HBM4EU science and policy for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Report of the stakeholder workshop on the prioritisation of substances for research under HBM4EU

20 November 2017, Directorate General Research and Innovation, Brussels, Belgium

HBM4EU work package 4

Authors and Acknowledgements

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1 Introduction

On 20 November 2017, a stakeholder workshop took place in Brussels, which had been organised by EAA and AGES. The aim of the workshop was to discuss priorities for future research under HBM4EU and to capture stakeholder input on substances nominated for monitoring and research under the project.

The process of prioritising substances under HBM4EU was underway, with members of the Stakeholder Forum and EU Policy Board, as well as National Hubs Contact points having submitted nominations for substances for research under the project.

The workshop provided a forum for discussion of the priorities put forward by stakeholders, an opportunity to discuss the evidence gaps identified in the mapping of knowledge needs, and a special focus on the societal concerns related to the substances/substance groups.

Participants consisted of a broader range of stakeholders than the HBM4EU Stakeholder Forum (see: https://www.hbm4eu.eu/stakeholders/), members of the EU-policy board and project partners involved in WP4. The list of participants is presented in table 1 below.

Table 1: List of participants in the stakeholder workshop on prioritisation

First Name	Last Name	Affilitation
Alick	Morris	European Commission
Silvia	Benda-Kahri	EAA: Environment Agency Austria
Jos	Bessems	VITO: Flemish Institute for Technological Research
Tine	Cattoor	CEFIC: European Chemical Industry Council
Natacha	Cingotti	HEAL Health and Environment Alliance
Dries	Coertjens	University of Antwerp
Francesco	Florindi	BBMRI: BioBanking and Molecular Resource Infrastructure
Philipp	Hohenblum	EAA: Environment Agency Austria
Tuomo	Karjalainen	European Commission
Peter	Korytar	European Commission
Joana	Lobo Pereira Vicente	EEA: European Environment Agency
Angeliki	Lysimachou	Pesticide Action Network Europe
Isabel	Maya Rubio	BUSINESS EUROPE
Daniela	Mihats	AGES: Austrian Agency for Health and Food Safety
Pelle	Moos	BEUC, The European Consumer Organisation
Tony	Musu	European Trade Union Confederation
Sophie	Norager	European Commission
Eva	Ougier	ANSES: French Agency for Food, Environmental and Occupational Health Safety
Sarah	Petras	WECF: Women Engage for a Common Future
Elke	Rauscher-Gabernig	AGES: Austrian Agency for Health and Food Safety
Ninja	Reineke	Chemtrust
Janice	Robinson	DUCC Downstream Users of Chemicals Coordination group
Christophe	Rousselle	ANSES: French Agency for Food, Environmental and Occupational Health Safety
Tatiana	Santos Otera	EEB: European Environmental Bureau

First Name	Last Name	Affilitation
Roberta	Savli	EFA: European Federation of Allergy and Airways Diseases Patients' Associations
Greet	Schoeters	VITO: Flemish Institute for Technological Research
Marko	Susnik	UEAPME: European Association of Craft, Small and Medium-sized Enterprises
Peter	Tramberend	EAA: Environment Agency Austria
Maria	Uhl	EAA: Environment Agency Austria
Danielle	Van Kalmthout	Gezinsbond
Hans	Verhagen	EFSA: European Food Safety Authority
Violaine	Verougstraete	EUROMETAUX

The workshop agenda is below.

AGENDA
10:00 Welcome
10:15 Introduction of Participants – Tour de table
10:30 Presentation of HBM4EU (VITO)
11:00 Overview of the Prioritisation Strategy (ANSES)
11:25 Introduction to the short list of nominated substances (EEA)
11:50 Questions, Discussion
12:00 Lunch
12:45 Short list of Substances (EAA)
13:15 Prioritisation of substances: group work
5 questions
10 substances
14:20 Coffee break
14:40 Prioritisation of substances: group work
15:40 Feedback from Groups
16:40 Wrap up and Closing
17:00 End

After a short introduction of the participants, the workshop started with a presentation of the European Human Biomonitoring Initiative (HBM4EU).

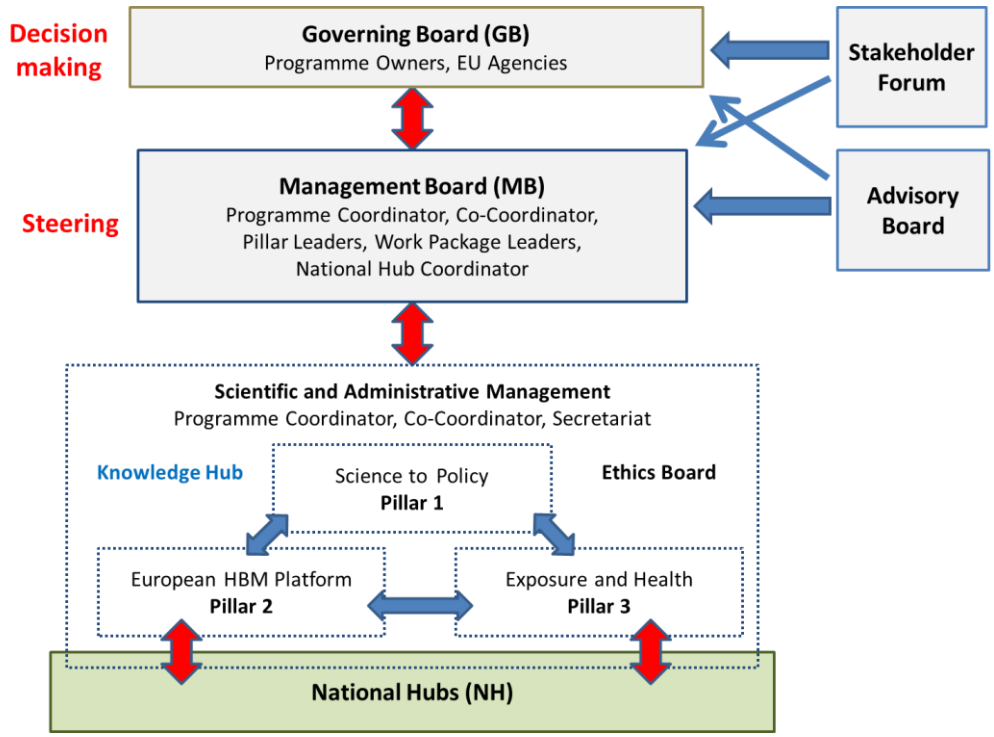
2 Presentation of HBM4EU - Greet Schoeters (VITO)

HBM4EU is a joint effort of 28 countries (24 EU Member States and associated countries as Norway, Island, Switzerland and Israel), the European Environment Agency (EEA) and the European Commission, co-funded under Horizon 2020, which started in 2017 and lasts for 5 years.

Within HBM4EU harmonised data will be collected and assessed in order to answer open policy relevant questions as defined by EU Services and partner countries, give policy makers fast and easy access to results and data, and bridge the gap between science and policy.

The HBM4EU management structure, shown in Figure 1, was presented.

Figure 1: HBM4EU management structure



HBM4EU is organised into work packages (WP) clustered under three pillars and will be implemented in close collaboration with stakeholders, policy makers at EU level and National Hubs:

- Pillar 1: Science to Policy (WP 4, 5, 6)
- Pillar 2: European HBM Platform (WP 7, 8, 9, 10)
- Pillar 3: Exposure and Health (WP 11, 12, 13, 14, 15, 16)

These work packages are supported by the programme management and coordination (WP 1), the Knowledge Hub (WP 2) and Internal Calls (WP 3).

The work packages under the Pillar 1 on science and policy include:

- Prioritising and input into the annual work plan (WP 4:) map the information needs at the beginning of the project, organise the prioritisation process and produce substance specific scoping documents
- Use of HBM results (WP 5): substance specific reporting, develop EU HBM health based guidance values, risk assessment using HBM data, structure the dialogue to develop options for policy actions
- Sustainability (WP 6): identify the need and options for a sustainable HBM initiative in Europe; identify other funding sources for capacity building; develop indicators to evaluate the impact of the programme, develop a concept for a sustainable programme

The involvement of stakeholders is foreseen in the following work packages:

- WP 2: promote the initiative by establishing dialogues with key stakeholders and potential partners → specific brochure for stakeholders

- WP 4: mapping the information needs of policy makers at both EU and national level, as well as input from stakeholders and experts as the information basis for the prioritisation process → October 2017-April 2018; October 2020-April 2021
- WP 5: structured dialogue to develop options for using HBM results at EU level, involving EU regulatory agencies via the Policy board, the Stakeholder Forum (SF) and input from the consortium → 2018
- WP 6: develop a set of indicators capturing societal, scientific, policy and stakeholder perspectives, to measure the performance and impact of the HBM4EU → M6, M30
- WP 6: build support amongst key institutional actors and stakeholders for a long-term, sustainable HBM initiative, determine long term needs of stakeholders → M16 workshop

When developing the project proposal, the first prioritisation was carried out which resulted in nine substances/groups, which have become the focus of HBM4EU activities in 2017 and 2018: phthalates and Hexamoll® DINCH, bisphenols, per-/polyfluorinated compounds, flame retardants, cadmium and chromium VI, PAHs, aniline family, chemical mixtures, and emerging substances.

Work packages under the Pillar 2 (European HBM platform) include:

- Survey design (WP 7): map existing HBM data and identify gaps, develop questionnaires, recruitment strategies, communication, protocols for biobanking and sample exchange
- Targeted fieldwork (WP 8): align current studies, where feasible, implement new targeted surveys, analysis of biobanked samples
- Lab analysis and quality assurance (WP 9): networks of laboratories, quality assurance and quality control, develop new analytical methods, harmonised analysis of biomarkers
- Data management and analysis (WP 10): data management and statistical analysis, derive EU-wide reference exposure values, make HBM data available via IPCHEM

Data management plan in line with GDPR (Regulation (EU) 2016/679), rapid access to HBM data for policy makers, stakeholder and public access to metadata and aggregated data (IPCHEM), statistical analysis of data at EU level by consortium.

Work packages under Pillar 3 include a large number of activities, such as linking HBM and health (WP 11), exposure pathways (WP 12), strengthen the evidence base (WP 13-14), and work on combined exposures (WP 15-16).

3 Overview of the prioritisation strategy – Christophe Rousselle (ANSES)

The prioritisation strategy of substances under HBM4EU was presented to the stakeholders. It is planned to carry out 3 prioritisation rounds under HBM4EU. During the first prioritisation round in 2015, priorities for the first annual work plan were developed. The HBM4EU consortium implemented an exercise to prioritize substances for action, taking into account both national and EU level policy needs for knowledge on chemical exposure and health impacts. The second prioritisation round is taking place from 2017 to 2018. The third prioritisation round is planned for 2020 to 2021. As far as prioritisation is concerned, the challenge is to elaborate a transparent and accountable process based on scientific evidence. Consultation of policy makers, scientists and stakeholders on the strategy is important to secure legitimacy, credibility and societal relevance for the monitoring and research activities under HBM4EU.

The tasks in the prioritisation process include: Mapping of needs – EEA (Task 4.1), Prioritisation strategy – ANSES (Task 4.2), Rapid response mechanism – ANSES (Task 4.3) and Producing scoping documents – VITO (Task 4.4).

The prioritisation strategy was elaborated in close collaboration between the partners involved in the continuum of Tasks 4.2, 4.3 and 4.4. The draft document was sent for consultation to the EU Policy Board, Management Board, National Hub Contact Points (NHCP) and the SF in June 2017. 24 comments were received from the EU Policy Board, 17 NHs and 6 Stakeholders. The prioritisation strategy document was revised accordingly and published on the HBM4EU website in September 2017 as Deliverable D 4.3 'Prioritisation strategy and criteria'.)

In Task 4.1 Steps in mapping knowledge needs (EEA) the following 3 steps have already been performed: 1st step: Survey of knowledge needs with the nomination of substances, 2nd step: Long list of nominated single substances and groups of substances and 3rd step: Initial ranking to produce a reduced list of nominated substances. Within the 1st step members of the EU Policy Board, NHCP and SF were asked to nominate a maximum of 5 substances or groups and to identify critical knowledge gaps. These experts were also asked to provide supporting information on the substances according to the prioritisation criteria of hazard properties, exposure characteristics, regulatory status, public concern and technical feasibility. From the long list of 92 substances/groups a reduced/short list of 23 substances/groups was obtained according to the number of times the new substances/groups of substances were nominated as foreseen in the prioritisation strategy. The re-nominations of substances/groups already included in the 1st list were forwarded to the Chemical Groups Leaders in order to feed the given information into the next version of the Scoping Documents.

As the next step background documents on the substances/groups will be elaborated to ensure having the most relevant information on the substances with regard to the 5 prioritisation criteria, as well as the quality of this information (Actors: ANSES, UBA, VITO, EEA).

This will be followed by the scoring and ranking of the substances/groups according to the defined prioritisation criteria and thereby a ranked list of substances will be obtained. Substances with the highest score should be the most relevant to be nominated for inclusion in the HBM4EU programme. Uncertainties and data gaps will be considered in the scoring phase, to be able to address not yet documented substances, but which merit to be considered today in a more forward looking and wide scale perspective of risk assessment and support policy (Actors: ANSES, UBA, VITO, experts from other institutions involved in the project).

At the end of the presentation opportunities for the stakeholders to further contribute to the prioritisation process were emphasized. They should give more insight into the societal concern towards the substances from the short list, thereby ensuring an attribution of global scores to the substances. Stakeholders could bring new knowledge on the substances/groups from the reduced list of nominations. Stakeholders will be asked to provide comments on the background documents and the scoring during the planned consultation period from mid-March to end of March 2018.

3.1 Introduction to the short list of nominated substances – Joana Lobo Vicente (EEA)

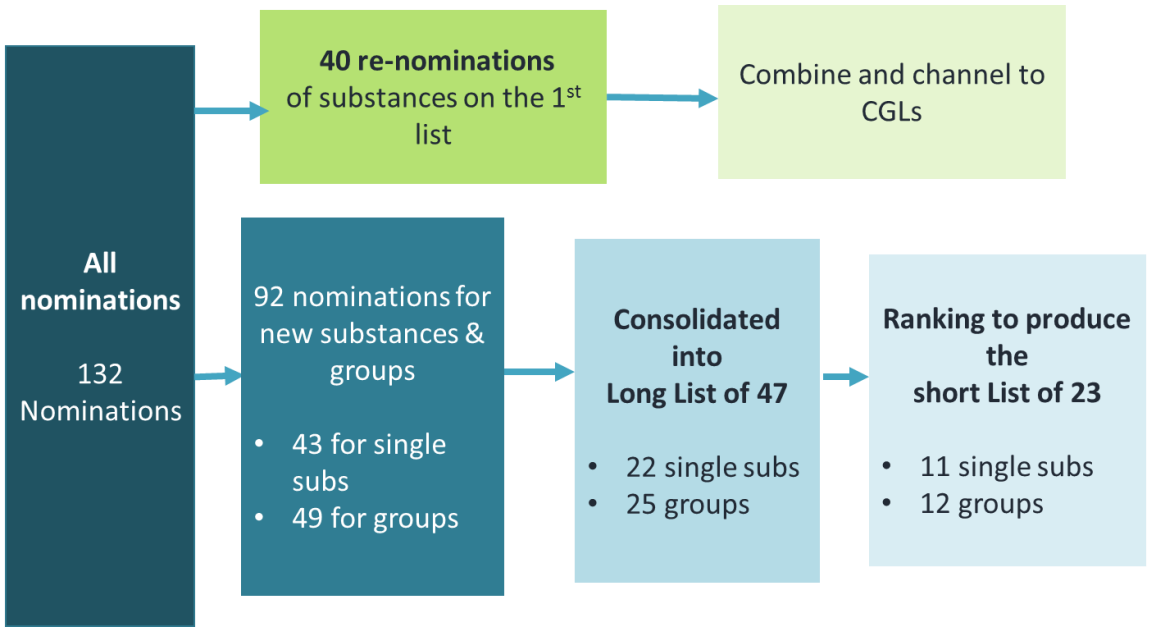
From July to September 2017 an online survey for the nomination of substances for research under HBM4EU was conducted. The survey participants could nominate new substances, and substance groups and/or re-nominate substances on the first list. The survey requested information on 5 prioritisation criteria (hazard, exposure, regulatory status, public concern and

technical feasibility). Members of the NHCP, SF, and the EU Policy Board were invited to participate.

In total, 132 responses from 24 countries, 3 members of the SF and 5 members of the EU Policy Board were received.

Figure 2 provides an overview of the process to produce the short list of 23 substances/groups.

Figure 2: Process to produce the short list of 23 substances/groups



In total, 23 substances were considered for the short list. From there, 2 substances/groups were nominated by the EU Policy Board, SF and countries, 10 substances/groups by the EU Policy Board and countries, 3 substances/groups by one/more countries and a stakeholder, 7 substances/groups just by the EU Policy Board, and one substance/group by just more than 1 country. The following substances in the short list were nominated by the SF: UV absorbers and filters, chlorpyrifos, siloxanes, glyphosate, and nanomaterials.

From January to February 2018 substances and substance groups on the short list will be scored against the prioritisation criteria. In February 2018, NHCPs, SF and EU Policy Board will be consulted on background documents and scoring. In March 2018, background documents and scores will be revised based on the feedback received. A joint meeting of the EU Policy Board and the HBM4EU Management Board will be held on 5/6 March 2018. In April 2018, a 2nd list of HBM4EU priority substances will be sent to the Governing board for comments and approval.

3.2 Short list of substances – Maria Uhl (EAA)

Hazard properties, exposure characteristics, regulatory status were presented for each of the substances and groups of substances listed below.

Short list of substances/group of substances identified within the second round of prioritisation:

- Mercury and mercury compounds

- Glyphosate [N-(phosphonomethyl)glycine]
- Arsenic acid and its inorganic compounds
- Nanomaterials
- Diisocyanates
- Lead and its compounds
- Pesticides authorised in the EU and metabolites
- Pyrethrines and Pyrethroids
- Acrylamide
- Quatenary Ammonium salts
- Mycotoxins, including deoxynivalenol (DON) and its metabolites and fumonisins B
- Aprotic solvents, including pyrrolidones
- Dimethoate
- Fipronil [(±)-5-amino-1-(2,6-dichloro-α,α,α-trifluoro-para-tolyl)-4-trifluoromethylsulfinyl-pyrazole-3-carbonitrile]
- N,N-diethyl-m-toluamide
- Perchlorate
- Phenolic benzotriazoles
- Polyethoxylated (POE)-tallowamine
- Substituted phenylenediamines
- UV absorbers and filters
- 2,6-di-tert-butyl-p-cresol
- Chlorpyrifos [0,0-diethyl 0-(3,5,6-trichloro-2-pyridinyl)-phosphorothioate]
- Siloxanes

3.3 Reducing the short list to 10 substances

On a flipchart the 23 substances/groups of substances were listed. Each participant received three stickers to mark the substances that he/she considered most important. This resulted in the list of the following 10 most important substances:

1. Pesticides authorized in the EU and metabolites: 9 votes
2. Glyphosate [N-(phosphonomethyl)glycine]: 6 votes
3. Siloxanes: 5 votes
4. Mercury and mercury compound: 4 votes
5. Arsenic acid and its inorganic metabolites: 4 votes
6. Nanomaterials: 4 votes
7. Lead and its compounds: 4 votes
8. UV absorbers and filters: 4 votes
9. Diisocyanates: 3 votes
10. Mycotoxins including deoxynivalenol, and its metabolites and fumonisins B: 3 votes

4 Group work to discuss relevant aspects and research on selected substance/groups

In working groups, stakeholders had the possibility to discuss one of the 10 prioritised substances/groups. The following questions were considered:

- Key messages
- What is the concern from a stakeholder perspective?
- Which knowledge gaps should be filled?
- How can HBM4EU address the concern?

- What kind of output/results do you expect from HBM4EU?
- How would you as a stakeholder use the result?

4.1 Pesticides authorised in the EU and metabolites (Hans Verhagen, Tony Musu, Jos Bessems)

One of the key messages was that we have to shift paradigm: i.e. from the current regulatory approval model of pesticides (animal models and extrapolation models) to real life data (i.e. HBM data). For sure, when reregistration is requested. In addition, clarification is needed on whether the current regulation provides sufficient protection for workers and consumers. In the case of pesticide mixtures, facts to support or refute suggestions for combination or additivity effects are needed.

There is concern of stakeholders about the occupational exposure. The actual use by workers, farmers, families should be taken into account - so far only models are used. There are hardly any measured data available. There seems to be a lack of policy responsibility for occupational and consumer exposure (not ECHA, not EFSA, but who then?). The correlation with effects by pesticides is necessary, not only the assessment of exposure.

Knowledge gaps should be filled by real external exposure data. HBM shall confirm the relationship (or absence thereof) between exposure and health effects (both for occupational exposure and consumer exposure). Exposures should be measured instead of being modelled.

As output/result from HBM4EU real facts, i.e. support for the hypothesis that there is a human health concern, or the falsification of the same hypothesis are expected.

Stakeholders would use the result of HBM4EU by including the workers' perspective in the pesticide regulation. For reregistration of pesticide active ingredients the producers shall deliver real measured data on internal exposure of workers and consumers.

4.2 Glyphosate [N-(phosphonomethyl)glycine] (Natascha Cingotti, Marko Susnik, Eva Ougier, Tuomo Karjalainen)

Standardised, accepted data and results should be collected, and harmonised methods and analytics applied. Stakeholders would use the information for communication to workers, decision makers, consumers, etc. Health effects should be linked to substances in the body and mixtures/real life exposure related to health.

There is concern about the adverse health effects: potential carcinogenicity, toxicity (reproduction, neurotoxicity), potential endocrine disrupting properties and about the use of the substance in mixtures for pesticides (adjuvants…). For Small and Medium Enterprises (SMEs) it is hard to trust the regulatory system. Discussion should be science based, not politically motivated. There is a need of more comparable data, because only limited data are available especially in the European Union.

Knowledge gaps exist on several levels: general comparable data, specific data of subgroups (farmworkers – how much of a given substance is in their bodies, how are their children exposed?) and mixtures.

HBM4EU should collect the information that is available and get what is missing. As output/result from HBM4EU, already available data should be made available. A high quality of data should be

gguaranteed. Data should be representative and harmonised. Specific subgroups should be taken into account.

Stakeholders would use the result of HBM4EU for communication and explanation, to search for substitutes or for the implementation of specific regulatory measures.

4.3 Siloxanes (Sarah Peters, Tatiana Santos, Christophe Rousselle, Janice Robinson, Pelle Moos, Sofie Norager)

Siloxanes are a heterogeneous group of substances with a high level of exposure. There is knowledge on a few specific substances and a lack of knowledge regarding their uses, exposure, life cycle, human biomonitoring and health. Little is known about time trends, or whether the levels are increasing. No information on the current exposure is available.

There is a concern from a stakeholder perspective regarding the lack of regulatory action, although siloxanes are theoretically regulated. The scope of the restriction is too narrow. Rinse-off products in which siloxanes are restricted only cover about 25% of the cosmetic products. Siloxanes very widely used in many applications resulting in a high exposure (inhalatory exposure, workplace exposure). Stakeholders are concerned about the potential of these substances to bioaccumulate in humans and possible health effect regarding the fertility and damage to the unborn child. In case of D4 and D5 there is a concern about endocrine disruption. The opinion of the scientific committee is still pending.

Within HBM4EU biomarkers should be developed and the question of bioaccumulation in humans should be addressed.

As output/result from HBM4EU biomarkers for the whole group/family of substances should be developed and current exposures and health effects should be assessed. Because these substances are an environmental concern (persistent and bioaccumulative), HBM4EU should address the question whether siloxanes are also a human health concern.

Stakeholders would use the result of HBM4EU to feed into/promote the process of restriction and authorisation and to raise awareness (e.g. labelling of cosmetics).

4.4 Mercury and mercury compound (Van Kalmthout Danielle, Joana Lobo Vicente, Tine Cattor, Isabel Maya Rubio)

Key messages include the interpretation of the results for the public in an understandable manner, and the coordination, alignment and integration of data and policy.

There is concern of stakeholders regarding fish consumption. Pregnant women may adapt their diet to a “healthy” one by eating more fish, which can be highly contaminated. Another point was traceability, and that multiple exposure pathways throughout life should be taken into account.

It was stated that mercury is a highly regulated substance and an alignment between different pieces of legislation should be made. Information on exposure levels should be made available and the exposure of the total population and specific exposure groups should be compared.

Within HBM4EU information should be collected and made available in one single database. Results should be presented for lay people.

As output/result from HBM4EU better and coordinated policies are expected. Consumer fact sheets for the nominated substances with an interpretation of the results should be prepared.

Stakeholders would use the result of HBM4EU for a comparison of reference values for the general population to exposure of workers and for communication to citizens.

4.5 Arsenic acid and its inorganic metabolites (Dries Coertjens, Ninja Reineke, Alick Morris, Greet Schoeters)

Key messages identified were: the health concern of neurotoxicity, the multisource exposure of vulnerable groups such as infants and workers and the added value for policy evaluation and consumer advice, to which the results from HMB4EU could contribute.

The concerns from a stakeholder perspective were the adverse health effect of neurotoxicity, the occupational exposure for which a limit value will be proposed in the near future, but also the general exposure. For example, in Belgium the population exceeds the limit values and also in the Scientific Opinion of EFSA the possibility of a risk to some consumers could not be excluded.

A baseline exposure level in the EU and trends according to geography, time, sectors of use and age groups should be estimated taking into account the different sources of exposure such as diet, water and workplace.

Within the HBM4EU project biomarkers for arsenic could be confirmed, analyses should be performed to get results on exposure. Also data that are already available should be collected.

As an output/result from HBM4EU it is expected to get a reliable data collection such as IPCHEM, that the sources of arsenic species will be identified and, based on the new information, that it will be possible to perform policy evaluation and give consumer advice.

4.6 Nanomaterials (Tine Cattoor, Dries Coertjens, Tatiana Santos, Markus Susnik)

As key messages were identified that nanomaterials are an important emerging topic, applications are increasing with a perceived knowledge gap; furthermore it is important to prioritise among the different nanomaterials and to develop detection methods.

The concerns from a stakeholder perspective are that it is not possible to group nanomaterials with one biomarker, that regulatory activities can only be started after description of the problem, that a clear definition for substances is needed, that hotspots should be identified, that exposure is becoming higher and that there is a general lack of knowledge and a lack of regulatory action. The nanomaterials are not covered by REACH.

The knowledge gaps to be filled are the development of methods for measuring nanomaterials in the body, validation of appropriate biomarkers, prioritisation of nanomaterials and their exposure and the behaviour of nanomaterials in the body.

HBM4EU can address these concerns by developing accepted methods for the different substances and by measuring. As output/results from HBM4EU new information is expected for example about specific nano-effects.

Stakeholder can use the results to protect workers, for risk assessment purposes, to raise awareness and communicate to the public and for more targeted regulatory action.

4.7 Lead and its compounds (Isabel Maya Rubio)

Because a lot of answers to the questions above were the same for all metals, it was proposed to find out whether it was possible to deal with the proposed metals together. As already stated for mercury, results should be interpreted for and made available to the public in an understandable manner.

A contamination of lead can be found in soils, drinking water and food and people are exposed via multiple pathways throughout their lives. In particular, the knowledge on the influence of exposure to lead on children's health should be increased. Also important is to study if the reference levels, which are applied to protect people, are still adequate.

Within HBM4EU information should be collected and made available in one single database. Understandable information should be provided for consumers. Updated epidemiological information should be made available.

Stakeholder expectations on HBM4EU concern better and coordinated policies , consumer fact sheets for nominated substances with an interpretation of the results and in general more scientific information.

Results of HBM4EU will be used by stakeholders for comparison of reference values for the general population to exposure of workers and for communication to citizens.

4.8 UV absorbers and filters (Danielle Van Kalmthout, Ninja Reineke, Naracha Cingotti, Pelle Moos)

The key messages were the wide use of UV absorbers and filters and gaps in regulation (such as for textiles and food contact materials). There is concern regarding endocrine disrupting properties and the occurrence in Danish children calls for further investigation.

The concerns from a stakeholder perspective are that they are suspected endocrine disrupters (CoRAP), in wide dispersive use in consumer products such as textiles and printing inks and listed on SIN-list. There is high exposure of children via sun cream with contradictory messages like “protects children from sun”. They have already been detected in Danish children. Different products may contain UV absorbers and filters which are regulated by different regulatory frameworks.

The knowledge gaps identified are that the European exposure is unknown (only information from Danish data), that there are only data on benzophenone, but not on the other substances and that the most important exposure routes are not known.

HBM4EU can address this concern by collecting and producing European data for benzophenones, by identifying which ones are endocrine disrupters and by clarifying the most important exposure routes.

The output/results from HBM4EU should be a European HBM study on benzophenones and estimation of exposure of young children, pre-natal exposure and exposure via breastmilk. Gain of more knowledge on endocrine disrupting mode of action is expected.

Stakeholder can use the result to improve regulation and protect health, raise awareness, to inform the public and to encourage companies to substitute these chemicals.

4.9 Diisocyanates (Janice Robinson, Alick Morris, Tony Musu)

One of the key messages is that there is a real risk from diisocyanates and not only a theoretical one, therefore it is important to prevent the onset. The risk related from diisocyanates is manageable because the information is available, these substances are occupational sensitizers. A main issue is that the life cycle of companies is too short. New companies start from the beginning and don't take up already gained knowledge.

So far there are no substitutes or the substitutes are less toxic, but frequently more used and therefore in the long run equally dangerous.

The concern from a stakeholder perspective focuses on the occupational exposure because they are potent chemical sensitizers (e.g. respiratory sensitizer). In several sectors there is less control such as SMEs. There are also consumer concerns.

The knowledge gaps to be filled are the lack of knowledge of consumer use and within the occupational setting knowledge gaps on the implementation and effectiveness of risk management measures (e.g. ventilation controls). Sustained maintenance measures are necessary.

HBM4EU can address this concern by providing the necessary information to raise awareness of workers, by using agreed biomarkers and by generation of results and trends. These points are also expected as output/results from HBM4EU.

Stakeholders could use the result to show measurements, to better implement regulations and close gaps in legislation, and to communicate to customers and inform the supply chain as an industry guidance.

4.10 Mycotoxins including deoxynivalenol, and its metabolites and fumonisins B (Hans Verhagen, Sophie Norager)

The main key message from this discussion group was that risk ranking for public health of all the hazards (not just mycotoxins) should be performed first. Related to mycotoxins there is a potential public health concern, for example very high levels of deoxynivalenol can be found in food such as cereals and cereal products. Deoxynivalenol is immunosuppressive. Everyone is exposed to deoxynivalenol and you can only prevent exposure if you don´t eat cereals. Deoxynivalenol is regulated in food in European Regulation 1881/2006. Masked or bound mycotoxins are phase II metabolites formed in the plant through conjugation with polar low molecular weight molecules such as glucose or sulfate and are currently neither routinely screened for in food nor regulated by legislation.

From a stakeholder perspective the public authority is responsible for the protection of consumers from mycotoxins, because consumers cannot choose and avoid exposure to these contaminants. Within the HBM4EU appropriate biomarkers should be identified and exposure should be related to adverse health effects or to the absence thereof.

As an output/result from HBM4EU in general a good database and biobank is expected. A clear correlation between compounds and adverse effects in different population groups should be established.

From a stakeholder's point of view, the results could be used as an information for the European Commission to develop a code of practice for agriculture and in the future to revise the maximum levels in food.

5 General feedback

Participants had the opportunity to provide a general feedback on the project. Following comments and questions were posted on a flip chart.

- Documents should be sent earlier to participants so they can liaise with their members
- For future workshops it would be very useful to get the list of substances earlier (to have time to discuss them with members and prepare)
- For the prioritisation: the hazard property should not determine the selection – this would favour mostly data-rich substances
- How will data gaps be taken into account in the prioritisation?
- The aim of HBM4EU should be to improve protection: this can be done by focussing on substances in need of regulation
- Feedback on work on mixture? – how is it going? Which mixtures are being looked at? Challenges?
- Will we have access to the individual nominations made by GB/MB/national hubs/stakeholders? Would be very useful to have refined discussion on policy questions
- Exposure to very young children (0-3) should be taken into account as exposed to many substances as well
- How will the tension between single health based guidance values and combined exposures be addressed?
- Clarifications welcome on organisation of work done to monitor vulnerable groups: pregnant women, young children, workers particularly exposed
- It would be good to get more information about the current HBM4EU research on the 1st prioritised substances – maybe at next stakeholder meeting
- Would welcome feedback on how work is progressing on 1st priority list/how advanced? Which substances/subgroups are looked at? Where is further input of stakeholders useful for future?

6 Key messages summarised by Maria Uhl

At the end of the stakeholder workshop Maria Uhl summarised the key messages, which were mentioned repeatedly for several /all substances. Research on the prioritized substances under HBM4EU shall fill the knowledge gaps identified by Stakeholders and policy makers. Multiple exposure pathways and vulnerable population groups such as workers and children are of utmost concern. Addressing occupational exposure and comparing exposure levels with reference values for the general population shall improve worker protection. The large group of nominated substances and substance groups necessitates a risk ranking procedure.

At the methodological level, it is required to develop, harmonise or confirm methods depending on the specific substances and substance groups. HBM4EU shall improve data quality, guarantee harmonisation and create reliable results. HBM4EU results shall feed into the different pieces of legislation and lead to alignment of legislation where needed. Last but not least, providing consumer advice and citizens' awareness raising are key requirements of HBM4EU.