

Prioritised chemicals: first actions planned by HBM4EU

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Overarching objectives of HBM4EU

- To harmonise procedures for HBM across the countries involved in the project
- To provide policy makers and the general public with comparable data on human internal exposure to chemicals
- To link data on internal exposure to chemicals to aggregate external exposure and identifying exposure pathways and upstream sources
- To generate scientific evidence on the causal links between exposure to chemicals and negative health outcomes
- To provide policy-makers and the general public with science-based knowledge on the health risks associated with chemicals exposure;
- To improve chemical risk assessment in the EU through the effective use of HBM data

Overarching objectives of HBM4EU

In short, the data and tools developed in the project will help have a better understanding of :

- the human exposure-response relationships focused on the selected priority substances
- the impact of environmental exposures on human health by translating HBM data into health risks

What has been done so far

Steering committee established in 2015 to guide the preparation of the project in close collaboration with EU Policy Board

Need to establish a list of chemicals prior to the start of the programme in order to have an immediate start of activities from day1 in 2017

Prioritisation exercise : Ad hoc phased methodology based on national and international experiences

Initial horizon scanning to identify 1st year substances with input from 22 countries

To identify in each country a priority list of 10 substances of most interest

- that are of concern to human health
- where there is evidence of human/ environmental exposure at EU Level
- of high relevance for policy use with open policy questions

What has been done so far

Specific questions :

Which is the health relevance ?

- Exposure evidence / potential health impact evidence/ public concern

What is the level of knowledge ?

- Experiences in country / methodology available /data to share available

Which are the specific research questions to be answered ?

- Exposure sources/ health outcomes/ causal link between exposure and human health

Which is the expected use for policies ?

Which actions are expected from HBM4EU project ?

What has been done so far

Partners :

Austria, Belgium, Cyprus, Czech republic, Croatia, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom, EEA

List of priority substances resulting from the consultation which reach consensus :

- **Phthalates and DINCH**
- **Bisphenols**
- **Per/poly-fluorinated compounds (PFASs)**
- **Flame retardants**
- **Cadmium and Chromium VI**
- **Polycyclic aromatic hydrocarbons (PAHs) concerning air pollution**
- **Anilines (anilines and MOCA)**
- **Chemical mixtures**
- **Emerging chemicals**

What has been done so far

A stepwise approach needed for developing the workplan for each chemical/ groups of chemicals

Appointment of chemical substance group leaders (CGL) by the steering committee with the following tasks:

To compile information on each substance /groupings of chemicals and build a workplan for the first year

Second round of questions for each grouping of chemicals request to countries on what data already exist at country level :

- Which substances were measured
- In which matrices
- In which study population (age, gender, representative or not, vulnerable groups, occupational setting, high exposure groups, etc.)
- With which methods (sampling/ analytical methods)
- And when exactly

What has been done so far

Following consultation with the EU Policy Board, for each substance group a compilation of information was made :

- Substance classification
- Policy-related research questions
- Identification of main activities to be carried out starting in 2017

e.g. Phtahlates and DINCH

Collection, comparison and evaluation of existing data and integration **into IPChem** (Y1 and Y3)

Establish european toxicologically derived guidance values (reference and HBM values) at European scale (Y1 and Y2)

What has been done so far

Main policy questions to be answered in 5 years: Phthalates/DINCH

- What is the current exposure of the EU population to phthalates and DINCH?
- Different exposure between countries? Why?
- Can we detect a significant decrease in levels in the population from 2007 to present in phthalates regulated under REACH?
- What are the high exposure groups?
- Are exposure levels above any health-relevant assessment levels?
- Should phthalates on the REACH candidate list 1 be subject to restriction on the basis of exposure of the EU population to levels of concern for health?

What we shall be doing in the near future

To aim at building a Database of comparable HBM data :

- Collecting and collating existing HBM data for the prioritised substance groups
- Making data available, as appropriate via IPCChem
- Determining which current policy questions can be answered using existing data

What we shall be doing in the near future

More specifically in 2017 :

- **HBM4EU website** to serve as an access point for results, including a link to IPCheM, as well as linking with other relevant projects.
- **Criteria for the prioritization process of the biomarkers and matrices** for the target substances.
- Template to provide a consistent approach to the submission of requests for action by HBM4EU under the **rapid response mechanism**
- **Data management plan** describing how existing and newly generated data are processed, managed, and quality controlled at the national level, harmonized, transferred and analysed at the European level and made available for different user communities.
- **List of the selected biomarkers, matrices and analytical methods** for substances included in the first round of prioritization.
- **List of criteria for selecting cohort studies**, that will have to be used to select data and samples needed for determining exposure-response associations for all priority substances.

What we shall be doing in the near future

- **Report on existing information and identifying gaps** about the substances prioritised in the preparatory (general population and occupational exposure)
- **Database of candidate laboratories** to perform the analysis of samples, to develop new methods and to support the QA/QC Program considering the substances included in the first round of prioritization
- **The first risk assessment** will make use of already existing HBM data and will develop draft protocols for use in specific policy domains eg. food safety, chemical safety, occupational safety
- **The statistical analysis plan** describes the statistical analyses that will be performed to test the hypotheses that are formulated as part of the study protocol for each of prioritized substances
- **Derivation of health based guidance value for first round priority substances** based on existing data

What we shall be doing: round 2017-2018

The prioritisation strategy to be built in the next round 2017-2018 :

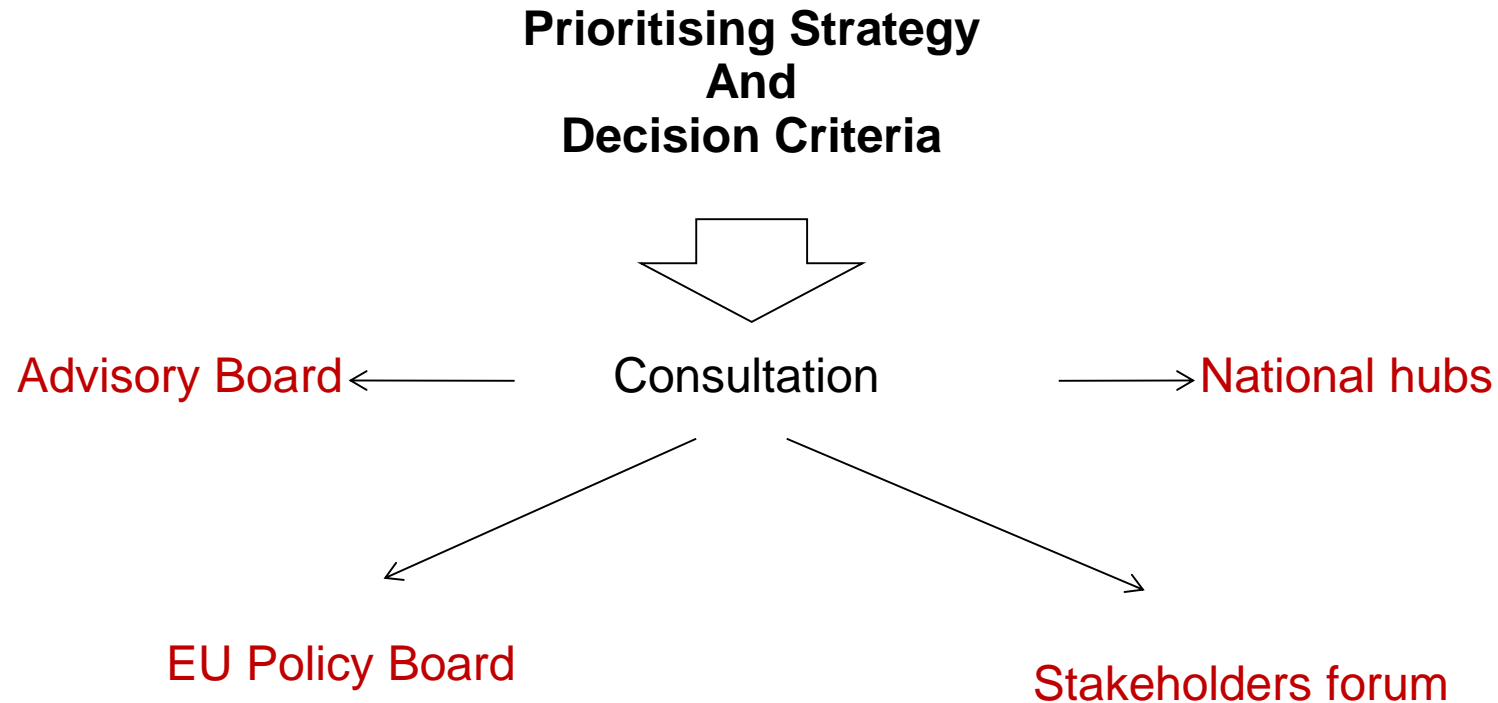
- To build on the experience of the prioritisation strategy developed in the preparation phase of the project
- To refine the approach developed in the preparatory phase taking on board existing protocols in different countries (e.g. Germany, France, Belgium, US and Canada, etc.) including the occupational perspective
- To make the process fully transparent and open to stakeholders

What we shall be doing: round 2017-2018

Decision criteria (WP 4) will be developed with a clear focus on :

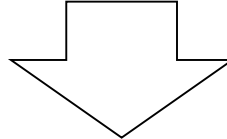
- Hazardous properties
- Exposure characteristics taking into account environmental, consumer and occupational exposure
- Biomarkers characteristics (current /past exposure; intra and / or inter-individual variability, etc.)
- Relationship between the biomarker level and external exposure, toxicokinetics, etc.
- Regulatory demands
- Societal concerns and perception
- Technical and financial feasibility

Prioritising strategy and criteria: round 2017-2018

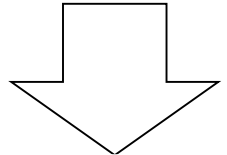


Prioritising strategy and criteria: round 2017-2018

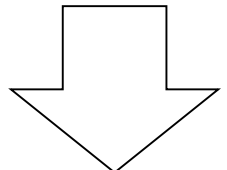
Revised Prioritising Strategy
And
Decision Criteria
Report



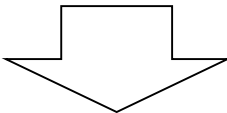
Management Board



Amended Report on Prioritising Strategy
and Decision criteria



Governing Board



Final PS and DC

Thank you for your attention