CIA Chemical Industries Association

Working for chemical and pharmaceutical businesses

Human Biomonitoring – Can the current HBM4EU project meet the expectation?

Background

Biomonitoring is used to measure the presence of man-made and natural chemical substances in wildlife and humans. In the case of humans this usually involves the analysis of blood and urine samples. Biomonitoring cannot, however, be used to identify adverse effects in a population in isolation, and any information arising from this activity must be assessed in context with other data including the level of exposure and importantly the plausibility of a link between the substance and the adverse effects observed. The tool itself is not new; it was originally developed some decades ago by the chemical industry to monitor the health of employees to allow action to be taken to eliminate or reduce the exposure source where necessary. Outside the workplace the main benefit of human biomonitoring (HBM) is the ability to be able to identify long-term trends within a population. To do this, a baseline threshold or limit is needed to compare results against in order to determine if there is a biological effect impacting on an individual's health associated with the presence of a specific substance or family of substances. Government policy makers across Europe are now asking more from the tool in terms of whether it can provide evidence of biological effects to assist them with chemical policy making decisions. Industry is supportive of this approach providing decisions are taken based on sound science; it is not yet clear whether current HBM activities can really meet this expectation.

Current Status

In order to answer societal concerns concerning whether there is the potential for some chemical substances to have adverse health effects following exposure, particularly on adult reproductive health or on vulnerable populations such as children, several EU organisations have instigated the Human Biomonitoring for Europe (HBM4EU) project. This co-funded project, running from 2017 to the end of 2021, includes the UK and the European chemicals industry. In addition to this project, national HBM programmes exist in some EU countries (e.g. Germany, Belgium, France, Slovenia, Sweden and the Czech Republic) and further afield in Canada, Japan, Korea and the United States.

Our Opinions and Actions

- CIA believes the HBM4EU project can be of great benefit for all involved parties providing studies are appropriately designed, conducted, evaluated and discussed in the scientific community. Our European trade body Cefic is a member of HBM4EU's Stakeholder Forum.
- The focus needs to be on biological (adverse) effect monitoring rather than biomonitoring (human, environmental) in isolation. Biomonitoring on its own is an indication of exposure to a substance and it must be recognised that detection of a man-made substance in humans and / or wildlife does not allow conclusions to be made regarding any potential adverse effects on the health of a population.
- To put measured exposures into context and evaluate their significance concerning any observed health effects it is therefore critical to have baseline thresholds, limits or some other health effect-based value to enable a comparison to be made. Scientifically derived limit values enable the interpretation of biomonitoring results with regards to possible health risks.
- There should therefore be a clear distinction between a substance having a potential health concern and the associated discussion around its 'actual health effects' or 'health risks'.
- When health effects or risks are assessed then it is important that medical associations / experts or occupational / environmental physicians are involved in this discussion, and agree with any conclusions that are formulated.
- For the investigation of the link between exposure to a substance or family of substances and observed adverse health effects, information on metabolism, toxicokinetics, biomarkers, human biomonitoring / biomonitoring equivalent values are needed in addition to a consideration of the hazard properties and exposure characteristics of the substance / family of substances.
- Interpretation and communication should be considered at an early stage, including information on the likely source(s) of substances detected, when the exposure occurred and whether there is a plausible mechanism that the level detected is causing harm. CIA is also of the opinion that the organisation performing the investigation and gathering the data should be responsible for the conclusions of the project rather than just providing data for a different organisation to interpret.
- It is important that human biomonitoring surveys are carried out using validated, published analytical methods performed

by laboratories that follow scientific, quality-assured processes to produce reliable results.

- The purpose of human biomonitoring in the workplace is to gather information on potential exposure of workers to man-made substances or families of substances and then compare these data with reference values to determine if there is a possible health risk or not, with action taken to eliminate or reduce the exposure source where necessary.

Conclusion

The CIA believes biomonitoring to be a useful tool provided it is carried out using validated analytical methods in accordance with sound science, and in the case of human biomonitoring good public health principles are followed. We stress the importance of the need to develop health effect-based limit values to enable a comparison to be made for determining potential health impacts that can be plausibly associated with the detection of man-made substances. The HBM4EU project also has a responsibility to interpret results using a risk management approach and communicate them to individuals and the wider society in such a way that does not cause unnecessary alarm.

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