

The U.S. Centers for Disease Control and Prevention has repeatedly stated:

“Just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease. The toxicity of a chemical is related to its dose or concentration in addition to a person’s individual susceptibility. Small amounts may be of no health consequence, whereas larger amounts may cause adverse health effects. Research studies...are required to determine which levels of a chemical may cause health effects and which levels are not a significant health concern.”

<http://www.cdc.gov/exposurereport/3rd/>

The US National Research Council’s Committee on Human Biomonitoring for Environmental Toxicants declared:

“In spite of its potential, tremendous challenges surround the use of biomonitoring, and our ability to generate biomonitoring data has exceeded our ability to interpret what the data mean to public health.”

National Academy Science (2006) *Human Biomonitoring for Environmental Chemicals*. National Academy Press. <http://newton.nap.edu/catalog/11700.html>

While Product Stewards can take some comfort in CDC’s statement, experience has shown that reliance on this statement is insufficient

The challenges of interpreting biomonitoring are the focus of several different governmental and political authorities (e.g., European Commission, U.S. government agencies, OECD etc.) and by research organizations in many regions across the world, including ICCA’s Long Range Research Initiative (<http://www.icca-chem.org/>).

With scientific or technologic advancement comes responsibility. There is a need for product stewards to pursue development and dissemination of chemical-specific methods and information necessary to help shape reasonable, risk-based decision making for those products that are, or may be, included in a reliable human biomonitoring program -- this is embodied in the ICCA position.

Such actions are natural coming from a responsible industry. They are also vital for promoting correct biomonitoring interpretations to the public and for implementing risk management, if warranted.



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ICCA’s Position on Human Biomonitoring

ICCA has developed and endorsed a forward looking position on human biomonitoring. The ICCA position was adopted, in part, to alert companies about the issue and to provide a direction for associations and companies to engage proactively to address the challenges biomonitoring results pose. **The ICCA position is not a call for industry-sponsored biomonitoring studies** — it is a call for industry Product Stewardship to better understand human biomonitoring and to address the implications of human biomonitoring within the continuous improvement cycle of Product Stewardship.

The ICCA position contains 4 elements

1) Support for the Development of Science-Based Exposure Information. Exposure information is part of the core scientific foundation for risk-based decision making and therefore product stewardship.

2) Support for Science-Based Biomonitoring Programs. It is of critical importance that biomonitoring studies be based on sound scientific and public health principles. Biomonitoring study processes – from design, sampling, conducting chemical analyses, evaluating data and reporting results – need to meet exacting scientific standards, practices and ethics.

3) Support for the Appropriate Use of Biomonitoring Information in Risk Assessment and in Creating Public Policy. Interpreting biomonitoring results and using the results for regulatory or other decision making requires risk assessment — the integration of hazard and exposure. While biomonitoring can foster further research, track exposure trends, and form a component of an exposure assessment, biomonitoring by itself cannot answer questions about risk or the safety of the substance.

4) Support for the Appropriate Interpretation and Communication of Biomonitoring Information to Promote Risk Based Decision Making. Collaborative efforts (government, private entities, professional associations, medical and scientific experts) are needed to interpret and communicate biomonitoring results. Development & dissemination of chemical-specific methods & information necessary to interpret biomonitoring results & to promote risk based decision-making is a responsibility that companies, sector groups & associations share with the broader government and private sector health and environmental community.



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Human Biomonitoring: Implications for Product Stewardship



An informational brochure for
chemical producers, distributors
and formulators

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www.icca-chem.org

What is Human Biomonitoring?

Human biomonitoring is the measurement of specific substances in the human body, usually through the analysis of blood, urine, breast milk and tissue samples. Typically, biomonitoring studies rely on informed volunteers to provide samples of fluid or tissue at a single point in time. Samples are then analyzed to measure trace concentrations of naturally occurring and/or synthetic substances.

Humans are continually exposed to substances in our environment — from naturally occurring chemicals (in air, water and soil or those produced by plants, animals) and natural events (such as forest fires and volcanoes) and from man-made materials (such as substances released from facilities, mobile sources and products during use). Although scientists have long understood that our bodies absorb substances from our environment, today's technology allows researchers to detect and measure extraordinarily low concentrations of these substances in human blood, urine, tissues and milk. This field of research is known as biomonitoring.

Advances in analytical chemistry methods have resulted in lower levels of detection. With this sensitivity the products of chemistry are increasingly being shown to be present in humans at low, but measurable, concentrations. Without discussion of the scientific analysis of the significance of the data to the overall healthfulness of the public, such information will pose real challenges to the entire supply chain. All sectors -- from manufacturers, to formulators and distributors, to retailers -- may be asked to address concerns when a human biomonitoring study suggests exposure to chemicals contained in products or released from sites.

Where Understanding of Human Biomonitoring Fits Within Product Stewardship

Product Stewardship is an integrated business process for identifying, managing and minimizing the health, safety and environmental risks throughout all stages of a product's life. Product Stewardship programs serve the best interest of society and our stakeholders -- customers, employees, shareholders, regulatory bodies and the public.

Biomonitoring addresses human exposures to chemicals; therefore, understanding and addressing biomonitoring and its challenges are clearly vital aspects of Product Stewardship.

Biomonitoring studies can generate concerns about specific materials, processes and uses by customers, employees and the public. Therefore, product stewardship programs will need to address the potential implications, positive and negative, that biomonitoring results can have.

The responsibilities of product stewardship to make continuous progress toward a shared vision of no accidents, injuries or harm to the environment are clearly engaged. There is a need to be attentive to signals of significant health effects that could be related to a given exposure or set of exposures. Effective communication with the concerned parties may avoid alarmist and distorting interpretations.

Product stewardship programs should review informational and communication needs generated by biomonitoring studies in the same way that these programs address the needs for hazard data, release or exposure information. This should be an integral part of the activities inherent in evaluating potential hazards, exposures and risks associated with the use of products.

Why Product Stewardship Programs Should Address Human Biomonitoring

Biomonitoring can demonstrate actual human exposure

Biomonitoring results, when obtained from scientifically valid investigations, can provide direct, compelling information of actual human exposures. In some cases however, the human body internally produces a chemical that is exactly the same as a chemical from an external source.

While scientists have long known that exposure to trace substances in the human environment is a certainty, many in the public have been unaware of this inevitability, and the public may react with concern.

Biomonitoring results can have an emotional component that other types of environmental monitoring lack. Biomonitoring results are "personal" and may elicit a sense of "outrage" when a person is informed of having been subjected to involuntary (perceived as "unnatural") exposures & potential risk.

Lack of information or misunderstanding can stimulate additional concerns and calls for regulatory action, such as product deselection, substitution, premature regulation or other risk management actions.

Human Biomonitoring Challenges Product Stewardship Programs to Better Understand:

How inherent chemical properties, such as persistence and bioaccumulation, may increase the likelihood of human exposure.

What other attributes would make a substance amenable to inclusion as a biomonitoring endpoint (such as daily episodic exposure for a significant frequency/duration).

How manufacture and use of chemicals could contribute to human exposure (sources, uses and releases) both upstream and downstream from a company's activities.

Methods and data that are needed to interpret and communicate biomonitoring in a risk context.

Ways to deal with multiple sources of potential exposures and multiple producers. (Chemicals are produced by industry, but exposures of humans are also due to natural and/or non-industrial, non-point sources.)