Consideration of vulnerable populations in risk assessment

Fact sheet series: Topics in risk assessment of substances under the *Canadian Environmental Protection Act, 1999* (CEPA 1999)

The Government of Canada has committed to improving the consideration of vulnerable populations in the assessment and management of substances.

In 2018, the Government consulted Canadians on the definition of vulnerable populations in the context of federal chemicals management activities, and following the consultation, defined vulnerable populations as groups of individuals within the Canadian population who, due to greater susceptibility or greater exposure, may be at an increased risk of experiencing adverse health effects from exposure to substances.

This fact sheet communicates how the Government currently considers vulnerable populations.

How subpopulations with the potential for greater susceptibility are considered

Understanding that some individuals are more susceptible than others to harm from substance exposures is an important principle of risk assessment. Humans may be more susceptible to the harmful effects of substances at certain life stages. For example, this may be the case when biological systems are developing, as in the fetus, and in infants and children, or when biological systems begin to function less effectively, as in the elderly. People may also be more susceptible due to sex-related differences in physical characteristics, hormone levels, or sex-specific organs. Differences in genetic background may also affect biological susceptibility.

A key step in the risk assessment of substances is to collect available health effects studies through information gathering. Specific tests and studies can help to determine if there is biological susceptibility at certain life stages or if sex-specific differences exist. If this information is not available, the Government relies on various approaches for data needs, such as the use of analogues and read-across, for the risk assessments.

The health effects assessment considers the potential for increased susceptibility during different life stages, in different sexes or genetic backgrounds, from the available studies. This may include consideration of critical effects such as reproductive impairment, developmental effects and endocrine effects.

As an example, the screening assessment of the Phthalate Substance Grouping identified that males exposed during development were most susceptible to the endocrine effects of phthalate exposure. Substances with endocrine-related modes of action can affect the development and function of reproductive organs. Observed effects such as reduced male fertility, feminization of males and male reproductive tract malformations differed in male animals based on their life stage, such as the developing young; infancy, childhood and puberty; and adulthood.

How subpopulations with the potential for greater exposure are considered

Certain segments of the population have the potential for increased exposure to substances due to differences in:

- physical characteristics (for example, body weight, breathing rate)
- life stage (for example, infancy, pregnancy)
- behaviours (for example, mouthing and ingestion of non-food items, crawling)
- culture (for example, particular diets or product use)
- geography (for example, living near commercial or industrial facilities)
- socio-economic status (for example, living in substandard housing, having limited consumer choice).

An overlap of differences that increase exposure may further increase vulnerability.

The information gathering stage of the risk assessment includes a search for data that may identify people with greater exposure than the general population in Canada. This could include information on the concentration of a substance in traditional foods or human milk, concentrations of a substance in the environment (water, soil, air) around industrial sources of release, or the amount of substance leaching from a product.

During the exposure assessment, distinct exposure estimates routinely derived for different age groups take into consideration physical and behavioural differences during different stages of life. For example, infants and children ingest a greater quantity of food, drinking water, soil and dust per kilogram of body weight than adults, which may result in greater exposure to a given substance. In addition, infants and toddlers spend more time on the floor or on the ground (while crawling or playing) and have a greater tendency to put non-food items into their mouths.

Other subpopulations considered in the assessment when there is sufficient information to do so include people living near sources of substance release (such as metal mining operations or refineries, or industrial centres) who may have increased exposure to substances from current or historical releases to the environment. As an example, the screening assessment of a substance found in gasoline, dicyclopentadiene (DCPD), considered subpopulations living near gasoline service stations or bulk storage facilities in the screening assessment because of increased concentrations of DCPD in the air they routinely breathe. For some substances, academic researchers, government or industry measure concentrations in the environment. For other substances, concentrations may be predicted using models.

For some substances, information from biomonitoring studies (such as the First Nations Biomonitoring Initiative or the Northern Contaminants Program) or from food and nutrition surveys in country foods (such as the First Nations Food, Nutrition and Environment Study) can be used to estimate the potential for increased exposure in Indigenous peoples.

While certain occupations may also result in a greater exposure, CEPA risk assessments to date have not considered occupational exposure. The Government is working with provinces and territories to enhance the protection of workers, including potential consideration of occupational exposure in future CEPA risk assessments.

How vulnerable populations are considered in risk characterization

Risk assessment of substances under CEPA 1999 makes use of a weight of evidence approach and the application of precaution. A subpopulation having

greater susceptibility or greater exposure to a substance than the general population, does not necessarily mean a potential risk will be identified. To assess risk, the critical health effects (the hazard) of the substance as well as the potential exposure are considered together, often through the development of a margin of exposure. The risk assessment may include estimates for individuals with greater biological susceptibility or greater exposure. A potential risk identified for a vulnerable population is taken into consideration during the risk management phase.

For example, the Government restricted the use of the substance, 1,2-Benzenedicarboxylic acid, mixed C8-11-alkyl and 2-ethylhexyl and hexyl and isononyl diesters, which is a mixture of phthalate diesters used in plastics. The risk assessment concluded that developmental and reproductive effects could result from infants and children being exposed to this substance in plastic child care articles (such as pacifiers, baby bottle nipples, toys). The Government restricted the use of the substance as a plasticizer in toys and child care articles in order to prevent this risk.

Next Steps

The Government will continue to support research and monitoring to help improve knowledge and understanding of vulnerable populations, and will develop approaches and tools to support risk assessment activities aimed at these populations.