POSITION PAPER

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Cefic position on human biomonitoring

- **European chemical industry companies are convinced of the benefits of adequately performed human biomonitoring (HBM) studies and are supportive of the HBM4EU initiative**
- **Validated and harmonized analytical methods should form the basis of any HBM study to get reliable results**
- **HBM can contribute to the assessment of potential health risks provided a scientifically-derived health-based guidance value and contextual information on exposures are available**
- **Communications on HBM results must be fact-based and objective**
- **Cefic will support further endeavours to develop HBM under Horizon Europe**

Summary

Human biomonitoring (HBM) comprises the analysis of human samples (for example blood or urine) to measure how workers or the general population are exposed to chemicals. The detection of a substance identifies exposure, but does not allow conclusions regarding its effects on health. HBM can contribute to the assessment of potential health risks by comparing measured exposure concentrations, provided a scientifically-derived health-based guidance value and contextual information on exposure sources are available. Chemical industry companies in Europe are convinced of the benefits of adequately performed HBM studies. As done for decades with implementing HBM programmes for workers, industry is supportive of HBM programmes for the general population, like the HBM4EU project. Communications on results is a key but sensitive element of HBM and must be fact-based and objective. Points to consider in this respect are mentioned below.

Introduction

For decades, human biomonitoring (HBM) has been an established method for the detection and identification of chemical substances and/or their metabolites in biological materials of humans (e.g. blood, urine). Thus, the analysis of chemical-specific biomarkers enables the assessment of internal chemical exposures aggregated across all sources and pathways. It has been applied as an information and control tool in both occupational health and safety programmes to persons potentially exposed to chemicals at the workplace, and as part of environmental health protection programmes to the general population.

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(1) *Human Biomonitoring at the workplace (Occupational health and safety)*

The purpose of human biomonitoring at the workplace, which may be part of health surveillance programs, is to gather quantitative information on worker exposure to chemical substances. When reference values can be derived, a comparison with the latter reveals whether a worker was exposed to a chemical at levels that are above a certain occupational exposure limit. If a possible risk is found, sources have to be identified and adequate measures have to be taken to reduce exposure. Thresholds and measurements are generally substance-specific.

(2) Human Biomonitoring of the general population (Public health protection)

In the context of environmental health protection, human biomonitoring programmes in the general population are thus far usually conducted by governmental authorities. Governmental HBM programmes are essential parts of national health reporting, *e.g.* the German Environmental Survey by the German Environment Agency (UBA) or the Health and Nutrition Examination Survey (NHANES) by the US Centers for Disease Control (CDC). In Europe, the HBM4EU initiative aims at coordinating and advancing human biomonitoring to provide evidence for chemical policy making.

These programmes serve to determine general background and peak exposures of persons who are not occupationally exposed to chemicals. Furthermore, if health-based guidance values exist, they can contribute to the assessment of potential health risks through comparison of the measured exposure. If these values are below the guidance values, the risk for adverse health effects is negligeable and, consequently, there is no need for action.

Human biomonitoring studies can help identify individuals or groups of persons with higher exposure values compared to the reference population. By way of repeated measuring, exposure trends can be depicted and groups classified in terms of their exposure. This information, along with information on metabolism, toxicokinetics, and health outputs can be used to help the interpretation of epidemiological studies when it comes to assessing the influence of certain substances on health.

The European Commission considers HBM as an essential element of its strategy to integrate health and environment through monitoring certain substances or their metabolites in humans, an element that reflects environmental exposures, diseases, genetic susceptibility and their potential relationship. The development of a coherent approach to HBM at the European level has involved multiple initiatives in the past decade, like DEMOCOPHES, COPHES and HBM4EU.

Cefic position on human biomonitoring

The European chemical industry is convinced of the benefits of adequately performed HBM programmes for occupational safety and public health protection. HBM surveys should be based on validated analytical methods (with specific biomarkers, adequate limits of quantification and reference standards), performed by qualified laboratories that follow scientific, quality-assured processes to produce reliable results. It is essential that results are put into context with information such as the source of the substance(s) detected (when identifiable), exposure scenarios, time of sampling in relation to exposure and how exposure levels compare to health-based guidance values.

The detection of a substance identifies exposure, but does not allow conclusions regarding its effects on health. In order to evaluate a potential health risk, further exposure, medical, and/or toxicological data must be included, and measured concentrations have to be compared with existing HBM health-based guidance values. Scientifically derived assessment values are essential for interpretation of HBM results. Expertise from a multidisciplinary team of exposure scientists, toxicologists, epidemiologists and medical doctors is necessary to assess possible health risks and derive health-based guidance values.

Cefic currently contributes and provides its strong support to HBM4EU

The HBM4EU initiative represents a novel collaboration between scientists and chemical risk assessors and risk managers, including several Commission services, EU agencies and representatives for the national level. HBM4EU is a five-year project, that kicked off in 2017 and will run to the end of 2021.

HBM4EU is an ambitious initiative and the scientific part of the project raises high expectations. As a member of the Stakeholder Forum of HBM4EU, Cefic closely follows the project and provides its technical expertise in occupational HBM to HBM4EU consortium, for example through comments and recommendations to scoping documents or fact sheets for HBM4EU priority substances.

<u>Cefic focuses particularly on the following aspects:</u>

Technical feasibility of procedures and analytics

- High-level validated and harmonized analytical methods (specific biomarker, adequate limit of quantification, reference standards, quality control schemes) applied by qualified laboratories should form the basis of any HBM project to get reliable results

- HBM4EU should take experiences derived by workplace biomonitoring into account (methodologies, quality, feasibility, etc)

HBM4EU and occupational exposure

Some regulations already require some HBM as part of the occupational health surveillance programs to assess exposures that are responsibility of subject matter experts within the companies.

HBM and link to health risks within HBM4EU

Health-based guidance values are a prerequisite to the interpretation of HBM data with regard to potential health risk. For the investigation of the link between exposure and health, information on metabolism, toxicokinetics, biomarker, and HBM/BE (Biomonitoring Equivalent) values are needed in addition to information on human hazard properties and exposure characteristics.

If HBM4EU aims at generating evidence of the actual exposure of citizens to chemicals and the possible health effects in order to support policy making, key actors should comprise occupational/environmental medical and toxicological expertise as well as exposure and communication experts.

Communication of results to broader audiences is a key element in the HBM4EU project. We agree with the 2019 strategy for the communication and dissemination of HBM4EU results that messages for citizens need to be straightforward, with illustrations and concrete recommendations whenever needed. Any such communication must also be fact-based. In its responsibility for adequate public understanding of its work and results, HBM4EU should offer interpretation or guidance that represents the underlying scientific facts in a balanced and objective manner. Stakeholder involvement is crucial and should be included in the development of such communications.

The key question is how HBM can be used in the general population health protection, taking into account the relevance of the detected values related to the effective exposure as well as the confounding factors in an overall risk assessment.

In conclusion, the chemical industry companies in Europe are convinced of the benefits of adequately performed HBM studies. If studies are appropriately conducted, evaluated and discussed in the scientific community, the HBM4EU program can be of great benefit for regulators, general population, workers, and industry.

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About Cefic
Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production.