HBM4EU

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HBM4EU NEWSLETTER

Newsletter n°1 - September 2017

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Europe gets the ball rolling

Two out of three European citizens are concerned about exposure to chemicals in their daily lives through food, air, drinking water and consumer products or other items, as well as in the workplace. At the same time, less than half of European citizens feel well-informed about the potential dangers of chemicals.[1]

The European Union's (EU) mission is to improve the health and well-being of its citizens. This broad objective includes ensuring that chemicals are used in ways that do not harm the environment or human health. The EU has established a stringent and comprehensive regulatory framework on chemicals, the implementation of which should be underpinned by solid scientific data. While Europe benefits from a high level of scientific expertise concerning people's exposures to chemicals and potential health effects, capacities are fragmented and evidence is not representative at EU level. It is therefore timely to bring Member States and the Commission together to deal with the challenge of chemical safety together, not only in terms of policy, but also from the perspective of science.

HBM4EU represents a big step in this direction and is expected both to deliver good practice, and to guide the debate on how Europe should tackle the persistent challenge of monitoring, understanding and regulating chemicals in the next decades.

As a first major success, HBM4EU has already brought together 107 research and policy institutions from 26 European countries.

At the EU level, policy makers cooperate through the EU Policy Board to bring forward their priorities. Many challenges lie ahead of HBM4EU, and diverse stakeholders are following the initiative closely and critically. The roles assigned to the Stakeholder Forum and the Advisory Board in providing strategic input are important to the credibility of the project. The Governing Board, meeting now in September for the first time, will be essential in providing political backup and supporting the discussion on sustainability.

1 Eurobarometer Survey on Chemical Safety, 2017

In this issue:

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The stakes are high, but we are convinced that we can deliver if we remain motivated and committed to working together efficiently and effectively. The Commission is proud of this initiative and eagerly looking forward to its impact and success in the near future!

Sofie Nørager, Tuomo Karjalainen, Arnd Hoeveler
European Commission, Directorate-General for Research & Innovation, Directorate E Health

WHAT we do

HBM4EU is a joint effort of 26 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020.

HBM4EU represents a novel collaboration between scientists and chemical risk assessors and risk managers, including several Commission services, EU agencies and national representatives. Running from 2017 to 2021, the project will build bridges between the research and policy worlds to deliver enhanced chemical safety.

Our research explores current questions in chemical risk assessment and management and will deliver answers that help policy makers to protect human health. Policy makers, stakeholders and scientists together shape the strategic direction of HBM4EU activities.

This collaborative approach ensures that our research will generate new knowledge that addresses genuine societal concerns.

There is a lack of comparable data at European level on aggregate exposure to single substances and to combinations of chemical substances. HBM4EU is working to harmonize procedures for human biomonitoring across the 26 participating countries, building scientific excellent in Europe, and producing comparable data on human internal exposure to chemicals.

We will explore the link between external exposure via different routes and aggregate internal exposure, with the aim of identifying upstream sources and informing policy efforts to mitigate exposure.

HBM4EU research will generate evidence on the causal links between human exposure to chemicals and health outcomes. We are investigating how exposure to chemicals affects the health of different vulnerable groups, such as children, pregnant women and workers.

Our work with chemical risk assessors aims to adapt chemical risk assessment methodologies to use human biomonitoring data and to account for the contribution of multiple external exposure pathways to the total chemical body burden.

To ensure our results inform the design of new policies and the evaluation of existing measures, we are in dialogue with the EU Policy Board. Our results will meet the needs of risk assessors and risk managers working to enhance chemical safety.

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Maria Uhl
Austrian Environment Agency

The HBM4EU contact point for Stakeholders, the Austrian Environment Agency, will facilitate an ongoing dialogue with stakeholders to ensure that a broad range of views are represented in the project.

STAKEHOLDER Engagement

Effective stakeholder engagement is crucial to the success and sustainability of the HBM4EU project. We are requesting input from NGOs representing environmental, health and consumer priorities, as well as trade unions and industry.

In return, these players have an opportunity to influence the project's strategic development.

It is our hope that stakeholder engagement will enhance HBM4EU work in a number of areas. Input to the identification of priority substances and the development of research priorities can help to ensure that HBM4EU research addresses genuine societal concerns. We hope to draw in the perspectives of consumers and patients. By engaging with chemical producers and downstream users, we will engage in a dialogue on safe substitution.

By engaging with stakeholders as multipliers in the dissemination of results, HBM4EU can contribute to increasing transparency about exposure to chemicals via consumer products and at the work place, as well as fostering the broader exchange of information in international networks.

Stakeholders will be involved both in issue framing and in the interpretation and evaluation of results. As a first step, HBM4EU will invite stakeholders to a workshop on priority substances in November 2017 in Brussels.

By adopting a participatory approach to stakeholder involvement, HBM4EU partners aim to increase the legitimacy and accountability of HBM4EU activities and results, and so enhance the credibility of policy actions and measures based on those results.

The Stakeholder Forum is the formal channel for stakeholder input to the HBM4EU project. Members include:

- Chem Trust
- Downstream Users of Chemical Co-ordination Group (DUCC)
- Eurometaux
- European Association of Craft, Small and Medium-Sized Enterprises (UAPME)
- European Chemical Industry Council (CEFIC)
- European Consumer Organisation (BEUC)
- European Environment Bureau (EEB)
- European Federation of Allergy and Airways Diseases Patients' Associations (EFA)
- European Trade Union Confederation (ETUC)
- Health and Environment Alliance (HEAL)
- Women in Europe for a Common Future (WECF)

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HBM4EU Priority Substances

Substances to be the subject of surveys and research under the project are known as HBM4EU priority substances.

The first exercise to prioritise substances was performed in 2015, and took into account policy needs for knowledge on chemical exposure and health outcomes at national and EU level.

An initial set of criteria was then produced, including such aspects as whether a substance is of concern to human health, whether there is evidence of human and/or environmental exposure at EU level and whether there are open policy questions. The financial and technical feasibility of monitoring the substances was also a criterion.

Substances were then assessed against these criteria. This first round of prioritisation resulted in the 1st list of HBM4EU priority substances, including the nine substance groupings that are the focus of current activities.

Policy questions for each substance group were then translated into research objectives. These formed the basis for the development of 2017 action plan.

Two additional rounds of prioritisation will be conducted during the five years of the project. The second round of prioritisation runs from 2017 to 2018 and will generate the 2nd list of HBM4EU priority substances, for inclusion in the Work Plans for 2019, 2020 and 2021.

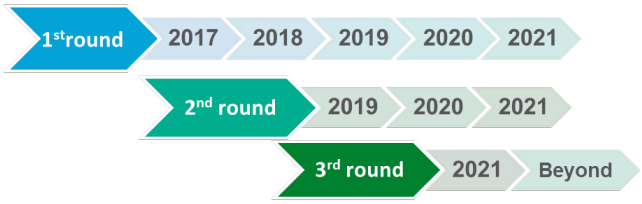
In implementing the strategy, we expect to receive critical feedback and gather lessons learnt. We then have a second opportunity to refine our approach for the third round of prioritisation in 2019 and 2020. This final round will generate the 3rd list of HBM4EU priority substances, for inclusion in the 2021 Work Plan, where feasible, and with the aim of feeding into a future European Human Biomonitoring initiative.

The timeframe for the three rounds of prioritisation is presented below, with the years indicating the timeframe in which activities on those substances will be implemented.

Current HBM4EU priority substance groups

- Phthalates and Hexamoll® DINCH
- Bisphenols
- Per-/polyfluorinated compounds
- Flame retardants
- Cadmium and chromium VI
- Poly aromatic hydrocarbons
- Aniline family
- Chemical mixtures
- Emerging substances

Timeframe for prioritisation rounds under HBM4EU



Catherine Ganzleben, European Environment Agency

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OCCUPATIONAL Health

Exposure to hazardous chemicals in the workplace has decreased over the years. At the same time, chemicals are still used in many occupational settings and new chemicals are constantly placed on the market. Exposure to specific chemicals at work may be significantly higher than the exposure of general population, making workers vulnerable to health effects.

For example, in specific sectors of manufacturing industry, levels of Bisphenol A have been observed in workers that are tens to several hundred times higher than those in the general population[1]. Although the number of highly exposed workers may be limited, it is important to protect workers and their families. Occupational exposure may also explain part of the variability in the chemical levels observed in the general population and needs to be explicitly acknowledged when interpreting population studies.

Although biomonitoring has been available as a tool for use in occupational health for many years, its use varies between countries. Collating data on occupational exposure that is representative at EU level remains challenging. EU wide data would be valuable in support the implementation of EU chemicals legislation, in particular REACH[2] and occupational safety and health (OSH) legislation.

HBM4EU will conduct targeted occupational surveys in order to collect representative biomonitoring data on occupational exposure to HBM4EU priority chemicals.

The first study is planned for 2018, and will focus on chromates in the surface treatment and welding sectors. This will support current legislative actions related to chromates under both REACH and OSH legislation. We will also test new biomonitoring methods specific to hexavalent chromium. Lessons learnt will be applied to other occupational surveys.

Other HBM4EU priority substances of relevance to the occupational setting include aniline forming diisocyanates, and phthalates and bisphenols. The latter two are used in the plastic and construction sectors, characterised by high numbers of employees and many SMEs.

As new chemicals hit the market, they may be detected in workers before levels can be measured in the general population. Non-targeted screening of chemicals among specific groups of workers can detect emerging chemicals of concern.

We look forward to working with policy makers to produce targeted knowledge in support of occupational health and safety.

Tiina Santonen, Finnish Institute of Occupational Health

1 Hines C et al., Annals of Work Exposures and Health, Volume 61, Issue 2, Pages 164–182; Heinälä M et al., Annals of Work Exposures and Health, Volume 61, Issue 1, Pages 44–55

2 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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PER- AND POLYFLUORINATED Substances

A substance group on the 1st list of HBM4EU priority substances is the group of per- and polyfluorinated substances (PFAS). PFAS have unique properties in that they can repel both water and oil, enabling industry to create valuable functionalities in products that generate high customer demand.

On the other hand, these unique properties present disadvantages that have been documented over recent years and, in some cases, decades. Various PFAS, or break-down products thereof, are extremely persistent and bioaccumulate in the environment and in human bodies. In addition, some PFAS are classified as hazardous to human health. Their widespread use and release, combined with their persistent and bioaccumulative properties, generates concern regarding potential impacts on health.

There are over 3,000 PFAS on the global market, with their application in products expected to expand1. Despite this, a limited number of PFAS have been registered under REACH. PFAS are often used in low volumes and therefore may not have met the tonnage thresholds subject to registration thus far. It remains likely that PFAS are present in products produced in Europe. The substances also enter the EU via imported articles, such as textiles. Finally, some groups of PFAS polymers, not covered by REACH, may also be precursors of persistent PFAS2.

In terms of regulatory action at global level, the production and use of perfluorooctance sulfonate (PFOS) and PFOS-related substances are regulated under the Stockholm Convention on Persistent Organic Pollutants.

1 KEMI, 2015, Occurrence and use of highly fluorinated substances and alternative, Swedish Chemicals Agency, Stockholm
2 OECD, 2013, OECD/UNEP Global PFC Group, Synthesis paper on per- and polyfluorinated chemicals (PFCs), Environment, Health and Safety, Envvironment Directorate, OECD, Paris

Other PFAS are currently under scrutiny for inclusion in the Convention. Some regulatory experts and scientists recommend assessing and managing PFAS as a group, given their extreme persistence and mobility1.

HBM4EU is exploring human exposure to PFAS, in particular that of vulnerable groups such as foetuses and children. We will investigate exposure to PFAS that have been banned, are currently under evaluation, and substances of emerging concern. Our work will also address potential risks to health and the mixture effects of PFAS.

Maria Uhl, Austrian Environment Agency

MANAGING Sensitive data

HBM4EU will work with datasets that include sensitive data, such as personal details and information on the health of study participants. In doing so, we must fully respect relevant legislation and ethics requirements.

The Data Management Plan for HBM4EU is a critical tool in delivering good data management. It describes the data management life cycle for all datasets collected, processed and/or generated under the project.

Our procedures ensure we comply with the General Data Protection Regulation (Regulation (EU) 2016/679), which enters into force in May 2018. The Regulation strengthens and unifies data protection for individuals within the EU. In addition, HBM4EU will comply with all relevant ethics requirements, both at EU and national level.

1 KEMI, 2016, Strategy for reducing the use of highly fluorinated substances, PFASs, Swedish Chemicals Agency, Stockholm

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HBM4EU aims to increase the availability of human biomonitoring data in order to multiply the benefits that can be generated through its use. To this end, human biomonitoring data analyzed within HBM4EU will be made accessible via IPCHEM, the European Information Platform for Chemical Monitoring.

IPCHEM is the reference access point for discovering chemical monitoring data collections managed by EU bodies, Member States, international and national organisations and research communities.

The Platform supports a more coordinated approach towards the collection and storage of data on the occurrence of chemicals and chemical mixtures in a range of media, and provides a one-stop online access point. It includes monitoring data on chemical occurrence in the environment, food and feed, and products and indoor air, as well as in humans.

One aim is to support work that investigates how chemicals transfer across media, leading to human exposure to chemicals. Another is to build knowledge on the exposure of humans and the environment to chemical mixtures and how that exposure changes over time. This responses to the Commission's 2012 Communication on the combination effects of chemicals.

There are clear synergies between IPCHEM and HBM4EU. We are identifying and collating existing human biomonitoring data held by our partners in 26 countries across Europe. The metadata will be made available via IPCHEM. This will allow users to easily identify existing datasets and contact the data owner to request access. Aggregated and single measurement data will be made accessible via IPCHEM to the extent possible, while respecting all ethics and legal restrictions.

We are reviewing existing human biomonitoring datasets against current policy questions, to determine what questions might be answered. Where we identify gaps in the available evidence, we will generate new human biomonitoring data through the implementation of targeted surveys and the analysis of biobanked samples. All new data generated under the project will be made available via IPCHEM, while respecting the requirements of the General Data Protection Regulation, as well as ethics requirements at national level.

Remy Sylvie, VITO

Ethics issues under HBM4EU:

1. Planning and implementing new studies with human participants, including children
2. Collecting data, including health data, from existing cohorts and studies and performing new analyses
3. Using cells and tissues from external projects
4. Using data from animal studies
5. Sharing data via IPCHEM

A webinar on ethics issues under HBM4EU is available on https://c.deic.dk/p9c1dsteg7l/

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6th Ministerial Conference on Environment and Health

The Sixth Ministerial Conference on Environment and Health was held on 13–15 June 2017, in Ostrava, Czech Republic. The Declaration emerging from the meeting identifies exposure to harmful chemicals as a health risk. Efforts to minimize the adverse effects of chemicals on health should be a component of national actions on environment and health.

A Compendium of Possible Actions sets the objectives of better monitoring exposures to hazardous chemicals and improving understanding of the associated burden of disease.

> Human biomonitoring is a public health policy tool; countries should support efforts to generate comparable human biomonitoring data.

HBM4EU partners were present at the conference and used the opportunity to promote our new initiative. Marike Kolossa-Gehring of the German Environment Agency and Sofie Nørager of DG Research and Innovation presented HBM4EU at a side-event, while Maria Pilar Aguar Fernandez of the Joint Research Centre highlighted synergies with IPCHEM. Jana Klánová, RECETOX then explained the role of the WHO/UNEP human milk survey in monitoring progress under the Stockholm Convention on Persistent Organic Pollutants. Discussions with the audience addressed how human biomonitoring can inform the development of targeted policy measures, as well as the evaluation of existing policies. The role of stakeholders at the national level in HBM4EU was also discussed, as well as the possible role of human biomonitoring in monitoring progress under the Minamata Convention on Mercury.

Collaborating on Chemical mixtures

Under HBM4EU, we will identify real-life exposure patterns to mixtures by evaluating existing data and producing new data. We aim to define priority mixtures and identify the principle drivers of mixture toxicity. As a second step, we will work on approaches to assess the potential health risks from mixtures.

HBM4EU is collaborating with a number of projects that address different aspects of the impacts of mixtures on human health and the environment. Projects include EDC-MixRisk, EuroMix, EU-ToxRisk and Solutions, as well as collaborations on cumulative risk assessment and the work of the European Food Safety Authority and the Joint Research Centre. We aim to identify synergies, share knowledge and ensure the interoperability of methods and results.

A joint workshop will be held in the Spring of 2018, providing a forum for scientific researchers and policy makers to discuss the current state of knowledge, identify gaps and prioritise areas for future research. The participation of chemical risk assessors and managers from the European Food Safety Authority, the Joint Research Centre, the European Environment Agency and Directorate General Environment, as well as Directorate General for Research and Innovation, should ensure that the new knowledge produced under these project serves policy needs. The ultimate aim is to maximise the impact of our work on mixtures on enhancing chemical safety.

Project contact & coordination

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