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HBM4EU science and policy for a healthy future

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A (phased) plan for action: from Human Biomonitoring to targeted policy action

Report of Case Study 1 – phthalates and bisphenols

Deliverable report

AD 5.4 First case study report

WP 5 – Translating results into policy

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1 List of abbreviations

ANSES	French Agency for Food, Environmental and Occupational Health & Safety
AOP	Adverse Outcome Pathways
BBP	Benzyl butyl phthalate
BBzP	Butyl benzyl phthalate
BEUC	The European Consumer Organisation
BPA	Bisphenol A
BPF	Bisphenol F
BPS	Bisphenol S
BP4,4’	4,4′-dihydroxybiphenyl
CEFIC	the European Chemical Industry Council
ChemSEC	The International Chemical Secretariat
CLP	EU regulation on classification, labelling and packaging
DEMOCOPHES	DEMOCOPHES is the acronym for a European project to test the feasibility of a human biomonitoring study in 17 European countries by means of common guidelines and using same methods.
DBP	dibutyl phthalate
DEHP	Bis(2-ethylhexyl) phthalate
DiBP	Diisobutyl phthalate
DnBP	di-n-butyl phthalate
DnPeP	di-n-pentyl phthalate
DiPeP	Diisopentyl phthalate
DHNUP	(DINP), and (DIDP).
DnHP	Di-n-hexyl Phthalate
DMEP	Di(methoxyethyl) phthalate
DEHP	di (2-ethylhexyl) phthalate
DiBP	Diisobutyl phthalate
DnOP	di-n-octyl phthalate
DiNP	diisononyl phthalate
DiDP	diisodecyl phthalate
DG ENV	The European Commission’s Directorate-General for Environment
DG GROW	The European Commission’s Directorate-General for Market, Industry, Entrepreneurship and SMEs
DG RTD	The European Commission’s Directorate-General for Research and Innovation
DG SANTE	The European Commission’s Directorate-General for Health and Food Safety
DH	The United Kingdom’s Department *of* Health and Social Care
DK	Denmark
DOMG	Flemish government Department of Environment and Spatial Planning
DUCC	Downstream Users of Chemicals Co-ordination group
ECHA	European Chemicals Agency
EDCs	Endocrine Disrupting Chemicals
EEA	European Environment Agency
EEB	The European Environmental Bureau
EFSA	European Food Safety Authority
ESTeSL	Lisbon School of Health Technology

EU	European Union
EWG	Environmental Working Group (US NGO)
FEICA	Association of the European Adhesive and Sealant Industry
HBM	human biomonitoring
HBMGV	Human biomonitoring guidance values
HEAL	Health and Environment Alliance
HIA	Health Impact Assessment
INSERM	The French National Institute of Health and Medical Research
IPCheM	Information Platform for Chemical Monitoring Data
NGO	Non-Governmental Organization
PVC	Polyvinylchloride
RAC	ECHA's Committee for Risk Assessment
RAPEX	Rapid Alert System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a EU regulation dating from 18 December 2006
RIVM	The Dutch National Institute for Public Health and the Environment
RMOA/PACT	Regulatory management option analysis/ Public Activities Communication Tool
SEAC	ECHA's Committee for Socio-economic Analysis
SIN LIST	The SIN (Substitute It Now!) List is a database of chemicals likely to be restricted or banned in the EU, composed by ChemSEc
SVHC	Substances of Very High Concern
TDI's	Tolerable Daily Intakes: an estimate of the *amount* of a substance in air, food or drinking water that can be taken in *daily* over a lifetime without appreciable health risk
UEAPME	Austrian Federal Economic Chamber
UBA	German Environment Agency
US	United States of America
VITO	VITO is an independent Flemish research organization in the area of cleantech and sustainable development
WECF	Women Engage for a Common Future
WP	Work Package

2 Authors and acknowledgements

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3 Introduction

The overall aim of task 5.5 is to develop and implement **structured and participatory processes** intended to facilitate the uptake of human biomonitoring (HBM) research findings by policymakers and stakeholders.

The organization of **multi-actor dialogues** on specific HBM topics is considered relevant as we believe that scientists, policymakers and stakeholders can all contribute with relevant expertise and should work together in 'translating' HBM data for policy-making, while also respecting each other's role.

In anticipation of new HBM research findings that will be produced within HBM4EU in the course of the coming years, University of Antwerp and the European Environment Agency organized in 2018 a **first case study on phthalates and bisphenols**.

For this first case study, it was decided to work on phthalates and bisphenols for various reasons. Firstly, because HBM data are already available for both substance groups (from previous research projects). In the context of HBM4EU, no new data have been generated yet. However, other relevant output from the project is already available, including strategies for further knowledge development and health interpretation. Secondly, policy initiatives have already been taken for both substance groups, some in response to HBM results. This makes it interesting to learn from these cases and to highlight points for improvement. And finally, both groups of substances are illustrative of broader discussions in the environment and health field, making the conclusions more widely relevant and applicable.

This case consisted of an iterative approach. After a first preparatory phase of desk research, a **series of interviews** were conducted with key actors in the area of phthalates and bisphenols (including policymakers, stakeholders and experts). As a next step, an **interactive workshop** was organized.

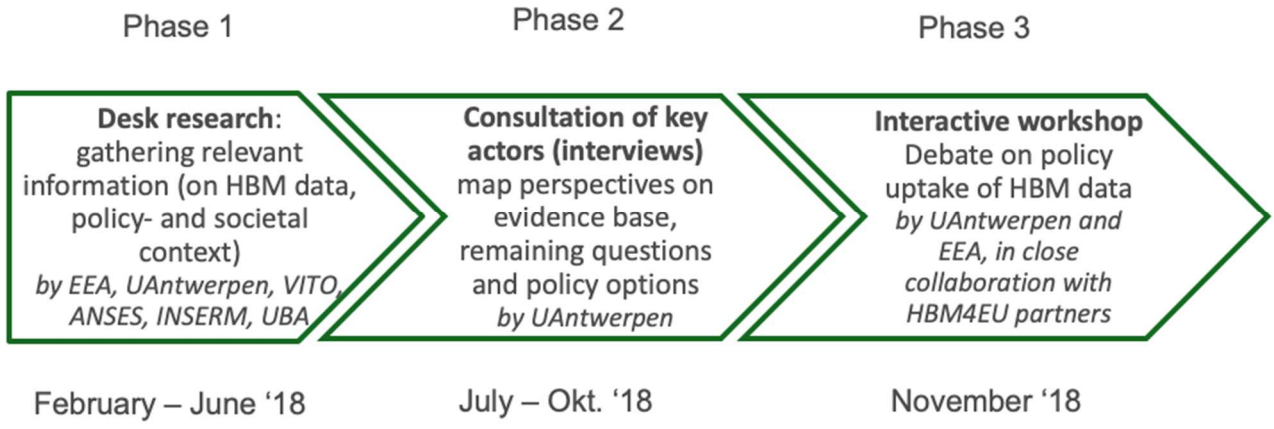

Figure 1: iterative process of the first case study

This deliverable first gives insights in the overall conclusions and recommendations that came out of the multi-actor dialogue on phthalates and bisphenols, but also provides detailed information on the methodology of the research as well as on its key outputs (the interviews and the workshop).

The set-up of the deliverable is visualized in the figure below.

Figure 2: Visualization of the set-up of the deliverable

4 Key messages: Conclusions and Recommendations

On the basis of this first case study, we can formulate a number of key messages, for the HBM4EU project, for improving the policy uptake of the research results, for the phthalates and bispenols case and for the further ambitions of task 5.5 within the project:

1. The presentations of the HBM4EU partners at the workshop, giving an overview of the ongoing work within HBM4EU, in particular on phthalates and bisphenols, clearly reflected the **variation in the types of knowledge that HBM4EU aims for**. On the one hand, the project has high scientific ambitions: harmonisation, quality control, development of new or improved methods to study health impact and exposure pathways. On the other hand, there is also a clear willingness within the project to develop data and tools that can help policy makers to advance their work in a context of complexity, uncertainty and controversy, such as EU representative data, accessibility of the data for policy makers and HBM guidance values for the interpretation of HBM results.

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2. Participants in the interviews and workshop underlined that (knowledge produced by) HBM(4EU) can be very relevant for policymaking. HBM can help to follow-up the effectiveness of legislation and other policy actions, and has an important signalling function with regard to new challenges and remaining gaps in policymaking.

   However, for the sustainable embedding of HBM at EU level, it is needed that HBM's role in policy making is made clear. On the longer term, it could be the ambition of HBM4EU to **enforce a clear role for HBM in the procedures for chemicals risk assessment, health impact assessment and chemicals regulation in the EU**. The lively discussions on this topic showed however that there is not yet agreement on how this should or can be achieved.

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3. **The strength of HBM at the EU level will depend largely on the continuous and thorough effort of the national Member States**. The Member States need to (continue to) invest in nationally representative HBM research. However, it is important that national authorities retain sufficient flexibility to use HBM for national or local priorities. Harmonisation and flexibility should be balanced in this respect.

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4. The added value of HBM is that it **triggers a holistic perspective on environment and health**. It enables discussions on the relative importance of exposure sources and on cumulative effects of mixtures of chemicals. This way it is a valuable tool to inform controversial debates, such as e.g. the one on endocrine disruption. This holistic perspective is **both a challenge and an opportunity for policy making**. A challenge, given the distribution of competences between policy domains. An opportunity, as it enables to think about cooperation and joint action across different policy domains. Dialogue and cooperation between different policy domains is considered to be essential and can be facilitated by HBM4EU's output.

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5. In order to maintain the support for HBM, it is particularly important to develop and actively **promote best practices and good examples that demonstrate the added value of HBM**. The phthalates case, and to a lesser extent also the bisphenol case, are considered good cases in this respect. HBM data of several European countries on phthalates from the

DEMOCOPHES project did play an important role in the risk assessment that underpinned a recent restriction proposal[1] for four phthalates prepared by Denmark and REACH.

The HBM4EU project, and specifically task 5.5, could also contribute to the further promotion of good examples of (the diversity of) policy instruments that can be applied, as well as other cases of multi-actor dialogue and joint reflection (see key message 6). For instance via scientific publication, the HBM4EU website and in relevant public fora.

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6. **The added value of HBM goes beyond strengthening regulation**. From the interviews, we could derive a broad overview of different policy instruments and good practices in relation to phthalates and bisphenols. They do not only relate to authorisation and restriction, but also to labelling, enforcement, promoting alternatives, information sharing and awareness raising, developing partnerships, education and strategy development. Furthermore these practices are not only implemented by governments (at EU, national or local level), but also by NGOs and industry, which e.g. play an important role in communication and developing and promoting alternatives.

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7. Our case study on phthalates and bisphenols, which aimed for a multi-actor dialogue on the existing knowledge base and (potential) implications of HBM results for policymaking, confirmed and underlined the need for dialogue and joint reflection on HBM research results. **Dialogue and joint reflection on HBM results are needed** in order to (a) develop legitimate and supported (risk) communication and (b) ultimately improve chances for cooperation between all actors involved. Once the HBM4EU project starts producing new HBM results, a well-structured and well-focused dialogue on the (most important) results could enforce the 'translation' of results into policy action.

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8. From our case study, we can clearly conclude that **not communicating about (new) HBM data, as well as about other output of the project such as guidance values, is not an option**. It is not up to scientists and authorities alone to decide on the relevance of new evidence. Joint reflection in order to put the data into perspective is a crucial step. Within the HBM4EU project a **supported procedure for communication and joint reflection could be developed, in which scientists, policy makers and societal stakeholders have their role.** The participants in our case study indicated their trust in the **possibility to find agreement on main conclusions and messages to be communicated**, or at least an agreement on the way of working (e.g. on how to interpret the data), even within a controversial context.

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9. Because **communication** on knowledge development **assumes transparency**, it is important that the HBM4EU website offers both non-technical summaries (that are well readable for lay people) AND technical details, also on the research design. Communicating about technical details allows communicating transparently about the assumptions and methodological choices, which makes the researchers less vulnerable to criticism from outside, as they have made their choices and assumptions explicit. Ideally, a dialogue about methodological choices is organized in a very early stage of the HBM research, so that consensus can grow upon the choices that are made and no disputes arise afterwards, when the results are there.

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[1] In the meantime this restriction proposal is adopted by the European Commission and will come into effect as of June 2020.

10. In order to further expand the policy relevance of HBM, as well as to develop good practices, it is important to further **develop a strategic agenda for the following years, to identify specific opportunities for HBM to be taken up in ongoing and planned policy processes**. In this context, it was recommended to sustain the consultation of and cooperation with the competent policy makers (from the EU Commision, agencies and national authorities). Furthermore, it was also proposed to involve legislators (from the EU parliament and the European Council) because of their role in the decision-making process on new legislation.

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In conclusion, **scientific knowledge** has its substantive quality (as clearly endorsed during the interviews and the workshop in the case of phthalates and bisphenols) but **should also GAIN rich contextual quality**. Exploring that context was exactly what we aimed for during this case study in order to strengthen the relevance and openness for policy uptake of the HBM4EU knowledge, whether it be the policy context or the wider societal context, EU-wide or at national level (as demonstrated by key messages 5 to 10). Facts do not speak for themselves. The joint interpretation of knowledge deserves a **case-by-case commitment of all parties in a well balanced configuration**: not only by experts and authorities but also a balanced representation of market parties, NGO's and citizens and intermediary professional groups (as demonstrated by key messages 6 tot 10.

The importance of this type of case-study workshops is noteworthy, to keep the collaborative engagemenet between scientists, policy makers and stakeholders and draw on future relevant key messages in HBM(4EU).

5 Meta-analysis of interviews with experts, policy makers and stakeholders

University of Antwerp organised several interviews between July and October 2018 with key actors in the fields of phthalates and bisphenols in the EU. Many of the interviewees not only participated in the interview, but also in the workshop that was organized on 8-9 November 2018. The main aim of the interviews was to map perspectives on the topic of phthalates and bisphenols, as a preparatory step to organizing the workshop.

In order to map the perspectives of different key stakeholders, we looked for a good diversity of types of respondents. In total we have had interviews with 27 people in 16 different interviews. We have interviewed colleagues from the HBM4EU consortium, i.e. scientific experts on phthalates and bisphenols, EU policy makers from several DGs and European agencies (EFSA and ECHA) and representatives from industry and NGOs.

Perspectives	Number of interviews/ interviewees
Experts on phthalates and bisphenols from the consortium	4/6
EU policy makers (DG's and agencies)	6/8
Industry	3/9
NGO's	3/3
	16/27

The interviews were open talks, but we tried to minimally address three main topics:

a) The current scientific knowledge and evidence base on phthalates and bisphenols.
b) Challenges and obstacles for policy making on phthalates and bisphenols, and the (potential) role of HBM(4EU).
c) The relevance of different policy instruments and good practices (at EU and national level)

Statements hereafter are based on a meta-analysis of the interviews (perceptions and opinions from interviewees), not on a scientific evaluation.

Interviewees were asked to reflect and speak openly on the topics from their own expertise, not (only) limited to the formal positions of their organisations. That is why we do not quote literally and do not mention names or organisations in this report.

A. The knowledge and evidence base on phthalates and bisphenols

Both substance groups have been studied for many years. This makes the cases of phthalates and bisphenols 'old' cases, but also prototypical cases. Respondents during the interviews underlined that it is important to still keep discussing these substance groups because they are so typical for the wider debates on chemicals safety and challenges for chemicals policy. Nobody stated that it is not relevant anymore to keep on discussing these topics.

With regard to the phthalates, we experienced during the interviews that there appears to be a growing scientific and societal consensus on the health concern for several phthalates. The best illustration for this growing consensus is probably the recent EU restriction proposal for four phthalates, prepared by ECHA and Denmark. This restriction proposal goes quite far in banning four phthalates and also recognizes the possible cumulative effects of exposure to these

substances. Which is quite unique in terms of chemical regulation regulation as chemical regulation has a history of a substance by substance approach. In particular, this argument for possible cumulative effects was reinforced by available HBM evidence from the European DEMOCOPHES project (see box 1).

Almost all interviewees acknowledge the importance of the restriction proposal and we do not note any fundamental objection (as opposed to more specific criticism about e.g. the scope of the restriction proposal and its implementation). There is also a willingness of most respondents to discuss challenges and obstacles for implementation of the restriction, as well as to discuss the relevance of potential other policy instruments that could help to phase out the use and exposure to these substances (see section three of this report).

On the other hand, for the bisphenols, we experienced in the interviews that this topic remains much more controversial. By which we mean that certain opinions are diametrically opposed to each other. As a consequence, it was more difficult during the interviews to discuss policy options, except for large-scale research that tries to 'solve' the controversy (such as the Clarity studies in the US, and potentially also in the context of HBM4EU).

Hereafter, we share some conclusions of our analysis of the interviews, specifically on phthalates and bisphenols.

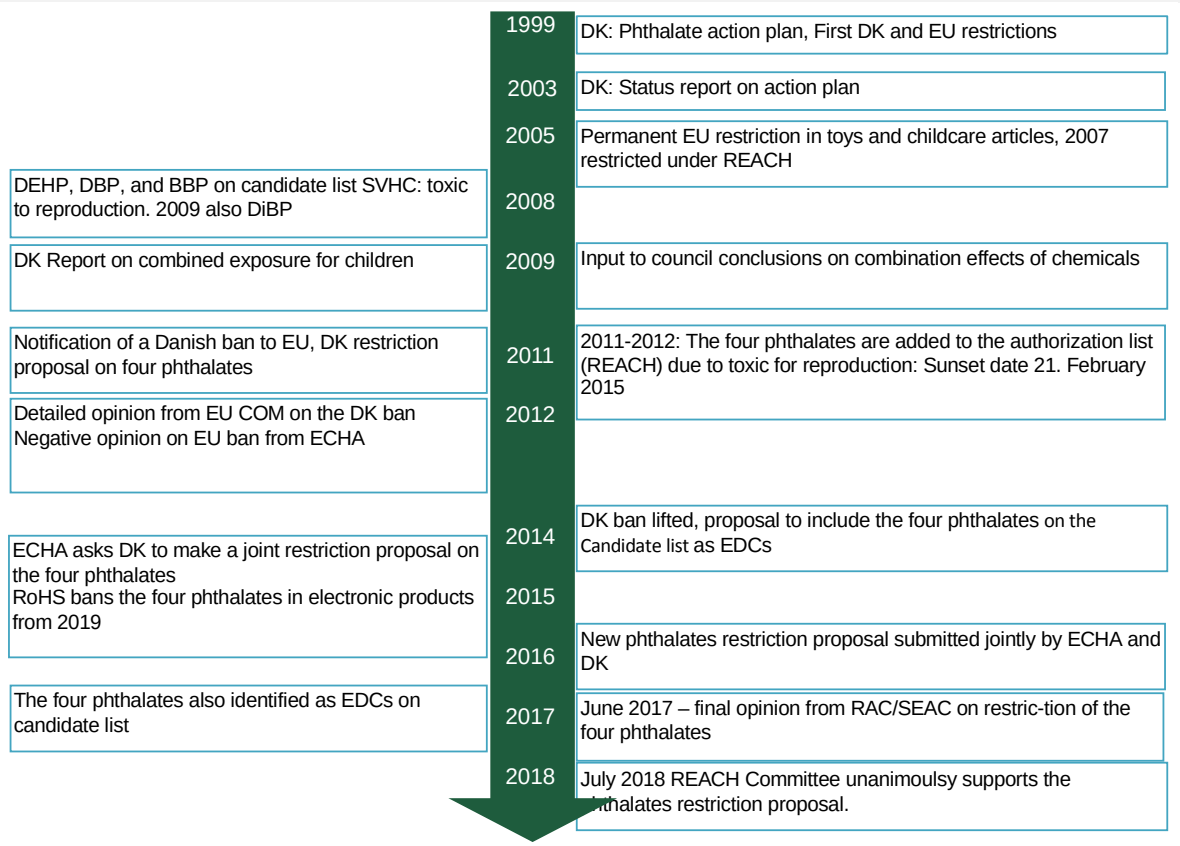
Box 1: the case of phthalates: often heard opinions and milestones mentioned in the interviews

- *'Innovation is at hand'*: HBM-data for phthalates from the DEMOCOPHES project (2011) were used in a health impact assessment (HIA) as a basis for the restriction proposal for four phthalates, submitted by ECHA and Denmark in 2016 and currently subject to a decision by the European Commission and EU Parliament.
    i) In this HIA the possible combined effects of exposure to these four phthalates were taken into account: calculations indicate that approximately 5% of children in the EU were at risk in 2011.
    ii) This restriction proposal aims for a further restriction of the use of these four phthalates, that were already subject to specific restrictions and authorisation.
    iii) The history of this phthalates case illustrates the importance of good quality data to support regulatory policy making. Previous attempts to ban or significantly restrict these phthalates have failed due to a lack of data (see figure 3 on the history of the phthalates restriction proposal).

- On the other hand the scientific methodology for assessing the combined effects is still debated. Several respondents indicate that a more detailed analysis of the data could give a better insight into the actual cumulative exposure. But for the time being, the individual HBM data could not be made available to the risk assessors.
- While acknowledging the importance of this restriction proposal, other respondents argue that it is all too little, too slow. Major points of criticism include:
    i) That only 4 of the 10 phthalates on the list of substances of very high concern (SVHC) are included. While these four are now being substituted by other substances.
    ii) And that the use of these phthalates in food contact materials (and several other uses) is excluded from the proposal, because it falls within the competence of another policy domain, while it is generally accepted that food is the main source of exposure.

- Other concerns are that a restriction alone will not be sufficient, but must also be enforced. According to industry representatives, most European companies are committed to innovation, partly because of the stricter regulations in the EU. On the other hand, (non-

compliant) imports from outside the EU can still distort the market. Enforcement, which is the responsibility of the national authorities, has been a bottleneck in the past.



Source: Andersson, A. (2018) *Phthalates – Human biomonitoring data used for risk management under REACH*, presentation HBM4EU conference, Vienna, 28/10/2018.

Figure 3: The history of the phthalates restriction proposal in Denmark and the EU (Andersson, 2018)

- When asked about the relevance of this innovative case to other cases, some respondents reply that this is only the beginning and that in the future even more attention should go to an integrated approach, in which similar substances are grouped and regrettable substitution is avoided. Other respondents, on the other hand, say that the specificity of the phthalates case cannot simply be transferred to other cases. The phthalates are well characterised and we know that they can have similar effects. Especially for larger groups of substances, e.g. endocrine disrupting substances, it will be very difficult to estimate the cumulative risks.

Box 2: the case of bisphenols: often heard opinions and milestones mentioned in the interviews

- The bisphenols case (mainly focussing on BPA) is characterized by a persistent controversy, fuelled by the discrepancy between standardised regulatory studies (used for formal risk assessments) that do not report health effects, and an increasing number of academic studies reporting effects at current exposure levels (low doses), but lacking reproducibility and therefore not meeting the quality standards for regulatory risk assessment.
    i) Some respondents question the quality of the often small scale academic studies, while other respondents warn for minimizing evidence from these studies and exaggerating scientific uncertainty in order to undermine any potential policy action.
    ii) An expert states that the academic studies at least indicate that there might be effects under specific circumstances, that are not noticed in a controlled environment of regulatory testing. This should lead to further investigation and a discussion on how to deal with this type of evidence in the procedures for risk assessment.
    iii) A large-scale study in the US (Clarity) aims to bridge the controversy on BPA, but has not yet been able to reach this goal up to now (end of 2018).

- In the meantime, BPA was added to the SVHC list and its use in thermal paper (e.g. cash receipts) will be banned in the EU from 2020 onwards. The use of BPA in thermal paper was assessed as a risk for workers (mainly cashiers), because BPA is not bound in this application and is therefore easily released.
    i) In a few EU member states additional actions are taken to minimise exposure to BPA.
    ii) However, some respondents do consider these initiatives as non-scientific, precautionary policy actions.
    iii) Other respondents criticise the fact that BPA in thermal paper is now being substituted by other bisphenols with similar characteristics.

- EFSA's risk assessment for BPA in food and food contact materials has been revised in 2015, introducing considerably lower TDI's, but still concludes that there is no health risk from BPA from food intake at current exposure levels.

- A weakness within this substance group is also that BPA is the subject of many studies, while other bisphenols have hardly been studied so far.
- HBM data have so far not been very decisive for this substance group, because in the past problems occurred with the quality control of the measurements. A first goal of HBM4EU for the bisphenols is therefore to guarantee quality controlled measurements.

Although there is much discussion and controversy with regard to the specific substance groups, the interviews also show that the main sources of controversy relate to the wider context. In this respect the following points were mentioned:

- The slow process of substance-by-substance assessments,
- The lack of knowledge on mixtures and cumulative exposure,
- The fragmented management (in the different policy domains) and implementation gaps,
- Divergent judgements on how to deal with uncertainties and the need for precautionary policy initiatives,
- The lack of transparency.

Nevertheless, the phthalates and bisphenols cases are found to be good cases to track progress with regard to these wider challenges. And HBM is judged to be an important trigger for innovation: (1) by showing real life/actual exposures and (2) trigger a more holistic approach.

B. The role of HBM(4EU) for policy making

A second big topic that was addressed in the interviews relate to challenges for policy making and the (potential) role of HBM(4EU) in this respect. Based on the input from the interviews, we could formulate 5 questions that were presented later on during the workshop as relevant topics for the debate. For the workshop, we prioritized the first two questions to be discussed in two break-out groups respectively.

i) 'How to deal with HBM data in risk assessment and regulation?'

This is a question that many of the respondents want to see answered. The phthalates case is already a good example of how it could be done. But up to now only a few of these cases exist in which HBM is successfully used, for risk assessment or for health impact assessment of chemicals and/or for regulatory purposes.

In the interviews, we heard several opinions on how to facilitate the use of HBM data:

- A first opinion is that the formal procedures have to be adjusted. Respondents mentioned making HBM obligatory in these procedures, but also to define quality requirements and the need to develop routines. Several respondents state that even when HBM data are available, it is often not taken into account. However, other respondents question the validity of many HBM studies (e.g. the representativeness of cross-sectional studies for real life exposure, or lack of proof for causal associations). Other barriers include the availability of the raw data for risk calculations and the absence of a generally accepted reference framework for interpretation.
- A second opinion is that – most probably – good quality data, if available, will find their way 'automatically' in the existing procedures and processes, as they did e.g. in the phthalates case. The DEMOCOPHES data were picked up by Denmark and ECHA for the restriction proposal and are now also studied by other policy actors, including EFSA.
- A third opinion is that we should organize joint reflections across policy domains more frequently and more structurally. Because HBM triggers a holistic perspective it is relevant for many different policy domains and sectors and can transcend the often fragmented policy debates. Respondents indicated that representatives of different policy domains regularly meet each other in the context of different projects and have the opportunity to enter into dialogue with each other and look over the walls of their respective policy domain. But in the end assessments and responsibilities are still organised per domain.
- A fourth opinion is that specific policy opportunities should be identified more actively, in order to feed in HBM data at the right moment. And by doing so, create precedents. This could be an ambition for the HBM4EU project.

Probably, there is a bit of truth in all four opinions and should rather be seen as complementary options for the better use of HBM data (not mutually exclusive).

ii) 'How to communicate on phthalates and bisphenols in a context of uncertainty?'

This is a question where many of the respondents are concerned about. All acknowledge the importance of communication, but it is clear that respondents have different expectations. In this respect, we noticed a well-known contrast between on the one hand those who believe that communication about risks is only necessary if serious facts are observed (in accordance with classical biomedical ethics) and on the other hand those who believe that communication about

research hypotheses, uncertain facts and the wider context is equally important. Based on the latter reasoning, it is up to the target audience itself (be it policy makers or the general public) to decide when a risk is significant within his or her own frame of reference. After all, these considerations often also involve a value judgement.

For the phthalates and bisphenols case, there are about as many respondents who think that communication about possible health risks is not necessary and can only cause anxiety, as others who find it very important to communicate in order to raise awareness. A difference of opinion that is likely to persist.

For the HBM4EU project on the other hand, it is generally accepted by all respondents that communication will be necessary. The research is financed with public money and citizens have the right to be informed. This opens up opportunities to discuss how to communicate on HBM4EU results. But even then the contrast in opinions remains: some say that scientists should clearly communicate what is known, in first instance to policy makers. While others say that scientists should be careful in presenting evidence as facts or certainties and should also communicate on complexity and what is not known or uncertain.

Several respondents also mentioned that they hope that a well-balanced communication on HBM4EU, both the project and its results, can help to prioritise policy attention (to work towards consensus on most problematic exposures, vulnerable groups or profiles, etc.) and can help to build trust of citizens in the EU's chemicals policy, as well as in science, EU industry and the market (i.e., trust in the safety of consumer products).

Both last points were introduced as two separate questions at the workshop:

iii) **'Can HBM help to prioritise policy action?'**
iv) **'How can HBM(4EU) help to build trust of citizens in the regulatory system?'**

And a fifth question relates to the last topic that was discussed during the interviews (see next section)

iii) **'What other policy instruments/actions gain legitimacy by the current HBM-evidence on phthalates and bisphenols?'**

C. The relevance of different policy instruments and good practices

From the interviews, we could derive a broad overview of potential instruments and good practices. They do not only relate to authorisation and restriction, but also to labelling, initiatives to improve enforcement, promoting alternatives, information sharing and awareness raising, etc. These (policy) actions are not only implemented by governments (at EU, national or local level), but also by NGOs and industry. Both NGO's and industry take up an important role in communication and in promoting alternatives, just to give a few examples (some good practices are mentioned below).

Other relevant policy instruments mentioned in the interviews relate to education, developing partnerships (e.g. between scientists and industry, or cities and regional governments that develop networks for voluntary action) and strategy development (e.g. in the context of the circular economy and non-toxic environment). Occasionally, financial instruments are also mentioned, such as a PVC tax. But while financial instruments are classic tools in the toolbox of policy makers (especially since the introduction of the polluter pays principle in the 1990s), we did not find many examples of them in this field.

The figure below provides an overview of different types of instruments for which HBM could be of importance. After that, we list several examples and good practices that were mentioned during the interviews and from our own desk research.

Figure 4: Overview of different types of policy instruments in the environment and health field

i) Regulation: registration, authorisation and restriction

In the EU, all chemicals manufactured or imported at volumes over one tonne a year must be registered under REACH. In addition, specific measures have been taken to limit human exposure to several phthalates and BPA at EU level and national level. A summary is included below. A more detailed description can be found in the scoping documents for phthalates and bisphenols on the HBM4EU website.

- For phthalates:
  - DEHP, DnBP, DiBP, BBzP, DnPeP, DiPeP, DHNUP, DnHP and DMEP are on the **REACH Candidate List of substances of very high concern**, due to their reprotoxic properties and for DEHP, BBzP, DnBP and DiBP since 2017 additionally due to their endocrine disrupting properties.
  - Four of the nine above mentioned phthalates are **subject to authorisation** since February 2015, i.e. DEHP, BBzP, DiBP and DnBP. Since June 2017, three other phthalates are included in the Authorisation List: DiPeP, DMEP and DnPeP with a sunset date of July 2020.
  - The current restrictions under REACH also cover some phthalates to a certain extent. Since reprotoxic substances are generally not allowed to be placed on the market in the EU as individual substances or in mixtures for supply to the general public when **concentration limits are equal or exceed 0,3%.**
  - Furthermore, the use of DEHP, DnBP, DiBP and BBzP is restricted in **plasticised materials of all toys and childcare articles** with a concentration limit of 0.1**%**. In addition, DiNP, di-n-octyl phthalate (DnOP), DiDP are restricted for all **children's toys and childcare articles** that can be placed in children's mouth with a concentration limit of 0.1%.
  - Current **efforts for a further restriction** of DEHP, DnBP, DiBP, and BBzP in consumer products have been initiated by ECHA (previously mentioned in this report).

- In addition to the REACH legislation, there is also **product-specific legislation** which regulates the use of certain phthalates, i.e. the **Cosmetic Products**' Regulation (EC/1223/2009), the regulation on **plastic materials and articles intended to come into contact with food** (EC 1935/2004 and Directives 80/590/ECC & 89/109/ECC), the **Medical Device** Directive (93/42/EWG), and the Restriction of Hazardous Substances Directive in **electrical and electronic equipment** RoHS2 (2011/65/EC).

- For bisphenols:
  - BPA is on the **REACH Candidate List of substances of very high concern** for Authorisation, based on its classification as toxic for reproduction and its endocrine disrupting properties. A number of bisphenols have been or are being assessed under the Community Rolling Action Plan and under the Public Activities Coordination Tool (PACT) List.
  - In January 2011, the European Commission adopted Directive 2011/8/EU, prohibiting the use of BPA for the manufacture of polycarbonate **infant feeding bottles**.
  - The use of **BPA in thermal papers** is restricted under REACH and will enter into effect in January 2020.
  - BPA, BPS and 4,4′-dihydroxybiphenyl (BP4,4') are **authorised for use in food contact materials** in the EU under Regulation 10/2011/EU, relating to plastic materials and articles intending to come into contact with foodstuffs.
  - A number of bisphenols are **subject to control** under health and safety legislation, environmental legislation and consumer legislation, as a result of their classification under the CLP Regulation.
  - In 2017, Directive 2017/164/EU established an indicative **occupational exposure limit value** of 2 mg/m3 over 8 hours for BPA.

At national level, several EU countries have additional restrictions on the use of BPA, e.g. in food contact materials, pacifiers and teething rings. I.e. in France, Denmark, Belgium, Austria and Sweden.

ii) Enforcement and market surveillance

In addition to clear regulations, it is also important to monitor and enforce compliance with the rules. In the EU, this is the responsibility of the national governments. Several respondents indicated that this is often a problem. Some countries are more active in this respect than others. E.g. The Swedish Chemicals Agency is quite active in reporting breaches of the regulations to the regional public prosecutor's office (Swedish Chemicals Agency, 2015).

At EU level, efforts are being made to exchange information and develop capacity. E.g. in the context of several EU Enforcement Networks for Chemicals, such as Forum, CLEEN, Administrative Cooperation Groups, Prosafe. These networks work on mutual projects, the interpretation of legislation, the exchange of inspectors, etc. These networks are invaluable for the enforcement authorities (Swedish Chemicals Agency, 2016).

The Rapid Alert System for dangerous non-food products (RAPEX) is a system used by the EU countries to exchange information about hazardous consumer products available on the market. A list of the notifications made to RAPEX is published every Friday regarding hazardous products reported by authorities in the EU member states. The list contains information about each product, its potential danger and the measures taken by the reporting country (Swedish Chemicals Agency, 2016).

Another good practice in the environmental field is the EU Action Plan on environmental compliance and governance. The action plan will be implemented over 2018-2019 with the help of EU countries and European networks of environmental agencies, inspectors, auditors, police, prosecutors and judges.

iii) Labelling

First of all there is the EU regulation on classification, labelling and packaging (CLP). The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union. This includes the well-known CLP pictograms, based on the United Nations' Globally Harmonised System (GHS). This includes e.g. the following pictograms:

- Exlamation mark = health hazard (e.g. respiratory irritation, dizziness, allergic skin reactions)
- Skull and bones = acute toxicity (fatal)
- The 'radiant man' (new since 2010) = serious health hazard (e.g. may be fatal, may cause damage to organs, may damage fertility or the unborn child, suspected of damaging fertility or the unborn child, may cause cancer, may cause genetic defects, may cause allergy or asthma symptoms, …)

Also of relevance here is **ecolabelling**, by governmental actors or by private actors as a form of self-regulation. The purpose of ecolabelling (i.e. environmental labelling) is to contribute to production and consumption with less negative impacts on the environment. The way to do this is by developing criteria for more environmentally friendly goods and services. The ecolabel criteria are based on the individual area of products and they determine the environmental impact of these in a life-cycle perspective (a life-cycle or cradle-to-grave analysis). The aim is to determine criteria which cover the best percentage of the market (20-30%). The task is to encourage environmentally adapted product development and to exploit market forces to achieve environmental benefits (Danish EPA, 2013).

The EU Flower and Nordic Swan ecolabels follow the ISO 14.024 standard and are subject to independent third-party control. The ecolabel criteria for a given area of goods are updated regularly, typically every four to five years, in order to follow developments in the market.

There is no general ban on phthalates or bisphenols in the eco-labelling system. The use of chemicals in articles is controlled instead on a category-by-category basis, with far from all articles currently being covered by eco-labelling criteria. One example is the Nordic Swan label that has included criteria on specific substances or categories of substances for several product categories. E.g. for baby products with textiles the criteria exclude the use of BPA, phthalates listed on REACH's annex CVII and in general substances that are considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects.

As more categories of articles are covered by the eco-labelling system and the existing criteria are revised, it can be expected that more restrictions will be introduced on phthalates (Swedish Chemicals Agency, 2015).

Other good practices with regard to labelling: the PHT label for medical devices containing the phthalate DEHP, labels on plastics (e.g. CE for certified plastic and the numbering system for the type of plastic, including number 3 for PVC, often containing phthalates), labels from NGO's such as the EWG labels in the US ('EWG verified') and last but not least the label on alcohol to discourage alcohol consumption during pregnancy, which is not related to phthalates or bisphenols, but is a good example because it is one of the most intuitive/consumer friendly labels in circulation.

iv) Informing and awareness raising

There is still a great deal of ignorance today about the chemicals contained in articles, among the general public but also e.g. among companies involved in importing goods. The need for information has grown as authorities, researchers, environmental organisations and also the media have increasingly highlighted the risks involved with hazardous substances, including in consumer products.

To enable consumers and business to make informed decisions resulting in lower risks, information campaigns and educational activities need to be used to supplement other instruments. To make a great impact, information needs to be specific, adapted for a target group and highlight definite courses of action. One could provide information about chemical regulations and risks, thereby making it easier for companies to do the right thing and for consumers, companies and the public sector to make informed decisions (Swedish Chemicals Agency, 2015).

Right to information about substances featuring in articles: It is a key issue for actors in the management chain of an article to have access to information about the content of hazardous substances. Without this information, it is not possible to assess or manage risks or to avoid articles containing unwanted hazardous substances. Therefore, companies, agencies involved in public procurement and consumers need to have access to information about the content of hazardous substances featuring in articles to be able to handle the article safely and make informed decisions. This information therefore ultimately helps create incentives for substituting hazardous substances in articles with alternatives which are safer from an environmental and health perspective.

Information support: It is important to disseminate knowledge about chemicals and the laws pertaining to them. This is where authorities have a responsibility to disseminate knowledge and provide support to companies. For instance, the Danish Environmental Protection Agency has produced guidelines advising companies on how they can substitute dangerous phthalates. These guidelines have been produced in collaboration with a number of Danish industry associations, which gives them greater clout. This document has been translated into English to make it easier to use outside Denmark.

Good practices: Especially the Nordic countries have a good track record in informing the public and companies about chemicals exposure, e.g. the Swedish Chemicals Agency has set up a website completely devoted to consumers. Consumers can obtain information about chemicals they encounter every day, enabling them to make informed choices and handle products safely. Many of their products are also available in English. Another good example is the leaflet on ‘chemicals and pregnancy’ developed by the Danish environmental protection agency, which was also used as a source of inspiration in many other countries. In some countries, this information task is taken up by civil society instead of by governments. For example in Belgium NGOs (i.e. family- and consumer organisations) take the lead in informing the public about endocrine disruptors.

In recent years, several **smartphone apps** have also been developed for consumers who want to know what substances are used in consumer products. Leading examples in this field include ToxFox in Germany (only for cosmetics), EWG app in the US (for many types of consumer products) and Think Dirty app in the US (only cosmetics). Currently a new European app is being developed funded by the LIFE programme of the EU (AskREACH) to inform consumers and companies on the presence of substances of very high concern (figuring on the REACH list) in consumer products.

v) Promoting alternatives

Another policy instrument to reduce exposure to certain chemicals is to promote alternatives for companies and consumers, on a voluntary basis. This can be in the form of other chemical substances (e.g. substitute phthalates in PVC plastics by other less harmful substances) or non-chemical alternatives (e.g. promoting alternatives for PVC plastics as such).

This is also encouraged within the REACH system, where authorisation obligations for certain substances are perceived as an inhibiting factor for the use of these substances. In 2018 ECHA has also published a new strategy promoting substitution to safer chemicals.

Also a few national governments are active in cooperation with industry in order to identify and promote alternatives. For instance, the Danish Environmental Protection Agency has produced guidelines advising companies on how they can substitute dangerous phthalates. These guidelines have been produced in collaboration with a number of Danish industry associations, which gives them greater clout. This document has been translated into English to make it easier to use outside Denmark.

Other initiatives include the SIN LIST (composed by several NGO's including CHEMSEC as an alternative SVHC list). SIN stands for Substitute It Now. More recently CHEMSEC has also develop 'Market Place', a meeting platform to bring together users and suppliers of substitutes. Bastaonline.se is a Swedish search engine to search for environmentally assessed building and construction products.

A problem for a smoother transition, however, is the fact that developers often do not want to share their knowledge with the competitors and also take out patents on new developments.

vi) Monitoring

In order to keep track of evolutions in the chemicals and environmental health field it is also important to have competent monitoring infrastructure and networks in place. If sustained in the future, HBM4EU could significantly improve this infrastructure. In addition to measurements in the environment and in products. With regard to the latter, the Swedish Chemical Agency has a great deal of experience in testing of chemicals in products and communicating about the results in an accessible manner, see for example their newsletter item on banned chemicals in e-commerce products. Such communication can also be used to increase public confidence in their authorities.

vii) Education

Because the students of today will become the new designers, managers, policy makers, etc. of tomorrow, several respondents emphasized the importance of education. Principles as sustainable development, circular economy and a non-toxic environment should be at the heart of today's education systems. Safety by design is a good practice in this respect. It was also mentioned that HBM does not always receive much attention in both medicine and toxicology today or e.g. in courses related to risk and health impact assessment.

In addition, education in general can encourage environmentally friendly and healthy behaviours, from an early age on. Education plays an important role in shaping the world vision of the new generation and should therefore receive a lot of attention.

viii) Partnerships

Another policy instrument regularly mentioned in the interviews are partnerships, especially to stimulate voluntary action of different types of stakeholders. Examples mentioned include the NonHazCities project, a partnership in the Baltic Sea Region that includes municipalities, regional authorities and other partners engaged to minimise emissions of hazardous substances from urban

areas towards the Baltic Sea. And Des Villes & Territoires Sans Perturbateurs Endocriniens in France, a partnerschip of local governments and stakeholders to decrease the use and exposure to endocrine disrupting chemicals.

Other types of partnerships include cooperation between governments and industry, e.g. to support substitution, such as in Denmark, or to develop new biomarkers for HBM research, such as in Germany.

ix) Strategy development

Since HBM mainly encourages holistic reflection, it is not only important for specific regulation of substances and sectors, but also for strategy development. In this respect, the respondents referred to several important EU processes of strategy development and transition management, such as the circular economy, the non-toxic environment and more recently the ambition to develaop a EU framework on endocrine disruption. HBM evidence can make an important contribution to the support for as well as (in a later stage) the monitoring of these strategies.

x) Financial/economic instruments

Environmental taxes can generally be designed to be either financing or controlling. The choice of tax depends completely on whether the desire is to finance a transition process or whether there is a need to quickly phase out a substance. It can work just as effectively as a restriction as the tax provides a strong incentive for modified behaviour.

Pursuant to the Danish PVC Tax Act (Act no. 253 of 19 March 2007) certain goods are subject to taxation when they contain phthalates. This Act requires Danish companies that manufacture goods which are covered by the scope of the Act and companies that receive such goods from abroad, to pay a tax. The tax on phthalates is based on the weight of the phthalates in the goods. The Act covers a large number of goods categories, including flooring material, cables, ring binders, gloves etc.

Another economic instrument is **green public procurement**, e.g. by governments. Chemical requirements in public procurement can be used as a suitable instrument for promoting substitution in the areas where the process of formulating regulations at EU level is progressing slowly. By using green procurement, the public sector can go further than the legislation and steer developments towards a non-toxic environment. Procurement should be a particularly effective instrument in areas where the public sector accounts for a large proportion of the market, for instance, in the healthcare sector and in pre-school institutions.

The EU's procurement regulation provide procurers with opportunities for taking into account green factors. However, procurers have occasionally experienced problems in setting out chemical requirements when there is often a lack of knowledge about the content of the substance in articles. Therefore, the need for effective tools and knowledge with a view to imposing relevant chemical requirements and monitoring them is vitally important to ensuring that the potential offered by procurement as an instrument is met (Swedish Chemicals Agency, 2015).

6 Workshop report

Workshop on policy uptake of HBM-results

EU Case study on phthalates and bisphenols

Brussels, 8-9 November 2018

Workshop report [final version_14/02/2018]

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A. Introduction

HBM4EU is a H2020 funded project aiming to support EU chemicals policy with the help of human biomonitoring (HBM) data. Because science not always 'speaks for itself', one task in the project is to organize participatory processes with policymakers, scientists and societal stakeholders in order to facilitate the uptake of research findings for policymaking.

In collaboration with the European Environment Agency, the HBM4EU consortium and DG RTD of the European Commission, the University of Antwerp co-organized a workshop on 8-9 November 2018 in Brussels. Representatives from the European Commission (several DG's), the EU agencies ECHA and EFSA, industry/companies, environment and health NGOs, a few national/regional authorities and experts attended the workshop to discuss the possibilities for policy uptake of HBM data on two substance groups, i.e. phthalates and bisphenols. This workshop is part of an EU case study on phthalates and bisphenols within HBM4EU.

About the EU case study on phthalates and bisphenols – As the first case study, it was decided to work on phthalates and bisphenols for various reasons. Firstly, because HBM data are already available for both substance groups (from previous research projects). In the context of HBM4EU, no new data has been generated yet (expected in 2019 and 2020). However, other relevant output from the project is already available, including strategies for further knowledge development and health interpretation. Secondly, policy initiatives have already been taken for both substance groups, some in response to HBM results. This makes it interesting to learn from these cases and to highlight points for improvement. And finally, both groups of substances are illustrative of broader discussions in the environment and health field, making the conclusions more widely relevant and applicable.

This case consists of a step-by-step approach. After a first preparatory phase of desk research, a series of interviews were conducted with key actors in this area (including policymakers, stakeholders and experts). As a next step, an interactive workshop was organized, of which this report is a reflection. In a final deliverable (due in February 2019) each step will be documented and recommendations will be formulated for HBM4EU and beyond.

The aims of the workshop were to:

- Present **ongoing work of HBM4EU** and its contribution to the knowledge development on environment and health, in particular on phthalates and bisphenols.
- Present a **meta-analysis of interviews** conducted in the summer of 2018 with key respondents in the field, bringing an overview of: (a) current opinions and perceptions on (science & policy on) phthalates and bisphenols, (b) ideas on future directions, paying attention to the potential role of HBM4EU.
- Have a **constructive dialogue** between scientific experts, policymakers and stakeholders **on the content of these presentations, how to communicate externally on the (expected) output** of HBM4EU and **how HBM4EU results can inform and support policymaking** at EU- and national level. In relationship to the latter, we did explicitly not only look at regulatory options, but also other types of measures (on the basis of good practices).
- In addition, we also want(ed) to **reflect on the process itself**, by jointly evaluating the initiative, discuss how to deal with the output of the workshop and how we can improve our efforts to facilitate policy uptake of HBM-results in the future.

Organisational aspects – as mentioned in the introduction of the workshop:

The ambition of the workshop was the exchange of views, on i) the current evidence base (including HBM-evidence), ii) the relevance of this evidence for policymaking, iii) challenges for policymaking and policy options (including a diversity of policy instruments) and iv) the role of HBM4EU in this context and how to facilitate the uptake of HBM-results.

What we did not aim for: i) interference in the process of policymaking, which remains the job of policymakers, ii) judge on the health impact of bisphenols and phthalates, iii) weigh or rank opinions, iv) force consensus or flatten views/opinions in order to reach an (undesirable) average opinion.

Participants were asked to reflect and speak openly on the topics from their own expertise, not (only) limited to the formal positions of their organisations. That is why we do not mention names or organisations in this report (only in the participants list). Participants were also encouraged to reflect from a helicopter perspective and not to go too much into the technical details. While we – of course – acknowledge that technical details may matter.

Audio-recording and reporting: the workshop was audio recorded to facilitate the reporting of the workshop and for subsequent research activities. The audio files and transcripts are stored safely on a secured server and are only distributed among the organizers of the workshop (i.e. researchers of UAntwerp).

Because we value the various opinions and nuanced arguments that were expressed, the transcripts will be processed in detailed reports (mentioning the different opinions and arguments that were raised). However, participants to the workshop will not be cited in their personal capacity nor on behalf of their organization. If nevertheless such a citation is deemed to be relevant, explicit permission will be requested from the participant. In this deliverable, a summary of the minutes is disclosed. A more detailed report, including a more complete overview of the arguments formulated by the different participants (in an anonymised way), can be requested with a motivated request.

In first instance, a draft report of the workshop will be produced. Participants will be given the opportunity to give feedback on this draft report. A final report will be produced as part of a deliverable for HBM4EU (due in February 2019) that will be made public on the website after approval of the management board and the European Commission.

Composition of the group of participants:

Participants for this workshop were personally invited, in a targeted way, to ensure that the group was not too big for the necessary interaction, but sufficiently diverse in composition. The intention was to find at least a few representatives for each of the categories as defined in the participants list below, in order to have a good variety in relevant perspectives. The organisers are very happy that they succeeded in getting such a diverse group of participants together.

Readers guide:

In this report a summary is provided for the different parts of the workshop.

In a final chapter we make an evaluation of this initiative, including an overview of the feedback that we received from the participants in the evaluation forms. We also reflect on the way forward.

A participants list and the workshop program is included in annex.

B. Summary and conclusions of day 1

On day 1, several presentations were programmed about the ongoing work and the first output of HBM4EU, in particular on phthalates and bisphenols. Also the EU policy context for both substance groups was presented. In between the presentations sufficient time was provided for questions and discussion. On the basis of these presentations and the discussions, a few general conclusions can be formulated.

i. Knowledge gaps and how HBM4EU wants to address these gaps:

It was mentioned in the discussion that although the debates on phthalates and bisphenols have been going on for several decades, both substance groups still remain a concern for human health while not fully regulated in the EU. This makes them important themes that receive a lot of attention. In the meantime, considerable progress has been made regarding our knowledge and understanding about the hazards and exposure of these substances and several policy initiatives have been taken (e.g. partial restrictions or inclusions as SVHCs in the REACH candidate list). But knowledge gaps remain. Addressing these gaps would be useful to inform future policy decisions and evaluate current measures. HBM4EU included both substance groups in its 1st list of priority substances and tries to address these gaps, as presented by several partners of the project during the workshop. Including:

<u>For both substance groups:</u>

- **Current exposure levels in Europe**, including identification of country differences and high exposure groups.
- Follow up of the **effectiveness of regulations** (at EU-level and national level, e.g. for different national regulations on BPA).
- **Interpretation in the context of health relevance**, also considering the effects of combined exposure.

<u>Specifically for the phthalates:</u>

- Continued **follow-up of exposure trends**: are regulated phthalates effectively phased out? And how is exposure to substitutes evolving?
- **Exposure pathway modelling**: what are the most important exposure sources? Which sources are not adequately addressed by current regulation? (In this respect, questions were raised about the fact that food contact materials were excluded from a REACH restriction proposal for four phthalates, as well as about import of products from outside the EU and enforcement of sectoral chemicals regulation.)
- New methods for **assessing (potential) health risks**: in particular related to substitutes and exposure to mixtures of phthalates (and other anti-androgenic compounds).

<u>Specifically for the bisphenols:</u>

- **Quality control** of sample collection and analysis, which has been a problem in the past for BPA (because of the potential contamination of samples and the importance of the time of sampling).
- Focus on **BPA substitutes** (BPS and BPF will be monitored in new aligned studies and other bisphenols will be studied in different work packages).
- Method development for establishing **exposure-health relationships** (including identification of relevant effect biomarkers and adverse outcome pathways (AOP) modelling).

Various supportive responses from those present – as well as the absence of critical reactions on the research program – show that there seems to be **broad support for this work** and that **relevant research questions** are put forward. Questions mainly relate to communication, health interpretation and how to facilitate policy uptake (see next two sections).

ii. Hard science, some pragmatism:

The presentations about ongoing work and first output of HBM4EU clearly showed the **variation in the types of knowledge** that HBM4EU aims for. On the one hand, the project has **high scientific ambitions**: harmonisation and quality control of HBM protocols and results, development of new or improved methods to study health impact and exposure pathways and sources. These efforts are expected to significantly improve the quality of HBM evidence in Europe and thereby contributing to reliable knowledge for decision-making in chemicals safety and health management.

On the other hand, there is a clear willingness within the project to help policymakers to advance their work in a context of complexity, uncertainty and controversy. And for this purpose, the HBM4EU project also explores pragmatic approaches. Two examples were presented in this respect:

i) the strategy to derive '**health-based' HBM guidance values**[2] for health interpretation, and
ii) the strategy to derive **EU-wide HBM reference values**[2] on the basis of existing data and new aligned studies.

From the presentation on the **derivation of 'health-based' HBM guidance values**[2], in particular for some of the phthalates (and expected for BPA and phthalate mixtures), it was clear that these guidance values should be seen as a **screening tool** and that the derivation is **based on the currently available toxicological and epidemiological knowledge**, including its limitations. This means that these have to be carefully interpreted and can also be adjusted as soon as new evidence becomes available. The speaker also stated that from a scientific point of view there are several reasons why these values should not be seen as safe levels at the level of an individual (or vice versa: as an indication of potential health damage when exceeded).Nevertheless, several participants emphasize the **importance of such values for policymaking and communication** and can be used for screening and prioritisation. The speaker stresses the importance of using it as a screening tool: '*providing information on which substances are present at levels well below, near or above threshold concentrations below which there is no risk for adverse effect anticipated according to current knowledge, is useful for assessing the relative priority to perform risk assessments.*'[3]

The extensive and partly controversial discussion after this presentation also included the recommendation for the HBM4EU project to **reconsider the wording**, especially the preposition **'health based'** can create ambiguity. This preposition originally meant to indicate that the guidance value is based on health considerations (observed from epidemiological studies, human or toxicological studies) and is not a legal norm (the latter is often a political compromise, and therefore not (only) 'health based'). However, most participants from different perspectives, seem to agree that the wording 'health based' can easily be misconceived. A **more neutral terminology** is proposed, potentially similar to the German 'human biomonitoring values'. After all, the derivation strategy for those values is similar to the strategy of HBM4EU.

In addition to the wording, it was also suggested to formulate a **clear definition** for the values. And another point of attention that was mentioned is the importance of **cooperation with other European authorities**, such as ECHA and EFSA, in order to do complementary work and clearly

[2] **Decision on terminology**: After the workshop, it was decided by the HBM4EU Management Board to adjust the wording of the 'health-based guidance values' to '**HBM Guidance Values**' (HBM-GV). The 'EU-wide HBM reference values' (i.e. European exposure data) will be referred to as '**European Reference Values**'.

[3] Technical information on the derivation of these HBM guidance values can be found in the respective presentation and in deliverable 5.2 on the HBM4EU website. The derivation strategy will also be published in a scientific paper (in preparation).

indicate the relationship between other existing values (not necessarily related to HBM, e.g. TDI[4] values) from EU institutions and projects.

Also regarding the strategy to derive **EU-wide HBM reference values[2]** (i.e. exposure values for the EU population, such as average concentrations as well as the range of concentrations) it was clear that pragmatic choices had to be made on the basis of what is realistically possible at the moment. A great deal of effort and inventiveness is needed to make available existing data from the member states (taking into account GDPR[5] and other barriers) and for new aligned studies hard choices had to be made in view of the budgetary context. Not all substances can be measured in all age groups and all countries. Nevertheless, hard work is being done to deliver data at EU level, hopefully from next year on.

Both presentations were also metaphorically referred to as '*the kitchen of HBM4EU*'. Because they show how the strategies are being implemented with the available resources and how sometimes pragmatic (but of course well-justified) choices have to be made.

iii. Importance of nuanced communication and joint reflection:

Last but not least, a point that regularly recurred in the discussion, from various perspectives, was the emphasis placed on the importance of a **well-substantiated and nuanced communication** Not only on the results of the project, but also on the research design, strategies for interpretation and the choices that are made along the way. The aforementioned discussion on the HBM guidance values is certainly a good example in this respect.

Joint reflection on these topics, not only within the scientific community but also with policymakers and stakeholders, can certainly contribute to this aim. The participants therefore expressed their **appreciation for the openness of the consortium to discuss these issues** (e.g. during this workshop).

C. Conclusions of day 2 - break-out group discussions

On day 2, two discussion groups were on the agenda. The central questions for both groups was: **'How can HBM(4EU) inform policymaking?'**

The initial intention was that a first group would focus on regulatory policymaking and a second group on other policy instruments (non-regulatory policy options). But because a lot of attention was paid to communication on day 1, it was decided to focus discussion group 2 mainly on communication, i.e. communication not only about HBM results, but also in a broader sense as a policy instrument.

The topic of phthalates and bisphenols was again proposed as a case, with the aim of having a more specific focus for the discussion. In practice, however it proved difficult to maintain this specific focus. The discussions focused mainly on HBM in general. We will come back on this point in the final chapter on evaluation.

As an introduction to the discussions, a meta-analysis of interviews with key actors in the field of phthalates and bisphenols was presented (including interviews with scientists, policymakers and stakeholders). The aim of these preparatory interviews was to map opinions on the evidence base, challenges for policymaking, the (potential) role of HBM and good practices for different policy options and instruments (both at EU-level and at the national level). This presentation can be found here.

[4] TDI = Tolerable Daily Intake
[5] GDPR = The EU General Data Protection Regulation

i. Group 1: HBM to support regulatory policymaking

As a starting point for this discussion group, the following question was presented:

> '**How to deal with HBM data in chemicals risk assessment and regulation?**' ('*How to reconcile a holistic approach with compartmentalised policymaking?*')
>
> – is the phthalates case a good example?

> In the preparatory interviews, several suggestions where formulated by key respondents:
>
> 1. "**The procedures have to be adjusted** (for risk assessment, health impact assessment and regulatory policymaking) – HBM should be made compulsory, quality requirements should be defined and routines should be developed."
> 2. "**Good quality data will find its way automatically**."
> 3. "**Joint reflection across policy domains should be organised** more frequently and more structurally, because of the transversal nature of HBM research."
> 4. "The HBM4EU project should more **actively try to identify policy opportunities**, in order to feed in HBM-evidence at the right time."

It was clear from the discussion that all four statements or suggestions were considered important to be discussed and analysed by participants around the table. This mainly illustrates that these statements should be seen as complementary to each other and not as mutually exclusive views. Nevertheless different views exist among different stakeholders.

Especially the first point which states that HBM should somehow be made compulsory in the EU's chemicals regulation process, received much attention in the discussion.

Hereafter, we thematically ordered the topics that were discussed during the 1.5h break-out session.

'Give HBM a clear role, but be realistic in making HBM compulsory…'

The first statement, on the need for a '**compulsory HBM**', gave rise to an intense discussion. Because of that some of the participants tried to rephrase this point as the need for a legal basis for HBM, or the need to define a **clear role** for HBM in the regulatory process. An important argument that was raised in favour, is that a legal basis at EU level is needed to **motivate the member states** to (keep on) investing in national HBM programs, by offering support for this infrastructure and creating a clear added value for the data at EU level.

Most of the participants seemed to agree on the relevance of information provided by HBM for policy making and the need to define a clear role for HBM, at least on the level of ambitions. And it was emphasized that a few weeks earlier during the HBM4EU conference in Vienna, a similar conclusion for a '*regulatory demand for human biomonitoring*' was formulated by a panel of high-level EU representatives.

At the same time there was also a plea for being realistic on **'what' to make compulsory** (the scientific network to generate the data, the use of the data, or both?) **and 'how' to do that** (in all the specific regulations, or at a more overarching level? For all substances, or only when data is available?). A few questions were also raised about the **feasibility**, especially in the short term: with regard to analytical methods to measure large numbers of chemicals, and who should pay for it (the financial feasibility).

Most of the participants seemed to agree that it is probably better to have some kind of **tiered approach**, or even a case-by-case evaluation, to decide when and how HBM would be most useful[6]. Also proportionality and affordability, for different types of EU companies, was mentioned as an important consideration. In a tiered approach also other types of data can be taken into account, such as toxicokinetic (TK) data. For a tiered approach, however, there is a need to have good **decision criteria** (e.g. criteria related to absorption and toxicological considerations were mentioned, as well as production volumes, although there was no consensus on this last point) as well as a scientific **network to perform HBM** in a quality-controlled way.

Regarding the discussion on 'what to make compulsory', whether the network or the use of HBM, it was also mentioned that this distinction is perhaps an artificial one. Because **the one depends on the other**. If no clear role/use is defined, then it is not realistic to expect that the network will be made mandatory.

A last important point that was mentioned is that it is not only important to define a clear role for HBM, but also that guidelines and quality requirements should be developed on how to deal with this type of data.

'Good quality data will find its way, but probably not automatically…'

Another opinion that was often voiced, especially with regard to the shorter term, is the importance of **good cases that proof the added value of HBM**. Also, in the current system good quality data can find its way. The **phthalates case** is a good example in that respect, where ECHA and Denmark used HBM data for a restriction proposal. Following the recent ECHA assessment of different phthalates, also EFSA was mandated by the EC to re-evaluate the safety of certain phthalates authorised for use in plastic food contact materials. Although the phthalates case also shows that the uptake of HBM in policymaking certainly does not work automatically. In most cases there is **no legal requirement** for including HBM data in the assessments, a**ccess to the data** is a bottleneck and **someone has to take the lead** to initiate a dossier. E.g. in the phthalates case the use of HBM data was a success because of the sustained effort of the Danish government.

Furthermore, the importance of **contextual information** was emphasized, e.g. on main sources, health effects and vulnerable groups, because for policymaking HBM is only one piece of the puzzle.

Currently, however, it is often **difficult to exchange the data** due to strict rules included in the informed consents of many studies, inspired by traditional **clinical ethics**.[7] This is especially the case for HBM in an occupational context, because proprietary rights for the data of employees providing the specimen are legally protected. Only the occupational physician is allowed to disclose the data to the person who delivered the biological sample. Nevertheless one of the participants states that the aggregated data of occupational HBM could potentially be very useful to learn e.g. about the effectiveness of risk management measures, not (only) on the level of a company but on an aggregated level.[8] **Changing the paradigm** on HBM from health surveillance to exposure assessment and risk assessment, with clearly different traditions on data privacy,

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[6] In the prioritisation strategy developed under Task 4.2. different criteria have been used to prioritise substances to consider in the HBM4EU Program. For this purpose also a tiered approach was developed. An overview of this prioritisation process can be found on the HBM4EU website.

[7] However, efforts are being made within the project to adapt the consent forms for future studies to make data sharing easier.

[8] In response to a draft version of this report, one of the participants adds that for the evaluation of exposure in an occupational setup the context of the sampling is of utmost importance, e.g. Personal protective equipment (PPE) applied or not, time of sampling (directly after shift, x hours following occupational exposure or even after the weekend), etc. The evaluation of occupational exposure and efficiency of PPE requires detailed context information.

could be part of the solution. Although it was also emphasized that health interpretation and the monitoring of possible health effects should remain an important part of HBM.

'The biggest advantage of HBM lies in its integrated focus, so it should get a central role in chemicals policy…'

The added value of HBM lies especially in its holistic/integrated approach. Because of that, it was suggested that it should also get a **central role** in policymaking on chemicals, which is not only the role of REACH, but involves many other sectoral legislation (e.g. on food, toys, cosmetics, pesticides, etc.). On the other hand, HBM is not in the first place a tool to inform specific sectoral regulation, because it does not relate to specific sources. It's main strength lies in holistically **evaluating the efficacy of regulation**, **and** by extension also **the way in which we deal with chemical substances today**. Having a HBM-network in place would help to follow overall trends better.

An important audience in this respect is not only the European Commission, but also the **legislative decision makers**, i.e. the European Council and the European Parliament, because of their role in the decision-making process on new legislation.

"HBM in the EU should be a collective endeavour, but an important role remains for the member states …"

The ambition of HBM4EU is to build a European HBM network based on (existing) **national programs**. This means that an important role remains for the member states, which must also retain their interest in the program. Harmonization should therefore be pursued without member states losing the **flexibility** to meet local or national concerns. On the other hand, a clear legal basis and support for HBM at EU-level were already mentioned earlier as important motivations for member states to invest in national programs and to generate national responsibility.

The member states also have an important role to play in the **policy uptake** of the data. They have the right of initiative to **prepare restrictions and classification dossiers** in the context of REACH and CLP and to submit them to ECHA for their assessment launching the procedure for a possible regulatory action to be taken by the European Commission once concluded that there is a need for an EU action to control the risk. Member States can also take other **complementary actions at national level**, including non-regulatory instruments.

"The polluter pays principle is not (fully) applied when it comes to HBM…"

Regarding the resources needed for HBM it was mentioned that in theory the EU applies the polluter pays principle, while this is not fully applied in practice when it comes to HBM. Current **HBM programs** are mostly **funded with public money** and in the context of registration and authorisation (under REACH) it is (in most cases) not a legal requirement for companies to perform HBM for exposure assessment, therefore this part of the dossiers is often underdeveloped. Up to now, only in a few cases HBM was imposed as an obligation for authorisations under REACH.

In this context it also became clear that the **current studies**, funded mainly by national authorities, are **not equipped** (financially, organisational and/or technically) **to also serve the specific information needs for registration and authorisation**. An alternative **financial instrument** was proposed whereby companies can co-fund HBM. However, interference of the companies in the research and interpretation of results should be avoided.

"Identify policy opportunities and develop a strategic agenda for the next few years …"

Whereas the bulk of the discussion focused on the level of ambitions, it was also proposed to identify specific **policy opportunities** and develop a **strategic agenda** for the next few years, so that the results of HBM4EU can be taken up as much as possible for policy development. This can

actually contribute to the good examples that are needed to prove the added value of HBM. These opportunities should be identified at EU level (e.g. priorities for the next few years for ECHA and EFSA) as well as for national authorities, e.g. in the context of REACH (for screening, RMOA/PACT[9], restriction proposals, etc.) as well as for national policymaking.

On the other hand, it was mentioned that there is certainly an **urgency** to critically evaluate and rethink the current chemicals regulation process and that several good examples already exist. A plea to also take significant steps that go beyond the development of individual cases.

ii. Group 2: Communication and non-regulatory policy options

In the set-up of the discussion in group 2, the focus was on communication and on non-regulatory actions. During the session, it turned out that participants intensively produced and exchanged ideas and remaining questions on the *communication* aspect, while non-regulatory policy options were not discussed in detail. However, an overview of good practices with regard to the diversity of policy options was presented at the start of day 2, as one of the results from the preparatory interviews (see also report of the interviews).

Hereafter, we thematically ordered the topics that were discussed during the 1,5h break-out session.

Why is it important to communicate about HBM results?

During the discussion, several motivations for communicating on HBM results were formulated.

Since HBM data provide strong evidence on real-life human exposure to chemicals and potentially related health effects, it is very relevant and powerful data to be used in communication with policymakers and citizens (the broad public). HBM results can or should incite policymakers to take action, but HBM data also need to be communicated to the public to raise awareness. However, in order to do so, the data must be put into perspective and evaluated concerning a possible health risk. Citizens have the right to be informed on potential health risks, but avoiding unnecessary concern is equally important (see 3.2.5). As intensively discussed on day 1 (see previous section in this report) the use of HBM guidance values could be an important tool for interpretation and communication, but must also be contextualised in the right way. In this respect, it is important to create the broadest possible consensus on these guiding values as well as on the way these values will be used in communication (see also 3.2.4).

Further, participants indicate that communication about HBM, both on the results and on the monitoring network itself, is important for trust-building and creating transparency. It shows that there is monitoring in place that can detect potential health risks in a timely way. It is also considered to be a reliable and trustworthy source of information for the follow-up of policy (see 3.2.8).

In order to build trust, participants mention some important conditions that should be fulfilled: (1) financing of a public HBM network should be independent from the chemical industry[10] and (2) there should be a transparent interpretation of the HBM results, independently by experts, but also involving policymakers, the industry and NGOs to decide on the relevance of the results for policy making, for industry and for society (see 3.2.3).

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[9] Regulatory management option analysis/ Public Activities Communication Tool

[10] This point contrasts to some extent with an earlier statement on the polluter-pays principle, which says that industry should contribute to the necessary resources for HBM. There are valid arguments for both points. It may also be possible to find a way in between to accommodate both arguments. For example, in Germany and the US there is a partnership between government and industry on (certain aspects of) HBM. The German example was cited by some participants as a good example, while the situation in the US was subject to some criticism. But this point was not discussed in detail at this workshop.

Creating transparency to the broad public

As HBM4EU is publicly funded research, the results of HBM4EU must be communicated publicly, for example on the HBM4EU website, because this contributes to building trust, as well as justification for the use of public money. Nevertheless there is some discussion on the content of the communication. Some say that all data should be made public. A transparency approach strengthens the people's feeling that environment & health risks are well monitored (see also 3.2.1). While others prefer summaries that are well readable and well understandable for lay people. The EU citizens have the right to be informed in a way that everybody is able to understand. Data without context are difficult to interpret. Both opinions are supported by valid arguments. A well-balanced middle way should be possible.

Further, also technical documentation must be available for interested parties. Because communicating transparently about assumptions and methodological choices makes the researchers less vulnerable to criticism from outside (see also 3.2.4).

Communication after joint reflection

In order to build support for conclusions that will be communicated, it is important that efforts are undertaken to try to find agreement on the content of the communication. This implies a joint reflection by scientists, policymakers, industry and NGOs.

It is important that policymakers, stakeholders and scientists have an intensive dialogue on HBM, not only at the end (when the HBM data are available) but from the set-up of HBM onwards. Otherwise the societal acceptance and the policy uptake of the results could be problematic. Participants therefore encouraged the effort so far for consultation and dialogue within the project and the explicit intention to continue along this path.

Being open on methodological options and decide on them jointly

As mentioned earlier, the HBM4EU website should not only offer non-technical summaries (that are well readable for lay people) but should also contain technical details on the research design. Communicating about technical details allows communicating transparently about the assumptions and methodological choices, which makes the researchers less vulnerable from criticism from outside, as they have made their choices and assumptions explicit.

Ideally, a dialogue about methodological choices is organized in a very early stage of the HBM research, so that consensus can grow upon the choices that are made and no disputes arise afterwards, when the results are there. Important aspects in this regard are e.g. the strategy for health interpretation using HBM guidance values and the strategy for deriving HBM reference values (EU representative exposure data) as presented and intensively discussed at this workshop on day 1.

Participants stress that a project such as HBM4EU has to provide robust, scientifically validated methods and only qualified and accredited labs with established quality control are eligible to undertake measurements hereby ensuring that people can trust the analytical results.

Communicating to individual participants: with interpretation tools, an action perspective and an outlook on policy responses

Several participants consider that people that participate in HBM studies should have the right to be individually informed about their own results. Not only because of the right to know, but also because personal data can play an important role in prevention (better awareness and potentially early detection of an increased risk). This communication needs to be nuanced (contextualised) and offering participants tools to interpret the results and help them to take individual action to reduce their exposure. Also if results are e.g. below guidance values, people should have the

opportunity to choose for themselves whether and what actions they want to take. Several HBM studies, such as e.g. FLEHS in Flanders, have many years of experience with reporting back individual results to study participants. An important point for attention is a dedicated communication in which the researchers (preferably a study doctor) are available in an accessible way for interpretation of the (individual) results, e.g. during information evenings and/or the possibility of a personal consultation. Although this is not always easy to organise, certainly not for nationally representative studies.

In communicating to individuals, it is also important to give an outlook on what policymakers are doing with the HBM results on group level, to avoid the perception that individual behavioural change is proposed as the only solution. Furthermore it was suggested to include information on the uses and added value of the chemicals that are being monitored, in order to have a balanced communication and avoid 'chemophobia'. E.g. the use of certain phthalates in medical devices can also save lives.

Communication to the public under conditions of uncertainty

What to do in cases where there is still (a lot of) uncertainty? Should there be communication to the public on potential risks? Some participants are in favour of communicating in all potential cases, and attribute a role in this to scientists and NGOs, particularly when policymakers are not choosing for a precautionary approach. Even when there is no proven link between observed exposure and the adverse effects, or when accepted guidance values are not exceeded, there still can be concern (e.g. because of uncertainty related to cumulative exposure, lack of trust in the communicator, or just because of precaution out of a personal worldview).

However, a participant states that in the case of phthalates and bisphenols the knowledge on exposure and hazards is already available for some time and uncertainty should not be exaggerated. Several other participants agree, especially for the four phthalates included in the recent restriction proposal. In cases where there is sufficient evidence, we do not talk anymore about precaution but about prevention. In these cases regulation is needed to close the remaining gaps leading to continued exposure and other supporting policy instruments (such as communication) can help to fasten the phase out of hazardous chemicals.

Communicating via intermediary organisations

Intermediary organizations, such as associations of medical doctors, NGOs and schools, can help to communicate HBM results. Intermediary groups are professionals or other (profit or non-profit) third parties that offer (social) services to specific target groups, such as social and community services, medical-, poverty- and social work organisations, schools and trainers, local government agencies as well as consultants. After all, these actors have more expertise and tools in order to reach specific target groups and to stimulate action (if needed). In formulating the messages for communication, cooperation between experts and intermediary groups is needed, to guarantee that the content of the communication is both correct and adapted to the specific target group(s).

One point of attention that was stressed in particular, is social inclusion, from a justice perspective. For which the involvement of intermediary groups working with specific societal groups is required. Especially for socially vulnerable groups, who are often exposed to greater risks (through a combination of higher vulnerability, sometimes also higher exposure due to certain lifestyle factors or quality of their living environment, and last but not least also a lack of resources – financially, intellectually and socially – to change their situation).

Communication to policymakers

HBM can help to evaluate the effectiveness of existing legislations (follow-up; see also 5.2.1), but has also an important signalling function: to pinpoint gaps in policymaking regarding the (efficiency of) risk management of chemicals, and to signal exposure to new emerging chemicals. On the other hand, the point that HBM is often presented as an early warning instrument is also criticised, because exposure has already occurred at the time of measurement. Especially when it concerns substances on the SVHC list (such as some of the phthalates and bisphenols) this can never be the intention. In that respect, one participant states that HBM is actually an 'end-of-pipe' measurement technique. Nevertheless, even after the identification of human exposure preventive action can be undertaken in order to reduce potential health risks as well as future exposure.

Several participants stress that scientists should help ‘translate’ the HBM results for policymaking, facilitating the policy uptake of HBM conclusions. Ideally in a dialogical way (two-way communication). As already mentioned earlier, policymakers (as well as stakeholders) should be involved in developing HBM studies from the start, jointly building a consensus on the way to operate (from problem framing and formulating the research questions to research design, data generation, interpretation and communication).

Interpretation of data also includes an evaluation of (different types of) uncertainties to be taken into account. A participant states however (as was also mentioned previously in the context of communication to the public), that uncertainty should not be over-emphasized either. And even in case of uncertainty, policy makers can still decide to undertake precautionary action, for which various policy instruments are available (not necessarily an immediate ban).

Communication on chemicals by NGOs and industry

Also stakeholders (both industry and NGO’s) take up an important role in communication on chemicals. The industry and retailers are even obliged to do so, in certain respects (see e.g. the CLP regulation). But they also take additional voluntary initiatives to inform users and customers. On the other hand, some participants criticize misleading labels on products. In any case, it is important to take into account that communication on scientific research results does not take place in a vacuum, but in a context in which many actors try to influence the framing on the same topics.

Another field in which NGOs and industry take up an important role in communication is the promotion of alternative chemicals/substitutes. E.g. ChemSEC has initiated MarketPlace, an online platform where producers and users can find each other to develop and introduce alternatives to harmful chemicals. However, communicating about alternatives is delicate, as there is criticism that MarketPlace promotes alternatives that have not been tested yet. Some participants therefore argue that communication on alternatives should be done by a competent authority, following an independent in-depth evaluation by qualified experts. The example of the substitute database of ANSES is put forward.

D. Evaluation of the workshop

19 out of 32 participants filled in the evaluation form. The numeric results are shown in the table below.

Most participants were satisfied or very satisfied with the workshop. Especially the opportunity for input and discussion received a high score, for both day 1 and day 2. As well as the timing for both days, which may be related to the time that was provided for discussion. In relative terms, slightly lower satisfaction scores were attributed to 'the conclusions that were formulated at the end'. Although only 3 participants indicated they were unsatisfied about this part. Nevertheless, we have indeed experienced that it is sometimes a challenge to summarize lively discussions, especially when there is only limited time to prepare for formulating the conclusions. At one point, even the conclusions became the subject of debate. However, that should certainly not be seen as a problem.

Table 1: Results from satisfaction survey

Please indicate how satisfied you are with regard to the following points:	Very satisfied	Satisfied	Unsatisfied	Very unsatisfied
In general with the workshop	7	12		
The attendance and composition of the group	7	12	1	
The information that was provided previous to the workshop	8	9	1	
The quality of the presentations (on day 1)	5	13	1	
The opportunity for input and discussion (on day 1)	**10**	**8**	1	
The quality of the presentations (on day 2)	5	12	1	
The opportunity for input and discussion (on day 2)	**11**	**7**		
The conclusions that were formulated at the end	3	12	3	
The timing of day 1 (13:00 – 17:30)	**13**	**5**		
The timing of day 2 (09:00 – 13:00)	**11**	**6**		

An additional question also assessed the extent to which the results of the workshop are relevant for use in the respective organisations and networks of the participants. Several participants indicated that this is indeed the case.

What I have learned, I will use in my organization, networks…	Absolutely!	Yes	Perhaps	No
	6	3	3	

Written comments:

In addition, the evaluation form also provided opportunity for written comments.

One participant states that there was **too much striving for consensus**. Although this may of course be the case, it was clearly stated in the introduction of the workshop (by the moderator) that striving for consensus was indeed not the ambition of the workshop.

A few other participants also state that the **discussions and the conclusions were too general,** and **sometimes too much personal interpretation**.

> *"Good to look for common ground but be careful with generalizing too much: keep the '?' in reflecting different views."*
>
> *"I had hoped for more specific discussions on bisphenols and phthalates."*

From the point of view of the organisers, we experienced indeed that the discussions tended to focus more on HBM in general than on the topic of phthalates and bisphenols. This may be partly because the questions were often formulated in general terms. And also because of the double ambition of the workshop: a specific case was chosen to enable a more focused discussion, but at the same time it was also the intention to use the case as an illustration of the broader ongoing discussions. We also felt that the participants themselves tended to open up the discussion more broadly.

Although this general discussion certainly also has its added value, especially at this stage of the project, it is nevertheless useful to think about how we could stimulate a better focused discussion in future initiatives.

The answer to this question may lie partly in other suggestions from participants: One participant states that **it would have been good to have the presentations in advance**. Another participant states that it was **not clear in advance which questions were raised**, to be answered in the end. Furthermore, it was also suggested to **include presentations on good practices** in the program:

> *"I think that we would all benefit from presentations on how HBM is already being used in EU legislation and in national policies. If we want to see how HBM can be used in policy, we need to understand the reality, to be able to discuss further opportunities and improvement. We all have different backgrounds, so we don't know about all existing legislation."*

In addition, the fact that we were not yet able to present new HBM data may also be part of the explanation. In the future we will have that input available.

In order to be more specific about the conclusions that we draw from this workshop, we will (in a next step) start a dialogue within the consortium, on the basis of this factual report, to develop supported conclusions and action points for future initiative. As was also requested by one of the participants:

> *"I think it will be important to see which concrete actions can eventually be taken as an outcome from this workshop and the project as such."*

We would like to thank all the contributors and participants to the workshop!

To be continued…

E. Workshop Participants list

Policymakers		8/11	9/11
Georg Streck	EU Commission/DG GROW	X	
Ana Maria Blass Rico	EU Commission/DG GROW	X	
Jonathan Briggs	EU Commission/DG SANTE	X	
Wim De Coen	ECHA, European Chemicals Agency	X	X
Katharina Volk	EFSA, European Food Safety Authority	X	X
Sofie Nørager	EU Commission/DG RTD	Welcome	Goodbye
Laia Quiros-Pesudo	EU Commission/DG RTD	X	X
National perspectives			
Karen Van Campenhout	Flemish government (DOMG); co-chair HBM4EU governing board	X	X
Hans Reynders	Flemish government (DOMG); Belgian national hub coordinator	X	X
Susana Viegas	ESTeSL-IPL, Portugal; Portuguese national hub	X	X
Margareta Warholm	Swedish Chemicals Agency, Swedish national perspective	X	X
Industry (companies and associations)			
Perry Walters	CEFIC - European Plasticisers	X	X
Tatsiana (Tanya) Dudzina	CEFIC - Exxon Mobile Biomedical Science Inc.	X	X
Rainer Otter	European Plasticisers/BASF SE	X	X
Irantzu Garmendia	Plastics Europe	X	X
Judith Giernoth	Covestro Deutschland AG	X	X
Divina Gomez	FEICA, Association of the European Adhesive and Sealant Industry	X	X
Laura Portugal	DUCC, Downstream Users of Chemicals Co-ordination group	X	X
Marko Susnik	UEAPME, Austrian Federal Economic Chamber	Late arrival	X
Barbara Lehmann	UEAPME, Austrian Federal Economic Chamber	X	
NGOs			
Pelle Moos	BEUC, The European Consumer Organisation	X	
Tatiana Santos	EEB, The European Environmental Bureau	X	X
Ninja Reineke	CHEM Trust	X	X
Valérie Xhonneux	HEAL / IEW, Inter-Environnement Wallonie	X	
Dorota Napierska	Health Care Without Harm Europe	X	X
Margriet Mantingh	WECF, Women Engage for a Common Future	X	X
HBM4EU			
Greet Schoeters	VITO	X	X
Jos Bessems	VITO	X	X
Joana Lobo Vicente	EEA	X	X
Marike Kolossa-Gehring	UBA, German Environment Agency	X	X

Eva Ougier	ANSES	X	X
Pierre Lecoq	ANSES	X	X
Robert Barouki	INSERM	X	X
Elena Tarroja	INSERM	X	X
Ilse Loots	University of Antwerp	X	X
Dries Coertjens	University of Antwerp	X	X
Ann Crabbé	University of Antwerp	X	X

Apologized for this workshop, but interested in following-up:

Maria Uhl	EAA
Rosa Lange	UBA
Catherine Ganzleben	EEA
Erik Lebret	RIVM
Ovnair Sepai	PHE
Christophe Rouselle	ANSES
Anna-Maria Andersson	Rigshospitalet, Copenhagen
Panagiotis Daskaleros	EU commission/DG SANTE
Peter Korytar	EU commission/DG ENV
Maarten Roggeman	ECHA
Anna Federica Castoldi	EFSA
Erwin Annys	CEFIC
Anna Lennquist	ChemSEC
Génon Jenssen	HEAL, Health and Environment Alliance
Michela Mastrantonio	Plastics Europe
Michel Cassart	Plastics Europe
Sven Gestermann	Covestro
Silke Tenbrock	OLIN
Erik Gravenfors	Swedish Chemicals Agency
Siiri Latvala	Swedish Environmental Protection Agency
Sonja Kapelari	Austrian national perspective

F. Workshop program

The PowerPoint presentations are available online, by clicking on the titles below.

Date & time	Draft agenda	Room & presenter(s)
	DAY 1 - 08/11/2018	
13:00-13:30	Registration and coffee	Foyer of CDMA SDR2, floor -1
13:30-14:05	**Welcome by Greet Schoeters (VITO, leader of science-policy pillar)** **Introduction by Ilse Loots (UAntwerp, facilitator)** **Objective and outline of the workshop** **Tour of the table**	CDMA SDR2, floor -1
14:05-15:50	**Presentations + discussion:** Sufficient time was provided for **questions and discussion** in between the presentations.	CDMA SDR2, floor -1
14:05	1. **How can HBM4EU contribute to policymaking on phthalates and bisphenols**? Policy context, legislation in place and challenges ahead.	Joana Lobo Vicente (EEA)
14:25	2. **Currently available HBM-evidence** in Europe and **ongoing work in HBM4EU** on phthalates, in relation to identified policy questions.	Marike Kolossa (UBA, CGL phthalates)
14:45	3. **Currently available HBM-evidence** in Europe and **ongoing work in HBM4EU** on bisphenols, in relation to identified policy questions.	Robert Barouki (INSERM, CGL bisphenols)
15:15	4. **Strategies for health interpretation**: development of health-based guidance values for HBM, for individual phthalates, BPA and phthalate mixtures. In relation to other existing limit values.	Eva Ougier (ANSES)
15:50	Coffee break	
16:10	5. Strategy for deriving **EU-wide HBM reference values** for the phthalates and bisphenols (Substances? Age groups? Geographical distribution?) – collecting existing data and new aligned studies.	Greet Schoeters (VITO) Robert Barouki (INSERM, pillar 3 leader)
16:45	6. **Linking HBM data to sources and health effects**: exposure modelling, adverse outcome pathways (AOP's), effect biomarkers.	
17:30	Closure of day 1	Ilse Loots (UAntwerp)

DAY 2 - 09/11/'18		
09:00-09:30	Welcome back coffee	
09:30-09:45	**Welcome and today's program by Ilse Loots (UAntwerp)** **Summary of the conclusions so far by Ann Crabbé (UAntwerp)**	CDMA SDR2, floor -1
09:45-10:00	Presentation of **conclusions of interviews** with experts, policymakers and stakeholders + introduction of topics for break-out group discussions.	Dries Coertjens (UAntwerp)
10:00-11:30	Break-out group discussions (2 groups) **How can HBM(4EU) inform policymaking? (at EU- and national level?) And how to facilitate this? Which role for HBM4EU?** • Group 1: HBM to support regulatory policy • Group 2: Communication and non-regulatory (policy) options	CDMA SDR2, floor -1
11:30-12:00	**Coffee break**	
12:00-13:00	**Plenary discussion, conclusions and way forward:** - Presentation of conclusions break-out groups + discussion - General conclusions - Way forward - Joint evaluation of this initiative, in order to improve our efforts for science-policy interaction in the context of HBM4EU.	CDMA SDR2, floor -1
13:00-14:00	Lunch	

7 Case selection and Methodology

A. Case selection

For the selection of a case at EU-level, a **pragmatic process** was preferred.

The **first ideas for potential cases** emerged as a result of (1) bilateral skype meetings organised in Spring 2017 by UAntwerpen with the other partners involved in task 5.5 (EEA, DH, ANSES, RIVM, VITO), (2) a discussion in a side-meeting of the Berlin consortium meeting in September 2017 and (3) a final discussion between EEA and UAntwerpen (skype meeting 12/10/2017).

Finally, **five potential topics** were selected and briefly documented. In order of preference:

- Case option 1: Phthalates and bisphenols
- Case option 2: Mixtures
- Case option 3: PFAS
- Case option 4: Available data in IPCheM (e.g. DEMOCOPHES results)
- Case option 5: Discussion on policy needs and questions for one of the other priority substances (as documented via questionnaire)

For a case option to be selected, we kept **a couple of general considerations** in mind:

- We looked for a case in which HBM and results from HBM4EU in particular, have/can have an added value for the societal and policy debate.
- Organising a dialogue on the case between different perspectives (from science, policy and society) is expected to be valuable and does not contain (too much) the risk of duplication of previous or ongoing initiatives.
- Cases should not be too controversial, to avoid being caught in a deadlock at an early stage. Cases should also not be too complex scientifically to guarantee that non-experts can also master a dialogue, at least for the parts that are relevant to them.
- Cases should be relevant for and complementary to other work packages of HBM4EU, or one of the priority substances/topics. This would allow for opportunities to collaborated.

To underpin the final decision for the case topic and build support for that case, we **consulted the partners involved in WP5** (meeting in November ‘17 in Antwerp) **and the members of the EU Policy Board** (meeting of the EU Policy Board, 13th of December ’17 in Brussels).

Case option 1, on phthalates and bisphenols, was supported by both the WP5 partners and the members of the EU Policy Board.

PREFERRED TOPIC FOR THE EU-CASE: PHTHALATES AND BISPHENOLS

In this paragraph, we summarise the results of a first screening of the topic phthalates and bisphenols (used as input for the consultations of the WP5 partners and the EU Policy board) as well as the advice of the WP5 partners and the EU Policy board.

First screening of the case: phthalates and bisphenols

(used as input for the consultation of the WP5 partners and EU Policy Board)

Opportunities	In **task 5.2 human biomonitoring guidance values** (HBMGV) for phthalates and BPA are being developed (2017-2018) and in **task 9.5 new analysis** are planned for DINCH and bisphenols on DEMOCOPHES samples (values should be available by the end of 2019). HBM-data for BPA and phthalates are already available from DEMOCOPHES and from some national studies and we will use these values to guide us through this process. The consequent report produced may be a living document, due to be updated early 2020 with results from the DEMOCOPHES samples. The first results of these tasks and studies might be a good **opportunity to initiate an interactive dialogue** between experts, EU policy makers and stakeholders on phthalates and bisphenols. Phthalates and bisphenols are also included in the 1st list of **priority substances for HBM4EU.**
Challenges	Scientific complexity: **still significant (technical) debate on HBMGV's** (e.g. how to communicate remaining disagreements and uncertainties?) Societal complexity: involving **a range of stakeholders**, exposure **linked with personal behaviours and lifestyle**, and this topic being **part of polarised discussions** (e.g. on endocrine disruption). Policy context: **some phthalates and BPA are already regulated**, other phthalates and bisphenols are not.
Relevant (starting) questions?	Taking into account the expected results of task 5.2 (and potentially also task 9.5), two (potential) points of discussion are: i. Technically: can we **build a consensus on the proposed HBMGVs**? And how to interpret these HBMGVs in relation to HBM-data? ii. Policy implications: assuming a consensus on the previous question, what would be the **consequences for policy and society**? What if internal concentrations are beneath/above HBMGV's? What if considerable differences are observed among subpopulations (e.g. socio-economic)? For phthalates and bisphenols, **cumulative exposure** and **uncertainties** should be taken into account. Therefore, other relevant questions are: iii. How to deal with single-substance HBMGV in the context of cumulative exposure (e.g. mixtures, or the debate on endocrine disrupting chemicals)? Is it feasible and desirable to prioritise substances and/or effects? E.g. on the basis of health impact? Or do we need an integrated health-based approach?

	iv. How to accommodate “health-based science” and “substance-based/sectoral policy making”? v. How do policy makers and stakeholders perceive the risks of exposure and its acceptability? vi. Which (policy) options are thought to be needed, effective and legitimate? a. For already regulated substances: how can HBM support phasing out? b. For non-regulated substances: how can HBM support the precautionary approach, in the context of uncertainty? On the other hand, it is also important to make explicit what we would not like to discuss: e.g. **avoid polarised discussions** on EDC-criteria, or just repeating the often-heard arguments pro and con stricter regulation. **Better focus on the (potential) added value of HBM.**
Need for a stepwise process? (analytic-deliberative approach)	Before starting any consultations, a **background document** should be compiled summarizing in an accessible way the **state of the art evidence** on phthalates and bisphenols as well as the broader context (e.g. **current policy initiatives**). This should guarantee that all actors involved can start from the same knowledge base and that discussions are grounded on the best available evidence. **Bilateral consultations** of key actors (scientists, policy makers and stakeholders) might be a good next step to **map diverse perspectives** on the topic(s). That would allow to unravel arguments, knowledge claims, (value) judgements and perceptions as well as focussing both on the evidence base and policy context. As a final step, an **interactive dialogue** (workshop) can be organised to facilitate interaction between, and integration of, different perspectives (as documented in the previous phase). Although (any repetition of) polarised discussions should be avoided, it is important to start from an **open agenda** towards a key public and create opportunities for all perspectives to be heard.
Added value of a participative approach?	**A multi-actor dialogue can support task 5.2 on HBMGV development** (maximise support for the deriving strategy) as well as the broader use of these HBMGV within and outside HBM4EU (e.g. in risk assessments). The topics of phthalates and bisphenols are **cross-cutting (crossing different policy domains)**, with the opportunity to involve different policy makers and sectors.

Advice of WP5 partners (November ’17) and the EU Policy Board (December ’17):

The WP5 partners advised to:

- Focus on the substances and the added value of HBM. Avoid controversial discussions, e.g. endocrine disrupting chemicals (EDC) criteria.
- Debate on the HBMGVs and its use is welcomed, because it can help to improve the strategy and build support for the HBMGV’s within and outside of HBM4EU. An important question is: when should it be decided to act?

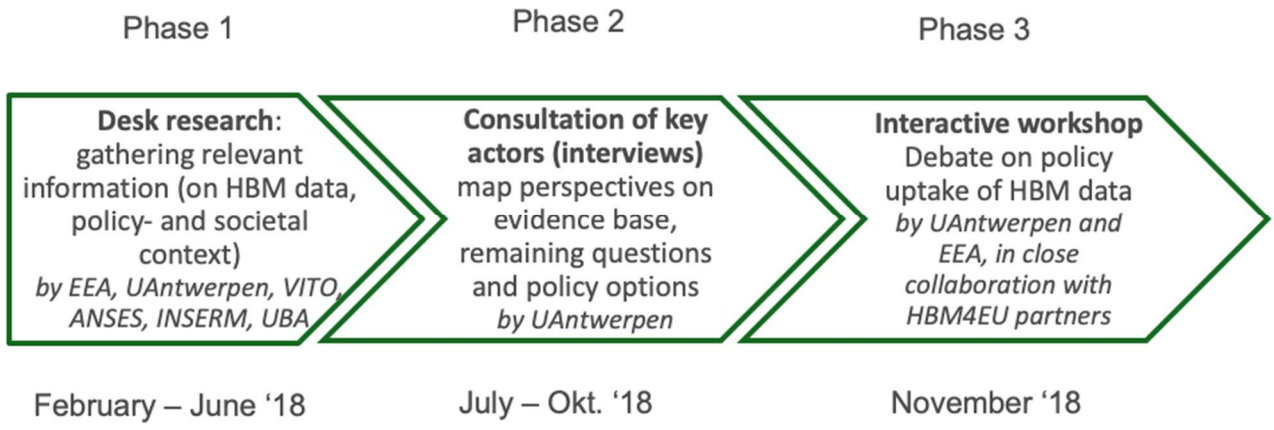
- Be aware that some phthalates and BPA are already regulated, while others are not. However, in both situations additional effort can be discussed.
- Related topics are PFAS and developmental toxicity. However, data for these topics is still scarce. This can be interesting in a comparative perspective (how to deal with data scarcity?)
- The topic of mixtures can be part of this case, because phthalates and bisphenols are often mixtures. On the other hand, there is already a lot ongoing for mixtures (e.g. in WP15).

The members of the EU Policy Board advised to:

- Take into account that different values and norms are used: e.g. for food safety, for occupational health, etc. in addition to HBMGV's. How do these values relate to each other? It is definitely relevant to discuss how these HBMGV's can/should be used in distinct policy or risk management contexts. It is also important to illustrate the complexity and uncertain context in which decisions need to be made.
- Also engage expert(s) in the field of occupational health in the dialogue.
- Phthalates and bisphenols (mainly BPA) have already been in the picture for many years (for regulation, but also for awareness raising, at least for BPA). One could say that the awareness is there, taking into account these past and ongoing processes.
- On the other hand, there are still many challenges left: e.g. regarding mixtures and substitution. This topic is a good case to also discuss these issues (in a targeted way). The policy debate on how to deal with mixtures and substitution is ongoing (e.g. in the policy context of the 'non-toxic environment'), and thus input from this case study might be useful.
- Others still stress the importance of a focus on single substances as well.
- It is definitely useful to also engage stakeholders, in addition to experts and policy makers. But important to have a balanced representation. It might also be useful to engage the competent authorities of (some of) the member states (for the EU these are important stakeholders as well).
- The EU Policy Board would welcome to be consulted on the next steps and more detailed work plan.

B. Development and implementation of the case on phthalates and bisphenols (EU-level) – work plan

*For this case we developed a **stepwise and iterative approach** (desk research -> bilateral consultation -> interactive workshop), in which each step builds on the previous one(s). This also enables to better distinguish evidence, knowledge claims/conclusions on the basis of evidence, different perspectives, underlying arguments and value judgements. Although we would like to make a distinction between these different elements, they are all important and relevant for decision-making.*



Phase 1: compiling a background document (desk research) and formulating current scientific conclusions (by a multi-disciplinary group of experts)

Before starting any consultations, a **background document** was compiled for our own internal work, summarizing the **state of the art HBM-evidence** on phthalates and bisphenols as well as the broader context (e.g. **policy initiatives and relevant stakes**). This helped us to overview the knowledge base and the available evidence.

The background document included:

- A scientific summary of:
  - The main characteristics of the substance groups
  - Available HBM data on phthalates and bisphenols (EU-wide and national data) – exposure levels, exposure-effect associations, determinants of exposure, …?
  - Available EU HBM HBGVs for phthalates (developed by HBM4EU)
  - Other relevant (first) results of HBM4EU and an overview of work in progress.
  - Current scientific conclusions and remaining complexity and uncertainties -> *to be formulated by multi-disciplinary group of experts?*
- Policy context: competent authorities and sectors, past and current initiatives (on EU-level as well as pioneer countries)
- Societal context: affected and interested groups/actors/stakeholders (stakeholder mapping), position papers, past or ongoing (participatory) processes/debates.

Phase 2: bilateral consultations of key actors (scientists, policy makers and stakeholders) to map perspectives on the HBM-evidence base and policy options

What?

The aim of the bilateral consultations of key actors was to unravel and document different perspectives on the topic(s): arguments, knowledge claims, (value) judgements and perceptions, focussing both on the evidence base and policy context.

- Experts were asked to judge the quality of the evidence base and comment on current conclusions and remaining uncertainties.
- Policy makers and stakeholders were asked to judge the policy relevance and societal relevance of the available evidence and comment on the current policy context.
- All actors were invited to suggest policy options.

These bilateral consultations complemented the information in the background document and provided input/inspiration for formulating questions for the third phase (interactive workshop). E.g. estimate where we are most likely to make progress.

How?

We identified (a limited number) of key actors that could cover the diversity of perspectives. Here you can find an overview of the names and affiliation of the respondents, in combination with the date of the interview and the interview modus (Skype/teleconference or in person).

The interviews took place between July 2018 and October 2018.

	Name respondents	Affiliation	Date	Modus of interview
	Policy makers			
1	Jonathan Briggs and Panagiotis Deskalors	EU Commission/DG SANTE	27 August 2018	In person
2	Maarten Roggeman	ECHA, European Chemicals Agency	4 September 2018	Skype
3	Georg Streck	EU Commission/DG GROW	5 September 2018	Skype
4	Ana Maria Blass Rico	EU Commission/DG GROW	7 September 2018	Skype
5	Katharina Volk and Anna Federica Castoldi	EFSA, European Food Safety Authority	5 October 2018	Skype
	Industry (companies & associations)			
6	Erwin Annys	CEFIC	27 August 2018	In person
7	Michel Cassart1, Sven Gestermann2, Silke Tenbrock3, Anna Papagrigoraki1, Judith Giernoth4	Plastics Europe BPA team: 1 Plastics Europe, 2 Covestro, 3 OLIN, 4 Covestro Deutschland AG	20 September 2018	Teleconference Unified meeting

8	Perry Walters1, Michela Mastrantonio2, Rainer Otter3	1CEFIC - European Plasticisers, 2 Plastics Europe, 3 European Plasticisers/BASF SE	11 October 2018	Teleconference Unified meeting
	NGOs			
9	Ninja Reineke	CHEM Trust	13 August 2018	Skype
10	Anna Lennquist	ChemSEC	4 October 2018	Skype
11	Génon Jenssen	HEAL, Health and Environment Alliance	12 October 2018	Skype
	HBM4EU			
12	Christophe Rousselle and Eva Ougier	ANSES	14 August 2018	Skype
13	Robert Barouki and Elena Tarroja	INSERM	24 August 2018	Skype
14	Rosa Lange	UBA	24 August 2018	Adobe Connect
15	Jos Bessems and Greet Schoeters	VITO	7 September 2018	Skype

Transcriptions of the interviews were made. Based on these transcriptions and notes, analyses were made, serving as an input for Phase 3.

Phase 3: organisation of a workshop with experts, policy makers and stakeholders

What?

As a final step, an **interactive dialogue** (workshop) was organised to facilitate interaction between and integration of different perspectives (as documented in the previous phase) and find common ground for future collaboration.
The aims of the workshop were to:

- Present **ongoing work of HBM4EU** and its contribution to knowledge development on environment and health, in particular on phthalates and bisphenols. (Including the development of health-based guidance values for phthalates and BPA, the strategy for generating EU-wide HBM reference values, and work on exposure modelling and adverse outcome pathways).
- Present a **meta-analysis of interviews** conducted in the summer of 2018 with key respondents in the field, bringing an overview of: (a) current opinions and perceptions on (science & policy on) phthalates and bisphenols, (b) ideas on how to evolve further, paying attention to potential roles of governments, NGOs, industry and scientists.
- Have a **constructive dialogue** between scientific experts, policy makers and stakeholders **on the content of these presentations, how to communicate externally about the (expected) output** of HBM4EU and **how it can inform and support policy making** at EU- and national level (on the basis of good practices). In relationship to the latter, we will explicitly not only look at regulatory options, but also other types of measures (awareness raising, information on prevention, labelling, etc.).
- Discuss how we should deal with the **output of the workshop** itself. One option is to write a position paper or memorandum of understanding with the conclusions of the workshop, but other options may be proposed for the valorisation and communication of the workshop's results. Furthermore, we are also interested in **evaluating this initiative** in order to improve our efforts for science-policy interaction in the context of HBM4EU.

Our ambition for this first workshop was to gather minimally 20 à 25 participants around the table, from the side of policy making (EU- and national level), science and societal stakeholders (industry/NGOs).