRV of lower than 12 µg/kg-bw/day (WHO 2007) is supported.*

The WHO (2007) used a TRV of 12 µg/kg-bw/day for Ni based on a human study by Nielsen (1999) that identified the oral provocation of dermatitis (see TRV "E" in MOECC Figure A1). This study included 20 Ni sensitized individuals who were exposed to Ni under fasting conditions after consuming a Ni reduced diet for 48 hours; 9 of the 20 individual's experiences a flare-up of dermatitis following a single dose of 12 µg/kg-bw of Ni sulphate administered in drinking water. Of these 9 individuals who developed symptoms, 3 experienced a severe reaction (2 individuals developed a maculopapular rash, and "baboon syndrome" was observed in another). The dose of 12 µg/kg-bw Ni in drinking water is considered by the WHO (2005) as an acute LOAEL in fasting subjects since adverse impacts were observed in 45% of the exposure individuals. No uncertainty factors (UF) were applied to this dose by the WHO (2005) because the test subjects represented a "highly sensitive population". Stantec also considered this TRV in the Port Colborne CBRA but only in the sensitivity analysis as they consider that it is overly protective for the general population.

However, other agencies determined that an UF may be warranted as adverse effects were observed after a single oral exposure to Ni. DEPA (2008) applied an UF of 7 to account for "sensitized" to "highly sensitized individuals". Although they provide no elaboration of the foundation of this UF, DEPA derived a TRV of 1.7 µg/kg-bw/day (see TRV "F" in MOECC Figure A1). Recently, EFSA (2015) relied on an analysis conducted by Jensen et al. (2006) and applied BMD modeling to the Jensen (2003) dermatitis data. The dose associated with a 10% adverse effect (BMD_{10}) was estimated to be 2.6 µg Ni/kg-bw with a lower 95th confidence limit ($BMDL_{10}$) of 1.1 µg Ni/kg-bw. Using the $BMDL_{10}$, EFSA considered the large inter-individual variability in the immune response that might not be covered by the limited number of individuals examined in the selected study and applied a margin of error of 10, resulting in an equivalent TRV of 0.11 µg Ni/kg-bw /day (see TRV "G" in MOECC Figure A1).

However, as noted by EFSA (2015), it cannot be predicted that all sensitized individuals will actually develop adverse reactions nor what percentage eventually will develop such reactions at the estimated levels of Ni intake. Since the studies included a highly sensitive study group exposed under fasting conditions to Ni sulphate in lactose capsules, absorption is assumed to be considerably higher than it would be from food. These considerations were used by EFSA to conclude that the use of these studies would be conservative for characterizing acute risks.

Based on these considerations, the MOECC does not support using these lower TRVs of 0.11 µg Ni/kg-bw or 1.7 µg/kg-bw/day for evaluating chronic exposure risk for dermatitis in the Port Colborne CBRA. However, the analysis by DEPA (2008) and EFSA (2015) refutes the argument that a TRV of 12 µg/kg-bw/day is overly protective for the general population as postulated in the CBRA. Instead, the MOECC believes that using the TRV of 11 µg/kg-bw/day based on reproductive and development effects in rodents is appropriate for evaluating the oral exposure of Ni in the Port Colborne CBRA but that the TRV of 11 µg/kg-bw/day may not be fully protective for Ni-sensitized individuals.

The TRV of 12 µg/kg-bw/day should be applied as an intake dose; not an uptake dose

As noted, Stantec used the 12 µg/kg-bw/day TRV in their sensitivity analysis to account for Ni dermatitis but in that analysis, they converted this intake dose TRV (i.e., how much Ni is ingested), to an absorbed dose TRV (i.e., how much of the ingested Ni is absorbed into the body).

In order to do so, Stantec relied on a number of assumptions outlined by Oller (2012). However, the current risk assessment paradigm that is followed by MOECC, Health Canada, and the US EPA is to rely on a TRV based on intake doses as they are related to the environmental media that is being monitored or regulated. For example, a TRV based on drinking water can be directly applied to a measured water concentration, and no assumptions on absorption are required for regulatory purposes.

At present, there are a number of limitations to assessing Ni exposure based on conversion of an intake dose to an uptake dose as there is insufficient knowledge about Ni absorption (especially in the toddler), and about absorbed doses that are associated with the toxicological effects. Currently, information on estimated Ni exposure based on absorption of Ni is limited to short term adult human studies or rodent studies. However, it is not clear how the toddler exposure can be estimated with any degree of confidence since there are data gaps in our understanding and questions as to how well the rat absorption data are predictive of absorption in humans. In addition, the California Environmental Protection Agency (CAL EPA) notes that the absorption rate of Ni in children may be several times higher than observed in adults (CAL EPA 2005). In light of these considerations, the conversion of the intake doses to uptake doses is not supported by the MOECC.

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Appendix B: Background Dietary Exposure to Ni in Port Colborne

Overall Conclusions on Dietary Exposure:

The ministry does not support using the estimated Ni concentrations in garden produce and supermarket foods that were developed for evaluating dietary Ni exposure in this CBRA, despite the extensive work that was done by Vale in attempting to develop a Port Colborne specific estimate for this exposure pathway. Deficiencies in sampling of both garden produce and supermarket food significantly limit the interpretation of these results and the final CBRA estimates for the Port Colborne diet fall within the low range of the expected community exposure to Ni through the diet. Instead of the estimates proposed in this CBRA, the ministry recommends that the overall average estimate from Health Canada's Total Diet Survey's between 2000 and 2007 should be used instead. Supermarket exposure should be similar throughout Canada and given that the available data from the CBRA report clearly indicate that Ni is elevated in local garden produce (i.e., locally grown fruits and vegetables), dietary exposure to residents of Port Colborne should be higher than the Canadian average; not lower as indicated in the report.

The ministry recognises that dietary sources of Ni is a major contributor to the baseline or background Ni exposure and recent findings from CCME and other regulatory sources have determined that dietary exposure alone may approach or exceed the recommended total daily intake of Ni from all sources. However, the ministry also acknowledges that there is variability and uncertainty associated with these estimates. As such, dietary estimates based on larger sampling of food such as the Health Canada Total Diet Survey are considered to be more reliable than the relatively limited information provided in this report. The overall average Health Canada estimated dietary exposure of Ni in food is 183.4 µg Ni/day or 11.14 µg/kg-bw/day for the toddler based on the 2000-2007 surveys (CCME 2015, Appendix 9). In contrast, the estimated dietary Ni exposure developed by Stantec for Zone B (the combined residential scenario) ranged from 150.9 to 169.7 µg Ni/day (or 9.1 to 10.3 µg/kg-bw/day) depending on how the garden produce data was used. These dietary estimates for Port Colborne are lower than the most recent Canadian estimate of exposure (CCME 2015), but within the low end of the year-to-year variation from the Health Canada Total Diet Survey (2000-2007).

The ministry's concerns with the dietary estimate used in the CBRA are primarily related to: (1) limitations in sampling design (a relatively small number of samples are available to characterize Ni concentrations in locally grown fruits and vegetables and the majority of available data is for soils with Ni concentrations less than 1,500 mg/kg) and (2) that the estimated contribution of Ni from the supermarket food basket is lower than predicted for the average Canadian consumer resulting in a lower total Ni dietary estimate for residents of Port Colborne than the Canadian average. Overall, the proposed Ni levels in locally grown garden produce combined with the estimated Ni levels for the supermarket food basket used in this CBRA is not adequate to represent community exposure to Ni from the diet.

Ideally, the total Ni dietary estimate should be re-assessed for the Port Colborne CBRA using the Health Canada Total Diet Survey Ni estimate for supermarket exposure and the contribution of Ni from local backyard produce. However, in absence of that reassessment, MOECC recommends that the Canadian average estimate of 11.14 µg/kg-bw/day developed by CCME, based on Health Canada Total Diet Survey (2000-2007) of total dietary intake, should be used for the toddler resident in the CBRA and in calculation of the RBSC.

While the CCME's (2015) total dietary estimate does not consider the contribution of Ni from local produce, MOECC considers it to be an upper bound estimate of the mean for the following reason: CCME calculated the average Ni concentrations in food by including non-detect samples at the method detection limit concentration instead of using ½ of the detection limit as was done in the CBRA and as recommended by the Country Foods Guidance of Health Canada (2010).

The ministry recognises that there is some uncertainty with this approach as it assumes that the contribution of Ni from local produce may be accounted for if the total dietary Ni exposure based on Health Canada Total Diet Survey (2000-2007) of total dietary intake is an upper bound estimate of the mean instead of the average estimate. That assumption may not be supported. As a result, MOECC recommends that proposed risk management measures recognize that Ni exposure from locally grown garden produce may be a concern and that measures to reduce this exposure pathway should be available (e.g., build raised garden beds and use clean topsoil for areas with elevated Ni concentrations in soil).

Limitations in Sampling Design

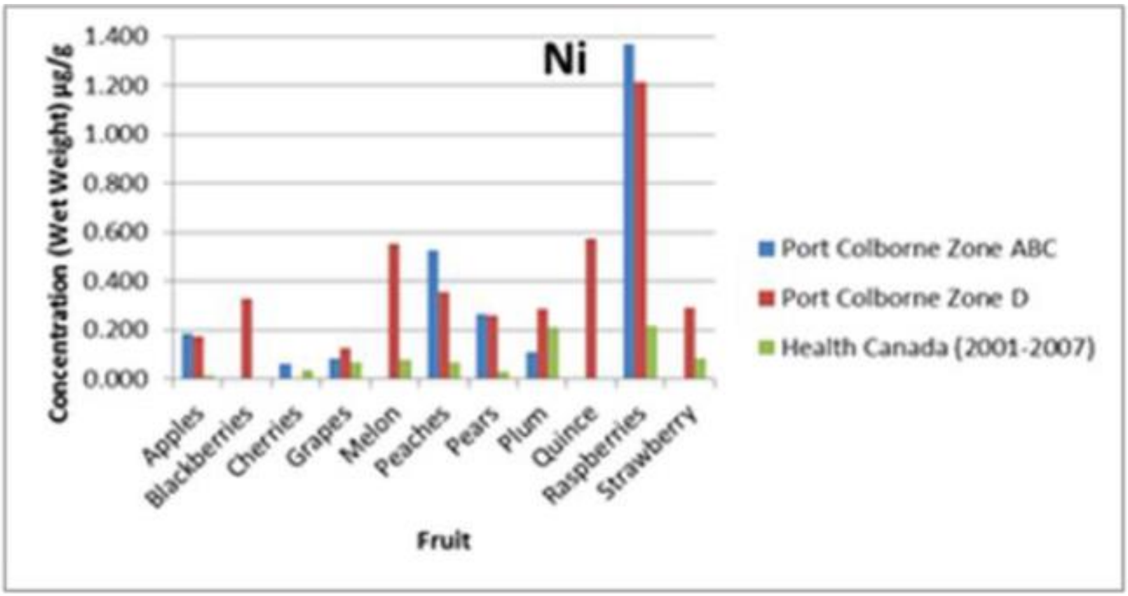
At first glance, the sample size for determining Ni in locally grown fruits and vegetables appears to be adequate in the CBRA report. For zone A, B, and C combined, a total of 30 fruits and 121 vegetables were collected. Similarly, Zone D had a total of 36 fruits and 102 vegetables collected. However, for individual fruits and vegetables, the sample size is often small (sometimes limited to one sample) and does not capture the range of Ni levels found in the garden soils examined. This should be viewed within the context to the larger multiyear composite samples collected by Health Canada in the Total Diet Study to characterize Ni levels in fruits and vegetables. The following table provides information on the number of times a fruit or vegetable was collected from the various zones

MOECC Table B1: Port Colborne Backyard Produce Samples

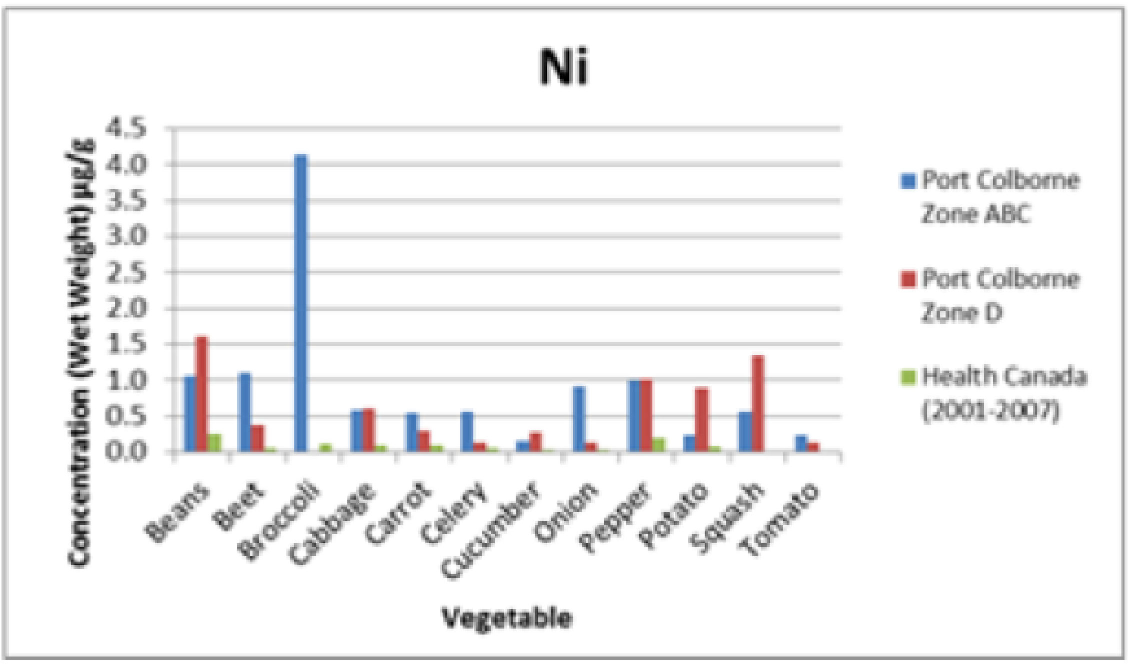
	Backyard Produce (Number of Samples Taken)	
	Fruit	**Vegetable**
Zone B (A, B, C)	30 (2, 1, 27)	121(0, 30, 91)
Zone D	36	102

It is clear from MOECC Table B1 that the majority of the samples for the combined zone A, B and C were determined from zone C (which doesn't include the most contaminated residential soil Ni levels). Overall, MOECC is concerned that the limited number of samples from the residential areas in Port Colborne significantly limits the interpretation of these results.

Despite the limitations in the available data for Ni concentrations in backyard garden produce, it is apparent that Ni concentrations are higher in fruits and vegetables from Port Colborne when compared to the average Canadian value. This is demonstrated in the CBRA report in Figure 3B.2 (Comparison of the Average Concentration in Backyard Fruits to the Average Concentration from the Health Canada Total Diet Study, 2001-2007) and Figure 3B.3 (Comparison of the average concentration in backyard vegetables to the average concentration from the Health Canada Total Diet Study, 2001-2007). These Figures are included below.



(Screen Grab Stantec 2014, Appendix 3B page 1-20)



(Screen Grab Stantec 2014, Appendix 3B page 1-21)

It is noteworthy that Ni levels are elevated even in samples collected from Zone D, an area with lower Ni soil contamination than found in Zone B. In addition, in some cases, there is very high uncertainty in the estimated Ni concentration in specific produce as the results are based on only one sample (e.g. the concentration for broccoli in Figure 3B-3 is based on a single sample). Another concern with the sampling design is that the majority of the data is for soils with Ni concentrations less than 1,500 mg/kg. No data is available for Ni levels in local garden produce when Ni soil concentrations exceed 6,680 mg/kg. According to the CBRA report (HHRA 2007), soil concentrations are a poor predictor of produce concentration; however, some relationships between soil Ni concentration and Ni concentrations in fruit (Peaches, Plums, and Strawberries) and vegetables (leafy vegetables, rhubarb) were identified in the CBRA report. A positive correlation of higher Ni in plants at higher soil Ni concentrations would be expected based on the results of the Crops ERA. While the backyard garden sampling was designed to represent community exposure, the available data does not reflect the upper end of expected soil Ni levels that can occur in residential gardens in Port Colborne (See MOECC Table B2 below). In addition, there is no information on the potential exposure to Ni from locally grown garden produce at the soil concentrations recommended in the CBRA report at the RBSCs (i.e., 48,000 mg/kg Ni in Zone B). Therefore, in absence of additional sampling, caution is warranted in using this information as part of developing the RBSC and in applying the recommended RBSC (that has not considered the potential for backyard garden produce grown in soil conditions at the RBSC) to contribute to the total dietary exposure.

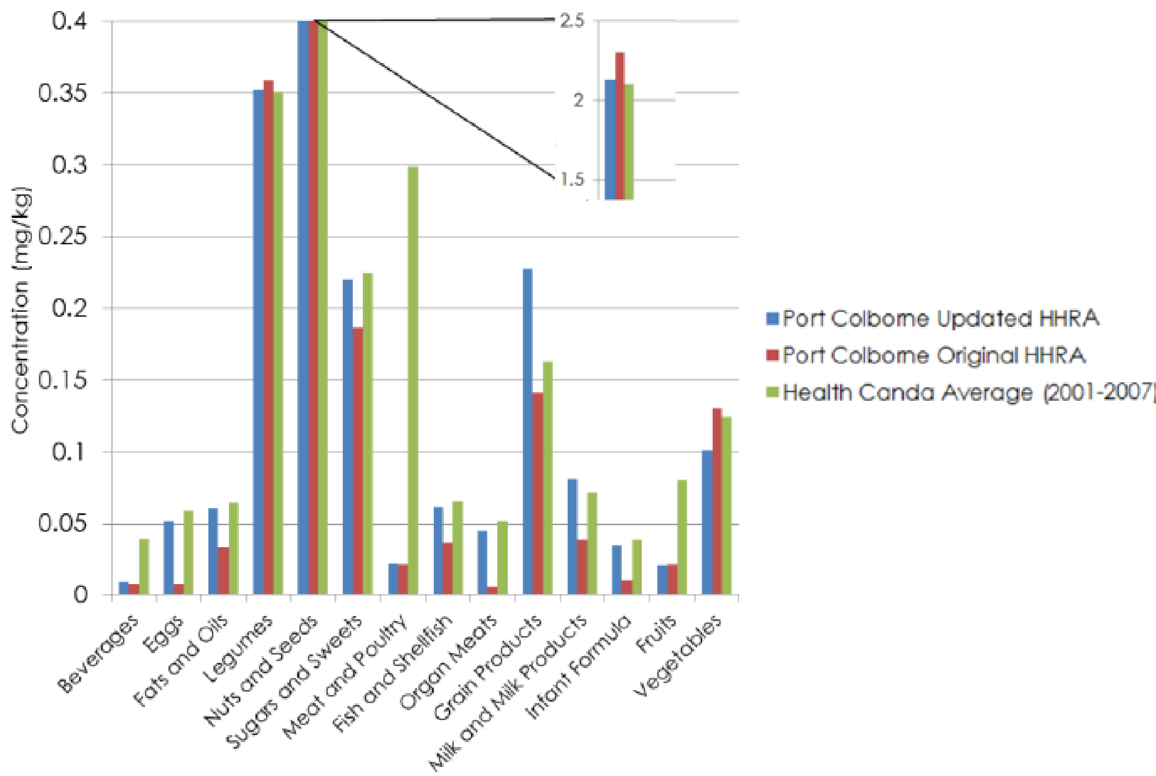
MOECC Table B2: Port Colborne Garden Soil Ni Concentrations

	Co-localized Garden Produce Soil Ni Concentrations			
Zone	**Average (mg/kg)**	**75th Percentile (mg/kg)**	**95th Percentile (mg/kg)**	**Maximum (mg/kg)**
B (ABC combined)	705	845	1552	6680
D	353	380	1450	2720

Estimated Contribution of Ni from the Supermarket Food Basket

For the supermarket exposure, the revised estimate developed by Stantec for Ni levels in various food products incorporates Port Colborne data supplemented with the Canadian data. This was done by Stantec using the following protocol: (1) for food categories with less than 10 samples, food concentrations were based on the average of the Port Colborne study but supplemented with the Canadian yearly averages (developed from a total of 8 data sets between 2001 and 2007) and (2) for food categories with 10 or more samples, concentrations food concentrations were estimated based on the higher of the upper confidence level of the (geometric) mean and the 75th percentile from the Port Colborne data only. As demonstrated in the CBRA report in Figure 3B.7 (Concentrations of Nickel in Supermarket Food), Ni concentrations used in the CBRA are generally similar to the Canadian average (2001-2007). However, notable exceptions are apparent where lower Ni concentrations are observed for the Port Colborne estimate for beverages, meat and poultry, and fruits (Figure 3B.7 provided below). For these food categories, it is unclear why the Port Colborne data should be lower than the Canadian average and raises questions regarding the adequacy of this Port Colborne specific Supermarket data to properly represent the community supermarket diet. It is noteworthy that consistent with the findings from the Crops ERA, higher Ni concentrations were observed for the Port Colborne estimate for the grain products food. The food categories beverages and meat and poultry are discussed in more detail below.

Figure 3B.7: Concentrations of Nickel in Supermarket Food



(Screen Grab Stantec 2014, Appendix 3B pp 1-29)

For the beverages food category, Ni concentrations are estimated to be 5 times lower in the CBRA than the Canadian average (HC Total Diet Study, 2001-2007). The discrepancy for this difference was not identified. However, the lower Ni content in this category reported for Port Colborne is similar to estimates reported by the US FDA and the UK. While a total of 11 samples were collected (see Table 3B.7 of CBRA report, Food Categories and Sample Sizes used in the Port Colborne Food Basket Study), MOECC believes this food category should be treated as if it had less than 10 samples and that the data should be combined with the Canadian yearly average for non-alcoholic beverages. This is because the Port Colborne estimate includes inappropriate beverages for a toddler such as white wine, whiskey, coffee, tea, beer, and caffeinated cola drinks ((see Table E.2-1 Supermarket Food Results (Beverages) - Port Colborne Determination of Gravimetric Metal Concentrations Port Colborne CBRA June-August, 2002 (Volume V - Appendix 19, Local Supermarket Food Basket 2007)). These beverages samples should not be used to represent a toddler's intake for the beverage food category.

For the Meat and Poultry food category, the estimate is based on 22 samples (Table 3B.7 Food Categories and Sample Sizes used in the Port Colborne Food Basket Study). The estimated Ni in this food category is substantially lower than the average Canadian (2001-2007) estimate. The CBRA report accounts for this discrepancy by noting that special control for Ni during sample preparation and cooking was done (including the avoidance of Ni containing utensils and pots), to avoid any contribution of Ni from sample preparation. This was done because an earlier Canadian Total Diet Survey (Dabeka 1995), observed that new stainless steel cookware contributed to the Ni content of food. This finding was supported by a limited study undertaken by Jacques Whitford 2007 (Volume V, Appendix 19, Attachment D, Cooked Food Screening Study Report) that reported no significant contributions of Ni occurred due to cooking in a well-used stainless steel pan in comparison to a ceramic pan. As mentioned in the CBRA report (page 1.25 of Appendix 3B, Changes in Input Assumptions and Data), Health Canada did not process food with specific control for nickel, that cookware is typically reused from year to year, and that Health Canada does not keep track of when specific cooking items are replaced with new ones. Therefore, Stantec concluded that "it is possible that the elevated concentrations of nickel reported in meat and poultry from the Health TDS (2001-2007) are due to the release of artificial nickel from the use of new stainless steel cookware". MOECC does not dispute that Ni may be released into the meats and poultry as part of food preparation and cooking. However, the Health Canada Total Diet Study contains appropriate and valid data as it uses food preparation and cooking methods that are reflective of typical cooking methods. It is unreasonable to assume that local residents in Port Colborne would not cook with stainless steel cookware and that they would not be replaced from time to time. In addition, given that Health Canada's data is based on a much larger multiyear sampling (2000-2007) and that they re-used cookware, any release of Ni associated with brand new stainless steel cookware would not be expected to repeatedly occur. It is also noted that the Health Canada Total Diet Study has recently been used by CCME (2015) to estimate total Ni dietary intake in developing the most recent Canadian Soil Quality Guideline.

Based on these examples, and given the limited Port Colborne sampling, MOECC recommends that for estimating the supermarket food basket, the Health Canada estimate should be used or that all food categories should be combined with the Canadian yearly averages. It is anticipated that this would result in a higher estimate of supermarket dietary exposure for the average Port Colborne toddler used in the CBRA.

Note: some discrepancies in reported values were noted between the written text in the updated CBRA report (2014) and the model provided to the ministry by Stantec. In order to facilitate the MOECC's review of the CBRA, the model values are reported.

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Appendix C: Bioavailability/Bioaccessibility of Ni in Port Colborne Soils to People via Ingestion Route

Overall Conclusions on Bioaccessibility:

The ministry supports the general argument that not all of the Ni in soil is biologically available. That is, if a person consumes soil containing Ni, not all the Ni would be available for absorption from the soil in the gastrointestinal tract (i.e., bioaccessible) and the resulting absorption of Ni into the bloodstream would be less than 100% (i.e., bioavailable). However, the ministry does not support the approach used in the risk assessment to estimate the bioaccessibility of Ni. Specifically, the ministry believes that the estimates are too low and, for the purpose of this risk assessment, underestimate Ni exposure from soil and the risk resulting from incidental ingestion. A summary of the key issues are provided below followed by a detailed discussion.

Summary of Key Issues:

1. ***MOECC does not support Ni bioavailability estimates from in-vivo studies with rats***

Laboratory studies on rats were conducted for this CBRA to estimate the amount of Ni that is absorbed from ingestion of Ni in Port Colborne soil. This *in-vivo* estimate is not supported by the ministry for the following reasons:

- Bioavailability studies using Ni: There is no approved method for estimating absorption of Ni from *in-vivo* studies. The approach followed for the other COCs in the risk assessment was based on *in-vitro* bioaccessibility studies. This information is also available for Ni and is more reliable for use in the risk assessment.
- Species tested: The bioavailability studies were conducted using adult rats.
    - Rats are not an appropriate species for estimating Ni absorption from the gastrointestinal tract because they have a different gut physiology from humans and do not reflect human absorption; and
    - The adult rat is not relevant for estimating bioavailability in a human toddler (which has the highest estimated exposure to Ni in soil through incidental ingestion).
- Experimental conditions: A single dose was used in the experiment.
    - Depending on the soil type, the bioavailability of Ni in soil may be greater at lower soil concentrations. Since mainly high soil Ni concentration were evaluated in these experiment, the estimated bioavailability may not be applicable to some of the Ni soil concentrations in Port Colborne that are appropriate for the residential community; and
    - The single dose tested was not sufficient to achieve steady state conditions as expected under chronic conditions thus limiting the interpretation of the study.

2. **MOECC does support using bioaccessibility estimates from *in-vitro* studies**

New bioaccessibility data has been provided and has contributed greatly to the understanding of bioaccessibility for the various soil types and has filled significant data gaps identified previously by MOECC.

The ministry reviewed the Ni bioaccessibility estimates made for the three soil types: fill, clay and organic soil; and recalculated the Ni bioaccessibility using all of the fill data (including the

2002 Exponent data for the fill soil that was omitted by Stantec) and using the 95th upper confidence limit of the mean (95th UCLM) rather than the mean. The 95th UCLM should be used in the risk assessment as a reasonably conservative and supportable estimate of the fraction of Ni in soil that is soluble in the human gastrointestinal environment and available for absorption. Based on the ministry's recalculations, the estimated bioaccessibility of Ni in soil is now much higher than those values used in the CBRA. Estimated Ni bioaccessibility that is supported by the MOECC is provided below (MOECC Table C1) along with a comparison to the values referenced in the CBRA sensitivity analysis. Additional discussion of the bioaccessibility values supported by the MOECC is provided in the detailed comment section below.

MOECC Table C1: Comparison of Stantec/Vale Bioaccessibility Calculations to MOECC Recalculations

Soil Type	Stantec Calculations (Mean) Ni Bioaccessibility (%)	MOECC Calculations (95th UCLM) Ni Bioaccessibility (%)
Fill	*8.7 (without 2002 Exponent data)	21 (with 2002 Exponent data)
Clay	9.4	15
Organic	22	32

* used in the sensitivity analysis by Stantec (note: 5.8% bioavailability was used in the CBRA)

Detailed Comments on Bioavailability and Bioaccessibility

1. ***Inappropriate Reliance on in-vivo Data Derived from Studies using an Adult Rat to Estimate the Relative Oral Bioavailability in Human Toddlers***

MOECC has significant concerns with the reliance on *in-vivo* data derived from studies using an adult rat to estimate the Relative Oral Bioavailability (ROB) for human toddlers. Specifically these concerns are:

- Inappropriate use of the rat model to investigate soil oral Ni bioavailability.
- Limitations in the *in-vivo* study design and context to existing literature on Port Colborne soil bioavailability.
- Limitation in the extrapolation of bioavailability information to predict absorption of Ni in toddlers.
- Inability to develop a ROB for toddlers because critical information is missing from the key studies used for the oral Ni TRV.

The inappropriate use of the rat model together with the limitations in the bioavailability testing preclude the use of this *in-vivo* bioavailability information in the determination of the ROB for use in the Port Colborne CBRA.

Inappropriate use of the in-vivo rat model to investigate Ni soil oral bioavailability.

In general, the rat model is an inappropriate model to investigate the soil oral bioavailability of Ni and is not recommended by other regulatory agencies. This is supported by Health Canada (2010), which notes that "…laboratory rat species appear to be inappropriate for *in-vivo* investigations of oral bioavailability from soil". Physiologically, the rat gut is different than humans, in that it has a two compartment stomach (including a fore-stomach) rather than a one compartment stomach. As a nocturnal feeder, the fore-stomach functions to store food for later digestion. Consequently the rat stomach does not reach a low pH of 1 -2 that is typical in humans under fasting conditions and associated with increased Ni uptake. In humans under experimental conditions, there is a decrease in Ni absorption when Ni is taken with food. Experimentally, a low pH has been demonstrated to liberate more Ni from Port Colborne soils thus increasing the available Ni for absorption. As a consequence, the rat model would not liberate as much Ni from soil as would be expected in humans under fasting conditions and cannot be relied on for estimating a health-protective soil Ni bioavailability estimate.

In soil bioavailability testing, the accepted *in-vivo* models rely on testing done with a juvenile pig (as used in the IEUBK US EPA model for Pb, US EPA 2002). The juvenile swine gut is more physiologically comparable to that of the human toddler. In the revised report, Stantec refers to the use of the rat *in-vivo* data as being the "gold standard" (page 3.77). This statement is not supportable. The "gold standard" would be a chronic, multiple exposure *in-vivo* study with juvenile pigs.

Limitation in the extrapolation of bioavailability information to predict absorption of Ni in toddlers.

There is an inherent limited ability to use animal models to make predictions on the absorption of Ni in the toddler. Even with available information in humans there is variability in absorption of Ni between the adult versus the toddler. This is highlighted by Cal EPA (2005) that considers Ni absorption in the toddler to be generally 10 times greater than the adult. In addition, Cal EPA 2005, which developed a child specific Ni TRV (chRD) do not recommend applying an adjustment for bioavailability or bioaccessibility when conducting an exposure assessment because of uncertainties associated with predicting update in toddlers (See also MOE 2011, HHRA review comment #18). Cal EPA recommendation supports a prudent approach when considering the ROB for the assessment of the toddler to ensure that Ni exposure from soil is not underestimated.

Compounding this issue is the fact that the rat model used by the proponent is an adult that does not represent a toddler stage. In rats, the juvenile stage is considered less than 21 days old.
In spite of these limitations, the *in-vivo* information is considered further by the ministry as the Ni oral TRV used in the CBRA was determined using a rat model and additional discussion is warranted.

Limitations in the in-vivo study design and context to existing literature on Port Colborne soil bioavailability.

Even though the rat was used in the determination of the Ni TRVs, there are general limitations in the study design (in addition to the above noted limitations to the rat model) that do not support the use of the *in-vivo* information in the ROB estimate. The *in-vivo* experimental design included the dosing of male Sprague-Dawley rats with a single gavage dose of $NiSO_4.6H_2O$ or with soil containing Ni. The absorption of the control test substance nickel sulfate has been reported as high as 39% (Vasiluk et al., 2011). This absolute bioavailability is substantially higher than what is expected under chronic conditions. Under chronic conditions, the absolute bioavailability is expected to be much lower in the low percent range (e.g., 5%) under steady state conditions. As steady state conditions were not reached in the experiment conducted for this CBRA, this raises concerns about the representativeness and utility of a single dose scenario to provide an estimate of the relative absorption between soil and the control test substance.

In these experiments, in order to detect absorbed Ni in urine, the rats received a large quantity of soil. It is expected that this will disproportionally affect the stomach pH, essentially mimicking greater feed state, in comparison to the control test substance dosing. It is also important to note that specific details on dosing were not available for the MOECC review (Vale 2012) and therefore our comments are based on the assumption that there are no concerns with that data.

An additional degree of uncertainty is raised in the ROB estimates (ranging from 5.8% to 22%) used in the revised CBRA report in comparison to a higher 56% reported in Vasiluk et al., (2011) for a Port Colborne soil sample (based on an absolute bioavailability of 22 ± 12% in comparison to the 39% absolute bioavailability of the control test substance ($NiSO_4.6H_2O$)). A direct comparison from this study to the Port Colborne CBRA cannot be made as a particle fraction of the soil sample tested (particle size ranged between 150-250 µm at a soil concentration of 1720 mg/kg) differs from the standard testing procedure and the vehicle for the control test substance dosing was different.

Inability to develop a ROB for toddlers because critical information is missing from the key studies used for the oral Ni TRV.

The absolute bioavailability or absorption of Ni was not determined in the rat study by Springborn 2001 (supporting the TRV of 11 µg/kg-bw/day) or the human study by Neilson et al., 1999 (supporting the TRV of 12 µg/kg-bw/day). This limits the ability to develop relative oral bioavailability estimates. While a ROB based on literature values could be estimated, it would be of limited value as most of the available information is confined to the adult and not the toddler receptor.

2. Inappropriate Screening and Analysis of in-vitro Bioaccessibility Data

Bioaccessibility can be determined in a test tube (referred to as an *in-vitro* assay) under standardized laboratory conditions. The procedure consists of a 2-step process that mimics conditions in the stomach (phase one) and the intestine (phase two). Although, an established method for determining Ni bioaccessibility in soil does not currently exist, the methods used in the CBRA to determine bioaccessibility in Port Colborne soils are similar to the method used and accepted by the US EPA (2007) for lead (Pb), arsenic (As) and some other metals. For Ni, the first phase of the process, that mimics conditions in the stomach (under acidic or low pH conditions) is the phase used in the assessment of Ni bioaccessibility.

In this CBRA update report, Stantec considered the *in-vitro* bioaccessibility data for Ni only in their sensitivity analysis. However, *in-vitro* bioaccessibility data was used in the main analysis for the other COC's (Cu, As and Co). The estimated ROB values for Ni in soil have been revised for each of the 3 soil types (fill, clay, and organic) in this CBRA update report but rely only on new data from Vale 2012 and previous data from JWL 2002. The *in-vitro* data developed by Exponent 2002 and used by the MOE in the Rodney Street Risk Assessment (2002) was not used.

The bioaccessibility values presented by Stantec in the updated CBRA report are generally higher than those in the earlier version of the CBRA, and now are specific to each soil type based on the new information from Vale 2012. For Ni, the revised *in-vitro* bioaccessibility values are 8.7% for fill soil, 9.4% for clay soil, and 22% for organic soil. These values are all higher than the previous version where Ni ROB was estimated at 4% for all 3 soil types.

MOECC reanalyzed the *in-vitro* bioaccessibility data for all three soil types using all of the bioaccessibility data (Exponent 2002, JWL, 2002 and Vale 2012). This re-analysis is presented below for each of the soil types.

Fill Soil Type: Inappropriate Analysis of in-vitro Bioaccessibility Data

Overall, a small number of soil sampling locations were used to represent the variability of Ni bioaccessibility in the Fill soil type. While the revised CBRA report suggests a sample size of 6, only 2 soil locations were tested (TP17 and TP9). The variability in the soil matrix has not been sufficiently addressed by using repeated sampling from the TP9 location (5 of the 6 soil samples used to determine the bioaccessibility estimate were from TP9 (see Table 3E-3). Although these soil samples cover a large range of Ni soil concentrations (from about 8,800 to 17,500 mg/kg), the bioaccessibility estimates for TP9 are relatively stable at 7.0 ± 0.8% (mean ± standard deviation). This can be compared to the one measurement at TP17 (soil Ni = 3,265 mg/kg), where the Ni bioaccessibility estimate is much higher at 17.0%. Comparing the results from TP9 and TP17 suggests that the Ni concentration in the soil and/or the soil sampling location has a strong influence on Ni bioaccessibility. The data was re-plotted by sample location to reflect the influence of sample location and soil conditions on Ni bioaccessibility (MOECC Figure C1).

Fill Soil Type: Inappropriate Screening of in-vitro Bioaccessibility Data

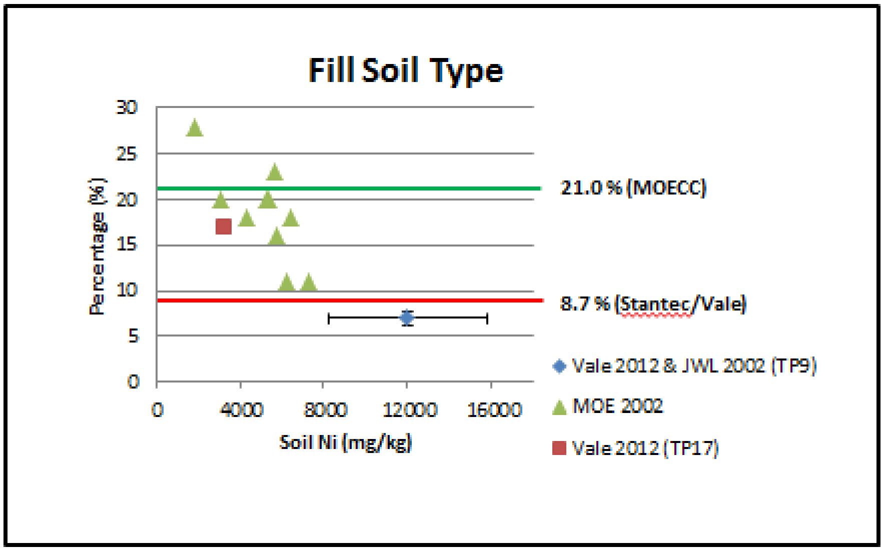
The original bioaccessibility information determined by Exponent (2002) should also have been used to estimate the bioaccessibility for the Fill soil type. This Exponent data was not used in the revised CBRA report by Stantec despite being used in previous version of the CBRA primarily due to concerns with potential interference from the glycine buffer used in the Exponent (2002) testing procedure. However, the effect of glycine buffer (isoelectric point pH 6) is limited to potential interference in the second phase (phase two - intestinal) bioaccessibility estimate; not the first phase (phase one - stomach) bioaccessibility estimate. MOECC believes the Exponent data is valid and should be used to determine Ni bioaccessibility since the phase one data is not compromised by the additional of the glycine buffer.

Another concern Stantec had with the Exponent data was that there was higher average bioaccessibility estimates in the Exponent (2002) samples which Stantec/Vale attribute to the presence of organic soils. As noted in the revised CBRA report, organic soils are predicted to have higher bioaccessibility than Fill or Clay soil samples. MOECC believes that the Exponent (2002) samples are representative of the Rodney Street community, which has been characterized using the general term of “Fill” to reflect the variable nature of the soil type and to reflect that it is neither organic or clay soil types. Together, the Exponent (2002) samples are considered by the MOECC to be valid phase one (stomach) bioaccessibility estimates that represent 10 sample locations within the Rodney street community at expected soil Ni levels (all less than 8,000 mg/kg) and therefore, were considered in the re-analysis of the Fill soil type.

Fill Soil Type: Re-analysis of the ROB

There appears to be a relationship between Ni bioaccessibility and soil Ni concentration where Ni bioaccessibility is higher at lower soil Ni levels (MOECC Figure C1). This relationship can be statistically determined with high confidence (see Section 3 below). However, MOECC believes that a reasonable conservative (i.e., erring on the side of caution) estimate is to use the 95% UCLM (an upper estimate of central tendency). This is consistent with the MOECC practice for all risk assessments. Using all of the bioaccessibility data (including the data from Exponent 2002) results in a 95% UCLM of 21% for fill soils (see MOECC Figure C1 and Table C2 below). Note: this recommended bioaccessibility estimate captures the range of bioaccessibility for soils with Ni concentrations <8,000 mg/kg (which range from 11 to 28%).

MOECC Figure C1



MOECC Table C2: The following data was used to determine the Fill soil bioaccessibility estimate:

		CBRA Report (2014)		**Re-analysis (MOECC)**		
In-vitro Experiment	**Sample Location**	**[soil]Ni mg/kg**	**Bioaccessibility (%)**	**[soil]Ni mg/kg**	**Bioaccessibility (%)**	
Vale (2012)	TP17	3265	17	3265	17	
Vale(2012)	TP9	13848	6.7	12007 ± 3752	7.0 ± 0.8	
Vale(2012)	TP9	17420	7.7			
Vale(2012)	TP9	8680	7.8			
Vale (2012)	TP9	8489	5.8			
JWL (2002)	TP9	11600	6.9			
Exponent (2002)	1			7310	11	
Exponent (2002)	2			1840	28	
Exponent (2002)	3			5370	20	
Exponent (2002)	4			6410	18	
Exponent (2002)	5			5620	23	
Exponent (2002)	6			5730	16	
Exponent (2002)	7			6200	11	
Exponent (2002)	8			5290	20	
Exponent (2002)	9			3040	20	
Exponent (2002)	10			4270	18	
			8.7		17.4	**Average (Mean)**
					21.0	**95^{th} UCLM**
					28.0	**95^{th} ile**

Summary Point Estimate of Bioaccessibility for Fill Soil Type

For the HHRA, the 95^{th} UCLM of the Fill soil type data at 21.0% bioaccessibility is supported as a CTE estimate. For the sensitivity analysis, the 95^{th} percentile at 28.0% bioaccessibility is supported as a RME estimate.

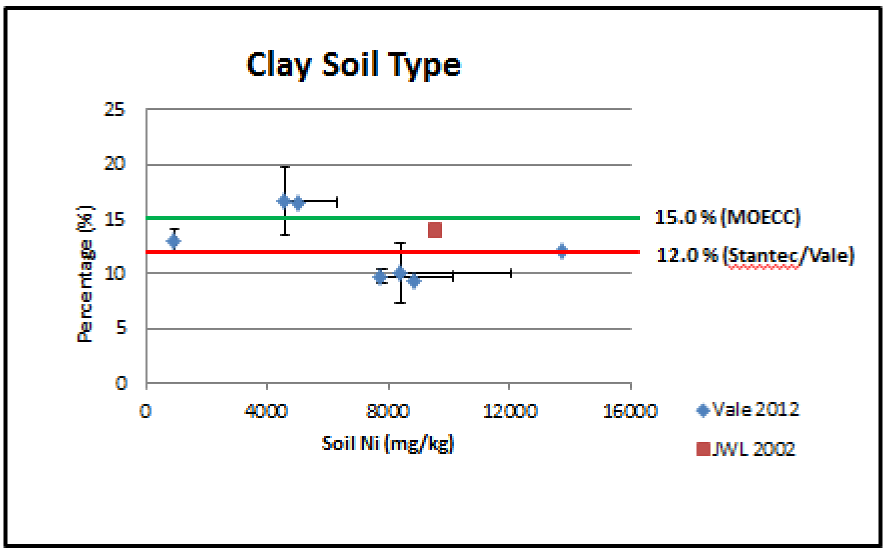
Clay Soil Type: Inappropriate Analysis of in-vitro Bioaccessibility Data

As with the fill soil type, many of the clay soil samples were taken from the same sampling location suggesting a greater number of soil locations than actually tested and raising concerns with treating the bioaccessibility estimates from the same location as independent discrete samples. As a consequence, the clay bioaccessibility data were re-analyzed by MOECC by sample location (MOECC Figure C2). It should also be noted that the amount of bioaccessibility information for the clay soils is vastly improved over previous versions of the CBRA. Instead of only one soil location, information is now available for 8 locations.

Clay Soil Type: Re-analysis of the ROB

Contrary to the results for the fill soil, there does not appear to be a relationship between Ni bioaccessibility and soil Ni concentrations. However, as with the fill soil, MOECC believes that a reasonable conservative estimate is to use the 95% UCLM. Using all of the bioaccessibility data (including the data from Vale 2012) results in a 95% UCLM of 15% for clay soils (see MOECC Figure C2 and Table C3 below). Note: this recommended bioaccessibility estimate captures the range of bioaccessibility for clay soils with Ni concentrations <8,000 mg/kg (which range from 10 to 17%).

MOECC Figure C2



MOECC Table C3: The following data was used to determine the clay soil type bioaccessibility:

		CBRA Report (2014)		Re-analysis(MOECC)		
In-vitro Experiment	**Sample Location**	**[soil]Ni mg/kg**	**Bioaccessibility (%)**	**[soil]Ni mg/kg**	**Bioaccessibility (%)**	
Vale (2012)	TP3	8912	9.4	8912	9.4	
Vale (2012)	TP5	9527	10.2	7775 ± 2344	9.8 ± 1.0	
Vale (2012)	TP5	8686	10.1			
Vale (2012)	TP5	5112	9.1			
Vale (2012)	TP6	13798	12	13798	12.0	
Vale (2012)	TP-J2	5816	14.5	4579 ± 1749	16.7 ± 3.0	
Vale (2012)	TP-J2	3342	18.8			
Vale (2012)	TPK2-1	968	12.2	939 ± 40	13.0 ± 1.0	
Vale (2012)	TPK2-1	911	13.8			
Vale (2012)	TP206	12495	7.9	8399 ± 3631	10.1 ± 2.8	
Vale (2012)	TP206	5572	9.1			
Vale (2012)	TP206	7131	13.2			
Vale (2012)	Hruska	5019	16.4	5019	16.4	
JWL (2002)	G3A	9580	14	9580	14.0	
			12		12.7	**Average (Mean)**
					15.0	**95^{th} UCLM**
					16.7	**95^{th} ile**

Summary Point Estimate of Bioaccessibility for Clay Soil Type

For the HHRA, the 95^{th} UCLM of the Fill soil type data at 15.0% bioaccessibility is supported as a CTE estimate. For the sensitivity analysis, the 95^{th} percentile at 16.7 % bioaccessibility is supported as a RME estimate.

Organic Soil Type: Inappropriate Analysis of in-vitro Bioaccessibility Data

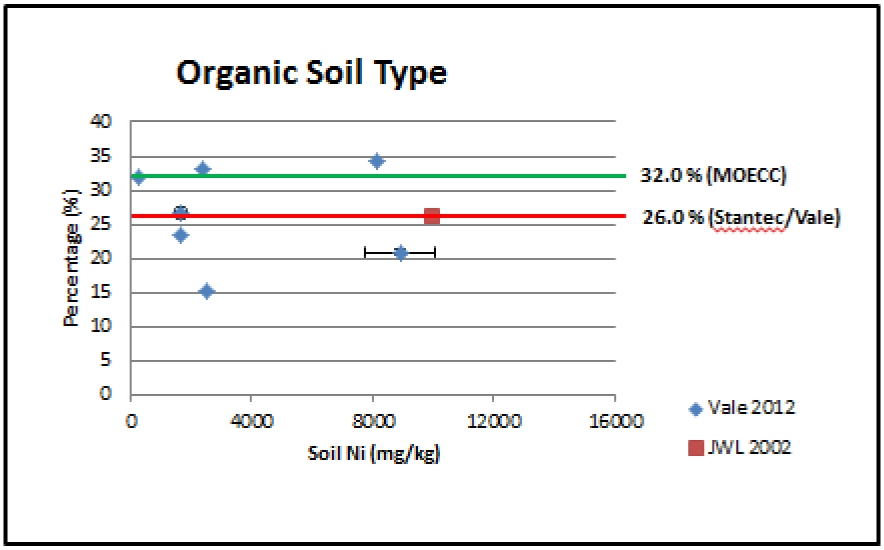
As with the fill soil type, many of the organic soil samples were taken from the same sampling location suggesting a greater number of soil locations than actually tested and raising concerns with treating the bioaccessibility estimates from the same location as independent discrete samples. As a consequence the organic bioaccessibility data were re-analyzed by MOECC by sample location (MOECC Figure C3). It should also be noted that the amount of bioaccessibility information for the organic soils is vastly improved over previous versions of this report. Instead of only one soil location, information is now available for 8 locations.

Organic Soil Type: Re-analysis of the ROB

As observed for the clay soil, there does not appear to be a relationship between Ni bioaccessibility and soil Ni concentrations. However, as with the fill soil, MOECC believes that a reasonable conservative estimate is to use the 95% UCLM. Using all of the bioaccessibility data (including the data from Vale 2012) results in a 95% UCLM of 32% for organic soils (see

MOECC Figure C3 and MOECC Table C4 below). Note: this recommended bioaccessibility estimate captures the range of bioaccessibility for organic soils with Ni concentrations <8,000 mg/kg (which range from 15 to 35%).

MOECC Figure C3



MOECC Table C4: The following data was used to determine the organic soil type bioaccessibility:

		CBRA Report (2014)		Re-analysis(MOECC)		
In-vitro Experiment	**Sample Location**	**[soil]Ni mg/kg**	**Bioaccessibility (%)**	**[soil]Ni mg/kg**	**Bioaccessibility (%)**	
Vale (2012)	Groetlarr	9754	20.6	8921 ± 1177	21 ± 0.5	
Vale (2012)	Groetlaar	8089	21.3			
Vale (2012)	SS20 Low Organic	239	32.0	239	32.0	
Vale (2012)	SS27 Med Organic	1640	23.5	1640	23.5	
Vale (2012)	SS25 V.High Organic	8125	34.4	8125	34.4	
Vale (2012)	Ni 1000c	2547	15.3	2547	15.3	
Vale (2012)	TP-R4	2369	33.1	2369	33.1	
Vale (2012)	TP-S	1980	26.0	1668 ± 210	26.7 ± 0.9	
Vale (2012)	TP-S	1527	27.0			
Vale (2012)	TP-S	1590	27.8			
Vale (2012)	TP-S in Qe	1574	25.9			
JWL (2002)	G1A	9980	26.0	9980	26	
			26		26.5	**Average (Mean)**
					32.0	**95th UCLM**
					34.4	**95th ile**

Summary Point Estimate of Bioaccessibility for Organic Soil Type

For the HHRA, the 95th UCLM of the Fill soil type data at 32.0% bioaccessibility is supported as a CTE estimate. For the sensitivity analysis, the 95th percentile at 34.4% bioaccessibility is supported as a RME estimate.

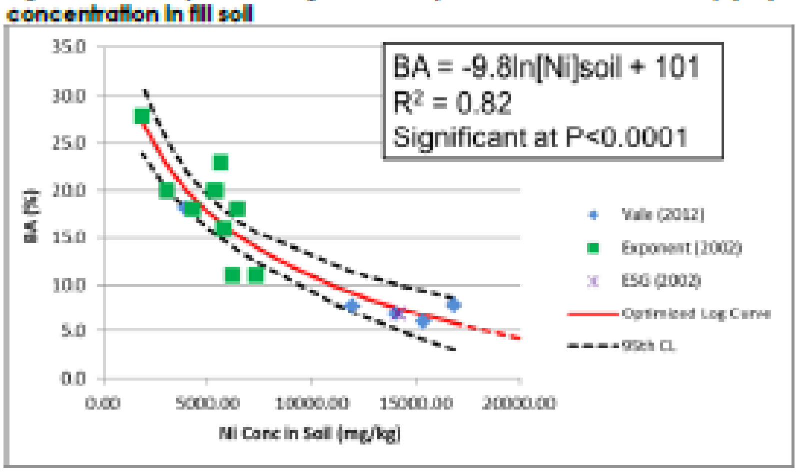
3. ***Other factors that combined reduce the overall confidence in the proposed bioavailability and bioaccessibility estimates.***

The ministry has low confidence in the revised CBRA report for the changes made to determine the Relative Oral Bioavailability based on Bioavailability and Bioaccessibility estimates for the following reasons:

- Only summary information is provided for both the bioavailability and bioaccessibility estimates in the revised CBRA; this includes new information (Vale 2012) presented for the first time to the MOECC. For example, the updated CBRA report does not provide any information on study design, lab reports (SOPs, QA/QC procedures) and methods of analysis.
- There are still inconsistencies in the reporting of sample information. For example, the sample locations as reported in Tables (e.g. Tables 3E-1 and 3E-2) is sometimes different than those indicated in Figures (e.g. map Figures 3E-3 and 3E-3).
- Figure 3E-4 line (including r^2) could not be reproduced by the ministry based on the information provided in Tables 3E-2 and 3E-3 (Figure 3E-4 provided below followed by the ministry's re- analysis in MOECC Table 5C).

Screen Grab: Figure 3E-4: Optimized log relationship between bioaccessibility (BA) of nickel and the concentration in fill soil (Updated Report 2014)

Figure 3E-4: Optimized log relationship between bioaccessibility (BA) of nickel and the concentration in fill soil



MOECC Table 5C: Ministry Re-analysis of fill soil bioaccessibility

	Log	**R^2**	
Fill Bioaccessibility with MOE (Exponent, 2002)	BA = -9.8 In {Ni} soil + 101	0.82	Reported
	BA = -9.98 In {Ni} soil + 101.9	0.717	Re-calculated
	BA = 32.99 - 0.003796 x [Ni] soil + 1.336E-7 x ([Ni] soil)^2	0.756	Re-calculated

Note: Even though the reported relationship in the CBRA report could not be reproduced; the potential change does not result in a significant difference in the bioaccessibility estimates, but a lower confidence in the equation (R^2). The Line of Best Fit statistics have not been used to determine the quadratic line, but it appears to have a better fit to the data.

Estimated Bioaccessibility (%) using the recalculated new line (Ln)

	Bioaccessibility (%)	
[soil]Ni mg/kg	**Measured**	**Calculated**
7310	11	12.4
1840	28	26.5
5370	20	16.4
6410	18	14.1
5620	23	15.9
5730	16	15.6
6200	11	14.6
5290	20	16.6
3040	20	22.7
4270	18	19.2
13848	6.7	6.0
17420	7.7	7.3
8680	7.8	10.1
8489	5.8	10.4
3265	17	22.0
11600	6.9	6.9

Discussion

Several meetings were held between Vale and the MOECC on Ni speciation work to investigate if distance from the refinery (i.e., the source) was related to Ni solubility (i.e., bioaccessibility) due in part to a decrease in particle size with distance (since smaller particles travels farther in air) and Ni speciation of these particles. In other words, the closer a soil is to the facility, the more likely it is to have larger particles associated with lower soluble Ni metal. Thus, the highest concentrations of soil Ni close to the facility may not be as bioaccessible as lower soil Ni concentrations farther from the facility. Based on the analysis conducted with this data, it appears to be the case for Fill soil where Ni bioaccessibility in soils with Ni greater than 8,000 mg/kg is much lower (about 7%) than Ni bioaccessibility estimates for soils with Ni less than 8,000 mg/kg (range from 10 to 28%). While this would be expected to hold true for all three soil types, the analysis was not able to support this for the clay or organic soils.

Summary Estimate of Bioaccessibility data for Fill Soil:

The ministry's re-analysis supports the Fill soil equation of BA = 32.99 - 0.0003796 x [Ni]soil + 1.336E-7 x $([Ni]soil)^2$, based on individual samples; not considering sample location. While the upper confidence limits for this relationship could be used to develop a site-specific bioaccessibility estimate for any given soil Ni concentration, the Ministry recommends that the 95^{th} UCLM of 22% be used instead (as discussed previously). A comparison of the bioaccessibility estimates from the updated CBRA report and the ministry's re-analysis is provided below (MOECC Table C6).

MOECC Table C6: Overall ROB Recommendations and Comparison Chart:

Soil Type		**Bioaccessibility/ROB**		
		CBRA Report (2014)	**Re-analysis (MOECC)**	**Estimate**
Fill	HHRA	5.8 %	21.0 %	CTE
		= -9.8 In {Ni} soil + 101	BA = 32.99 - 0.0003796 x [Ni]soil + 1.336E-7 x $([Ni]soil)^2$	CTE
	Sensitivity	8.7 %	28.0 %	RME
Clay	HHRA	9.4 %	15.0 %	CTE
	Sensitivity	12 %	16.7 %	RME
Organic	HHRA	22 %	32.0 %	CTE
	Sensitivity	26 %	34.4 %	RME

References:

Cal EPA, 2005. Development of Health Criteria for School Site Risk Assessment Pursuant To Health and Safety Code Section 901(g): Child-Specific Reference Doses (chRDs) for School Site Risk Assessment – Cadmium, Chlordane, Heptachlor, Heptachlor Epoxide, Methoxychlor, and Nickel. Integrated Risk Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Final Report. December 2005.

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Appendix D: Outdoor Soil to Indoor Dust Ratio in Port Colborne

Overall Conclusions on the outdoor soil to indoor dust ratio:

Based on a limited number of samples, the ratio between Ni in indoor dust and Ni in soil was estimated in this CBRA to be 0.2 (i.e., dust contains 20% of the total Ni that is found in soil from the Port Colborne community). This ratio was used in the CBRA to estimate the Ni concentration of indoor dust from measured Ni concentrations in soil as part of developing the RBSC. The ministry has concerns with this ratio primarily because the dataset is too small to develop a robust estimate and also because the ratio of Ni in indoor dust to Ni in soil is often much higher than 0.2 below a soil Ni concentration of 2,000 mg/kg.

The ministry agrees that given the uncertainty associated with the limited data available, a ratio of 0.2 could be considered an acceptable qualitative value for characterizing soil with Ni concentrations greater than 2,000 mg/kg. However we do not support using this ratio for soils with Ni concentrations less than 2,000 mg/kg. Instead, MOECC calculated a ratio of Ni in indoor dust to Ni in outdoor soil of 0.56 for Ni concentrations < 2,000 mg/kg using a modified dataset of the CBRA's dust and soil data.

MOECC notes that while the ratio of 0.2 may be acceptable at the RBSC proposed in the CBRA (e.g., 48,000 mg/kg for the Rodney Street community), it is inappropriate to use for developing a RBSC at soil Ni concentrations less than 2,000 mg/kg. Quantitatively, the use of this ratio is limited for the following reasons: (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 ratio greater than 0.2); and (3) it does not account for the variability across the distribution of the data.

For Ni concentrations less than 2,000 mg/kg, the ratio of 0.56 determined by the MOECC lies between the generic default values of 0.39 used in the Rodney Street Risk Assessment Report (MOE, 2002) and a ratio of 0.7 used in the US EPA's Integrated Exposure and Uptake Biokinetic (IEUBK) model for lead exposure to children (US EPA, 2002). MOECC is aware that even higher indoor dust to outdoor soil ratios in residential areas has been reported in the literature. However, these higher estimates are derived at relatively low soil Ni concentrations (as compared to the large range of elevated Ni soil concentrations observed in Port Colborne soil) and are often influenced by indoor sources of Ni that are independent of the outdoor soil.

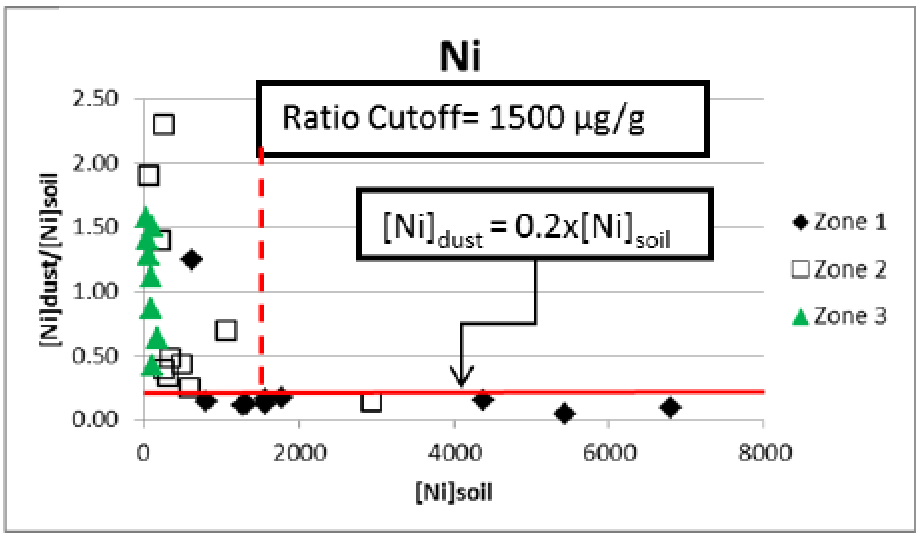
The ratio used for Ni in indoor dust to outdoor soil is also much lower than that observed for the other compounds of concern in this CBRA. For example, the concentration of arsenic in dust is 5 times the levels in soil. Similarly, copper dust concentrations are 2 times and cobalt dust concentrations are equal to the outdoor soil concentrations. These higher ratios for the other COCs are likely due to the fact that the soil concentrations are not as elevated (when compared to Ni) than background levels and do not reflect the wide range of soil concentrations as observed with Ni. MOECC is also aware that a higher residential ratio of Ni in indoor dust of 4.3 times the outdoor soil concentration was determined as part of the Sudbury Soils Study from a much larger dataset (n = 88; SARA, 2005). However, this higher ratio for Sudbury (which ranged from 1.5 to 32 times the outdoor soil) than observed for Port Colborne would be expected as the Sudbury data had lower Ni soil concentrations (from 22 to 3,390 mg/kg; mean = 480 mg/kg), and there continues to be an active sources of Ni from aerial emissions in Sudbury. Overall, despite the limited paired samples from the Port Colborne dataset (n=15 from zones 1 and 2), a site-specific ratio calculated from the limited available data is preferred than using a literature default value.

In summary, the basis of a ratio of 0.2 proposed by Stantec is limited and at best can be used to predict Ni in dust for soil Ni concentrations greater than 2,000 mg/kg. MOECC supports the use of a Ni in indoor dust to Ni in outdoor soil ratio of 0.56 when soil Ni concentrations are less than 2000 mg/kg.

Limitations in Data and Analysis

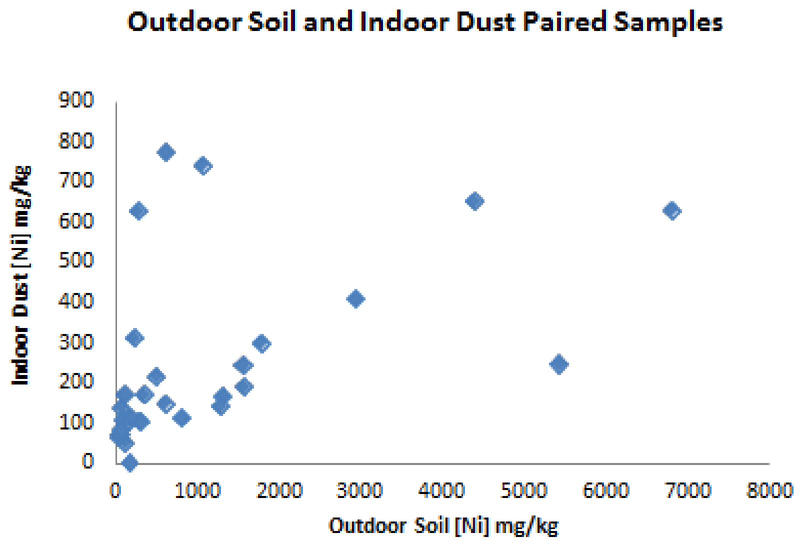
In MOECC Figure D1 (Concentration Ratio Plots for COCs - Nickel), the ratio of 0.2 proposed by Stantec is represented by a red line. As noted in the CBRA report, based on a "visual inspection" of these 28 co-localized soil and indoor dust samples, Stantec identified a Ni concentration of 1,500 mg/kg as a inflection point or as a "ratio cut-off" and selected a ratio of 0.2 that appears to reflect an upper estimate of the 6 datapoints above this concentration.

MOECC Figure D1 (Figure 3B.1; Screen Grab Stantec 2014, Appendix 3B pp 1.12)



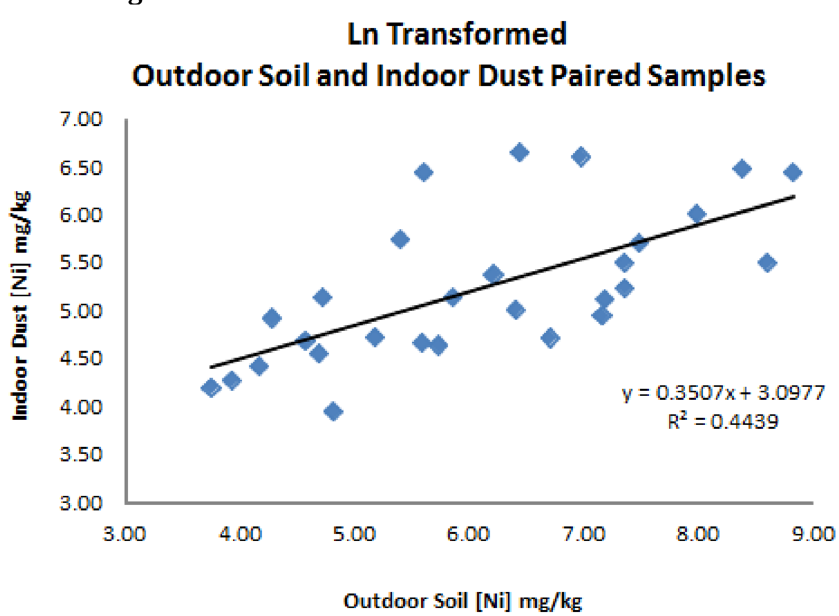
However, most of the data is for soil Ni concentrations below 1,500 mg/kg (n=21 of 28 samples). The large variability of the Ni in indoor dust to Ni in outdoor soil ratio in these samples is also clearly evident at Ni concentrations < 1,500 mg/kg ranging from 0.1 to 2.3. The limited number of samples at the higher soil Ni concentrations (n = 6 for Ni > 1,500 mg/kg; n = 4 for Ni > 2,000 mg/kg) is insufficient to properly characterize the variability and uncertainty inherent in this ratio and severely limits meaningful statistical interpretation of this data at these Ni concentrations. An indication of this variability can be seen when the actual dust and soil data is plotted (MOECC Figure D2).

MOECC Figure D2



While a weak linear relationship can be determined (r^2 = 44) when comparing the natural log of Ni in indoor dust to the natural log of Ni in outdoor soil (MOECC Figure D3), this plot clearly illustrates the high variability in this relationship.

MOECC Figure D3



Ni Concentration at Inflection Point or "Ratio Cut Off"

In the CBRA update report, Stantec states that the ratio of 0.2 is "conservative for predicting the concentrations in dust when the concentrations in soil exceed the ratio cut-off in each CR plot. Ratio cut-offs were established by determining the soil concentration where the data clearly departs from the horizontal relationship." However, since this ratio cut-off was based on visual observation and not on statistical analysis, the ratio of 0.2 and the "ratio cut-off" of 1,500 mg/kg can't be supported quantitatively. However, qualitatively, MOECC recognizes that:

- At low Ni outdoor soil concentrations, other indoor sources of Ni can contribute to the observed higher ratios of Ni in indoor dust to Ni in outdoor soil concentrations and likely contribute to the higher variability of the data, and
- At higher Ni outdoor soil concentrations, indoor sources of Ni are less influential

Based on this qualitative assessment, it is reasonable to expect that a decrease in Ni concentrations in dust to soil ratios would be expected as soil Ni concentrations increases over the observed range of soil Ni concentrations. However, it is not clear where the cut-off should be that distinguishes between high and low soil Ni concentrations. Based on the limited data, it appears that 1,500 mg/kg may be too low as out of the 6 datapoints between 1,000 and 2,000 mg/kg, one value greatly exceeds this ratios (i.e., sample #205: soil = 1,064 mg/kg, ratio = 0.7). As a result, MOECC believe that the ratio cut-off point should be 2,000 mg/kg instead of 1,500 mg/kg. Despite the limited number of paired samples, the ratio of 0.2 is greater than the maximum calculated ratio of 0.16 observed in this dataset. Therefore, MOECC recommends using the ratio of 0.2 only if soil Ni concentrations exceed 2,000 mg/kg.

Re-analysis of the Paired Outdoor Soil to Indoor Dust Ratio

In order to address concentrations below 2,000 mg/kg, the paired dust and soil data was re-analyzed (raw data provided in MOECC Table D1). Only soil data from Zone 1 and 2 with soil Ni concentrations greater than 200 mg/kg but less than 2,000 mg/kg were used in this re-analysis to minimize the likelihood of other indoor sources of Ni influencing the results and to focus on the concentration range of interest. The modified dataset had a smaller number of paired samples (n=15) with soil Ni concentrations ranging from 222 to 1,783 mg/kg. The overall average soil and dust Ni concentration was calculated to be 835 and 291 mg/kg respectively.

Based on this re-analysis, the average (arithmetic mean) of 0.56 is recommended by MOECC for use in the calculation of the RBSC when soil Ni concentrations are less than 2,000 mg/kg. Although a higher dust to soil ratio is expected for homes with soil Ni concentrations below 200 mg/kg (as high as 2.3), the overall contribution of Ni in dust to overall Ni exposure at this soil Ni concentration is relatively minor.

Overall, MOECC recognizes that there is uncertainty with this estimate and that further paired sampling would be required to better characterize the relationship between Ni concentrations in indoor dust and outdoor soils.

MOECC Table D1 - Data used to determine the outdoor soil to indoor dust ratio. Data was extracted From Table 3B.2: Concentration of paired samples of outdoor soil and indoor dust (vacuum samples of soft surface only) from Port Colborne homes.

	CBRA Report (2014)			**Re-analysis (MOECC)**			
Sample ID	Soil [Ni] (mg/kg)	Dust[Ni] (mg/kg)	Soil [Ni] / Dust [Ni]	Soil [Ni] (mg/kg)	Dust[Ni] (mg/kg)	Soil [Ni] / Dust [Ni]	
101	1319	167	0.13	1319	167	0.13	
103	6800	629	0.09				
104	5428	247	0.05				
106	1560	245	0.16	1560	245	0.16	
107	625	775	1.24	625	775	1.24	
108	1278	141	0.11	1278	141	0.11	
109	1783	300	0.17	1783	300	0.17	
110	814	112	0.14	814	112	0.14	
112	4384	652	0.15				
113	1563	189	0.12	1563	189	0.12	
201	496	217	0.44	496	217	0.44	
202	2935	409	0.14				
203	603.5	150	0.25	603.5	150	0.25	
204	351	170	0.48	351	170	0.48	
205	1063.5	743	0.7	1063.5	743	0.7	
206	72.25	138	1.91				
207	272	628	2.31	272	628	2.31	
208	222.75	312	1.4	222.75	312	1.4	
209	268.25	106	0.4	268.25	106	0.4	
210	310	104	0.34	310	104	0.34	
301	96.5	108	1.12				
302	177.75	113	0.64				
304	109	95	0.87				
305	123.5	52	0.42				
306	172	N/A	N/A				
307	42.5	67	1.58				
308	51	72	1.41				
309	113	170	1.5				
310	64.75	83	1.28				
				835	291	**0.56**	**Average**

Appendix E: Soil Ingestion Rate Exposure Assumption

Overall Conclusions on Soil Ingestion Rate:

The ministry has considered the alternative incidental soil ingestion rate (SIR) of 110 mg/day for the toddler receptor and find that it is reasonable for use in the CBRA. However, this represents a Central Tendency Exposure (CTE) estimate in the calculation of exposure from the soil and dust pathways. The ministry also considers the SIR of 200 mg/day to be valid for use in the CBRA as a Reasonable Maximum Exposure (RME) estimate. The SIR of 200 mg/day has been identified as conservative assumption (MOE, 2011) and MOECC maintains its use in the development of Brownfields (O. Reg. 153/04) soil standard setting. The incidental SIR is the key exposure assumption used in the CBRA in estimating exposure from the combined soil and dust pathways. As the SIR does not distinguish between soil and dust it may be assumed for both the soil and dust exposure pathways using the 45:55 ratio as assumed in the US EPA's Integrated Exposure and Uptake Biokinetic (IEUBK) model for lead in children (US EPA, 2002). In addition, as done in the CBRA, the soil pathway may also be pro-rated for winter snow cover, where exposure to soil outdoors is considered negligible or zero.

It is recognised that the SIR inherently has limitations in estimating the amount of soil and dust ingested. In fact, the US EPA (2011) noted that the SIR has an overall "low" confidence rating. Given these limitations and based on the rationale provided by Stantec in the CBRA, the ministry can support using a SIR of 110 mg/day as a CTE in the CBRA. However, the ministry does not agree with the statement that "A soil/dust ingestion rate of 200 mg/day (MOE, 2011) for a toddler is not supported by current literature or recommendations by the US EPA (1997, 2011) and Health Canada (2009, 2012) for application as a chronic intake." It should be noted that the children's SIR in the US EPA's 2011 Exposure Factor Handbook recommends 100 mg/day (rounded from 110 mg/day) for ages 1 to <6 years as a population central tendency estimate. The upper percentile recommendation for soil and dust ingestion of 200 mg/day for 3 to < 6 years old is based on the 95^{th} percentile value obtained from modelling (Ozkaynak et al., 2011) and from the 95^{th} percentile value obtained from tracer studies (Stanek and Calabrese, 1995). In addition, the Ozkaynak et al., (2011) modelling (probablistic human-activity-based-physical model) was limited to the 3 to < 6 years old child; a younger age category would have been preferred, to cover the age around the 2 year old toddler when hand-to-mouth activity is assumed to be higher.

In consideration of the US EPA 2011 Exposure Factor Handbook, the OSWER Directive 9200.1-120 (2014) (which applies to Superfund sites) considers 200 mg/day as an upper bound estimate for residential child soil ingestion rate as their standard default exposure factor. This recommendation supersedes the Risk Assessment Guidance for Superfund: Human Health Evaluation Manual (RAGS), Parts A through E.

In summary, the MOECC supports the use of SIRs of 110 and 200 mg/day within the CBRA as CTE and RME estimates respectively. Furthermore, it is recommended that in calculating the RBSCs that the CTE and RME estimates are used to bracket risk management considerations.

References:

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