Background document to the stakeholder consultation on the

European Human Biomonitoring Initiative (HBM4EU)

Friday 9th December 2016

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Background

This document provides background information to participants to the stakeholder consultations on the European Human Biomonitoring Initiative, HBM4EU, to be held on Friday 9th December 2016.

The stakeholder consultation will entail three sessions.

In the **first session**, participants will hear about best practices in using human biomonitoring from different interest groups, including the European Food Safety Authority, the European Chemicals Agency, Health Canada, BASF and Health and Environment Alliance.

In the **second session**, the HBM4EU project team will provide an introduction to the consultation process, outlining our ambition to work collaboratively with stakeholders and setting out the objectives of the session. Participants will then break into two consultation groups to allow for effective consultation on two key areas, namely:

1. Stakeholder research needs linked to prioritised chemicals, mixtures and emerging substances, as well as future priorities; and
2. Involving stakeholders in the HBM4EU: expectations, needs and requirements.

In a **final session**, rapporteurs from each break out group will provide feedback on the issues discussed. In conclusion, Marike Kolossa-Gehring of the German Environment Agency and Greet Schoeters of the Flemish Institute for Technological Research, the Coordinator and the Co-coordinator of HBM4EU respectively, will then outline their vision regarding the way forward for stakeholder involvement in the HBM4EU project.

This document briefly outlines the objectives of the consultation and provides an overview of the opportunities currently foreseen to enable stakeholders to engage in a dialogue with HBM4EU project partners. Additional background is then provided to support stakeholder participation in the two break-out groups, including an overview of the issues for discussion and some key questions. Finally, contact details are provided.

Objectives of the session on the stakeholder consultation

It is the ambition of the HBM4EU partners to collaborate with a range of stakeholders throughout the implementation of the project. Effective stakeholder participation is essential to ensure the credibility, legitimacy and accountability of HBM4EU project activities and results.

We would like to use this opportunity to outline our needs for stakeholder input to HBM4EU activities in order to make them more responsive to societal needs. To this end, we look forward to a rich exchange with stakeholders, with the objective of establishing contacts and building trust as a basis for an ongoing dialogue.

Stakeholder input to HBM4EU: opportunities and needs

A number of channels will exist for stakeholders to provide input to the HBM4EU project.

The formal channel for stakeholder input to the HBM4EU project is via the **Stakeholder Forum**. The Stakeholder Forum is expected to consist of up to 10 representatives of EU level stakeholders, with selection criteria to be developed by the HBM4EU Consortium early in 2017. The Stakeholder Forum will meet in September of each year and will provide strategic input to the project. The HBM4EU partners will also engage actively with the Stakeholder Forum, through workshops and written requests for input on particular processes. We will also be available for meetings with key stakeholders, organised via the Stakeholder Forum, to address ongoing questions and concerns and provide feedback.

HBM4EU will have a website, as well as a presence on social media. The website will promote the initiative to external audiences, provide details regarding ongoing processes to which stakeholder can contribute and provide a platform for the dissemination of research outputs, technical guidance and methods. The official web site of the HBM4EU initiative is under development. The interim web site contains initial background information and will link to the official web site when ready: http://www.eea.europa.eu/themes/human/human-biomonitoring. As of early 2017, we will encourage you to follow us on twitter @HBM4EU.

Stakeholders at national level will also have an opportunity to provide input via the **National Hubs**. The National Hubs will coordinate human biomonitoring activities at the national level and will feed national priorities into HBM4EU. The organisation of stakeholder involvement at national level will be the responsibility of the National Hubs. Contact details for the National Hubs in all partner countries will be made available on the HBM4EU website in early 2017.

The HBM4EU programme would like to request stakeholder input to key processes, listed below.

Strategy for the prioritisation of chemicals for monitoring and research: In order to identify chemicals for analysis and research activities, we apply a systematic, transparent and participatory prioritisation strategy. Prioritisation will be performed bi-annually throughout the programme, from 2017 to 2018 and again from 2019 to 2020. The process will involve the active participation of the Stakeholder Forum, the EU Policy Board and the National Hubs. The priority substances to be addressed by HBM4EU from 2017 to 2018 were identified in collaboration with the European Commission services and agencies, and are listed in Annex I together with key policy questions.

Knowledge hub: The effective and targeted dissemination of outputs from the HBM4EU is crucial to ensuring that our results are understood and used for the protection of human health by key audiences. We would like to receive input from the different interest groups on how best to tailor or communicate outputs to maximise their impact.

Science to policy: We will pilot an action plan for the joint interpretation of HBM4EU results for further use by experts, policy makers and stakeholders. This will allow for a systematic translation of the results into concrete policy actions.

Sustainability: We will be exploring options for a sustainable European Human Biomonitoring (HBM) initiative beyond 2021. We will consult with stakeholders in 2017 and 2018 to capture their priorities for a future European programme.

Consultation Group 1 - Stakeholders' research needs linked to prioritised chemicals, mixtures and emerging substances as well as future priorities

HBM4EU includes an ambitious research programme to develop a better understanding of human exposure-response relationships focused on the selected priority substances (the first list of priority substances is listed in annex I together with the associated policy questions). One of the major aims of HBM4EU is to provide the data and tools to help us understand the impact of environmental exposures on human health by translating HBM data into health risks.

Making the most out of HBM surveys: Our research will draw on different types of HBM surveys and studies. Surveys using a random sample of the general population of a country characterise nation-wide exposure. Cross-sectional studies assess human population at one moment in time. Longitudinal studies follow participants over time. Birth cohorts are a type of longitudinal survey that assess the perinatal exposure and follow up on the children's health effects later in life. Targeted HBM studies monitor the actual exposure of a defined subgroup of the population living or working at a certain place, having specific lifestyles, or being in an especially susceptible phase of life. The range of different HBM surveys can provide valuable data on time trends, regional differences and occupational exposure, as well as on the exposure of vulnerable populations. As a first step, HBM4EU will take advantage of existing biosamples from available surveys and cohorts following a comprehensive inventory of such studies.

Questions for discussion:

- What priority should be given to each type of studies?
- One of the questions that came up for several priority chemicals is to provide information on the current exposure of the EU population. We would like to get input on which population characteristics to prioritise when sampling the European population?
- For example:
    - Which age groups should be included?
    - Do we need country and regional representation?
    - Should we sample both rural and urban populations?
    - How to capture socio economic status?

Delineating the most likely exposure pathways: The determination of health-based guidance values depends, inter alia, on multidisciplinary studies that attempt to correlate internal dose and health outcome. The identification of exposure sources is important to inform public health decisions to prevent or minimise exposures. Based on experiences gathered in other EU projects and in national HBM programmes, HBM4EU will develop questionnaires to collect data about factors that can determine exposure, including data on the local environment, demographics, socio-economic status, consumption related habits, lifestyles, diet and health. Exposure models will also be used to identify the major exposure routes and sources, thereby supporting policy making.

Questions for discussion:

- What methods are available to enable us to integrate environmental studies with human biomonitoring and health studies?

Integrating HBM and health studies: By facilitating cooperation and coordination across existing HBM programmes and national and international health surveys and populations studies, HBM4EU will promote linkages between HBM data and health data in future HBM programmes in order to add value and improve cost efficiency.

Questions for discussion:

- What are the best means to support the inclusion of HBM in health surveys?

Supporting causality through a multidisciplinary approach: Establishing a causal link between exposure and human health is a major challenge for science and regulators. For single substances, research will integrate mechanistic studies using classical as well as innovative toxicological methods to identify Molecular Initiating Events, follow up Key Events at cellular and organ level and document Adverse Outcomes. On the epidemiological track, exposure levels and health outcomes observed in cohort studies, including susceptible developmental life stages, adults and workers, will be analysed for their causal relation by applying biomarkers, in part by using novel omics technologies and novel statistical tools. To enable us to interpret HBM data, we will use PBTK (physiology-based toxicokinetic) modelling to derive the toxicologically relevant tissue level doses and will analyse mixture effects using effect biomarkers.

Questions for discussion:

- What are the best ways to support the integration of mechanistic studies with HBM population studies in the framework of a systems medicine approach, with the aim of providing the strongest scientific support to policy makers?
- How should we make sure that the research on effect and molecular biomarkers in cohorts benefits from novel toxicological concepts derived from experimental research?
- Which concrete steps should be taken for the selected priority compounds for 2017 to 2018?

Contributing to a better assessment of mixture effects: Every single substance, once it enters the body, will exhibit its health effects in concert with all other (xenobiotic) substances from previous and simultaneous exposures, and in interaction with a person's genetic makeup and acquired characteristics. These combined and/or simultaneous exposures derive from a range of different exposures routes, both involuntarily and voluntarily. These mixtures and their effects present a major challenge to current science and to chemical risk assessment and management. The initiative will develop tools to identify the most relevant mixtures for health effects from available studies, confirm their possible toxicity and develop multi-country studies, notably related to the health effects of exposure to mixtures of pesticides.

Questions for discussion:

- What criteria should HBM4EU use to prioritise mixtures?
    - Chemical groups?
    - Exposure patterns?
    - Product composition?
    - Actual mixtures that are present in the population?
    - Mode of action?
    - Other criteria..?
- How could the initiative rapidly contribute to support the integration of the mixture concepts in regulatory frameworks?

Developing tools for early signal identification: Current HBM programmes are primarily based on the targeted analysis of chemicals with known hazardous properties for human health. Such programmes are therefore limited in their ability to monitor not yet known or assessed emerging chemicals. Different approaches will be used to identify emerging substances. Among them, non-targeted screening approaches could be used to generate this crucial, and currently missing, information. This research activity will feed potential new compounds into the strategy for the prioritisation of future substance groups for research and analysis under HBM4EU. It will address policy makers' needs for markers of "early signalling" of human exposure to chemicals, as well as developing appropriate methods for the generation of the initial data required to prioritize further monitoring for chemicals not included in existing HBM programmes.

Questions for discussion:

- How relevant is the focus on the detection of emerging substances through human biomonitoring?
- How might we integrate data on emerging substances with early warnings of chemical exposure via ecosystems or consumer products?

General questions for discussion:

- Does the research programme outlined in HBM4EU fulfil the objective of bridging human biomonitoring and health effects?
- Would the stakeholders like to suggest further approaches?

Consultation Group 2 - Involving stakeholders in the HBM4EU: expectations, need and requirements

HBM4EU will build knowledge on the exposure of the European population to chemicals and will translate HBM results into health guidance values and indicators. In addition, HBM4EU will refine chemical risk and health impact assessment procedures by enhancing the use of HBM data.

Our results will facilitate the evaluation of existing policies and will support new policy measures and interventions aimed at reducing environmental exposure to chemicals and improving product and food safety. An additional outcome will be awareness raising amongst stakeholders and citizens on how to reduce exposures. Our results will also serve to guide future research, contributing to the establishment of a sustainable European Human Biomonitoring Initiative post 2021.

In order to ensure that HBM4EU results will be acknowledged and applied by different potential users, we will launch a dialogue between the HBM research community, policy makers and stakeholders in order to capture the range of different perspectives. Together, these actors can frame the interpretation of results and steer their translation into politically and technically feasible policy options that match the needs and expectations of European citizens, stakeholders and policy makers.

Under HBM4EU, stakeholders will also be asked to contribute to decisions on research priorities, by providing input to the prioritization of chemicals for monitoring and research. As a first step in 2017, we will request written input from the Stakeholder Forum on priorities for action, including nominations for priority substances and, where relevant, specific populations for investigation. In the autumn of 2017, we will organise a stakeholder workshop to discuss stakeholder input. The outcomes of the stakeholder consultation on HBM4EU research priorities will be consolidated into a report, with stakeholders provided with an opportunity to comment.

We will organise a focus group with members of the general public, in order to draw in the perspectives of non-experts and capture “hidden stakes”. The aim of these focus groups will be to represent, to the extent possible, the European public.

The consultation process on the prioritisation of chemicals for future research will capture input from policy makers and scientists from across Europe and beyond. In consolidating priorities, we will apply a transparent prioritisation strategy, with decision criteria to be developed by the HBM4EU partners in 2017. Stakeholders, as well as policy makers and scientists, will have an opportunity to feed into the design of the strategy.

In Consultation Group 2, participants will not only discuss the opportunities for, but also the challenges of, initiatives for a joint reflection on the science-policy nexus for chemical risk

governance. Researchers and policy makers are often confronted with challenging questions in the field of risk assessment and risk management, such as:

- How can we effectively capture stakeholder concerns in the prioritization of chemical risks?
- Can high public concern be a criterion for priority setting, if that risk is considered to be negligible by scientists?
- Which results should be communicated to the public at large?
- How can risks be communicated without trivializing them?
- How can we avoid fear mongering?

The Eurobarometer 2014 on the attitudes of European citizens towards the environment revealed that the top three most trusted sources of information on the environment are scientists, non-governmental organisations and television. The HBM4EU partners must respond to the challenge of how best to communicate scientific results generated under HBM4EU via the knowledge hub. We will need to communicate messages in the context of scientific uncertainties related to study design and the interpretation of results. We will also need to tailor our communication to address non-scientific audiences.

In consultation group 2, moderators will guide three subgroups through a series of intertwined questions that all relate to the challenges of stakeholder participation in risk governance. During the session, the moderators will welcome oral input and discussion. We also invite participants to write down and drop their personal suggestions in a box.

Questions for discussion:

- **Who** should be invited to participate in a joint reflection on the science-policy nexus for chemical risk governance?
    - Which stakes do we consider relevant?
    - What are the hidden stakes in the field of HBM?
    - How can we give voice to these hidden stakes, such as the unborn child and future generations?

- **How** to structure joint reflection on HBM research and results?
    - How can we move beyond informing stakeholders to establishing an ongoing dialogue?
    - What platforms are required to enable an exchange of ideas and opinions?
    - How can we best structure procedures for stakeholder input to the Strategy for the prioritisation of chemicals for monitoring and research? And to a future European programme?
    - How can we explore and communicate domestic priorities via the national hubs?
    - Do you have proposals for guiding principles for scientific processes, and for the exploration of policy options?

- **How** to communicate via the knowledge hub?
    - How should we tailor our communication products to reach a range of stakeholder audiences?
    - What communicate channels should we use for which audiences?

- **What** are the additional questions stakeholders want to address?

- **Initial feedback** on HBM4EU?

HBM4EU contact point for stakeholders

The Austrian Environment Agency is responsible for maintaining the dialogue with stakeholders under HBM4EU. For all enquiries, please contact: stake-hbm4eu@umweltbundesamt.at

Annex I: First list of priority substances under HBM4EU

HBM4EU substance group	Main policy questions to be answered in 5 years
Phthalates and DINCH	1. What is the current exposure of the EU population to phthalates and DINCH? 2. Different exposure between countries? Why? 3. Can we detect a significant decrease in levels in the population from 2007 to present in phthalates regulated under REACH? 4. What are the high exposure groups? 5. Are exposure levels above any health-relevant assessment levels? 6. Should phthalates on the REACH candidate list 1 be subject to restriction on the basis of exposure of the EU population to levels of concern for health?
Bisphenols	1. What is the current exposure of the EU population to BPA, BPS and BPF and possibly other bisphenols? 2. Do different regulatory controls across the EU lead to different exposures? 3. Are exposure levels of concern for health? Is occupational exposure of cashiers a health concern? 4. What is the toxicity of BPA substitutes? 5. Are health risks age and gender dependent? Can we find evidence for low-dose effects and effects within mixtures? 6. How can this feed into an assessment of the Tolerable Daily Intake (TDI) for BPA of 4 µg/kg/day, as set by the European Food Safety Authority (EFSA)? 7. Is it important to eliminate legacy BPA from material cycles (i.e. waste till receipt rolls) when implementing a circular economy in order to protect human health?
Per/poly-fluorinated compounds (PFASs)	1. What is the current exposure of the EU population to PFASs and do they exceed Guidance values (reference and HBM values), where available? 2. Are there differences in exposure of the EU population to regulated and non-regulated PFASs? 3. Has restriction of PFOS under REACH led to a reduction in exposure, especially for children? 4. Is exposure driven by diet, consumer exposure, occupation or environmental contamination? 5. Which areas and environmental media in Europe are contaminated with PFASs? 6. How can this feed into an assessment of the TDI for PFOS and PFOA set by EFSA? 7. Is it important to eliminate legacy PFASs from material cycles (i.e. waste electronic equipment) when implementing a circular economy in order to protect human health?
Flame retardants	1. What is the current exposure of the EU population to flame retardants, both legacy compounds and new substitutes? 2. Does exposure differ between countries? Why? 3. Have restrictions under REACH and under the Stockholm Convention led to a significant decline in exposure to restricted compounds and is this uniform across the EU? 4. Which population groups are most at risk? 5. Should brominated flame retardants be regulated under REACH? 6. Is it important to eliminate legacy flame retardants from material cycles (i.e. waste furniture) when implementing a circular economy in order to protect human health?

Cadmium	1. What is the current exposure of the EU population to cadmium? 2. Does exposure differ between countries? Why? 3. Is there a link between high soil contamination with cadmium and human exposure via dietary sources? 4. Which population groups are most at risk? 5. Are environmental quality standards for cadmium in water sufficiently restrictive to protect human health from exposure to cadmium via the environment and via dietary sources? 6. Provide information to EFSA on exposure to cadmium at population level to feed into the Commission assessment of measures to address dietary exposure to cadmium, foreseen under Commission Recommendation of 4 April 2014 on the reduction of the presence of cadmium in foodstuffs (2014/193/EU).
Chromium VI	1. What are the current exposure levels to hexavalent chromium at workplaces in Europe? 2. What is the impact of authorization of chromates on exposure levels e.g. in surface treatment activities? 3. What is the current exposure of the EU population to chromium VI? 4. Does exposure differ between countries? Why? 5. To inform decision making on the granting of authorisations for the chromium VI compounds on the REACH authorisation list. 6. Is the limit of 50 µg Cr/L for total chromium in water intended for human consumption and natural mineral waters sufficiently protective? 7. What is the impact of the limit of 3 ppm of chromium VI in leather articles imposed in May 2015 on consumer exposure?
Polycyclic aromatic hydrocarbons (PAHs)	1. What is the current exposure of the EU population to PAHs? 2. What is the current exposure of different occupational groups? 3. Does exposure differ between countries? Why? 4. Can we see a decline in exposure to the eight PAHs restricted under REACH? 5. Inform the development of legislation specifically targeting exposure to PAHs through ambient air. 6. Is there an association between air quality and human exposure to PAHs?
Anilines (anilines and MOCA)	1. What is the current occupational exposure to aniline and MOCA in the EU? 2. What is the impact of REACH on exposure levels of anilines?
Chemical mixtures	1. What chemicals make up the unintentional mixtures to which the EU population is exposed via multiple pathways? 2. How do these unintentional mixtures vary across countries? 3. What are the impacts of chemical mixtures on human health? 4. How can this inform risk assessment for mixtures, including EFSA's work on pesticides?
Emerging chemicals	1. Provide early warning of the presence of unknown and emerging chemicals in the EU population. 2. Inform the REACH process to identify substances of very high concern. 3. Inform the development of an EU Strategy for a non-toxic environment, as foreseen under the 7th Environment Action Programme.