HBM4EU science and policy for a healthy future

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WP 4 - Prioritisation and input to the annual workplan

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2 Glossary

AGES	Austrian Agency for Health and Food Safety
ANSES	French Agency for Food, Environmental and Occupational Health & Safety (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail)
AOEL	Acceptable Operator Exposure Level
ARfD	Acute Reference Dose
BP-3	Benzophenone-3
BDs	Background Documents
BLV	Biological Limit Value
BMDL	Benchmark Dose Level
BGV	Biological Guidance value
CLP	Classification, Labelling, Packaging
DEET	N,N-diethyl-m-toluamide
DEMOCOPHES	Demonstration of a study to Coordinate and Perform Human Biomonitoring on a European Scale
DMA	Dimethylarsinic Acid
DMF	N,N-dimethylformamide
DON	Deoxynivalenol
EAA	Austrian Environment Agency
ECHA	European Chemicals Agency
ED	Endocrine disrupting
EEA	European Environment Agency
EEB	European Environmental Bureau
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization
HBGV	Health-based Guidance Value
HBM	Human Biomonitoring
HEAL	Health and Environment Alliance
IARC	International Agency for Research on Cancer
iAs	Inorganic Arsenic
IPCHEM	Information Platform for Chemical Monitoring
JRC	Joint Research Centre
MAK Commission	German permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area
4-MBC	3-(4-methylbenzylidene)camphor
4,4-MDI	4,4-methylenediphenyldiisocyanate
MOE	Margin of Exposure
MMA	Monomethylarsonic Acid
NEP	1-ethylpyrrolidin-2-one
NH	National Hub
NIOSH	National Institute for Occupational Safety and Health
NMP	1-methyl-2-pyrrolidone

OEL	Occupational Exposure Limit
OSH	Occupational Safety and Health
PBTK	Physiologically Based Toxicokinetic
POEA	Polyoxyethylene tallow amine
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	Reference Dose
SCOEL	Scientific Committee on Occupational Exposure Limits
SVHC	Substances of Very High Concern
RIVM	Netherlands National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu)
2,4-TDI	2,4-diisocyanato-1-methylbenzene
2,6-TDI	1,3-diisocyanato-2-methylbenzene
UBA	German Environment Agency (Umweltbundesamt)
VITO	Flemish Institute for Technological Research (Vlaamse Instelling voor Technologisch Onderzoek)
WHO	World Health Organization
WP	Work Package

3 Abstract

This deliverable documents the implementation of the prioritisation strategy in order to identify the 2nd list of HBM4EU Priority Substances. The strategy was implemented over a one year period, from July 2017 to June 2018.

The first exercise to prioritise substances for action within HBM4EU was performed in 2015 and resulted in the nine substance groupings that have been the focus of HBM4EU activities in 2017 and 2018. HBM4EU partners built on the experience gained with the first prioritisation exercise to make the process of prioritising substances for future analysis under HBM4EU more accountable, transparent and legitimate. The prioritisation strategy as described in Deliverable 4.3 on the Prioritisation strategy and criteria was developed in 2017 and was approved by the 1st meeting of the HBM4EU Governing Board in September 2017.

The prioritisation strategy was implemented in two distinct tasks: the mapping of knowledge needs; and the prioritisation of substances.

The objective of the task to map knowledge needs was to understand the demands of the National Hubs, EU policy makers and members of the HBM4EU Stakeholder Forum for human biomonitoring evidence on specific substances and substance groups, by asking them to nominate substances for research under HBM4EU. A short list of nominated substances was produced on the basis of policy demand for knowledge and consensus across nominating partners.

The objective of the prioritisation of substances was to implement a systematic and science-based approach to ranking substances on the short list against a set of prioritisation criteria. The proposed set of prioritisation criteria included: hazardous properties; exposure, including environmental, consumer and occupational exposure pathways; regulatory status; societal concern; and technical feasibility. Substance were scored against three of these criteria and then ranked. Substances were also categorised according to the availability of evidence.

The ranked short list of substances was communicated to the HBM4EU Management Board and the European Union (EU) Policy Board, so they could reflect on the scientific and policy merit of conducting research on each substance and identify a draft list of priorities substances.

The draft 2nd list of HBM4EU Priority Substances was agreed at a joint meeting of the HBM4EU Management Board and the EU Policy Board in March 2018. The resulting draft 2nd list of prioritised substances was sent to the Governing Board for approval in May 2018. The Governing Board approved the list, which is presented in the table below.

Table 1: 2nd list of HBM4EU Priority substances

Substance
Acrylamide
Aprotic solvents
Arsenic
Diisocyanates
Lead
Mercury
Mycotoxins (focus on DON)
Pesticides: glyphosate, chlorpyrifos, fipronil and pyrethroids
UV filters – benzophenones

4 Introduction

This report documents the implementation of the prioritisation process for the selection of substances and substance groups to be the subject of research under HBM4EU. The first exercise to prioritise substances for action within HBM4EU was performed in 2015 and was not open to stakeholders. Prior to project kick-off in January 2017, the consortium implemented an exercise to prioritise substances for action, taking into account both national and EU level policy needs for knowledge on chemical exposure and health outcomes. This led to the 1st list of HBM4EU Priority Substances.

With the aim of opening up the process to stakeholders and making it transparent, legitimate and accountable, the HBM4EU Prioritisation Strategy was developed in 2017. The proposed strategy was approved by the 1st meeting of the HBM4EU Governing Board in September 2017. The process was first described in Deliverable 4.3 on the Prioritisation strategy and criteria.

This report now complements that document with a detailed description of the implementation of the process in 2017 and 2018, in order to generate the **2nd list of HBM4EU Priority Substances**.

The process drew in input from the HBM4EU Management Board, the EU Policy Board, the National Hubs and the Stakeholder Forum, as well as consulting a broader range of stakeholders and discussing priorities with citizens at a focus group. This report documents the various processes employed to consult with these different actors.

In addition, this report includes details on the substances that these different partners proposed for inclusion under the HBM4EU programme, as well as identifying those substances that were short-listed and ultimately prioritised for research. As such, each section of the report both describes the implementation of a process and documents the results of the process. Thus, this deliverable will document the prioritisation process and will provide the evidence to support the proposed 2nd list of priority substances.

Table 2 below provides an overview of the sections of the report and how they capture the work done to deliver the prioritisation of substances under work package 4.

Table 2: Report sections and content

Report section	Content
5	Objectives and development of the prioritisation strategy
6	Key steps in the prioritisation strategy
7	Mapping of knowledge needs, including: Online survey and producing draft background documents Stakeholder workshop on prioritisation Focus group with citizens
8	The prioritisation of substances, including: Revision of the background documents Scoring of substances Categorisation of substances Consultation on background documents, scoring and categories Ranking the substances
9	Joint meeting of the HBM4EU Management Board and the EU policy Board
10	Consultation with the Governing Board
11	2nd list of HBM4EU priority substances

5 Objectives and development of the prioritisation strategy

5.1 Objectives of the prioritisation strategy

HBM4EU aims to generate new knowledge on human exposure to chemicals in Europe and the resulting impacts on human health. This knowledge should support the efforts of policy makers to enhance chemical safety in Europe, as well as serving the needs of a range of stakeholders. Our results should be used to generate positive impacts for European society in terms of improved health.

The selection of substances to be the subject of research activities under HBM4EU represents a critical step towards achieving these objectives. In order to secure the **legitimacy**, **credibility** and **societal relevance** of our work, HBM4EU partners consulted policy makers, scientists and stakeholders on the strategy for the prioritisation of substances for both monitoring and research activities under the project.

At the same time, the nominations of the different parties invited to participate in the strategy for the prioritisation of substances do not have the same weight in the process.

As a Horizon 2020 project, HBM4EU addresses societal challenges to health and wellbeing for European citizens. It is a principle objective of the project to bridge the divide between science and policy at European level and to generate results that meet the knowledge needs of European Union (EU) policy makers. Priority is therefore given to the nomination of substance by the members of the **EU Policy Board**, with the aim of delivering on this key objective. In addition, 70% of the funding for HBM4EU comes from the European Commission, given the Commission a key stake in the project.

Input from the National Hubs is also highly valued, and will help us to ensure that the project also serves the knowledge needs of national policy makers and to establish whether national and European level priorities are aligned. The National Hubs provide 30% of the funding for HBM4EU and so have a voice in shaping the strategic direction of the research.

Selected substances will be the subject of research at European level. It is therefore important that HBM4EU addresses knowledge gaps on chemical exposure and resulting health impacts that have relevance at European level and generates results that benefit European society. Substances that are exclusively of local or national concern were therefore not considered.

We also requested input from members of the Stakeholder Forum. This valuable input allowed us to assess the social relevance of research activities on nominated substances, and drew in additional evidence and knowledge. At the same time, it is important to acknowledge that the nominations submitted by members of the Stakeholder were given a lower weight in the prioritisation strategy.

As such the strategy for the prioritisation of substances was not based entirely on scientific evidence. It was also guided by an imperative to produce knowledge in support of policy making at European level. The resulting **2nd list of HBM4EU Priority Substances** reflects a broad consensus on the principle substances and substance groups and addresses some of the concerns of all parties involved.

This report documents the prioritisation process in the interest of accountability and transparency. All documentation related to the process will be made available on the HBM4EU webpages on the prioritisation strategy.

5.2 Development of the prioritisation strategy

The first exercise to prioritise substances for action within HBM4EU was performed in 2015, taking into account both national and EU level policy needs for knowledge on chemical exposure and health outcomes. As a first step, substances for which knowledge is needed to support current EU policy making were identified through close dialogue with an EU Policy Board. Input from the national level was fed in through a Steering Committee, composed of national representatives and established to guide the preparation of this proposal.

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 proposed at both national and EU level were then systematically assessed against these criteria, based on information provided from both EU and national levels. This first prioritisation exercise resulted in the nine substance groupings that will be the focus of HBM4EU activities in 2017 and 2018.

The 1st list of HBM4EU priority group of substances includes:

- phthalates and Hexamoll® DINCH;
- bisphenols;
- per-/polyfluorinated compounds;
- flame retardants;
- cadmium and chromium VI;
- PAHs;
- aniline family;
- chemical mixtures; and
- emerging substances.

HBM4EU partners have built on the experience gained with the first prioritisation exercise to make the process of prioritising substances for future analysis under HBM4EU more accountable, transparent and legitimate.

The prioritisation strategy was developed by the French Agency for Food, Environmental and Occupational Health & Safety (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, ANSES) in 2017, with input from the European Environment Agency (EEA), the Flemish Institute for Technological Research (VITO) and the German Environment Agency (UBA). The prioritisation strategy was approved by the Governing Board at their first meeting in September 2017. The process is described in Deliverable 4.3 on the Prioritisation strategy and criteria.

6 Key steps in the prioritisation strategy

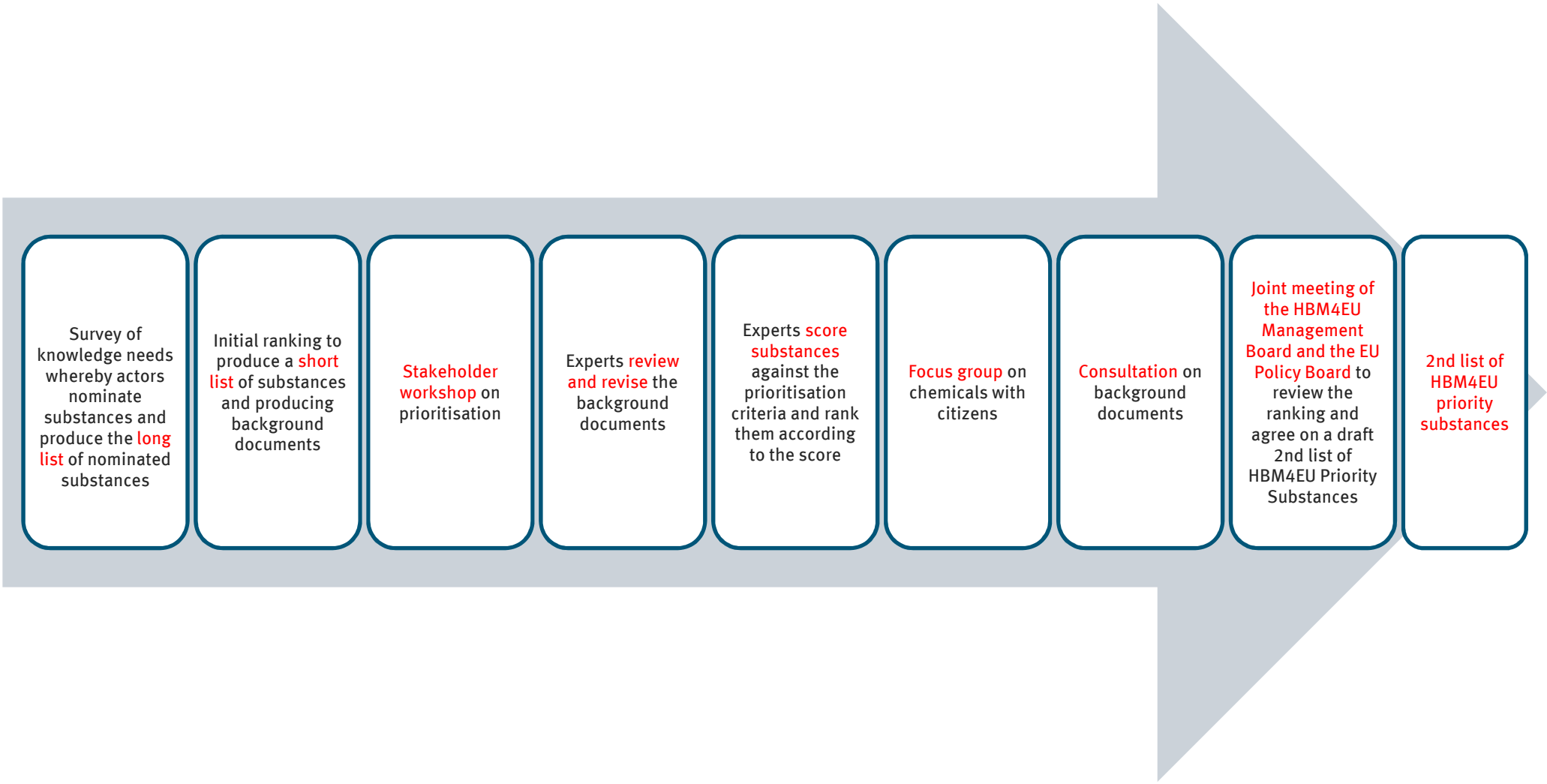
The prioritisation strategy was implemented in two distinct tasks:

- the mapping of knowledge needs; and
- the prioritisation of substances.

The EEA led implementation of the task on the mapping of knowledge needs, supported by the Austrian Environment Agency (EAA). ANSES led the task on the prioritisation of substances, supported by a team of experts from VITO and UBA. In practice, all partners closely collaborated in delivering a coherent prioritisation strategy.

Figure 1 presents the breakdown of key steps in the process across these two tasks. Table 2 then provides more details on each step, together with the timeframe of implementation from July 2017 until April 2018. The process and results of the mapping of knowledge needs are described in section 7 of this report, while the prioritisation of substances is addressed in section 8.

Figure 1: Overview of the prioritisation strategy



Key steps in implementing the prioritisation process are set out in table 3 below.

Table 3: Key steps in implementing the prioritisation strategy and timing

Timing	Step in the prioritisation strategy
Task on mapping of needs (Task 4.1)	
July to September 2017	We ran an online survey in which we asked members of the EU Policy Board, the National Hub Contact Points and the members of the Stakeholder Forum to nominate substances and/or groups of substances for work under the project. Survey participants were asked to justify their nominations by submitting information against the prioritisation criteria.
1st half of October 2017	We collated the survey results to produce a long list of all nominated substances and substance groups. This involved consolidating multiple nominations for single substances and for groups of substances where there was overlap.
2nd half of October 2017	We reduced the long list down to a short list, by identifying: those substances for which EU policy makers identified a need for evidence at EU level; and those substances for which there was support from more than one National Hub and substances nominated by one National Hub and by at least one member of the Stakeholder Forum.
October 2017	We produced background documents on each of the substances and substance groups on the short list. We first mapped the evidence submitted in the online survey against the five prioritisation criteria to produce draft documents.
20 November 2017	We organised a stakeholder workshop on prioritisation, allowing for an open discussion on substances on the short list. Discussions enabled HBM4EU partners to learn about stakeholder priorities and concerns in detail. Discussions focussed specifically on the substances on the short list, and gathered stakeholder input on the level of concern. Workshop outputs were summarised in a workshop report, with the results used to improve our understanding of the criterion “public concern” in the prioritisation strategy.
February 2018	In February 2018, EAA and the Austrian Agency for Health and Food Safety (AGES) organised a focus group discussion with members of the public, to draw in the perspectives of non-experts. The aim was to have an open discussion with lay people on the short list of nominated substances, and capture the priorities of the European public.
Task on prioritising substances (Task 4.2)	
November 2017 to February 2018	Experts reviewed and refined the draft background documents on each of the substances and substance groups on the short list.
1st half of February 2018	A group of experts scored the substances on the short list against the prioritisation criteria using an adapted Delphi method. The substances were then ranked according to their overall score. Each substance was also categorised on the basis of available evidences regarding especially human biomonitoring data, exposure data and availability of biomonitoring analytical methods.
2nd half of February 2018	Members of the Stakeholder Forum, the EU Policy Board and the National Hubs were consulted on the background documents and scores and given an opportunity to provide additional information and comment on the scores.
March 2018	Experts revised the background documents and score for each substance and/or group according to comments received in the consultation.
6 March 2018	The HBM4EU Management Board and the EU Policy Board held a joint meeting to review the final ranking and agree on a draft 2nd list of HBM4EU priority substances, taking into account the results of the prioritisation strategy, available project resources and political priorities.
1 May 2018	The HBM4EU Governing Board approved the draft 2nd list of HBM4EU Priority Substances.

7 Mapping of knowledge needs

7.1 Objectives and process steps

The objective of the task to map knowledge needs (Task 4.1) was to **understand the demands of the National Hubs, EU policy makers and members of the HBM4EU Stakeholder Forum** for HBM evidence on specific substances and substance groups. These three groups of actors are the principle end-users of results generated under HBM4EU, and we therefore aimed to get a comprehensive understanding of their specific needs. Key steps that enabled us to reach this objective included running an online survey requesting the nomination of substances for research under HBM4EU, a stakeholder workshop and a focus group discussion with citizens on chemicals.

A second objective was to **gather and collate the evidence required to undertaken the prioritisation exercise**. In requesting input via the online survey, we asked respondents to identify the substances or substance groups that they would like HBM4EU to work on, as well as identifying questions that they would like HBM4EU to address and describing the role that HBM activities might play in answering those questions. We also asked them to submit available evidence against the prioritisation criteria, to support us in gathering the information required to assess their proposals. The prioritisation criteria were developed and agreed in 2017 and are described in Deliverable 4.3 on the Prioritisation strategy and criteria. This approach both responded to the limited time and resources available in the project to support prioritisation, and aimed to open up the process of gathering evidence to support prioritisation to all actors. Collating all nominations into a “long list” of the knowledge needs expressed by these various actors, enabled us to look across those needs to assess commonalities and divergence.

A third objective was to **produce a short list** of approximately 25 substances and groups of substances, to be assessed in detail under the task on the prioritisation of substances (Task 4.2). Our goal was to prioritise those substances and substance groups for which there was a demand for knowledge to support policy making at EU level, whilst also capturing priorities from the National Hubs, where there was consensus, and responding to the needs of stakeholders.

Finally, we produced **draft background documents** on each substance or substance group on the short list, with the objective of systematically feeding the knowledge needs and collated evidence into the process for the prioritisation of substances.

Key steps in the mapping of needs included the following:

1. Online survey for the nomination of substances for research under HBM4EU;
2. Collating information and producing the **long list** of all nominated substances;
3. Ranking all nominations to produce the **short list;**
4. Producing **draft background documents** on the substances and substance groups on the short list.
5. Organising and capturing results from a **Stakeholder workshop** on prioritisation under HBM4EU; and
6. Organising and capturing results from a **citizens’ focus group** on chemicals.

These steps are described in turn below and the results presented.

7.2 Online survey on the nomination of substances for research under HBM4EU

The **online survey on the nomination of substances for research under HBM4EU** ran from July to September 2017 and was open to the National Hubs, the members of the Stakeholder Forum and the members of the EU Policy Board (table 4).

Table 4: Actors invited to participate on the nomination of substances for research under HBM4EU

National Hubs	Stakeholder Forum	EU Policy Board
Austria Belgium Croatia Cyprus Czech Republic Denmark Finland France Germany Greece Hungary Iceland Ireland Israel Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Slovakia Slovenia Spain Sweden Switzerland United Kingdom	ChemTrust	Directorate-General for Health and Food Safety (DG SANTE)
	Downstream Users of Chemicals Co-ordination Group (DUCC)	Directorate-General for Environment (DG ENV)
	Eurometaux	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)
	European Association of Craft, Small and Medium-Sized Enterprises (UAPME)	Joint Research Centre (JRC)
	European Chemical Industry Council (CEFIC)	Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL)
	European Consumer Organisation (BEUC)	Directorate-General for Research and Innovation (DG RTD)
	European Environmental Bureau (EEB)	European Environment Agency (EEA)
	European Federation of Allergy and Airways Diseases Patients' Associations (EFA)	European Food Safety Authority (EFSA)
	European Trade Union Confederation (ETUC)	European Chemicals Agency (ECHA)
	Health and Environment Alliance (HEAL)	
	Women in Europe for a Common Future (WECF)	

Representatives from each organisation could nominated **up to five substances or substance groups**, by completing the full online survey for each nomination.

The survey is included in Annex I to this report. In the survey, participants were asked to nominate the substance or substance group and then to explain the policy-related questions they proposed HBM4EU research activities address. They were also able to propose specific research activities.

We asked survey participants to identify their needs for **new knowledge** and to describe how they might use that knowledge to generate benefits for society.

We then asked participants to provide information against the prioritisation criteria, as described in Deliverable 4.3 on the Prioritisation strategy and criteria. The criteria are:

- hazardous properties;
- exposure, including environmental, consumer and occupational exposure pathways;
- regulatory demand;
- societal concern; and
- technical feasibility.

We asked participants to identify specific knowledge gaps that might be addressed by HBM4EU. Participants were encouraged to upload relevant reference materials and articles on the nominated substances or substance groups.

Survey participants were also able to re-nominate substances on the first list of priority substances. The rationale for this was that the first prioritisation exercise was not open to members of the Stakeholder Forum. Allowing for re-nominations allowed the HBM4EU partners to gather input on the research priorities of stakeholders on the substances and substance groups on the 1st list of HBM4EU Priority Substances. The first list includes the following groups of substances:

- phthalates and Hexamoll® DINCH,
- bisphenols,
- per-/polyfluorinated compounds,
- flame retardants,
- cadmium and chromium VI,
- PAHs,
- aniline family,
- chemical mixtures, and
- emerging substances.

7.3 Collating survey input and producing the long list

We received 131 responses to the online survey. One respondent experienced problems with the online tool and submitted a nomination by email, which we accepted, to make a total of 132 nominations. In terms of who responded, we received responses from 24 National Hubs, four members of the Stakeholder Forum and six members of the EU Policy Board.

The use of an online survey tool meant that the results could be downloaded as individual completed surveys, as well as automatically collated into an excel file containing the full survey results for all participants. Using excel, we produced a full list of all nominated substances organized according to which actor nominated which substance or substance group, available in Annex II.

The next step was to tease out re-nominations of substances on the 1st list of HBM4EU Priority Substances, of which there were 40. Annex III provides a list of the substances on the 1st list that were denominated by whom. The knowledge needs, research proposals and evidence in these survey responses were channelled to the Chemical Substance Group Leaders for their information and reflection when revising the Scoping Documents for the substances on the 1st list in November 2017.

We then consolidated the 92 nominations for new substances by substance and substance groups, to produce a long list of new single substances and substance groups nominated. This entailed looking for overlap across nominations. For single substances, we chose to include both a single substance and compounds associated with a single substance. Thus, we combined “mercury” with “mercury and its compounds”.

For substance groups, we consolidated some single substances and smaller groups into large groups. Table 5 provides an overview of nominations for single substances and smaller groups that we consolidated into groups when producing the long list.

Table 5: Nominations that were consolidated into larger groups to produce the long list

Nominations	Combined into group
Pesticides authorised in the EU Pesticides and biocides Metabolites of active substances used in pesticides	→ Pesticides
Aprotic solvents Pyrrolidones	→ Aprotic solvents
Mycotoxins Mycotoxins Aflatoxins DON and its metabolites Fumonisin B	→ Mycotoxins
Nanomaterials Nanomaterials Nanomaterials Nanoparticles Nano titanium dioxide	→ Nanomaterials

The long list is included in Annex IV and includes 48 new substances and substance groups, of which:

- 24 are single substances and
- 28 are substance groups.

7.4 Ranking nominations to produce the short list

The next step was to reduce the long list down to a manageable short list of approximately 25 substances and substance groups that could be assessed in greater detail in the task on the prioritisation of substances.

In Deliverable 4.3 on the Prioritisation strategy and criteria, we had envisaged that we would have significant convergence across nominations and suggested that substances will be selected for the short list on the basis of having been nominated by at least:

- Nine National Hubs, representing just over a third of the countries; and
- A member of the EU Policy Board.

In practice, there was less commonality across the nominations than expected, meaning that we had to adapt these criteria:

- to include all substances and groups prioritised by the EU Policy Board, with the objective of meeting EU knowledge needs for policy support; and
- to include substances nominated by two or more National Hubs, or by at least one National Hub and one member of the Stakeholder Forum.

According to these criteria, the short list of 23 substances includes:

- Two substances that were nominated by the EU Policy Board, one or more National Hub and members of the Stakeholder Forum;
- Ten substances that were nominated by the EU Policy Board and one or more National Hub;
- Seven substances that were nominated just by the EU Policy Board;
- One substance nominated by more than one National Hub; and
- Three substances nominated by at least one National Hub and one member of the Stakeholder Forum.

The short list is in table 6 below, with the substance ranked according to the number of times it was nominated.

Table 6: Short list of nominated substances and substance groups

#	Substance or group	Actors who nominated the substance or group			
		EU Policy Board	No. National Hubs	National Hubs	Stakeholder Forum
1	Mercury and mercury compounds	EEA	8	Slovenia, Portugal, Iceland, Austria, Czech Republic, Spain, Cyprus, Croatia	-
2	Glyphosate, N-(phosphonomethyl)glycine	EC - DG RTD	5	Belgium, Netherlands, Latvia, Spain, Switzerland	2
3	Arsenic acid and its inorganic compounds	EC - DG EMPL	3	Belgium, Hungary, Spain	-
4	Nanomaterials	EEA	4	Denmark, Slovakia, France	1
5	Diisocyanates	EC - DG EMPL	2	Finland, UK	-
6	Lead and its compounds	EC - DG EMPL	2	Hungary, UK	-
7	Pesticides authorised in the EU & metabolites	EC – DG SANTE, EFSA	1	Austria	-
8	Pyrethrines and Pyrethroids	EEA	2	Slovenia, France	-
9	Acrylamide	EFSA	1	Netherlands	-
10	Quatenary ammonium salts	EEA	1	Norway	-
11	Mycotoxins, including aflatoxins, deoxynivalenol (DON) and its metabolites and fumonisins B	EFSA	2	Portugal, Luxembourg, Netherlands	-
12	Aprotic solvents, including pyrrolidones	ECHA	1	Germany	-
13	Dimethoate	EC - DG SANTE	-	-	-
14	Fipronil	ECHA	-	-	-
15	N,N-diethyl-m-toluamide	ECHA	-	-	-

#	Substance or group	Actors who nominated the substance or group			
		EU Policy Board	No. National Hubs	National Hubs	Stakeholder Forum
16	Perchlorate	EFSA	-	-	-
17	Phenolic benzotriazoles	ECHA	-	-	-
18	Polyethoxylated (POE)-tallowamine	EC - DG SANTE	-	-	-
19	Substituted phenylenediamines	ECHA	-	-	-
20	UV absorbers and filters	-	2	Denmark, Norway	1
22	Chlorpyrifos	-	2	Spain, Israel	1
23	2,6-di-tert-butyl-p-cresol (BHT)	-	2	Germany, France	-
23	Siloxanes	-	1	Norway	1

7.5 Producing draft background documents on the short list substances

In order to ensure that all the information submitted by survey participants on substances on the short list fed into the task on the prioritisation of substances, we produced **draft background documents**. These documents started by identifying the substances or substance groups concerned, as well as who nominated the substance or group. Knowledge gaps and proposed research activities were also included. The documents went on to systematically organise evidence submitted against the prioritisation criteria. The principle sections of the documents are listed in box 1.

Box 1: Outline of the draft background documents

1. Substance identification
2. Actors that nominated the substances or group
3. Overview of the information submitted
4. Knowledge gaps and proposed research activities
5. Hazardous properties
6. Exposure characteristics
7. Regulation and policy
8. Public concern
9. Technical feasibility
10. References
11. Contacts of actors nominating substances

The draft background documents are available on the HBM4EU webpages on prioritisation, together with subsequent updates of the documents.

7.6 Stakeholder workshop on prioritisation

On 20 November 2017, a **Stakeholder Workshop on Prioritisation** was held in Brussels, organised by EAA and AGES. The aim of the workshop was to discuss priorities for future research under HBM4EU and to capture stakeholder reflections on the societal relevance of HBM4EU generating new knowledge on the substances on the short list.

The workshop provided a forum for discussion of stakeholder priorities, with a particular focus on the societal concerns related to the substances and groups.

Workshop participants included a broader range of stakeholders than the HBM4EU Stakeholder Forum, so opening up the discussion to additional stakeholders. Members of the EU Policy Board and project partners involved in Work Package 4 also participated.

In introduction, the EEA briefly presented the prioritisation strategy and the short list, with an explanation of the ranking process. EAA and AGES then facilitate a discussion on the substances on the short list, in order to better understand the priorities of stakeholders and the reasoning behind these priorities.

In terms of the methodology used to structure the discussions, the 23 substances and groups on the short list were listed on a flip chart. Each participant then received three stickers and was asked to mark the substances that s/he considered most important, as a means of prioritising substances for general discussion. Participants prioritised the following 10 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: 3 votes

Participants then had the possibility to discuss the 10 substances and groups in smaller groups, reflecting on the following questions:

- 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?

In summary, the results of this workshop consultation were:

- Research on the prioritised substances under HBM4EU should explicitly address 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.
- Monitoring occupational exposure and comparing exposure levels against reference values for the general population can be used to improve worker protection.
- The large group of nominated substances and substance groups necessitates a ranking procedure based on risk.

- HBM4EU should develop, harmonise and validate analytical methods for prioritised substances.
- HBM4EU should improve data quality, guarantee harmonized approaches to data production and analysis and generate reliable results.
- Results should be fed into policy review processes for the different pieces of legislation on chemicals, and stimulate the better alignment of legislation, where relevant.
- HBM4EU has a role in providing consumer advice and informing citizens about chemical safety.

For the detailed report of the Stakeholder Workshop on Prioritisation, please see Annex V of this report.

7.7 Citizen focus group and survey on human biomonitoring

In support of the mapping of needs and with the aim of better understanding the views of European citizens on chemical safety in general and human biomonitoring as a tool, EAA and AGES conducted an online survey on human biomonitoring and a focus group with citizens.

The report of these two actions were submitted as an additional deliverable and made available on the HBM4EU website. A brief summary of key results is provided below.

7.7.1 Survey on human biomonitoring

The aim of the survey was to gain information of the interests, needs, and questions of European citizens and to receive input on the short list of nominated substances that would be subject to prioritisation under task 4.2, in order to take them into account within HBM4EU. The evaluation was carried out by questionnaires. It was not the aim to have a representative sample of the Austrian or the European Public. During February and March 2018, a questionnaire was made available online, in English and German.

In total, there are questionnaires from 341 participants, 214 English-speaking and 127 German-speaking. The participants were on average 41.7 years old. It mainly reached people with a university degree (88.6%). Two people only had a compulsory school leaving certificate.

Most of the participants (89.4%) are concerned about chemicals in their daily life. With respect to chemical exposure, chemicals in consumer products and pesticides in food are regarded as most important. 96.8% of the participants responded that they are aware that chemicals in products might have hazardous properties. Chemical compounds in drinking water and food are considered as extremely dangerous by the participants.

Feedback was also provided on the the short list of nominated substances. Substances that were estimated as being especially hazardous were also the best known, including mercury, lead, arsenic acid, bisphenol A and phthalates. PAH, diisocyanates, mycotoxins, acrylamide, dimethoate, substituted phenylenediamines, flame retardents and moca and aniline were also rated as hazardous by the majority of the respondents. The most frequently mentioned unknown substances were phenylenediamines, POE-tallow amine, 2.6-di-tert-butyl-p-cresol, dimethoate, phenolic benzotriazoles, diisocyanates, anilin compounds, aprotic solvents, chlorpyrifos, siloxanes and N-N-diethyl-m-toluamide.

For 17.5% of the participants the most effective way of tackling problems of chemical exposure is applying stricter pollution controls in industrial activities and applying stricter controls in food safety. Regarding the HBM4EU project, 77.4% of the participants would like further information about the initiative. Participants identified websites, social media and scientific publications as relevant communication channels.

7.7.2 Citizens focus group on chemicals

In February 2018, EAA and AGES organised a focus group discussion with members of the public, to draw in the perspectives of non-experts. The aim was to have an open discussion with lay people on interests, needs, and questions related to human biomonitoring and the HBM4EU initiative.

The focus group took place in Austria, with the Austrian population serving as model for other countries. The group was heterogeneous based on age, sex, marital status, education, labour status, and household size. EAA and AGES facilitated the discussions with lay people, by providing a concise and digestible introduction to the substances on the reduced list.

The focus group conducted on 23 February 2018 in Vienna included 14 citizens of different social backgrounds. These citizens are consumers, as well as being individuals with body burdens of chemicals and environmental pollutants. They are therefore directly affected by the scientific results emerging from HBM4EU and future political measures based on these results.

The participants expressed their expectations and concerns regarding human biomonitoring and their views regarding the responsibilities of business/industry, politics, scientists and consumers to prevent personal exposure on one hand and the dispersal of pollutants on the other.

A central focus of the discussion was the evaluation of consumers' possibilities to prevent exposure, but also of their limits (e.g. regarding the access to information and possibilities and costs of alternatives and for changing consumption behaviour) and the support consumers expect from science, politics and business. The interconnectedness of the different stakeholders' actions became very clear in the discussion and the need to cooperate was strongly emphasized.

The participants underlined the importance of more and better disseminated scientific knowledge regarding chemicals in products, environmental pollutants and their health risks that feeds into political measures.

The involved citizens think that a sustainable and harmonized European human biomonitoring network would help to better protect human health and the environment.

8 The prioritisation of substances

8.1 Objectives and process steps

The **objective of this process** was to implement a systematic and science-based approach to ranking substances against a set of prioritisation criteria. The propose set of prioritisation criteria included:

- hazardous properties;
- exposure, including environmental, consumer and occupational exposure pathways;
- regulatory status;
- societal concern; and
- technical feasibility.

However, when scoring the substances, it was not considered possible to robustly score substances on the basis of the regulatory status, since this is a very broad category. In addition, HBM4EU deliberately aims to produce evidence on substances that are not well known, and therefore likely to not be covered by existing regulations. It was also not considered relevant to score substances against technical feasibility. Rather information against these two criteria were considered in the broader reflections on categorisation of the substances on the short list after the scoring and ranking (see section 8.3.1 below). Thus substance were only scored against three criteria: hazardous properties, exposure and societal concern.

Partners involved in this work met at a workshop in November 2017, in order to review the results of the mapping of knowledge needs and plan the work to **revise the draft background documents** and score and categorise the substances.

Single substances and substance groups were **scored according to an elaborated guidance, partly employing an adapted Delphi method** involving the participation of experts from the task 4.2 partners (ANSES, UBA and VITO) in a dedicated workshop organised by ANSES in February 2017. Experts from WP8 (targeted field work surveys), WP15 (mixtures) and WP16 (emerging substances) were also invited, in order to capture a broad range of expertise.

Once the substances had been scored, they could then be ranked according to the scores. The **aim of ranking substances** on the short list produced under the mapping of knowledge needs was to inform a decision on which substances to include on the 2nd list of HBM4EU Priority Substances.

In addition, substances on the short list were **categorised from A to D**. The categories provide information on the current level of a substance's available knowledge under the criteria of hazardous properties, exposure characteristics and availability of validated HBM measurement methods. They also provide us with an indication towards the current regulation status of a substance.

This information served to inform a reflection by the HBM4EU Management Board and the EU policy Board on the kind of research that can be conducted on specific substances, and the allocation of work across HBM4EU work packages.

Key steps in the prioritisation of substances included the following:

1. Review and revision of the draft background documents;
2. Scoring substances against the prioritisation criteria;
3. Categorising substances according to data availability;
4. Ranking substances according to the scores; and
5. Consulting relevant parties on the background documents and revising the documents, as relevant.

8.2 Review and revision of the background documents

The short list and the draft background documents produced under the mapping of knowledge needs based on input from the survey (see sections 7.4 and 7.5) were presented and discussed at a meeting of work package 4 partners, including EEA, ANSES, VITO, UBA and INRA, in November 2017.

In addition, partners discussed how to tackle the quality of evidence assessed in the background documents. We agreed that the experts reviewing the documents would assess whether evidence was of sufficient quality for inclusion on the basis of their expertise.

From November 2017 to February 2018, experts reviewed the background documents and revised them to include any missing information on hazard properties, exposure characteristics, regulatory status, public concern and technical feasibility for HBM measurement. Table 7 below identifies the HBM4EU partners that reviewed the document for each substance, including a lead reviewer and an additional reviewer. The choice of partners to review the background documents was based on their expertise on specific substances.

Table 7: List of the lead reviewers and reviewers for each background document

Scientific name	Leader	Reviewer
Mercury & its compounds	ANSES	UBA
Lead & its compounds	ANSES	VITO
Aprotic solvents	ANSES	VITO
Mycotoxins (Aflatoxins + Deoxynivalenol (DON) & its metabolites + Fumonisins B)	ANSES	UBA
Substituted phenylenediamines	ANSES	UBA
Nanomaterials	ANSES	UBA
Acrylamide	UBA	ANSES
Dimethoate	UBA	ANSES
N,N-diethyl-m-toluamide (DEET)	UBA	VITO
Phenolic benzotriazoles	UBA	VITO
UV absorbers and filters	UBA	VITO
2,6-di-tert-butyl-p-cresol (BHT)	UBA	ANSES
Chlorpyrifos	UBA	VITO
Diisocyanates	UBA	ANSES
Glyphosate + Polyethoxylated (POE)-tallowamine	VITO	UBA
Arsenic acid & its inorganic compounds	VITO	ANSES
Pyrethroids	VITO	ANSES

Scientific name	Leader	Reviewer
Quatenary ammonium salts	VITO	ANSES
Fipronil	VITO	ANSES
Perchlorate	VITO	UBA
Siloxanes	VITO	UBA

8.3 Scoring substances on the short list

The experts responsible for reviewing and revising the background documents for each substance also proposed both scores for those substances. The proposed scores and categories were then discussed at a **two-day expert workshop on scoring the substances**, held at ANSES in Paris on 8-9 February 2018.

In order to ensure a systematic approach was taken by all experts and as the lead on task 4.2 on the prioritisation strategy, ANSES proposed a method for scoring each substance against the prioritisation criteria, which is described below. ANSES also provided the experts with extensive links to website and documents relevant to each of the prioritisation criteria to facilitate their work.

The proposed scores and the respective justification were presented and discussed during the workshop held at ANSES in early February 2018. Eleven experts participated in this workshop, representing partners from several work packages across HBM4EU (WP4, WP5, WP8, WP12, WP15 and WP16). At the workshop, participants reached consensus on the score attributed to each substance.

Partners also reflected on how to tackle and ultimately score groups of substances. Scoring the groups of substances was done on a case-by-case basis, as captured in box 2 below.

Box 2: Approaches to scoring groups

- For some groups (e.g. Aprotic solvents, Quaternary ammoniums salts, Cyclic siloxanes, Phenolic benzotriazoles, Substituted phenylenediamines, Lead and its compounds, Mercury and its organic compounds), scoring was done only on the lead substance identified by the nominating entities or identified by the partners which were lead reviewers of the background document.
- For other groups based on common uses or on common physical characteristics such as Nanomaterials or UV filters, it was not possible to score the group as a whole due to their diverse chemical properties. Therefore, it was decided to subdivide the groups in different subgroups (Carbon nanotubes within the nanomaterial group, benzophenones within the UV filters group) or by identifying lead substances (nano TiO2, nano Silver).
- For the remaining groups (Pyrethroids, Arsenic and its inorganic compounds, Carbon nanotubes (itself being part of the Nanomaterial group)), scoring was done considering the complete database gathered on the different substances among the group. This was done where the substances within the group shared identical chemical properties. In this case, the scoring of the group reflects a “worst-case scenario”, because for each criteria, the identified most severe characteristics among the different substances within the group were considered for scoring).

Substances were scored against the prioritisation criteria under a three-step methodology:

1. Weighting the established group of prioritisation criteria (hazard properties, exposure characteristics, and public concern) according to their relative importance for prioritising substances in HBM4EU, by means of an adapted Delphi method
2. Scoring the substances/group of substances towards each group of criteria
3. Calculating a global score for each substance, by summing the products of the weighting score attributed to each individual group of criteria multiplied by the score given to the substance towards the group of criteria of concern.

These three-steps are described in detail below.

8.3.1 Step 1: Weighting the prioritisation criteria according to their relative importance for prioritising substances in HBM4EU

The process of weighing the prioritisation criteria according to their relative importance involved two rounds of expert consultation.

In the first round, ANSES sent table 8 below to the eleven experts that would participate in the scoring workshop in February 2018, two months in advance of the workshop (December 2017). The table lists the five prioritisation criteria. Experts were asked to award a percentage (from 0 to 100%) to each criterion according to its estimated importance for the scoring of the substances in the prioritization process. The sum of the weighting scores should reach 100%.

Experts had the possibility to justify the given weighting scores and add comments.

Table 8: Table for weighting the groups of criteria – 1st round

Group of criteria	Name of the expert
	Weighting score (total score = 100%)
Hazardous properties Toxicity of substances and severity of effects, known or potential: carcinogenicity, mutagenicity, reprotoxicity, neurotoxicity, immunotoxicity, endocrine disrupting potential	
Exposure characteristics Multimedia exposure, production volume, environmental contaminant, human exposure known, prevalence of exposure, susceptible population exposure…	
Regulatory status Existing or request for European legislation, national regulations, toxicity reference value (TRV), support to public health policy, techno-economic and social feasibility to reduce the exposure…	
Public concern Evidence towards social concern	
Technical feasibility Availability of biomarker(s) and validated analytical methods to perform HBM or request for their development or improvement	

ANSES then compiled the weighting percentages awarded by each expert for each criterion, and calculated the median of the weighting scores.

The median, as well as the lowest and highest weighting percentages attributed to each criterion were then sent to the eleven experts at the beginning of January 2018**.** Each expert could see her/his own weighting percentages, and could compare her/his given score with the median score. A teleconference was held to allow for discussion of the weighting percentages.

The question as to whether **regulatory status** and the **technical feasibility** criteria are relevant to the scoring exercise was raised. Indeed, less-known substances for which analytical biomonitoring method do not yet exist are just as important as substances for which validated analytical methods already exists. Indeed, under HBM4EU research activities are dedicated for the development of analytical methods. For regulatory status, while the scoring could be oriented towards the perceived need for monitoring an existing regulation and/or the need for risk management at the EU-level, the partners did not have the evidence to support such a judgement. Likewise, proposing a higher score for substances already regulated is not appropriate in our prioritization process, as this would bias towards regulated substances.

The regulatory status and the technical feasibility criteria are important aspects that were considered for the substances categorisation and when taking the final decision on which substances to include on the 2nd list of HBM4EU priority substances.

The experts were able to comment and/or change their weighting, after considering the median scores and the discussion during the teleconference. Experts were then asked to send their revised weighting percentages back to ANSES by the end of January 2018, using the template shown in table 9 below.

Table 9: Median scores for weighting each group of criteria, 2nd round

Name of the expert					
Criteria	**Median score**	**Lowest score**	**Highest score**	**Individual answer from expert X**	**Revised score (if you want to keep the weighting score attributed during the 1st questionnaire, please write NO in the field)**
Hazardous properties					
Exposure characteristics					
Public concern					

The revised weighting percentages were compiled and the median scores (W_i) were calculated for each of the three criteria. The median score W_i attributed to each criterion was used for the final calculation of the substances scoring. The weighting percentages proposed by the experts in the 2nd round and the final weighting percentages are presented in table 10 below.

Table 10: Median weighting percentages for the three prioritisation criteria

Experts	1	2	3	4	5	6	7	8	9	10	11	
Group of criteria	Score (0 to 100)											**Median weighting score**
Hazardous properties	30	35	50	40	40	40	30	40	40	50	25	**40**
Exposure characteristics	50	45	40	40	40	40	50	40	40	30	50	**40**
Public concern	20	20	10	20	20	20	20	20	20	20	25	**20**

8.3.2 Step 2: Scoring the substances/group of substances towards each group of criteria

ANSES developed a proposal for a harmonized approach to scoring the substances against the criteria hazardous properties and exposure characteristics. The approach is adapted from the Greenscreen tool[1], whereby an individual substance's hazardous properties and exposure characteristics were scored either as 'high', 'moderate' or 'low' based on their estimated severity. They could also be scored as a 'data gap' where it was considered that more data was needed to score the substance.

ANSES also developed guidance for how to score the criterion public concern.

8.3.2.1 Scoring the criterion 'hazardous properties'

In order to score each substance against the criterion hazardous properties, hazard classifications or research results for ten endpoints were allocated to three classes of estimated severity, namely high, moderate and low. The scores in table 11 were proposed to reflect the severity of endpoints, or otherwise to reflect when a data gap made attributing a score impossible.

Table 11: Scores attributed to high, moderate and low severity of hazardous properties, and to unknown properties due to data gaps

Severity and level of certainty	High	Moderate	Low	Data gap – unknown
Score	**6**	**3**	**1**	**2**

Substances for which no concern was ever raised toward an endpoint and/or studies demonstrated negative results toward this endpoint, were not scored zero (blank line) but were considered as of 'low' severity. This reflects the fact that current toxicological tests might not be sufficient to identify hazardous properties against all endpoints. In addition, due to the limited timeframe of this task, the team was not able to undertaken an extensive literature search to be sure of the absence of hazards. The team therefore decided to adopt a precautionary approach.

Apart from the harmonized classification under the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008), CLP self-notifications (provided by EU manufacturers/importers) were only considered when a majority of manufacturers/importers notified a classification (i.e. > 50%). When very few of them notified it, it was considered to be a data gap.

[1]See: https://www.greenscreenchemicals.org/: GREENSCREEN tool version 1.3 (Last Updated: March 8, 2016)

Table 12 below provides an overview of how different hazard classifications for different endpoints were scored, and was used as a supportive tool for the partners involved in revising the background documents and scoring the substances. Deviations from these scores were allowed with appropriate justification and according to expert judgement.

Table 12: Scores attributes to different hazard properties

Endpoint [a]	Source	Severity & level of certainty			
		High	Moderate	Low	Data gap
Carcinogenicity	EU – CLP (H-Statements)	Carc. 1A or 1B (H350 or H350i)	Carc. 2 (H351)		
	EU – SVHC List	Candidate List			
	IARC	Group 1 or 2A	Group 2B	Group 4 (or Group 3 in specific cases)	Group 3
	Peer-reviewed literature				
Mutagenicity	EU – CLP (H-Statements)	Muta. 1A or 1B (H340)	Muta. 2 (H341)		
	EU – SVHC List	Candidate List			
	Peer-reviewed literature				
Reproductive toxicity	EU – CLP (H-Statements)	Repr. 1A or 1B (H360F, H360FD, H360Fd)	Repr. 2 (H360Df, H361f, H361fd)		
	Peer-reviewed literature				
Developmental toxicity	EU – CLP (H-Statements)	Repr. 1A or 1B (H360D, H360FD, H360Df, H362)	Repr. 2 (H360Fd, H361d, H361fd)		
	Peer-reviewed literature				
Endocrine activity	EU – SVHC List (article 57f)	Candidate List			
	BKH List (EU)		Cat. 1 or cat. 2	Cat. 3	
	TEDX List (US)		Inclusion on the list		
	Peer-reviewed literature				
	EU – CLP (H-Statements)	STOT RE 1 (H373)	STOT RE 2 (H373)		

Endpoint [a]	Source	Severity & level of certainty			
		High	Moderate	Low	Data gap
STOT RE (Systemic toxicity after repeated exposure)	Adverse effects on e.g. liver, kidneys, cardiovascular function,… after chronic exposure to the substance, indicated from peer-reviewed literature	Yes	Suspected	No	
Neurotoxicity*	Scorecard	Strong evidence	Suspected	No	
	Peer-reviewed literature				
Immunotoxicity*	Scorecard	Strong evidence	Suspected	No	
	Peer-reviewed literature				
Respiratory sensitizer	EU – CLP (H-Statements)	Resp. Sens. 1A or 1B (H334)			
	EU – SVHC List (article 57f)	Candidate List			
	Peer-reviewed literature				
Skin sensitizer	EU – CLP (H-Statements)*	Skin. Sens. 1A or 1B (H317)			
	Peer-reviewed literature				
Score for each column					
Balanced score					

[a] only the highest score for each endpoint was retained

*If not yet addressed in another entry (to avoid double counting)

In order to calculate the substances' score towards the criterion hazard properties, the sum of the scores obtained for different endpoints are considered. For each endpoint, the highest (i.e. highest severity) score for each endpoint was added, reflecting a precautionary approach.

The balanced score for the 'hazard properties' was then obtained after division of the resulting sum by 60, which is the maximum severity score a substance could obtain (i.e.10 endpoints with severity score at 6).

8.3.2.2 Scoring against the criterion ‘exposure characteristics’

The same scores were used to reflect the weight of the three classes of severity of human exposure to a substance, high, moderate and low, or in case a data gap prevented a certain judgement on the severity of exposure (see table 11 above).

Table 13 below provides an overview of how information relevant to human exposure was translated into scores. This table was used as a supportive tool for the partners involved in revising the background documents and scoring the substances. Deviations from these scores were allowed, with appropriate justification and according to expert judgement.

Table 13: Scores attributes to different properties and information relevant to exposure

Criteria	Source or specification	Severity & level of certainty			
		High	Moderate	Low	Data gap
Persistency & or bioaccumulation potential ***(only the highest score is counted here)***	EU – SVHC List (articles 57d & 57e for PBT and vPvB)	Candidate List			
	Peer-reviewed literature	Persistent AND evidences of bioaccumulation or significant biological mammals half-life	Persistent (without evidence of bioaccumulation) OR significant biological half-life in mammals		
Tonnages	ECHA*	> 1000 tpa	10-1000 tpa	< 10 tpa	
Extent of exposure	ECHA*	EU wide	Country/regional	Hotspot	
Routes of exposure	Peer-reviewed literature	Multipathway exposure (oral, inhalation, dermal)	Multipathway (only 2 routes of exposure)	One route of exposure	
Passage of placental barrier	Peer-reviewed literature	Strong evidence	Limited evidence	No	
Exposed populations	Workers	Widespread (different activity sectors) and professional uses	Some professional / industrial uses	Intermediate use only	
	General population	Evidence of wide multi-media exposure - dispersive use	Limited evidence of exposure through external media	No significant exposure	
	Vulnerable groups exposed	Neonates, children, pregnant women			
Level of concern of the exposure	Biomonitoring data	Recent HBM data above or close to an established health-based HBM guidance value for the substance of concern		Recent HBM data well below an established health-based HBM guidance value for the substance of concern	
	External exposure data	Recent external exposure data above or close to a regulatory reference value		Recent external exposure data well below a regulatory reference value	
Score for each column					
Balanced score					

*or references from scientific literature

Calculation of the balanced score for the 'Exposure characteristics' criteria is done by adding the 'level of concern' scores and by dividing the sum by 60, which is the maximum 'level of concern' score a substance could obtain (i.e. 10 sub-criteria with severity score at 6).

8.3.2.3 Scoring against the criterion 'public concern'

At the Stakeholder Workshop organized on the 20 November 2017 in Brussels, participants were asked to vote for the 10 substances/groups of substances from the short list that they considered as most important to include in the HBM4EU initiative. The number of votes attributed to each substances was used to inform the scoring of substances against this criterion, with the results presented in table 14.

Table 14: Scoring public concern for each substance based on the results of the Stakeholder workshop

Substance / Groups	Number of votes	Rank	Related Score
Pesticides authorised in the EU & metabolites	9	1	9
Glyphosate	6	2	6
Siloxanes	5	3	5
Mercury & its compounds	4	4 ex-aequo	4
Arsenic & its compounds			
UV absorbers & filters			
Nanomaterials			
Lead & its compounds			
Pyrethrines & pyrethroids	3	5 ex-aequo	3
Mycotoxins			
Chlorpyrifos			
Diisocyanates			
POE-tallowamine	2	-	2
Quaternary Ammonium salts			
Perchlorate	1	-	1
Aprotic solvents			
Acrylamide			
Dimethoate	0	-	0
Fipronil			
N, N-diethyl-m-toluamide			
Phenolic benzotriazoles			
Substituted phenylenediamines			
BHT			

Information on whether the substance is included in the SIN list[2] and/or in the Trade Union List for REACH authorisation[3], and whether NGO campaigns were conducted towards the substance were also considered for the scoring towards this criterion, as presented in table 15 below.

Each substances was awarded a total score to a maximum of 11, on the basis of an assessment of these three dimensions of public concern.

[2] http://sinlist.chemsec.org/
[3] https://www.etuc.org/IMG/pdf/TUListREACH.pdf

Table 15: Scoring against the criteria public concern, including the results of the stakeholder workshop, inclusion on the SIN list and coverage under NGO campaigns

Evidence of public concern		Related score
Number of votes (from the Stakeholders having participated in the November 2017 workshop)	x	*See table above*
Inclusion in the SIN List and/or in the Trade Union Priority List for REACH Authorisation	No	0
	Yes	1
Recent NGO campaigns/media coverage	No	0
	Yes	1
Total score		
Balanced score (Total score / 11)		

8.3.3 Step 3: Calculating a global score for each substance

In order to calculate a global score for each substance and thereby to rank the substances, the scores against each of the three criteria were grouped into a table (see example table 16 below). The scores (S_i) where then multiplied by the median weighting score awarded to each criterion, as detailed in section 8.3.1 . Calculation of the sum of the products of these scores gives the **global score** for the substance of concern.

Table 16: Method for calculating the global score of the substance

Group of criteria	Score toward the group of criteria (S_i)	Median weighting score (W_i)	Result
Hazardous properties	S_1	40	S_1*40
Exposure characteristics	S_2	40	S_2*40
Public concern	S_3	20	S_3*20
Global score			Sum of the products of S_i by W_i

8.4 Categorisation of substances

The aim of the categorisation exercise was to provide a picture of the state of evidence for each substance and explicitly identify knowledge gaps that might be addressed through human biomonitoring activities under HBM4EU. Activities to produce knowledge on category B to E substances should serve to increase the level of knowledge on these substances and move them into a higher category, ideally into the Category A. Category E substances should directly be addressed under WP16 dedicated to the emerging substances.

The categories A to E are described in box 3 below.

Box 3: Description of categories A to E

‣ **Category A** substances are substances for which HBM data are sufficient to provide an overall picture of exposure levels across Europe, and interpretation of biomonitoring results in terms of health risks is possible. Risk management measures may have been implemented at national or European level[4]. Improvement of knowledge for these substances will therefore focus on policy-related research questions and evaluation of the effectiveness of existing regulatory measures.

‣ **Category B** substances are substances for which HBM data exists, but not sufficiently to have a clear picture across Europe. Also, knowledge on the extend of exposure, levels and impact on the human health should be improved, in order to give policy makers relevant and strategic data to establish appropriate regulations and improve chemical risk management. Analytical method and capacities to monitor the substances across Europe might have to be improved.

‣ **Category C** substances are substances for which HBM data scarcely or don't exists. Efforts to develop an analytical method to obtain relevant HBM results are needed. Hazardous properties of the substances are suspected, yet greater knowledge on toxicological characteristics and effects on the human health is needed.

‣ **Category D** substances are substances for which a toxicological concern exists but HBM data are not available. HBM4EU research may be focused on the development of suspect screening approaches permitting to generate a first level of data enabling to document the reality of human exposure and better justify further investment in a full quantitative and validated method development.

‣ **Category E** substances are substances not yet identified as of toxicological concern and for which no HBM data are available. A bottom-up strategy will be applied, consisting to non-targeted screening approaches coupled to identification of unknowns capabilities for revealing, and further identifying, new (i.e. not yet known) markers of exposure related to chemicals of concern for HBM (parent compound or metabolite).

The categorisation of substances was done mainly based on the availability of human biomonitoring data for each substance. The allocation of substances to the categories A to D was based on an expert judgement and was performed by the lead expert responsible for reviewing and revising the background document for each substance.

Substances were allocated to the **category that best reflects the information** available according to the definition above. The **criteria** on the substances **regulatory status** and on the **technical feasibility to perform human biomonitoring** were also been taken into account.

Regarding the categorisation of **groups of substances**, the number of substances in the nominated groups of substances of the short list is quite heterogeneous (e.g. the number of lead compounds versus the number of pyrethroids). Where possible, and depending on the number of substances within the group, categorisation was performed for each one of the substances or at least for the identified substances leaders in the group.

8.5 Consultation on the background documents, scores and categories

In order to make the prioritisation process transparent and accountable, a consultation on the background documents, scores and categories was foreseen. In February 2018, the revised background documents, including the scores and the categories, were sent to the EU Policy Board, the National Hubs and the members of the Stakeholder Forum for comments and feedback. The level of feedback received is documented in table 17 below.

[4] This will keep substances with wide HBM data but not yet any risk management measure(s) IMPLEMENTED in this category. Otherwise, there is no category for that group as category B (indirectly) assumes 'no risk management measures'.

Table 17: Summary of feedback received for different actors against each substances

Substance background document	Actors that provided feedback
Acrylamide	Austria National Hub, Belgian National Hub
Aprotic solvents	Austria National Hub
Arsenic	Austria National Hub, Slovenia National Hub
BHT	EFSA
Chlorpyrifos	Austria National Hub, Israeli National Hub
DEET	ECHA
Glyphosate	ECHA
Lead	Israeli National Hub, EFSA
Mercury	Belgian National Hub, Spanish National Hub, EFSA
Mycotoxins	Dutch National Hub
Nanomaterials	Belgian National Hub, Danish National Hub, French National Hub
Perchlorate	Belgian National Hub, Israeli National Hub
Pesticides	French National Hub

In the majority of cases, actors provided additional information for inclusion in the background document, while agreeing with the scores. Revisions were proposed to the scores for mercury and for glyphosate.

For **mercury**, the Spanish National Hub proposed a re-evaluation of the scores for elemental mercury versus methyl-mercury, reflecting the fact that methyl-mercury is more hazardous.

For **glyphosate**, ECHA noted that the ECHA Risk Assessment Committee (RAC) has evaluated glyphosate in the process of harmonised classification and labelling. The RAC opinion[5] states that glyphosate is not carcinogenic. This later evaluation should be used as the basis for the scoring for carcinogenicity and not the earlier IARC conclusion. It was argued that this would more accurately reflect the current knowledge of glyphosate within the EU as not being carcinogenic. In addition, concerning the endocrine activity scoring, EFSA has concluded that glyphosate does not have endocrine disrupting properties based on the available information and no data gaps were identified in the context of this evaluation[6].

The scores for these substances were updated accordingly. It should be noted that for glyphosate, this deviates from the precautionary approach adopted under the prioritisation strategy to base the scoring on the most severe evidence of health effects, with the explicit aim of aligning the evidence base for decision making under HBM4EU with the most recent EU risk assessments.

In addition, two actors also provided feedback on the scoring methodology.

[5] ECHA RAC (2017) Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N-phosphonomethyl)glycine, ECHA 2017

[6] EFSA (2017) Peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate, EFSA Journal

8.6 Ranking the substances

The global scores were calculated for each substance and the substances were ranked according to their global scores. The final ranking of the substances, revised according to the consultation, is presented in table 18 (ranked by global score) and 19 (ranked by global score within categories A-D).

Table 18: Ranking of substances based on their global score against the criteria hazard, exposure and public concern. Substances shaded in blue are to be monitored under the multi-annual Community control programme for 2018, 2019 and 2020, see Commission Implementing Regulation (EU) 2017/660

	Name	Hazard score	Exposure score	Public concern score	Global score	Categorisation
1	Arsenic inorganic compounds	27.2	38	9	**74.2**	**B**
2	Lead (Group: Lead & its compound)	25.3	36	9	**70.3**	**A**
3	Acrylamide	27.2	36.8	5.4	**69.4**	**B**
4	Aflatoxin B1 (Group: Mycotoxins)	30.8	27.2	5.4	**63.4**	**B**
5	Chlorpyrifos	13.3	29.2	20	**62.5**	**B**
6	Dimethoate	12.4	31.2	18	**61.6**	**C**
7	Pyrethroids	16	27.2	18	**61.2**	**B**
8	Permethrin (Group: Pyrethroids)	14	28	18	**60**	**B**
9	Mercury (Group: Mercury & its organic compounds)	17.2	28	10.8	**56**	**A**
10	DDAC (Group: QACs)	9.2	32.8	12.8	**54.8**	**C**
11	Methylmercury (Group: Mercury & its organic compounds)	22	23.2	9	**54.2**	**B**
12	Nano titanium dioxide (Group: Nanos)	16	26.8	10.8	**53.6**	**D**
13	4,4-MDI, 2,4-TDI & 2,6-TDI (Group: Diisocyanate)	18	28	7.2	**53.2**	**C**
14	Glyphosate	7.2	32	12.8	**52**	**B**
15	Deoxynivalenol (Group: Mycotoxins)	18	28	5.4	**51.4**	**C**
16	BP-3 (Group: UV filters-Benzophenones)	12.8	29.2	9	**51**	**B**
17	D4 (Group: Cyclic Siloxanes)	5.6	33.2	11	**49.8**	**C**
18	N,N-dimethylformamide (DMF) (Group: Reprotoxic aprotic solvents)	16	30	3.6	**49.6**	**B**
19	Nano silver (Group: Nanos)	14	26	9	**49**	**D**

	Name	Hazard score	Exposure score	Public concern score	Global score	Categorisation
20	BHT	14	32.8	1.8	**48.6**	C
21	Fumonisin B1 (Group: Mycotoxins)	18	24	5.4	**47.4**	C
22	Fipronil	16.8	25.2	3.6	**45.6**	C
23	Perchlorate	13.2	30	1.8	**45**	C
24	1-methyl-2-pyrrolidone (NMP) (Group: Reprotoxic aprotic solvents)	12	27.2	3.6	**42.8**	B
25	UV-328 (Group: Phenolic benzotriazoles)	12	27.2	1,8	**41**	C
26	Carbon nanotube (CNTs) (Group: Nanos)	12.8	18.8	9	**40.6**	D
27	BENPAT (Group: Substituted phenylenediamines)	15.2	24.8	0	**40**	D
28	POE-tallowamine	12	20	3.6	**35.6**	C
29	N,N-diethyl-m-toluamide (DEET)	7.2	25.2	0	**32.4**	C

Table 19: Ranking of substances and substance groups based on their category, alongside their global score against the criteria hazard, exposure and public concern

Name	Hazard score	Exposure score	Public concern score	Global score	Categorisation
Category A					
Lead (Group: Lead & its compound)	25.3	36	9	**70.3**	A
Mercury (Group: Mercury & its organic compounds)	17.2	28	10.8	**56**	A
Category B					
Arsenic inorganic compounds	27.2	38	9	**74.2**	B
Acrylamide	27.2	36.8	5.4	**69.4**	B
Aflatoxin B1 (Group: Mycotoxins)	30.8	27.2	5.4	**63.4**	B
Chlorpyrifos	13.3	29.2	20	**62.5**	B
Pyrethroids	16	27.2	18	**61.2**	B
Permethrin (Group: Pyrethroids)	14	28	18	**60**	B
Methylmercury (Group: Mercury & its organic compounds)	22	23.2	9	**54.2**	B
Glyphosate	7.2	32	12.8	**52**	B
BP-3 (Group: UV filters-Benzophenones)	12.8	29.2	9	**51**	B

Name	Hazard score	Exposure score	Public concern score	Global score	Categorisation
N,N-dimethylformamide (DMF) (Group: Reprotoxic aprotic solvents)	16	30	3.6	**49.6**	B
1-methyl-2-pyrrolidone (NMP) (Group: Reprotoxic aprotic solvents)	12	27.2	3.6	**42.8**	B
Category C					
Dimethoate	12.4	31.2	18	**61.6**	C
DDAC (Group: QACs)	9.2	32.8	12.8	**54.8**	C
Diisocyanates (4,4-MDI, 2,4-TDI & 2,6-TDI)	18	28	7.2	**53.2**	C
Deoxynivalenol (DON) (Group: Mycotoxins)	18	28	5.4	**51.4**	C
D4 (Group: Cyclic Siloxanes)	5.6	33.2	11	**49.8**	C
BHT	14	32.8	1.8	**48.6**	C
Fumonisin B1 (Group: Mycotoxins)	18	24	5.4	**47.4**	C
Fipronil	16.8	25.2	3.6	**45.6**	C
Perchlorate	13.2	30	1.8	**45**	C
UV 328 (Group: Phenolic benzotriazoles)	12	27.2	1.8	**41**	C
POE-tallowamine	12	20	3.6	**35.6**	C
N,N-diethyl-m-toluamide (DEET)	7.2	25.2	0	**32.4**	C
Category D					
Nano titanium dioxide (Group: Nanos)	16	26.8	10.8	**53.6**	D
Nano Silver (Group: Nanos)	14	26	9	**49**	D
Carbon nanotube (CNTs) (Group: Nanos)	12.8	18.8	9	**40.6**	D
BENPAT (Group: Substituted phenylenediamines)	15.2	24.8	0	**40**	D

9 Joint meeting of the EU Policy Board and the HBM4EU Management Board

The final ranking of substances on the short list was then sent to the HBM4EU Management Board and the EU Policy Board.

EEA and DG RTD engaged in bilateral discussions with the members of the EU Policy Board to better understand the policy rationale behind the nomination of specific substances.

On 5 March 2018, the EU Policy Board and the HBM4EU met separately in order to reflect on the substances on the short list, the ranking and their priorities for action.

At the meeting of the HBM4EU Management Board, EEA presented the ranked list, together with some additional reflections on the policy relevance of each substance group, drawn from the bilateral discussions. Members of the Management Board discussed each of the substances and groups of substances, starting from the first substance ranked on the list according to the global scores. Discussions focused on the relevance and possible interest of including each substances or substance group in the HBM4EU programme.

Certain substances that had been ranked highly were not considered a priority for research under HBM4EU.

- Human biomonitoring was not considered to be the right tool to explore human exposure to **nanomaterials (rank 12, 19 and 26)**. This was because of the lack of analytical methods and the tendency for nanoparticles to conglomerate, so confounding results. Nanomaterials could be considered under work package 16 on emerging substances, but there are currently no available resources in this work package. Nanomaterials were therefore de-prioritised.
- Regarding the **cyclic siloxanes (rank 17)**, experts noted that earlier method development had failed, pointing to the difficulty in avoiding sample contamination. While some joint methods are available, single substances cannot be differentiated. Cyclic siloxanes were therefore de-prioritised.
- **Quaternary ammonium compounds (rank 10)** were not considered a priority, due to the relatively low hazard score.

Agreement was reached on the substances to be prioritised from the scientific perspective of the Management Board. Suggestions of activities to be undertaken for each substance/group of substances were also discussed.

A meeting of the EU Policy Board ran in parallel with the Management Board meeting. Its members also discussed the ranking and agreed on the priorities from a policy perspective.

On the 6th of March 2018, a bilateral discussion with both members of the Management Board and the EU Policy Board took place in order to agree on the 2nd list of priority substances. Overall, the two boards had chosen the same substances for prioritisation, with three additional substances (see table 20).

The Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) and Directorate General for Employment, Social Affairs and Inclusion (DG EMPL) expressed their interest in including diisocyanates, which was agreed. The Management Board argued for the inclusion of arsenic, which was also agreed.

Consensus was reached on the substances to be prioritised for inclusion on the draft 2nd list of HBM4EU Priority Substances.

Table 20: Substances prioritised by the Management Board and the EU Policy Board

	Management Board	Policy Board
1	Lead	Lead
2	Mercury	Mercury
3	Aprotic solvents	Aprotic solvents
4	Acrylamide	Acrylamide
5	Mycotoxins	Mycotoxins
6	Pesticides and pyrethroids	Pesticides and pyrethroids
7	Arsenic	
8		UV filters – benzophenones
9		Diisocyanates

The substance included on the 2nd list includes the majority of the top ranking substances. The outcome therefore reflects an effective approach that captures both the systematic ranking based on scientific evidence and the policy priorities at European level.

10 Consultation with the Governing Board

In May 2018, the draft 2nd list of HBM4EU priority substances was sent to the Governing Board for approval. The Governing Board approved the list.

In May and June 2018, Chemical Substances Group Leaders were identified and started work to develop activities to be implemented regarding each of the substance groups. These activities will then be incorporated into the future HBM4EU annual work plans.

11 2nd List of HBM4EU Priority Substances

The 2nd list of prioritised substances is presented in table 21 below. Deliverable 4.5 on the 2nd list of HBM4EU priority substances provides a more detailed summary of the rationale for the selection of each substance and group of substances on the 2nd list of HBM4EU Priority Substances. Proposed activities are also outlined in the deliverable 4.5, for consideration by the Chemical Substance Group Leaders.

Table 21: 2nd list of priority substances (alphabetical order)

Substance
Acrylamide
Aprotic solvents
Arsenic
Diisocyanates
Lead
Mercury
Mycotoxins
Pesticides: glyphosate, chlorpyrifos, fipronil and pyrethroids
UV filters – benzophenones

12 Evaluation of the process

An evaluation of the second round of prioritisation is foreseen for 2019. All actors that were involved will be consulted in a systematic fashion, with the aim of gathering feedback and improving and streamlining the future process.

Annex I: Online Survey for the 2nd list of priority substances

science and policy
for a healthy future

Survey requesting the nomination of substances for research under HBM4EU

Introduction

Aim of this survey

The aim of this survey is to gather nominations for substances and groups of substances to be the subject of research under HBM4EU from 2019 to 2021.

We are requesting nominations from the National Hubs, the members of the Stakeholder Forum and the members of the EU Policy Board.

HBM4EU uses human biomonitoring research to produce new knowledge at a European scale on human exposure to chemicals and potential risks to health. This new knowledge should answer policy-related questions and support chemical policy making. The objective is to address current knowledge gaps and contribute to chemical safety in Europe.

For more information on HBM4EU and on the bodies participating in this survey, please refer to our website at www.HBM4EU.eu

Practical details

Each National Hub and each member of the Stakeholder Forum or EU Policy Board can submit a maximum of five nominations.

You can only submit one nomination at a time.

To submit another nomination, please re-enter the survey using the link sent to you by email (https://www.hbm4eu.eu/private/surveys/substance_nomination_2017/) and complete the survey again.

You can partly complete the survey, save your input and then return to the survey multiple times to finalise your input and submit.

To ensure that your input is saved, please only navigate using the survey buttons at the bottom of the page, not using the browser navigation buttons at the top left hand of your screen.

Where questions are not relevant to your nomination or where you cannot answer them, please leave them blank.

The deadline for the submission of the completed survey is 30 September 2017.

HBM4EU will transparently document the prioritisation process on our website in order to make the process publicly accountable. Please note that all material that you submit will be included in this documentation.

We will also identify which substances and substance groups each actor nominates.

Should you have questions concerning this survey, please contact HBM4EU@eea.europa.eu

What can you nominate?

You can nominate single substances as well as groups of substances. You can also nominate chemical mixtures and emerging substances.

It is also possible to re-nominate substances that are already on the first list of priority substances. The first list includes the following groups of substances:

- phthalates and Hexamoll® DINCH,
- bisphenols,
- per-/polyfluorinated compounds,
- flame retardants,
- cadmium and chromium VI,
- PAHs,
- aniline family,
- chemical mixtures, and
- emerging substances.

The research activities foreseen for these substance groups are described in scoping documents, available on the HBM4EU website at www.hbm4eu/the-substances/. Planned research is already ambitious and we expect that work on some of these substance groups will continue after 2018.

What information are we asking for?

In completing the survey, we ask you to first identify the substance or substance group and then to explain the policy-related questions that you would like HBM4EU research activities to answer. You can also propose research activities that you consider relevant.

HBM4EU aims to address current knowledge gaps through human biomonitoring and related research, and generate benefits for society in terms of improved chemical safety. We therefore ask you to identify your needs for new knowledge and briefly describe how you might use that knowledge to generate benefits for society.

We then ask you to provide information against a set of prioritisation criteria, including hazard, exposure, regulatory status, social concern and technical feasibility. We also ask you to identify specific knowledge gaps that might be addressed by HBM4EU. Please also upload relevant reference materials and articles that provide evidence on the substances or substance groups that you have nominated.

How will we use your input?

We realise that the survey demands extensive input from your side. Your input is critical to the prioritisation strategy and we are very grateful for your valuable time and energy.

The information that you provide will be used by HBM4EU partners in the prioritisation strategy to support the assessment of nominated substances against the prioritisation criteria.

In May and June, you were consulted on the prioritisation strategy itself. We are currently revising the strategy according to your feedback. A revised strategy will be presented to the HBM4EU Governing Board in September 2017.

As mentioned above, all the inputs to the survey will be compiled and will be made publicly available on the HBM4EU website in the interest of transparency and information sharing.

Thank you very much!

Step 1: Your contact details

We ask you to identify yourself and your institution.

This will enable us to track which institution nominates which substances and groups of substances.

Should we have questions regarding your nomination, then we will contact you by email.

1. Applicant Name

2. Which institution do you represent?

3. Please enter your email address

4. Please indicate whether you are a:
    - National Hub Contact Point
    - Member of the EU Policy Board
    - Member of the Stakeholder Forum

5. If you are a National Hub, please identify your country

Step 2: Nomination of a chemical substance or group of substances

In this section, we ask you to please identify a single chemical substance or a group of substances that you would like to nominate for work under HBM4EU.

You can also request HBM4EU to work on chemical mixtures or emerging substances.

You can only nominate one chemical substance or one group of substances each time you complete the survey.

To nominate additional substances or groups, please complete and submit the survey again.

1. Please select your preference from the list below

    - A single chemical substance
    - A group of substances
    - Chemical mixtures
    - Emerging substances

Single substance

Here you can nominate a single substance.

1. To ensure that we can correctly identify the substance, please provide the relevant CAS number and/or the EC number. For a description of these numbering systems, please place your cursor over the relevant ?

    - Scientific name
    - CAS number
    - EC number
    - Other name(s)

Group of substances

Here you can nominate a group of substances. The rationale for nominating a group of substance can include: the use of common analytical methods for detection; substances put to common uses; and/or substances that exhibit similar toxicological profiles.

1. Please provide a name for the group of substances

2. Please identify the rationale for the grouping.
    - Common analytical methods can be used to analyse multiple substances in one matrix.
    - The substances have similar uses, with the possibility of substitution within the group.
    - The substances have a similar toxicological profile.
    - If you have another rationale for grouping the substances, please briefly describe it below.

3. If possible, please identify a “lead substance” in this group that captures the principle characteristics of the group. This will allow us to broadly judge the risks associated with the substance group.

4. In the box below, we ask you to upload a file (word, excel or CSV) listing the substances belonging to the group. Please include the CAS numbers for all substances.

Chemical mixtures

Please tick the box below if you would like HBM4EU to continue working on chemical mixtures

Continue working on chemical mixtures

Emerging substances

Please tick the box if you would like HBM4EU to continue working on emerging substances

Continue working on emerging substances

Step 3: What new knowledge do you need?

In this section, please identify the questions that you would like HBM4EU to address and describe the role that human biomonitoring activities can play.

1. We also ask you to describe the kind of activities that could produce knowledge.

2. Please tick all the boxes that describe the research activities that would answer your questions

    - New data on a specific population groups or subgroups
    - Development of new research activities
    - New approaches to the analysis of existing data

3. Please propose any other relevant research activities below.

Step 4: Hazardous properties

Please enter information regarding the hazardous properties of the substance that you have nominated.

We ask that you provide details of the classification of the substance according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). In the case of substances that are carcinogenic, please also provide the classification according to the International Agency for Research on Cancer (IARC).

We would be very grateful if you could provide references and/or hyperlinks or if you could upload relevant materials on the hazardous properties of the substance/s that you nominate.

If you have nominated a group of substances, we encourage you to upload any available material that provides an overview of the toxicity profiles of substances in the group.

If you have requested further work on chemical mixtures or emerging substances, please reference any relevant materials regarding methods for assessing their hazardous properties.

Where you do not consider a question relevant, please leave the field blank.

Current knowledge gaps regarding hazardous properties

1. In the text box below, please describe any specific knowledge gaps regarding the hazard profile of the substance, or group of substances.

Hazard classifications

1. If the substances is a carcinogen, please identify the IARC classification.
2. If the substance is a carcinogen, please enter the CLP classification.
3. If the substance is a mutagen, please enter the CLP classification.
4. If the substance is toxic to reproduction, please enter the CLP classification.
5. Is the substance classified for Specific Target Organ Toxicity on the basis of single exposure (STOT-SE)?
6. Is the substances classified for Specific Target Organ Toxicity on the basis of repeated exposure (STOT-RE)?
7. Is the substance neurotoxic?
8. Is the substance immunotoxic?
9. Is the substance a respiratory sensitizer?
10. Is the substance an endocrine disruptor?

Other classifications

11. Is the substance a Substance of Very High Concern?
12. Please enter information on any other relevant classifications.
13. In your opinion, is the substance an emerging substance?

Persistence and bioaccumulation potential

14. Is the substance Persistent, Bioaccumulative and Toxic (PBT)?

15. Is the substance very Persistent and very Bioaccumulative?

16. Is the substance very Persistent?

17. Additional information and references

18. Please add any other information that you consider relevant.

Please list relevant references and provide hyperlinks, where available. Alternatively you can upload files below.

Please upload available materials on the hazard characteristics of the substance or group of substances in the file drop below.

Step 5: Exposure characteristics

In this section we ask you to provide information about exposure to the substance or substance group.

We also ask you to identify whether human biomonitoring data is currently available for the substance or group of substances.

Where information on exposure is a critical knowledge gap, we ask you to describe the type of data needed to address the knowledge gap.

Please also provide references, hyperlinks and/or upload materials, where available.

Where you do not consider a question relevant, please leave the field blank.

Current knowledge gaps regarding exposure

1. Please describe knowledge gaps in understanding exposure to the substance and explain how human biomonitoring might address those gaps.
2. Is human biomonitoring data on the substance or group of substances available?

If yes, please provide references to publications or datasets. Please include hyperlinks, where available.

Exposure media

3. Please identify the media through which human exposure takes place.
    - Multisource exposure
    - Air
    - Water
    - Food
    - Soil
    - Consumer products

4. If exposure occurs through consumer products, please specify product types in the box below.

5. Please identify any other media through which exposure may take place.

Exposure sources, production volumes and environmental releases

6. Please identify sources of exposure in the box below.

7. If available, please provide the production volume according to the ECHA database.

8. Has the substances been recognised as an environmental contaminant? If yes, please provide references to any relevant sources of monitoring data.

9. Is data about environmental release of the substance available, for example in the European Pollutant Release and Transfer Register (E-PRTR)? If yes, please provide details in the box below.

Human exposure

10. Please tick all relevant human exposure routes
    - Dermal
    - Inhalation
    - Oral
    - Trans placental

11. Please estimate the prevalence of population exposure.
    - There is widespread exposure of the general population
    - There is widespread exposure of workers
    - Certain sub-populations are exposed
    - Exposure takes place at hot spots
    - The prevalence of exposure is unknown

12. Other comments on the prevalence of exposure.

13. Please tick all groups that may be highly exposed to the substance or groups of substances

    - Infants and children
    - Adults
    - Pregnant women
    - Elderly people
    - Men
    - Women
    - Individuals of lower socio-economic status
    - Workers (professional and/or industrial)

14. Please identify any other highly exposure groups.

Vulnerable groups

15. Please identify any vulnerable groups.
    - Infants and children
    - Adults
    - Pregnant women
    - Elderly people
    - Men
    - Women
    - Individuals of lower socio-economic status
    - Workers (professional and/or industrial)

16. Please identify any other vulnerable population groups.

Additional information and references

17. Please add any other information on exposure that you consider relevant.

Please list relevant references and provide hyperlinks, where available. Alternatively you can upload files below.

Step 6: Regulatory status

In this section, we request information on regulations currently in place that aim to reduce or eliminate exposure to the substance. This can include both hard policies, such as bans, as well as soft measures such as awareness raising.

We request information on the regulatory status of the substance at the level of the European Union (EU). We also ask the National Hubs to complement this with information from your countries.

Our aim with requesting this information is to better understand the kinds of policy questions related to the substances that might be answered using human biomonitoring data.

For groups of substances, please identify regulations that apply to substances in the group, where possible.

Please identify any current policy questions relating to the substance or group of substances that you have nominated.

Where you do not consider a question relevant, please leave the field blank.

1. Is the substance covered by Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2. Please identify all other EU policies that apply to the substance or substance group in the box below. This can include policies in the domain of occupational health and safety, food safety, environment and consumer safety.

3. Please identify any regulations that you know of that apply to the substance or substance group at national level, either in Europe or beyond.

Current policy questions

4. Please outline current policy questions on the substance or substance group in the box below. Please indicate how human biomonitoring might answer these questions.

Regulatory guidance values

5. Please provide details of any toxicity reference values that are available for the substance in the box below. Please provide reference to relevant materials.

6. Please provide details of any biomonitoring guidance values that are available for the substance in the box below. Please provide reference to relevant materials.

Additional information and references

7. Please provide references for any risk assessments on the substance that are publicly available in the box below.
8. We also welcome references for materials that address the potential to reduce human exposure to the substance.

You may either provide references and hyperlinks in the text box below, or alternatively you may upload files.

Step 7: Public concern

HBM4EU should address questions that are socially relevant, and as such we want to understand whether specific substances or groups of substances are of particular concern to the public.

In this section, we ask you to provide an evidence regarding the level of public concern about the substance or group of substances that you have nominated.

Where you do not consider a question relevant, please leave the field blank.

1. Please identify any materials that provide evidence of the social concern regarding the substance or substance group. This may include the results of surveys conducted by Eurobarometer, campaigns conducted by specific interest groups, media coverage or other relevant materials. You are welcome to include materials from both the European and national level.

2. Is the substance included on the SIN List managed by ChemSec?

Step 8: Technical feasibility

In this section we request information on the technical feasibility of conducting human biomonitoring research on the nominated substance or substance group.

This will allow us to understand whether human biomonitoring work is feasible, or whether HBM4EU would first need to develop or adapt existing methods.

1. Please indicate whether biomarkers are available for the substances in the drop down box below.
2. Please indicate whether analytical methods are available for the substances in the drop down box below.
3. Please describe any work that would be required to develop new methods to allow for human biomonitoring activities on this substance or substance group.

Additional information

4. Please provide any additional information on the feasibility of conducting human biomonitoring research on the substance or substance group. Please provide references, where available, or upload files in the file drop below.

Annex II: List of all nominations received via the online survey by actor

Substance or substance group	Actor
Nominations by National Hubs	
Continue working on chemical mixtures	Austria
Mercury and mercury compounds	Austria
Flame retardants	Austria
Pesticides and biocides	Austria
Per- and polyfluoroalky substances (PFASs) (PFOS, PFOA)	Austria
Arsenic compounds; speciation of arsenic is necessary	Belgium
Glyphosate	Belgium
Flame retardants	Belgium
PAHs	Belgium
Phthalates and Hexamoll® DINCH	Belgium
Benz(a)pyrene	Croatia
Bisphenol A	Croatia
Mercury	Croatia
IODINE	Cyprus
Mercury and methylmercury	Cyprus
Continue working on chemical mixtures	Cyprus
Alkylphenols (Nonylphenol (NP))	Cyprus
Mercury and mercury compounds	Czech Republic
per/poly fluorinated substances	Czech Republic
Flame retardants (NBFR)	Czech Republic
Continue working on emerging substances	Czech Republic
Polyaromatic hydrocarbons (PAHs) (benzo[a]pyrene and 27 other chemicals commonly used)	Czech Republic

Chemical UV absorbers and filters (Benzophenone-3)	Denmark
Polychlorinated biphenyls (PCB-28, 52, 101, 118, 138, 153 and 180)	Denmark
Continue working on emerging substances	Denmark
Nanomaterials	Denmark
Flame retardants (proposed to be kept on the list of prioritised substances)	Denmark
Diisocyanates (4,4-methylenediphenyldiisocyanate, cas 101-68-8)	Finland
2,6-di-tert-butyl-p-cresol	France
Folpet	France
Titanium dioxide (nanoform)	France
Pyrethroïds	France
Cyclomethicone (Octamethylcyclotetrasiloxane)	France
2,6-di-tert-butyl-p-cresol	Germany
Benzothiazole-2-thiol	Germany
Bis(2-ethylhexyl)terephthalate	Germany
Triclosan 5-chloro-2-(2,4-dichlorophenoxy)phenol	Germany
Pyrrolidones (1-methyl-2-pyrrolidone)	Germany
Cadmium	Iceland
Cadmium	Iceland
Methylmercury	Iceland
Continue working on emerging substances	Israel
Continue working on chemical mixtures	Israel
Organophosphate Pesticides – Chlorpyrifos	Israel
Pesticides authorised in the EU (Our proposal is to conduct a selection based on information available at EFSA)	Italia
Hexavalent Chromium (CrVI)	Italy
PAHs	Italy
Continue working on emerging substances	Italy
Continue working on chemical mixtures	Italy

Per-polyfluorinated compounds	Italy
Dioxins	Latvia
Glyphosate (phosphonomethyl-amino)-acetic acid	Latvia
Glyphosate (phosphonomethyl-amino)-acetic acid	Latvia
Mycotoxins	Luxembourg
Acrylamide	Netherlands
Glyphosate (isopropylammmonium salt)	Netherlands
Aflatoxins (Aflatoxin B1)	Netherlands
Triazoles (prothioconazole)	Netherlands
Parabens (propyl paraben)	Netherlands
Quatenary Ammonium salts (Dialkyl C8-C10 dimethylammonium chloride)	Norway
UV-substances; octocrylene and homosalate	Norway
Siloxanes	Norway
New flameretardants including decabromdiphenyl ethane and tri-substituted phosphate esters	Norway
Perfluorinated substances including fluorinated polyethers	Norway
Diisononyl hexahydrophthalate	Portugal
Mercury	Portugal
Polycyclic aromatic hydrocarbons (PAHs) (Benzo[a]pyrene)	Portugal
Mycotoxins (Aflatoxin B1)	Portugal
Nanoparticles (carbon nanotubes, titanium dioxide)	Slovakia
POPs (indicative NDL-PCB and/or dioxin like DL-PCB) (Sum of PCB (six indicator NDL-PCB and one DL-PCB 118)	Slovenia
PAHs	Slovenia
Mercury	Slovenia
Pyrethrines and Pyrethroids	Slovenia
Arsenic (As)	Spain
Chlorpyrifos	Spain
Mercury and methylmercury	Spain

N-(phosphonomethyl)glycine	Spain
Phthalates/DINCH: RENOMINATION	Spain
Medium chained Chlorinated Paraffins	Sweden
Isothiazolinones	Sweden
Short chained Chlorinated paraffines	Sweden
Glyphosate, N-(phosphonomethyl)glycine	Switzerland
PAHs	Switzerland
Aromatic isocyanates	Switzerland
Cadmium and Chromium VI	Switzerland
Continue working on chemical mixtures	UK
Vanadium	UK
Beryllium	UK
Cadmium	UK
Hexavalent chromium	UK
Manganese	UK
Polycyclic Aromatic Hydrocarbons (PAHs)	UK
Lead compounds	UK
Nickel compounds	UK
Diisocyanates	UK
Nominations by members of the EU Policy Board	
Fipronil (±)-5-amino-1-(2,6-dichloro-α,α,α-trifluoro-para-tolyl)-4-trifluoromethylsulfinyl-pyrazole-3-carbonitrile	ECHA
N,N-diethyl-m-toluamide	ECHA
Aprotic solvents	ECHA
Phenolic benzotriazoles	ECHA
Substituted pheynlenediamines	ECHA
Mercury, mercury compounds	EEA

Nanomaterials	EEA
Pyrethroid insecticides	EEA
Acrylamide	EFSA
Perchlorate	EFSA
Deoxynivalenol (DON) and its metabolites	EFSA
Fumonisins B	EFSA
Glyphosate	DG RTD
Diisocyanates	DG EMPL
Arsenic acid and its inorganic compounds	DG EMPL
Lead and its compounds	DG EMPL
Dimethoate	DG SANTE
Polyethoxylated (POE)-tallowamine	DG SANTE
Metabolites of active substances used in pesticides	DG SANTE
Nominations by members of the Stakeholder Forum	
Chlorpyrifos 0,0-diethyl 0-(3,5,6-trichloro-2-pyridinyl-phosphorothioate	HEAL
Mancozeb	HEAL
Glyphosate	HEAL
Bisphenols (BPA)	HEAL
Organophosphorus flame retardants	HEAL
Methoxycinnamates	CHEM Trust
UV filters (Benzophenone group)	CHEM Trust
Flame retardants	CHEM Trust
Per and polyfluorinated compounds (PFAS)	CHEM Trust
Bisphenols	CHEM Trust
Glyphosate	EEB
Per- and polyfluoro alkyl substances (PFASs)	EEB

Phthalates & DINCH	EEB
Siloxanes	EEB
Nanomaterials	EEB
Diesel fumes	ETUC

Annex II: Substances from the 1st list of HBM4EU Priority Substances that were re-nominated and actors submitting re-nominations

Table 22: List of substances that were re-nominated and relevant actors

Substance or substance group	Actors that submitted re-nominations	
	National Hubs	Member of the Stakeholder Forum
Bisphenols	Croatia	HEAL, ChemTrust
Chemical Mixtures	Austria, Israel, Italy, Cyprus, UK, Switzerland	
Cadmium	UK, Iceland, Switzerland	
Chromium VI	Switzerland	
Emerging substances	Israel, Italy, Czech Republic, Denmark	
PAHs	Italy, Belgium, Czech Republic, Switzerland, Slovenia, Poland, UK	
Flame retardants	Austria, Belgium, Czech Republic, Norway	HEAL, ChemTrust
PFAS	Austria, Czech Republic, Norway, Italy	ChemTrust, EEB
Phthalates and DINCH	Belgium, Spain	EEB

Annex IV: Long list of nominated substances

Table 23: Long list of nominated substances and substance groups showing nominating actors, ranked according to the criteria of being an EU policy priority and broad support, with the short list highlighted in green

#	Substance identity			Actors that nominated the substance or group			
	Substance or substance group	CAS number	EC number	Member of the EU Policy Board	Number of National Hubs	Which National Hubs	Member of the Stakeholder Forum
1	Mercury and mercury compounds	7439-97-6 (Hg); 22967-92-6 (MeHg)	231-106-7	EEA	8	Slovenia, Portugal, Iceland, Austria, Czech Republic, Spain, Cyprus , Hungary	
2	Glyphosate, N-(phosphonomethyl)glycine	1071-83-6	213-997-4	DG RTD	5	Belgium, The Netherlands, Latvia,Spain, Switzerland	HEAL, EEB
3	Nanomaterials			EEA	3	Denmark, Slovenia, France	EEB
4	Arsenic acid and its inorganic compounds	7440-38-2	231-148-6	DG EMPL	3	Belgium, Hungary, Spain	
5	Diisocyanates			DG EMPL	2	Finland, United Kingdom	
6	Lead and its compounds	7439-92-1		DG EMPL	2	Hungary & United Kingdom	
7	Pesticides authorised in the EU & metabolites			DG SANTE, EFSA	1	Austria	
8	Pyrethrines and Pyrethroids			EEA	2	Slovenia, France	

#	Substance identity			Actors that nominated the substance or group			
	Substance or substance group	CAS number	EC number	Member of the EU Policy Board	Number of National Hubs	Which National Hubs	Member of the Stakeholder Forum
9	Acrylamide	79-06-01	201-173-7	EFSA	1	The Netherlands	
10	Quatenary ammonium salts			EEA	1	Norway	
11	Mycotoxins, deoxynivalenol (DON) and its metabolites and fumonisins B			EFSA	2	Portugal, Luxembourg	
12	Aprotic solvents, including pyrrolidones			ECHA	1	Germany	
13	Dimethoate	60-51-5		DG SANTE			
14	Fipronil (±)-5-amino-1-(2,6-dichloro-α,α,α-trifluoro-para-tolyl)-4-trifluoromethylsulfinyl-pyrazole-3-carbonitrile	120068-37-3		ECHA			
15	N,N-diethyl-m-toluamide (DEET)	134-62-3	205-149-7	ECHA			
16	Perchlorate	14797-73-0	623-712-9	EFSA			
17	Phenolic benzotriazoles			ECHA			
18	Polyethoxylated (POE)-tallowamine	61791-26-2	500-153-8; 932-738-2	DG SANTE			
19	Substituted pheynlenediamines			ECHA			
20	UV absorbers and filters				2	Denmark, Norway	Chemtrust
21	2,6-di-tert-butyl-p-cresol	128-37-0	204-881-4		2	Germany, France	
22	Chlorpyrifos 0,0-diethyl 0-(3,5,6-trichloro-2-pyridinyl-phosphorothioate	2921-88-2	220-864-4		2	Spain, Israel	HEAL
23	Siloxanes				1	Norway	EEB
24	Aflatoxins				1	Netherlands	
25	Alkylphenols				1	Cyprus	

#	Substance identity			Actors that nominated the substance or group			
	Substance or substance group	CAS number	EC number	Member of the EU Policy Board	Number of National Hubs	Which National Hubs	Member of the Stakeholder Forum
26	Aromatic isocyanates				1	Switzerland	
27	Benz(a)pyrene	50-32-8	200-028-5		1	Croatia	
28	Benzothiazole-2-thiol	149-30-4	205-736-8		1	Germany	
29	Bis(2-ethylhexyl)terephthalate	6422-86-2	229-176-9		1	Germany	
30	Cyclomethicone				1	France	
31	Folpet	133-07-3	205-088-6		1	France	
32	Iodine	7553-56-2	231-442-4		1	Cyprus	
33	Isothiazolinones				1	Sweden	
34	Manganese	7439-96-5			1	United Kingdom	
35	Medium chained Chlorinated Paraffins				1	Sweden	
36	Nickel compounds				1	United Kingdom	
37	Parabens				1	Netherlands	
38	POPs (indicative NDL-PCB and/or dioxin like DL-PCB)				1	Slovenia	
39	Short chained Chlorinated paraffines				1	Sweden	
40	Vanadium	7440-62-2	231-171-1		1	United Kingdom	
41	Triazoles				1	The Netherlands	
42	Triclosan 5-chloro-2-(2,4-dichlorophenoxy)phenol	3380-34-5	222-182-2		1	Germany	
43	Dioxins: sum of PCDDs and PCDDFs; dioxin-like polychlorinated biphenyls (PCBs)				1	Latvia	
44	Polychlorinated biphenyls				1	Denmark	

#	Substance identity			Actors that nominated the substance or group			
	Substance or substance group	CAS number	EC number	Member of the EU Policy Board	Number of National Hubs	Which National Hubs	Member of the Stakeholder Forum
45	Beryllium	7440-41-7	231-150-7		1	United Kingdom	
46	methoxycinnamates						1
47	Mancozeb	8018- 01-7					1
48	Diesel fumes						1

Annex V: Report of the stakeholder workshop

Report of the Stakeholder Workshop for HBM4EU work package 4 on 20 November 2017 in Brussels at DG RTD

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 24 below.

Table 24: 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

First Name	Last Name	Affilitation
Christophe	Rousselle	ANSES: French Agency for Food, Environmental and Occupational Health Safety
Tatiana	Santos Otera	EEB: European Environmental Bureau
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 provided in the box 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).

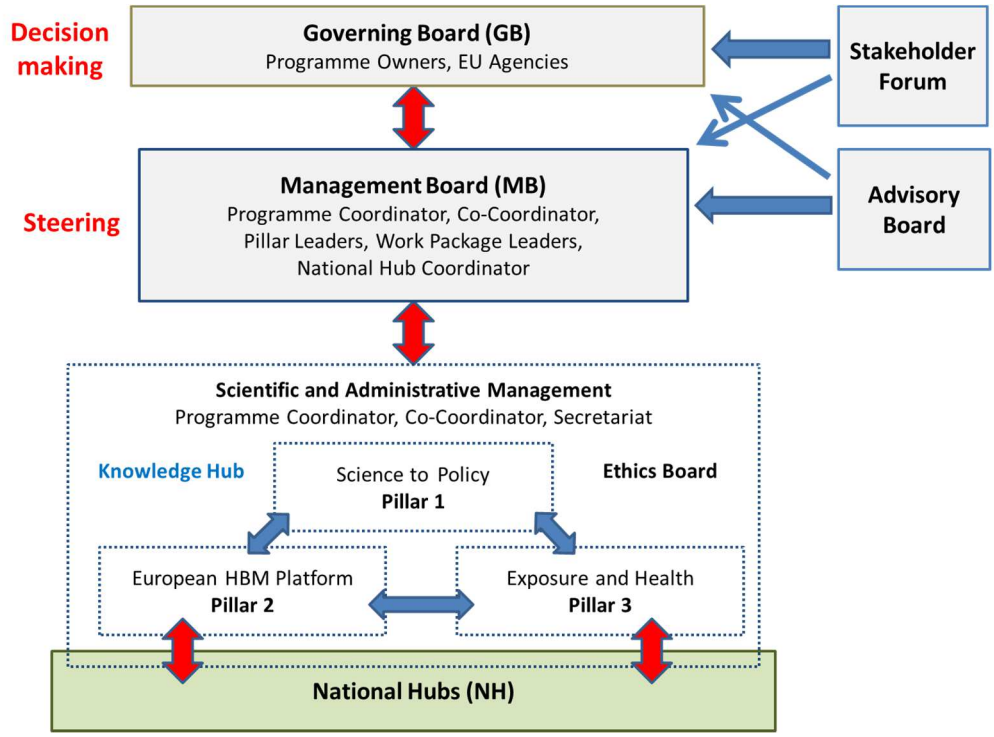
Presentation of HBM4EU - Greet Schoeters (VITO)

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, which is shown in Figure 2, was presented.

Figure 2: 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).

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.

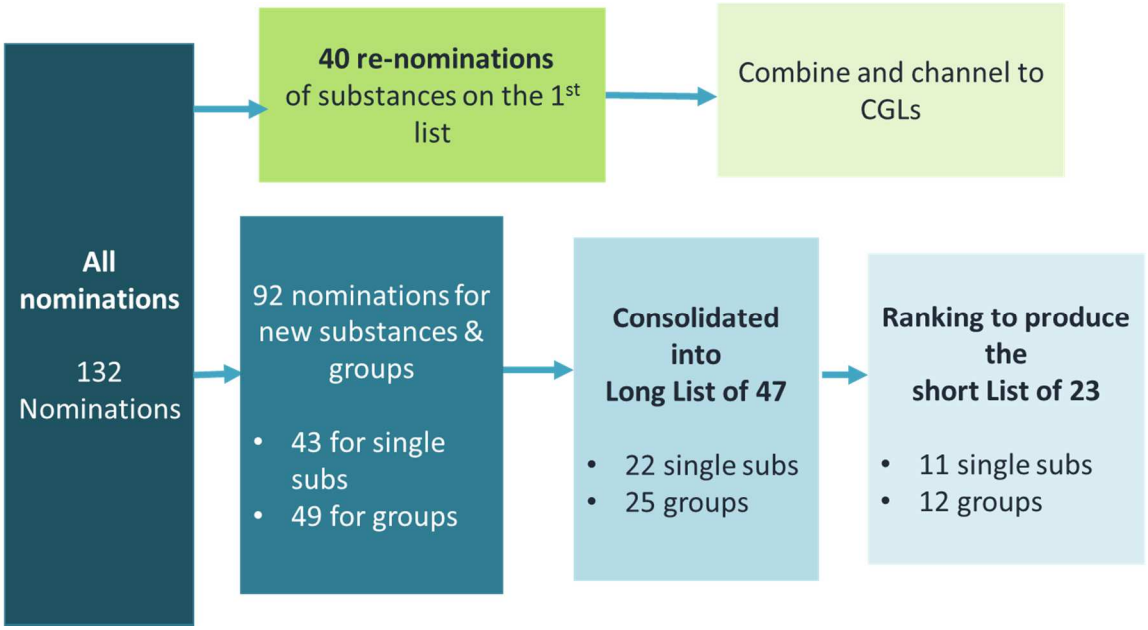
Introduction to the short list of nominated substances – Joana Lobo Vicente (EEA)

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.

Short list of substances – Maria Uhl (EAA)

Hazard properties, exposure characteristics, regulatory status were presented for each substance/group 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

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

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?

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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?

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.

Annex VI: Form for providing feedback on the background documents

Form for providing feedback on the background documents

Please use this form to provide structured feedback on the background documents that the HBM4EU partners have produced for each of the substances or groups of substances on the short list. The background documents are addressed to the National Hubs, Stakeholders as well as the EU Policy boards and Management Board for consultation. The deadline for providing feedback is the 1st of March 2018.

Please send the completed forms to: Joana Lobo Vicente at Joana.Lobo@eea.europa.eu

Please complete one form for each background document on which you would like to provide feedback.

We ask you to provide feedback on the information included in the background documents.

You can address the knowledge gaps and proposed research, as well as the evidence presented under each of the prioritisation criteria. Should you propose additional relevant information for the prioritisation process, please provide references and hyperlinks together with an explanation.

You are also invited to comment on the scores attributed to each criterion. Prior to that, please consult the explanatory note on the scoring approach, entitled "**HBM4EU Scoring Methodology**".

You may also want to comment on the categorisation.

Name of the substance or group of substances covered by the background document you would like to comment

Your details:

Name:
Organisation:
Role in HBM4EU:

Comments on the knowledge gaps and proposed research outlined in the background document:

Feedback on the proposals:

Comments on the hazardous properties:

Feedback on the information:
Feedback on the scoring:

Comments on the exposure characteristics:

Feedback on the information:
Feedback on the scoring:

Comments on public concern:

Feedback on the information:
Feedback on the scoring:

Comments on the section on regulations and policies relating to the substance or group:

Feedback on the information:

Comments on the technical feasibility on conducting human biomonitoring on the substance or group:

Feedback on the information:

Comments on the category to which the substance or substance group has been assigned:
