Summary of the stakeholder consultation on HBM4EU

09th December 2016, Brussels, Belgium

1. Introduction

On 8th December 2016, the European Human Biomonitoring Initiative, known as HBM4EU, was launched at an event hosted by the European Commission and the Slovak Presidency of the Council of the European Union (EU). This event was followed by a stakeholder consultation on the 9th December with the aim of gathering input from a range of stakeholders on the principle that can be addressed through human biomonitoring (HBM) in Europe. The stakeholder consultation represented the start of an ongoing collaboration between HBM4EU partners and stakeholders. This summary captures the key points emerging from the presentations and discussions during the stakeholder consulatation. Presentations are available for download at the launch website.

2. Best practices

In the session on **"best practices",** representatives of the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), Health Canada, BASF SE, Germany and the Health and Environment Alliance discussed the use of HBM in their fields, pointing out opportunities for the use of HBM in risk assessment processes, as well as reflecting on stakeholder engagement.

3. HBM4EU consultation channels and processes requiring stakeholder input

In a first step, Catherine Ganzleben from the European Environment Agency introduced the planned consultation process within HBM4EU and identified the principle channels for stakeholder input, stressing where specific input is welcome and needed. The timeframe for stakeholder input is summarised in Table 1 below.

A **Stakeholder Forum** will be established by May 2017, to include representatives from non-governmental organizations (NGOs), civil society organizations, industry associations, employers' organisations and trade unions. The first meeting of the Stakeholder Forum will be held in September 2017.

The **HBM4EU website** will serve as a platform for interaction with stakeholders, by providing an overview of the project, making results available and supporting online surveys to gather stakeholder input.

By May 2017, HBM4EU will propose a **Strategy for the prioritisation of new substances for research under HBM4EU**, including a set of criteria that will be used to prioritise substances. From 15 May to 15 June 2017, stakeholders will be asked to provide their feedback on the strategy and criteria. The prioritisation strategy and decision criteria will be finalised and sent for approval to the HBM4EU Governing Board in September 2017.

Over a three-month period from 15 May to 15 August 2017, members of the Stakeholder Forum will be invited to provide **input on priorities for action** under HBM4EU, including both nominations for substances to be the subject of future research activities and, where relevant, specific population groups for investigation.

In addition, a broader range of stakeholders will be invited to nominate substances for future research via the HBM4EU website from August to October 2017.

A **stakeholder workshop** will be organised in the autumn of 2017, providing a forum for open discussion with a range of stakeholders on priorities for future research activities under HBM4EU.

By early 2018, HBM4EU partners will score all nominated substances against the decision criteria. The Stakeholder Forum will be consulted on the proposed scoring. The scores will then be finalised and used to produce a **second list of priority substances** in May 2018.

National Hubs will also have opportunities to feed into the prioritisation process. The contact details for national hubs will be made available on the HBM4EU website (as of March 2017).

In February 2018, HBM4EU will organise **focus groups with members of the public** to gather input on public priorities for activities under HBM4EU.

Early in 2018, HBM4EU will conduct a survey regarding stakeholder expectations for a sustainable HBM initiative beyond 2021. This will feed into the development of a proposal for a **possible future initiative**.

4. Stakeholders' research needs linked to prioritised chemicals

The session on **'research needs'** was moderated by Robert Barouki, Director of the Department Toxicology, Pharmacology and Cell Signalling of INSERM, France, and Nicolas Olea, Director of the Department of Radiology and Medical Physics of the University of Granada, Spain. They described the research issues to be addressed regarding HBM and surveys, exposure pathways and evidence for causality, as well as questions related to mixtures and emergence.

The audience was very supportive of the inclusion of appropriate research on exposure and health within the initiative, with many attendees identifying this as critical for the interpretation of HBM data for policy making. Stakeholders identified a number of priorities. Working on mixtures in the context of HBM was mentioned several times, as well as deciphering the effect of low doses, the use of computational modelling and the identification and validation of relevant effect biomarkers. Unbiased identification of emerging substances was also perceived as particularly important and promising. Various types of HBM studies were also discussed, with a strong emphasis from part of the audience on the relevance of targeted cohort studies (birth cohorts for example). There was also support for representative cross-sectional studies allowing researchers to delineate time-trends and observe geographical differences. In general, there was a willingness and enthusiasm from stakeholders to participate in the discussions on the research aspects. NGOs noted that they would need to be supported in order to be able to devote the time and effort required for effective participation. All dates and details will be made available on the HBM4EU website.

5. Involving stakeholders in HBM4EU

Ilse Loots, Dean of the Faculty of Social Sciences of the University of Antwerp, introduced a number of challenges and questions related to involving stakeholders in the interpretation of HBM results. Stakeholders were invited to provide written feedback though a distributed template.

The question "**Who to invite for joint reflection?"** led to the conclusion that the term "consumer" is too narrow, and that we should rather refer to "citizens" or even "human beings". It was further mentioned that trade unions, health services, medical professionals (both occupational and environmental medicine), women and youth groups, health insurance organisations (e.g. Association Internationale de la Mutualité [AIM], a member of HEAL), risk assessors, emergency planners, consumer product safety organisations at national level and consumer (complaints) organisations should be involved. For specific questions, it may be relevant to consult food producers and processers, food safety authorities, agricultural authorities, specific industries, patient associations and user or exposed groups. A broader range of stakeholders will be invited to the stakeholder workshop in October 2017; lay persons will be involved through focus groups in 2018 and 2020.

It was stressed that individual HBM data needed to be explained personally by medical practitioners, parameter by parameter (both in occupational settings and in population studies), when communicating individual results to participants. This would require the training of health professionals to deliver these messages.

Stakeholders from NGOs, as well as from industry, called attention to the fact that their input can only be guaranteed if they are well informed and involved from the very beginning.

Since the Stakeholder Forum will have a limited number of members, a more extensive list of stakeholders will be invited to a stakeholder workshop, foreseen for September 2017. Stakeholder engagement at national level will be encouraged via the National Hubs. The need for coordination with other projects and initiatives in Europe and beyond, such as HEALS, EXPOsOMICS, BBMRI-ERIC, or NHANES was addressed. Collaborating with the many projects and initiatives already in progress is of added value both for them and HBM4EU.

How to address the needs of hidden stakes such as next generations or the unborn child was one of the questions addressed as well as **how to structure joint reflection on HBM results?** Suggestions came along with the previous topic.

Under the topic **additional questions or ideas**, the `behavioural insights team´ in Great Britain and 'Knowledge platforms' in the Netherlands were introduced as examples of best practice. The importance of investing in trust building was discussed intensively. For transparency, guidelines and principles for engagement are valuable.

6. Summary and closing

The consultation process was wrapped up by the HBM4EU Coordinator Marike-Kolossa Gehring, Head of the Section Toxicology, Health Related Environmental Monitoring of the German Environment Agency and the Deputy Coordinator Greet Schoeters, Programme Manager of Environmental Health, VITO Belgium. This first consultation demonstrated that stakeholder involvement offers many possibilities to enhance HBM4EU work. From research perspective, these include the identification of priority substances, priorities for research on effects, development of safe(r) substitutes for hazardous substances. By engaging with stakeholders, HBM4EU can contribute to increasing transparency about exposure to chemicals via consumer products and at the work place. Engaging with stakeholders can also serve to identify concerns of consumers and patients and ensure that these concerns are addressed under HBM4EU, as well as fostering the broader exchange of information in international networks.

7. Contact details

The meeting was the first step in the dialogue between HBM4EU partners and the stakeholder community.

Further input can be provided to: stake-hbm4eu@umweltbundesamt.at

Table 1: Timetable for Stakeholder involvement January 2017 to September 2018

May-June 2017	• 15 May to 15 June: Stakeholder Forum is requested to provide feedback on the proposed prioritisation strategy and criteria
May-Aug 2017	• 15 May to 15 August: Stakeholder Forum is requested to nominate substances for future research under HBM4EU
Aug-Oct 2017	• Stakeholder are invited to submit nominate substances via the HBM4EU website - August to October 2017
Sept-Nov 2017	• Final prioritization strategy and decision criteria • **September, 5th: 1st meeting of the Stakeholder Forum** • October/November: Stakeholder workshop on priorities for future research under HBM4EU
Jan -Feb 2018	• HBM4EU produces background documents scoring each nominated substance
Mar-April 2018	• Stakeholder Forum is invited to provide feedback on the proposed scoring of nominated substances • Focus group with members of the public on priorities for action under HBM4EU
May 2018	• HBM4EU produces a proposed 2nd list of priority substances for future research • Report on the stakeholder consultation process
Sept 2018	• 2nd proposed list of priority substances is sent for approval by the Governing Board • 2019 annual work plan is sent for approval by the Governing Board