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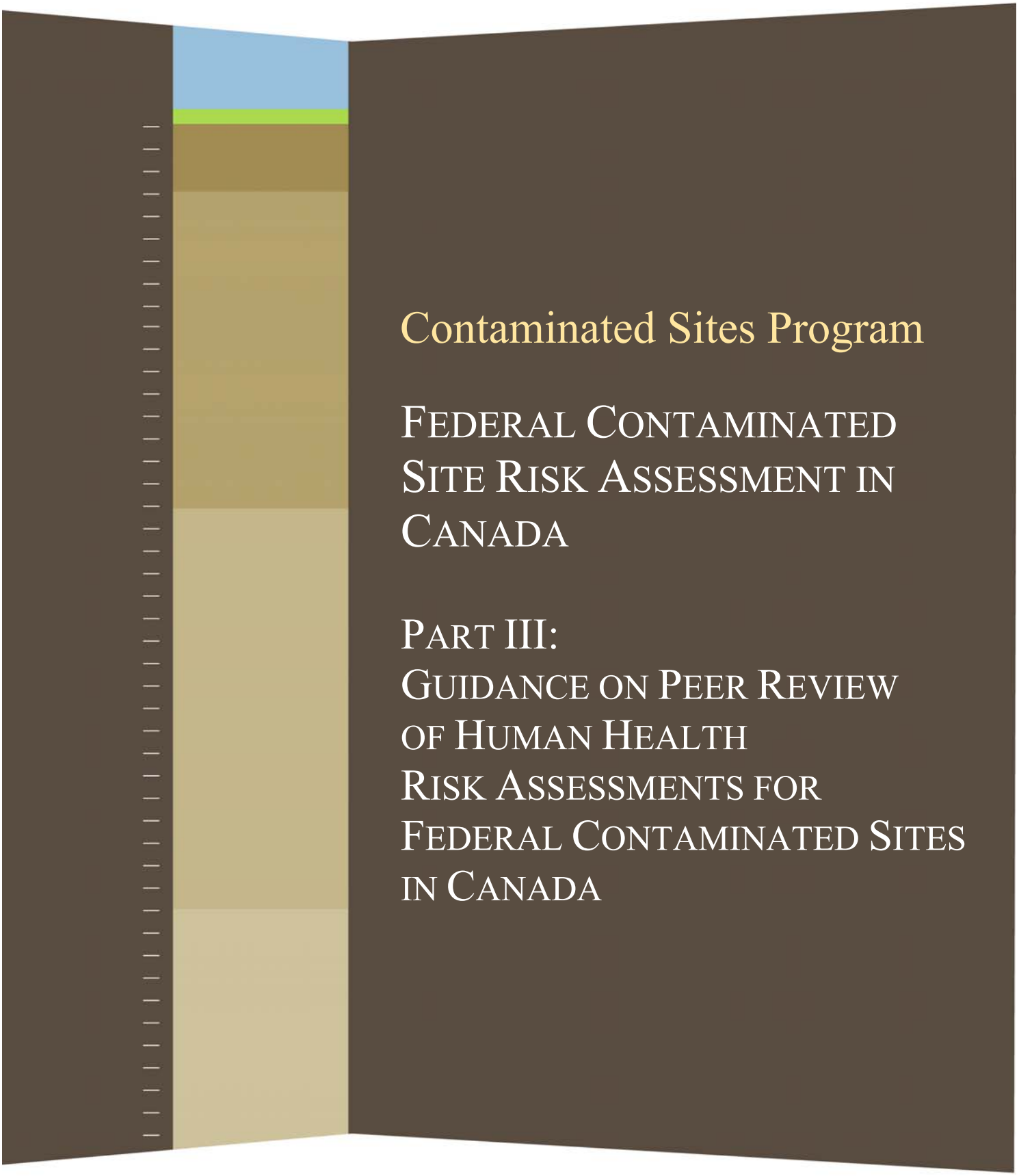

Contaminated Sites Program

Federal Contaminated Site Risk Assessment in Canada

Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada

Canada

FEDERAL CONTAMINATED SITE RISK ASSESSMENT IN CANADA

PART III:
GUIDANCE ON PEER REVIEW OF HUMAN HEALTH RISK ASSESSMENTS FOR FEDERAL CONTAMINATED SITES IN CANADA

September 2004

Prepared by:

Environmental Health Assessment Services
Safe Environments Programme

Our mission is to help the people of Canada
maintain and improve their health.
Health Canada

Published by authority of the
Minister of Health

Également disponible en français sous le titre :
Partie III : Le guide sur l'examen par les pairs des évaluations des risques pour la santé humaine des lieux contaminés fédéraux au Canada

This publication can be made available in/on computer diskette/large print/audio-cassette/braille upon request.

Cat. H46-2/04-369E
ISBN 0-662-38246-3

PREFACE

This guidance document has been prepared to assist in the peer review of federal contaminated site human health risk assessments submitted to Health Canada. These assessments range from basic preliminary quantitative risk assessments (PQRAs) to complex site-specific risk assessments (SSRAs).

Federal Contaminated Site Risk Assessment in Canada: Part III: Guidance on Peer Review of Human Health Risk Assessments was prepared by the Environmental Health Assessment Services Division, Safe Environments Programme, Health Canada, in support of the Federal Contaminated Sites Accelerated Action Plan (FCSAAP). The FCSAAP is a program designed to provide improved and continuing federal environmental stewardship as it relates to contaminated sites located on federally owned or managed properties.

Also in support of the FCSAAP are three additional guidance documents for conducting PQRAs and SSRAs of federal contaminated sites: 1) *Federal Contaminated Site Risk Assessment in Canada: Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA);* 2) *Federal Contaminated Site Risk Assessment in Canada: Part II: Health Canada Toxicological Reference Values (TRVs);* and 3) a guidance document for conducting complex site-specific risk assessments, which is currently being prepared by Health Canada and will be published when completed.

Questions, comments, criticisms, suggested additions or revisions to this document should be directed to:

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http://www.hc-sc.gc.ca/hecs-sesc/ehas/contaminated_sites.htm

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ABBREVIATIONS AND ACRONYMS

ATSDR	Agency for Toxic Substances and Disease Registry
CAEAL	Canadian Association of Environmental Analytical Laboratories
CCME	Canadian Council of Ministers of the Environment
COPC	Chemical of potential concern
ESA	Environmental site assessment
FCSAAP	Federal Contaminated Sites Accelerated Action Plan
IRIS	Integrated Risk Information System
MOEE	Ontario Ministry of Environment and Energy
PAHs	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
PCE	Tetrachloroethylene = perchloroethylene
PHCs	Petroleum hydrocarbons
PQRA	Preliminary quantitative risk assessment
PRGs	Preliminary remediation goals
RAIS	Risk Assessment Information System
SSRA	Site-specific risk assessment
TCE	Trichloroethylene
TRV	Toxicological reference value
U.S. EPA	United States Environmental Protection Agency
VOCs	Volatile organic chemicals

1. INTRODUCTION

A checklist has been formulated to assist in conducting peer reviews of human health risk assessments of federal contaminated sites submitted to Health Canada. It is intended that the peer review will be completed directly on the checklist provided in Appendix B, by responding "yes" or "no" to each question and, where appropriate, adding a short explanation or cross-reference as to where the information may be found in the risk assessment report. As well, the checklist has been designed such that an answer of "no" to any question requires a suitable explanation. If that explanation is not contained within the report, follow-up and resolution by the report author and/or the initiating department may be required before the report is deemed complete and acceptable.

The guidance outlined in Appendix A is intended to supplement the checklist by providing explanations of some of the key checklist questions/items, as well as references for sources of additional information.

In addition to Health Canada's guidance for conducting a preliminary quantitative risk assessment (PQRA) (Health Canada, 2003a), information on preparing risk assessments may be found in documents produced by the Canadian Council of Ministers of the Environment (CCME) (1996), the Ontario Ministry of Environment and Energy (MOEE) (1996a), and the U.S. Environmental Protection Agency (U.S. EPA) (1989).

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TABLE 1
Contaminants Commonly Associated with Various Industrial Operations

INDUSTRIAL OPERATION	POTENTIAL CONTAMINANTS
Agricultural operations	Pesticides, metals (as components of pesticides)
Battery recycling, disposal	Metals, pH changes
Coal gasification	PAHs, PHCs
Dry cleaning	Tetrachloroethylene (PCE) and degradation products (trichloroethylene, 1,1-dichloroethylene, cis- and trans-1,2-dichloroethylene, vinyl chloride)
Electrical equipment/transformers	PCBs, PHCs (mineral oils)
Electroplating	Metals, pH changes
Machine shops, metal fabrication	Metals, VOCs, degreasing solvents (trichloroethylene = TCE) and degradation products (1,1-dichloroethylene, cis- and trans-1,2-dichloroethylene, vinyl chloride)
Mining, smelting, ore processing	Metals, pH changes
Petroleum production, distribution, processing, storage	PHCs, benzene, toluene, ethylbenzene, xylenes (BTEX), PAHs, lead, methyl tert butyl ether (MTBE)
Road salt storage	Sodium adsorption ratio (SAR), electrical conductivity (EC), chloride, sodium
Wood preservation	Pentachlorophenol, PAHs, PHCs, arsenic, chromium, copper

***Note*:** The above list is not intended to be exhaustive of all industrial operations or contaminants.

APPENDIX A
Guidance on Checklist for Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada

Appendix A: Guidance on Checklist for Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada

Report title: _____

Report author: _____

Report date: _____

Reviewed by: _____

Date reviewed: _____

QUERY	SUPPLEMENTARY EXPLANATION
1. PROBLEM FORMULATION	
• Is the purpose of the risk assessment clear? (i.e., why is the risk assessment being conducted?)	The risk assessment report should contain a clear explanation of the purpose for conducting the risk assessment (e.g., contamination found in soil, etc.). As described in the Health Canada (2003a) PQRA guidance document, PQRAs and complex site-specific risk assessments (SSRAs) are not independent, but represent opposite ends of a continuum of complexity in risk assessment. The purpose of the risk assessment should support the selected level of complexity of the risk assessment.
• Is the scope of the risk assessment clear? (e.g., on-site versus offsite, current versus future land use, all types of receptors, etc.)	Sometimes, for a valid reason, the scope may be narrowed and this should be explained (e.g., remediation of a specific chemical is planned and, therefore, is not part of the scope).
• Is Health Canada the only regulatory agency to be satisfied with the risk assessment? (i.e., is the site to remain under federal control or is provincial approval also required?)	If there is a potential for offsite effects, or if the site is being divested by a federal department, then the requirements of another regulatory jurisdiction (e.g., provincial) may need to be addressed in addition to the requirements of Health Canada.
• Does the risk assessment address current land use and conditions only? If "no", consult Health Canada for additional guidance.	In general, for federal contaminated sites, only current land use and conditions will be addressed.

QUERY	SUPPLEMENTARY EXPLANATION
1.1 Site Characterization	
• Note that some of the information requested below may be provided in a supplemental (environmental site assessment or ESA) report rather than the risk assessment report. If so, indicate the title of the report(s) here.	The results of site investigations should be summarized in the risk assessment report, including a description of the sampling methodologies; the number, location, and depth of the samples collected; and the analytes for which the samples were tested. A site location map, presenting key site features (buildings, surface water, etc.), and a site plan, presenting all sample locations, should be included in the risk assessment report.
• Does the report include a description of historical land uses?	The risk assessment report should describe the past, current, and, if applicable, the proposed future use of the site. The historical land use information should be used to identify potential chemicals of concern (see Section 1.4, below).
• If groundwater on the site, or in the vicinity of the site (within 500m), is used as a source of potable water, was the groundwater tested?	The source of potable water for the site and the surrounding area should be documented, and groundwater should be tested if used as a source of drinking water.
• Are all relevant site characteristics documented (e.g., soil type, direction of groundwater flow, distance to nearest surface water body)?	Regional information concerning the topography, geology, and hydrogeology of the area should be provided.
• Does the report include a site plan?	A description of the area surrounding the site, including the land use and occupation (if applicable), should also be provided.
• If the report refers to groundwater monitoring wells, are borehole logs and details of the monitoring well installations provided? • Is depth to groundwater reported?	If there are potential exposure pathways due to affected groundwater or due to volatilization of organic chemicals from soil or groundwater, then the risk assessment report or a referenced ESA report should include borehole logs, descriptions of monitoring well installations, measurements of the depth to groundwater, a contour of groundwater flow direction, etc.

QUERY	SUPPLEMENTARY EXPLANATION
1.2 Sample Collection	
• Have all relevant media been tested (e.g., soil, groundwater)? • Make a note here if any other media were tested as well (e.g., surface water, sediment, soil gas, indoor air, outdoor air, vegetation and/or other biota).	Based on the historical land use information, chemicals of potential concern are identified and tested in soil and, possibly, groundwater, surface water, sediment, soil gas, indoor air, outdoor air, vegetation and/or other biota.
• Is there a description of the sampling methodologies? • Did the sampling methodologies follow a standard method, such as from the CCME, the U.S. EPA, province, etc.?	The CCME (1993) and MOEE (1996b) have developed guidance documents that provide information on sampling methodologies and chemical analysis of samples. Proper sampling techniques are important to make sure the sample is representative of the medium sampled, to reduce the likelihood of chemical loss during sampling (for volatile organic chemicals), and to prevent contamination of samples. If field screening methods were used during the sample collection (e.g., headspace vapour measurements), then these methods should be described in the risk assessment report.
• Were sufficient samples collected from the appropriate locations that you are confident that the likely maximum concentration has been found? (i.e., were all 'hot spots' and known/suspected areas of contamination sampled?)	A variety of methods could have been used to select sampling locations, including random, systematic (grid), targeted (at known or suspected 'hot spots' or in locations of frequent/continuous receptor occupation), etc. The soil sampling conducted at a contaminated site during typical ESAs is usually targeted at zones of known or suspected contamination. In most cases, the sampling will not be random, and areas with elevated concentrations will typically receive more frequent sampling than areas without contamination. Therefore, the maximum concentrations determined from such targeted sampling will likely exceed the true average, on-site concentrations of contaminants in soil. The peer reviewer should be comfortable that the likely maximum or near-maximum concentration has been reasonably defined.

QUERY	SUPPLEMENTARY EXPLANATION
1.3 Sample Analyses	
• Were the chemical analyses completed by a laboratory that was certified by CAEAL or other organization for the analyses?	The Canadian Association of Environmental Analytical Laboratories (CAEAL) certifies laboratories for specific analytical methods. The risk assessment should state whether the data were analyzed by a laboratory certified for the tests conducted.
• Does the report or referenced ESA report include laboratory Certificates of Analysis?	
• Does the report include a description of quality assurance and quality control measures employed?	The risk assessment should provide a description of quality control and quality assurance measures employed in sampling and analysis (e.g., were duplicate samples tested, was a field blank tested, did the laboratory test spiked samples, etc.).
• If on-site contaminants are known to degrade (e.g., TCE → vinyl chloride), were analyses conducted for those degradation products?	In many cases, particularly for TCE, the degradation products can be as toxic or more toxic than the parent compound. It is important that degradation products be investigated where appropriate.
1.4 Identification of Chemicals of Potential Concern (COPCs)	
• Did the list of contaminants that were selected for analysis include all those typically associated with the historical uses of the site?	Table 1 lists contaminants typically associated with a variety of land uses and industrial operations. The risk assessment report should include analyses for contaminants expected to be present in association with the current or previous land use.
• Were all COPCs screened using CCME guidelines? • If no, list the agencies from which other screening guidelines were obtained (province, the U.S. EPA, etc.).	For further consideration in the risk assessment, chemicals are often screened by comparing the available analytical results with guidelines such as those in the CCME *Canadian Environmental Quality Guidelines* (CCME, 2002). The risk assessment should document the comparison of the analytical results with the guidelines and clearly indicate the chemicals selected for further analysis. The measured background concentrations in soil reported in MOEE (1993) may also be used to screen for chemicals of concern.

QUERY	SUPPLEMENTARY EXPLANATION
• For guidelines from agencies other than the CCME, were the selected guidelines appropriate for the samples, chemical analyses, and land uses at the site?	In many cases, the land use of the site in question will not precisely match an agricultural, residential, commercial or industrial land use as defined by the CCME or the provinces when they set the guidelines. The peer reviewer must be comfortable that the guidelines selected for screening are for the most appropriate default land use category. Also, U.S. EPA preliminary remediation goals (PRGs) are often used for screening in instances when no CCME or provincial guideline exists. PRGs are derived on the basis of 100% of the toxicological reference value (TRV) for non-carcinogens, whereas the CCME, Ontario and some other provinces derive their guidelines on the basis of only 20% of the TRV. When U.S. EPA PRGs are employed, they should be divided by 5 (i.e., reduced so that they are based on 20% of the TRV) in order to be comparable to CCME and provincial policies on procedures for guidelines derivation.
• Are the units of measurement the same as those of the guidelines?	It is important that the units of measurement be the same as those of the guidelines or that the units are converted properly. Errors are often made when concentrations in mg/kg are compared to guidelines in units of μg/kg, or vice versa.
• Are degradation products identified as COPCs even if not detected?	In general, for sites where tetrachloroethylene and/or trichloroethylene are identified, their degradation products (even if not detected) should be included as chemicals of potential concern when future land use is being evaluated in the risk assessment, because they may be produced in the future. When current land use is the focus of the risk assessment, but it is anticipated that the land use will not change for the foreseeable future, then consideration of degradation products may also be relevant.
• Were COPCs screened using the maximum measured on-site concentrations?	For consistency, Health Canada (2003a) specifies that maximum concentrations should be used for screening of COPCs. However, where sufficient data exist, some other statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) may be applied, at the discretion of the risk assessor. The peer reviewer should be comfortable that the selected statistic, if not the maximum value, is justified and supported by a statistical analysis and by sufficient sample size for the site in question.

QUERY	SUPPLEMENTARY EXPLANATION
• If a statistic other than the maximum concentration was used for COPC screening, is a statistical analysis of the data presented?	If the risk assessment uses concentrations other than the maximum measured concentrations for the analysis, then any statistical evaluation of the data must be fully documented.
• If a statistic other than the maximum concentration was used for COPC screening, is the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given sample size and other factors?	Peer reviewers must use their judgement. The peer reviewer should be comfortable that the selected statistic, if not the maximum value, is justified and supported by a statistical analysis and by sufficient sample size for the site in question.
2. EXPOSURE ASSESSMENT	
• Is the use of the property (for purposes of the risk assessment) clearly explained?	The risk assessment should clearly describe the present and proposed future use (if different from the present use) of the property.
• If there is a potential for offsite exposures are offsite land uses and receptors identified?	If there is a potential for offsite migration of chemicals, then offsite land uses should also be described.
• Were exposure calculations conducted using the maximum measured on-site concentration(s)?	If the risk assessment uses concentrations other than the maximum measured concentrations for the analysis, then any statistical evaluation of the data must be fully documented.
• If the maximum concentration was not used, was the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given sample size and other factors?	The statistical analysis should be consistent with the number of samples collected. It is not uncommon that limited data are overanalyzed.

QUERY	SUPPLEMENTARY EXPLANATION
2.1 Receptors and Pathways	
• Have all relevant receptor age groups been identified (infant, toddler, child, teen, adult)?	Health Canada (2003a) and the CCME (1996) define five age groups for receptors: adults (20 to 70 years of age), teens (12 to 19 years of age), children (5 to 11 years of age), toddlers (7 months to 4 years of age) and infants (0 to 6 months of age).
• If all relevant receptor age groups have not been identified, has the most sensitive age group been identified?	In some cases, a risk assessment will focus only on what has been defined as the most sensitive age group or receptor group. For example, toddlers are often considered the most sensitive age group due to having the greatest intake per unit of body weight of any age group. Other sensitive age groups may be identified for toxicological reasons. For example, exposure to methyl mercury is a concern for women of child-bearing age, to protect against teratogenic effects.
• Have all potentially sensitive receptor population groups been identified (e.g., the elderly, First Nations communities)?	The risk assessment should also identify the presence of any potentially sensitive receptors. For example, exposure to methyl mercury or other bioaccumulative substance, is a concern for subsistence fishing populations (First Nations communities; sports fishers who consume their catch) due to high intake rates relative to the general population.
• Have all relevant exposure pathways been considered? • For those pathways that were excluded, was their exclusion adequately justified?	Health Canada (2003a) provides a checklist of potential exposure pathways to be considered in a risk assessment. These pathways may include direct contact with soil (incidental ingestion of soil, dermal contact with soil, inhalation of suspended particulate matter), ingestion of groundwater, inhalation of vapours (indoors and/or outdoors) arising from contaminated soil and/or groundwater, contact with surface water (ingestion, dermal absorption), and ingestion of food. The risk assessment should clearly state the pathways that are of concern and provide justification for any pathways that are eliminated. Health Canada (2003a) also presents the equations for estimating the dose via each pathway.

QUERY	SUPPLEMENTARY EXPLANATION
• Were all receptor exposure characteristics (body weight, inhalation rate, etc.) drawn from accepted Canadian sources (Health Canada, *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson, 1997), the CCME, etc.)? • If an alternate source of receptor characteristics was used, was this because no Canadian data or value has been published? • If alternate sources for exposure characteristics were used, was the source/citation clearly documented? • If alternate sources for exposure characteristics were used, are the assumptions used appropriate and adequately justified?	The physical and behavioural characteristics of each receptor group should be documented, with references, in the risk assessment. Preferred sources of this information for Canadian risk assessments are: Health Canada (2003a), CCME (1996) and Richardson (1997). For characteristics not included in these documents, the U.S. EPA *Exposure Factors Handbook* (U.S. EPA, 1997) and the U.S. EPA *Child-Specific Exposure Factors Handbook* (U.S. EPA, 2002) may be used.
• Were assumptions regarding exposure duration and exposure frequency appropriate and adequately justified?	Often the exposure frequency and duration must be assumed; these assumptions should be clearly noted in the risk assessment to assess their validity. Typical assumptions for a PQRA are provided in the Health Canada (2003a) guidance document. However, in many cases the risk assessor will have to apply his/her professional judgement in defining such assumptions. The peer reviewer should consider whether such assumptions are reasonable.
• Does the report include sample calculations? • Can those calculations be reproduced? (i.e., check the math)	It is very important for peer reviewers to confirm the accuracy of mathematical calculations. Errors occur far more often than you might imagine.

QUERY	SUPPLEMENTARY EXPLANATION
• Are all equations dimensionally consistent and are all units correct (i.e., are the dimensions and the units the same on both sides of the 'equal' sign)?	Dimensionally consistent means that the dimensions (and units) are the same on both sides of the 'equal' sign (e.g., a dose in mg/kg/d on one side and a concentration in mg/kg on the other side are not dimensionally consistent). It serves as a quick check that the equations are correct; that the equation actually produces the units indicated for the equation product. Unit-related problems are the most common mistakes in risk assessments.
2.2 Environmental Fate Modelling	
• Are models used to predict the environmental fate of any COPC? (e.g., is a model used to estimate the groundwater concentration from the soil concentration? Is a model used to predict the rate of migration of a COPC in groundwater? Is an equation used to predict the indoor air concentration of a volatile substance from the concentration in soil or groundwater?- etc.) • If yes, are the names, sources and citations for the model(s) identified? • Has the model(s) been peer reviewed or published by an authoritative source (such as the CCME, Environment Canada, the U.S EPA, etc.)? (i.e., is the model 'generally accepted'?) • If a unique model was created from first principles, seek comment and assistance from an appropriate expert to determine its validity and applicability.	In general, a simple model is more appropriate for application in a simple (preliminary quantitative) risk assessment. Be wary of instances when a complex model and complex treatment of data are applied to a relatively simple situation or to very limited input information. If a model is used for calculation of chemical concentrations in one medium from measured concentrations in soil (or groundwater in the case of indoor air), questions to be considered include: What is the reference for the model? Has it been peer reviewed? Is it readily available? Is the complexity of the model appropriate for the situation, number of samples and risk assessment complexity? Why was this particular model selected? Is a complex model applied to a preliminary quantitative (simple) risk assessment? Does the model attempt to make too much out of very limited input data (i.e., does it suggest greater precision in the model results than the input data could conceivably deliver)? Are model results given with far more significant digits than the available data can justify?
• Is the selected model(s) designed for the type of application to which it was applied?	Is the model intended for use for the type of chemicals considered in the risk assessment (e.g., many models are intended only to be applied to non-ionizing organic chemicals and extrapolation to other chemicals may not be appropriate)?
• Are all model assumptions and equations explained?	

QUERY	SUPPLEMENTARY EXPLANATION
• Are intermediate results included (e.g., predicted concentrations at relevant locations) and do they make sense?	Intermediate calculations (e.g., concentrations at specific locations) should be presented so that, even if the calculations are not readily reproduced by hand, the sensibility of the calculations may be evaluated.
	Environmental fate models are most likely to be used to evaluate the transport of vapours from soil or groundwater to indoor or outdoor air, to predict down-gradient concentrations in groundwater, to predict concentrations in adjacent surface water, or to predict concentrations in produce, meat, or milk that are consumed. Readily available references for each of these types of models are discussed below. **Vapour Transport Modelling** CCME (1996) and CCME (2000) both present dilution factors for soil gas to indoor air (the ratio of the chemical concentration in soil gas to the concentration in indoor air). Both approaches are acceptable, but CCME (2000) provides a more complex approach, providing dilution factors for: a) residential buildings with and without basements; b) commercial/industrial buildings; c) coarse and fine-grained soils; and d) as a function of the depth or distance of contamination from the building. The dilution factors presented in either CCME (1996) or CCME (2000) may be used as a screening tool to estimate concentrations of a volatile contaminant in indoor air from the concentration in soil gas. Dilution factors presented in CCME (2000) were derived using a model known as the Johnson and Ettinger model; the model is readily available from the U.S. EPA (2000, 2001). Site-specific application of the Johnson and Ettinger model permits inclusion of site characteristics (e.g., soil permeability, depth to groundwater, etc.) that may result in lower predicted indoor air concentrations. Alternate models may be used, but the equations and assumptions should be documented and intermediate calculations (e.g., the dilution factor and the predicted indoor air concentrations) should be provided to permit an evaluation of whether the results are reasonable (by comparison, for example, to the results in CCME (2000)).

QUERY	SUPPLEMENTARY EXPLANATION
	Vapour Transport Modelling (continued) Volatilization from soil or groundwater to outdoor air is generally of less concern compared to volatilization to indoor air; however, at sites where there is no indoor air exposure, outdoor air may be a concern. This is particularly true for construction workers involved with short-term excavation activities to install underground utilities, or during remediation. The U.S. EPA (1996) provides a simple model for estimating chemical concentrations in outdoor air as a result of contaminated soil or groundwater. **Groundwater Modelling** Commercial or proprietary models for predicting the migration of contaminants in groundwater may be used and the assumptions, equations, and results should be clearly documented in the risk assessment report. The CCME provides two approaches to calculating contaminant concentrations in groundwater, as part of the development of the guidelines for petroleum hydrocarbons (PHCs) (CCME, 2000, 2001). The first approach is a simple steady-state mixing dilution model and is the same as the approach in CCME (1996). The second approach is a dynamic advective-dispersive model, which accounts for retardation by organic matter, anaerobic biodegradation, and dispersion. A spreadsheet is available from the CCME (2003) to perform the calculations for these approaches and may be used to assist in evaluating the results in a risk assessment report. **Uptake into Produce, Meat, or Milk** Estimating chemical concentrations in produce, meat, or milk is generally highly uncertain. CCME (1996) presents simple equations, derived by Travis and Arms (1988), for estimating concentrations of organic chemicals in produce, meat, and milk. Baes et al. (1984) and ORNL (1998) present uptake factors for inorganic contaminants in plants. Stevens (1992) presents tissue biotransfer factors for estimating the concentration of metals in beef as a result of the rate of intake of metal in the diet.

QUERY	SUPPLEMENTARY EXPLANATION
3. HAZARD ASSESSMENT	
• Were all toxicological reference values (TRVs) drawn from Health Canada? • If no, was it because Health Canada had no TRV for the subject COPC?	Health Canada (2003b) provides a list of TRVs for a large number of chemicals and is the preferred source for risk assessments prepared for Health Canada. If alternate values are used in the risk assessment, then a reference should be provided and their selection justified. For chemicals not listed in the Health Canada (2003b) TRV document, TRVs may be obtained from another peer reviewed source. Health Canada (2003a) lists the following sources of information, in order of preference: U.S. Environmental Protection Agency (U.S. EPA, 2003) online database known as the "Integrated Risk Information System" (IRIS): http://www.epa.gov/iris/index.html World Health Organization (WHO); information available at various sources including: http://www.inchem.org/; http://jecfa.ilsi.org/index.htm Netherlands National Institute of Public Health and the Environment (RIVM): http://www.rivm.nl/bibliotheek/rapporten/711701025.pdf U.S. Agency for Toxic Substances and Disease Registry (ATSDR, 2003): http://www.atsdr.cdc.gov/toxpro2.html
• Are the selected TRVs clearly stated, with references, for each chemical and for each pathway?	
• Are the health effects associated with each COPC and the basis for the TRVs described?	The risk assessment should include a description of the health effects for each chemical of concern and the basis for the selected TRV (refer to Health Canada, 2003c, 1996a, 1996b).
• If dermal absorption is a pathway evaluated, are dermal absorption factors drawn from Health Canada advice? • If no, were the sources of dermal absorption factors referenced?	Oral and dermal exposures are often summed, for comparison to an oral TRV. In such cases, a dermal absorption factor should be applied, since dermal absorption is usually much lower than oral absorption. These factors are listed in the Health Canada (2003a) guidance document and also in MOEE (1996c). For chemicals not listed in either of these references, the Risk Assessment Information System (RAIS) (ORNL, 2003; http://risk.lsd.ornl.gov) is an online database containing dermal absorption factors as well as TRVs.

QUERY	SUPPLEMENTARY EXPLANATION
• Has 100% oral bioavailability been assumed? (If a variable representing bioavailability is not included, then 100% is implicitly assumed). • If no, then were the values based on tests of on-site soil?	Absorption factors for ingestion are usually 100% in preliminary quantitative risk assessments. Oral bioavailability is commonly measured *in vitro* as bioaccessibility (% solubility in simulated gastric fluid), which depends upon the properties of the soil and the site-specific characteristics of the contaminant. In complex risk assessments, direct assays of contaminant bioaccessibility may be conducted to directly measure potential bioavailability. Therefore, if a value for oral bioavailability of less than 100% is used, ideally it is based on site-specific measurements of bioaccessibility.
• If no bioaccessibility tests of on-site soil were conducted, did the study or literature from which the oral bioavailability value was obtained investigate sites with the same source of contamination? (same industry or industrial process, etc.)	The form of the chemical may vary depending upon its source. For metals, for example, the bioavailability is relatively low for mine tailings, but is relatively high for deposits from ore roasting/processing. The bioavailability value should be based on a similar source of the contaminant.
• If no tests of on-site soil were conducted, did the study or literature from which the oral bioavailability value was obtained investigate sites with the same soil characteristics? (similar grain size [fine or coarse], same type of soil [sand, silt, clay, etc.], similar organic carbon content, etc.)	Bioaccessibility and bioavailability tend to increase as soil grain size decreases or as soil organic matter content decreases.
• If inhalation was a pathway evaluated, was absorption by this pathway assumed to be 100%? (if a variable representing inhalation bioavailability is not included, then 100% is implicitly assumed).	Absorption factors for inhalation are usually 100% in preliminary quantitative risk assessments.
• If inhalation absorption was less than 100%, was the source of the inhalation absorption factor referenced and is it appropriate to the contaminant?	All absorption factors less than 100% must be fully explained and referenced.

QUERY	SUPPLEMENTARY EXPLANATION
4. RISK CHARACTERIZATION	
• Are the results of the risk assessment clear?	The risk assessment report should provide a clear statement of the predicted risks and hazard quotients for each chemical and for each exposure pathway.
• For chemicals and pathways affecting the same target organ, are the hazard quotients summed for non-cancer effects?	Hazard quotients should be summed for chemicals that affect the same target organ. Generally, oral and dermal exposures will be summed.
• Are all non-cancer hazard quotients less than 0.2 (or other level defined as acceptable)?	The definition of an acceptable hazard quotient depends upon the jurisdiction. Health Canada considers hazard quotients of 0.2 or less as acceptable. If any other agency has been identified as having jurisdiction (for example, provinces for offsite areas), then the acceptable hazard quotient may be different and should be documented in the risk assessment.
• For carcinogens, have risks been summed for chemicals and pathways causing the same form of cancer?	Risks for chemicals that produce the same form of cancer should be summed. Generally, oral and dermal exposures will be summed.
• Are all cancer risks less than 1×10^{-5} (or other level defined as essentially negligible)?	Health Canada considers risks of one in one hundred thousand (1×10^{-5}) or less as essentially negligible. If any other agency has been identified as having jurisdiction (for example, provinces for offsite areas), then the negligible risk level may be different and should be documented in the risk assessment.
• Is the uncertainty of the results discussed?	The risk assessment should provide an evaluation of the uncertainty in the results. This evaluation may be largely a qualitative discussion for preliminary risk assessments, or may be quantitative in complex risk assessments. In either case, the report should indicate the variables and assumptions for which the results are most sensitive.

QUERY	SUPPLEMENTARY EXPLANATION
5. RISK MANAGEMENT	
• If any non-cancer hazard quotients exceed 0.2 or any cancer risks exceed 1 x 10^{-5}, are remedial or risk management measures proposed? • If yes, are the proposed measures consistent with the spatial scale of the site and the magnitude of the risks? (i.e., do the risk management options appear to be 'over-kill'?)	If the calculated risks or hazard quotients exceed the levels considered acceptable by Health Canada (or other jurisdiction, if applicable), then the risk assessment report may provide recommendations for remediation (i.e., calculation of remedial criteria) and/or a detailed description of risk management measures to control exposures to acceptable levels.
• If ongoing monitoring or risk management measures are recommended, is the responsible department or agency clearly identified, if other than the Client department that solicited the risk assessment?	
6. OVERALL COMMENTS	
• Is the risk assessment report acceptable? • If no, list all concerns, outstanding issues, required explanations, and/or data requirements. Use separate sheets as necessary.	Following review of the risk assessment, is the risk assessment report acceptable? Are there any outstanding issues that require clarification or more information? Are there any follow-up actions to be taken?

APPENDIX B
Checklist for Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada

Appendix B: Checklist for Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada

Report title: _____

Report author: _____

Report date: _____

Reviewed by: _____

Date reviewed: _____

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
1. PROBLEM FORMULATION				
• Is the purpose of the risk assessment clear? (i.e., why is the risk assessment being conducted?)				
• Is the scope of the risk assessment clear? (e.g., on-site versus offsite, current versus future land use, all types of receptors, etc.)				
• Is Health Canada the only regulatory agency to be satisfied with the risk assessment? (i.e., is the site to remain under federal control or is provincial approval also required?)				
• Does the risk assessment address current land use and conditions only? • If "no", consult Health Canada for additional guidance.				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
1.1 Site Characterization				
• Note that some of the information requested below may be provided in a supplemental (environmental site assessment, or ESA) report rather than the risk assessment report. If so, indicate the title of the report(s) here.				
• Does the report include a description of historical land uses?				
• If groundwater on the site, or in the vicinity of the site (within 500m), is used as a source of potable water, was the groundwater tested?				
• Are all relevant site characteristics documented (e.g., soil type, direction of groundwater flow, distance to nearest surface water body)?				
• Does the report include a site plan?				
• If the report refers to groundwater monitoring wells, are borehole logs and details of the monitoring well installations provided?				
• Is depth to groundwater reported?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
1.2 Sample Collection				
• Have all relevant media been tested (e.g., soil, groundwater)? • Make a note here if any other media were tested as well (e.g., surface water, sediment, soil gas, indoor air, outdoor air, vegetation and/or other biota).				
• Is there a description of the sampling methodologies?				
• Did the sampling methodologies follow a standard method, such as from the CCME, the U.S. EPA, province, etc.?				
• Were sufficient samples collected from the appropriate locations such that you are confident that the likely maximum concentration has been found? (i.e., were all 'hot spots' and known/suspected areas of contamination sampled?)				
1.3 Sample Analyses				
• Were the chemical analyses completed by a laboratory that was certified by CAEAL or other organization for the analyses?				
• Does the report or referenced ESA report include laboratory Certificates of Analysis?				
• Does the report include a description of quality assurance and quality control measures employed?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
• If on-site contaminants are known to degrade (e.g., TCE → vinyl chloride), were analyses conducted for those degradation products?				
1.4 Identification of Chemicals of Potential Concern (COPCs)				
• Did the list of contaminants that were selected for analysis include all those typically associated with the historical uses of the site?				
• Were all COPCs screened using CCME guidelines? • If no, list the agencies from which other screening guidelines were obtained (province, the U.S. EPA, etc.).				
• For guidelines from agencies other than the CCME, were the selected guidelines appropriate for the samples, chemical analyses, and land uses at the site?				
• Are the units of measurement the same as those of the guidelines?				
• Are degradation products identified as COPCs even if not detected?				
• Were COPCs screened using the maximum measured on-site concentration?				
• If a statistic other than the maximum concentration was used for COPC screening, is a statistical analysis of the data presented?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
• If a statistic other than the maximum concentration was used for COPC screening, is the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given sample size and other factors?				
2. EXPOSURE ASSESSMENT				
• Is the use of the property (for purposes of the risk assessment) clearly explained?				
• If there is a potential for offsite exposures, are offsite land uses and receptors identified?				
• Were exposure calculations conducted using the maximum measured on-site concentration(s)?				
• If the maximum concentration was not used, was the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given the sample size and other factors?				
2.1 Receptors and Pathways				
• Have all relevant receptor age groups been identified (infant, toddler, child, teen, adult)?				
• If all relevant receptor age groups have not been identified, has the most sensitive age group been identified?				
• Have all potentially sensitive receptor population groups been identified (e.g., elderly; First Nations communities)?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
• Have all relevant exposure pathways been considered?				
• For those pathways that were excluded, was their exclusion adequately justified?				
• Were all receptor exposure characteristics (body weight, inhalation rate, etc.) drawn from accepted Canadian sources (e.g., Health Canada, *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson, 1997), the CCME, etc.)?				
• If an alternate source for receptor characteristics was used, was this because no Canadian data or value has been published?				
• If alternate sources for exposure characteristics were used, was the source/citation clearly documented?				
• If alternate sources for exposure characteristics were used, are the assumptions appropriate and adequately justified?				
• Were assumptions regarding exposure duration and exposure frequency appropriate and adequately justified?				
• Does the report include sample calculations?				
• Can those calculations be reproduced? (i.e., check the math)				
• Are all equations dimensionally consistent and are all units correct (i.e., are the dimensions and the units the same on both sides of the 'equal' sign)?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
2.2 Environmental Fate Modelling				
• Are models used to predict the environmental fate of any COPC? (e.g., is a model used to estimate the groundwater concentration from the soil concentration? Or to predict the rate of migration of a COPC in groundwater? Is an equation used to predict the indoor air concentration of a volatile substance from the concentration in soil or groundwater? Etc.)				
• If yes, are the names, sources and citations for the model(s) identified?				
• Has the model(s) been peer reviewed or published by an authoritative source (e.g., the CCME, Environment Canada, the U.S. EPA, etc.)? (i.e., is the model 'generally accepted'?) • If a unique model was created from first principles, seek comment and assistance from an appropriate expert to determine its validity and applicability.				
• Is the selected model(s) designed for the type of application to which it was applied?				
• Are all model assumptions and equations explained?				
• Are intermediate results included (e.g., predicted concentrations at relevant locations) and do they make sense?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
3. HAZARD ASSESSMENT				
• Were all toxicological reference values (TRVs) drawn from Health Canada?				
• If no, was it because Health Canada had no TRV for the subject COPC?				
• Are the selected TRVs clearly stated, with references, for each chemical and each pathway?				
• Are the health effects associated with each COPC and the basis for the TRVs described?				
• If dermal absorption is a pathway evaluated, are dermal absorption factors drawn from Health Canada advice?				
• If no, were the sources of dermal absorption factors referenced?				
• Has 100% oral bioavailability been assumed? (If a variable representing bioavailability is not included, then 100% is implicitly assumed).				
• If no, were the values based on tests of on-site soil?				
• If no bioaccessibility tests of on-site soil were conducted, did the study or literature from which the oral bioavailability value was obtained investigate sites with the same source of contamination? (same industry or industrial process, etc.)				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
• If no tests of on-site soil were conducted, did the study or literature from which the oral bioavailability value was obtained investigate sites with the same soil characteristics? (similar grain size [fine or coarse], same type of soil [sand, silt, clay, etc.], similar organic carbon content, etc.)				
• If inhalation was a pathway evaluated, was absorption by this pathway assumed to be 100%? (if a variable representing inhalation bioavailability is not included, then 100% is implicitly assumed).				
• If inhalation absorption was less than 100%, was the source of the inhalation absorption factor referenced and is it appropriate to the contaminant?				
4. RISK CHARACTERIZATION				
• Are the results of the risk assessment clear?				
• For chemicals and pathways affecting the same target organ, are the hazard quotients summed for non-cancer effects?				
• Are all non-cancer hazard quotients less than 0.2 (or other level defined as acceptable)?				
• For carcinogens, have risks been summed for chemicals and pathways causing the same form of cancer?				
• Are all cancer risks less than 1×10^{-5} (or other level defined as essentially negligible)?				

QUERY	YES	NO	N/A	EXPLANATION/REFERENCE TO SECTION IN RISK ASSESSMENT REPORT
• Is the uncertainty of the results discussed?				
5. RISK MANAGEMENT				
• If any non-cancer hazard quotients exceed 0.2 or any cancer risks exceed 1 x 10^{-5}, are remedial or risk management measures proposed?				
• If yes, are the proposed measures consistent with the spatial scale of the site and the magnitude of the risks? (i.e., do the risk management options appear to be 'over-kill'?)				
• If ongoing monitoring or risk management measures are recommended, is the responsible department or agency clearly identified, if other than the Client department that solicited the risk assessment?				
6. OVERALL COMMENTS				
• Is the risk assessment report acceptable? • If no, list all concerns, outstanding issues, required explanations, and/or data requirements. Use separate sheets as necessary.				

NOTES:

- N/A = not applicable
- The above checklist should be completed in conjunction with the report entitled *Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada*.

- The checklist has been designed such that an answer of NO to any question requires follow-up and suitable explanation or resolution by the report author and/or the initiating department before the report should be defined as complete and acceptable.