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Supplemental Guidance on Human Health Risk Assessment for Country Foods ($HHRA_{Foods}$)

Federal Contaminated Site Risk Assessment in Canada

Canada

Erratum

Page 13, above Section 5.4, Equation 5.1 and 5.2.

(5.1)

$$\text{Tissue}_{\text{wet weight}} = \text{Tissue}_{\text{dry weight}} / ((100- MC)/100)$$

Where:
MC = moisture content expressed as a percent

(5.2)

$$\text{Concentration}_{\text{whole weight}} = \text{Concentration}_{\text{lipid weight}} / ((100 - LC)/100)$$

There are errors in the equations as printed (above). The corrected forms of the equations are as follows:

Equation 5.1

$$C_{ww\ tissue} = C_{dw\ tissue} \times (1\text{-}MC)$$

Where:

$C_{ww\ tissue}$ = wet weight tissue concentration (ug/g)

$C_{dw\ tissue}$ = dry weight tissue concentration (ug/g)

MC = moisture content (decimal fraction)

Equation 5.2

$$C_{ww\ tissue} = C_{lipid} \times LC$$

Where:

$C_{ww\ tissue}$ = wet weight (whole weight) tissue concentration (ug/g)

C_{lipid} = lipid weight concentration (ug/g)

LC = lipid content (decimal fraction)

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FEDERAL CONTAMINATED SITE RISK ASSESSMENT IN CANADA

SUPPLEMENTAL GUIDANCE ON HUMAN HEALTH RISK ASSESSMENT FOR COUNTRY FOODS ($HHRA_{FOODS}$)

October 2010

Prepared by:
Contaminated Sites Division
Safe Environments Directorate

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PREFACE

The Federal Contaminated Sites Action Plan (FCSAP) is a program of the Government of Canada designed to ensure improved and continuing federal environmental stewardship for contaminated sites located on federally owned or operated properties. Guidance documents on human health risk assessment (HHRA), prepared by the Contaminated Sites Division of Health Canada, in support of the FCSAP, are available on our website and may also be obtained by contacting the Contaminated Sites Division at: cs-sc@hc-sc.gc.ca.

This guidance document (*Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods*) was prepared to address issues of harvesting and ingestion of foods grown at contaminated sites. It was developed as a result of repeated requests for Health Canada's advice from contractors, federal departments, provincial/territorial agencies and others inquiring about recommended practices at contaminated sites, where ingestion of foods from contaminated sites can present potential exposures and risks. As is common with any national guidance, this document will not satisfy all of the requirements presented by contaminated sites, custodial departments or risk assessors in every case.

As the practice of HHRA advances, and as the FCSAP proceeds, new and updated information on soil quality guidelines, drinking water guidelines, Toxicological Reference Values (TRVs), contaminant bioavailability, human characteristics and exposure factors, and other aspects of HHRA will be published. As a result, it is anticipated that revisions to this document will be necessary from time to time to reflect this new information. Health Canada should be consulted at the address below to confirm that the version of the document in your possession is the most recent edition and that the most recent assumptions, parameters, etc., are being used.

In addition, Health Canada requests that any questions, comments, criticisms, suggested additions or revisions to this document be directed to: Contaminated Sites Division, Safe Environments Directorate, Health Canada, 99 Metcalfe Street, 11th Floor, Address Locator: 4111A, Ottawa, ON K1A 0K9. e-mail: cs-sc@hc-sc.gc.ca

See also: www.hc-sc.gc.ca/ewh-semt/contamsite/index-eng.php

ABBREVIATIONS AND ACRONYMS

BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BTF	Biotransfer Factor
CAEAL	Canadian Association for Environmental Analytical Laboratories
CCME	Canadian Council of Ministers for the Environment
COPC(s)	Chemical(s) of potential concern
DDD	Dichlorodiphenyldichloroethane
DDE	Dichlorodiphenyldichloroethylene
DDT	Dichlorodiphenyltrichloroethane
DQO	Data Quality Objectives
DQRA	Detailed Quantitative Risk Assessment
DW	Dry weight
HHRA	Human Health Risk Assessment
MDL	Method Detection Limit
PCBs	Polychlorinated Biphenyls
PCDD	Polychlorinated Dibenzo-p-Dioxin
PCDF	Polychlorinated Dibenzo Furan
POP	Persistent Organic Pollutant
PQRA	Preliminary Quantitative Risk Assessment
QA/QC	Quality Assurance/ Quality Control
SCC	Standards Council of Canada
U.S. EPA	United States Environmental Protection Agency
WW	Wet weight (also referred to as fresh weight)

1.0 INTRODUCTION

1.1 Background

Food is a significant vector for contaminant exposure in all populations. In some instances, food ingestion can be a significant pathway of exposure within a risk assessment of a contaminated site, particularly when chemicals have the ability to bioaccumulate in the food chain and when the consumption of non-commercial food such as backyard garden produce and country foods, constitute a significant portion of an exposed person's diet. Country foods are defined as those that may be produced in an agricultural (not for commercial sale) or backyard setting or harvested through hunting, gathering or fishing activities. Agricultural produce, fish, shellfish and livestock that are harvested or grown commercially are regulated under other authorities, including the *Food and Drug Act* and are not a subject of interest of this report.

The harvesting of berries, mushrooms, or other vegetation on a contaminated site, hunting on or near contaminated sites, or the consumption of fish and seafood from water bodies adjacent to and potentially impacted by a contaminated site is known to occur. Whether or not to consider a country food ingestion pathway a risk is not always evident from local land use on and around a contaminated site. Urban residential lands may or may not include backyard gardens. Remote wild lands may or may not be suitable for hunting game or for harvesting plants, fruits or berries. The food ingestion pathway is not typically considered operable for commercial or industrial lands. However, unique exceptions may apply, particularly with respect to off-site transport of contaminants or to trespassers gaining unauthorized access to a property. It is important to note that the presence of legal restrictions on the harvesting and consumption of fish, shellfish and wild game within the area of a contaminated site does not necessarily represent a valid reason for dismissing this exposure pathway. Restrictions may sometimes be the result of known contamination at a site or surrounding areas, but active exploitation of the affected resource by the local population may continue despite the official restriction.

Historically, there has been little guidance available with respect to the sampling and analysis of country foods, such as backyard produce, wild produce such as fruits, berries and mushrooms, and wild game and fish at contaminated sites in Canada. There is only fragmented guidance from the United States Environmental Protection Agency (U.S. EPA) concerning the consumption of such foods. Human health risks related to contaminated sites are typically assessed using a multi-pathway exposure model. Within this model, the consumption of produce, fish, shellfish and game from, or affected by, a contaminated site can potentially represent a significant component of total chemical exposure. The procedures used for assessing risks from this pathway are currently *ad hoc* and inconsistent. Therefore, the provision of guidance on this aspect of contaminated sites risk assessment is considered a priority.

Traditional/country food use by Aboriginals as a percent of total dietary energy was found to vary from a low of 6% in communities close to urban centers, to a high of 40% in more remote areas and this proportion has changed little in the last 40 years (Van Oostdam et al., 2005). More than 250 different species of wildlife, plants and animals were identified in surveys of Aboriginal country food consumption. Regional differences in species consumption are due to ecosystem variety and cultural preferences. There is a large literature base examining country food preferences of Aboriginal communities in Canada and the reader is referred to the CINE (2008) website for further information on publications and databases on Aboriginal consumption of country food.

In Canada, research on self-provisioning or country foods has largely focused on the activities of Aboriginal populations. Until recently, there were only a few case studies of self-provisioning in non-Aboriginal communities. Using a cross-Canada survey, Teitelbaum and Beckley (2006) found that self-provisioning is a culturally embedded activity that is an important component of life for many rural households and was not based on income or employment status. Foraging for wild edibles is a widespread activity, with over half of the 2000 respondents (52%) reporting eating foraged edibles. Consuming food from home gardens was also prevalent (42%), as was the consumption of wild game (44%).

1.2 Purpose

This document provides guidance the sampling design, analysis and estimation of human health risks from country foods at federal contaminated sites in Canada.

Human health risk assessments for federal contaminated sites can generally be divided into two categories based on the level of effort and complexity: 1) Preliminary Quantitative Risk Assessment (PQRA)(HC, 2010a); and, 2) Detailed Quantitative Risk Assessments (DQRA)(HC, 2010b). The distinction made between PQRA and DQRA reflects the level of effort warranted for assessment. The type of risk assessment will, in most cases, greatly influence the scope and available budget to assess the food ingestion pathway.

Although tissue concentration data of consumed food items can increase the certainty associated with human exposure assessment, the collection of these data can require a significant level of effort and cost that is not typically a requirement of a PQRA. In DQRA, such data may be desirable, but circumstances at the site may preclude the collection and analysis of tissue residues (e.g. time of year or cost associated with collection). Therefore, this guidance also

includes information related to the estimation of chemical concentrations in country foods in the absence of site-specific measurements. However, the variance and uncertainty associated with these latter calculation methods may be quite high and the estimates highly conservative (Suter, 2007) relative to direct measurement.

2.0 KEY CONSIDERATIONS OF A COUNTRY FOODS STUDY

Key considerations for assessing risks associated with contaminated food include:

1. When to consider the evaluation of country foods;
2. Developing a conceptual model for country foods evaluation;
3. Developing sampling plans when site-specific tissue residue data are required;
4. Modelling (estimating) tissue concentrations when direct sampling and analysis will not be conducted;
5. Determining appropriate chemicals of potential concern (COPC) concentrations in country foods for use in risk assessment;
6. Determining appropriate ingestion rates of country foods;
7. Estimating exposure to each COPC from the ingestion of country foods; and,
8. Characterizing risks associated with exposure to the COPCs in country foods, including the selection of appropriate toxicological reference values for each COPC.

2.1 When to Consider a Country Foods Study

The country foods ingestion pathway is only considered complete if there is a source of contamination, a receptor (consumer of country foods), and a mechanism (pathway) for the contamination to move from the source into the country foods, and subsequently to the receptor (via ingestion of the food). To assess when it is both beneficial and feasible to pursue the evaluation of a pathway, a series of questions need to be answered during the development of the conceptual model for the site:

1. Does a contaminated site represent a significant source of chemical contamination to potentially harvestable plant or animal species?
2. Is there a transport mechanism for contaminants from the contaminated soil, groundwater, surface water and/or sediment at the site to reach potential harvestable species onsite or offsite?
3. Can the chemicals of potential concern bioaccumulate or bioconcentrate in the edible tissue of harvestable species?
4. Are local plants and animals being harvested, and if so, what tissues are being consumed?
5. What are the consumption patterns and characteristics of the consumers (people), with respect to those harvested plants or animals?

2.2 Developing a Country Foods Ingestion Conceptual Model

A risk assessment of any contaminated site will include a general site conceptual model. This general model will include the determination of whether or not country foods ingestion is an operable exposure pathway. If this pathway is operable, a detailed country foods ingestion conceptual model may also be useful, which will expand specifically on this pathway and will guide any country foods study that is deemed necessary for the site. A narrative should accompany the conceptual model to explain why pathways are complete or incomplete, and explain other issues such as species and tissues commonly consumed, cooking preparation, seasonal consumption patterns, etc.

The conceptual model for country foods exposure identifies contaminants of potential concern (COPC), receptors that may be affected either at a site or off-site, the types of foods (e.g., produce, game, fish) that may be affected by the COPC, and the routes by which these foods are affected (e.g., uptake from soils, atmospheric deposition, irrigation water, etc.). This pathway-specific conceptual model is a sub-component of the overall conceptual model for the site.

The foods that are identified in this conceptual model should include those plants and organisms that are consumed by people and that may be affected by the COPC at a site. These include plants in direct contact with contaminated soil, animals and other organisms that consume the plants and incidentally ingest contaminated soil, secondary and tertiary consumers that may be affected through food chain transfer, and the biota that can be affected by contaminated sediment (plants, invertebrates and fish). In addition, some sites may contain vegetation used as medicinal plants and herbs that are used by First Nations or local communities.

3.0 SAMPLING CONSIDERATIONS FOR COUNTRY FOODS

Collecting tissue samples is preferred to modelling because accumulation coefficients (from air, water, sediment or soil into specific foods or food organisms) from various models and literature sources can vary by orders of magnitude compared to actual measurements. This is due in part to site-specific factors such as soil characteristics, bioavailability and bioaccessibility, and the source and form of the COPC. In some cases, the sampling of tissues already harvested by a local community or accompanying local hunters and fishers may be necessary due to logistical or other constraints (e.g., season, or sampling large sea mammals). However, potential difficulties, and hence larger uncertainties, may arise with sampling tissues previously harvested by a local community. These include the inability to accurately determine harvesting patterns (e.g., location or time-of-year of harvesting) or food processing variables (e.g., length of time frozen) because of a lack of documentation of previously harvested material.

Tissue sample collection should reflect local methods of collection, preparation and consumption. Particular attention should be paid to the potential consumption of fatty tissues, since these are often the sites of accumulation of persistent organic compounds.

3.1 Sampling Design

Sampling should focus on those species that are consumed locally and are most likely to be exposed to a source of contamination. As such, it is necessary to understand the sources, distribution and transport of contaminants, the migratory habits of the species (relating to the frequency and duration of species exposure to COPCs arising specifically from the site in question), and the local consumption patterns before a sampling plan can be developed.

3.1.1 Spatial and Temporal Considerations

Sampling should take place where there is contamination, either on-site or off-site, if relevant, and in appropriate habitat for the harvested species. Samples should be taken from locations that are used as harvesting locations, and from locations with high contaminant concentrations (in soil, sediment, etc). The incorporation of spatial components into sampling design should include sampling along transects through gradients of contamination, or sampling areas with distinct levels of contamination. A fully- random sampling design is ideal, but budget, access, species migration patterns and seasonal factors may preclude this option (as many samples would be required).

Every reasonable attempt should be made to ensure that the sampling collects tissue residue concentrations that represent the range of levels attributable to the site, including the reasonable maximum concentration. In doing so, the conservative nature of the human health risk assessment is maintained and there is a high degree of certainty that risks will not be under-estimated or overlooked.

Spatial considerations differ among species. For example, tissue burdens in highly mobile wildlife represent the accumulated contaminant concentrations for their entire foraging or hunting range and not necessarily solely from the location from where animals were collected. In contrast, contaminant concentrations in plants will reflect contaminant levels at their sampling location. For sedentary species such as shellfish or small mammals with a small foraging range, sampling locations should focus, where possible, on those areas that are within or immediately adjacent to environmental media characterised as having the highest contaminant concentrations. Samples from less contaminated areas within the site are also of value in terms of correlating the soil or sediment concentrations with tissue concentrations, but the worst-case samples and nearby areas which are harvested is the priority.

As with the choice of sampling locations, the sampling time should be chosen, when possible, to coincide with harvesting patterns, but also to provide a worst-case tissue residue concentration within the expected human harvesting cycle. Thus fish, shellfish and wild game samples should be collected when it is reasonable for people to be harvesting them, but also when tissue residue concentrations are expected to be maximized with respect to species exposure to the on-site contaminant source.

3.1.2 Sample Number

Consideration should be given to the design of the sampling program, the numbers of samples to be collected and the statistical interpretation of data, particularly when dealing with large or complex sites. More samples will be required where measured parameters are anticipated to be subject to a high degree of uncertainty or variability.

The number of samples from background or reference sites should, at a minimum, equal the number of samples collected at a contaminated site. In some cases, literature reference values may be available for use as background or reference values.

For a relatively simple risk assessment, it is recommended that a minimum of 5 to 10 tissue samples be taken for each specie and tissue of interest. This number of samples provides a reasonable estimate when there is one area or one source of contamination within a site. When there are multiple areas or sources of concern, a minimum of 5 to 10 tissue samples

should be collected for each subject area. The maximum impacted area and area most likely to be frequented for the harvesting of an identified food species should be identified. Co-located samples of soil or sediment may be of use for risk management considerations.

For a more detailed risk assessment or when a location is unlikely to be revisited for additional sampling, the minimum recommended sample size is 20 for fish and shellfish. This value is recommended for use within the Metal Mining EEM Guidance document (Environment Canada, 2002) and is supported by empirical data (Munkittrick, 1992).

It should be noted that the collection of 5, 10 or 20 samples of large mammalian species may be impractical or impossible due to limited population size and migratory patterns for a given contaminated site. Legal restrictions on the number of animals harvested (e.g., regulatory limits to harvesting) must also be considered. It may be advantageous to coordinate sample collection with local hunters who could provide samples for analysis.

Tissue samples must not be composited to provide a single average residue value for a site. An important result of the residue analysis is a measure of the variability associated with the contaminant concentrations in the tissues. Not only does this provide a means of estimating a limit of confidence on the central tendency measure of concentration for use in the human health exposure assessment, but it also allows for meaningful comparisons of site residue data to similar residue data from a reference site or from published literature.

In situations where management decisions may be required, such as determining whether closure of a particular fishery should be considered, particular attention should be paid to the number of samples collected and the statistical degree to which they represent the harvestable resource (fish, etc) and the potential exposure to COPCs presented to an impacted community. In these situations, the statistical analysis will be critical to defining the variability in contaminant concentrations in country foods and tissues, which will subsequently influence the variability in potential exposures of persons consuming those country foods and tissues. Where high variability is evident in the country food residue concentration dataset, a larger number of samples may be required to achieve an acceptable level of confidence in the data, and the management decisions made from those data.

3.2 Tissue Sample Considerations

Harvested species may contain contaminants within their tissues, and, plants may also have external contamination in the form of soil or dust adhering to their surfaces. Tissue sample collection should reflect local methods of collection, preparation and consumption.

Fruits or vegetables are generally harvested for consumption when ripe or nearly ripe, and therefore produce should be sampled as it approaches maturity. The collection and preparation of samples should closely mimic 'as consumed' produce. For example, root vegetables may be consumed with the peel on or peel off. Therefore, in some risk assessments, it may be appropriate to submit both "peeled" and "unpeeled" samples of roots and tubers. This information may be utilized later in risk management; for example, "peeled" carrots may be acceptable for consumption, but due to soil adsorption, "unpeeled" carrots may not be recommended.

Produce and vegetation samples should be collected with co-located soil samples taken from the root zone. Detection limits sufficiently sensitive to enable comparison with agricultural land use guidelines/standards should be requested from the laboratory undertaking the analysis. The soil should be collected from the rhizosphere (root zone) of sampled plants, which is typically 0.15 to 0.30 m below ground surface for tilled soil and garden produce. However, for fruit trees and other woody plants and shrubs that may provide country foods, root depth is greater and soil should be collected up to 1.0 m below ground surface. Similarly, sediment samples may be taken with samples of sedentary seafood to enable risk management considerations.

The harvesting of target game species may be influenced by the gender, age/maturity and size of individuals. Local preferences may exist, or there may be legislative control of the sex, age or size of animals harvested. Examples include limiting hunters to the collection of male turkeys and size limits for certain sport fish species. Local fisheries and wildlife managers should be contacted to confirm the gender, age and size of target species that are typically retained for consumption. Sample collection should reflect these patterns so that tissue samples reflect local use.

Contaminant accumulation can vary with gender, age and size of individual harvested organisms. For example, mercury concentrations in fish tissues tend to increase over the life of the fish, as accumulation outpaces depuration (Porcella, 1994). Where possible, the species, gender, age, date of collection, location, and type of tissue should be established and recorded for each sample.

Food is most often consumed in a processed form after a preservation treatment and/or cooking that can potentially alter the concentration and chemical form of a contaminant from that in raw food. Devesa et al. (2008) found significant changes in the concentration and speciation of arsenic following various preparation and cooking techniques. A significant factor in estimating human intake of polychlorinated biphenyls (PCBs) from fish consumption is the loss of PCBs during cooking. It has long been known that the total amount of PCBs and DDT actually consumed in cooked fish may be significantly lower than the levels present before cooking

because lipids (and lipophilic compounds like dioxins) tend to be removed from the fish during cooking (Sherer and Price, 1993; Wilson et al., 1998; Bayen et al., 2005). When animals are sacrificed prior to tissue sample collection, it is essential that methods be employed that will not affect the concentration of contaminants. Either physical or chemical methods may be used. If chemical methods are used, it is necessary to ensure that the chemical does not interfere with tissue chemical analysis. Gullet (1987) provides methods for birds that are applicable to mammals and provides pertinent factors to consider when choosing an appropriate technique.

3.2.1 Species Identification

A fundamental consideration in preparation for sampling is the confirmation of the identity of the target species. Common names of species and their life stages may cause confusion as they can vary amongst regions and cultures and may refer to more than one species. Therefore, confirmation of scientific species names is recommended. In cases where a number of closely related or similar species are locally identified by a common name, additional information may be warranted if collection and consumption patterns vary between these related species. An experienced biologist should lead the sample collection.

It will also be necessary to consult with fisheries or wildlife management agency personnel, fishermen, hunters or the local community to confirm which species are harvested and the types of tissues harvested and the frequency of their consumption. Taxonomic keys are available for plants, fish, invertebrates and other harvested organisms, from academic sources or, in some cases, government agencies. Local wildlife researchers or natural museum staff can indicate those references and resources that will be most useful for species identification. The use of field guides published for use by the general public is discouraged, as they typically cover too broad a geographic region, are intended more for nature appreciation than strict taxonomic identification and are often out of date in terms of scientific names, distributions and other pertinent information. Identification of game birds and mammals is usually more straightforward and may not require detailed keys; however field staff must be able to distinguish their target species from amongst similar local species.

3.2.2 Sample Collection Methodology

The choice of suitable collection methods will depend on the target species, habitat, season, legal and safety requirements and the need to collect specific tissue samples in good condition for analysis. Detailed discussion of collection methods is beyond the scope of this guidance document. The reader is referred to texts on ecological risk assessment (e.g., Suter et al., 2000; Suter, 2007); researchers at the Canadian Wildlife Service of Environment Canada, Parks Canada or Fisheries and Oceans Canada; local provincial fisheries or wildlife management personnel; and published scientific literature, particularly those studies that will be used as a source of background concentrations.

The collection of plant material for residue analysis is a relatively simple procedure and discrete parts of a plant need to be sampled separately as appropriate (roots, foliage, seeds, fruit, etc.). Guidance on the sampling of vegetation is provided in the "Standard Guide for Sampling Terrestrial and Wetlands Vegetation" (ASTM, 2008). This guide is specific to wetlands vegetation; however, many of the principles are applicable to other vegetation. For a description of sampling methods for berries, see Hale (2004).

Target species such as waterfowl may only be seasonally associated with a site if they migrate. In addition, the seasonal collection of these species for food may be based on seasonal differences in susceptibility to capture or the presence of desirable life stages or size classes. The choice of capture technique should match site conditions, which should be determined prior to application for a collection permit and mobilization of the field crew. Some species and certain site conditions demand specialized equipment and experienced local knowledge in order to safely and effectively obtain samples.

Site access, local customs and legally-enforced fishing, hunting or collecting seasons may also influence the collection of target species at a site. Consultation with local fisheries or wildlife management personnel can confirm these details. The sampling of fish from commercial or recreational catches should be conducted with a member of the study team accompanying the fishers to ensure that fish are collected from areas relevant to the project.

3.2.3 Analytical Considerations for Sample Testing

Prior to the initiation of food sample collection, the analytical laboratory being considered for testing should be contacted to verify that it is qualified to conduct the required analysis. Considerations include whether:

- The laboratory is accredited for the chemical(s) and media of concern, and has Standards Council of Canada (SCC) or Canadian Association for Environmental Analytical Laboratories (CAEAL) accreditation.
- The laboratory can meet detection limits for each COPC, as determined by the risk assessor prior to sampling. Detection limits should be less than CCME or other tissue guidelines for the contaminant and species of interest, less than relevant food contaminant guidelines published in the Canadian *Food and Drugs Act* and regulations, and/or less than risk-based or background concentrations for the species and tissues of interest based on a review of published literature.

- The laboratory should be capable of establishing the minimum tissue sample size required for each analyte. (Although discouraged, in some situations it may be necessary to composite the edible tissues of several organisms to satisfy analytical requirements for minimum tissue sample size. If necessary, this should be restricted to samples collected in the same area and season and the samples should be similar in terms of size, age, sex, breeding status, etc. to minimize the potential for contaminant dilution or masking within-sample variability. Environmental media samples (e.g., soil, sediment) co-located with food samples should not be composited).
- The laboratory uses an acceptable methodology for sample digestion, extraction and analysis.
- The laboratory provides advice on sample preparation and suitable tools, containers and preservatives for each COPC. The Laboratory provides information on optimal holding times for tissues and proper handling for shipping of samples to the laboratory.
- The laboratory is aware of any requirements for determining moisture or lipid content or for reporting concentrations on a dry weight versus wet weight basis in tissues.

In addition, the project manager should also verify that appropriate laboratory Quality Assurance/Quality Control (QA/QC) procedures are in place, and discuss requirements for field QA/QC. The laboratory should be contacted in advance to assess if it has adequate sample storage if a large number of samples will be collected.

3.2.4 Chemical Speciation and Metabolic Products

For PQRA or simple DQRA, it is usually assumed that a substance is present in its most toxic form. However, in a complex DQRA, risks may be estimated for the ingestion of foods with elevated concentrations of COPCs that have several chemical forms, potentially exhibiting a range in toxicity (as is the case for arsenic, chromium and mercury). In some cases, a particular chemical may be more prevalent in some food sources than others (Borak and Hosgood, 2007; Schoof and Yager, 2007), which may or may not be the same as the chemical species found in other media or biota at the site. In addition, cooking and food preparatory methods may change the proportion of chemical species from the raw form (Devesa et al., 2008; Bayen et al., 2005). The risk assessor should identify these issues in the design stage of the risk assessment to ensure that the samples submitted to the testing laboratory are prepared for consumption in the same manner as practiced by the affected community, and analyzed for the appropriate chemical species.

Chemicals, particularly organic chemicals, are frequently metabolized in biota and therefore, a parent COPC may not be detected in analyzed samples. However, when these substances are metabolized into another toxic moiety which may bioaccumulate in biota, the metabolites may still pose a human health risk. Therefore, it is important to understand the toxicokinetics of COPCs in biota in order to ensure that potentially toxic metabolites are addressed when appropriate. For example, the absorbed dose of DDT is often converted to DDE and DDD after ingestion by animals (WHO, 2000); therefore, if DDT is present at a site, then DDE and DDD should also be analyzed in the country foods, regardless of whether DDE is found in other media at the site.

The chemical contaminant analysis of organics will be dependent on a dedicated chemical analysis laboratory, preferably with high resolution mass spectrometry capabilities. For example, analytical methods should be adequate to generate congener-specific data for coplanar ("dioxin-like") PCBs, PCDDs and PCDFs. Aroclor-based estimates of total PCB concentrations and low-resolution congener-specific approaches to PCB analysis will provide only a limited capacity to evaluate potential human health risks.

3.3 Field Sampling

3.3.1 Collection Permits

In all cases where fish, shellfish or game species are to be sampled, formal permission must be obtained from the relevant government agencies. Scientific collection permits must be sought well in advance of the desired collection period to allow for review by agency personnel and potential discussion of alternate techniques or timings to accommodate conservation concerns. For example, electro-fishing may not be permitted at a site during the spawning period of a non-target fish species, or collection methods may be altered to reduce potential impacts on rare, threatened or endangered species. The target species will determine which agencies must be contacted for the appropriate permits. However, the following statements can be used as a general guide:

- Freshwater fish and shellfish are typically managed by provincial agencies with the exception of water bodies within national parks, which are managed by Parks Canada;
- Marine fish, anadromous fish and marine shellfish are under the jurisdiction of Fisheries and Oceans Canada;
- Resident gamebirds and terrestrial mammals are managed provincially;
- Rare and endangered plants are managed provincially;
- Migratory birds are the responsibility of the Canadian Wildlife Service; and,
- Marine mammals fall under the federal *Fisheries Act* and are therefore managed by Fisheries and Oceans Canada.

There may be other permitting requirements, such as those for scientific collections in ecological reserves or national parks, collections that may affect species at risk. Such cases should

be addressed early in the agency consultation process. It is essential that the proposed sample collection activities are documented and described adequately to support agency review and screening for additional permit requirements such as special training, seasonal constraints or limitations on gear. The following information should generally be sufficient to begin permit discussions:

- Purpose of the study/collections;
- Project manager contact information;
- Target species, with some selection rationale;
- Location of sampling sites/areas, including reference sites/areas;
- Collection period;
- Collection methods;
- Number of individual organisms required; and,
- Names of personnel who will undertake the collections.

The possession and transport of collected whole organisms or tissue samples may also be subject to additional permits. This is particularly important if the samples will be transferred to an analytical laboratory outside of the province or territory in which they were collected. Possession and transport permits may include special requirements for handling, packaging and labelling of samples.

Post-collection responsibilities typically include the submission of data, usually in a specified report format. These requirements are documented and can be confirmed with a permitting agency to ensure that appropriate data are collected in the field to meet their report standards.

3.3.2 Site Access or Collection Restrictions

Collections within parks and ecological reserves may be prohibited or require special permission or additional formal permits. The study team should also be aware that special permission may be required to undertake collections on First Nations lands or lands subject to land claims. Scientific collection permits do not grant access to private property; potential study area access restrictions must be assessed and permission arranged prior to initiation of a collection. Land ownership within a proposed study area can be confirmed with the local municipality or other planning jurisdiction, and the landowners should then be contacted to seek access. Local fisheries or wildlife agency staff may be valuable allies in these discussions, as they can speak to local concerns and are recognized authorities within their communities.

3.3.3 Field Sample Sheets

The objectives of a sampling program should be clearly outlined and field staff should be adequately trained. Field sample sheets should be prepared in advance to promote consistency in field recording and reporting. Opportunity to record ancillary observations should also be provided to allow some quantitative and qualitative data to be collected that can be used to explain trends and/or data outliers. Field staff should be able to identify major soil characteristics (soil type, moisture, colour), and different plant and animal parts and characteristics since only certain species/parts may need to be collected for analysis. In addition, it is recommended that the same field personnel collect all of the samples, or if several teams are required, adequate training should be provided to minimize variation in sampling techniques and recording.

3.3.4 Sample Preparation

Any dissections of the whole organism in order to obtain samples of specific tissues should be performed on a clean, dry surface free of soils and/or sediments from the contaminated areas. Any instruments used should be rinsed with an appropriate solvent between dissections in order to minimize cross-contamination. Special considerations for sample handling may apply, depending on the site, the tissues collected and the COPCs. For instance, if nickel is of concern at a site, in order to minimize contamination of a sample, instruments made of stainless steel, an alloy containing nickel, should not be used. Plastic tools are suggested for use in this instance. Similarly, plastic instruments should not be used when collecting tissues for organic contaminant analyses. Split samples from at least 5% of the replicates should be prepared and submitted for duplicate analyses.

3.3.5 Sample Labelling

All tissue samples should be appropriately labelled with the date of collection, sample location, tissue type and a unique reference number.

3.3.6 Sample Containers and Preservatives

As with tissue collection, appropriate sample containers and cleaning solvents should be used that minimize cross-contamination of the tissues collected and the contaminants of interest. The testing laboratory can provide a list of recommended preservation techniques and holding times to guide project managers and clients in making correct choices for particular samples. Typically, all samples submitted to the testing laboratory should be kept at 4°C until the time of analysis and be analyzed within the maximum holding time. The sample handling may depend on the nature of the COPC to be analyzed and should be confirmed with the testing laboratory prior to initiation of a field program.

3.3.7 Chain of Custody

It is necessary for each sample or group of samples to be accompanied by a chain-of-custody record from the time of

sampling in order to trace possession. The record will contain the following information:

- Client name;
- Project name or sampling address;
- Sample ID;
- Date and time of collection;
- Size of sample containers;
- Analysis required;
- Storage requirements for samples (e.g., temperature);
- Signature of all individuals involved in the chain of possession; and,
- Inclusive dates of possession.

3.3.8 Sample Hold Time

Good-quality data requires that analyses be performed within specified holding times. The assay laboratory must complete analysis within the specified times or must notify the project manager of any expired holding times prior to proceeding with analysis.

3.4 Quality Assurance and Quality Control

Quality control (QC) samples should be collected and analyzed whenever the precision and/or bias of the sampling and analysis process must be determined. The collection and analysis of appropriate QC samples, as part of a Quality Assurance (QA) program, can help ensure that the quality of the data collected is known, and that it meets a project's data quality objectives. To establish the data quality objectives, the degree of certainty that is required must first be determined. Quality Assurance consists of those activities that assure that a defined standard of data quality with a stated level of confidence is met.

A project's data quality objectives (DQO) should be defined at the outset of the project to establish acceptable levels of data precision, bias, representativeness, completeness, comparability and detection limits. Quality assurance procedures, including the collection of field QC samples and their required frequencies, should be established in order to monitor whether the DQOs are being met. Quality control results should be reviewed and interpreted on an on-going basis and the QA procedures modified as necessary. At project completion, an evaluation of the project data quality should be presented in a report.

3.4.1 Field Quality Assurance and Quality Control

Field quality control samples indicate the precision (random variation) and bias (systematic error) associated with field sampling. The types of samples that may be collected and analyzed to quantify the data precision or bias include:

- Field duplicate – a split of the same sample that measures sampling precision;
- Field replicate – repeat sampling from the same location also measures sampling precision; and,
- Blank samples - indicate whether samples have been contaminated during the sampling, shipping or analysis stages. Types of blanks include trip, field, reagent and equipment:
  - Trip blank: used to detect cross-contamination between samples during transport of the sample containers to the site and back to the laboratory;
  - Field blank: used primarily to detect contamination present in the sampling environment (e.g., air). In general, a field blank should be collected during each day of sampling;
  - Reagent blank: analyzed to detect any background contamination present in de-ionized water or distilled water used during sampling (e.g., rinsing equipment); and,
  - Equipment blank: analyzed to detect any contamination associated with sampling equipment.

Samples should be labelled and a field card should be completed for each sample. Samples prepared in the field should be stored at an appropriate temperature, as determined by the testing laboratory (e.g. on ice in a cooler) and submitted to the testing laboratory within acceptable holding times (defined for each COPC with the testing laboratory during the scoping process). The wearing of gloves, proper decontamination and other QA/QC procedures should be respected and documented.

3.4.2 Laboratory Quality Assurance and Quality Control

Laboratory QA/QC samples indicate the precision (random variation) and bias (systematic error) associated with laboratory analysis. The types of samples that may be analyzed to quantify the data precision and bias are as follows:

- Laboratory duplicates, which are splits of the same sample, taken in the laboratory and used to measure precision of the analytical method used;
- Spiked samples, which are samples to which a known quantity of a substance has been added. The sample is run on the analytical instrument to assess instrument bias and to determine whether the sample matrix has an influence on the quality of the result; and
- Reference standards, which are samples prepared by a laboratory or an outside body and contain specified concentrations of chemicals with a specified margin of error. The reference standards are used to calibrate analytical instruments.

3.5 Background/Reference Samples

The overall goal of collecting background or reference samples is to distinguish site-related contamination from naturally occurring or non-site related concentrations of chemicals. There are two types of 'background' levels of chemicals (U.S. EPA, 1989):

1. Naturally occurring concentrations of chemicals in the absence of influences from humans or anthropogenic activities (i.e., representing pristine conditions); and,
2. Concentrations of chemicals that are locally ubiquitous due to geologic sources (common in regions of mining activity, for example), atmospheric transport and other non-point sources of chemicals released to the environment from human activity.

For PQRA or simple DQRA, scientific literature sources may provide data on representative, non-anthropogenic contaminant levels in wild vegetation, fish, shellfish or game in Canada. These sources may be adequate to provide reference or typical COPC levels in biota and/or comparable tissues from regions unaffected by the contaminated site. However, for the risk assessment of a complex site, site-specific background samples may be advantageous.

Reference vegetation samples should be collected from a background area adjacent to a site that is outside of the zone of influence of contamination. Ideally, the reference location should have similar soil type (grain size, organic matter content etc.) and samples from both the reference site and the site of interest should be collected at the same time (during the same sampling programme). The species collected and analyzed should be the same as from the potentially contaminated site.

For fish and game, reference sites should be sufficiently distant to ensure that foraging and home ranges are unlikely to include the contaminated site. For larger species, particularly ungulates and sea mammals, this may be more problematic and must be considered on a case-by-case basis. In addition, every effort should be made to choose reference or background locations that have similar characteristics, in terms of ecological habitat, geography and geology to the contaminated site. Ideally, the only significant difference between the reference location and the contaminated site should be the contaminant concentration in the environment.

3.5.1 Arctic and Subarctic Regions

A large body of published and unpublished information is now available on contaminants in Canadian arctic biota, human exposure to contaminants, and the human health implications of these contaminants (Muir et al., 2005a; NCP, 2003).

Measurements of persistent organic pollutants (POPs) and heavy metals in the Canadian Arctic began in the early 1970s with measurements of PCBs and DDT in seals and polar bears and mercury in fish and marine mammals. At that time, the presence of these contaminants was viewed largely as background information for studies nearer source regions (Muir et al., 2005b). In the late 1980s, the observation that Inuit people in northern Quebec, consuming traditional diets which included marine mammals, had higher PCBs and mercury than residents of southern Canada (Dewailly et al., 1989; Kinloch et al., 1992) stimulated a major expansion of contaminant measurements since the early 1990s under the Northern Contaminants Program (NCP) managed by Indian and Northern Affairs Canada. Approximately 100 "legacy" persistent organochlorines (OCs) (including PCBs, DDTs, chlordanes, dieldrin, hexachlorocyclohexanes (HCHs) and chlorobenzenes (ClBz)) have been measured in most studies funded under NCP. Several major studies have also focused on inorganic mercury, selenium and methyl mercury. A few studies have measured up to 25 elements including arsenic, cadmium and lead.

3.6 Health and Safety

In addition to health and safety concerns posed by collection methods and study area environmental conditions, the collection and processing of wild organisms may also pose specific health risks to field and laboratory staff. Shellfish may accumulate harmful bacteria and toxins; *Salmonella* is present in turtles and other animals; and mammalian game animals may be carriers of diseases that can be transmitted to humans such as rabies, leptospirosis, brucellosis and tuberculosis. Workers may also come into contact with external parasites while in the field or handling animals and could be exposed to Lyme disease or other pathogens.

Consultation with local fisheries and wildlife managers and public health officials can identify likely disease hazards for a geographic area of the study and target species, as well as appropriate precautions. These issues may also be relevant for non-target species if they are likely to come into contact with collection gear or require handling to be released from traps.

Protective measures will be specific to the species, collection methods and tissues required, but will generally include the cleaning and disinfecting of gear, tools, clothing and the work area. In addition, the use of personal protective equipment such as gloves, goggles, face shields, masks, and disposable clothing may be required to limit the potential for contact with and accidental ingestion or inhalation of contaminated blood, urine, feces or body fluids. Specific requirements must be determined for each project prior to the collection of samples.

4.0 MODELLING TISSUE CONCENTRATIONS

For various reasons, it is not always possible or warranted to collect site-specific tissue data at a contaminated site (e.g., limited project scope, cost, out-of season, remote site, etc.). In such cases, it might be necessary to predict the concentration of COPCs in country food using mathematical modelling. A risk assessor would typically conduct modelling if site-specific tissue concentrations were not readily available and/or a PQRA or simple DQRA is being conducted where only soil and groundwater samples were collected previously. Modelling of COPC uptake into tissue is generally conservative and may overestimate concentrations of COPC by orders of magnitude. However, in the absence of tissue data, modelling can be used in an initial risk assessment to provide a conservative estimate of risk. If modelling results suggest a potentially significant risk associated with estimated concentrations of COPC in tissue, it is recommended that sampling of tissue be conducted to confirm and/or replace modelled results.

Since the accumulation of COPC in plants and animals depends on a number of factors, such as the physico-chemical characteristics of a substance, the behaviour and metabolism of an organism, the form in which a chemical is consumed, and the detoxifying mechanisms of an organism, all of which can vary among species and sites, it is rarely possible to get numerically-accurate estimates without site-specific investigation. However, the risk assessor should undertake a thorough search of the scientific literature to determine if information of such factors exists on the species/contaminant of interest.

All models are simplifications of natural systems or processes and thus suffer from limitations. The simplest models provide indications of the potential pathways and, generally, rough estimates of accumulation, usually combining the contributions from a number of exposure pathways and accumulation mechanisms into a single numerical estimate. As the models increase in sophistication, it is possible to begin to account for contributions from specific sources and pathways, and these include many of the mass balance models that have been developed. Those that also incorporate physiological and/or biochemical pathways and processes typically have the greatest success in approximating measured outcomes, but these are also the most difficult to populate with meaningful data. For more complex models, a greater number of input parameters (often as assumed or default values) are required to run the model. Increased complexity does not always equate to increased accuracy or validity of tissue residue level predictions.

Models can provide an initial indication as to whether the bioaccumulation of a chemical could be a concern, but actual data from the site may be needed to permit calibration of the models. The complexity of the modelling employed should be consistent with the overall complexity of the risk assessment. Simple models are adequate for simple risk assessments (such as PQRA); complex methods are appropriate for DQRA, particularly since complex models often require numerous site-specific variables. The need for additional validation will often depend on the outcome of the initial modelling. In cases where conservative models estimate that risks are low or negligible, there may be little need or value for undertaking field validation. Alternatively, marginal or significant estimates of risk may need verification through additional field sampling to determine whether potential risks identified by the modelling are accurate.

All uncertainties and data gaps associated with uptake modelling should be noted in the report, along with their implications to the results of the risk assessment. The factors and other relationships established between contaminant concentrations in the environment and those in the tissues of fish, shellfish and wild game tend to be associated with a high degree of variability and uncertainty. To compensate for this, models are significantly biased towards maximising the estimates of tissue residue levels. Sample et al. (1998) collated data used to derive the bioaccumulation constants for the uptake of lead by a variety of mammalian species. For any given concentration of lead in soil, the concentration in a mammal varies over 1 or 2 orders of magnitude. This range can have a considerable effect on the estimate of potential human exposure and subsequent predicted risks associated with the consumption of mammals.

It is also important to note that many uptake models typically provide an estimate of whole- animal residue levels and not the tissue-specific residue levels for muscle or organ meat. The whole body residue may over-estimate or under-estimate the actual contaminant residue levels in the specific tissue of interest. This uncertainty is difficult to quantify and further decreases the ability to strongly rely on whole-organism residue level estimates as a surrogate for tissue-specific levels within the context of the human health exposure assessment. As mentioned earlier, various processing, preparation and cooking methods can alter contaminant concentration and such considerations are not incorporated in any current models.

Detailed discussion of uptake models is beyond the scope of this guidance. U.S. EPA (2003), Suter (2007) and Suter et al. (2000) and references therein provide extensive discussion for uptake models of biota. The risk assessor is also encouraged to undertake literature search for more recent information on the species of interest and to determine if any regional or site-specific uptake models have been published. Suter et al. (2000) provides data or equations for estimating ingestion of water, soil and foods and inhalation rates for wildlife species. Note that any modelling conducted for a federal human health risk assessment should be discussed with Health Canada representatives in advance of a risk assessment.

In summary, there are three major disadvantages in using uptake models, which can have a potentially major source of uncertainty and conservatism in estimates of concentrations in country foods:

1. The factors that affect the accumulation of contaminants from media (i.e., pH, total organic carbon, temperature, etc) to biota are often unknown. If such factors are known, they may be difficult to integrate in the models.
2. Frequently, little is known about the bioaccumulation of contaminants on a tissue-specific level for many plant and animals and therefore modelling is not tissue-specific.
3. Changes in the concentrations of contaminants or the proportion of chemical species or forms can be greatly affected by food preparation and cooking and such factors are not accommodated in the models.

4.1 Types of Uptake Models

Models available for use can generally be classified into three main categories: (1) uptake factors, (2) empirical regression models, and (3) mechanistic bioaccumulation models. Typically, the use of uptake factors is common for plants and aquatic animals, while the use of mechanistic bioaccumulation models is restricted to terrestrial animals. Non-linear model equations are less commonly used but have been applied for both plants and animals. An overview of each of the model type categories is presented in the following sub-sections and is based on Suter (2007).

4.1.1 Uptake factors

Uptake factors are quotients of ratios of chemical concentrations in biota to concentrations in associated abiotic media. Uptake factors are also referred to as transfer coefficients, or particularly in aquatic studies, as bioconcentration factors (BCFs). In aquatic systems, uptake factors from studies that include exposure through food are called bioaccumulation factors (BAFs). Uptake factors from soil or sediment are often referred to as biota sediment/soil accumulation factors. Multiplication of an uptake factor by the chemical concentration in an abiotic medium produces an estimate of chemical concentrations in a tissue or organism. While uptake factors may be simple to use, variance and associated uncertainty in the estimates may be quite high.

Uptake factors are calculated as:

(4.1)

$$UP = C_B / C_M$$

Where:

UP = uptake factor
C_B = concentration in biota (mg/kg)
C_M = concentration in contaminated media (mg/kg or mg/L)

An implicit assumption in the use of uptake factors is that uptake is a simple linear function of media concentrations with an intercept of zero. However, uptake is usually nonlinear with respect to soil concentration for inorganic elements (Alsop et al., 1996; Sample et al., 1998; Efroymson et al., 2001a, b). Consequently, the use of uptake factors at highly contaminated sites may grossly overestimate actual concentrations in biota. In addition, uptake models assume that soil properties do not significantly affect uptake, which is generally not the case.

4.1.2 Non-linear Model Equations

Empirical regression models are derived using concentrations in biota and abiotic media from contaminated sites. Generally, regression models are preferable to simple uptake factors. Physical and chemical parameters known to influence bioavailability and the uptake of contaminants from media, such as pH, cation exchange capacity, and organic matter content, can be included in multiple regression models. Consequently, regression models may explain more of the variability of the data and are likely to result in improved estimates of tissue concentrations by permitting more site-specific information to be included. Regression models can also address thresholds and nonlinearities in bioaccumulation. Because of saturation kinetics or equivalent processes, the rate of accumulation typically decreases at higher concentrations of contaminants. Uptake is usually modeled by fitting a power function:

(4.2)

$$C_B = a(C_M)^B$$

where a and B are fitted parameters.

While nonlinear regression methods may be used to fit these models to bioaccumulation data, it is easier to log-transform the data and then conduct simple linear regression analyses. Regression models based on log-transformed data, while linear in log-space, are nonlinear in untransformed space. The regression model for transformed data may be expressed as:

(4.3)

$$\text{Log}(C_B) = a + B(\log C_M)$$

4.1.3 Mechanistic (or Toxicokinetic) Models

Toxicokinetic modeling has a number of potential advantages. It can represent situations in which an environment or an organism is changing (e.g., variable emissions or an organism moving among areas of differing contamination).

When differences in sensitivity of species and life stages are due to differences in kinetics, toxicokinetic models can substitute for toxicological extrapolation (i.e., dose–response) models.

When organisms take up a contaminant from one medium, such as water, the basic first order toxicokinetic model is:

(4.4)

$$d\ C_B dt = k_u\ C_M\ -\ k_e C_B$$

where k_u and k_e are the uptake and elimination rate constants. At equilibrium, k_u equals kp, the derivative is zero, the concentrations are constant, and static uptake factors or regression models apply. This first-order model has been used to assess risks based on critical body residues and other toxicodynamics (Kooijman, 1981; McCarty and Mackay, 1993; Legierse et al., 1999; French-McCay, 2002).

If organisms are assumed to be exposed to two media such as the solid and aqueous phases of sediments or soils, the first-order kinetic model is:

(4.5)

$$dC_B dt = (k_{u1}\ C_{M1}\ -\ k_{u2}\ C_{M2})\ -\ k_e C_B$$

Toxicokinetic modeling can elaborate in a number of directions, depending on the needs of an assessment and their practicality given available information (Reddy et al., 2005). The rate constants might be treated as variable functions of environmental characteristics (e.g., temperature), organism characteristics (e.g., size and lipid content), or characteristics of the chemical of concern (e.g., solubility). The media concentrations may be dynamic. Higher-order kinetics may be employed, and multiple compartments may be added to the environment or the organism.

So far, toxicokinetic modeling has shown more promise than utility in risk assessment. This is partly because static, equilibrium assumptions have been sufficient in risk assessments. Also, there is a paucity of information concerning kinetics, both basic knowledge of processes and specific knowledge of rates and compartment characteristics. Finally, nearly all toxicity data are expressed as external exposure concentrations or administered doses rather than internal concentrations.

5.0 REPRESENTING COPC CONCENTRATIONS IN COUNTRY FOODS RISK ASSESSMENTS

5.1 Wet (Fresh) Weight versus Dry Weight

It is important that the concentration data and the food intake rate data reflect the same tissue weight basis. Laboratory analytical results are typically reported on a dry weight basis (ug of contaminant/g dry weight of the food item). However, consumption rates of various foods provided by Richardson (1997) and other sources are reported on a wet weight basis (also referred to as fresh weight or 'as consumed'; grams of food wet weight consumed per day). If analytical data have not been requested on a wet weight basis and are reported by the laboratory as ug of contaminant/g dry weight of a food item, they will need to be converted from dry weight to wet weight according to the following formula (5.1).

In the absence of sample-specific moisture content data, default values are available in the U.S. EPA *Exposure Factors Handbook* for a variety of fruits and vegetables (U.S. EPA, 1997).

5.2 Lipid Weight versus Whole Weight

For lipophilic compounds, food item (tissue) concentrations may be reported on the basis of the lipid content of a food item (as ug/g lipid). In the absence of sample-specific lipid content data, default values are available in the *Exposure Factors Handbook* (U.S. EPA, 1997) for a variety of fruits and vegetables and for a variety of lipophilic food items (fish, meat, dairy). These can be converted from ug/g lipid to ug/g whole wet weight according to the formula (5.2).

5.3 Maximum Concentration versus Mean Concentration

In situations where country food residue data have been collected, different statistics of the collected data can be used to represent the concentration of a contaminant in a food item from which exposure is estimated. In a PQRA, where limited data are usually available, the maximum measured concentration is recommended for use in exposure calculations. However, in a DQRA, where sample size is deemed sufficient and the collected samples are considered representative of the tissue levels affected by the site of interest, it is possible to use a statistic representing the 'central tendency' of the data (e.g., mean or median). Where data are sufficient and representative of a site, a more realistic estimate of the typical or average concentration for exposure and risk calculations is appropriate. However, more conservative estimators (such as the 95% upper confidence limit of the

mean or median + 2*MAD (median absolute deviation)) are commonly used to maintain conservatism in the risk assessment.

For federal sites in Canada, use of the geometric mean is not recommended. The geometric mean is a statistical representation of the central tendency of data that are log-normally distributed. However, this statistic is not representative of the average concentration to which consumers of fish, shellfish or game will be exposed. Reimann and Fitzmoser (2000) and U.S. EPA (2002) also recommend against use of geometric mean. The arithmetic mean is a more appropriate representation of the average or typical concentration to which a consumer of a given food item will be exposed.

(5.1)

$$\text{Tissue}_{\text{wet weight}} = \text{Tissue}_{\text{dry weight}} / ((100- \text{MC})/100)$$

Where:
MC = moisture content expressed as a percent

(5.2)

$$\text{Concentration}_{\text{whole weight}} = \text{Concentration}_{\text{lipid weight}} / ((100 - \text{LC})/100)$$

5.4 Dealing with Non-detected Contaminant Concentrations in Country Food Samples

In many cases, the proportion of country food concentrations reported as "less than detection limit" may be high. Analytical data sets frequently include both reported concentrations (detects) and reported inability to detect the chemical (non-detects). Consequently, the low end of the distribution of concentrations is censored. Non-detects do not indicate that a chemical is not present, but merely that it is below the method detection limit (MDL) or quantification limit. If a chemical is detected in some samples from a site, it is possible that it is also present at low concentrations in samples reported as non-detects.

For simple DQRAs, this problem can be handled simply and conservatively by substituting half of the detection limit for the non-detect observations prior to calculating the mean or other statistic to be employed as the concentration for exposure calculations. If a more robust treatment of non-detected measurements is required, such as for application in a probabilistic risk assessment, methods to impute concentration values for reported non-detects are available (Suter, 2007; SAS Institute, 2008; Newman and Dixon, 1990; Newman et al., 1995; UNCENSOR, 2003; Kaplan and Meier, 1958; Schmoyer et al., 1996; U.S. EPA, 2008).

6.0 CONSUMPTION RATES FOR COUNTRY FOODS

Assumed consumption rates of country foods by human receptors can have a major influence on the calculation of exposure to COPCs at a site and subsequent estimation of associated health risk. There are two methods of estimating the ingestion rates for country foods:

1. Using generic or referenced ingestion rates; or,
2. Identifying site-specific ingestion rates through surveys and studies.

Because of differences in country food consumptions rates, ingestion rates may differ between Aboriginal and non-Aboriginal populations.

Derivation of site-specific food ingestion rates is not recommended for a typical PQRA, but should be considered in a DQRA. The level of effort will depend on the types of foods and receptors considered for each site.

6.1 Generic or Referenced Ingestion Rates

It is possible to use literature-referenced values to estimate food consumption at a contaminated site. However, where possible, some consultation is recommended in order to tailor the risk assessment to the subject population or receptor group and site. For a generic residential land use, it is often assumed that 10% of produce ingested is grown on-site (CCME, 2006); however this can be adjusted based on site-specific information, including the size of a garden and the dietary habits of individual's resident at or near a subject property. In an agricultural land use scenario, it is assumed that 50% of the produce ingested is grown on-site and 50% of the meat and 100% of the milk is from the site (CCME, 2006). Similar to residential land use, this can be altered based on site-specific information.

Appendix B provides Canadian data for generic consumptions rates. Also, some country food consumption statistics for rural non-Aboriginal communities can be found in Teitelbaum and Beckley (2006). Appendix C provides scientific literature, both generic and site-specific, on country food consumption for many Aboriginal communities.

6.2 Site-specific Food Ingestion Rates

Generic food ingestion rates are typically derived for large communities and are not applicable for populations that are not well represented in the data summarized by Richardson (1997). This may include rural, remote communities or Aboriginal communities where geographical locations influence dietary habits. In some cases, the literature does not reflect the food consumption rates of certain foods (e.g., medicinal plants, fish or other traditional foods) or choices of a specific community. For example, Richardson and Currie (1993) have demonstrated how fish consumption in First Nations communities increases with the degree of isolation of those communities.

Generally, site-specific country food ingestion rates will only be achieved through a survey of the affected community. It is not within the scope of this report to provide details concerning the design or the conduction of a survey; however, if it is deemed that generic consumption values from literature sources are not adequate for a specific site and no values can be found in the scientific literature, then general guidance on surveys can be found in Appendix A and references therein.

Traditional foods and consumption rates can vary widely depending on the geographical location of a community, particularly for Aboriginal peoples. For example, the diet of Coastal First Nations groups is likely to include a large proportion of marine fish compared to an inland community where caribou and wild game consumption is typically higher. Although not exhaustive, information and literature sources on First Nations food consumption can be found in Appendix C. Similarly, people in northern communities consume less fruits and vegetables compared to people in southern communities due to the limited growing season. In addition, remote communities, whether First Nations or not, may have distinctly different food consumption patterns based on the availability of fresh produce and game.

6.3 Community Surveys of Food Preferences and Consumption Patterns

In most cases, the development of a conceptual model benefits from a survey of the local human population to determine harvesting and consumption patterns, as well as to characterize the receptors, if they are thought to be unique or different from the general population. For example, a subject population may have differing body weights, food preferences and consumption patterns. Such surveys help to ensure that the country foods risk assessment properly and accurately characterizes potential exposures. A survey would typically include:

- Harvesting patterns such as harvested species, harvesting season, quantities harvested, harvesting locations (onsite and offsite);
- Characteristics of the consumed species such as migratory patterns, home range and other life history characteristics;
- Consumption patterns such as frequency/amounts consumed, tissue types consumed and methods of cooking or other food processing;
- Whether foods are eaten seasonally or only during hunting trips, or whether foods are preserved and consumed throughout the year; and,
- Receptor characteristics such as age/gender distribution in the community population, and any unique population characteristics relevant to risk assessment.

Since consumption patterns can differ among communities, it is necessary to consult, often first-hand, with those members of the affected community that consume country foods to ensure that the appropriate species and tissues have been identified and considered. Rural communities and Aboriginal peoples may consume tissues that are not typically considered in risk assessments for urban communities. For example, sport fishers typically consume only the skinless, boneless fillet, while Aboriginal communities may use all parts of the fish. Similar differences in consumption and preparation occur with respect to mammals, where Aboriginal community members may consume organ meats and other tissues that can contain higher concentrations of COPCs than do muscle tissues.

Guidance on the development and implementation of surveys can be found in Appendix A. Additional guidance can be found in documents such as Kuhknlein et al (2006) and U.S. EPA (1998). The level of detail and amount of data collected will be dependent on the scope, complexity and budget of a country foods study. If a detailed survey is not possible, there will be greater uncertainty in the degree to which a country food study is representative of an affected community as a whole. However, sometimes data can be obtained from published scientific literature or from databases available at the Centre for Indigenous Peoples' Nutrition and Environment (CINE, 2008) website or elsewhere.

7.0 INTEGRATING A COUNTRY FOODS STUDY INTO A RISK ASSESSMENT

The preceding guidance focuses primarily on the components of problem formulation and exposure assessment phases of a risk assessment related to the country foods pathway. The data generated by a country foods study are normally only one component of a larger human health risk assessment, typically involving multiple exposure pathways. Detailed guidance on performing risk assessments is provided by Health Canada for PQRA, as well as for DQRA.

Where risks associated with the consumption of contaminated food items are found to be unacceptable, data gaps and uncertainties should be identified. In particular, in cases where deficiencies in sampling design significantly limit the interpretation of results, or where data are determined not to be adequately representative for an affected community, additional sampling should be made.

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APPENDIX A

OUTLINE OF A COUNTRY FOODS SURVEY

An outline for some essential data requirements is provided here for a country foods survey to be used in risk assessment. It is based on Kuhnlein et al. (2006) and U.S. EPA (1998). Refer to these references for more detailed guidance on developing and administering country foods surveys. It is important to customize a survey to the setting, nature and extent of contamination, and local population, as well as the survey administration method (e.g. personal interview, telephone interview, focus group, or mail). Consultation with First Nations and Inuit communities should be undertaken where appropriate.

Data Requirements for Risk Assessment

A1 Receptor Characteristics (Household Information)

Household information can be used to help characterize the local population. Alternatively, reliable census data, if available, may also be used. The following data are considered essential for a risk assessment when collected via a country foods survey (Table A.1).

Table A.1 Receptor Characteristics

Household member	Age	Sex	Pregnancy/lactation status	Relationship to Survey Respondent

A2 Harvesting and Consumption of Traditional Foods

A list of all traditional foods consumed by the community should be compiled based on information provided by those surveyed and include the seasons when these foods are harvested, the locations they come from, and how the foods are prepared (Tables A.2 and A.3).

Table A.2 Country Food Harvesting

Country Food Item Consumed	Local/Common Name	Harvesting Location(s) and Distance from Residence	Season(s) /Month(s) Harvested (days/ season; months/year)	Age/Characteristics of Harvested Food (size, length, etc)

Table A.3 Country Food Preparation/Consumption

Country Food Item	Frequency Consumed (days/week)				Preservation Method (fresh, frozen or preserved)	Parts Consumed	Preparation Methods	Cooking Methods
	Spring	Summer	Fall	Winter				

In some cases, further data may be required for more complex country foods assessments. These may include more specific details about harvesting locations, or 24-hour recall surveys to help further quantify the frequency with which particular food items are consumed. The needs for more refined data from a country foods survey will be site-specific; some examples of these data can be found in Kuhnlein et al. (2006) and U.S. EPA (1998).

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APPENDIX B

GENERIC REFERENCE INGESTION RATES FOR NON-ABORIGINAL

Generic Reference Ingestion Rates for non-Aboriginals

Using generic or referenced ingestion rates is the most common method of assessing ingestion for a human health risk assessment. The main source of ingestion rates for Canadian populations is the *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson, 1997). The Canadian data upon which these rates were based are somewhat dated (*ca*1970-72). However, pending the collection and publication of more recent data and information, these data represent the best Canadian data available.

Food consumption habits have undoubtedly changed from the 1970s. There is some evidence that consumption of fruits and vegetables has increased and the variety of foods stuffs consumed from both North America and worldwide has also increased (Statistics Canada, 2008). In addition, Canadian data from the early 1970s was collected primarily from urban populations and consequently, there is some doubt as to its applicability to rural, non-Aboriginal populations. Rural populations generally do not have access to the variety of foods available in urban centres and may rely more on self-provisioned foods. As with the Aboriginal consumption of country foods, rural non-Aboriginal country food consumption will likely vary with geographic location and the availability of country foods, as well as local habits and cultural values. Without information on the country food consumption patterns of a local rural population, a high degree of uncertainty will be associated with food consumption estimates using generic models.

Generic Canadian data on food consumption provided by Richardson (1997) are based on a study conducted in 1970-1972 as part of the Nutrition Canada Survey. This was a 24-hour recall survey of statistically representative samples of the Canadian population, including Inuit and First Nations groups and representatives of different regions and income levels. Generic consumption rates for various foods are provided for different age groups and include infants (0-0.5 yr), toddlers (0.6-4 yrs), children (5-11 yrs), teens (12-19 yrs), adults (20-59 yrs), seniors (60+ yrs) and all adults (20+ yrs). Data are presented for males, females, and males and females combined. The data were presented as an arithmetic average (with associated standard deviations) for participants in that survey. The data were lognormally distributed and the values are also described in terms of probability density functions, which can be used in a probabilistic risk assessment. As stated in Richardson (1997), more recent surveys of food consumption have been conducted in all provinces, although compiled and published data are only available for Nova Scotia and Quebec. Richardson (1997) presents food consumption rates for the following composite food groups:

- Baby Formulae: baby food formulae;
- Milk and Dairy Products: whole milk, 2% milk, skim milk, milk-based instant breakfast, evaporated milk, cream, ice cream, natural cheese, cottage cheese, and processed cheese;
- Meat and Eggs: beef steak, roast and stewing beef, beef hamburger, pork, veal, lamb, poultry, organ meats, cold cuts, luncheon meats, canned luncheon meats, wieners, baby food meat/ poultry/eggs, wild game, wild birds, and sausages;
- Fish and Shellfish: marine fish, canned salmon, canned tuna, canned sardines, freshwater fish, and shrimp;
- Root Vegetables: carrots, onions, rutabagas, turnip, beets, and potatoes;
- Other Vegetables: corn, cabbage, celery, green peppers, lettuce, cauliflower, broccoli, green beans, peas, tomatoes, mushrooms, cucumbers, baby food vegetables, asparagus, rhubarb, greens, squash, popcorn, and beans;
- Fruits and Juices: oranges and grapefruit, apples, processed apple products, bananas, grapes, peaches, pears, plums and prunes, cherries, melons, strawberries, blueberries, pineapple, raspberries, other berries, fruit pies, raisins, baby food fruit, citrus juices, grape juice, other fruit juices, and tomato juice;
- Cereals and Grains: bread, rolls and biscuits, all-purpose flour, cookies, Danish and donuts, crackers, pancakes, cooked cereals, cold cereals, rice, pasta, muffins, baby food, and cereals;
- Sugar and Sweets: white sugar, pancake syrup, jams, honey, puddings, candy, gelatine desserts, and baby food desserts; and,
- Fats, Nuts and Oils: butter, cooking fats and salad oils, margarine, peanuts, sauces and gravies, peanut butter, other nuts and seeds, and animal cooking fats.

Although Canadian food consumption rates presented by Richardson (1997) are generally recognized as the primary source for ingestion rates in Canada, it is possible to obtain additional food consumption rates from other sources such as Statistics Canada (2008), U.S. EPA (1997), US Dept. Agriculture (2008), and scientific literature. Fish consumption patterns were recently reviewed by the Food Directorate of Health Canada (HC, 2007) and may provide additional useful information for estimating exposures and risks presented by the consumption of fish.

Food consumption rates from several studies are compiled in the U.S. EPA *Exposure Factors Handbook* (U.S. EPA, 1997). Volume II includes food ingestion values that are based on a three-day dietary record from 15,000 individuals from a variety of households (three years combined). The primary data set for the fruit and vegetable consumption rates were collected in 1989-1991 (U.S. EPA, 1997). The food ingestion rates are provided for individual vegetables and fruits and consumption rates are also provided for dairy products, fish and shellfish, grains and other various home-produced items. U.S. EPA recently released its Child-specific Exposure Factors Handbook (U.S. EPA, 2008), which provides a review of studies on ingestion rates of food and other exposure characteristics.

The US began conducting the *Continuing Survey of Food Intakes by Individuals* (CSFII) in 1985, subsequently combining it with *the National Health and Nutrition Examination Survey* (NHANES). The data was collected in *What We Eat in America* (WWEA, US Dept. Agriculture, 2008), the dietary interview component of the NHANES. WWEIA is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The survey is performed annually, and detailed data are compiled, including intake rates for specific food items and age, racial and regional differences. New nationwide dietary intake data for the years 2003-2004 are now available for public use.

Until such time as new data become available, the Contaminated Sites Division of Health Canada recommends that Richardson (1997) be used as the source for ingestion rates for major food groups, unless specific data are available for a particular site. Richardson (1997) also includes fish and wild game ingestion rates specific to native populations, which should be applied when appropriate. Site-specific data are generally not available in a PQRA. However, in a DQRA, it is important to include as much site-specific data as possible. If background exposure information on contaminant levels in purchased food is required, please contact the Contaminated Sites Division of Health Canada.

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APPENDIX C

RESOURCES FOR ABORIGINAL DIETARY CONSUMPTION OF TRADITIONAL FOODS

First Nations, Inuit, and Me´tis people remain deeply dependent on country foods. Because of the harsh northern climate, there has been relatively little urban and industrial development of the Arctic and Subarctic. Prior to European contact, First Nations people of Cree and Chipewyan descent populated the Subarctic. These peoples lived largely by hunting caribou and moose and by fishing (Ray, 1996). Inuit, who hunt marine mammals and barren-ground caribou in addition to fishing, inhabit the Arctic. The Me´tis, the third Aboriginal group, are peoples of First Nation and European descent and they reside mainly in subarctic communities (Van Oost-dam et al., 2003). Aboriginals continue to rely on traditional foods, which are highly seasonal in their availability and limited in their variety.

Traditional "country foods" for Inuit and First Nations peoples consist of a wide variety of foods gathered and prepared to meet nutritional and cultural needs (Deutch, 2002). For Canadian Inuit, intakes of traditional/country food do not seem to have significantly changed over the last 20 years. Country food use for women and men 20–40 years of age is highest in Inuit communities followed by the Dene and Metis of the Mackenzie River basin in the NWT and then the First Nations people of the Yukon. The consumption of traditional foods is based on many factors including species availability, geographic location, and traditional values. Current literature regarding food consumption is summarized at the end of this Appendix for various communities and geographic areas in Canada. However, a literature search for more recent information is also highly recommended.

CACAR-I (CACAR, 1997) was among the first to extensively document the importance of traditional/country food as a source of nutrients. Since CACAR-I, however, documentation of the Canadian Arctic food systems has vastly improved. The importance of traditional/country food in the diet of Nunavik Inuit (Blanchet *et al.*, 2000) and the diet of pregnant women in the Inuvik region (Tofflemire, 2000) has been better documented. Three major studies of dietary intake in Arctic communities have been completed by the Centre for Indigenous Peoples' Nutrition and Environment (CINE 2008; several publications are available at this site).

Kuhnlein (2002a) documented the average weekly frequency of consumption of main traditional/country food items during late winter and fall in the major indigenous geographical areas. More than 250 different species of wildlife, plants and animals were identified in workshops attended by community residents as forming the rich framework of the traditional/country food systems of Arctic peoples. The yearly average days per week for various food items consumed was summarized. Regional differences in species used most frequently are due to ecosystem variety and cultural preferences.

Wein and Freeman (1995) conducted a survey of country food consumption in four native communities in the Yukon. The frequency and variety of country foods consumed was found to be strongly influenced by geographic location. For example, communities located near highways tend to have lower traditional country food consumption since the locations of these communities were dictated by the location of the highway rather than on an abundance of traditional country foods. Furthermore, the presence of the highway brings the convenience of non-traditional or commercial foods. Conversely, communities located where traditional country foods are abundant reported higher country food consumption. Foods consumed also vary from community to community based on cultural traditions.

Since the amount and composition of native country food consumed varies from one community to another, communities should be consulted prior to establishing consumption rates. If the scope of the risk assessment cannot accommodate such a study, the references contained in this appendix may be useful for estimating the consumption of traditional country foods consumed in various areas. These references are comprehensive but do not cover all groups consuming country foods.

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www.amap.no/Assessment/ScientificBackground.htm

Canadian Arctic Resources Committee. Canadian citizen's organization.
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Centre for Indigenous Peoples' Nutrition and Environment (CINE). Independent, multi-disciplinary research and education resource for Indigenous Peoples, created by Canada's Aboriginal leaders at McGill University.
www.mcgill.ca/cine/research/publications/

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