Assessing exposure of people in Canada and the environment to substances in products

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

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Chemical substances in products

Everyday products and manufactured goods are made of chemical substances. Paints, cleaning products, furniture, and toys are examples of products available to consumers. Other examples of everyday products include cosmetic and natural health products, such as shampoo, lotions, vitamins, and toothpaste. People in Canada and the environment can be exposed to substances that are present in products. This occurs from their use and release into the environment, including through product disposal.

In this fact sheet, the general term "products" is used to refer to all products that are available to consumers. This includes "consumer products" (as specifically defined under the *Canada Consumer Product Safety Act*), cosmetics, natural health products, non-prescription drugs, and other therapeutic products. This fact sheet does not cover direct or indirect exposures to substances present in foods or food packaging materials. Also, pest control products undergo scientific evaluations by Health Canada under the *Pest Control Products Act*.

A number of federal laws govern chemical substances for the protection of human health and/or the environment, including laws that apply to products. These include the *Food and Drugs Act*, *Canada Consumer Product Safety Act*, *Pest Control Products*

Act, and the *Fertilizer Act*, as examples. *Canadian Environment Protection Act, 1999* (CEPA) covers a range of activities that can affect human health and the environment, and it acts to address any pollution issues, such as from substances, that are not covered by other federal laws. Therefore, assessments of existing substances and new substances are carried out under CEPA and often include looking at the exposure of people in Canada and the environment to substances from products.

Products may come in different formats, such as liquids (for example, paint), gels (body wash, adhesive), semi-solids (deodorants, glue, face paint), or powders (laundry detergent, make-up) that are stored in various container types. Products may also be hard or formed articles, also called "manufactured items" in CEPA, such as furniture, clothing, textiles or toys. Substances in products may be:

- intentionally added as part of a formulation or mixture (an ingredient); or
- present unintentionally, left over from the manufacturing process

Information used for human health and ecological exposure assessment

Information from various sources is evaluated to assess the risk to people in Canada and the environment from exposure to substances in products. These information sources include data obtained within Canada or from other jurisdictions, including peer-reviewed literature and databases, assessments, survey data collected from industry under section 71 of CEPA, or other mandatory or voluntary information gathering tools to gain commercial information on uses and volumes in commerce in Canada [including information provided by stakeholder groups or through Significant New Activity (SNAc) provisions, where applicable], on product testing, on safety data sheets (SDS), and in the case of new substances, on exposure information included in a new substance notification. It should be noted that producing an SDS is not a legal requirement for products available to consumers; however, they are used to inform the assessment when they are available.

Qualitative and quantitative approaches of assessing exposure

For human health and the environment, exposure assessments of substances in products may be quantitative or qualitative. For a quantitative assessment, calculated or measured numerical values are used to estimate the exposures. In such a case, the quantitative exposure estimates may be based on predictive computer models or on the results of environmental monitoring or human biomonitoring studies (measurements of substances in the environment or in people) conducted in Canada. Monitoring data can provide an estimate of overall exposure from all sources of the substance, including from products.

Estimates of exposure for people in Canada or the environment are influenced by certain physical and chemical properties of the substances in the product, product use patterns, release pathways, knowledge of a substance's rate of entry and fate in the

body and the environment. In the absence of data, conservative assumptions that are protective of human health and the environment are used.

In other cases, exposures to substances in products are qualitatively determined, meaning estimates are not calculated numerically. Qualitative assessments are generally applied when available information indicates that exposure is not expected or would be minimal or when data are limited. The Risk Assessment Toolbox further explains when a qualitative approach might be used.

Human exposure to substances in products

People may be exposed to substances from the direct use of products (for example, applying lotions to your skin or spraying a product) or indirectly through the environment, such as water, outdoor and indoor air, soil, and dust. This type of exposure is estimated quantitatively, when data are available.

Direct human exposure from the use of products

Various approaches to estimate direct exposure from products have been employed by Health Canada, including the use of computational approaches and predictive models. Under the Chemicals Management Plan, different models have been used in numerous assessments for both existing and new substance assessments. The procedure followed is based on the properties of substances contained in the products, available data, and type of assessment. In estimating human exposures to substances from products, the models account for dermal (skin), inhalation (breathing), and oral (mouth) routes of exposure, depending on how the product is used. Some of these models or tools can estimate more specific dermal exposures (for example, fluids spilled onto the hand to mimic a certain activity) and air exposures (breathing in fumes) from the use of different types of paints, as examples.

Indirect human exposure from the environment

Estimating human exposure to substances from products, through environmental media (air, water, drinking water, dust, and soil), can be called "indirect" exposure. This type of exposure looks at different stages of the product lifecycle, from manufacture through to the use and disposal of a product, where environmental releases of substances from the product may occur. Estimates of potential exposures from the environmental releases of substances from products are based on conservative assumptions, monitoring, or modelled data. Sometimes predictions of exposures to the environment are used to estimate these indirect exposures to humans.

For human health assessments, the environmental exposure estimates from the release of substances during the manufacture of products may be used to predict the potential for exposure through drinking water, air, dust or soil. The use or disposal of a product will also influence its potential for exposure. For example, products that are rinsed off or

disposed of down the drain (such as shampoo or body wash) will enter a wastewater treatment system (WWTS) which may result in the substance being released to natural water systems. Also, landfill disposal and the potential for contaminated water runoff through WWTSs may result in substances entering surface waters (streams and lakes), as further explained in the environmental exposure section of this fact sheet.

Exposure estimates for substances in the indoor environment, such as indoor air or dust, may include long-term indirect exposure to substances from products. Sources may reflect incidental releases (for example, emissions from furniture) and intentional releases during the use of products (for example, spraying a cleaning product) as well as the release of substances into dust through gradual product breakdown.

Use of human biomonitoring data to estimate exposure

As mentioned, sometimes human biomonitoring data are used to estimate exposure. Biomonitoring is the measurement of substances in human tissues and fluids (for example, blood or human milk). The measurement tells how much of a substance, its precursors or metabolites are present in a person. Finding a measurable amount of a substance in the body, however, does not necessarily mean that an adverse health effect will occur or that it is causing harm.

Biomonitoring is a useful exposure assessment tool because the amount of substance measured can reflect all sources, routes, and durations of exposure to a substance. It is a direct measurement of the uptake and metabolism of a substance; however, linking measured amounts with exposures depends on a range of other factors, and it can sometimes be difficult to identify specific sources of exposure that led to the substance being present in the body. The fact sheet on the use of human biomonitoring data in assessment provides more information.

Exposure scenarios for human health

A variety of exposure scenarios involving products used by people in Canada are considered in the human exposure evaluation of an assessment. Scenarios are identified and characterized as follows:

1. All data and information, as described above, used to evaluate potential exposures to substances from various products are collected and considered for relevance to the Canadian population.
2. The most likely routes of human exposure are determined (for example, inhaled, absorbed through skin, or eaten), taking into consideration the physical and chemical properties of the substance, as well as the product use patterns. For example, a spray cleaner may result in exposure from the inhalation and dermal routes, but either dermal or inhalation exposure may be greater, depending on the physical properties of the substance.

3. Products leading to the greatest potential exposure are identified through consideration of the route of exposure, the amount of the substance in products, product amount used, and the duration and frequency of product use.
4. Exposure estimates can account for differences in exposures for various age groups and subpopulations who may have greater susceptibility or greater exposure (such as children, pregnant women or unique geographic or cultural subpopulations), where applicable. The differences may incorporate age-group specific exposure factors, such as body weight or frequency of hand-to-mouth exposures for young children.
5. The highest potential exposure estimates are initially the starting point in the exposure assessment; however, quantitative exposure estimates are further refined during the risk characterization stage of the assessment. This is when the exposure information is brought together with hazard (health effects) information about the substance to determine risk.

Exposure of the environment to substances from products

Scenarios to assess levels of the substance in the environment from products are selected according to analysis of the product's life cycle and the environmental medium where the substance is released (for example, water, air or soil). This includes exposure from the use of products as well as from product manufacture and formulation (earlier in their life-cycle). Environmental monitoring data of a substance in air, water, sediment, soil or organisms, may be used when assessing exposure of living organisms to substances from products. Models may also be used to estimate levels of a substance in the environment. Both environmental monitoring data and the use of models often provide complementary information for an assessment.

Manufacturing and formulation of products

Releases of substances to aquatic ecosystems or to air, with potential deposition to soil, may occur at industrial sites where products are manufactured or formulated. The resulting exposure of organisms or wildlife may be estimated using monitoring data, if available, on the levels of a substance in the environment close to the industrial site or point of release from a WWTS. Monitoring data on the concentration of a substance in WWTS effluent (discharged wastewater or outflow) can also be used to estimate exposure. In addition, calculations may be made to estimate releases of a substance at the manufacturing and formulation stage and the resulting levels in the environment.

For releases to aquatic ecosystems, these calculations are based mainly on the quantity of the substance used at the industrial site, the portion of the substance that may be lost during the industrial process, the effectiveness of substance removal by industrial and/or municipal WWTSs, and the dilution capacity of the water body (for instance, a lake or a river) that receives the effluent from the industrial facility or WWTS.

When substances are released to the environment through a WWTS, some will end up in the wastewater sludge resulting from the removal of solids from the wastewater. Substances in wastewater sludge have the potential to reach soil through the application of biosolids (treated sludge) to land. A model that considers the concentration of the substance in biosolids (treated wastewater sludge) can be used to estimate the resulting concentration in soil, due to the application of biosolids onto land, and exposure of soil-dwelling organisms and wildlife.

Substances may sorb (that is, "stick") to sediment when released to lakes and streams. The levels of a substance in sediment can be estimated by considering physical and chemical properties of the substance to determine how much it will sorb to sediment.

Releases of a substance to air from stack emissions due to product manufacture or formulation may also occur. When that is the case, atmospheric dispersion modelling can estimate the deposition rate to soil. Based on this rate, the level of a substance that is expected to be found in soil, after a certain period of time, can be estimated.

Product use and disposal

Releases of substances present in products can also occur to aquatic or terrestrial ecosystems after the products have been used. For instance, substances in products, such as soaps, toothpastes, and detergents, are released "down the drain," travel through sewers and end up in a WWTS. As described above, for releases to WWTSs from manufacturing and formulation of products, potential exposures to surface waters, sediments, and to soils (from application of biosolids) are estimated.

The concentration of a substance in water bodies that receive WWTS effluents, resulting from use and "down the drain" releases may be estimated using a modelling tool (called the Consumer Release Aquatic Model) developed by Environment and Climate Change Canada. This model combines the WWTS treatment level, distribution of dilution factors of the receiving water body, and the per person water discharge. Other factors, such as per person consumption of products or total amount of product used by people in Canada, are considered within the model. The results of the model include a distribution of expected concentrations of the substance in water close to WWTS effluent discharge points. WWTS removal rates may be based on measured data or estimated using models.

Products may also be disposed of as solid waste (in garbage) and end up in landfills. Most landfills in Canada discharge their leachate (the liquid that drains from a landfill) to WWTSs. Therefore, their contributions may be considered qualitatively through WWTS data.