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Review

# A review of human biomonitoring data used in regulatory risk assessment under Canada's Chemicals Management Program☆

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ABSTRACT

As a part of the Chemicals Management Plan launched in 2006, the Government of Canada is assessing and managing, where appropriate, the potential health and ecological risks associated with approximately 4300 substances under the Canadian Environmental Protection Act (1999). Since that time, nearly 3000 substances have been assessed, with human biomonitoring (HBM) data playing an increasingly important role for some substances. Case studies are presented, including both inorganic and organic substances (i.e., selenium, triclosan, phthalates), which highlight the impact and overall role HBM has had in regulatory decision making in Canada for these three substances as well as criteria used in the application of HBM data in human health risk assessment. An overview of its limitations in terms of how and when HBM data can be applied, when assessing human health in a regulatory setting, is discussed as well as the role HBM data can play in priority setting.



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## 1. Introduction

Globally, there are 70,000 to 100,000 chemicals in commerce, with amounts manufactured and used in the trillions of pounds (Woodruff, 2015). In Canada, the Domestic Substances List includes over 23,000 chemicals as being in commerce, with assessment activity focused on over 4300 chemical priorities under the Chemical Management Plan (CMP). Chemical inventories have also been reported in other countries as ~100,000 chemicals (Europe), ~84,000 chemicals (United States, or US), ~39,000 chemicals (Australia, Korea), and ~28,000 chemicals (Japan) (CIRS, 2011). Many of these countries report and monitor human exposure to environmental chemicals through the measurement of a chemical and/or its metabolite(s) in various biological matrices (e.g., serum, plasma, whole blood, urine, breast milk) via national surveillance programs. Measuring concentrations of chemicals in the human body has been in routine use in industry and parts of the wider public health community for more than 50 years (Choi et al., 2015). Internally, Health Canada has identified approximately 340 unique substances that have been measured in the general population across 5 different biological matrices (i.e., urine, plasma, serum, whole blood, breast milk) from over 20 countries including Canada (i.e., Canadian Health Measures Survey (CHMS), and other countries e.g., US Centre for Disease control National Health and Nutrition Examination Survey (NHANES), Demonstration of a study to Coordinate and Perform Human biomonitoring on a European Scale, Flemish Environment and Health Survey, Korean National Health and Nutrition Examination Survey, Human Biomonitoring of Environmental Chemicals in Israel, Czech Republic Human Biomonitoring Project, Catalan Health Interview Survey and the German Environmental Survey for Children for which human biomonitoring (HBM) data are available.

In Canada, approximately 4300 substances under the CMP have been identified as priorities for assessment under the Canadian Environmental Protection Act (CEPA), (1999). Since 2006, over 2700 substances have been assessed with over 130 substances concluded to be toxic, as defined under CEPA (1999). These "screening assessments" include a focus on general population health as well as assessing ecological risk. A "Risk assessment Toolbox" delineates the various types of approaches that can be considered for assessing a substance or group, including broad based approaches to more in-depth assessments that consider cumulative risk (Government of Canada, 2016). Of the 2700 substances assessed, ~230 (or ~10%) had HBM data available in various biological matrices (see Fig. 1), 62% of the 230 substances were organic and the remainder was inorganic substances. Breast milk, urine, whole blood and serum were the dominant matrices, accounting for approximately 75% of the HBM data. For the remaining 1550 substances that will be assessed during 2016–2020, it is estimated that 15–20% will have HBM data; which provides opportunities to apply this type of data in human health risk assessments in various ways. The increase in the number of HBM studies reflects, in part, the risk assessment community's call for more and improved exposure data in the general population (Albertini et al., 2006). As the number of HBM programs and types of chemicals monitored increases, there is also an increasing awareness of the public to the presence of chemicals in people. There are often challenges in communicating individual health risks associated with chemicals measured in a population or a sub- population biomonitoring study. With this increased awareness comes a need to communicate to the public not only the significance of the presence of a chemical in the general population but also potential sources and relating concentration with available toxicology (and epidemiological) data to initiate discussions of potential health risks.

There are a number of advantages in using HBM data in regulatory risk assessment. The use of HBM data may allow for direct and a more precise assessment of the distribution of risk in a given population, incorporating individual variability in exposure and kinetics (e.g., absorption, distribution, metabolism and excretion) (WHO, 2015). HBM data can be reflective of the absorbed dose into the human body and can provide a measure of integrated exposure from different exposure sources. This includes indoor and outdoor air, soil, dust, water, food and/or potential exposures from consumer products, including drugs and vitamins. However, some chemicals may simply pass through the body with little or no absorption, or be absorbed and distributed, or, depending on the specific chemical, be metabolized and excreted. Biomonitoring data incorporates exposures from all routes (i.e., oral, dermal and inhalation), all sources of exposure and can be useful for confirming exposures, estimating dose levels, and evaluating human health risks (US EPA, 2012).

There are a number of challenges in utilizing traditional methods (i.e. deterministic exposure estimates based on algorithms and/or modeling and concentrations of a chemical in media such as water, food, air or products) of estimating exposure to all these sources, especially when there are limited environmental monitoring data available or when trying to identify which products a substance may be found in. Building exposure models requires making many assumptions which introduces uncertainties in exposure estimates (e.g., product use frequency or concentrations). Based on a review of the use of HBM data in food safety assessments under the European Food Safety Authority, Choi et al. (2015) indicated that HBM data can reduce assumptions required when estimating dietary exposure to chemical substances and is

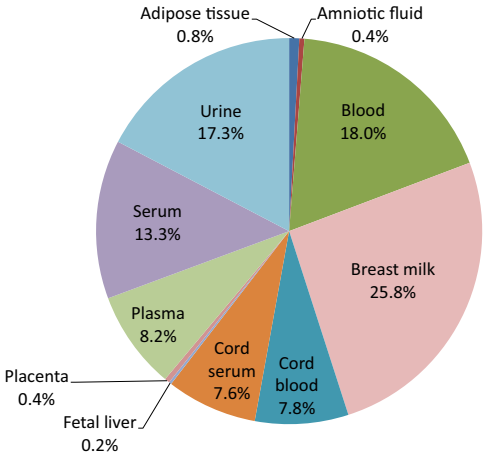


**Fig. 1.** Availability of HBM data in different matrices for CMP substances (2006–2012).