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Guidance for Evaluating
Human Health Impacts
in Environmental Assessment:

COUNTRY FOODS

Canada

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Également disponible en français sous le titre :
Conseils pour l'évaluation des impacts pour la santé humaine dans le cadre des évaluations environnementales : Les aliments traditionnels

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
Email: **hc.publications-publications.sc@canada.ca**

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Any questions or comments on this document may be directed to:
Environmental Assessment Program, Ottawa, Ontario K1A 0K9
Email: **hc.ead-dee.sc@canada.ca**

1 ACRONYMS

ACRONYM	MEANING
AMAP	Arctic Monitoring and Assessment Programme
CEAA 2012	*Canadian Environmental Assessment Act*, 2012
CCME	Canadian Council of Ministers of the Environment
CHHAD	Chemical Health Hazard Assessment Division
COPC	contaminant of potential concern
EA	environmental assessment
EIS	environmental impact statement
FNFNES	First Nations Food, Nutrition and Environment Study
HHRA	human health risk assessment
HQ	hazard quotient
ILCR	incremental lifetime cancer risk
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-p-dioxin
PCDF	polychlorinated dibenzofuran
PHC	petroleum hydrocarbon
RA	Responsible Authority
TRV	toxicological reference value

2 PURPOSE OF THIS DOCUMENT

This document provides generic guidance on predicting human health risks associated with contaminants affecting country foods (also known as traditional foods) in federal environmental assessments (EA) of proposed major resource and infrastructure projects. It presents the principles, current practices and basic information Health Canada looks for when it reviews the environmental impact statement (EIS) or other reports submitted by project proponents as part of the EA process.

It was prepared for the benefit of proponents and their consultants and to support an efficient and transparent project review process. The foundational information described here should be supplemented appropriately with additional information relevant to specific projects.

The guidance was also prepared for responsible authorities and stakeholders to the EA process to communicate our normal areas of engagement and our priorities within these areas to help ensure that sufficient evidence is available to support sound decisions. As part of its review, Health Canada may suggest that a responsible authority (RA), review panel or others collect information not specifically described here in order to assess the health effects of specific projects. As the guidance provided here is generic and designed to support EA under multiple jurisdictions, the scope of our review will also be amended according to specific jurisdictional requirements.

Country foods are linked to culture and identity, and are consumed more frequently in Indigenous communities. Consumption of country foods leads to significantly improved nutrient intake; however, when country foods are impacted by contaminants, risks of consuming contaminated foods may outweigh the benefits. While the primary consumers of country foods are members of Indigenous populations, some types of country foods are consumed by the general population.

Health Canada updates guidance documents periodically and, in the interest of continuous improvement, accepts comments and suggestions at the following address: **hc.ead-dee.sc@canada.ca**

Please verify that you are reading the most recent version available by consulting:
www.canada.ca/en/services/health/publications/healthy-living.html#a2.5

3 INTRODUCTION AND CONTEXT

Health Canada provides expertise to assist RAs, review panels and/or other jurisdictions leading environmental assessments to determine whether there are potential health risks associated with proposed projects and how to prevent, reduce or mitigate them.

Health Canada provides its expertise in health risks associated with air quality, drinking and recreational water quality, radiation, noise and country foods when it reviews and provides comments on information submitted by proponents in support of proposed projects. Health Canada also provides guidance to help stakeholders, including responsible authorities, review panels and affected communities, to better understand how to conduct health assessments for proposed major resource projects.

This document concerns the assessment of health risks associated with the consumption of potentially contaminated country foods. It contains information on the division of roles and responsibilities for issues related to country foods at various levels of government in Canada; health effects associated with contamination of country foods; indicators of these effects; and steps in Health Canada's preferred approach to assessing health effects related to consumption of contaminated country foods.

This publication provides technical guidance on defining country foods on a project basis, and assessing baseline conditions and the longer term anticipated impacts should the project proceed. As with all EA work, cumulative effects are a core element of country food assessment, as are mitigation and follow-up monitoring. While this guidance does not address possible changes in country foods abundance, it is nevertheless recognised that projects may damage habitat and disperse wildlife, altering abundance and availability; therefore this aspect should also be considered when assessing environmental impacts of proposed projects, in accordance with current federal and provincial legislation.

APPENDIX A: Country Foods in Environmental Assessment Checklist may be used to verify that the main components of a risk assessment for country foods are completed, and to identify where this information can be found within an EA document.

APPENDIX B: Additional Information on Health Canada Human Health Risk Assessment Documents provides a list of references prepared by HC or prepared under contract for HC that contains material which may be relevant to a risk assessment for country foods.

APPENDIX C: Sources of Toxicological Reference Values presents publications/resources where toxicological reference values can be found.

APPENDIX D: Thematic Reference List identifies publications that are not cited in this document but may be useful in preparing documentation for country food issues addressed in environmental assessments, by the following themes:

- Overall Country Foods and Human Health Risk Assessment
- Dietary Surveys and Methodologies
- Canadian Council of Ministers of the Environment Guidelines
- Information about Canadian Dietary Intake, Including Indigenous
- Risk Communication and Risk Management
- Northern Contaminants Program and Arctic Monitoring and Assessment Programme
- Country Food Contamination Monitoring Programs
- Canadian Data Sources of Contaminant Levels in Country Foods

4 GOVERNMENT ROLES AND RESPONSIBILITIES WITH RESPECT TO COUNTRY FOODS

In Canada, different levels of government play a role related to food safety. Federal departments and agencies with roles concerning country foods include Health Canada, Indigenous Services Canada, and, if the foods are sold commercially, the Canadian Food Inspection Agency. Certain aspects of country food safety and availability may be also covered by provincial and territorial regulators. In the environmental assessment context, the depth and breadth of the analysis of food safety will vary; as territories and parts of provinces operate under different environmental assessment regimes ("North of 60"), verifying appropriate legislation is encouraged.

4.1. HEALTH CANADA

Health Canada is typically asked to undertake reviews of environmental impact statement (EIS) or other reports for a proposed project, subject to federal EA legislation. For example, under the *Canadian Environmental Assessment Act*, 2012 (CEAA 2012), Health Canada's primary role is to make available project-related specialist or expert information and knowledge in its possession. In that role, Health Canada focuses on the following:

- An effect of any change that may be caused to the environment with respect to the health of Indigenous peoples (paragraph 5[1][c])
- An effect of a change that may be caused to the environment and linked to a federal authority's power, duty or function, on the health of all Canadians (paragraph 5[2][b])

Among other things, Health Canada sets standards for the safety and nutritional value of all foods sold in Canada. It exercises this mandate under the authority of the *Food and Drugs Act* and the *Food and Drug Regulations*. The department can provide expertise about the potential impacts of projects on country food quality and safety through choice and use of appropriate toxicological reference values (TRV), and review risk assessment methodology. Health Canada can also provide expertise about the design and administration of dietary surveys, sampling of country foods for analysis, and the development and delivery method of consumption advisories.

Health Canada funds the First Nations Food, Nutrition and Environment Study (FNFNES), which collects baseline data on the dietary intake, food security status, and environmental contaminant exposure of adult First Nations living on reserve in 93 randomly selected First Nations communities south of 60° north latitude across Canada between 2007 and 2018. The available reports are posted at **www.fnfnes.ca/download**. These publications provide comprehensive information about diet pattern, including average and range of daily intake of country foods, and baseline levels of selected chemical contaminants in country foods. The study is ongoing and more information is added as it becomes available.

4.2. INDIGENOUS SERVICES CANADA

Indigenous Services Northern Contaminants Program (previously the Indigenous and Northern Affairs Canada's program) works to reduce and, wherever possible, eliminate contaminants in traditionally harvested foods, while providing information that assists informed decision making by individuals and communities in their food use. It addresses concerns about human exposure to elevated levels of contaminants in wildlife species that are important to the traditional diets of northern Indigenous peoples of the Yukon, Northwest Territories, Inuvialuit, Nunavut, Nunavik, and Nunatsiavut. Information on this program can be found at **www.science.gc.ca/eic/site/063.nsf/eng/h_7A463DBA.html**

4.3. CANADIAN FOOD INSPECTION AGENCY

While Canada's food safety standards for commercial foods are established by Health Canada, the Canadian Food Inspection Agency provides all federal food inspection services related to commercial foods and enforces the standards established by Health Canada. Its authority is provided through both Canada's *Food and Drugs Act* and the *Canada Agricultural Products Act.* Commercial foods available to the public that could be contaminated by a project's activities are subject to these acts.

4.4. PROVINCIAL AND TERRITORIAL GOVERNMENTS

Various provincial and territorial departments and agencies have a role in, among other things, monitoring foods that may be contaminated and issuing consumption advisories.

5 EVALUATING THE POTENTIAL CONTAMINATION OF COUNTRY FOODS IN ENVIRONMENTAL ASSESSMENTS

5.1. COUNTRY FOODS

The term "country foods" will be used in this document, although some stakeholders prefer the expression "traditional foods." Country foods are defined as all foods sourced outside of commercial food systems. These include any food that is trapped, fished, hunted, harvested or grown for subsistence or medicinal purposes, outside of the commercial food chain. This definition encompasses the following food items:

- Aquatic and terrestrial fauna fished, trapped, hunted, and/or harvested (e.g., game animals and birds, fish, and seafood) for domestic consumption
- Produce harvested from naturally occurring sources (e.g., berries, seeds, leaves, roots, and lichen)
- Plant tissues (e.g., roots, bark, leaves, and seeds) ingested for medicinal or other uses (e.g., teas)
- Produce (e.g., fruits, vegetables, and fungi) grown in gardens, and/or home orchards
- Aquatic and terrestrial fauna (and its by-products) produced for domestic consumption but not for market (e.g., ducks, chickens or other fowls, eggs, and dairy products)

It is also possible that foods sold commercially are contaminated by a project's activities. More information on this issue can be found at **www.hc-sc.gc.ca/fn-an/securit/index-eng.php**.

5.2. COUNTRY FOODS AS A PATHWAY IN A HUMAN HEALTH RISK ASSESSMENT

Within the risk assessment of a proposed project, ingestion of contaminants via food can be a significant pathway of exposure, particularly when chemicals that may increase as a result of project activities possess the ability to bioaccumulate or biomagnify in the food chain; and/or when the consumption of country food may constitute a significant portion of an exposed person's diet.

The potential health risks associated with elevated levels of chemicals in country foods are examined in an EA through a human health risk assessment (HHRA) for country foods. The HHRA is a process used to estimate the exposure that individuals may receive from consumption of country foods and to identify whether there may be potential risks associated with that exposure, accounting for the cumulative effects of current and proposed projects. An HHRA provides increased defensibility for any conclusions of an EA. It can also be used to provide a quantitative estimate of the potential risks in an exposed population, and highlight the need for and guide the development of appropriate mitigation measures, follow-up, monitoring plans, remediation, and/or risk management approaches to reduce or eliminate the potential human health risks associated with the project activities.

Guidance offered in this document is not designed nor intended as a substitute for the sound professional judgement of a qualified and experienced risk assessment practitioner. Many risk assessments for country foods conducted to support EAs will present unique situations not specifically addressed here. Risk assessors are encouraged to ensure that their assessments address all relevant potential risks. The methods described in this document do not negate the need for sound professional judgment. If alternative or unique approaches are considered appropriate, these should be sufficiently documented and described to enable peer review and they should also be evaluated for their impact on risk estimates relative to the application of the standard methods prescribed.

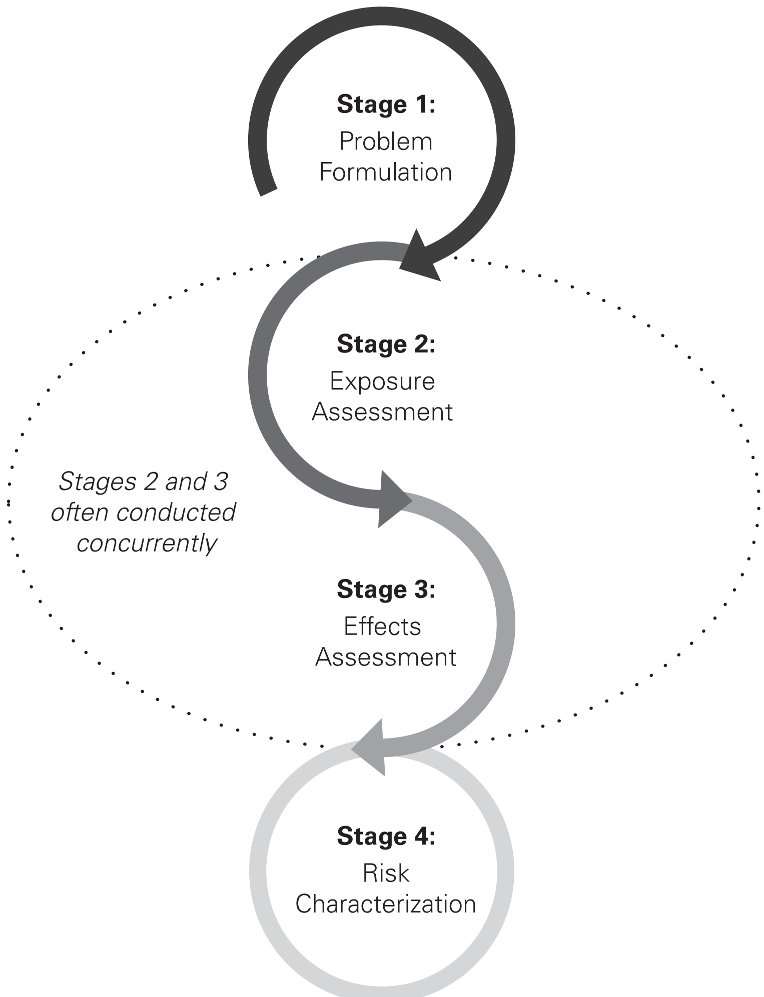
The EIS Guidelines prepared by the Canadian Environmental Assessment Agency (CEAA) outline the need to conduct an HHRA when elevated concentrations of contaminants of potential concern (COPC) are predicted in one or more environmental media for a proposed project. The level of detail required to evaluate potential human health impacts may vary from project to project, and where there are no predicted pathways that may result in exposure to the population, a qualitative/screening approach may be sufficient. For projects with operable pathways and a potential for human exposure to contaminants, a quantitative risk assessment can provide an estimate of potential human health risks associated with chemicals released from various stages of the proposed project.

The information that is part of an HHRA is discussed under the following headings:

Stage 1: Problem Formulation
Stage 2: Exposure Assessment
Stage 3: Effects/Toxicity Assessment
Stage 4: Risk Characterization

Figure 5.1 illustrates the sequencing of these stages according to Health Canada's suggested approach to assessing the potential risk associated with consumption of impacted country foods using an HHRA.

Figure 5.1: Human Health Risk Assessment Process



5.2.1 Stage 1: Problem Formulation

The purpose of problem formulation is to determine:

1. if the proposed project can release chemicals that may impact environmental media;
2. if there are ***operable exposure pathways*** present through which elevated levels of chemicals associated with the proposed project may affect individuals.

In this stage of the project, the appropriate type of HHRA is also determined. The key tasks in problem formulation (US EPA 2014) are as follows:

A. Develop a conceptual model

B. Develop an analysis plan

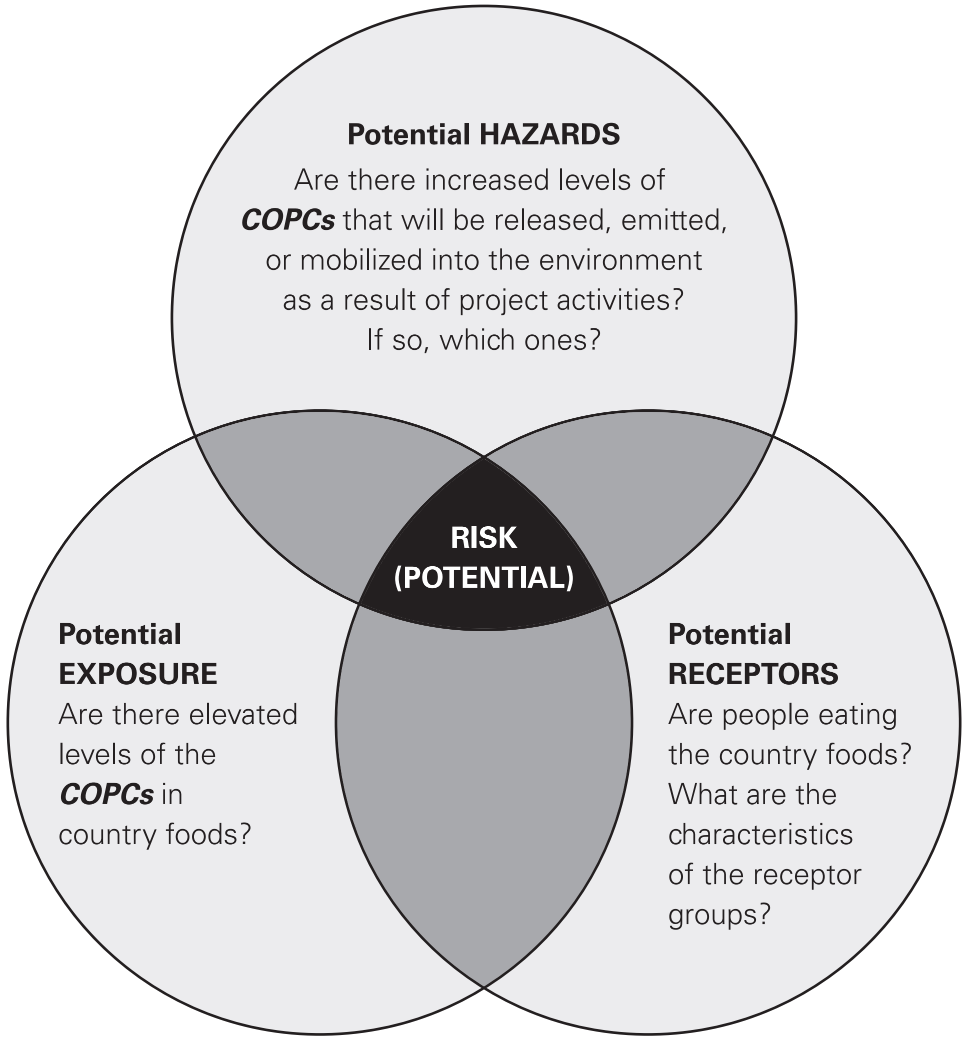
A. CONCEPTUAL MODEL

A conceptual model is a visual representation that identifies:

- the sources of potential hazards (e.g., COPCs associated with the project);
- the exposure pathways via the environmental media that may be impacted (e.g., air, water, soil, sediment, and ultimately concentrations in the foods);
- the individuals (receptors) who may consume the foods.

The key components of the conceptual model are described in Figure 5.2 which illustrates that all of these components must be present in order for there to be a potential risk.

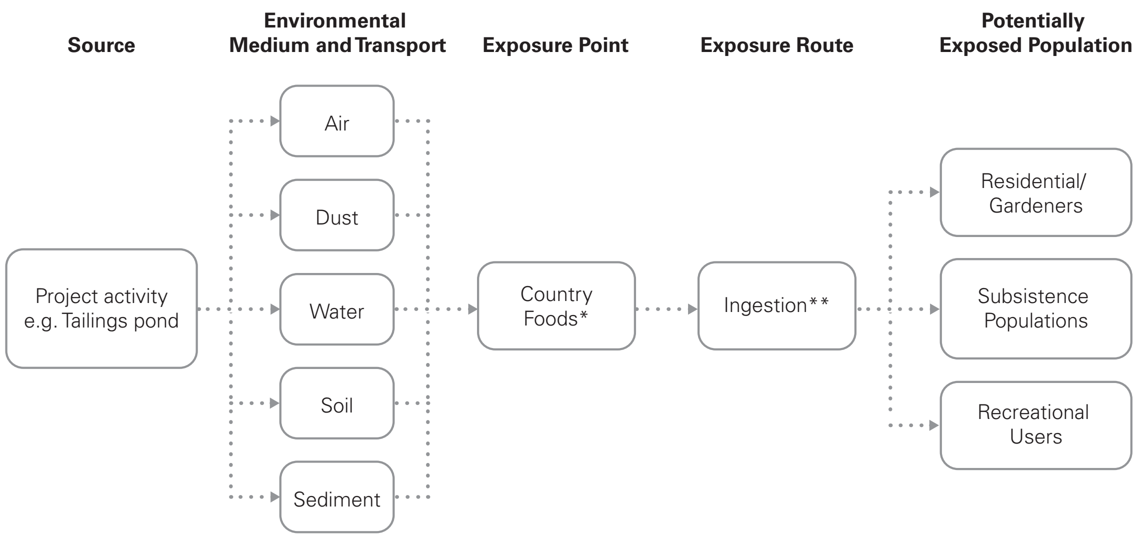
Figure 5.2: Risk Components Relationship for Country Foods



All substances that may be elevated in environmental media as a result of project activities may be initially considered as COPCs. However, if the predicted concentrations plus the baseline concentrations are calculated to be below guidelines/standards/criteria for the impacted medium, the problem formulation phase of the risk assessment may conclude that the particular substance does not need to be carried forward as a COPC in a quantitative risk assessment. However, in the case of country foods, where there are usually no guidelines/standards/criteria available for screening that environmental medium, the COPCs would be carried forward into a quantitative risk assessment to identify whether there may be health risks associated with the predicted concentrations.

Figure 5.3 provides an example of a project-specific conceptual model associated with a specific activity/component of the project.

Figure 5.3: Example of a Human Health Site Conceptual Model



* Country Foods, or traditional foods, include any food that is trapped, fished, hunted, harvested or grown for subsistence or medicinal purposes, outside of commercial food chain, and that is not regulated under the *Food and Drugs Act*.

** Inhalation or dermal expose may occur if contaminated plants used for medicinal purposes are burned and inhaled, used on the skin (i.e. to heal wounds), or if contaminated soil comes into contact with the skin.

Making the decision about the need for an HHRA
If the conceptual model determines that individuals are likely to consume foods that may be impacted by project activities, then it is recommended the HHRA includes the country food exposure pathway. For those EAs where country foods are not considered to be an operable exposure pathway, the HHRA should provide a clear rationale for not including country foods as a medium in the HHRA (e.g., no increase of COPCs in any foods that may be consumed by individuals currently or in the future).

i. Hazard Identification—Increased Levels of COPCs in Country Foods

The first step in the development of a conceptual model is to determine whether project activities may result in increased levels of COPCs in country foods through impacts to other media (e.g., release of chemicals to air, water, soil, sediment).

Does the project involve the release, the emission, the mobilization or the modification of one or more COPCs in the environment, which may result in increased concentrations of COPCs in country foods?

The main elements of hazard identification that should be documented are the following:

- Factors that may determine the likelihood of contaminant release, emission, mobilization, and/or modification in the environment, such as:
    - the nature of the project to be undertaken
    - the release of contaminants from stack emissions
    - atmospheric emissions from other sources
    - the materials and chemicals present
    - excavation and construction
    - the transportation of materials
    - potential flooding
    - the rerouting of waterways
    - waste management
    - releases of contaminated water due to leaking and leaching
- The baseline concentrations of each COPC in each media (e.g., air, water, soil, sediment, food).
- A summary of the modelling conducted for each COPC, identifying predicted concentrations in environmental media (the identification of the COPCs should reference where any supporting information is found in the EA documentation).
- Identification of all potential COPCs selected in each EA, which may be elevated in the environment for each stage of project activities.

- Identification of the parameters used to model concentrations in country foods (e.g., estimated concentrations of COPCs in various environmental media that will then result in increased concentrations in country foods).
- Summary of the predicted values of COPCs in all edible tissues of plants/animals that are consumed.

Table 5.1 lists typical COPCs that may be released from common project types. Project-specific HHRA requires a site-specific identification of possible COPCs.

Table 5.1: Typical COPCs Possibly Contaminating Country Foods by Activity Type/Industrial Sector

Main Sector/ Activity	Sub-Sector	COPC/General Country food Contamination
Construction and Transportation		Dependent on types of construction vehicle or mode of transportation. For vehicles burning fossil fuels, associated contaminants may include polycyclic aromatic hydrocarbons (PAHs), metals, and trace elements (e.g., arsenic, copper, lead, manganese, sulphur, zinc).
Electric power generation and transmission	*Hydro-electric*	Methylmercury (methylation process occurring during the inundation of reservoirs)
	Nuclear	Radionuclides
Mining, extraction and smelting	*Aluminum*	Metals, particularly aluminum; fluorides; PAHs and polychlorinated dibenzo-p-dioxins (PCDDs)/polychlorinated dibenzofurans (PCDFs) in smelting;
	Gold	Chromium, arsenic, mercury, cadmium, cyanide, PAHs and PCDDs/PCDFs (smelting),
	Mixed metals	Metal and trace elements (depending on the content of ore and the natural environment), PAHs, PCDDs/PCDFs (smelting)
	Nickel	Metals including nickel, aluminum, cadmium; PAHs; PCDDs/PCDFs (smelting)
	Ferrous/steel	Metals including manganese, tin, zinc; PAHs and PCDDs/PCDFs (smelting);
	Uranium	Metals and trace elements (e.g., arsenic, cadmium); radionuclides including uranium (U), radium (226Ra), lead (210Pb), and polonium (210Po)
Petroleum production, distribution, processing and storage	*Bitumen (oil sands) extraction*	PAHs, petroleum hydrocarbons (PHCs), heavy metals, and trace elements (e.g., aluminum, arsenic, cadmium, chromium, iron, lead, mercury, molybdenum, nickel, selenium, sulphur, vanadium, zinc)
	General (transportation, etc.)	Metals, PHCs, benzene, toluene, ethylbenzene, xylenes, PAHs, lead, and methyl tertiary butyl ether
	Coal gasification	Metals, PAHs, and PHCs

ii. Exposure—Transport Pathways into Country Foods

The purpose of this step is to identify all potential ways by which country foods can be exposed to COPCs—these are referred to as transport or exposure pathways. An exposure pathway includes consideration of the contaminant source, release mechanism(s), transport mechanism(s) within the relevant environmental medium (or media), transport residency media, and exposure routes. The exposure route refers to how a country food comes into contact with a COPC (e.g., water or soil ingestion; inhalation of particulates or volatile compounds; dermal contact).

The conceptual model should identify, for each COPC, all operable transport pathways for the COPCs to migrate from potential project contaminant sources to country foods. Several common examples are provided in Table 5.2.

Table 5.2: Identification of Possible Contaminant Transfer Pathways into Country Foods

		PATHWAY COMPONENTS		
	Sources and Contaminants	**Transfer Mechanism**	**Release Mechanism**	**Transport Residency Media**
EXAMPLES	Slurry discharge (e.g., metals, volatile organic compounds)	Contact of slurries with soil, surface water or groundwater used for irrigation	Uptake into plant tissues, incidental ingestion by herbivores, adsorption on plant material, entrainment into dust, inundation leading to methylation of mercury resulting in uptake by country food species	Produce, fish and other aquatic organisms, wild game, poultry, eggs and dairy, juice or wine, plant materials used for tea
	Stack emissions (release of COPCs to air)	Aerial deposition onto plants, soils, sediments, surface water	Uptake into plant tissues, incidental ingestion by herbivores, and adsorption on plant material resulting in uptake by country food species	Produce, fish and other aquatic organisms, wild game, poultry, eggs and dairy, juice or wine, plant materials used for tea

iii. Receptors

The problem formulation stage identifies all individuals that may be impacted by the proposed project currently and in the future. In the case of the country food component, these would be human receptors that do or will consume potentially contaminated country foods. Such human receptors include individuals that are present or expected to be present in the future within the spatial boundaries of the project and/or could be impacted by country foods as well as individuals with permanent residences or temporary use areas (e.g., cabins, recreational use, seasonal occupancy, transient use for country food collection). When identifying potential receptors, consideration should be given to potentially sensitive and/or unique receptors that may be exposed to increased levels of risk due to physiology, health status, behaviour, and/or lifestyle. Examples include seniors, pregnant or nursing mothers and infants (particularly where COPCs are known to biomagnify or exhibit potential neurotoxic or fetotoxic effects), and consumers of higher quantities of local country foods that may receive greater exposure to COPCs. The HHRA should also identify individuals that may be exposed outside of the spatial boundary. For example, an adult hunter in the area may bring food back to a non-impacted area where others (family members, community members, elders, etc.) may consume the foods with elevated levels of COPCs; in this case, while the adult may be the only receptor at the site, all age groups that consume the foods would need to be addressed in the HHRA.

Are human receptors consuming (currently or likely in the future) country foods in the potentially affected areas?

The third element of the site conceptual model is to adequately determine current or future possible transport pathways to human receptors. The HHRA should clearly identify what country food species and tissues may be consumed, and their seasonal consumption amounts, from the impacted areas. References should be provided for all receptor characteristics along with rationale for assumptions made. For instance, it is not sufficient to simply assume that 10% of foods may be consumed from the local area without rationale for that assumption. Engaging potentially affected communities and integrating traditional knowledge into the environmental assessment are important for obtaining data representative of the project area.

When creating a list of locally consumed country foods, it is helpful to consult the FNFNES data (see section 4.1) as well as conduct local surveys and engage Indigenous communities that may have an interest in or be affected by the project. More information on this subject can be found at **www.sciencedirect.com/science/article/pii/S0195925509000845** and **www.ontario.ca/page/environmental-assessments-consulting-aboriginal-communities**.

Some receptor characteristics are provided in HC guidance (2012). Table 5.3 provides a suggested format for capturing receptor details that will support the site conceptual model and the HHRA.

Table 5.3: Identification of Possible Receptors

	Receptor and characteristics	Species Consumed	Tissue(s) Consumed	COPC(s)
EXAMPLES	Subsistence fisher	Northern pike (Esox lucius)	Skin, flesh, organs (liver)	Methylmercury
		Whitefish (Coregonus sp.)	Skin, flesh, organs (liver), roe	
	Indigenous population 1 (specify), 10 km from project boundary	Dungeness crab (Metacarcinus magister)	Flesh, hepatopancreas	Dioxins and furans, PAHs, PCBs
	Indigenous population 2 (specify)	Bearberry (Arctostaphylos spp.); black, gold and red currant, and gooseberry (Ribes spp.); blueberry/ bilberry, black huckleberry (Vaccinium spp.)	Berries, leaves for tea	Metals
	Backyard fruit growers in the city, 30 km from the project	Apple (Malus spp.), pear (Pyrus spp.), raspberry, strawberry	Fruit	PAHs

B. ANALYSIS PLAN

Not all EAs will require the completion of a quantitative HHRA—a qualitative approach may be sufficient (e.g., if there are no active or potential exposure pathways). However, for projects with an identified potential exposure to elevated levels of contaminants, a quantitative assessment would be required as there are no applicable regulatory guidelines against which concentrations of COPCs in foods can be screened. Also, it is recommended that a quantitative HHRA be conducted in the following cases:

- The project is proposed for a region that is already experiencing high background levels of certain contaminants (e.g., methylmercury, cadmium, selenium).
- The project contribution, in conjunction with cumulative effects from existing developments or foreseeable projects, leads to substantive increase of one or more COPCs.

Existing guidelines and standards for commercial foods are developed with consideration of commercial food consumption patterns which have relatively limited variability in Canada, in particular with respect to staple foods. Country foods can present a substantial level of variability in the types and amounts of country foods consumed, thus the need for a project-specific quantitative characterization of all COPCs that may impact country foods.

If country foods are identified as a pathway, the usual approach is a *multi-media HHRA* including all environmental media (air, dust, sediment, water or soil) and exposure pathways (ingestion including country foods, other foods and water; inhalation and dermal absorption). Generally, if country foods is an operable pathway for COPCs, it is very likely there is another active pathway (e.g. air, soil and water) of exposure.

Recent Canadian Environmental Assessment Agency EIS Guidelines have specifically outlined the need to conduct an HHRA for a proposed project when elevated COPC concentrations are predicted in environmental media. The analysis plan should specify what kind of HHRA will be carried out, and should provide justification for the approach.

5.2.2 Stage 2: Exposure Assessment

The objective of the exposure assessment is to estimate the concentration of each COPC to which individuals may be exposed. Exposure to COPCs is predicted using various models to estimate the concentrations of COPCs in the applicable environmental media and in different assessment scenarios. A quantitative exposure assessment is conducted for the country food component of the HHRA by using estimated exposure for each COPC in all foods. Such analysis should be conducted for each phase of the project (e.g., construction, operation, decommissioning), unless it can be justified that one phase is representative of all other phases and presents a major source of contamination. It is preferable that baseline data be measured in foods from the area and estimated for future stages of the project. An exposure assessment should be completed for all relevant age groups (e.g., even if only the adults hunt in the impacted areas, all other members of the population may consume the foods).

In order to collect and use appropriate site-specific information, HC recommends obtaining consumption patterns for different foods for the specific population/communities of interest and/or similar populations that consume foods from the impacted area. For example, British Columbia's coastal communities may have different consumption patterns compared to British Columbia's inland communities. The HHRA report should provide referenced data for the consumption frequency of each type of food (i.e., seasonal consumption) as well as the daily amount consumed (i.e., serving size or g/day). This information is required to estimate exposure to each COPC associated with consumption of country foods. Published literature may be used, where available, if data refer to similar populations with similar consumption patterns.

The *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson 1997, p. 4154) provides standard consumption rates for fish and wildlife by First Nations. The FNFNES summary reports contain information on types, amounts and frequency of foods consumed by adults in First Nations communities across Canada (South of 60°) (Chan et al. 2014, 2012, 2011). For the areas where no data are available and generic consumption amounts may not be available or applicable, a country food consumption survey may be conducted with the local population to obtain the information required to complete a risk assessment for country foods. The FNFNES methodology also includes samples of two types of dietary intake questionnaires, a food frequency questionnaire (FFQ) and a 24-hour recall.

If a published literature source was used, the report should provide a rationale for its use (i.e., timing, geographical and population scope) and discuss any data gaps or extrapolations. The key steps in determining country food consumption are outlined below.

A. CHARACTERISING RECEPTORS

In the problem formulation section of the HHRA, individuals that may be exposed to the COPCs through consumption of country foods were identified (e.g., the receptors). The exposure assessment part of the risk assessment summarises the specifics of each of the receptor groups, such as age, estimated body weight, and consumption rates of each food type. All receptor groups should be included, and a quantitative risk assessment completed for each. For instance, toddlers may consume more food than adults on a body weight basis, therefore receiving greater exposure to COPCs, which is why all age groups need to be considered.

If a survey is conducted to identify local consumption rates of foods, the country food consumption survey should include the following information:

- receptor characteristics (i.e., age, gender, cultural affiliation, etc.), including receptors with atypical consumption patterns due to occupational, recreational, and cultural activities relevant to country food consumption (e.g., hunters, trappers, fishers)
- a list of the country foods consumed, including common and scientific names of species
- the source of country foods (i.e., where the food is typically harvested and how it is obtained—hunted, fished, gathered, etc.)
- specific tissues (skin, fatty flesh, muscular flesh or organs) or parts of plants (roots, leaves, flowers, berries, seeds, etc.) that are consumed
- the typical portion size for each tissue or part of plants consumed, using standard measures such as measuring cups or spoons, or weights
- the frequency of consumption (i.e., the number of servings per week or month or season, and if there are any seasonal patterns and variations due to special events such as celebrations or holidays)
- the typical method of preparation: skin on/off, washing, peeling, cooking (raw, fried, baked, etc.), drying, fermenting, and any other preparation methods that may affect the COPC concentration of the foods consumed
- traditional knowledge (i.e., species consumed, when the foods are consumed, their residence times, and times of increased consumption of specific foods such as, seasonal patterns or migration periods)

B. ESTIMATING RECEPTOR EXPOSURE TO BASELINE LEVELS OF COPCS

The baseline scenario represents the current levels of potential contaminants in an area, including those from existing sources, and describes the existing conditions for the proposed project area. The baseline levels of contaminants should be documented in order to evaluate the extent of possible environmental changes related to future project activities (and thus the subsequent potential impacts on human health). Comparing predicted COPC concentrations for the proposed project activities to the baseline concentrations provides information on the potential impact of the proposed project.

The baseline concentrations of the COPCs in country foods that are assessed in the HHRA should be measured or estimated. The analysis should address the following:

- Sampling design—identify locations where each sample was obtained; for vegetation samples, it is recommended that co-located soil samples in the root zone also be collected and analysed to assess uptake rates.
- Sample size—sufficient to allow the testing laboratory to meet detection limits that are applicable in an HHRA, without compositing of samples (or minimizing compositing of samples).
- Species and tissue sampling—identify which species (plant and animal) and tissues are most representative of country food consumption (accounting for the fact that some species and tissues may have higher concentrations of COPCs due to bioaccumulation and biomagnification, and some plants are known hyperaccumulators).
- Field collection—provide a summary of the methods used to collect the foods, including the procedures to limit potential cross-contamination and sampling biases.
- Contaminant-specific issues—where toxicity differs based on COPC speciation, the report should identify what samples are speciated, with rationale, and consider the bioavailability for metals where relevant (in the absence of detailed information, it is commonly assumed that 100% of COPC present in animal tissues is bioavailable and absorbed by humans in the gastrointestinal tract, as many toxicity reference studies are based on food ingestion studies).
- Laboratory selection—confirm that the laboratory selected is able to obtain data for each COPC in tissue with a detection limit that is sufficiently adequate to confidently conclude on the potential risks to human health. Where guidelines are available, the detection limits should be less than such guidelines for the contaminant and species of interest, and/or less than risk-based or background concentrations for the species and tissues of interest based on a review of published literature.
- Quality assurance—provide a summary of the quality control/quality assurance plan implemented for the sampling program, including data for duplicate samples, etc.
- Laboratory analytical reporting—the analytical report for the COPCs will include information for the concentrations of COPCs in both dry weight and wet weight (e.g., conversion of wet [as consumed] versus dry [preparation for sampling] units). For lipophilic organic compounds (i.e., PCDDs), results may be reported on a lipid basis (modified from HC 2010b, section 3.0).
- Optional—determination of exposure to COPCs through market food ingestion, as certain contaminants of concern associated with the proposed project may be present in commercially available foods, are naturally occurring (e.g., metals) or are associated with other anthropogenic processes unrelated to the proposed project. Combining these values in the risk characterization for the ingestion pathways may be appropriate in order to adequately characterize risk.

It is important to include all relevant data related to baseline samples, including the number of samples collected, the number of non-detectable samples, the minimum and maximum concentrations, and any statistical evaluation undertaken (e.g., mean, median, upper 95% confidence limit of the mean).

Information about exposure to COPCs through market food ingestion can be found in published literature, including the following sources:

- Health Canada's *Canadian Total Diet Study (***www.hc-sc.gc.ca/fn-an/surveill/total-diet/index-eng.php**) provides information about market food contamination levels. The above website also includes a hyperlink to the average dietary intakes of various chemical contaminants that have been estimated using food residue data collected through the Total Diet Study and Canadian food consumption data.
- The *Canadian Community Health Survey (***www.hc-sc.gc.ca/fn-an/surveill/nutrition/commun/cchs_guide_escc-eng.php**) provides some information on market food ingestion rates in Canada.

If exposure to COPCs through market foods is not included in the HHRA, then a referenced, scientific rationale for exclusion should be included (e.g., retail foods have a low contribution to COPC exposure).

For further information on sampling methodology for country foods, refer to HC's supplemental guidance on risk assessment for country foods (2010b).

C. PREDICTED EXPOSURE ASSESSMENT

The objective of the exposure assessment is to estimate the levels of COPCs to which individuals may be exposed from the consumption of country foods using information on the amount of each COPC in the consumed foods, the amount of foods consumed and their frequency of consumption.

For the country food pathway, the exposure assessment section will provide an estimate of predicted COPC concentrations in each of the country foods consumed over the life of the project, and will account for cumulative effects. The risk assessor should ensure that the values used are appropriate for the exposed population and the report should provide sufficient rationale to justify the use of the values identified, noting whether the value is conservative or whether the value may result in an underestimate of exposure.

Consumption surveys are a good way to obtain site-specific information to use in an assessment. Results of such consumption surveys should be presented in terms of wet weight tissues to replicate the "as consumed" conditions. Also, it is good practice to evaluate potential risks associated with the most impacted areas where foods are likely to be obtained (e.g., backyard garden, specific lake or river) rather than adopting averages over larger areas.

Where a preliminary analysis suggests a potential for unacceptable human health risks, further assessment may be necessary to resolve conservatism and uncertainty in the HHRA process before the actual extent of the human health risk can be fully quantified and defined.

5.2.3 Stage 3: Effects/Toxicity Assessment

In the context of an HHRA, the effects assessment component of an EA is typically referred to as the toxicity assessment stage. This stage of the risk assessment involves identifying the potential toxic effects of each COPC and summarizing TRVs published by regulatory agencies, which will then be used to characterize potential risks in Stage 4 of the HHRA. A brief summary of the key health concerns associated with exposure to each COPC should be provided in the HHRA report or appendix. The summary should discuss both cancer and non-cancer endpoints, where appropriate.

The toxicity assessment is conducted for all identified COPCs and considers all receptor groups, including sensitive receptors. Depending on the mechanism of toxicity, the toxicity assessment either provides an estimate of how much exposure to a chemical can occur without any anticipated adverse health effects (threshold effect chemical) or establishes a relationship between the exposure dose of a chemical and the probability of developing an adverse health effect such as cancer (non-threshold effect chemical).

Although it is a separate step, the effects assessment should be conducted in conjunction with the exposure assessment. Information obtained during the exposure assessment, such as exposure duration (short-term versus long-term), can influence the effects assessment, and the mechanisms of toxic action (e.g., local versus systemic) can affect how the exposure assessment is performed. The effects assessment considers the site conceptual model developed during the problem formulation because TRVs are often exposure route-specific and are occasionally specific to certain sensitive receptors. The TRVs and exposure doses must be compatible with each other (i.e., if the exposure is expressed as a daily dose per unit body weight, the TRV should also be expressed in the same form).

For threshold-acting contaminants, TRVs are expressed as tolerable daily intakes or reference doses for the oral pathway; for non-threshold contaminants, TRVs are expressed as slope factors for the same pathway. Further information on toxicity assessment is found in HC's detailed quantitative risk assessment guidance (2010a) and risk assessment for short-term exposure guidance (2013).

It is recommended that TRVs be obtained from reputable regulatory agencies—ideally Canadian sources where available—and that the most current values are applied in the EA as older TRVs may no longer be scientifically defensible or relevant. APPENDIX C: identifies possible sources of TRVs for environmental assessments.

If no published TRVs are available, or if there is compelling evidence that the published TRVs are inappropriate (e.g., outdated or based on a different exposure route or chemical form), then new TRVs may be required. De novo development of TRVs should only be undertaken by individuals qualified and experienced in toxicology, and only after HC has been consulted. Further information on toxicity assessment is found in Appendix B of HC's detailed quantitative risk assessment guidance (2010a).
If a TRV for a specific COPC is not available from any regulatory sources and cannot be derived from published literature, an alternative TRV may be substituted that is based on a structurally similar compound with similar mechanisms of action and fully supported with referenced scientific rationale.

5.2.4 Stage 4: Risk Characterization

The purpose of risk characterization is to provide an estimate of potential risks to human health via consumption of country foods considering the potential exposure. The approaches described below are most commonly used, but are not an exhaustive list of methods that could be employed to characterize human health risks.

The risk estimates are typically separated into cancer and non-cancer endpoints.

Carcinogens (genotoxic) are generally assessed as non-threshold (i.e., any exposure may lead to a theoretical increase in the incidence of cancer). The increase in risk is calculated as an incremental lifetime cancer risk (ILCR). The estimated lifetime average daily dose will be multiplied by the appropriate slope factor to derive a conservative estimate of the potential ILCR associated with that exposure. Cancer risks will be deemed to be "essentially negligible" (de minimis) where the estimated ILCR is ≤ 1 in 100,000 ($\leq 1 \times 10^{-5}$). The rationale for this essentially negligible risk level is presented in Appendix C of HC's preliminary quantitative risk assessment guidance (2012).

ILCR = Lifetime Average Daily Dose (μg/kg/d) x Cancer Slope Factor $(\mu g/kg/d)^{-1}$

OR in the case of airborne contaminants with a unit risk value in units of $(\mu g/m^3)^{-1}$

ILCR = Air Concentration $(\mu g/m^3)$ x Fraction of Time Exposed x Cancer Unit Risk $(\mu g/m^3)^{-1}$

Most non-carcinogens are generally assessed as threshold contaminants (i.e., there is a level known as a no observed adverse effect level (NOAEL) below which exposure is not associated with adverse human health outcomes). The risk associated with a certain level of exposure to these contaminants is calculated as a hazard quotient (HQ). Where an HHRA evaluates only project-related exposures (excluding background estimated daily intake for sources not related to the project, including consumer products, food, air, and water), risks associated with an HQ ≤ 0.2 will be deemed negligible. Where risks associated with the project and the estimated intake from background sources are combined, the resulting HQ would be compared to a target value of 1.0. A target HQ of 1 basically means that the exposure from the project plus background does not exceed the toxicological reference value. If the HQ of 1 is exceeded, it may indicate a situation of non-negligible risk and the assessment may require further refinement. An HQ benchmark of 1 is generally used if levels of COPCs from background sources (in addition to exposure from the project, such as market foods, air, water, soil) have been included in the risk calculations. If exposure to COPCs from background sources is not included in the exposure calculations prior to comparing to a target HQ of 1, the risk may be underestimated. If a target value other than 1.0 is used, a detailed rationale must be provided to clearly justify the choice of this value. This is consistent with the CCME (2006) and has become accepted common practice in Canada.

With regard to mixtures of chemicals, for concomitant exposures to multiple COPCs determined to have similar target tissues and mechanisms of action, non-cancer HQs should be assumed to be additive and summed for those contaminants. All exposures from the project (country foods plus other exposures from media that may be impacted by the project) need to be added to obtain a final HQ associated with the project. All information used to derive final conclusions should be clearly documented to allow for peer review.

For concomitant exposures to multiple carcinogens determined to have similar target tissues and mechanisms of action, the risks should be assumed to be additive and thus summed. Health Canada may be consulted as needed regarding similarity of mechanisms of action and the need to aggregate risks. All other carcinogens with unique mechanisms of action, target organs, and/or forms of cancer should be assessed individually. Similarly for carcinogens, ILCRs for COPCs causing the same form of cancer in the same target organ should be added together. Health Canada (2012) suggests using the same methodologies for summing toxic equivalence factors and potency equivalence factors.

A risk characterization summary (i.e., HQs for non-carcinogens, and ILCRs for carcinogens) should be provided for every COPC and receptor for each of the following scenarios:

- current (baseline) levels
- predicted post-project levels (project alone and cumulative effects—this project and all other known proposed projects)
- predicted post-decommissioning (should there be any) levels

If there are exceedances of either the target HQ or ILCR, additional mitigation measures should be considered in the conclusion/discussion section of the HHRA as well as a review of the assumptions made in the risk assessment and determining if further work is needed to refine the level of risk.

5.2.5 Uncertainty Analysis

Data gaps and/or assumptions made when conducting the assessment may lead to an underestimation or an overestimation of potential human health risks, which may result in the development of inappropriate risk management strategies, monitoring, and/or follow-up programs. For example, if standard rates of consumption for the general public are used instead of dietary exposure data related to the regional study area outlined in the project, then the risks due to COPC exposure for certain groups with higher than average consumption of the country foods (e.g., hunters, fishers) may be underestimated.

In order to account for these data gaps/assumptions, it is good practice to include a discussion in the HHRA on uncertainties in a risk assessment for country foods. Some of the contributors to uncertainties related to exposure assessment for country foods result from the following:

- Adequacy of data collected to assess baseline levels of COPCs in foods
- Variability in the contaminant levels in foods
- Use of surrogate data for one type of country food to apply to other types of country foods for which there are no data
- Use of mathematical models to predict COPC exposure from country foods that results from project activities
- Availability of local data regarding dietary exposure to COPCs
- Use of food consumption amounts that are not specific to the subject population

- Use of short-term dietary intake (e.g. 24-hour recall, 1-week FFQ) data alone to make projections about lifelong intakes, particularly in the case of foods infrequently consumed
- Uncertainties in TRVs
- Potential for synergistic/antagonistic effects of multiple COPCs

5.2.6 Conclusion/Recommendations

This section of the analysis contains the information concerning potential human health effects, including the uncertainties identified in the assessment, and the accompanying rationale or justification of the final conclusion. The need for monitoring and/or follow-up programs, risk mitigation strategies, and risk management approaches should also be described. Including a well-structured HHRA in the EIS clearly articulates potential impacts on human health as a result of the project and increases the defensibility of the conclusions.

Conclusions presented in the report should be sufficiently detailed and appropriate for the specific project; for example, they should be based on quantitative estimates of the potential risks in an exposed population, discuss the need for mitigation measures, and outline how the follow-up monitoring plans and/or risk management approaches were developed.

5.3. MITIGATION

The EIS should identify whether mitigation may be appropriate to address potential human health risks associated with contamination of country foods where the HHRA has identified that exposure to one or more COPCs may exceed the target HQ or ILCR.

Mitigation measures generally reduce the anticipated impact of sources rather than constraining pathways or receptors. Mitigation measures may include the following:

- Reducing airborne emissions (e.g., closed-loop processes or emissions scrubbers for industrial projects)
- Containing contaminated water and/or soils to prevent access by species that are consumed as country foods
- Where necessary, developing consumption advisories when increases in COPC levels in foods are unavoidable and ensure appropriate education/communication to the affected population
- Providing and/or facilitating access to reasonable substitutions for contaminated country foods item(s)
- Consulting with local populations on the appropriateness and acceptability of proposed mitigation measures

5.4. MONITORING

In the context of an EA, monitoring is generally conducted to determine the accuracy of predicted COPC levels in country foods obtained by modelling, thus ensuring that people are not exposed to unacceptable levels of COPCs in country foods. The questions below can be used as a starting point to assist in determining if a monitoring plan is appropriate:

- Is there significant public concern about the possibility of country food contamination?
- Is there uncertainty about one or more predicted COPC levels in country foods?
- Based on predicted COPC levels in country foods, are there likely exceedances of HQ/ILCR targets (or are the estimates close to target levels)?
- Are there any available results of human biomonitoring suggesting elevated COPC levels in the population?
- Is there a history of country food contamination in areas close to the proposed project area?
- Is there potential for novel COPCs—substances not on the Domestic Substance List or substances with limited data on uptake into country food species and/or human health effects—to be released, emitted or mobilized as a result of project activities?
- Are new technologies and/or substances being used during the project activities?

Key considerations in developing a monitoring plan are the following:

1. When to start monitoring
2. Where to monitor
3. Frequency and duration of monitoring
4. What species and tissues to sample
5. The need for human biomonitoring
6. Which contaminants to monitor
7. Sample collection that reflects when country foods are typically harvested, collected, fished, and/or hunted (e.g., when foods are ripe/in season)
8. Communication plan

In cases where monitoring results demonstrate COPC levels significantly beyond modelled results, a revision of the HHRA may be warranted, using the updated information. The outcome of such assessments may indicate the need for different or additional mitigation measures.

5.4.1 When to Start Monitoring

Baseline levels of COPCs in country foods should be measured as part of the EA prior to the project start. If those levels were neither measured nor comprehensive, then it is recommended that they be identified prior to project start. Baseline levels of COPCs in different foods will be variable, and there is a lack of data on tissue concentrations for many COPCs in foods. Baseline levels can also be established using a reference site (i.e., nearby site with similar environmental conditions, but outside the zone of influence of the project).

A. MONITORING DURING CONSTRUCTION

To have the most robust and accurate data, it is advisable to start country food monitoring during the construction phase of a project if:

- vehicles and/or other diesel-powered equipment will be used;
- start-up activities (e.g., vegetation clearing, excavation, damming, blasting) may mobilize contaminants; and/or
- waste management options include incineration.

B. MONITORING DURING OPERATIONS

Country food monitoring begins after project operation commences and continues for a defined period during this phase.

C. MONITORING DURING DECOMMISSIONING

If decommissioning is a foreseeable part of the project, it may be appropriate to continue country food monitoring during the decommissioning phase, especially if there is the possibility of COPC emission, release, mobilization, and/or modification in the environment (e.g., tailing ponds).

5.4.2 Where to Monitor

Monitoring should be conducted in the areas where potential effects are most likely to occur and where country foods are being harvested. The report usually describes the local study area and a larger regional study area, which ideally should be delineated for each environmental medium that may be impacted. Delineation should also be performed for country foods.

5.4.3 Frequency and Duration of Monitoring

The scheduling of country food monitoring should reflect:

- emissions during initial operation of a project until contaminant levels peak and a pattern of declining contaminant levels is determined;
- when modelling indicates likely increases in contaminant concentration in relevant media;
- growth and migratory patterns of the species being monitored.

In addition to scheduled monitoring, additional monitoring may also be conducted to reflect specific incidents. For instance, increased monitoring may be appropriate in cases of spills/accidental releases, or if monitoring of other media (e.g., air, water, soil) indicates elevated levels of contaminants (above that modelled for the purpose of the EA).

5.4.4 What Species and Tissues to Sample

An appropriate choice of species for monitoring is contingent on the following:

- Actual species and tissues consumed
- Feasibility of collecting enough samples to estimate exposure
- Representation of different growth rates and trophic levels for foods consumed
- Ability to obtain enough tissue from different edible tissue types (i.e., organs, muscle, fat) to complete an analysis

In some cases, the sampling of species, which are not actually consumed but are widely available and representative of consumed species in terms of contaminant exposure and metabolism, may be appropriate as a supplemental data source, but not as the only data source. Also, when sampling migratory wildlife (e.g., caribou), it is important to consider sampling other consumed species (e.g., deer) that may be more reflective of year round COPC exposure as a result of the project.

Consider the following when choosing tissues to sample:

- Actual consumption of the tissue (frequency and amount of consumption). Some tissues, normally organs, are only consumed irregularly at particular times of the year, but may be consumed in large amounts by specific populations which may be of a concern from both acute and chronic toxicity perspectives.
- How representative the level of contaminant in the analyzed tissue is of the level in other tissues of the same species also consumed by humans.

5.4.5 The Need for Human Biomonitoring

In some cases, human biomonitoring can be an appropriate tool to follow the migration of contaminants through the food chain, up to human consumers. Such monitoring may be particularly considered when background levels of COPCs in country foods are already raising concerns or may pose risks when certain foods are consumed without limitations. Biomonitoring may consist of sampling body fluids, human hair or other tissues; however, given the more invasive nature of this procedure, it should be adequately planned and carried out in consultation with affected communities and in collaboration with representatives of Indigenous peoples.

5.4.6 Which Contaminants to Monitor

If a contaminant is identified as a COPC for the proposed project, it should be included in the monitoring plan. If a COPC is excluded from the monitoring plan, an appropriate rationale (e.g., monitored through regional monitoring programs) should also be included.

If any novel contaminants are identified during project activities, it is good practice to monitor them and complete a risk assessment. Also, it should be decided what detection limits will be used for each COPC and if the same detection limits will be used for all tissues sampled.

5.4.7 Sample Collection

There are generally two approaches to choosing a sample appropriate for country food monitoring:

1. A sufficient number of samples for each tissue of interest should be collected during each sampling period in order to obtain a statistically significant sample size (a predefined number of samples from species representative of a range of age, gender, and size characteristics). Care should be taken to consider population size in a sampling program in order that it does not inappropriately deplete the existing population. Additionally, the size of each sample submitted for analysis should be sufficient to obtain the required analytical detection limit (the analytical laboratory should be consulted prior to sampling to identify the size requirements for each sample).
2. Paralleling actual hunting or harvesting patterns by collecting specimens donated by community members who hunt, gather or harvest country foods. This method reduces costs, tends to be more reflective of the actual species and tissues that are consumed, and makes use of traditional ecological knowledge. However, when this method is used, it may be difficult to obtain a statistically significant sample size, and there are inter-sample reliability issues and bias to consider (variability in preference for species, size, gender, etc.) Additionally, it is important to document how the samples are collected and whether any contaminants are introduced during collection. It is often, however, the only practical method of collecting samples. If this method is used, the uncertainty section of the report should identify potential uncertainties associated with the samples.

5.4.8 Communication Plan

Including a communication plan, if appropriate, related to the distribution of monitoring reports to local, provincial, territorial, federal, and First Nations and Inuit health authorities and communities is a key part of monitoring. The communication plan would include the steps that will be taken if there are any exceedances of established benchmarks or if there are no exceedances.

6 ASSESSMENT OF CUMULATIVE EFFECTS

Assessing the cumulative effects of projects is a central element of the EA and applies equally to the country foods and other HHRA aspects of the assessment. The cumulative effects scenario represents the potential environmental effects of the existing baseline plus project scenario in combination with effects from reasonably foreseeable future projects within the same area of influence. Reasonably foreseeable future projects include those that are approved but not yet operating, and/or other proposed or likely developments within the potentially impacted area. This scenario provides an estimate of human health risks in the future when other facilities are also in operation. The Canadian Environmental Assessment Agency has issued guidance on assessing cumulative effects (entitled *Assessing Cumulative Environmental Effects under the Canadian Environmental Assessment Act, 2012)* and it is available at: **www.canada.ca/en/environmental-assessment-agency/news/media-room/media-room-2015/assessing-cumulative-environmental-effects-under-canadian-environmental-assessment-act-2012.html**).

In the case of country foods, an assessment of cumulative effects should include the following:

- Changes in levels of contaminants in country foods resulting from all past, present, and known future projects.
- Whether all past, present, and/or known future projects could result in possible changes in contaminant exposure due to access to new sources of country foods (e.g., access to country food sources that were previously inaccessible such as the creation of a new road, which could result in fishing and hunting in areas where there was previously no fishing or hunting, and fish repopulation of a rehabilitated tailings pond) and/or changes in levels of country food consumption amount.
- Where COPCs have similar endpoints, it may be necessary to not only address cumulative effects, but also the additive effects.

7 FOLLOW-UP PROGRAMS

A follow-up program required by the legislation means a program for:

a. Verifying the accuracy of the EA of a project; and

b. Determining the effectiveness of any mitigation measures.

It may be appropriate to consider a follow-up program for country foods if one of the following applies (note that this is not a comprehensive list and is not a substitute for professional judgement):

- There is uncertainty about the modelling of COPC emissions, release, mobilization or deposition in the environment and uptake in country food sources.
- There is potential for novel COPCs to be introduced into country foods.
- It is uncertain whether proposed mitigation measures will be effective (e.g., the use of novel technology or complex systems).
- The unexpected contamination of country foods or operational changes alter the levels or nature of the contaminants released.

Health Canada may make available information or knowledge regarding a follow-up program upon request by a responsible authority, review panel or other jurisdiction conducting the EA.

For further and up-to-date information on follow-up programs, contact the appropriate regulator.

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APPENDIX A COUNTRY FOODS IN ENVIRONMENTAL ASSESSMENT CHECKLIST

This checklist will help verify that the main components of a country food assessment are completed. It is useful to include this checklist in the EA to identify the locations of the key components of a country food assessment, especially if the information is found in multiple sections of the EA documentation.

OVERALL		
✓	***Item***	
	1. Worked examples are included for calculations in a quantitative risk assessment.	
	2. Units are clearly stated and consistent (or conversion calculations are included as appropriate).	
	3. Assumptions are clearly stated and justified.	
HHRA—PROBLEM FORMULATION		
✓	***Item***	***Section in EA***
	4. All COPCs as result of project activities are identified.	
	5. Possible impacted media (air, dust, sediment, water or soil) which could result in increased COPC concentrations in foods that may be consumed are identified.	
	6. All plant/animal/fish/fowl species that may be consumed as country foods are identified and carried forward in the risk assessment.	
	7. All current and likely future consumer groups are identified.	
	8. A detailed rationale is included for not completing a country food assessment if the conclusion is that this assessment is not necessary.	
	9. A discussion is included about whether or not a multimedia HHRA was considered and conducted for any COPC with an identified risk and multiple pathways.	
HHRA—EXPOSURE ASSESSMENT, EFFECTS ASSESSMENT, AND RISK CHARACTERIZATION		
	10. The amount and frequency of consumption of each food are provided for eaters only and/or a justification is provided for assumed consumption levels if dietary intake is not available.	
	11. Current (baseline) COPC levels are documented in edible tissues for each of the country foods consumed by the population. If pre-existing data were used, a rationale for their use is included, making reference to timing and to geographical and population scope, and discussing any data gaps or extrapolations.	
	12. Likely exposure to contaminants from market food consumption is identified (optional).	
	13. A summary of the sampling program, locations of samples, and analytical data is included.	
	14. A summary of the TRVs is provided, with rationale for each TRV.	

HHRA—EXPOSURE ASSESSMENT, EFFECTS ASSESSMENT AND RISK CHARACTERIZATION (CONT'D)		
✓	***Item***	***Section in EA***
	15. A risk characterization (HQs for non-carcinogens, and ILCRs for carcinogens) is included for the following: a. Each COPC for i. Current (baseline) levels ii. Predicted post-project levels (project alone and including cumulative effects of this project and all other known proposed projects) iii. Predicted post-decommissioning (should there be any) levels b. Each receptor group, as appropriate c. Summing HQs and ICLRs when appropriate, based on similar mode of actions/ target organs	
	16. The report identifies and explains whether or not any HQs exceed benchmark levels for acceptability for non-carcinogens, and whether or not any ILCRs exceed targets for carcinogens; and a rationale for benchmark selection is included.	
	17. A discussion of uncertainties associated with assumptions in the assessment is included.	
MITIGATION		
	Scenarios and rationales for the inclusion or exclusion of mitigation are included.	
	A discussion regarding mitigation approaches and a rationale for the chosen approach(es) are included.	
MONITORING		
	Rationales for the inclusion or exclusion of monitoring are included.	
	A discussion about monitoring approaches and a rationale for the chosen approach(es) are included.	
	A communication plan is included, if appropriate.	
CUMULATIVE EFFECTS AND FOLLOW-UP PROGRAM		
	Cumulative scenarios and effects are considered.	
	Additional mitigation and/or monitoring are considered if cumulative effects on country foods exceed the project-only scenario.	
	The country food section (as required) of the follow-up program is described.	

APPENDIX B ADDITIONAL INFORMATION ON HEALTH CANADA HUMAN HEALTH RISK ASSESSMENT DOCUMENTS

The documents listed below provide HHRA guidance for federal contaminated sites in Canada. Risk assessments of contaminated sites are based on known existing levels of COPCs and are not universally applicable to HHRAs intending to support EAs, where concentrations of contaminants are modelled for various media over the lifetime of a project. However, these documents contain valuable guidance applicable to EAs—relevant information and document locations are identified below. Please note that these documents can be accessed directly from Archives Canada publications web page (links to PDF format provided); however, these links will not lead to Health Canada's Contaminated Sites program, where multiple documents can be requested.

Health Canada (2012). *Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0*. Ottawa, Ontario: Environmental Health Assessment Services, Safe Environments Program. **http://publications.gc.ca/collections/collection_2012/sc-hc/H128-1-11-632-eng.pdf**

- Prescribes, to the degree possible, standard exposure pathways, receptor characteristics, TRVs, and other parameters required to quantitatively and consistently assess potential chemical exposures and human health risks.

Health Canada. (2010a). *Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals ($DQRA_{CHEM}$)*. Ottawa, Ontario: Environmental Health Assessment Services, Safe Environments Program. **http://publications.gc.ca/collections/collection_2011/sc-hc/H128-1-11-639-eng.pdf**

- Most risk assessments conducted to support environmental assessments will have similar considerations of those described in the DQRA guidance.

Health Canada (2010b). *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods ($HHRA_{FOODS}$)*. **www.hc-sc.gc.ca/ewh-semt/pubs/contamsite/country_foods-aliments_locale/index-eng.php**

- Listing of some country foods that may be consumed
- Sampling methodology for country foods, including considerations for the number of samples that may be required
- Resources for Indigenous Dietary Consumption of Traditional Foods
- Limited discussion on modelling tissue concentrations and the use of uptake models for a HHRA incorporating country foods

APPENDIX C SOURCES OF TOXICOLOGICAL REFERENCE VALUES

Source	Description	Availability
Health Canada. Chemical Health Hazard Assessment Division (CHHAD)	TRVs used by CHHAD in health risk assessments for chemicals in foods	Unpublished. For questions related to TRVs, contact CHHAD at **bcs-bipc@hc-sc.gc.ca**
Health Canada. *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors*	TRVs for a number of substances found at contaminated sites	**www.hc-sc.gc.ca/ewh-semt/pubs/contamsite/part-partie_ii/index-eng.php**
United States Environmental Protection Agency. *Integrated Risk Information System (IRIS)*	TRVs provided for hundreds of substances	**http://cfpub.epa.gov/ncea/iris/index.cfm**
Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives. *Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives*	Details on tolerable intakes for many substances	**www.who.int/foodsafety/publications/jecfa/en/**
Agency for Toxic Substances and Disease Registry. *Minimal Risk Levels for Hazardous Substances*	List of minimal risk levels for oral (and inhalation) routes for many substances	**www.atsdr.cdc.gov/mrls/index.html**

APPENDIX D **THEMATIC REFERENCE LIST**

D.1 OVERALL COUNTRY FOODS AND HUMAN HEALTH RISK ASSESSMENT

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Federal/Provincial/Territorial Committee on Environmental and Occupational Health. (2004). *Canadian handbook on health impact assessment – Volume 4: Health Impacts by Industry Sector*. Ottawa, Ontario: Health Canada. Available at: **http://dsp-psd.pwgsc.gc.ca/Collection/H46-2-04-363E.pdf**

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Health Canada. (2009). *Concentration of Contaminants & Other Chemicals in Food Composites.* Available at: **www.hc-sc.gc.ca/fn-an/surveill/total-diet/concentration/index-eng.php**

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D.8.1 Programs

Canadian Wildlife Service, Environment Canada.
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The Canadian Wildlife Service has a wildlife contaminants monitoring program that provides some information on baseline levels of contaminants in country foods.

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