



Survey requesting the nomination of substances for research under HBM4EU

Introduction

Aim of this survey

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

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

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

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

Practical details

Each National Hub and each member of the Stakeholder Forum or EU Policy Board can submit a maximum of five nominations. You can only submit one nomination at a time.

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

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

To ensure that your input is saved, please only navigate using the survey buttons at the bottom of the page, not using the browser navigation buttons at the top left hand of your screen. Where questions are not relevant to your nomination or where you cannot answer them, please leave them blank.

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

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

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

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

What can you nominate?

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

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

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

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

What information are we asking for?

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

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

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

How will we use your input?

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

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

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

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

Thank you very much!

Step 1: Your contact details

We ask you to identify yourself and your institution.

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

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

1. Applicant Name
2. Which institution do you represent?
3. Please enter your email address
4. Please indicate whether you are a:
 - National Hub Contact Point
 - Member of the EU Policy Board
 - Member of the Stakeholder Forum
5. If you are a National Hub, please identify your country

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

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

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

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

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

1. Please select your preference from the list below
 - A single chemical substance
 - A group of substances
 - Chemical mixtures
 - Emerging substances

Single substance

Here you can nominate a single substance.

1. To ensure that we can correctly identify the substance, please provide the relevant CAS number and/or the EC number. For a description of these numbering systems, please place your cursor over the relevant “?”
 - Scientific name
 - CAS number
 - EC number
 - Other name(s)

Group of substances

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

1. Please provide a name for the group of substances
2. Please identify the rationale for the grouping.
 - Common analytical methods can be used to analyse multiple substances in one matrix.
 - The substances have similar uses, with the possibility of substitution within the group.
 - The substances have a similar toxicological profile.
 - If you have another rationale for grouping the substances, please briefly describe it below.
3. If possible, please identify a “lead substance” in this group that captures the principle characteristics of the group. This will allow us to broadly judge the risks associated with the substance group.
4. In the box below, we ask you to upload a file (word, excel or CSV) listing the substances belonging to the group. Please include the CAS numbers for all substances.

Chemical mixtures

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

Continue working on chemical mixtures

Emerging substances

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

Continue working on emerging substances

Step 3: What new knowledge do you need?

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

1. We also ask you to describe the kind of activities that could produce knowledge.
2. Please tick all the boxes that describe the research activities that would answer your questions
 - New data on a specific population groups or subgroups
 - Development of new research activities
 - New approaches to the analysis of existing data
3. Please propose any other relevant research activities below.

Step 4: Hazardous properties

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

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

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

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

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

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

Current knowledge gaps regarding hazardous properties

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

Hazard classifications

2. If the substance is a carcinogen, please identify the IARC classification.
3. If the substance is a carcinogen, please enter the CLP classification.
4. If the substance is a mutagen, please enter the CLP classification.

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

Other classifications

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

Persistence and bioaccumulation potential

15. Is the substance Persistent, Bioaccumulative and Toxic (PBT)?
16. Is the substance very Persistent and very Bioaccumulative?
17. Is the substance very Persistent?
18. Additional information and references
19. Please add any other information that you consider relevant.

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

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

Step 5: Exposure characteristics

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

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

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

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

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

Current knowledge gaps regarding exposure

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

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

Exposure media

3. Please identify the media through which human exposure takes place.
 - Multisource exposure
 - Air
 - Water
 - Food
 - Soil
 - Consumer products
4. If exposure occurs through consumer products, please specify product types in the box below.
5. Please identify any other media through which exposure may take place.

Exposure sources, production volumes and environmental releases

6. Please identify sources of exposure in the box below.
7. If available, please provide the production volume according to the ECHA database.
8. Has the substances been recognised as an environmental contaminant? If yes, please provide references to any relevant sources of monitoring data.

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

Human exposure

10. Please tick all relevant human exposure routes
- Dermal
 - Inhalation
 - Oral
 - Trans placental
11. Please estimate the prevalence of population exposure.
- There is widespread exposure of the general population
 - There is widespread exposure of workers
 - Certain sub-populations are exposed
 - Exposure takes place at hot spots
 - The prevalence of exposure is unknown
12. Other comments on the prevalence of exposure.
13. Please tick all groups that may be highly exposed to the substance or groups of substances
- Infants and children
 - Adults
 - Pregnant women
 - Elderly people
 - Men
 - Women
 - Individuals of lower socio-economic status
 - Workers (professional and/or industrial)
14. Please identify any other highly exposure groups.

Vulnerable groups

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

Additional information and references

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

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

Step 6: Regulatory status

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

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

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

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

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

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

1. Is the substance covered by Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
2. Please identify all other EU policies that apply to the substance or substance group in the box below. This can include policies in the domain of occupational health and safety, food safety, environment and consumer safety.
3. Please identify any regulations that you know of that apply to the substance or substance group at national level, either in Europe or beyond.

Current policy questions

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

Regulatory guidance values

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

Additional information and references

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

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

Step 7: Public concern

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

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

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

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

Step 8: Technical feasibility

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

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

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

Additional information

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