

APPENDIX I

RESPONSE TO COMMENTS



GENERAL COMMENTS

Reviewers:

EZH = Ellen Z Harrison, Cornell University

SP = Sanya Petrovic, Health Canada

TS = Dr. Tim Sly, Ryerson University

RAE = Dr. Rebecca A. Efroymson, Oak Ridge Laboratory

#	Comments and Responses
1	<p>Reviewer: Ellen Z Harrison, Cornell University</p> <p>The review focuses on human health aspects.</p> <p>A. Risk from chemical exposure</p> <ul style="list-style-type: none"> • The general approach is sound and appropriate. The pathways of exposure that are assessed for the most part include the relevant pathways and receptors. However, there are many aspects of the RA that make it non-conservative and many of the assumptions made are not appropriate. <p>See response to specific comments.</p>
2	<p>Reviewer: EZH</p> <p>The failure to make use of the recent report prepared by the National Research Council of the U.S. National Academy of Sciences is puzzling and disappointing. That 2002 report, <i>Biosolids applied to land</i>, includes the review of risks posed by land application of sewage sludges and addresses many of the factors considered in the RA.</p> <p>National Research Council 2002. <i>Biosolids applied to land</i>. National Academies Press, Washington D.C.</p> <p>The US study was considered along with other studies. A specific reference has been added to Section 3.1.4 of the main report.</p>
3	<p>Reviewer: EZH</p> <p>The use of deterministic values rather than a probabilistic approach, the failure to define the rationale for many of those single point values, and the lack of identification of the type of person that those values represent (the receptor characteristics) is a critical shortcoming.</p> <p>Agreed. Jacques Whitford has added clarification on the rationale for choosing the deterministic approach in Section 2 and included discussion in Table 5-36 of the uncertainty analysis. A probabilistic approach was outside the scope of work.</p>
4	<p>Reviewer: EZH</p> <p>In places the document reads like a rationalization for dismissing risks that might be posed. The RA, for example, tries to minimize the fact that the cancer risk for Arsenic (As) to the toddler in the home use scenario exceeds the MOE cancer benchmark. RA on p x states “the many assumptions used in the calculations tend to overestimate the risk, meaning the actual risk may be overstated.” In fact, a number of critical assumptions may be underestimating exposure and risk.</p>

#	Comments and Responses
	<p>Harrison, E.Z., M.B. McBride and D.R. Bouldin. 1999. Land Application of Sewage Sludges: An Appraisal of the US Regulations. <i>International Journal of Environment and Pollution</i>. p. 1-36, V. 11 (1).</p> <p>The wording will be rephrased to discuss specific conservative assumptions. The following text has been added to the executive summary:</p> <p>“For example, a number of conservative assumptions were adopted such as assuming twice the recommended pellet application rate in calculating amended soil concentrations, assuming that toddlers will ingest 20 mg/day of pellets for 208 days per year for 4.5 years, and use of limited trace organic data which, based on personal communication, was greater than background concentrations.”</p>
5	<p>Reviewer: EZH</p> <p>Page 78 states that the ingestion rate of backyard produce is very conservative since it assumes that everyone has a garden. In performing a RA such as this one, the objective is not to assess overall risk to the population of Toronto, but to assess the risks to a home gardener using pellets. The fraction of the population with gardens is irrelevant. This confusion raises concerns about the underlying approach to conducting the RA.</p> <p>Agreed. Jacques Whitford to rephrase conservative assumptions as it is a conservative estimate because it represents a reasonable maximum exposure scenario.</p>
6	<p>Reviewer: EZH</p> <p>The point estimates used for a number of parameters are questionable due to both variability and uncertainty. Because of this variability and uncertainty, calculations of the final risk numbers are also uncertain. The RA should at least provide a sensitivity analysis to assess the impact of the deterministic assumptions on the results and to identify key parameters that have a large impact on the risk assessment outcome. A revised risk assessment using probabilistic methods could be conducted using realistic worst case data and scenarios that incorporate variability and uncertainty.</p> <p>A quantitative assessment of uncertainties was outside of the scope of the current assessment. A qualitative discussion is provided as is considered appropriate when a quantitative uncertainty analysis is not performed. The reviewer is referred to Response to Comment #3.</p>
7	<p>Reviewer: EZH</p> <p>Risk from pathogens</p> <p>The section is not thorough, well written or well constructed. The appendix G is a much better review of the pathogen issues.</p> <p>The section will be replaced with a briefer, more concise summary and specifics of the limitations of the pathogen study.</p>
8	<p>Reviewer: EZH</p> <p>Report format and wording</p> <p>There should be a fuller Table of Contents that describes the contents of the appendices and pages on which things can be found, e.g. including pages for each individual chemical profile.</p> <p>Appendix G is listed in the TOC but there is no header for that section and the pages are not numbered.</p> <p>Jacques Whitford will include either a full TOC or a TOC for each appendix.</p>

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9	<p>Reviewer: Sanya Petrovic, Health Canada</p> <p>The review focuses on human health. In general, the risk assessment has followed standard procedures. There are some issues that require additional clarification. The report is arranged in a logical manner and is easy to follow.</p> <p>No response required.</p>
10	<p>Reviewer: Tim Sly, Ryerson University</p> <p>The review focuses on biological issues, although the peer reviewer has added some general remarks.</p> <p>The appendix by Susan Springthorpe and Syed Satter is well put together. However, the syntax, grammar, and vocabulary and style of the main report is “muddy”. The peer reviewer strongly recommends a detailed review and re-write by someone familiar with technical writing.</p> <p>See Response to Comment #7.</p>
11	<p>Reviewer: TS</p> <p>Upper Bounds... there is increasing concern with the use of worst-case measures and extreme safety margins, particularly as these are multiplied together, thus compounding the error. There are many examples of a final risk probability that exceeds the estimate arrived at when using the “most likely” data input points by 10^3, 10^4, or 10^5 times.</p> <p>The use of the 95% upper bound is such a factor that makes sense by itself, but contributes to unacceptable estimates of risk in compounded form. This is also a common criticism of the use of “deterministic” risk assessment, when a “stochastic” method such as monte-carlo or latin hypercube will allow a risk estimate to be expressed more usefully and accurately as an area under (and around) a probability curve on an x-y plot. See Keenan for arguments.</p> <p>A probabilistic assessment was outside of the scope of the current assessment. Further discussion of the use of 95th percentile values has been included in Table 5-36 of the uncertainty section.</p>
12	<p>Reviewer: Rebecca A. Efroymson, Oak Ridge Laboratory</p> <p>The review focuses primarily on the ecological risk assessment although the peer reviewer has read some of the introductory materials to understand the potential exposure pathways. The reviewer has not checked any of the tables for accuracy of TRV values or uptake factor equations.</p> <p>The risk assessment is well written, and the conclusions and uncertainties are generally reasonable.</p> <p>No response required.</p>

1. SPECIFIC COMMENTS

#	Issues/Sections	Comments
13	Executive Summary: General	<p>Reviewer: EZH</p> <p>In general, the summary is a reasonable reflection of the contents of the RA. Thus the comments of the RA would also be relevant to the summary.</p> <p>No response required.</p>
14	Executive Summary: p. viii	<p>Reviewer: EZH</p> <p>“In general, where there were information gaps, conservative assumptions were made in order to assure that risks were not underestimated.” That is highly misleading. While some conservative choices were made, non-conservative assumptions made for one or two parameters can greatly influence the resultant risk estimation.</p> <p>Jacques Whitford has included specific examples of conservative assumptions adopted in the risk assessment to pg xiii of the Executive Summary as:</p> <p>“For example, conservative assumptions such as deriving amended soil concentrations based on twice the recommended application rate of pellets, assessing the toddler as a sensitive receptor and assuming the direct ingestion of pellets by toddlers, city parks workers and residential adults.”</p>
15	Executive Summary: Worker vs residents	<p>Reviewer: EZH</p> <p>The statement is made that risks would be greater for workers than for residents. This is misleading and should be deleted. While exposure may be greater, it is recognized that workers represent a healthy population of adults, not representative of the population at large. It has been estimated that 20% of the population represents people at increased risk due to age, medical issues, pregnancy or other factors.</p> <p>Jacques Whitford has reworded the statement (Executive Summary, p. xii) to read:</p> <p>“Exposure to such entities increase with frequency and duration of handling, as well as quantities used and therefore exposure would be greater for workers than for residents.”</p>
16	Executive Summary: Worker vs residents	<p>Reviewer: SP</p> <p>It is stated that the risks from pathogens would be greater for workers, due to increased handling and care should be taken to minimize exposures. It is appropriate to minimize exposures; however, the risk assessment assumed that toddlers may ingest the pellets but not workers, which suggests that toddlers may receive greater exposure.</p> <p>Disagree. The city parks worker scenario includes direct ingestion of pellets. Clarification has been provided (Executive Summary, p.xii).</p> <p>“Because of the increased contact time for workers routinely handling large quantities of pellets, and therefore increased exposure via inhalation, accidental ingestion, and dermal pathways, some degree of care to minimize potential exposures to trace biological entities during handling would be reasonable.”</p>



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17	Executive Summary: Prions	<p>Reviewer: EZH</p> <p>The summary should include the statement that inactivation of prions is highly unlikely. The summary and the body of the RA suggest that rules should be implemented that disallow discharge of blood and blood products and cite the situation in the UK. As written, it seems to imply that if rules are implemented it means that these items “are not disposed” into the sewer system. Rules are important, but it is naïve to suggest that they will be fully effective.</p> <p>Agreed. The following has been added to this section (p. xiv, Executive Summary):</p> <p>“Implementation of policies, however, would not prevent the introduction of blood and blood products into the sewer systems from domestic sources but instead act as a guideline to decrease contributions by industry and institutions.”</p>
18	Executive Summary: p. xv	<p>Reviewer: EZH</p> <p>“the presence of biosolids in soil has been found to reduce the mobility of metals in soil and therefore uptake into plants” is not accurate and should be deleted.</p> <p>The statement will be replaced with a specific referenced citation.</p>
19	General	<p>Reviewer: EZH</p> <p>Parts of the summary read as though they are a rationalization for why the use of pellets is not a significant risk. The conclusion seems to have come before the assessment. For example on pages xvii-xviii the discussion regarding the exceedance of several thresholds is “explained away.” Among other things the summary states that the exceedance “is marginal and within the range of uncertainty of the assessment.” Would it not be equally valid to suggest that values that are marginally lower than the threshold might represent a significant risk given the uncertainty of the assessment? Particularly for the ecological assessment where no margin of safety is provided in calculating the hazard quotient.</p> <p>The statement will be reworded to reference specific conservative factors.</p>
20	Table 3-3	<p>Reviewer: SP</p> <p>Table 3-3 provides a summary of metals and pathogen standards for different jurisdictions. No information was provided for Australia, though page 14 identifies that Australia and certain US states produce pellets for use in residential situations.</p> <p>Western Australia provides guidelines rather than standards. A brief discussion has been added to Section 3.2.7.4.</p>
21	Section 5: Human health risk from chemical exposure: Conceptual model	<p>Reviewer: EZH</p> <p>The conceptual site model figures are useful. They clearly show the pathways that were assessed for the several receptors.</p> <p>No response required.</p>

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22	Land use scenario	<p>Reviewer: SP</p> <p>The RA specifically did not address agricultural land use. If the pellets are sold commercially, is it possible that they could be applied to agricultural land? In this case, the ingestion of foods from an agricultural site is assumed to be greater than in a residential scenario (CCME considers for an agricultural site 50% of meat and produce, and 100% of milk consumed by residents is produced on site) and this risk assessment would not be representative. Additionally, tilling of agricultural land could result in greater airborne particulate concentrations.</p> <p>This is considered outside the scope of the current assessment. In addition, the intent is to market the pellet in packages impractical for agricultural use of the scale suggested. No further response is required.</p>
23	Receptor characteristics	<p>Reviewer: EZH</p> <p>The RA is not clear on whether the assessment is addressing an average receptor, a reasonable worst case receptor or a highly exposed receptor. Many of the deterministic values used in the RA are not well explained and thus do not allow the reader to evaluate the receptor characteristics. For a number of the factors, the values used seem to represent average and not reasonable worst case exposures.</p> <p>The values will be re-examined to ensure that their basis is clear.</p>
24		<p>Reviewer: EZH</p> <p>The RA should be addressing a reasonable worst case, not the average person. The receptors being evaluated should be persons on the relatively high end for exposure and risk. In which case it would be appropriate to use of values representing a reasonable high-end (90-95th percentile).</p> <p>We disagree with the use of multiple extreme conservative assumptions. As pointed out by some of the peer reviewers, overly conservative (e.g. 95th percentiles) or multiple conservative assumptions lead to results that are unrealistically conservative and this should therefore be avoided. Further discussion has been added to Table 5-36 of the uncertainty section.</p>
25		<p>Reviewer: EZH</p> <p>The RA should be assessing risks to a vegetarian home gardener which is not an unreasonable case. The RA should also address a toddler that spends more than an average amount of time outside as might well be the case for the child of a vegetarian home gardener (since that parent probably spends more time outside than average).</p> <p>See Response to Comment #24. Further discussion has been added to Table 5-36 of the uncertainty section.</p>

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26		<p>Reviewer: EZH</p> <p>There is no discussion or rationalization why particular values were selected and no indication what kind of person is reflected in the values selected.</p> <p>Disagree. The selected receptors are reflective of the proposed uses of pellet application. Each receptor is clearly introduced in the main report with a potential exposures table outlining all possible routes of exposure. The values that were adopted in the risk assessment are clearly referenced in each receptor characteristics tables. Furthermore, the receptors selected are standard receptors used in risk assessment analyses. Appendix C and each receptor table outlines the applicable references. No further response is required.</p>
27	Single vs multiple scenario exposure	<p>Reviewer: EZH</p> <p>RA should address simultaneously the risks posed to toddlers from exposure to pellets and soils and through ingestion of garden produce.</p> <p>The uptake of EoPCs in garden produce has been evaluated taking into consideration the estimated concentration of amended soils. Simultaneously, residential toddler scenario also evaluated exposures to amended soils and pellets via ingestion, dermal and inhalation pathways. The reviewer is referred to Table 5-20 for the calculated garden soil concentrations, Figure 5-5 for a conceptual model of the toddler exposure pathways, Appendix E for the exposure assessment and risk evaluation calculations and Appendix B for the garden produce concentration equation.</p>
28		<p>Reviewer: EZH</p> <p>Need to assess the risks to city workers applying pellets to parks and using sludge at home. It would seem reasonably likely that a person working in grounds keeping and using sludge pellets at work would be a gardener and would use pellets at their home.</p> <p>The reviewer is referred to Table 5-36 of the main report, which qualitatively addresses the scenario involving a city parks worker who works with pellets and applies pellets at home. No further action required.</p>
29		<p>Should not ignore inhalation/ingestion of dust for this worker since it would seem that there might be a fair amount of exposure during mowing. Moderate activity is more consistent with this type of work.</p> <p>See Response to Comment #28.</p>

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30	Biosolids analytical data	<p>Reviewer: EZH</p> <p>Using the 95% UCLM value for sludge cake contaminant concentrations seems appropriate since a pellet user would be getting pellets from different batches over the years they use sludge. The comparison of sludge pellet data to the cake data is useful. In looking at the cake data, it appears that there are no data from 2002 which is puzzling.</p> <p>Agreed. The cake data dates were mislabelled. The 2002 cake data, previously dated as 2003, were included in this study. Appendix E has been corrected to reflect this change.</p> <p>The lack of data regarding organic chemicals in the Toronto sludge is disappointing and surprising.</p> <p>Jacques Whitford to add comment on limitations of data in Table 5-45.</p>
31	Biosolids analytical data	<p>Reviewer: SP</p> <p>It is appropriate that the risk assessment considered the potential risks from metals. It is understood that the pellets data set was small (16 samples) and therefore the biosolids cake data set from a longer time period was used to represent concentration of chemicals in pellets.</p> <p>No response required.</p>
32	Cake vs pellet data for metals	<p>Reviewer: SP</p> <p>Appendix F provides the average concentrations for metals in the pellet data (2001-2003) versus biosolids cake data (1996-2003) and the p value from a t-test. Information was not provided for the maximum, minimum and 95th percentile concentrations in pellet data compared with cake data.</p> <p>Agreed. Jacques Whitford to include descriptive statistics of pellet data into Appendix F. For the 95th percentile concentration, the reviewer is referred to Table 4-2 of the main report.</p> <p>The p values were not presented for a comparison of pellet data and biosolids cake data from 2001-2003 to reflect the contaminant concentrations during the same time period. It is not known whether there are variations over time that may influence the contaminant concentrations and thereby influence the comparison of the data sets.</p> <p>The statistical analyses to identify whether the biosolids cake data is representative of the pellet chemistry should be more rigorous to demonstrate that the sampling bias introduced by different sample types does not materially affect the contaminant concentrations used in the RA.</p> <p>As noted by the reviewer in comment #31, some of the more recent data is unavailable. The report also discusses and takes into account changes in the sewer use by-laws and justification of the data sets selected based on these changes that may impact on biosolids quality. Further analysis of this is not considered warranted given the high variability of the data. More rigorous analysis would not be expected to yield more conclusive information. No further response required.</p>

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33	Organic contaminants	<p>Reviewer: SP</p> <p>Text was not provided to identify whether there is a reason why the levels of PCBs and dioxins may actually be higher in Toronto biosolids when compared to other Ontario biosolids (e.g., is there greater loading at this plant than in other treatment plants).</p> <p>There is insufficient information to conclude that these chemicals are higher in Toronto biosolids and the reasons for any difference are outside the scope of the assessment. No further response required.</p> <p>The pellets are 97% solids versus the cake which is 30% solids (page 11). Dioxins and PCBs are expected to be adsorbed to the solid phase rather than in the liquid phase. It is expected that the levels of these organics would therefore be elevated in the pellets compared with the biosolids cake from this treatment plant.</p> <p>These chemicals may actually be volatilized to some extent during the pelletization process. No further action required.</p>
34		<p>Reviewer: SP</p> <p>It is noted that polycyclic aromatic hydrocarbons were not identified as potential contaminants in biosolids. Rationale is not provided for this. Published literature is attached for reference (Bright and Healey, 2003)</p> <p>Data on PAHs were considered insufficient for a quantitative evaluation of risks. Jacques Whitford acknowledges that the report does not provide an exhaustive list of chemicals in biosolids as this is considered beyond the scope of the assessment. No further response is required.</p>
35	Dioxins	<p>Reviewer: SP</p> <p>In Table II the data for pellets for dioxins appears to be the mean concentration rather than the 95th UCLM concentration when compared with Table 4-1 (page 31). Please confirm these data are accurate or provide footnote to indicate which values were used for the risk assessment calculations.</p> <p>Agreed. Jacques Whitford has included a footnote to Table II of the executive summary indicating that the concentrations of trace organics are based on mean concentrations.</p>
36	Cr, p 35	<p>Reviewer: EZH</p> <p>Does not make it clear how the Cr III vs Cr VI question was addressed. The assumption appeared to be that none of the Cr was VI, which is not a valid assumption. Rather some fraction should be assumed to be Cr VI.</p> <p>Jacques Whitford will elaborate on the deficiencies of the data to better characterize chromium species and discuss the predominance of CrIII based on soil chemistry. The following text has been included in Section 5.1 and further discussion has been included in the uncertainty analysis.</p> <p>“Total chromium was measured by the City of Toronto. Chromium is a naturally occurring element that is most commonly found as the chromium III and chromium VI (hexavalent chromium) forms in the environment (ATSDR, 2000). Chromium III can persist and accumulate in soils because of its association with relatively inert phases while chromium VI, however, is more soluble and is not readily adsorbed onto particulate matter. Although</p>

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		<p>little literature exists on the species of chromium present in soils, it is believed that nearly all the chromium in soils (excluding those contaminated with chromium VI) is likely present as chromium III (Environment Canada and Health Canada, 1994; ATSDR, 2000). This conclusion is based on limited sample data and the environmental fate of chromium III and chromium VI.</p> <p>Although the material of interest is biosolids rather than soil, in the long term pellets would be integrated into the soil phase. Additionally, the greater solubility of Chromium VI would indicate that Chromium III is more likely to be present in the biosolids than Chromium VI which would not be expected to adsorb to particulate matter and precipitate out of waste water to the extent of Chromium III.</p> <p>Since the specific species of chromium were not measured, Chromium III was evaluated as an EoPC to be representative of total chromium instead of Chromium VI. This is considered appropriate because it is unlikely that Chromium VI is the dominant species and therefore selecting Chromium VI to be representative of total chromium would grossly overestimate risk.”</p> <p>A screening level evaluation of Chromium as Chromium VI has been included in the uncertainty section.</p>
37	Cr	<p>Reviewer: SP</p> <p>Data for chromium were not speciated and all chromium was assumed to be chromium III. The risk assessment indicated that assuming all chromium was hexavalent (the more toxic species) could result in an overestimate of risk. However, assuming that none of the chromium is hexavalent could underestimate risk. Generally, soils are speciated for chromium to identify the concentrations of Cr³⁺ and Cr⁶⁺ separately for the purpose of screening chemical concentrations and risk assessments. There is no evidence presented to suggest that hexavalent chromium will not be present in the pellets and ultimately in the amended soils.</p> <p>Although CrVI may be present in the pellets, there are insufficient data to determine relative concentrations. A semi-quantitative analysis of CrVI has been included in the uncertainty analysis section; however collection of additional data (which is outside our scope) is required to properly answer this question.</p>
38	Soil concentrations	<p>Reviewer: EZH</p> <p>The RA is not clear as to how soil concentrations were calculated.</p> <p>A sample calculation will be included.</p>
39		<p>Reviewer: EZH</p> <p>It does not seem to include assumptions regarding soil bulk density which would be needed to calculate the final mixed concentration. It also recognizes that the assumed application duration of 25 years is purely arbitrary.</p> <p>Disagree. The reviewer is referred to the discussion in Section 5.3.7.1, p. 66 which states that the bulk density is 0.63.</p>

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40	Mixing depth:	<p>Reviewer: EZH</p> <p>No rationale was provided for why surface application was assumed to be mixed to a depth of 5 cm. USEPA used a depth of 2 cm in their assessment of the risks posed by dioxins (USEPA, 1999b).</p> <p>USEPA. 1999b. Office of Water. Risk Analysis for the Round Two Biosolids Pollutants performed by Abt Associates</p> <p>Jacques Whitford has been included the following discussion in Section 5.3.7.1:</p> <p>“A surface soil mixing depth of 5cm and garden soil depth of 15cm were selected to be consistent with the derivation of the OTR₅₀ developed by the Ontario Ministry of the Environment. Soil samples were collected throughout Ontario at 0 to 5cm depth for all areas except gardens or tillage, where 0 to 15cm depth was considered (MOE, 1993)”.</p> <p>In addition to the above reference, a discussion of uncertainty has been included in Table 5-36.</p>
41		<p>Reviewer: EZH</p> <p>The NRC report (2002) suggests that the assumed mixing depth of 15 cm for the home garden scenario is likely too high. When spading a garden, unless that garden is double-dug (which takes more energy than most gardeners have), 10 cm is a more reasonable assumption. This value is also suggested as more representative of even agricultural applications (NRC, 2002).</p> <p>Please see Response to Comment #40.</p>
42	Soil concentrations	<p>Reviewer: SP</p> <p>The levels of chemicals that will accumulate in soils is based on a 25 year application. If the intent is to sell the pellets for longer than this time, it is possible that a site could receive annual applications of pellets for a longer duration. The concentrations of contaminants in soils, and the subsequent risks could be higher than estimated based on this risk assessment if used for longer durations. This is particularly the case for arsenic with a risk close to the target risk level of 1×10^{-5} and mercury with a hazard quotient of 0.1 in residential soil. The risk assessment should consider the concentrations of contaminants in soils assuming a realistic application period. It has not been identified in the report whether the pellets will be removed from sale after 25 years or if another risk assessment will be conducted if pellets are used for longer than 25 years.</p> <p>25 years is the expected lifetime of the pelletizer. If operation and sale of pellets is to continue beyond this, further review would be required and field studies should be undertaken to reduce uncertainties. Because of the assumed application rate at twice the recommended rate, use by workers could continue for up to 50 years since application rates are not expected to be consistently high for these scenarios. No further response required.</p>

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43		<p>Reviewer: SP</p> <p>Mixing depth:</p> <p>A mixing depth to 5 cm for lawn soils and up to 15 cm for garden soils seems to be reasonable, but this is not the area of the review's area of expertise.</p> <p>No response required.</p>
44		<p>Reviewer: SP</p> <p>It may be appropriate to include a recommendation in the report to have annual sampling of soils in a park to confirm the results of the modelling.</p> <p>Jacques Whitford agrees that field studies are appropriate if application is to continue beyond the study window of 25 years.</p>
45	Soil ingestion	<p>Reviewer: EZH</p> <p>No weight of a single pellet is provided. What fraction of the assumed soil ingestion rate would be represented by a single pellet? That information is relevant to the assumed 20 mg/day value for ingesting of pellets by toddlers.</p> <p>Jacques Whitford weighed an average of 11 pellets at 121mg. Information on the size of pellets has been added to Section 4.3 of the main report.</p>
46		<p>Reviewer: EZH</p> <p>The values used in the RA are half of that suggested by USEPA in the exposure factors handbook (100 vs 200 mg/day) (1999a). In its most recent sludge-related risk assessment, the USEPA used 400 mg/day as the rate of child soil ingestion (USEPA, 1999b). It is generally recognized that soil ingestion values are very uncertain. Reasonable conservatism would suggest using the higher value or a probabilistic distribution or doing a sensitivity analysis to see the impact that such uncertainty might have.</p> <p>Given the great uncertainty and variability, it is necessary to examine and discuss the impact of the potential for a higher rate of ingestion.</p> <p>USEPA. 1999a. Office of Research and Development. National Center for Environmental Assessment (NCEA). Exposure Factors Handbook (EFH). EPA/600/C-99/001. CD ROM.</p> <p>The soil ingestion rates selected by Jacques Whitford are based on recommended daily ingestion rates from Richardson, 1997 and Health Canada, 2003. These rates are specific to Canadians. Further discussion has been included in Table 5-36 of the uncertainty section.</p>
47		<p>Reviewer: EZH</p> <p>It should also be explicitly stated that pica behavior is not being included in the assessment. It has been suggested (NRC, 2002) that pica behavior, when as much as 10 mg/day or more might be ingested, may be important in assessing acute exposures.</p> <p>Jacques Whitford to include mention of pica children in Section 5.5.3 as an acknowledgement that pica children exist, but have not been addressed in this work. In addition, little is known on the acute health effects of the EoPCs.</p>

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48	soil ingestion	<p>Reviewer: SP</p> <p>The soil ingestion rates are appropriate, and it is noted that it was conservatively assumed that toddlers ingest 80 mg soil plus 20 mg pellets. But the potential for risks associated with pica behaviour in children was not identified.</p> <p>See response to comments 46 and 47.</p>
49		<p>Reviewer: SP</p> <p>The percent ingestion rate from amended soils is 100% which is appropriate, we assume that all soils ingested are from the site.</p> <p>No response required.</p>
50		<p>Reviewer: SP</p> <p>It is noted that only toddlers are assumed to directly ingest pellets which provides a conservative estimate for the non-carcinogens. For the carcinogenic compounds, ingestion of only the soils and no direct ingestion of pellets for other age groups may not be conservative.</p> <p>Given the amount of pellets the toddler is assumed to ingest for 4.5 years (20% of daily ingestion), it is considered adequate for the carcinogenic compounds. Residential adults and workers applying pellets are also assumed to ingest pellets. No further response required.</p>
51		<p>Reviewer: SP</p> <p>Workers were assumed to not directly ingest pellets, which is appropriate only if the directions for use stipulate that gloves be worn at all times during contact with pellets.</p> <p>Disagree. The city parks worker scenario did include direct pellet ingestion. The reviewer is referred to Section 5.3.3.1 which provides a discussion of potential exposure pathways and a graphical representation (Figure 5-1) of exposure pathways affecting the city parks worker including direct ingestion of pellets.</p>
52	Pellet ingestion	<p>Reviewer: SP</p> <p>The RA assumed that toddlers may ingest pellets, but the assessment did not identify the potential for other age groups to directly ingest pellets. Is it possible for pellets to adhere to the hands of other age groups, and subsequently be ingested? Is it possible for pellets to adhere to the fur of domestic animals and be tracked into the home thus resulting in additional direct exposure to pellets?</p> <p>Jacques Whitford has included discussion into Table 5-36 of the uncertainty analysis. It's considered unlikely that other age groups would ingest pellets.</p>
53	Inhalation rate	<p>Reviewer: SP</p> <p>The inhalation rate from US EPA is more conservative than Health Canada recommendations.</p> <p>No response required.</p>

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54	Time spent outdoors	<p>Reviewer: EZH</p> <p>1.5 hours/day assumed for outdoor activity for the toddler does not represent reasonable worst case.</p> <p>The US EPA (2002) Child Exposures Handbook recommends 60 minutes/day for children playing on grass or gravel. Therefore, 1.5 hours/day was considered appropriately conservative. No further response is required.</p>
55		<p>Reviewer: EZH</p> <p>4 hours/day assumed for the golfer seems high.</p> <p>The US EPA (1997) Exposures Handbook, cites a study by Tsang and Klepis, 1996 who studied the time activity patterns of the US population. Statistics for the number of minutes spent outdoors at a park/golf course, on average for all adults was found to be 198.603 minutes/day (N=503) or 3.3 hrs/day. The assumed time spent playing golf outdoors of 4 hours/day is considered appropriately conservative. No further response required.</p>
56	Body weight and gender	<p>Reviewer: EZH</p> <p>It is inappropriate to use a deterministic value of 70.7 kg as the body weight for adults. 70.7 kg is an average male and does not reflect women who have a lower body weight (and also consume more vegetables according the USEPA 1999a).</p> <p>The average body weight of 70.7 kg is based on Richardson, 1997 and is reflective of the average adult Canadian, taking into consideration variations between both genders. No further response required.</p>
57	Body weight	<p>Reviewer: SP</p> <p>The body weight values are appropriate (note that there is an error with the teen weight as identified in the comments), per HC guidance.</p> <p>Agreed. The teen body weight should be 59.7kg as per Health Canada (2003) guidance. The correct body weight was used in the calculations. Jacques Whitford has revised the text within Appendix C.</p>
58	Exposed skin surface area	<p>Reviewer: SP</p> <p>The exposed skin surface area is less conservative than Health Canada recommendations by almost half for most age groups as this risk assessment assumed only lower arms and legs for exposure, rather than upper and lower arms and legs exposed per Health Canada guidance. The exposure assumed 208 days/year (e.g., May - Oct), but over the summer in Toronto (June-Sept) it is expected that children will be in their bathing suits and since the assumptions have already excluded 5 months (Nov-April) where more clothing is worn, it may not be conservative to assume only lower arms and legs are exposed.</p> <p>The consideration of the forearms and lower legs as exposed body surface area is based on the US EPA recommendation that 25% of the body's total surface area should be considered during summer exposures. The reviewer is referred to Appendix C for further discussion. Additional discussion has been included in the uncertainty section in Section 5.5.3.</p>

#	Issues/Sections	Comments
59	Soil loading	<p>Reviewer: SP</p> <p>Health Canada recommends the value used for hands and a lower value for the rest of the body.</p> <p>Agreed, Health Canada does recommend different values for the hands and remaining body. Assuming a lower soil loading for the arms and legs would result in decreased exposure via the dermal route, therefore this exposure is considered conservative and appropriate. No further response required.</p>
60	Dermal exposure	<p>Reviewer: SP</p> <p>Health Canada assumes that dermal exposure is one event per day (e.g., effectively 24 hour exposure), as people do not generally bathe immediately following exposure to soils. Therefore, for ingestion and dermal exposure it is irrelevant that people spend 1.5 hours outdoors in contact with amended soils, this parameter is of interest for inhalation exposure only.</p> <p>Recommend a row in table C-2 for "percent dermal exposure to amended soils" (it should be 100%).</p> <p>Dermal exposure included exposure time to account for the different concentrations in pellets, amended soil at 5 cm depth and amended soils at 15 cm depth. No further response required.</p>
61	Bioavailability	<p>Reviewer: SP</p> <p>The report (page 40) identifies an oral bioavailability factor of 0.24 for arsenic via ingestion of soils, 0.003 for cobalt in soil and 0.57 for lead in soils. These are values from literature references for soils and are not considered to be acceptable for use for pellets as the fraction organic carbon content and other characteristics could result in a different bioavailability compared with that from the soils in the literature referenced study.</p> <p>It is recommended that oral bioavailability factors from soils be excluded from the risk assessment, and data specific to biosolids be identified to determine the oral bioavailability of COPCs via ingestion of biosolids (e.g., does arsenic bioavailability increase with increased fraction organic carbon pellets?).</p> <p>Since no data on this specific to biosolids are available, discussion has been included into Table 5-36 as a source of uncertainty.</p>
62	Plant uptake	<p>Reviewer: EZH</p> <p>The NRC report (2002) has a lengthy section discussing plant uptake considerations that should be used in reworking the RA. The NRC report finds that the assertion that contaminants applied in biosolids are less available is not validated and does not consider the extent to which any binding is reversible or would change as soil conditions change.</p> <p>Since the calculations do not assume any reduction in plant uptake, no changes are required.</p>

#	Issues/Sections	Comments
63		<p>Reviewer: EZH</p> <p>The values for the uptake of contaminants into plants that are used in the RA are not appropriate. The RA uses data that are average values based on a very limited data set (Baes, et al, 1984) for some contaminants and for others includes many non-food plants (Efroymson, 2001).</p> <p>The most recent published literature on this was considered and the values selected are thus considered appropriate. No further action is required.</p>
64		<p>Reviewer: EZH</p> <p>Measured plant uptake values are highly variable depending on factors such as different soils (pH has a large impact for some contaminants), different environmental and climatic conditions (which may vary from year to year as well as from location to location) and different crops (there are very large differences among crops and even among varieties of the same crop plant)!</p> <p>This can be further elaborated on in Table 5-36 of the uncertainty section. The following text has been included in Section 5.3.7.2:</p> <p>“Soils in Southern Ontario do not have low pH which would affect the uptake of EoPCs by plants. The 97.5th percentile Ontario Typical Range (OTR₉₈) pH for soils, as reported by the MOE (1993), is 7.5 for Old Urban/Parkland.”</p> <p>Soil pH has a large impact on cadmium availability and uptake. The RA suggests that sludge will cause the pH to be elevated, thus depressing plant uptake of metal cations. However, while sludge use can cause an elevation of pH initially, subsequent depression of pH by 1-1.5 units may occur when organic matter decays and cations leach (NRC, 2002).</p> <p>The assessment is specific to pellets, not sludge, and a significant pH depression is not anticipated for pellet applications. No further response required.</p>
65		<p>Reviewer: EZH</p> <p>In performing a risk assessment for the use of pellets in a home garden, it would seem advisable to use data from crops that might be expected to be grown in a home garden and to use data that represent a relatively high uptake since a garden might well be situated on a relatively “risky” soil (in the case of cadmium this would be soils with low pH).</p> <p>Soils in Toronto exhibit fairly consistent pH levels and low pH soils are not expected. See Response to Comment #64.</p>

#	Issues/Sections	Comments
66	Dietary intake	<p>Reviewer: EZH</p> <p>It would seem reasonable to assess the risks based on the diet of a vegetarian home gardener (National Research Council, 2002). The RA plugs in values for vegetable and fruit consumption but does not include information about what type of person those numbers represent.</p> <p>Home gardeners eat more vegetables than those who do not garden and females eat more than males (USEPA, 1999a) and a vegetarian would eat more vegetables than a non vegetarian. The RA should be explicit about what the characteristics of their assumed receptor are. That receptor should represent a reasonable worst case.</p> <p>See Response to Comments #24, 25, 26.</p>
67	Ingestion rate of vegetables	<p>Reviewer: SP</p> <p>ingestion of vegetables values appear to be from Health Canada recommendations</p> <p>Agreed. Vegetable ingestion rates are from Health Canada. No further response required.</p>
68	Percent of vegetables from home garden	<p>Reviewer: EZH</p> <p>The RA uses a value of 7% for the percent of vegetables consumed that are home grown. A value of 17% is recommended by USEPA in the Exposure Factor Handbook (1999a) for the percentage of home grown vegetables consumed by the home gardener.</p> <p>The US EPA Exposure factor handbook's recommendation is not location specific. Due to the different climate experienced in Ontario then all American states, on average, 7% is considered appropriate. No further response is required.</p>
69	Percent of vegetables from home garden	<p>Reviewer: SP</p> <p>For establishing residential guidelines, CCME assumes that 10% of produce is grown in a backyard garden.</p> <p>10% is considered high for urban/residential areas based on other studies undertaken in the region. Further justification will be provided.</p> <p>Table C-2 (Appendix C) provides values for fraction of produce consumed from the site, with 0.07 for all age groups, except 0.007 for a composite receptor. Please confirm the correct data were used for the risk assessment calculations.</p> <p>The composite receptor takes into consideration that an assumed 0.07 fraction of produce is consumed from the site. Jacques Whitford has corrected Table C-2 in Appendix C.</p>
70	Averaging time	<p>Reviewer: SP</p> <p>An averaging time of 75 years was used for adult workers exposed to carcinogens (Table 5-7). Health Canada currently recommends an averaging time of 56 years for adults, as the exposure starts in adulthood.</p> <p>Jacques Whitford has included a discussion into Table 5-36 of the uncertainty analysis.</p>

#	Issues/Sections	Comments
71	Background exposure	<p>Reviewer: EZH</p> <p>The RA should include values for the background exposure to the contaminants. It is stated that a value of 0.2 for the hazard quotient is used in part to address the fact that background exposure is not taken into account. For some contaminants, there may be sufficient background exposure that the incremental exposure from sludge pellets is a concern. Without including the background values, we cannot make a conclusion.</p> <p>The methodology used is consistent with jurisdictional guidance and the acceptable benchmark of 0.2 employed. No further response required.</p>
72	Calculated dose for each pathway	<p>Reviewer: EZH</p> <p>It would be useful to include RA figures or a table that shows the calculated doses for each of the pathways for each of the contaminants assessed or at least for the contaminants that score a hazard quotient or exposure ratio within 100 fold of the cut off values (As, Cd, Hg, Ni, Pb, Zn, PCDD/Fs per table 5-34). This table would enable the reader to evaluate the contribution of each pathway (at least according to the assumptions and calculations of the RA) to the total exposure burden. This would help reader to evaluate the sensitivity of the calculations to the assumptions made for the different pathways.</p> <p>Jacques Whitford has included two graphical depictions of the percent contributions of individual ingestion/dermal pathways to the overall arsenic cancer risk for the residential composite adult adult as Figure 5-7.</p>
73	Toxicity values	<p>Reviewer: SP</p> <p>It is noted that the report did not use Health Canada recommended toxicity reference values, but selected toxicity reference values from this and other jurisdictions.</p> <p>TRVs were selected in accordance with MOE guidance.</p>
74	Uncertainty and variability	<p>Reviewer: EZH</p> <p>The RA did not provide a sensitivity analysis. A more quantitative analysis of how changes in some of the input assumptions on the conclusion is preferred.</p> <p>A quantitative uncertainty analysis is outside the scope of the current assessment. No further response required.</p>
75		<p>Reviewer: EZH</p> <p>The first paragraph of section 5.5 reads as though it is designed to convince the reader of the safety of the practice being evaluated. There is no uncertainty analysis, rather a general description of what it is.</p> <p>An uncertainty analysis may be either quantitative or qualitative in nature depending on the item being addressed. A quantitative assessment for specific uncertainties has been included into the uncertainty section.</p>

#	Issues/Sections	Comments
76		<p>Reviewer: EZH</p> <p>Table 5-36 contains a useful list of assumptions and the justifications for them. But it is not clear why it is in the section. The description and justification are not detailed enough to answer the questions raised. In many places the table overstates the conservatism and does not recognize the non-conservative assumptions.</p> <p>An uncertainty analysis is a discussion of factors which, if varied, would result in a different risk outcome. The analysis can be qualitative, quantitative or both in nature, where appropriate. The assumptions that are presented in Table 5-36 provide the reader with the major assumptions adopted in the risk assessment. It is these factors that would most affect the outcome of risk. No further response required.</p>
	Section 6	Biological Agents
77	Risk from microbial contamination of soil	<p>Reviewer: SP</p> <p>Deborah Schoen of HC's Quebec regional office is initiating work on preparing a guidance document on methods to assess human health risks posed by microbial contamination of soil.</p> <p>Microbial contamination of soil risk assessment is outside the defined scope of work. No further response required.</p>
78	p.97, para 1-4	<p>Reviewer: TS</p> <p>The peer reviewer is pleased that the earlier reference to “pressure” has been removed as a characteristic of the pellet processing system, as it is clearly not possible to provide an elevated <u>atmospheric</u> pressure in a “continuous” system.</p> <p>No response required.</p>
79	p.11, para 4	<p>Reviewer: TS</p> <p>The RA states that the pellets are reported to be more than 99% pathogen free. The citation is an unpublished source that appears to be from the entity involved in the pelletization process. It would be important for a neutral entity to verify the reduction. Given the high levels of pathogens in unprocessed biosolids, a 99% reduction is not adequate for the production of a product considered acceptable for use by the public.</p> <p>The assessment has not attempted to determine what level of reduction may be “adequate” and can only refer to the limited guidance available from regulatory agencies on this topic. No further response required.</p>
80	p. 98, para 2	<p>Reviewer: EZH</p> <p>“The pelletization process seems to be a potentially suitable decontamination technology to make biosolids safe to use” is not backed up in the discussion or Appendix G. Questions are raised due to the dry heating, the lack of data on the pellets, the potential for regrowth, etc. The dry heat issue seems particularly important to address through research and monitoring.</p> <p>Information recently received from the Toronto Works Department indicates that although a dry heat is applied, the moisture in the pellets yield 100% humidity within the pelletizer. Further discussion on this has been included.</p>

#	Issues/Sections	Comments
81		<p>Reviewer: EZH</p> <p>Missing from the discussion is evidence that there is the potential for pathogenic organisms to be “sheltered” by being embedded in organic particles. This has been studied in dental endoscopes and has been suggested as possibly an issue in sludges (Lewis).</p> <p>Lewis, D.L. 1999. A sterilization standard for endoscopes and other difficult to clean medical devices. <i>Practical Gastroenterology</i>. Vol. 23 pp.28-56.</p> <p>Lewis, D.L. (1999) High-level disinfection of flexible endoscopes: A microbiologist's point of view. <i>International Review of Modern Surgery</i>. pp. 77-83.</p> <p>It is acknowledged that this could be the case. However, given that the source of the information is from dental endoscopes and that this report already states that further evaluation and testing of the pellets generated at ABTP should be carried out, Jacques Whitford has not specifically included this reference in the text of the report.</p>
82	p.98, para 3	<p>Reviewer: TS</p> <p>The peer reviewer does not think that “helminth eggs” constitutes one of the “pathogen classes”. “Helminths” is sufficient, (including as it does, the trematodes, the nematodes, platyhelminths, and the protozoa).</p> <p>Agreed. Jacques Whitford has changed all references to helminth eggs to helminths in the main report. Appendix G, the U of Ottawa appendix, however, remains unchanged.</p>
83	<p>p.99, para 1: (s. 6.2)</p> <p><i>“...The spores of C. perfr have been considered as a suitable indicator of the presence of fecal material but may not be suitable during the heat treatment of sludges because of their high resistance to heat...”</i></p>	<p>Reviewer: TS</p> <p>Appendix G is the source of this statement. It makes sense to say that <i>C. perfringens</i> is a good indicator of fecal contamination in the appendix because it is stated in the context of testing drinking water. However, the statement on p. 99 is illogical as the vast proportion of the matter present in the pellets is fecal in origin. The heat resistance of the organism makes it an excellent indicator of fecal matter, enduring relatively high heat treatment.</p> <p>Note also only SOME classes of <i>C.perfringens</i> are heat resistant, and only SOME classes of <i>C.perfringens</i> are pathogens. Further, the 8-10 minutes mean generation time (MGT) is encountered only under optimum temperatures, substrates, redox, and other environmental factors, and these would not likely be encountered during the manufacture storage or use of the pellets.</p> <p>Agreed. The text has been modified.</p>
84	p. 99, section 6.3	<p>Reviewer: EZH</p> <p>What is the evidence/data/citation for the comment that virus numbers in pellets are likely to be small? In the discussion no mention is made of the potential risks to toddlers ingesting pellets.</p> <p>The justification is given in Appendix G. A reference to this will be added. Adequate methods are not available to quantify risks to toddlers from ingestion of pellets.</p>

#	Issues/Sections	Comments
85	Risk from pellet ingestion	<p>Reviewer: SP</p> <p>Ingestion of pellets by toddlers was identified as a potential exposure pathway in a residential scenario for exposure to metals but no discussion was provided regarding potential exposure to pathogens in this exposure scenario. The implications of the discussion that virus may not be totally deactivated and that the minimal infectious dose for virus is extremely small for toddlers ingesting pellets and exposure for other residents has not been discussed.</p> <p>The discussion of pathogens in the context of this report was to provide a broad overview of the issues associated with pellet application to land. See response to #84.</p>
86	p. 100, Section 6.4	<p>Reviewer: EZH</p> <p>Should state that there is likely to be much less inactivation under dry heat conditions.</p> <p>See response to comment #80.</p>
87	p. 100, section 6.6	<p>Reviewer: TS</p> <p>Much of the content of section 6.6 is factually vague or incorrect. The reviewer offers the following text as more clear and correct.</p> <p>Section 6.6 can be headed Prion Disease</p> <p><i>“These are transmissible spongiform encephalopathies (TSEs) generally associated with normal cellular prion protein that has become infectious due to a conformational change (Prusiner, 2000). TSEs include for example scrapie, bovine spongiform encephalopathy (BSE) and chronic wasting disease (CWD) in animals, and several versions of Creutzfeldt-Jakob disease (CJD) in humans.</i></p> <p><i>Although transmission through feces or urine has not been demonstrated (Tan et al., 1999), the evidence for actual transmission through blood transfusion has been increasing. Transmission has been established for ingestion and iatrogenic procedures. While the possibility of prion disease agents replicating in the natural environment is unknown and probably remote (Gale et al., 1998), some evidence exists for the survival in soil/pasture of the infectious prion associated with scrapie (REF PENDING). The current understanding of the process necessary to deactivate the infectious prion protein suggests that the process by which biosolid pellets are produced would not alter the infectivity appreciably (REF PENDING). The diseases are extremely rare, and no “outbreak” of TSE exists among humans in Canada. However, as with most countries, Canada has a (known) cause-specific mortality rate for “spontaneous” CJD of approximately one per million population per year. Should TSEs become a concern in Ontario, precautionary measures may be necessary to prevent biosolids from acting as a fomite.”</i></p> <p>The offered text will be taken into consideration.</p> <p>Reference for survival of prions in soil/pasture:</p> <p>Brown, P. and Gajdusek, D.C., 1991. Survival of scrapie virus after 3 year interment. Lancet 377: 269-270.</p>

#	Issues/Sections	Comments
88	p. 101, last paragraph	<p>Reviewer: TS</p> <p>It is okay to adopt the UK policy regarding abattoir operations in preventing prions from entering the system.</p> <p>But some clarification is needed.</p> <p><i>“In the UK any animal which is symptomatic (i.e. it could be positive) is subject to testing of the brain stem using immunohistochemistry (IHC) - this is the gold standard for detecting prion presence. Such an animal, if found to be positive, will not be rendered but incinerated. If negative, it can proceed but remember that a >30 month old animal is NOT used for human food in any case, and NO ruminant-to-ruminant passage is allowed in any case.</i></p> <p><i>Animal organs were never disposed of into the sewage system in any case. Such materials (brain, skull, eyes, spleen, spinal cord) are disposed of using incineration in the UK. Fine screens across drains would prevent lumps of fat and other semi-solids for accidentally entering the system, but would not actually prevent entry of ANY infective prion if in blood or other fluids or semi fluids.</i></p> <p><i>Something we are NOT clear about is whether "rogue" or abnormal prion particles are present in faeces of a person suffering from CJD for instance. But as Syed Sattar say, the risk of this is vanishingly small. In fact the whole idea of risk of prion diseases though dried sewage is vanishingly small.”</i></p> <p>Jacques Whitford to provide clarification.</p>
89	prions	<p>Reviewer: EZH</p> <p>The RA should clearly state that given what we know, it is highly unlikely that prions will be inactivated by the sewage treatment and pelletization processes. It should also not overstate the potential effectiveness of enacting rules to keep them from the sewer system.</p> <p>Clarification will be made.</p>
90	p. 102 summary (s 6.7)	<p>Reviewer: EZH</p> <p>The summary in the report mentions the potential use of phages for monitoring. That is the first mention of them and it should be explained how/why they are potentially good indicators.</p> <p>A brief discussion of this can be added.</p>
91	p. 102 para 1 (s 6.7): Para 2: Para 3: Para 4: Para 5:	<p>Reviewer: TS</p> <p>Suggested revision: “The literature suggests that a minimum process time of 60 to 90 minutes at a temperature of 80C achieves the destruction of most pathogens. The pellets should be routinely monitored for selected pathogens until a sufficient history confirms the value of monitoring only certain parameters”</p> <p>Para 2: No changes</p> <p>Para 3: No changes</p> <p>Para 4: Remove... redundant</p> <p>Para 5: No changes</p> <p>No changes</p> <p>Agreed. Jacques Whitford to remove paragraph 3.</p>

#	Issues/Sections	Comments
92	Confirmatory test for pathogen content	<p>Reviewer: SP</p> <p>The number of samples and procedures that should be adopted to ensure that the pathogenic content of the pellets are not a significant health concern has not been specified.</p> <p>This recommendation is outside the scope of work of this report.</p>
93	Pathogen regrowth	<p>Reviewer: EZH</p> <p>The issue of potential regrowth of pathogens is mentioned, but not in regard to regrowth on the soil at the time of use. Rather it is considered only as a storage issue.</p> <p>Further discussion will be added.</p>
94	endotoxins	<p>Reviewer: EZH</p> <p>Symptoms reported by neighbors to sludge land application sites are often consistent with exposure to endotoxins and endotoxin levels in sludges are expected to be high. Thus potential endotoxin exposure should be addressed in the RA.</p> <p>Epidemiological studies have not conclusively connected the symptoms experienced by neighbours to sludge land application sites with exposure to the sludge. As a result, the National Research Council has recommended that the US EPA conduct more thorough epidemiological studies to confirm preliminary findings. Therefore, although exposures may be high (though this will vary since the current study addresses pellet use and not sludge use), the actual risk may not be.</p>
95	Unexpected events	<p>Reviewer: EZH</p> <p>The risk assessment should address what would happen in the case of an unforeseen malfunction in the pelletizer. What mechanisms are or will be in place to provide knowledge that the necessary processing has not taken place? What will be done to prevent distribution or to recall product? Appendix G mentions the need for various control strategies and these should be employed if pelletization moves forward.</p> <p>We concur and these issues should be addressed by Works and Emergency Services or Toronto Public Health.</p>
96	Uncertainty	<p>Reviewer: SP</p> <p>There is uncertainty associated with the potential risks associated with the biological agents in pellets. There does not appear to be a specific recommendation to quantify potential risks associated with biological agents.</p> <p>Appendix G suggests that workers minimize exposure to pellets. Additionally, this reports states that “the potential for infections of minor wounds must be considered a priority”. If these pellets are applied in a residential or parks scenario, will there be a requirement to post a notice to alert people to minimize exposure? It is common for toddlers to have minor scrapes that would not be washed immediately. Additionally, it was assumed in the risk assessment that toddlers could ingest the pellets.</p> <p>This is outside the scope of the current assessment.</p>

#	Issues/Sections	Comments
97	Label	<p>Reviewer: SP</p> <p>The label for pellets (page 17) does not appear to include a statement regarding potential pathogens and ensuring the product is kept away from children. The caution appears to indicate that “this fertilizer contains copper and should be used only as recommended”. It is noted that the risk assessment did not identify copper as the major human health concern.</p> <p>The label does not appear to caution restricted use within a specified distance to surface water or upgradient of drinking water wells. This does not appear to have been addressed in the risk assessment.</p> <p>The report regarding biological issues identifies that “complete rehydration of the pellets, if it occurs prior to land spreading, could permit some pathogen growth to occur”. This caution does not appear on the label and residential use of pellets could result in variable storage environments.</p> <p>The content of the current label is outside the scope of this assessment.</p>
	Section 7	Ecological Risk Assessment
98	p. 33, Sect 4.3.	<p>Reviewer: RAE</p> <p>The peer reviewer ideally would have liked to see such an evaluation without the felt. For example, does rain water move the pellets downhill on slopes where land application is permitted?</p> <p>The experiment was initially undertaken without the felt; however, the pellets quickly disappeared into the thatch layer and could not be observed. No further response required.</p>
99	p. 103, 1 st set of numbered bullets	<p>Reviewer: RAE</p> <p>The assumptions for the ecological risk assessment need to be clarified. The peer reviewer believes that gardens were not considered, but gardens are listed in bullet 1. Also, if gardens were considered, then incorporation into 15 cm would have been assumed (as stated on p. iv), which is inconsistent with these bullets? Also, the 15-cm incorporation garden scenario is presented in Table 7-1, p. 106, when it is not listed as a scenario on p. 103 or on p. iv. And (p. 105, 2nd para, last sentence) if gardens were not explicitly considered, then why is the concentration in the top 15 cm mentioned here?</p> <p>Gardens were considered but not evaluated. Gardens has been deleted from Bullet Number 1.</p>

#	Issues/Sections	Comments
100	p. 104	<p>Reviewer: RAE</p> <p>Need to clarify throughout the document that ecological risk assessment for pets was conducted on an individual rather than a population basis. For example, The final bullet on p. 104 says “the ERA does not consider effects on individuals of a single species. . . this philosophy is intended to be protective of exposed biota at the population level” The peer reviewer believes that this is incorrect with respect to pets.</p> <p>The reviewer is correct that pets were evaluated as individuals. Other animals were evaluated on a population basis. The toxicity reference values selected for pets were considered appropriate to the protection of pets as individuals. Although some of the values selected for other animals are the same as those selected for pets, they were selected based on levels considered protective of species on a population basis. All references to this in the text will be checked for accuracy.</p>
101		<p>Reviewer: RAE</p> <p>The bullet on p. 155 states that the assessment endpoint is “populations of birds of mammals . . .” On the next page, health effects in pets is listed as a measurement endpoint. The assessment endpoint on p. 115 should be more inclusive of the assessment endpoint for pets.</p> <p>The assessment endpoint is correctly identified in the executive summary. The same text will be inserted on page 155 as follows:</p> <ul style="list-style-type: none"> ➤ Wildlife Assessment Endpoint: Populations of birds or mammals that may be reduced as a result of increased mortality or decreased reproduction because of the presence of constituents of concern in soils. ➤ Pet Assessment Endpoint: Individual pets that may have increased risk of health effects because of the presence of constituents of concern in soils.
102	p. 105, sect. 7.1	<p>Reviewer: RAE</p> <p>Consider mentioning that fertilizers often/usually decrease plant diversity (and perhaps invertebrate diversity), even though diversity is not a stated endpoint.</p> <p>This is outside the scope of the current assessment.</p>
103	p. 105, para 3	<p>Reviewer: RAE</p> <p>The statement is made that “ecotoxicity guideline criteria are developed based on effects on the most sensitive species for which toxicity data are available.” Please check this statement, relative to the MOE and CCME ecotoxicity criteria. Many guideline criteria are developed based on a percentile of a sensitivity distribution, not the lowest concentration of the distribution. The CCME standards for hydrocarbons in soil are likely based on the 25th or 50th percentiles (depending on land use) of the combined effects data set for plants and soil invertebrates. The statement is suspicious because if the criterion were equivalent to the toxicity value for the most sensitive species, then the MOE and CCME criteria listed in Table 7.1 would be expected to be the same.</p> <p>Agreed. The statement will be removed.</p>

#	Issues/Sections	Comments
104	p. 107. 1 st bullet	<p>Reviewer: RAE</p> <p>The phrase “virtually any suitable habitat” is vague. Any species can be said to reside in suitable habitat. It is the range of suitable habitat types that is important. 2nd bullet. Please clarify the meaning of “surface runways.”</p> <p>The statement regarding habitat will be replaced:</p> <p>“It is common in moist forests, open country, and brush, but can be found in virtually any habitat, urban or rural, where it’s able to find food and burrow”.</p> <p>The statement regarding surface runways will be replaced:</p> <p>“This is a small herbivorous vole which makes its burrows along open areas in grasses or other herbaceous vegetation”.</p>
105	p. 107, last 2 bullets	<p>Reviewer: RAE</p> <p>These entries provide more specific exposure information than the other bullets. Consider rewriting these in a parallel form. The bullet for domestic dog is confusing. Was a large or small dog chosen as representative? I see that a typical size cat was chosen. Also, please provide a reference for the 2% soil ingestion assumption for dogs and cats, esp if the value did not come from the EPA wildlife exposure factors handbook.</p> <p>Further clarification/refinement will be made.</p>
106	p. 107	<p>Reviewer: RAE</p> <p>Are deer or rabbits potentially exposed in Toronto or on Toronto-owned lands?</p> <p>Deer and rabbits are potentially exposed in the Greater Toronto Area.</p> <p>Consider the following possible exposure scenarios. Deer or rabbits might ingest biosolids pellets before they are incorporated into soil. Deer ingest soil or other materials to fulfill mineral salt requirements that they do not get from forage. For example, Sample and Suter (2002) found that deer consumed coal ash, presumably to meet sodium requirements. Similarly, when forage quality is poor, rabbits reingest their own fecal pellets, and might (possibly) find the pellets palatable for their organic and salt content. The pellets might remain in pelleted form for weeks before several days of rain break them up, esp during drought conditions. The authors should consider whether or not these scenarios should be evaluated. In addition, deer (and farm animals) have been observed to suffer from copper toxicity when molybdenum levels in soil (usu from fertilizer) are high. The authors should consider whether or not this type of effect could apply here.</p> <p>Sample, BE, and GW Suter II, 2002, Screening evaluation of the ecological risks to terrestrial wildlife associated with a coal ash disposal site. Hum Ecol Risk Assess 8:637-656.</p> <p>Jacques Whitford recognizes rabbits may incidentally ingest their own fecal pellets, however, based on a limited experiment conducted by the project team, the pellets were found to be readily dissolved once watered and applied to land as well as disappearing quickly into the thatch layer of a lawn. Therefore, the availability of the pellets to wildlife for consumption is believed to be limited. Reference to this experiment will be added into the ERA sections.</p>

#	Issues/Sections	Comments
107	p. 115, last para	<p>Reviewer: RAE</p> <p>The term “measurement endpoint” is no longer being used by EPA. In EPA (1998, below), the agency provides an explanation for “Why was measurement endpoint changed? ”The agency wanted a term that was not as confusing and that included measures of ecosystem characteristics, life-history considerations, or exposure. Is Ontario or Canada still using the “measurement endpoint” term? EPA 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F. Risk Assessment Forum, EPA, Washington, DC.</p> <p>This term has been replaced with “measure of effect” throughout the report.</p>
108	p. 121-123, xvii	<p>Reviewer: RAE</p> <p>This text concerns EHQs. In Table 7-7, only a few EHQs are presented with 2 significant figures (TCDD housecat, arsenic housecat, and arsenic dog). These values should be presented with one significant figure, and should all be 1. Then the 2nd para on p. 121, should say 1 instead of 1.0. Then the question arises about whether an EHQ equivalent to 1 is of potential concern or only an EHQ above 1. In this paragraph, it is written “An EHQ value greater than one indicates that a risk cannot be ruled out based on the analysis performed.” Whether the threshold for concern is 1 or above 1 is a policy decision that should be informed by the nature of the TRVs. Do these represent doses that are assumed to have an effect or are assumed to be the highest dose that does not have an effect? This study may be able to justify eliminating the 3 TRV values of 1 from potential concern.</p> <p>Agreed. The EHQs will all be reported to 1 significant figure.</p> <p>The following text will be inserted:</p> <p>The TRVs for both arsenic and dioxins and furans exposure to house cats and arsenic exposure to dogs are based on NOAELs for chronic effects (reproduction effects over 3 generations). Since the NOAELs are set at 10 times more conservative values than the LOAELs, EHQ values of 1 are considered to indicate no expected risk.</p>
109	p. 122, para 3; also p. xviii	<p>Reviewer: RAE</p> <p>As in para 4, it should be noted that an EHQ of 3 is within the range of uncertainty of the assessment performed. The uncertainty is probably about an order of magnitude and certainly at least a factor of 3. (That is not to say that an EHQ of 3 is not of potential concern.)</p> <p>The following will be added:</p> <p>... the results indicate that some degree of risk cannot be ruled out based on the analysis performed. The amount by which the estimated hazard quotients are slightly greater than 1 is within the range of uncertainty of the assessment performed.</p>

#	Issues/Sections	Comments
110	Table 7.9, p. 125	<p>Reviewer: RAE</p> <p>Please add the assumption that an application rate of double the recommended application rate was used (p. vii).</p> <p>Table II of the Executive Summary (p.vii) does note the assumed application rate is double that of the recommended rate. The reviewer is referred to note a in Table II.</p>
111		<p>Reviewer: RAE</p> <p>Somewhere in the report, it should be acknowledged that bioavailability is higher in acidic soils. One possible location is in Table 7.9, p. 126. The first “over estimate” might be changed to read “over estimate, except in acidic soils.” The reviewer is not sure whether any soils in Toronto are acidic.</p> <p>City of Toronto soils are not expected to be acidic. Please see Response to Comment #65.</p>
112	Emerging issues	<p>Reviewer: EZH</p> <p>The section should include the concentrations of the chemicals discussed that are reported in the literature for sludges.</p> <p>The concentrations that would be found in sludges are not considered applicable to the current study on pellets for these chemicals. No response required.</p>
113	Antimicrobials	<p>Reviewer: SP</p> <p>Issues regarding loading of antimicrobials in the environment from application of biosolids do not appear to have been addressed.</p> <p>Agreed. These were not addressed in the current study.</p>
114		<p>Reviewer: SP</p> <p>Risks posed by antibiotics and other drug residues in sludge is a growing concern (as briefly mentioned in the emerging issues section). Liz Innes of Health Canada has data and information on this issue. Risklogic prepared a summary for Health Canada of the levels and other characteristics for each of a number of human drug residues commonly in the environment. An observed issue is the contamination of groundwater due to land application of sewage sludge containing drug residues. Data on levels in sludge applied versus gw were available in the literature, so it would be possible to examine this potential pathway/risk by extrapolating observed data. The Risklogic report could be obtained from Liz Innes (along with other information and materials).</p> <p>We concur that a generic semi-quantitative evaluation of this could be undertaken; however, this is not specific to Toronto or Toronto’s pellets and is thus outside the scope of the current assessment. No further response required.</p>

#	Issues/Sections	Comments
115	Conclusion	<p>Reviewer: SP</p> <p>There do not appear to be conclusions and recommendations for monitoring amended soils over time to confirm the results of modelling.</p> <p>The conclusions identify that there may be a risk associated with exposure to arsenic, but also indicate that this risk is likely overstated. It is noted that there are assumptions in the report that may not be overly conservative (e.g., application for only 25 years to soils, use of bioavailability factors for soils that may not be relevant to biosolids, paucity of chemistry data specific to pellets). No monitoring requirements have been identified to ensure that exposures remain below an acceptable level.</p> <p>There does not appear to be a specific conclusion regarding the acceptability of use and potential risks associated with biological agents</p> <p>The conclusions section 9.2.3 regarding biological agents identifies that risks increase with frequency and duration of handling and that risks would be greater for workers than for residents. This appears to be inconsistent with the assumption that toddlers would ingest pellets whereas workers are assumed to not ingest pellets</p> <p>The conclusions section identifies that confirmatory testing with respect to biological entities is limited but does not recommend specific testing requirements.</p> <p>The purpose of the report is to provide Toronto Public Health with the necessary information on which to make recommendations. The recommendations themselves are outside the scope of the current assessment.</p> <p>The report also does not attempt to determine what should or should not be acceptable but rather it relies on existing regulatory guidance on acceptability of risks or concentrations.</p>



2. COPY EDITS

Section/issues	Comments	Response
Biosolids concentration data	Tables should be clearly labelled as dry weight values (e.g. Table 4-2, mean concentration data)	Agreed. A note has been added to Table 4-2.
Table 5-8	Table 5-8 for landfill worker characteristics includes a composite receptor. Is this relevant?	The Composite Receptor considers carcinogenic EoPCs and therefore is relevant. No changes required.
Table 5-14	Potential Toddler Exposure- Home use scenario, has an entry (the 4 th row) that seems to be relevant to adults and not to toddlers which is covered in the last row	Agreed. Table 5-14 has been revised.
Table 5-36	Table 5-36 states that ‘only cake data set contained organic...’ should “contained” be changed to “was analyzed for”?	Agreed. The text has been revised.
p.99, paragraph 2 (6.3), line 3	“enterviruses” should read “enteroviruses”	Agreed. The spelling error has been corrected.
p.100, para 3 (6.6)	spelling error: should read “ <u>C</u> reutzfeldt-Jakob”	Agreed. The spelling error has been corrected.
p.101, para 2	run-on sentence: “ <i>There is currently.....ruled out</i> ” Should be two sentences, or use semi-colon.	Agreed. The sentence has been divided into two sentences.
p. xiv, last para	exceedance should be exceedance	Agreed. The spelling error has been corrected.
p. 10	phosphorus should not be spelled phosphorous, unless used as an adjective (or unless this is a Canadian spelling). This is a common misspelling in the US.	Phosphorous is a Canadian spelling.
p. 103, bullet 3	consider referring the reader to p. 66	
p. 106	The “4” following CCME in the 1 st column should be a superscript.	
p. 107	Italicize species names.	Agreed. Species names have been italicized.
p. 111	last text, change kg/kgfw to kg/kg fw	Agreed. The text has been revised.
p. 116	2 nd bullet. Change affects to effects	
p. 121	What does RTD stand for?	
Use consistent abbreviations	EoPC is used, as well as EPC (p. 121) LOAEL and NOAEL are used, as well as LOEL and NOEL (p. 126)	EoPC refers to Entities of Potential Concern while EPC refers to Exposure Point Concentration. LOAEL and NOAEL will be used.

Section/issues	Comments	Response
Appendix B, Section 1.2.1	Section 1.2.1 equation indicates AF_{dermal} = bioavailability factor – ingestion. Additionally, the equations in this appendix should stipulate “relative bioavailability” be used.	Agreed. The text has been revised.
Appendix C	<p>The receptor characteristics for a teen in Appendix C, table C-1 states 57.9 kg, whereas Health Canada recommends 59.7 kg. Please ensure that the risk assessment calculations incorporate the correct values.</p> <p>The reference list for Appendix C is incomplete. No reference is provided for EC 2004 and Richardson 1997.</p>	<p>See Response to Comment #57.</p> <p>The reference list has been updated.</p>