Guidance on Human Health Risk Assessment for Environmental Impact Assessment In Alberta

Alberta Health and Wellness

August 2011

Government of Alberta

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Special thanks for the valuable peer-review and editorial comments from:

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1.0 INTRODUCTION

1.1 Background

Environmental assessment is a key element of Alberta's process for the review and approval of new major industrial projects. An environmental impact assessment (EIA) is required where the scale and complexity of certain proposed projects or activities create the potential for significant adverse environmental effects as outlined under the *Environmental Protection and Enhancement Act* (EPEA).

The environmental assessment process in Alberta requires the preparation of an EIA report. These reports provide information on the potential environmental, health, social, economic and cultural impacts of the proposed project or activity. The EIAs are reviewed by a cross-ministry team led by Alberta Environment (AENV) to identify project uncertainties and determine if the information provided meets the project Terms of Reference (AENV, 2008). Alberta Health and Wellness (AHW) takes part in this review process providing advice to AENV regarding a proponent's assessment of potential human health impacts related to the proposed project as presented in the EIA report.

Human Health Risk Assessment (HHRA)

A systematic and well documented process to define and quantify potential human health risks from exposure to chemicals released from a proposed project alone and in combination with other past, present, and future projects in a region.

Although the assessment of potential health impacts is an important part of an EIA, limited guidance has been available historically to assist proponents in the completion of a health impact or risk assessment; as a result, the methodology, level of detail and completeness of health impact or risk assessments incorporated into EIAs are often inconsistent. Although some published guidance is available for assessing risks associated with industrial activities such as combustion facilities, many EIA practitioners rely on guidance developed by various jurisdictions for the assessment of health risks associated with contaminated sites. Human health risk assessment (HHRA) for contaminated sites typically addresses contaminants historically released to the environment (especially to soil,

groundwater and surface water) as a result of past facility operations, as opposed to releases or emissions related to future activities. However, the underlying scientific principles are essentially the same in both situations. To ensure that these principles are applied consistently and defensibly to the evaluation of new projects in Alberta, there is a need for guidance specific to the completion of health impact or risk assessments as part of an EIA.

1.2 Scope and objectives of guidance document

The primary objective of this document is to provide general guidance for the completion of a HHRA as part of an EIA, with the overall goal of ensuring quality, consistency and completeness of risk assessments conducted in Alberta. The guidance is not intended to be a prescriptive technical protocol for the quantitative assessment of health risks.

Instead, the present guidance outlines the general requirements for HHRA conducted as part of an EIA, to ensure that the scope of the assessment is appropriate, that the applicable receptors and exposure scenarios and appropriate data sources have been considered, and that acceptable methods have been used in the estimation of risks. It is important to note that while professional judgment is an essential component of any HHRA, proponents are encouraged to provide as much supporting information and evidence as possible to support their professional judgment. The expectation is that the knowledge, experience and judgment of the risk assessor, applied within the general framework of the present guidance, will facilitate adherence to seven key principles integral to the HHRA. The HHRA should be:

- Consistent: Similar methodology is used in each HHRA (as outlined in this document), with the recognition of the unique characteristics to specific projects.
- Transparent: It is clearly documented what was done and why.
- Reproducible: Reviewers are able to reproduce results based on the information presented in the report.
- Defensible: The results are scientifically defensible.
- Comprehensive: All relevant risk factors are considered.
- Cautious: The appropriate degree of conservatism is incorporated to guard against uncertainties.

- Useful: Addresses fully and clearly the relevant health concerns in potentially affected human populations.

The intention of this document is to clarify the elements of an HHRA that will assist AHW with its project decision-making process. Following these principles may reduce the requirement for supplemental information and further analysis arising from regulatory review. However, each project is unique and other information may be required to aid AHW in its decisions.

1.3 Organization of guidance document

Section 2.0 of this guidance document provides a general description of the regulatory context and process for environmental assessment in Alberta, the regulatory requirements and objectives of the HHRA and the governing considerations with respect to the protection of human health. Section 3.0 provides guidance in the scoping of HHRA, identifying general requirements, scenarios, data sources and other considerations and linkages to other components of the EIA report. The methodology for HHRA is described in Section 4.0, with reference to existing sources of information that provide more specific technical guidance. Application of the findings of the HHRA to the selection and implementation of mitigation or risk management strategies is discussed in Section 5.0, and other issues and considerations having a bearing on human health are discussed in Section 6.0.

2.0 CONTEXT

2.1 Regulatory framework and process for EIA

Alberta's Environmental Assessment process is governed by the *Environmental Protection and Enhancement Act* (EPEA, 1992) with the aims of supporting sustainable development, integrating environmental protection into project planning, predicting and mitigating environmental, social, economic and cultural impacts, and facilitating public involvement in project review. EPEA and the associated *Environmental Assessment Regulation* and *Environmental Assessment (Mandatory and Exempted Activities) Regulation* set out the criteria used to determine whether a project or activity requires an EIA report. An EIA report is

generally required when the complexity and scale of a proposed project or activity could have the potential for significant adverse environmental effects. The EIA report summarizes the nature of the proposed activity, the potential local and regional environmental effects, proposed mitigation strategies and issues requiring further investigation and monitoring.

AENV is responsible for the administration of Alberta's laws governing environmental assessment. However, Section 11 of EPEA states that *"The Minister [of the Environment] shall, in recognition of the integral relationship between human health and the environment, co-operate with and assist the Minister of Health and Wellness in promoting human health through environmental protection.*" It further states that EIA reports under the Act must include a component that identifies issues related to human health. AHW has a mandate under the *Public Health Act* to ensure that a nuisance as defined in the Act is not created, (i.e. *"a condition that is or that might become injurious or dangerous to the public health…."*). More specifically, under the *Nuisance and General Sanitation Regulation "No person shall create, commit or maintain a nuisance"*.

AENV is the lead agency in the provincial process for reviewing EIA reports; the review teams (air, water, terrestrial, health, socio-economic) review the EIA reports. If the information provided in the EIA report is unclear or insufficient to understand the potential impacts of the project, supplemental questions (Supplemental Information Requests, SIR) are prepared and submitted by AENV to the project proponent. At the end of the process, AENV makes a decision that the EIA report is complete based on the advice from the review teams. Within this process, AHW acts as the human health review team lead and provides advice to AENV on the EIA report. The health team analyzes the information in the EIA and reviews the proponent's assessment of the risks to human health.

2.2 EIA requirements and terms of reference

The general requirements for information to be included in an EIA report are outlined in EPEA. These include, but are not limited to: a project description; an identification of existing baseline environmental conditions; a description of potential environmental, social, economic and cultural impacts, including cumulative, regional, temporal and spatial considerations; an analysis of the significance of the identified impacts; an identification of issues related to human health;

monitoring and mitigation plans; contingency plans and other requirements. The Terms of Reference issued by AENV provide the project-specific requirements for an EIA report. Proposed Terms of Reference are prepared by the proponent, under the guidance of AENV. The proposed Terms of Reference are subjected to reviews by the regulatory agencies and the public as prescribed by the Act and regulations, and are ultimately issued in final form by AENV.

The requirement to address human health is addressed explicitly above, as well as implicitly in the context of environmental, social, economic and cultural impacts. Health risk assessment requirements are typically addressed directly in the Terms of Reference. Scoping of the HHRA is discussed further in Section 3.0.

2.3 Health protection goals

The HHRA, as part of an EIA, should prescribe methods and assumptions that ensure that the exposures and potential risk for adverse human health effects are not underestimated. Health effects that can be assessed quantitatively are compared to benchmarks or protection goals. These benchmarks are established on the basis of exposure limits related to the toxicity of the respective chemicals. The meaning and interpretation of a benchmark depend upon the nature of a chemical and its mode of toxic action.

2.3.1 Non-carcinogens

Non-carcinogens are understood, based on best available evidence, to exhibit a threshold dose or exposure level below which adverse effects are not expected to occur.[1] The exposure limit for such a chemical is usually a cautiously-established concentration or dose, related to this threshold, to which it is believed a receptor can be exposed over a period of time without risk of adverse effect. The protection goal for a threshold chemical is that the total exposure of an individual to such a chemical should not exceed the exposure limit. Predicted exposure in

[1] The principle of threshold dose could also be applied to epi-genetic carcinogens. These carcinogens do not attack DNA leading to subsequent genetic alteration. Consequently, the cancer mechanism would not be operative at exposures below a threshold at which adverse effects do not occur.

excess of this limit does not necessarily imply that adverse effects will occur, only that there is a potential for adverse effect that should be examined further.

2.3.2 Carcinogens (DNA-reactive or genotoxic)

Non-threshold chemicals or genotoxic carcinogens are treated as a matter of precautionary public health policy, such that they are considered to pose a non-zero risk of cancer at any level of exposure and the risk of cancer is considered to increase with degree of exposure. As a result, it is necessary for regulatory agencies to specify a level of carcinogenic risk that is considered acceptable, tolerable, or essentially negligible for setting guidelines, standards or for assessing exposure from substances released by industrial projects. The appropriate cancer risk assessment level is established through policy by health and environmental regulators, which considers the desired level of human health protection, balanced with background risks and social, economic and legal factors. The exposure limit for a carcinogen is expressed as the concentration or dose at which the cancer risk is considered acceptable, tolerable, or essentially negligible.

Incremental Lifetime Cancer Risk

The incremental increase in lifetime cancer risk, over and above the risks experienced by the general population due to background environmental exposures, associated with a specific project or activity.

For the purpose of assessing carcinogens in HHRAs, regulatory agencies such as AHW, Health Canada and AENV consider an incremental lifetime cancer risk (ILCR) of 1 in 100,000 to be “essentially negligible” (Health Canada, 2009a, 2009c; Alberta Environment, 2007). The term “incremental” refers to the increased lifetime cancer risk, over and above the risks experienced by the general population due to background environmental exposures, associated with a specific project or activity. In other words, the benchmark for screening and review purposes for a carcinogen is that the ILCR associated with a project or activity above background should not exceed 1 in 100,000. The common quantitative cancer risk assessment protocols rely upon an estimate of a cancer slope factor (lifetime cancer risk per unit of chemical dose) or unit risk (lifetime cancer risk per unit of chemical concentration) that is derived from animal experiments (adjusted for application to humans) or epidemiology studies. The cancer slope factor or unit

risk used is normally an upper (95%) bound estimate of this slope to assure that the low dose cancer risk is not underestimated. As such, the cancer risk estimates do not represent the expected cancer risk, but rather an upper bound estimate of maximum plausible cancer risk.

The acceptable or tolerable cancer risk of 1 in 100,000 was specifically developed to address cancer risks that are above background. There are no regulatory benchmarks of acceptable or tolerable cancer risk for background cancers. Consequently, background environmental media concentrations should not be included in the calculation of ILCR. However, a lifetime cancer risk (LCR) for background concentrations should be calculated separate from the ILCR. There may be a few exceptions to this requirement pending further discussion with AHW. Since there are no regulatory benchmarks of acceptable cancer risk level for background cancers, it is important that the LCR be assessed using a relevant slope factor or unit risk. A risk ratio should not be generated; instead, a comparison to daily intakes (inhalation or ingestion) should be presented and discussed.

Sections 4.5 and 5.1 provide additional discussion on risk assessment and management decisions pertaining to cancer risk estimates.

2.3.3 Outcomes

The primary outcome of a quantitative HHRA is normally an estimate of the risk of potential adverse health effects on an individual, community or population that could arise from changes in environmental quality due to the proposed project alone and combined with the cumulative impact from other existing and planned projects, as well as inclusion of ambient or background conditions in the region. By comparing the predicted risks with the relevant protection goals, the overall effect of a project on human health, and the significance of the effect, can be assessed. A further outcome is the identification of requirements for risk management, mitigation or monitoring strategies that may be incorporated into the project design or operation.

3.0 SCOPING OF HUMAN HEALTH RISK ASSESSMENT

3.1 Study boundaries

Study boundaries established for the EIA fall into two categories: spatial and temporal. These boundaries will also generally apply to the HHRA, although at the outset of the HHRA it must be established that the boundaries are appropriate and applicable, to ensure that human health risks are adequately assessed.

3.1.1 Spatial boundaries

The spatial boundaries for HHRA will generally be based on the regional and local study areas as defined in the EIA. However, local study area boundaries may vary depending on the anticipated spatial distribution of potential impacts based on the specific release, transport and exposure mechanisms. For example, the air quality study area may differ from the surface water quality study area due to different mechanisms of chemical transport. Adequate definition of these study area boundaries from the standpoint of potential human exposure is critical to the identification of human receptors for the HHRA.

3.1.2 Temporal boundaries

Temporal boundaries for the EIA are typically expressed in the context of the stages of a project (e.g. baseline, construction, operation, reclamation and post-reclamation). Temporal considerations for HHRA include both the nature of exposure (acute versus chronic) as well as the durations over which chronic exposures may occur and the timeframes over which potential health risks may be presented. Consideration of acute and chronic exposure and health effects must be combined with appropriate receptor life stages and exposure durations and, where applicable, the potential for manifestation of future health effects should be considered in the assessment of lifetime health risks.

3.2 Identification of receptors

3.2.1 General public

The focus of the HHRA as part of an EIA is the assessment of the potential adverse health effects on a relevant receptor which may be an individual, community or population that could arise from changes in environmental quality due to the proposed project alone and combined with the cumulative impact from other existing and planned projects, as well as inclusion of ambient or background conditions in the region. An inventory of receptor locations and receptor categories is generally compiled to identify appropriate receptors for the HHRA. Depending on the exposure pathways of concern, health risks may be assessed for all receptor locations or just those considered critical. Various receptor age classes are considered, as appropriate to the receptor category and setting. Selection of critical receptors is discussed further in Section 4.0.

3.2.2 Critical subgroups

In addition to the assessment of potential health risks to members of the population in general, consideration must be given to individuals within a population who may be at greater risk. In the context of this guidance, critical subgroups are considered to be those whose lifestyle and behavioural characteristics may contribute to greater chemical exposures than the general public. This would include children or individuals consuming greater than average proportions of country foods and other natural foods (i.e. Aboriginal peoples and residents subsisting predominantly on locally grown produce, and traditional foods such as, plants, wild game and fish).

Populations may also be characterized as those whose physical characteristics or conditions may result in an increased likelihood of adverse effect to a given level of exposure (e.g. the elderly, and persons suffering from existing medical conditions such as asthma). Individuals with these characteristics or conditions are considered in the health assessment typically through the use of safety or uncertainty factors incorporated in the exposure limits.

3.3 Assessment scenarios

The requirements of an EIA, as outlined in EPEA and amplified in the *Guide to Preparing Environmental Impact Assessment Reports in Alberta (AENV, 2009a)*, include an evaluation of baseline conditions and an assessment of the potential impacts of the project or activity, including cumulative considerations. These are normally addressed by assessing human health risks under four scenarios or cases: the baseline case; the application case; the planned development and project alone case. The first three scenarios are considered to account for cumulative effects since the risk of potential adverse health effects on an individual, community or population that could arise from changes in environmental quality due to the proposed project alone are combined with the cumulative impact from other existing and planned projects, as well as inclusion of background conditions in the region. The project alone case is applicable to AHW's requirements for HHRA and is not part of AENV's *Guide to Preparing Environmental Impact Assessment Reports in Alberta (AENV, 2009a)*.

Scenario

A description of environmental and development conditions at a certain time to allow comparisons of change (e.g. pre-development, current, and reasonably foreseeable future). The common scenarios are: project alone, baseline case, application case and planned development case.

3.3.1 Baseline case

The baseline case considers potential environmental effects and associated health risks under present, pre-project conditions, including current ambient environmental conditions, existing sources of chemical emissions (existing facilities), and the contribution of future projects or activities that have been approved. The baseline case is assessed by evaluating the potential health risks associated with existing concentrations of chemicals in relevant environmental media, obtained from the results of regional monitoring and/or the results of a project-specific baseline environmental sampling program. The use of existing measured data is supplemented by modelling predictions to account for the contribution of approved projects that have not yet commenced operations.

3.3.2 Application case

The application case, involves consideration of the anticipated emissions of the proposed project in combination with baseline conditions. In other words, assessment of the application case takes into account existing and approved facilities together with the proposed project. The contribution of the project relative to baseline conditions should be evaluated under all relevant life stages of the project, including construction, operation, reclamation and post-reclamation. Additionally, assessment of the operating phase should include normal operations as well as upset conditions (e.g. accidental releases, start-up and shut-down conditions, flaring). Justification must be provided for the exclusion of any project stage or operating condition from consideration.

3.3.3 Planned development case

The planned development case considers the potential risks associated with the project in combination with other existing and approved projects as well as planned or proposed projects and other reasonably foreseeable future activities in the region. In other words, the planned development case is the application or project case combined with future projects. The objective is to ensure that the combined exposures and potential risks associated with all anticipated sources of chemicals to the regional environment are understood.

3.3.4 Project alone case

For many proposed projects, the predicted human health risks in the application case may be of similar magnitude to those in the baseline case. This is accentuated by the practice in HHRA of rounding estimated health risks to one, or at most two, significant figures. This accepted practice acknowledges the degree of uncertainty in the quantification of health risks. However, it also masks the contribution of the project alone to total health risk, particularly if the risks associated with the project are more than an order of magnitude lower than baseline risks. Consequently, health risks should be evaluated under “project only” conditions, in order that the contribution of the project can be assessed on its own, and the results can be used in the

communication and consultation process. The project alone case considers potential environmental effects and associated health risks under project conditions only.

A further benefit of assessing health risks on a "project only" basis is in the evaluation of ILCR for carcinogens. Unlike threshold compounds, in which exposure from all sources including background is compared with applicable exposure limits, carcinogenic risk is expressed in incremental terms for the purposes of assessing the significance of a particular source of exposure. For the reasons stated above, the ILCR risk related to the project is not readily obtained from the application (baseline plus project) case.

3.4 Exposures and effects to be considered

The HHRA must address health risks associated with both short-term (acute) and long-term (chronic) exposures, as appropriate to the various exposure pathways and the characteristics of the receptors. For most human exposure pathways, long-term exposures and associated effects are of greatest concern. However, for inhalation exposure to chemicals in air, short-term exposures may be more critical, in part as a result of the temporal and spatial variability of chemical concentrations in air, the potential for higher short-term concentrations and the possibility of specific short-term chemical release events.

3.4.1 Acute exposures

Acute exposures are typically considered to be those in the order of several days or shorter. The Agency for Toxic Substances and Disease Registry (ATSDR) defines acute exposures as between one and 14 days (ATSDR, 2009). The actual durations of exposures considered in the acute risk assessment will depend upon the averaging period(s) considered in the exposure modelling and the exposure durations for which exposure limits are derived or expressed. Acute exposures are commonly evaluated for 15 minute, 1 hour and 24 hour exposure durations, although other averaging times may be used where relevant. It is important to ensure that the exposure limit or toxicity benchmark selected for the evaluation of acute risks is consistent with the exposure averaging time, or that suitable factors are applied for extrapolating between averaging times. It is also important to provide a rationale for the averaging time used.

3.4.2 Chronic exposures

Chronic exposures are typically those occurring over periods of months to years; the ATSDR considers chronic exposure to be 365 days or longer (ATSDR, 2009). In chronic exposures over such periods the average exposure would be compared to chronic exposure limits or toxicity values. Risks associated with long-term exposure to carcinogens are expressed as ILCR above background and are in most cases based on estimating the lifetime average daily exposure, a function of the overall exposure duration which is then amortized over an individual's life span forming a composite receptor.

Chronic exposures may be continuous or may be repeated discrete exposures over such periods; in either case the average exposure would be compared to chronic exposure limits or toxicity values. Exposure-averaging for repeated exposures should be appropriate to the time frame over which exposures may occur and effects may be anticipated. Exposure-averaging must also remain consistent with the exposure conditions applied in the derivation of the toxicological benchmarks incorporated in the risk assessment. Short-term repeated events may also need to be compared with acute exposure limits.

The ATSDR (2009) also defines the term subchronic, which refers to intermediate exposures of greater than 14 days and less than 365 days (other agencies may use different ranges to define intermediate exposures). Seasonal or construction exposure scenarios, for example, could give rise to subchronic exposure, although these are seldom explicitly considered in HHRA conducted for an EIA. The availability of subchronic exposure limits or toxicity values is limited. In the absence of a toxicity benchmark derived for a short term (acute or subchronic) exposure period, short-term exposures should be compared with exposure limits or toxicity values applicable to longer term exposures to ensure that risks are not underestimated. However, such comparisons must be clearly flagged and carefully explained to avoid any possible confusion about the meaning of the comparisons provided.

3.5 Data sources and linkages to other components of EIA

HHRA represents one component of an EIA. Other components include assessments of the quality of air, surface water, groundwater, soil, vegetation and wildlife. Although these are

essentially independent assessments, some or all may have a direct bearing on the assessment of human health risks, due to the potential for human exposure to multiple environmental media. The relevance of a particular component of the EIA to HHRA depends on the nature of the project, the source(s) of emissions to the environment, the anticipated fate and transport of the chemicals of potential concern, and the type and behavioural characteristics of the receptors present. The relevance will generally become apparent at the problem formulation stage of the HHRA and the resulting linkages will provide information on data requirements and potential data sources for the HHRA. It is important to note that changes to any one of these components may require the HHRA to be updated. The linkages between different components of the EIA and HHRA are discussed briefly below.

3.5.1 Air quality

The air quality assessment for an EIA typically uses emission rates, background or ambient air quality data, meteorological data and modelling techniques to estimate the spatial and temporal distribution of chemical concentrations in air within the study area. The results of the air modelling, which is performed for the defined assessment scenarios, are used directly as inputs to the HHRA. It is expected that the predicted deposition values from the air modelling will be used in the human health multi-media exposure model. There is a direct linkage between the problem formulation stage of the risk assessment and the air modelling, in that initial modelling is used to facilitate the identification of chemicals of potential concern for risk assessment, and critical receptor locations identified at this stage are used in the air modelling. It is essential that these components of an EIA be coordinated in conjunction with one another.

3.5.2 Surface water quality

Surface water quality may be affected by discharge of various types of water and waste water from a project, as well as by atmospheric deposition resulting from air emissions. The estimation of chemical concentrations in surface water is also an outcome of the surface water quality component of the EIA, and may be a direct input to the HHRA, depending on the importance of surface water to the identified human exposure pathways. Surface water may be a source of drinking water or may sustain fish and other aquatic species that are of importance

as a food source for human receptors. In addition, surface water may be used for recreational purposes. Appropriate exposure assumptions are necessary to address the different exposure scenarios.

3.5.3 Groundwater quality

Groundwater quality may be affected by, among other things, solid waste management and discharge of water and waste water from a project. In addition, groundwater may be impacted by the leaching of chemicals from soil that has been subject to atmospheric deposition or otherwise affected by chemicals. Groundwater is potentially critical to a number of human exposure pathways, including consumption of drinking water, uptake by crops and other edible plants, interconnectivity with surface water including associated accumulation in fish and as a result of groundwater use for irrigation or livestock watering. Where groundwater may be impacted, the potential chemical concentrations should be estimated and used as input to the HHRA.

3.5.4 Soil quality

Soil quality may be affected by atmospheric deposition, solid waste management, contamination and subsequent remediation, land discharge of water and wastewater, or partitioning from impacted surface water and groundwater. Several human exposure pathways originate from chemicals in soil, including direct soil ingestion, dermal contact and dust inhalation, uptake by crops and edible plants, and consumption of livestock or wildlife ingesting impacted soil and food. Chemical concentrations in soil should be estimated in order to assess the importance of these exposure pathways.

3.5.5 Effects on food sources

Human food sources that may potentially be impacted by chemicals released from a project or facility include crops, livestock, backyard produce, wild plants, wild game and fish. The potential impacts on both quality and availability of food sources are important considerations in an EIA.

Depending on the nature of the chemical(s), the exposure pathways may involve uptake into the relevant foods from soil, water, foliar deposition and vapour absorption. In some cases, atmospheric deposition may be the initial mechanism of chemical transfer to the soil, surface water or groundwater, such that predicted soil and water concentrations would be the inputs for the subsequent prediction of uptake into plants and animals used as food. However atmospheric deposition and vapour absorption should also be considered directly in the assessment of uptake into foods, particularly leafy plants and fruit.

An ecological risk assessment (ERA) may form part of an EIA. While the primary focus of an ERA is the assessment of potential impacts to the health of ecosystem components such as terrestrial and aquatic organisms, wildlife and vegetation, the results of the ERA can provide valuable information and inputs to the HHRA, particularly where food chain pathways involving plants and animals exist.

3.5.6 Other effects

Other consequences of a proposed project, which may potentially have adverse effect on human health, include noise, heat, light, dust, odour and safety. Noise, heat, light and odour can also be aesthetic issues that may contribute to the level of concern, stress and anxiety experienced by local residents. Public safety is also often a major concern of people living in the vicinity of a proposed project. Factors contributing to public safety concerns include increased traffic volumes and the potential for accidents associated with the proposed project such as spills, fires, explosions etc. These issues are typically addressed in the EIA although, with the exception of tangible health effects such as those related to dust (particulate matter), they are usually not explicitly addressed in the HHRA section because they cannot be quantified using standard HHRA methodology.

3.6 Complexity and level of effort for HHRA

The complexity and, consequently, the required level of effort vary between HHRAs. The appropriate level of detail and complexity for a particular application will likely be dictated by the outcome of the problem formulation stage of the HHRA. They will depend on the source,

chemical, exposure pathway, and receptor combinations that require evaluation. Direct exposure, such as inhalation exposure to chemicals in air, may be evaluated by comparison of modeled air concentrations with published human health-based exposure limits. Other exposure pathways, particularly those related to food consumption, may require more complex multi-media exposure modelling.

4.0 HUMAN HEALTH RISK ASSESSMENT PROCESS

4.1 Overview of HHRA framework

HHRA is generally carried out according to a common framework that was originally established by the US EPA in the 1980s for human and ecological risk assessment of Superfund sites (NAS, 1983; US EPA, 1986; US EPA, 1989). This framework has subsequently been adopted by many jurisdictions, including Health Canada (2009a, 2009c), the Canadian Council of Ministers of the Environment (CCME, 2006), EnHealth (2002) and Alberta Environment (2007) and is now widely accepted as a standard basis for HHRA. The framework, illustrated in Figure 4.1, comprises four main stages: problem formulation, toxicity (or hazard) assessment, exposure assessment and risk characterization.

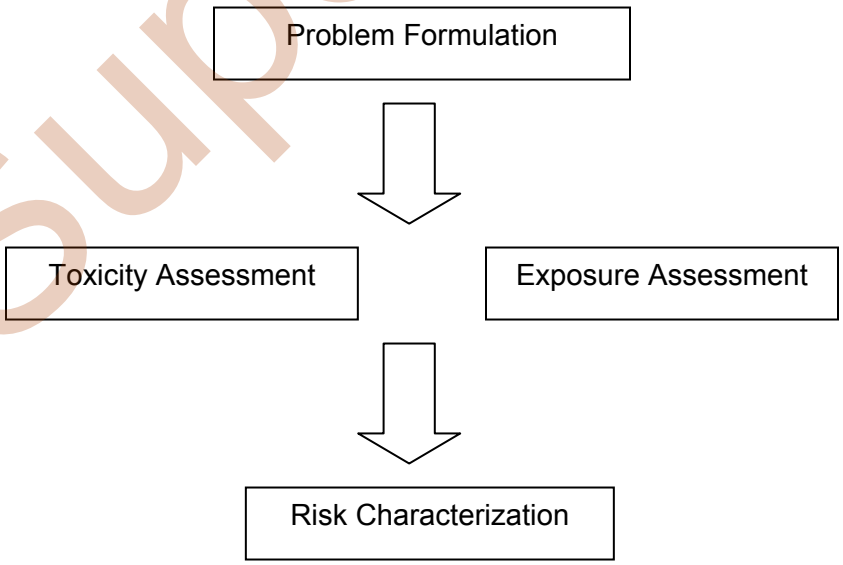

Figure 4.1 Human Health Risk Assessment Framework

These four stages are the minimum components of a complete risk assessment and may be carried out on a stand-alone basis. However, in the context of an EIA, an HHRA is normally part of a larger, integrated process that includes data collection and validation, risk assessment, risk management/mitigation, and communication/consultation.

The main stages of the risk assessment process are described in the following sections. Detailed guidance for HHRA may be found elsewhere (e.g. US EPA, 1989; NERAM, 2000; EnHealth, 2002; US EPA, 2005; Health Canada, 2009a; Health Canada, 2009c). The following sections summarize the approach and discuss considerations specific to HHRA for EIA.

4.2 Problem formulation

Problem formulation is the first stage of any risk assessment and involves screening of the three main components of human health risk: chemicals, receptors and exposure pathways. The screening is based on a thorough characterization of the project and its setting. The objective of the problem formulation stage is to develop a conceptual model that describes the project and its interactions with the surrounding human population and the environment on which their health depends. The conceptual model also assists in determining what additional data may be required to complete the risk assessment, and which of the chemicals, pathways and receptors are significant and most relevant to the project and surrounding area.

The goal of this stage is to focus the quantitative risk assessment on those chemicals, pathways and receptors that have the greatest potential to contribute to health risk. It is at this stage of the assessment in which AHW should be engaged to ensure that the scope and nature of the risk assessment is adequate. Input from other stakeholders should also be considered, as it might impact the overall design of the HHRA. How input from stakeholders was incorporated into the HHRA should be explained.

4.2.1 Chemical identification and screening

All chemicals and substances associated with a project or facility must be identified. This includes not only chemicals anticipated to be present in planned emissions or discharges, but

chemicals that are used, handled, stored or disposed and which may be inadvertently or accidentally released to the environment under various conditions such as fugitive emissions and spill scenarios. The identification of chemicals is normally a part of the facility design process. Substances identified must also include criteria air pollutants such as nitrogen dioxide, sulphur dioxide and particulate matter, precursors of chemical transformation products that have the potential to cause adverse effects, and other environmental contaminants that may be present in emissions from the project.

The chemicals and other substances identified are then screened in order to ensure that those having the potential to impact human health are retained as chemicals of potential concern (COPC) and carried forward to subsequent stages of the risk assessment.[2] A number of approaches are commonly used for chemical screening including:

1) *Toxicity-based:* This method utilizes the concept of toxic potential, whereby the toxic potential of a given chemical is determined as the product of its emission or deposition rate and toxicity (this is commonly expressed as ratio of the emission or deposition rate and a risk-based exposure limit). The toxic potentials of all identified chemicals are ranked and summed. Those chemicals with the greatest toxic potentials, whose combined toxic potential represents the major part of the total toxic potential (typically 99%), are retained for further consideration in the risk assessment.

Persistence and Bioaccumulation-based: This screening method is typically applicable to indirect pathways whereby the potential for human exposure is dependent on chemical uptake into secondary media; it involves consideration of the fate and persistence of chemicals. In particular, bioaccumulative substances such as polycyclic aromatic hydrocarbons (PAH), may be screened according to their persistence and potential for bioaccumulation. For example, an approach could be used whereby criteria such as half-life in soil, octanol-water partitioning coefficient (K_{ow}) and other physical-chemical properties are applied to assess persistence and potential for bioaccumulation of a given chemical.

[2] Criteria pollutants, if being emitted by a proposed project, will automatically screen on to all assessments and, consequently, would not go through a screening process.

Alternative screening methods may be used, but must be scientifically defensible and applicable to EIAs. Depending on the potential exposure pathways and scenarios being considered and the availability of appropriate screening criteria, a screening must always consider *both* toxicity-based, and persistence and bioaccumulation-based criteria. As well, a chemical screening must be done for the ingestion/inhalation pathways and for each exposure duration (acute and chronic) if they are being evaluated in the HHRA.

Where modelling has been conducted to estimate exposure concentrations, such as air quality modelling, maximum predicted exposure concentrations can be compared directly with screening criteria. The screening criteria should be based on published exposure limits or guidelines. Additional conservatism is generally introduced by adopting the lowest available criteria and utilizing maximum predicted exposure concentrations. The goal of the screening is to ensure that no chemical with the potential to cause adverse effects is excluded. When using published exposure limits, the limits selected must be confirmed to be health-based. The limits must also be appropriate to the exposure scenario (e.g. acute or chronic) and exposure route (e.g. inhalation or oral) and sufficiently cautious to account for other sources or pathways of exposure, interactions with other chemicals, uncertainties and other considerations that may arise during the detailed risk assessment.

If chemicals are present for which chemical-specific toxicity data are not available, they are typically grouped with similar substances and represented by surrogate compounds. Chemicals should not be excluded from further consideration on the basis of an absence of appropriate screening criteria or toxicity data. If chemicals are excluded for other reasons, full justification should be provided.

It is important to note that any chemicals identified as a specific concern by stakeholders and regulators, which are being released from a project, should be addressed in the HHRA.

The screening process should be fully documented, transparent and reproducible and justification should be provided for the exclusion of chemicals or groups of chemicals from further consideration in the risk assessment. If a screening process is not used, then all the chemicals must be evaluated in the risk assessment.

4.2.2 Receptor identification and screening

Receptor

A hypothetical individual who has specified characteristics, behaviour and location which allow an estimation of exposure via multiple exposure routes.

The locations of all receptors present in the study area or critical receptors must be identified. This would include identification of residences, agricultural, commercial, industrial and institutional facilities, recreational areas and areas subject to Aboriginal and other traditional land use. As part of this identification process, the receptor types (e.g. residential, agricultural recreational, transient, Aboriginal) and age classes (e.g. infant, toddler, child, adult) likely to be present would be identified. Health Canada (2009a, 2009c) defines standardized age classes for receptors and the potential for them to be present based on land use. Where a permanent receptor location is not identified at the maximum point of impingement (MPOI) or equivalent, a recreational or transient receptor should be evaluated at that location. Consequently, an estimate of the duration of transient exposure will be necessary.

Consideration should be given at the receptor screening stage to critical receptors (as described in earlier Section 3.2.2) whose potential for exposure to a chemical may be greater than the defined generic receptor categories. The selection of receptors is also dependent on exposure pathway and is therefore related to the screening of exposure pathways discussed below.

4.2.3 Exposure pathway identification and screening

Potential exposure pathways are identified for all COPC and receptors identified previously. An exposure pathway requires a chemical source, a mechanism of release, a transport mechanism in the relevant environmental medium (or media), a point of exposure (receptor) and an exposure route (mechanism of intake). For an exposure pathway to be operative, all of the above elements must be present. If any are absent or inactive, the exposure pathway is inoperative. Typical exposure pathways include:

- Inhalation of volatile substances or particulate matter;
- Ingestion of water, soil, agricultural produce, vegetation, fish and game; and,
- Dermal contact with soil or water.

Once the potential exposure pathways have been identified, pathway screening is conducted in association with receptor screening to eliminate those pathways that are inoperative and identify those remaining pathways that should be included through to the conceptual model. Not all pathway/receptor combinations are necessarily carried forward to the detailed risk assessment. Further screening may be undertaken to exclude pathways whose contribution to exposure for a particular chemical and exposure route are expected to be insignificant. However, all potential exposure pathways are amenable to assessment under baseline or background conditions, even pathways that are not likely to be affected by the proposed project. Further to this, even though project impacts to a particular medium (e.g. groundwater or surface water) may be negligible, other associated pathways (e.g. ingestion of water) should still be considered if they contribute to the overall or total multi-media chemical loading to human receptors and, as such, should be assessed in the risk assessment.

4.3 Toxicity Assessment

Toxicity assessment is conducted for all chemicals of potential concern, and is generally conducted in parallel with the exposure assessment (described later in Section 4.4) to ensure that the resulting toxicity values are appropriate to the exposure scenario being considered. It involves identification of the potential toxic effects of these chemicals and the estimation of either: a maximum dose or concentration of each chemical to which a receptor can be exposed without an appreciable risk of adverse health effect (threshold dose or concentration); or, depending on the type of chemical, the relationship between dose and incidence or severity of adverse effect (dose-response relationship).

4.3.1 Exposure limits

The objective of the toxicity assessment is to establish appropriate exposure limits for each chemical of potential concern. Exposure limits are typically selected from values published by appropriate regulatory agencies or, in cases where appropriate regulatory values are not available, the development of *de novo* values based on the critical evaluation of published toxicity studies.

Exposure Limit

The amount or dose of a chemical that is unlikely to produce adverse human health effects.

Exposure limits may be used both for chemical screening (as described previously in Section 4.2.1) and for quantitative estimation of risks. The availability and selection of appropriate values depends to some extent on the exposure pathways being considered. For certain direct exposure pathways such as air inhalation or ingestion of drinking water, health-based regulatory exposure limits, such as acute or chronic ambient air quality objectives or drinking water guidelines, may be used as exposure limits provided that the basis is clearly understood, defensible and consistent with the health protection goals applicable in Alberta. Otherwise, published regulatory exposure limits from accepted sources should be used.

Exposure limits are expressed in various forms, depending on the class of chemical and route of exposure. For threshold chemicals (non-carcinogens), exposure limits are typically expressed as reference concentrations (RfC) for acute and chronic air exposures and reference doses (RfD) for exposure to other media via routes other than inhalation. These are sometimes referred to as tolerable concentrations and tolerable daily intakes, respectively. For carcinogens a risk-specific concentration (RsC) is commonly specified for air exposure and a risk-specific dose (RsD) is used for other pathways. Risk-specific concentrations and doses are calculated from cancer slope factors or unit risks derived for the particular chemical and for each relevant exposure route, although some sources of toxicological information publish only the slope factor or unit risk. The risk-specific concentration or dose is directly linked to the target cancer risk; it is therefore essential that the target cancer risk implicit in the RsC or RsD be specified, and that values adopted from other jurisdictions be adjusted to be consistent with the 1 in 100,000 incremental lifetime risk level above background considered acceptable in Alberta.

Sources of toxicity information commonly used in Alberta include the following:

- AENV (2009b) Alberta's Ambient Air Quality Objectives: http://environment.alberta.ca/645.html; http://environment.alberta.ca/1066.html
- Health Canada (2009b) Toxicity Reference Values: http://www.hc-sc.gc.ca/ewh-semt/pubs/contamsite/part-partie_ii/index_e.html
- US Environmental Protection Agency Integrated Risk Information System (IRIS): http://www.epa.gov/iris
- California Environmental Protection Agency: http://www.oehha.ca.gov/risk/ChemicalDB/index.asp

- Agency for Toxic Substances and Disease Registry Minimal Risk Levels (MRLs): http://www.atsdr.cdc.gov/mrls/index.html
- World Health Organization: http://www.inchem.org/; http://jecfa.ilsi.org/index.htm; http://www.euro.who.int/air
- Netherlands National Institute of Public Health and the Environment (RIVM): http://www.rivm.nl/en/

While Health Canada (2009a) specifies a hierarchy of preferred values, AHW recommends that the most cautious value be used for HHRA conducted as part of an EIA. The rationale for the selection of toxicity values or exposure limits should be provided for all chemicals. Detailed scientific rationale should be provided for the adoption of values less stringent than any published regulatory benchmark.

In some cases it may be appropriate to consider the bioavailability of a chemical related to the exposure route and exposure medium being considered compared to the bioavailability related to the exposure route and medium used to derive the exposure limit, particularly if an exposure limit is being extrapolated from one exposure route to another. Bioavailability is normally evaluated through the use of relative absorption factors (RAFs). RAFs have been published by Health Canada (2009b) for extrapolating oral exposure limits to the dermal exposure route; at this time a RAF of unity is normally assumed for all other extrapolations, such as applying oral exposure limits to inhalation exposure limits or *vice versa*. For more information on bioavailability assessment, Health Canada's detailed quantitative risk assessment guidance (Health Canada, 2009c) can be consulted. In any assessment of bioavailability, it is cautious to assume 100% bioavailability for the exposure route and medium used to derive the exposure limit; since most are defined based on the administered dose, not the absorbed dose. Consequently, RAFs should only be applied when the absorbed dose in the toxicity study is known and accounted for in the exposure limit.

4.3.2 Toxicity of chemicals with no environmental regulatory exposure limits

In some cases, there may be chemicals of concern for which no environmental regulatory agencies have established exposure limits. The absence of a regulatory exposure limit is not considered grounds for excluding a chemical from an HHRA.

The development of *de novo* exposure limits is beyond the scope of this document. Methods for de novo derivation of exposure limits are provided by Health Canada (2009a), as well as the USEPA. It should be noted that other regulatory limits, such as occupational exposure limits should be searched, but such regulatory limits cannot be directly applied to environmental exposures without some rational judgement to adjust for the differences which inevitably exist between occupational and general population exposures, not to mention different receptor susceptibility. In addition, a surrogate approach may be appropriate for evaluating toxicity. If the chemical can be grouped with similar compounds (e.g. polycyclic aromatic hydrocarbons, or PAH) that could reasonably be expected to have similar modes of toxicity, then the most cautious exposure limit defined for a chemical in that group may be used to represent the toxicity of the entire group. If this approach is taken, all of the chemicals in the defined group must be treated as having additive toxicity (described in Section 4.3.3).

4.3.3 Toxicity of mixtures

Most HHRAs involve more than one chemical of potential concern. Whenever exposure to multiple chemicals occurs, there is the potential for the toxic effects of both chemicals together being different from the effects of independent exposure to the chemicals. Possible chemical interactions include:

- additivity (the combined effects of two or more chemicals is equal to the sum of the individual effects)
- antagonism (where one chemical blocks or reduces the effect of another)
- synergism (where the combined toxicity of two or more chemicals is greater than the sum of the individual effects)
- potentiation (where one chemical increases the toxicity of another without necessarily being toxic itself).

For some closely related groups of chemicals, these interactions are explicit in exposure limits defined by regulatory agencies. For example, several regulatory agencies have defined potency

equivalence factors (PEFs) or toxic equivalency factors (TEFs) for carcinogenic PAH, relating the toxicity of individual PAH to that of benzo(a)pyrene in order to evaluate the cancer risk of a mixture of PAH.

However, due to the large number of possible combinations of chemicals which may be associated with a particular source or project, regulatory agencies do not typically specify approaches for assessing the effects of mixtures for anything other than well-defined chemical groups. It is the responsibility of the risk assessor to evaluate all chemicals of concern in an HHRA for potential chemical interactions. In general, it is considered cautious to assume that the effects may be additive, unless it can be specifically demonstrated that different chemicals have different mechanism of action on the same cellular target.

4.4 Exposure assessment

The exposure assessment, which is typically conducted in parallel with the toxicity assessment, consists of an estimation of the intake by human receptors of the chemicals of potential concern. Estimation of the intake rate, or dose, involves the determination (by direct measurement and/or predictive modelling) of the chemical concentration in each relevant exposure medium and the estimation of the intake rate for the respective medium; the combination of concentration and intake rate yields the estimated intake.

4.4.1 Fate and transport considerations

The estimation of chemical concentrations in various exposure media is normally performed using some form of chemical fate and transport modelling. For instance, chemical concentrations in air at identified receptor locations are estimated using air dispersion modelling conducted for the various assessment cases as part of the air quality component of the EIA. Modelling is also commonly performed to assess chemical fate and transport in other media, as well as in multiple media where required to evaluate indirect exposure pathways. Numerous fate and transport models are available for the modelling of chemicals in various media; model selection should take into account applicability and relevance to the transport media and processes, defensibility and regulatory acceptance of the model(s), and availability of appropriate data (Health Canada, 2005; Mitchell et al., 2006). Data requirements for fate and

transport modelling include physical and chemical properties for the chemicals of potential concern, bioconcentration and bioaccumulation factors for the relevant media, and site-specific or area-specific meteorological, hydrogeological and soil data as appropriate. The use of a particular model should be justified, transparent, reproducible and selection of model input parameters should be supported with reference to appropriate primary literature sources.

The use of proprietary fate and transport models in HHRA poses a problem for reviewers if no means are provided by the risk assessor to allow the reviewer to be able to validate the model predictions. The model predictions must be made available in a format that allows reviewers to test the validity of model predictions. Submission of model data in spreadsheets that allow running of the model under the terms of a confidentiality agreement regarding use of the model may be one way to overcome this challenge.

4.4.2 Exposure concentrations

Predicted exposure concentrations under the four project assessment scenarios are typically obtained using modelling. However, for the assessment of background exposures, site-specific or area-specific measurements of chemical concentrations in relevant exposure media should be obtained. Examples of measured data include concentrations in ambient air, surface water, groundwater, soil, fish and vegetation and, if available, wild game. In general, exposure media sampling are required to help characterize the baseline case. Measured background concentrations of chemicals in the various environmental media will be added to the predicted concentrations of chemicals for the baseline case. Background data for water, soil, air, fish and vegetation should be collected and analyzed to provide direct point-of-exposure concentration data for input to the HHRA. As a variety of sampling procedures and statistics may be employed, a rationale must be provided in support of the methods used. As recommended by Health Canada (2009a) in most cases it is expected that the maximum measured chemical concentration will be used, unless appropriate justification can be provided to support the use of another statistic (i.e. the data are sufficiently numerous and rigorous to warrant an alternate statistical treatment). If current and statistically robust regional data are available these may also be used in combination with or in comparison to data collected from study area.

4.4.3 Intake modelling

Where the exposure limits are expressed in terms of dose or intake, it is necessary to estimate the human intake of the chemical. The daily intake of a chemical from a particular medium is calculated (in general) as the product of the concentration in the exposure medium and the intake rate of that medium, normalized to body weight. This daily intake will represent average or typical intake if calculated employing the average chemical concentration, or will represent maximal intake if the maximum chemical concentration is employed. An exposure term, to account for exposure frequency and duration, and a bioavailability or absorption factor are applied as appropriate. Detailed equations for the estimation of intake rates may be found in various sources (e.g. Health Canada, 2009a, 2009c; CCME, 2006; US EPA 2005). Standard human exposure factors (receptor characteristics, intake rates, time-activity patterns etc.) are available in various published sources (e.g. Richardson, 1997; CCME, 2006; EHD, 1998; US EPA 1997 & 2005). Preferences should generally be given to Canadian sources, although the use of data from other countries may be appropriate if Canadian data are either lacking or dated. Bioavailability or relative absorption factors are identified in the toxicity assessment.

Human exposure factors should be selected to represent relevant receptor(s) and should consider the presence of critical receptors (as described in earlier Section 3.2.2) where necessary. Behavioural and consumption characteristics of Aboriginal receptors should take into account traditional knowledge and land use. In addition, information obtained from the community consultation process should be considered, as appropriate, in assigning or modifying receptor characteristics. Full justification and references must be provided for the selection of human exposure factors, including the outcomes from the community consultation.

4.5 Risk characterization

The risk characterization stage combines the outcomes of the toxicity assessment and exposure assessment to provide a quantitative estimate of risk. In the HHRA, risk is normally expressed as a ratio of estimated exposure concentration or dose to the reference concentration or dose, respectively, for threshold chemicals (non-carcinogens) or as an ILCR (for carcinogens). In the EIA it is common to use the concept of concentration ratio (CR) or exposure ratio (ER) to facilitate comparison of risks associated with both classes of chemicals. For threshold

chemicals, the CR or ER is the ratio of the estimated receptor exposure to the exposure limit; for carcinogens, the ratio is equal to the estimated exposure concentration or dose to the risk-specific concentration or dose, respectively, where the latter are expressed in relation to the accepted target ILCR (i.e. 1 in 100,000). The potential risk expressed as an ER is calculated as follows:

$$Exposure\ Ratio\ (ER) = \frac{\text{Exposure estimate}}{\text{Exposure limit (RfD or RsD)}}$$

ERs are typically presented summed for multiple exposure pathways (ingestion, inhalation, dermal absorption) as appropriate. In cases for exposures by inhalation, the potential risk is expressed as a CR, calculated as follows:

$$Concentration\ Ratio\ (CR) = \frac{\text{Concentration in air}}{\text{Exposure limit (RfC or RsC)}}$$

CRs or ERs of less than or equal to unity or one (i.e. ≤ 1) indicate that the risk of adverse human heath impact is within the range considered acceptable. As the CRs or ERs approach one, greater assurance of the validity of the assumed or default values may be required to assure that they are not unreasonably precautionary. Depending on the magnitude, CRs or ERs greater than unity do not necessarily indicate that adverse health effects are expected to occur, or that the health risks are considered unacceptable. A ratio greater than unity or one (i.e. > 1) is normally a trigger for further evaluation of the significance of the estimated risks (described Section 5.1), a need for locally validated data as opposed to reliance on default assumptions or may indicate the need for risk management of the project.

The risk characterization stage also includes the evaluation of uncertainties in the risk assessment, as well as the reporting and presentation of the risk assessment. These components are discussed, separately, in the following sections.

4.6 Uncertainty analysis

Human health risk assessment, like many predictive processes, is subject to uncertainty. Risk assessment involves a number of assumptions, both in terms of assigning parameter values and in modelling physical, chemical and biological processes. These assumptions necessarily involve uncertainty, generally as a result of lack of data or knowledge regarding parameter values and processes. However, the results of a risk assessment are also subject to uncertainty as a consequence of natural variability in human receptor characteristics amongst the population, the distribution of chemical concentrations in the environment, and other factors. Uncertainty due to lack of information can generally be reduced somewhat by the collection of additional data. Uncertainty due to natural variability cannot be reduced by additional data, although further data can facilitate the understanding and characterization of this uncertainty. Assumptions used in HHRA are typically cautious to account for uncertainty and ensure that human health risks are not under predicted. An uncertainty assessment specific to each of the four stages outlined in the risk assessment framework (Figure 4.1) should be provided.

The main purpose of evaluating uncertainty at the risk characterization stage is to assess the degree of confidence in the risk estimates. A discussion of uncertainty places the results into context and assists in the communication of risks to the public. For example, overly cautious assumptions may be used at the outset or screening stage of a risk assessment. The uncertainty analysis also serves to guide the collection of additional data and, in this context, may be undertaken iteratively as the risk assessment proceeds. If predicted risks are found to be within the range considered acceptable, further data and detailed modelling may not be required. However, if initial risks are found to exceed target levels, refinement of the assumptions, collection of additional data and more detailed modelling may be required.

4.7 Reporting

HHRAs conducted for EIAs are subject to detailed review by regulatory agencies and stakeholders. They must be consistent with the seven principles outlined in Section 1.2. The HHRA report must therefore be comprehensive and complete, documenting assumptions, inputs and modelling methods and the quality and quantity of data, in sufficient detail to facilitate

the replication of the results if necessary (accompanied by a worked example). The report must document the rationale for screening of chemicals of potential concern, receptors and exposure pathways, and must contain detailed justification for the selection of toxicity reference values or exposure limits. As well, included in the report, there should be an interpretation of the results of HHRA and discussion of potential mitigation measures.

A sample outline for a risk assessment report is available in Appendix A. Alternative formats are also acceptable, provided all of the required information is included.

5.0 RISK MANAGEMENT AND MITGATION

5.1 Interpretation of HHRA results

The results of an HHRA are generally interpreted in the context of both the overall levels of human health risk under the various assessment scenarios and the contribution of the proposed project alone[3] to estimated risk. Overall levels of risk are compared with levels considered generally acceptable through the use of a CR or ER. Due to the conservatism in the establishment of the toxicity benchmark(s) and in the risk assessment process itself, an estimated CR or ER greater than one does not necessarily imply that risks are unacceptable or that adverse health impacts are expected. Care is necessary to present unambiguous estimates of risk and their applicability to potentially affected individuals because a failure to do so may raise public concern even in cases where an accurately estimated risk may be negligible, but the precautionary assumptions may appear high enough to raise public concerns.

As noted previously, a CR or ER of less than or equal to one normally indicates that risk estimates are within the range considered acceptable. A CR or ER exceeding one should be discussed further both in the context of the project alone and various assessment scenarios. The nature and likelihood of potential adverse human health effects should be described as well as the overall conclusions of the HHRA. As well, the significance of the estimated risks should

[3] It should be noted that even though a proposed project alone may not increase risks appreciably beyond the existing levels, unless the project contribution is demonstrated to be zero, these elevated risk levels and their implications to human health should be discussed.

be assessed in the context of the assumptions made in the HHRA including a description of the overall strengths and limitations (including uncertainties) of the assessment and their impact to the level of estimated risk.

Further action may be required depending on the magnitude of the exceedance starting with closer scrutiny of the default assumptions and how appropriate is their degree of precaution. There may be a need for incorporating mitigative measures or some other form of risk management into the planning, design and implementation phases (construction, operation, reclamation) of the project if default assumptions are validated as reasonable.

5.2 Incorporation of results into project design, operation and monitoring

Mitigation

The elimination, reduction or control of adverse environmental effects of a project.

If project contributions to human health risk are found to be significant, mitigation measures may be required. A discussion of the mitigative options that may be considered for various types of project or facility is beyond the scope of this document. Conceptually, however, mitigation or risk management strategies fall into two main categories: measures that are incorporated into the planning or design of a project with the aim of reducing emissions of chemicals of potential concern; and measures that are aimed at reducing the exposure of human receptors. The former may include further treatment or recovery of waste or emissions streams, modification of operating procedures in response to conditions (e.g. meteorological) that may result in higher exposures. The latter category may be further divided into engineered or physical measures aimed at reducing exposure concentrations (e.g. point of use water treatment) and administrative measures (e.g. access controls, relocation of receptors).

Environmental monitoring may be used to assist with the implementation of, and to verify the effectiveness of, mitigation measures. Monitoring may include stack and fugitive emissions monitoring, ambient air monitoring, personal exposure monitoring, or periodic sampling of discharge streams and environmental media such as water, soil, vegetation, wild game and fish.

5.3 Incorporation of results into regulatory approval conditions

Any of the above measures could also form the basis for conditions that may be attached to the regulatory approval of a project application. Conditions may include specific requirements related to the design and operation of a facility, as well as the implementation of monitoring programs, risk management plans, or other measures aimed at protection of the human population.

Regulatory approvals issued by Alberta Environment are subject to appeals from the approval holder, or if directly affected parties file a statement of concern when the approval is advertised, such parties may have a right of appeal to the Environmental Appeals Board. Resolution of human health issues within the environmental impact assessment can help reduce the range of issues which may be subject to appeal

6.0 OTHER CONSIDERATIONS RELATED TO HHRA

6.1 Baseline community health

While the HHRA is usually more focused towards the quantitative assessment of the physical health of individuals or populations, specifically those health factors or indicators that may be directly affected by changes brought about by a project, current health status of a region should also be considered. Baseline community health studies have been undertaken for selected areas of the province. Baseline community health studies are not normally undertaken on a project-specific basis, although information regarding health conditions and health issues affecting the local population is generally obtained as part of the community consultation process. However, where local studies are available, they should be considered in the HHRA. Available information from such studies may include exposure to locally elevated concentrations of certain chemicals and associated health effects and local incidence rates of health conditions such as respiratory ailments, etc. This type of information is valuable for identifying critical receptors (as described in earlier Section 3.2.2), as well as in interpreting the HHRA in the context of population baseline, project and cumulative risks.

Any consideration of community health must be realistic in relation to the limited ability of any study method to discriminate health issues in a small population let alone to assign causation. Raising unrealistic expectations for what can be accomplished with community health studies can lead to community outrage when it later becomes evident that the studies are inevitably inconclusive.

6.2 Public concerns

As noted above the public consultation process may yield certain information on community health conditions. The process should also identify health-related issues and concerns of local residents, including those of Aboriginal communities. If there is a local perception that, for instance, a chemical being released by a project is impacting air quality, the EIA report should address this issue even if the relevant pathways may not otherwise have been identified as significant in the context of the proposed project through the initial screening. The identification of public concerns with respect to health issues is therefore very important in determining the scope of the HHRA. EIA reports are also important for informing the public of the potential effects of a project.

6.3 Socio-economic considerations

A number of linkages exist between socio-economic considerations and individual and population health. A number of socio-economic factors are health determinants, as discussed below, in terms of their effect on general well-being. Socio-economic considerations are explicitly addressed in a separate component of an EIA report; however, the potential for these factors to impact health, whether tangibly or otherwise, should be considered in conjunction with the results of the HHRA in interpreting the potential health impacts.

6.3.1 Health determinants

The general health of individuals and populations is determined by the interaction of a number of factors related to both physical health and socio-cultural well-being. These determinants of health include (Health Canada, 2004):

- Personal health practices and coping skills;
- Income and social status;
- Social support networks;
- Employment and working conditions;
- Social and physical environments;
- Education and literacy;
- Healthy child development;
- Biology and genetic endowment;
- Gender;
- Culture; and
- Health services

Most of these should be considered to some degree (often qualitatively) in the various components of an EIA. Other indicators which may be addressed in the HHRA include changes to quality or way of life, changes in social or cultural patterns, stress and fear. The latter are less amenable to quantification and may not be identified by the risk assessor other than through stakeholder consultation.

6.4 Traditional knowledge and land use

Traditional knowledge and land use, associated with Aboriginal communities and populations, are key considerations in the assessment of human health risks. Firstly, Aboriginal receptors may be at greater risk than the general population due to behavioural, cultural and lifestyle factors linked to environmental exposures (e.g. consumption of traditional foods), and as such, may be identified as critical receptors. Information on food sources, consumption rates, activity patterns and other behavioural characteristics should be collected through community consultation and incorporated explicitly into the risk assessment. In addition, information gathered from such consultation may provide important insight on linkages between HHRA and

other components of the EIA related to the terrestrial and aquatic environment. For example, identifying past studies or relevant experience can yield critical perspectives.

6.5 Spill and emergency response plans

- As noted in Section 3.5.6, public safety is often an important concern amongst residents in the vicinity of a project or facility. Concerns caused by the safety risks associated with upset events are typically addressed in spill and emergency response plans. Notification, emergency services and evacuation plans are all components of these plans that may involve, or directly affect, members of the public. Although the potential risks that necessitate these plans are not conventional human health risks in the sense of those addressed in the HHRA, the mitigation of these risks is closely linked to other risk management strategies associated with human health risk.

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GLOSSARY

AENV	Alberta Environment
AHW	Alberta Health and Wellness
CSF	Cancer Slope Factor
EIA	Environmental Impact Assessment
EPEA	*Environmental Protection and Enhancement Act*
ERA	Ecological Risk Assessment
HHRA	Human Health Risk Assessment
ILCR	Incremental Lifetime Cancer Risk
K_{ow}	Octanol-water partitioning coefficient
LCR	Lifetime Cancer Risk
MPOI	Maximum Point of Impingement
PAH	Polycyclic Aromatic Hydrocarbons
RfC	Reference Concentration
RfD	Reference Dose
RsC	Risk Specific Concentration
RsD	Risk Specific Dose
SIR	Supplemental Information Request

Appendix A – Sample Report Outline

1.0 Introduction
- 1.1 Project description
- 1.2 Terms of reference (EIA report TOR)
- 1.3 Approach and methodology
- 1.4 Scope of risk assessment

2.0 Background Information
- 2.1 Regional health conditions
- 2.2 Background environmental quality

3.0 Problem Formulation
- 3.1 Project and site characterization
- 3.2 Chemical identification and screening
- 3.3 Receptor identification, characterization and screening
- 3.4 Exposure pathway identification and screening
- 3.5 Conceptual model – acute exposure
- 3.6 Conceptual model – chronic exposure

4.0 Toxicity Assessment
- 4.1 Acute exposure limits and/or toxicity reference values
- 4.2 Chronic exposure limits and/or toxicity reference values
- 4.3 Health effects associated with chemical mixtures

5.0 Exposure Assessment
- 5.1 Chemical concentrations in air
  - Background air quality
  - Air modelling
- 5.2 Chemical concentrations in surface water
  - Background surface water quality
  - Surface water modelling
- 5.3 Chemical concentrations in soil and groundwater
  - Background soil and groundwater quality
  - Soil and groundwater modelling
- 5.4 Chemical concentrations in vegetation, produce, livestock, fish and wildlife
  - Background concentrations
  - Multi-media modelling
- 5.5 Acute exposure estimation
- 5.6 Chronic exposure estimation

6.0 Risk Characterization
- 6.1 Acute health risks
- 6.2 Chronic health risks – non-carcinogens
- 6.3 Chronic health risks – carcinogens
- 6.4 Discussion of health risks under baseline conditions
- 6.5 Discussion of health risks under application (or project) conditions
- 6.6 Discussion of health risks under future development case
- 6.7 Discussion of uncertainties, limitations and conservatism

Appendix A (continued)

7.0 Mitigation and Monitoring

8.0 Conclusions

9.0 References

Appendices

A Summary of community health consultations
B Chemical-specific toxicity evaluations
C Raw data
D Model inputs and exposure equations
E Worked example

