

DEFINING VULNERABLE POPULATIONS

A first step towards a policy framework on vulnerable populations

Purpose

The purpose of this consultation document is to seek broad input on a proposed definition of vulnerable populations within the context of chemicals management. Although the Government currently take vulnerable populations into consideration in its chemicals management program, there are opportunities to strengthen our approach. Seeking input on this document is a first step towards the development of a policy focussed on enhancing the protection of vulnerable populations through the assessment and management of risks associated with certain chemicals, in particular under the *Canadian Environmental Protection Act, 1999* (CEPA).

Background

Chemicals are an integral part of everyday life, essential to our health, wellbeing, economy, our communities and our homes. While chemical substances provide benefits, they may also have harmful effects on human health and the environment if not properly managed. The Government of Canada created the [Chemicals Management Plan](#) (CMP), with the aim of reducing the risks posed by chemicals to Canadians and their environment. This is accomplished by assessing certain chemicals used in Canada, and if found harmful to human health and/or the environment, appropriate measures are developed and implemented. The key federal statutes used by the program are CEPA, the *Canada Consumer Product Safety Act*, the *Food and Drugs Act*, and the *Pest Control Products Act*.

The CMP is delivered jointly by Health Canada and Environment and Climate Change Canada, with engagement from stakeholders and the expert science community.

Why we are engaging on this topic

The Government is committed to continuously improving the consideration of vulnerable populations in the assessment and management of chemicals. It is an opportune time to further consider vulnerable populations as the Government is setting new directions and objectives for chemicals management post 2020. Although engagement with stakeholders has been ongoing throughout the CMP, more recent discussions have been focused on what a chemicals management program could encompass after the current CMP objectives are met. During these discussions, the Government has heard that enhancing consideration of vulnerable populations is a key area of interest for stakeholders.

Furthermore, in June 2017, the House of Commons Standing Committee on Environment and Sustainable Development submitted its report on the review of CEPA. This report contains 87 recommendations to improve the Act and its implementation, some of which included re-examining how vulnerable populations are considered. In June 2018, the [Government submitted a follow-up response](#) to the Committee, outlining its commitments to those recommendations. This response included a commitment “to develop, engage on, and publish under CEPA a policy on vulnerable populations, which will include a definition of vulnerable populations and the objectives of the program, including the framework for how Health Canada considers vulnerable populations as part of risk assessments.”

The importance of moving forward in this area was also highlighted by a [focus session \(panel\)](#) on the “lived experiences” of Canadians impacted by chemical exposures as part of a May 2018 meeting of the [Chemicals Management Plan Stakeholder Advisory Council](#). The panel represented the perspectives of

the following groups: people with multiple chemical sensitivities, youth, indigenous women, workers in some occupational settings, as well as those in a lower socio-economic status.

How we consider vulnerable populations in current chemicals management activities

Health Canada recognizes the importance of considering vulnerable populations when delivering on its mandate to help Canadians maintain and improve their health¹. This is primarily achieved through science-based policy approaches. The *Pest Control Products Act* is one example of federal chemicals management legislation that explicitly requires consideration of different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors.

Whether considering vulnerable populations by policy or by legislation, Health Canada takes a [weight of evidence approach and applies precaution](#) when conducting a risk assessment. Exposure scenarios unique to certain populations and specific health effects that are unique to certain life stages are also considered.

Understanding the types and levels of chemical exposures in vulnerable populations is an important aspect of chemicals management. Currently, exposure information is obtained in different ways including from biomonitoring and surveillance studies such as the [Maternal-Infant Research on Environmental Chemicals \(MIREC\) study](#), the [Canadian Health Measures Survey](#), the Plastics and Personal-care Products use in Pregnancy Study, and the [Canadian House Dust Study](#). Food surveillance studies, such as the [Canadian Total Diet Study](#), are used to inform exposure levels to Canadians, whereas targeted food surveys are used to identify individuals with greater than normal levels of exposures to certain chemicals in the food supply (for example, bisphenol A in infant formula).

Exposure information is gathered from many sources such as Government research funded under the CMP, models which predict levels of exposure to chemicals (for example, exposure resulting from use of products in indoor settings), and through industry and other stakeholder submissions.

Understanding why some people are more susceptible to chemical exposures than others is another important aspect of chemicals management, specifically for risk assessment. For example, it is recognized that humans can be more susceptible to the harmful effects of chemicals at certain life stages such as during periods of rapid development at prenatal stages. Health Canada takes vulnerable populations into account in its risk assessments for new and existing substances under CEPA based on available information. This information can include information on how the chemical is used; study results submitted by manufacturers and importers; as well as measured and modelled concentrates in various media and in the built environment. To the extent that information is available, the risk assessments characterize exposure and risk to specific subpopulations. This includes individuals within the general population who, due to increased biological susceptibility and/or increased exposure, may be at a greater risk than the general population. To date, the focus has been mostly on infants and children, pregnant women, Indigenous Peoples and those living in the vicinity of commercial or industrial facilities.

Vulnerable populations identified during risk assessment are also considered in the risk management phase (e.g., guidelines, standards, regulations and education). Risk management actions are aimed at

¹ <https://www.canada.ca/en/health-canada/services/science-research/reports-publications/about-science-research/primer-scientific-risk-assessment-health-canada-health-canada-2010.html>

reducing exposures of chemicals to vulnerable populations that are most susceptible and/or where exposure is highest. For example actions may focus on managing products for children, such as the prohibition of bisphenol A in polycarbonate baby bottles and the prohibition of diethyltoluamide (DEET) in personal insect repellants for infants younger than 6 months. Risk management may also focus on providing advice specific to a subpopulation, such as pregnant women (for example, mercury and fish consumption advice) or to others (for example, information provided to the chief medical officers and nutritionists in northern regions of Canada on risks related to selenium). Another example is risk management which focuses on managing industrial releases due to concerns for nearby residents (for example, the use of pollution prevention planning for toluene diisocyanates in the manufacturing of foam).

How other jurisdictions consider vulnerable populations in chemicals management

Other jurisdictions also consider vulnerable populations in chemicals management activities, either by policy or by recognition in law. Two chemicals management regimes of note include the Regulation (EC) No. 1907/2006 of the European Parliament and the Council of the Registration, Evaluation, Authorisation and Restriction of Chemicals ([REACH](#)) and the United States (U.S.) *Toxic Substances Control Act* ([TSCA](#)).

REACH specifies that it may be necessary to identify different endpoints (possible effects of concern) for each relevant human population (for example, workers, consumers and humans exposed indirectly via the environment) and possibly for certain vulnerable sub-populations (for example, children, pregnant women); for different routes of exposure (oral, dermal, inhalation); and, for different exposure durations.

The TSCA was amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (*Lautenberg Act*) and now requires the Environmental Protection Agency (EPA) to consider risks to “potentially exposed or susceptible subpopulations” across the regulatory process for chemicals (for example, in prioritization, risk assessment, risk management).

Issue for consultation: Proposed definition of vulnerable populations

For the assessment and management of chemicals Health Canada and Environment and Climate Change Canada are proposing to adopt the following definition of vulnerable populations:

“a group of individuals within the general Canadian population who, due to either greater susceptibility and/or exposure, may be at greater risk than the general population of experiencing adverse health effects from exposure to chemicals”

For the purposes of the proposed definition of vulnerable populations, individuals with greater biological susceptibility include those who may be more vulnerable due to biological or health status including:

- life-stages where there is a change in normal development or function of biological systems, including the developing fetus during pregnancy, infants, children, youth and the elderly. Certain life stages are more susceptible to impacts on development, including from exposures to chemicals with endocrine related modes of action;
- sex-related susceptibilities such as impacts on reproduction including from exposures to chemicals with endocrine related modes of action; and,

- individuals who may be more susceptible to the impacts of chemicals due to pre-existing health conditions, such as illnesses or genetic disorders or due to heightened sensitivity to chemicals.

For the purposes of the proposed definition of vulnerable populations, individuals with greater exposures may include:

- infants and children who may have greater exposures to certain chemicals due to behavioural reasons such as soil and dust ingestion,
- people living near industrial or commercial facilities or any other area with elevated levels of pollutants, including mixtures,
- indigenous Peoples and communities who may be significantly impacted, due to their close ties to the land and their consumption of country and traditional foods,
- individuals with dietary habits different from the general population, including individuals with special dietary requirements, newborns and infants, new immigrants, or individuals in hunting and fishing communities consuming country foods which may have elevated levels of certain chemicals,
- individuals who may have increased exposure to chemicals due to their usage patterns, such as greater use of cosmetics by youth,
- individuals, who for occupational reasons, may be exposed to higher levels of chemicals; and,
- individuals, who for socio-economic considerations may be exposed to higher levels of chemicals, for instance through compromised housing conditions.

Although this proposed definition focusses primarily on physiological and exposure considerations, individuals' unique backgrounds (such as culture, language, geography, disability) can impact how the individuals are exposed to chemicals as well as influence their understanding, and how they manage risks related to chemicals.

The proposed definition of vulnerable peoples is consistent with the factors already considered when assessing risks to major identifiable subgroups under the *Pest Control Products Act*, including pregnant women, infants, children, women and seniors.

Health Canada's proposed definition of vulnerable populations is similar to that in the TSCA, as amended by the *Lautenberg Act*. The TSCA defines vulnerable populations as "a group of individuals within the general population (...) who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers or the elderly".

Moving forward towards a policy framework

As outlined in the June 2018 follow-up report submitted to the House of Commons Standing Committee on Environment and Sustainable Development, there are a number of actions that can be implemented to strengthen how vulnerable populations are considered in chemicals management.

Feedback received through this consultation will set the stage for subsequent consultations on how the Government of Canada can incorporate consideration of vulnerable populations in a more comprehensive and transparent manner under its chemicals management activities, in particular under CEPA. Additionally, this will include applying a vulnerable populations lens as part of a broader Sex and Gender-Based Analysis throughout the chemicals management framework.

A policy framework for vulnerable populations would encompass identifying actions across the chemicals management continuum ranging from research, monitoring and surveillance to risk assessment and risk management to public outreach. For example, there are certain populations that may not be adequately captured by Health Canada's current biomonitoring programs, such as Indigenous Peoples, people living near contaminated sites, people in rural communities, people from different socioeconomic backgrounds and new immigrants. Health Canada is considering developing smaller, more targeted biomonitoring studies to examine the potential exposures to these populations. These data will allow us to comprehensively assess and address risks to these populations. Health Canada is also working with provincial and territorial governments to determine if there is a greater role Health Canada could take in supporting provinces and territories in their mandates related to workplace exposures to chemicals.

This consultation is also a first step towards the development of a policy focussed on enhancing the protection of vulnerable populations through the assessment and management of risks associated with certain chemicals, which was a commitment made by the Government in its June 2018 follow-up report.

The House of Commons Standing Committee on Environment and Sustainable Development made a number of recommendations which intersect with vulnerable population considerations such as recommendations on endocrine disrupting substances and combined exposure to multiple chemicals. These will both be a focus of future consultations.

How to provide input

We are seeking input on the proposed definition as well as the illustrative examples in this paper by November 15, 2018. Please provide comments to the following address: hc.esrabsdirector-directeurberse.sc@canada.ca. Health Canada will establish a mechanism for sustained input from stakeholders and experts as we advance consideration of vulnerable populations in a more comprehensive and transparent manner.