HBM4EU science and policy for a healthy future

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Prioritisation strategy and criteria

Deliverable Report

D 4.3

WP 4 - Prioritisation and input to the Annual Work Plan

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The scope of the present deliverable was modified on a common request sent to UBA in July 2018 by EEA, on behalf of Anses and VITO, to cover Tasks 4.1.and 4.2. The task 4.4, part of the workflow for prioritisation, is described in the Deliverable 4.2.

This deliverable was indeed originally intended to cover Task 4.2 only as per AWP2017. However, it became soon obvious to WP4 task leaders (EEA, Anses and VITO) that the prioritisation process was a continuum starting with the mapping of needs to the finalisation of the scoping documents.

The Coordinator (UBA) agreed to this proposal in July 2017.

1 Introduction to the prioritisation of chemicals under HBM4EU

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

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

At the same time, it is important to openly acknowledge that the nominations of the different parties invited to participate in the strategy for the prioritisation of substances do not have the same weight in the process.

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

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

At the same time, selected substances will be the subject of research at European level. It is therefore important that HBM4EU addresses knowledge gaps on chemical exposure and resulting health impacts that have relevance at European level and generates results that benefit European society. We therefore give priority to substances that have been nominated by a significant proportion of the partner countries, in order to ensure that we address questions of relevant at European level. Substances that are exclusively of local or national concern will not be prioritised.

We also request input from members of the **Stakeholder Forum**. This valuable input will allow us to assess the social relevance of research activities on the substances that are nominated. At the same time, it is important to acknowledge that the nominations submitted by members of the Stakeholder have a lower weight in the prioritisation strategy.

As such the strategy for the prioritisation of substances is not based entirely on scientific evidence. It is also guided by an imperative to produce knowledge in support of policy making at European level.

2 First prioritisation round

Our first exercise to prioritise substances for action was performed in 2015, taking into account both national and EU level policy needs for knowledge on chemical exposure and health outcomes.

As a first step, substances for which knowledge is needed to support current EU policy making were identified through close dialogue with an EU Policy Board. Input from the national level was fed in through a Steering Committee, composed of national representatives and established to guide the preparation of this proposal.

An initial set of criteria was then produced, including such aspects as whether a substance is of concern to human health, whether there is evidence of human and/or environmental exposure at EU level and whether there are open policy questions. The financial and technical feasibility of monitoring the substances was also a criterion.

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

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

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

The consortium then compiled information on substance classification, policy-related research questions and research objectives. This formed the basis for the development of activities for inclusion in the 2017 HBM4EU work plan.

HBM4EU partners have built on the experience gained with the first prioritisation exercise to make the process of prioritising substances for future analysis under HBM4EU more accountable, transparent and legitimate. We are now in a position to propose a refined prioritisation strategy that is more systematic, transparent and open to stakeholders.

3 Future prioritisation rounds

Two additional rounds of prioritisation will be conducted during the five years of the project.

The **2nd round of prioritisation in 2017 and 2018** will generate the 2nd list of HBM4EU priority substances, for inclusion in the 2019 and 2020 work plans.

In implementing the strategy, we expect to gather lessons learnt. We will then have a second opportunity to refine the strategy for the **3rd round of prioritisation in 2019 and 2020**. This final round will generate the 3rd list of HBM4EU priority substances, for inclusion in the 2021 work plan

and with the aim of feeding into a new European Human Biomonitoring initiative after the close of this current project.

The timeframe for the prioritisation rounds is presented in figure 1 below.

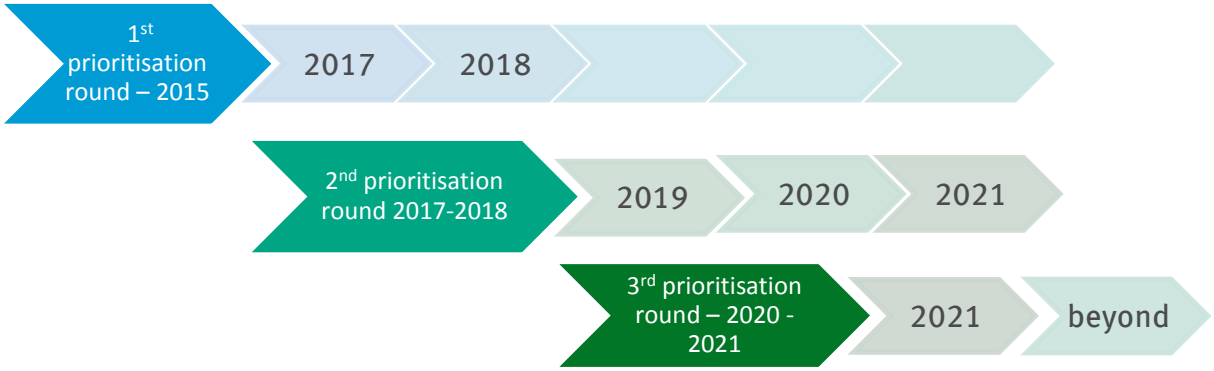

Figure 1: Prioritisation rounds under HBM4EU

4 Transparency

The prioritisation process will be comprehensively documented, with all documents made available on the HBM4EU website. We will produce a report summarising the prioritisation strategy and providing an overview on how the steps were implemented and the rationale behind decision making on final nomination of the substances or groups of substances to be included on the HBM4EU work plans.

In addition, documentation used during the strategy will be made publicly available on the HBM4EU website. This will include the full list of substances nominated (see section 8) and information on which actors nominated which substances. Materials submitted to support nominations of substances will also be made available on the HBM4EU website.

5 Overview of the proposed strategy for the prioritisation of substances

The strategy involves three tasks, including:

1. Mapping the knowledge needs of policy makers, stakeholders and scientists: nomination of substances and first ranking;
2. The prioritisation of substances against criteria; and
3. The production of scoping documents on possible HBM4EU activities on prioritised substances.

The outputs resulting from the sequential implementation of the three tasks will ultimately feed into the development of the annual work plans for HBM4EU.

Figure 2 below shows how the tasks under work package 4 feed into one another.

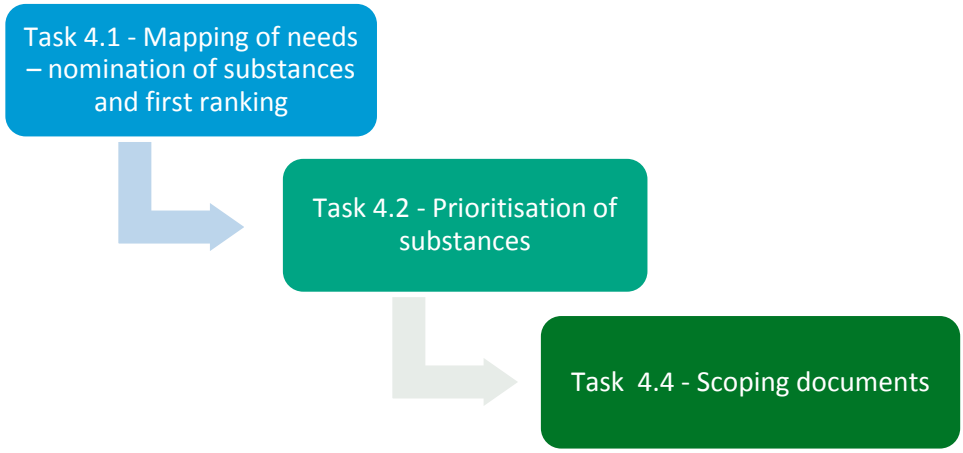

Figure 2: Strategy for the prioritisation of substances

These tasks can be broken down into a number of key steps, summarised in figure 3 on the next page. In the sections below, each of these tasks and the steps involved are described in greater detail.

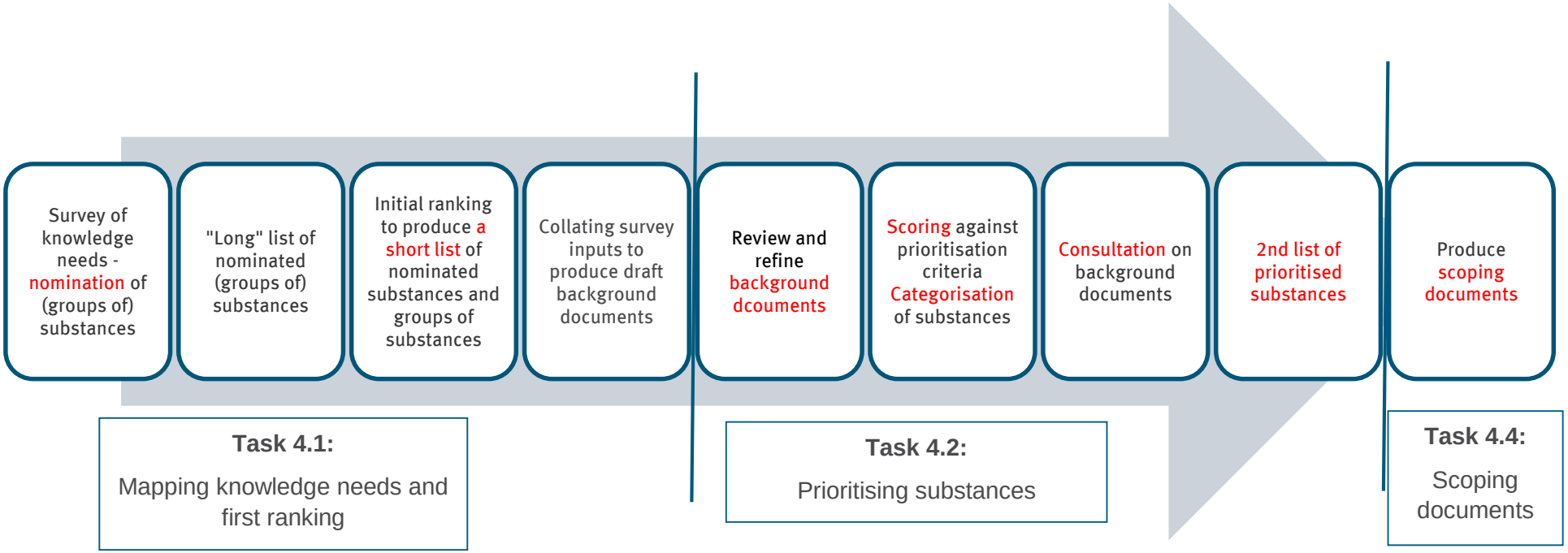

Figure 3: Key steps under each task in the proposed strategy

The timeframe corresponding to each task is available in the next paragraph.

6 Implementing the strategy of prioritisation of substances

The strategy will be implemented in the second half of 2017 and in early 2018, with the timeframe for implementation shown in table 1 below.

We will produce a **2nd list of HBM4EU priority substances by April 2018**.

The HBM4EU partners will then identify the key policy questions for the prioritised substances and translate these questions into activities for the 2019 HBM4EU Work Plan.

The list will then be sent to the Governing Board for their consideration and approval in September 2018.

Table 1: Timeframe for the implementation of tasks and steps

Tasks	Step	Actors	Timeframe
Task 4.1 **Mapping knowledge needs and first ranking**	1 - Collating the nominations of substances / groups of substances performed by the National Hubs, the members of the EU policy Board and the members of the Stakeholder Forum via an online survey, to produce: a) a "long" list of nominated substances b) a complementary list of groups of substances	EEA IRAS EAA AGES NHC	**October 2017**
	2 - Initial ranking to produce a short list of approx. 30 nominated substances and groups of substances (see section 7.4)	EEA	**Early October 2017**
	3 - Production of draft background documents for single substances and groups of substances on the short list	EEA	**End of October 2017**
	4 – Stakeholder Workshop on the prioritisation of substances under HBM4EU	EAA AGES EEA	**24 November 2017**
Task 4.2 **Prioritising substances**	1 – Planning meeting to discuss the short list of substances and substance groups and to plan work and allocate roles	Experts from: ANSES UBA VITO	**November 2017**
	2 - Reviewing and revising the draft background documents to improve their quality and accuracy.	ANSES UBA VITO IRAS	**November 2017 to January 2018**

	3 - Workshop on the prioritisation of substances and groups of substances on the basis of the draft background documents. a) For single substances: - Allocation of a category (A to D) on the basis of the availability of data and expert judgement (see section 9.1) - Quantitative and qualitative scoring against prioritisation criteria (see section 9.2) b) For groups of substances: - Qualitative scoring against prioritisation criteria (see section 9.2)	ANSES UBA VITO	**Early February 2018**
	4- Consultation period a) Consulting key actors (National Hubs, Stakeholder Forum) on the background documents including scoring and ranking of substances within each category.	ANSES NHC EAA AGES	**Mid-February to early-March 2018**
	b) Joint meeting of the EU Policy Board and the Management Board to discuss the background documents and scoring for the short list of substances and substance groups. The outcome of the meeting will be a draft 2nd list of HBM4EU priority substances. The Management Board will also identify Chemical Group Leaders for the 2nd list of substances.	ANSES UBA VITO EEA, MB EU Policy Board	**Mid-March 2018**
	5 – Revision of background documents and agreement on a final list c) Revising the background documents, as well as the assigned scores and categories, according to feedback from the National Hubs and Stakeholder Forum and discussions with the EU Policy Board and Management Board. d) Producing a final list and seeking confirmation from the EU Policy Board and the Management Board. Seeking agreement from the Management Board on the Chemical Group Leaders for the proposed substances and substance groups.	ANSES UBA VITO	**Mid-March to end of March 2018**
	6 - Producing a 2nd list of priority substances (Deliverable 4.5) and identifying Chemical Group Leaders (CGLs)	ANSES	**7 April 2018**

Task 4.4 **Scoping documents**	7 - Development of scoping documents setting out research objectives for the 2nd list of priority substances	VITO CGLs UBA	**7 June 2018**

7 Task 4.1 - Mapping knowledge needs and first ranking

7.1 Who will be consulted?

In mapping knowledge needs, we will consult with a number of key actors, including:

- the members of the **EU Policy Board**;
- the **HBM4EU National Hubs**; and
- the members of the **Stakeholder Forum**.

The EU Policy Board includes:

- the Directorate-General for Health and Food Safety
- the Directorate-General for Environment
- the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
- the Joint Research Centre (JRC)
- the Directorate-General for Employment, Social Affairs and Inclusion
- the Directorate-General for Research and Innovation
- the European Environment Agency (EEA)
- the European Food Safety Authority (EFSA)
- the European Chemicals Agency (ECHA)

The Stakeholder Forum is the formal channel for stakeholder input to the HBM4EU project and was established in May 2017. The eleven members of the Stakeholder Forum were selected by the HBM4EU Management Board and the EU Policy Board and include the following:

- Chem Trust
- Downstream Users of Chemical Co-ordination Group (DUCC)
- Eurometaux
- European Association of Craft, Small and Medium-Sized Enterprises (UAPME)
- European Chemical Industry Council (CEFIC)
- European Consumer Organisation (BEUC)
- European Environment Bureau (EEB)
- European Patients Forum (EPF)
- European Trade Union Confederation (ETUC)
- Health and Environment Alliance (HEAL)
- Women in Europe for a Common Future (WECF)

7.2 What information will they be asked to provide?

We will run an online questionnaire survey asking participants to identify current knowledge gaps and nominate substances and/or groups of substances for future research under HBM4EU.

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.

Survey participants will be asked to broadly describe the new knowledge that they would like the HBM4EU project to produce and to explain how this knowledge will support their work. We will ask survey participants to describe their questions and briefly explain how they might use the new knowledge in their work to generate benefits for society. This input will help us to understand the knowledge gaps that HBM4EU should address.

Survey participants will be able to:

- Nominate single substances (see section 7.2.1);
- Nominate groups of substances (see section 7.2.2);
- Request further work on mixtures; and/or
- Request further work on emerging substances.

We also ask survey participants to describe the kinds of research activities that would generate the knowledge that they need. This may include:

- New data on a specific population groups or subgroups;
- Development of new research activities;
- New approaches to the analysis of existing data; and/or
- Other activities proposed by the survey participants.

The survey explicitly requests information on each nominated substance against the five proposed groups of prioritisation criteria (see Annex 1), namely:

1. Hazard properties;
2. Exposure characteristics;
3. Regulatory status;
4. Public concern; and
5. Technical feasibility.

It is crucial to our methodology that survey participants provide some evidence against these criteria in order to justify their nomination and to enable the HBM4EU partners to assess the nominated substances. HBM4EU does not have the resources to gather extensive evidence for all nominated substances, rather we depend on survey participants to submit knowledge with their nominations.

We do expect survey participants to be able to justify their nominations of substances for research at European level under HBM4EU, and to be able to provide some evidence to support this justification. Implementation of research activities will entail a significant mobilisation of resources across the 26 HBM4EU partner countries and we therefore aim to address critical knowledge gaps that will inform policy making at European level.

At the same time, we recognise that completing the survey demands time and resources from participants and we are very grateful for this valuable input. There is no threshold of information required to support a nomination, meaning that nominations will not be rejected on the basis of lack of information.

In addition, it is likely that several participants will nominate the same substances or groups of substances. We will collate the information submitted by all survey participants to produce a dossier on each nomination. These materials, or references to materials subject to copyright, will be made available on the HBM4EU website.

We recognise that this will lead to some duplication of effort. For the next round of prioritisation, we will consider implementing a two tiered approach, whereby a first round of nominations does not require the submission of information and information is then requested for a short list of substances. However, for this first round we face considerable time constraints and do not have the flexibility to implement a two tiered approach.

The quality of materials submitted will be assessed on the basis of expert judgement during the prioritisation process. We do not anticipate establishing formal rules for the admission of information to the prioritisation strategy. The final result of this prioritisation strategy will be research activities, not regulatory decisions.

7.2.1 Nomination of single substances

The nomination of **single substances** will facilitate the implementation of a systematic and transparent prioritisation process; since individual substances can then be scored against common criteria (see Annex 1 and 2). The single substances identified under the survey will then be collated to produce a **"long" list of substances nominated by survey participants**.

For the purpose of illustration, Annex 3 provides examples of information supplied against the criteria for two substances: Cadmium (CAS number: 7440-43-9) and Perfluorooctanoic acid (CAS number: 335-67-1).

7.2.2 Nomination of groups of substances

When nominating groups of substances, we will ask the survey participant to explain their rationale for the grouping. These may include:

- 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.

Alternatively, the survey participants may provide another rationale for grouping the substance.

Where possible, we also ask the survey participants to identify a lead substance in the group that captures the principle characteristics of the group. This will allow us to broadly judge the risks associated with the substance group.

This will produce a complimentary list of groups of substances. We expect that some substances will be nominated both as single substances and within groups. Where relevant, we will collate information and determine whether to proceed with single substances, or to consider a group of substances. In taking these decisions, we will look at the rationales provided for grouping by the different parties that nominated groups of substances.

7.3 How many substances can each party nominate?

The members of the EU Policy Board, the 26 National Hub Contact Points and the members of the Stakeholder Forum have all been asked to complete the survey, from **July to September 2017**.

Each National Hub and each member of the Stakeholder Forum and member of the EU Policy Board will be able to propose **5 substances**, leading to a maximum of 230 substances (see table 1 below). In practice, we anticipate that the actual number will be lower as substances will be nominated by more than one party.

Table 1: Possible number of nominations by the different actors involved

Bodies	Survey participant	Maximum number of substances
National Hubs	26 National Hub Contact Points	130
Stakeholder Forum	11 members	55
EU Policy Board	9 members	45
Maximum total		230

All nominations will then be collated to produce a **"long" list of nominated substances /groups of substances**.

7.4 First ranking of the nominated substances / groups of substances to produce a short list

We will then rank the long list of nominated substances to produce a **short list of approximately 30 substances and/or groups of substances**. The ranking step is critical to reducing the large number of nominations down to a short list of substances and substance groups that will then be subject to a more rigorous prioritisation, entailing significant time and resources.

Substances will be selected for the short list on the basis of having been nominated by at least:

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

**It is difficult to anticipate how many times substances will be nominated by different parties, so there may be a need to alter the proportion of National Hubs required to bring the long list down to a manageable short list. If there is more convergence in the nominations, then the proportion of National Hubs may be increased, with greater divergence then the proportion may be reduced.*

As mentioned in the introduction, the nominations for different parties do not have the same weight.

Nominations submitted by the EU Policy Board have the most weight. This responds to the project objective of delivering results that serve the EU policy making agenda. It also reflects the reality that 70% of the funding for the project comes from the European Commission.

When considering the nominations for the National Hubs, we will select those substances for which a concern has been identified by a third of the participating countries. The rationale for this is to ensure that the project focuses on substances that are of concern at EU level. It is not an objective of the project to focus on substances that are of concern at local or national level, since questions regarding these substances can best be addressed at those levels. The nominations from the National Hubs therefore has less weight than those from the members of the EU Policy Board.

Nominations from stakeholders have the lowest weight in the ranking exercise. When selecting between two or more substances that have been nominated by the EU Policy Board and that meet the threshold for the number of National Hubs, preference will be given to those substances and groups of substances that have **also been nominated by a stakeholder**.

7.5 Producing draft background documents on the substances/groups of substances included in the short list

EEA will collate the information provided by survey participants when nominating substances and substance groups into **draft background documents** for each single substance and group of substances on the short list. The documents will identify which actors nominated the substance or group and will systematically organise the information against the prioritisation criteria. They will also flag cases where a single substance has also been nominated in a substance group.

7.6 Stakeholder workshop on the prioritisation of substances under HBM4EU

In November 2017, EAA and AGES will organise a stakeholder workshop on the prioritisation process. The workshop will include a broader range of stakeholders than just the members of the Stakeholder Forum.

This will provide space for an open discussion with stakeholders on the substances nominated for inclusion in the 2nd list of priority substances. EEA will provide a presentation on the substances included on the short list, explaining how the short list was produced. EAA and AGES will facilitate a discussion on the substances on the short list, in order to better understand the rationale behind the priorities of stakeholders.

EAA and AGES will produce a report of the workshop, capturing the key positions and outcomes. This will then feed into the revision of the draft background documents, in particular providing evidence against the criterion on social concern.

The report will be included in the overall report on the stakeholder consultation and the mapping of needs, to be produced by EEA in 2018.

8 Task 4.2 - Prioritisation

Under task 4.2, a prioritisation process will be performed on the **short list of about 30 substances and substance groups** identified under task 4.1. The output from this process will be the 2nd list of HBM4EU priority substances.

This will involve the following key steps:

1. November 2017: A planning meeting to review the short list of substances and substance groups, to plan the work to review and update the draft background documents, and to allocate responsibilities amongst partners.
2. November 2017 to end of January 2018: Reviewing and revising the draft background documents to improve their quality and comprehensiveness.
3. Early February 2018: Workshop on prioritisation, at which experts from UBA, VITO and ANSES will score the substances and substance groups on the short list against the prioritisation criteria using the Delphi method. Single substances will also be categorised into category A to D, based on the availability of HBM data (see section 9.3.1).
4. Mid-February to early-March 2018: Consultation on the background documents.
    a. Written consultation with the National Hubs and the Stakeholder Forum, from mid-February to early March.
    b. Joint meeting of the EU Policy Board and the Management Board in mid-March to discuss the background documents, the scores and the categorisation of substances and substance groups on the short list. The aim of the meeting will be

to agree on a draft 2nd list of HBM4EU priority substances. The Management Board will also be ask to identify Chemical Grop Leaders on the basis of selection criteria.

5. Mid-March to end of March 2018: Revision of background documents and agreement on a final list
    a. Anses, UBA and VITO will revise the background documents according to the feedback received from the stakeholders and from the EU Policy Board and the Management Board;
    b. Anses will produce a final list and seek confirmation from the EU Policy Board and the Management Board by email.
6. 7 April 2018: Proposal for a final 2nd list of HBM4EU priority substances (Deliverable D4.5), to be sent to the HBM4EU Governing Board in September 2018 for approval.

8.1 Planning workshop

ANSES will organise a planning meeting with UBA, VITO and EEA in early November 2017 to review the short list of substances and substance groups, to plan the work to review and update the draft background documents, and to distribute the work amongst partners.

EEA will provide an overview of the nominated substances and explain the short list of substances. The draft background documents produced under task 4.1 will form the work documents for the workshop. Additional work may be needed to improve the documents if the quality of the information in the draft documents is inadequate or if gaps are identified. The work to review and update the draft background documents will be distributed amongst ANSES, UBA and VITO, on the basis of expertise with the substances and substance groups.

In addition, partners will also consider cases where substances have been nominated as single substances as well as in groups, and take decisions on how to proceed with these substances. The rationale for grouping and the number of nominations for single substances versus groups are expected to be factors in deciding how to move forward.

8.2 Updating the background documents

The **background documents** for **single substances and substance groups** on the short list will collate all the evidence submitted under the survey of knowledge needs (task 4.1) against the criteria. In reviewing the documents, Anses, VITO and UBA will assess whether the documents are of sufficient quality to allow for a robust scoring against the prioritisation criteria and will identify any gaps in the information provided. Where necessary, some additional research may be required to improve the documents.

By the end of January 2017, the background documents for the substances and substance groups on the short list will have been reviewed and revised.

8.3 Workshop to score and categorise substances and substance groups

ANSES will organise a workshop in early February 2018 on prioritisation, at which experts from UBA, VITO and ANSES will score the substances and substance groups on the short list against the prioritisation criteria using the Delphi method Single substances will also be categorised into category A to D, mainly based on the availability of HBM data.

8.3.1 Categorisation of substances

The categorisation of substances will be done mainly based on the availability of human biomonitoring data for each substance. The aim is to identify knowledge gaps that might be addressed through human biomonitoring activities under HBM4EU. Activities related to the categories B to E substances which are integrated in the HBM4EU work plans should serve to increase the level of knowledge on these substances and move them into a higher category, ideally into the Category A.

The allocation of substances from the short list to the categories A to D will be based on an expert judgement using the information in the background documents. Category E substances should directly be addressed under WP16 dedicated to the emerging substances.

The categories A to E are described here below:

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

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

- **Category C** substances are substances for which HBM data scarcely or doesn't exists. Efforts to develop an analytical method to obtain relevant HBM results need to be done Hazardous properties of the substances are identified, yet greater knowledge on toxicological characteristics and effects on the human health is needed. Interpretation of HBM data is not possible, due to the lack of HBM guidance values.

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

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

The proposed category for each single substance will be documented in the background document. Substance groups are expected to include a range of substances, distributed across categories.

8.3.2 Scoring the substances and substance groups

Participants at the workshop will attribute a score for each substance and substance group on the short list against each of the five prioritisation criteria. The criteria are:

1. hazardous properties;
2. exposure, including environmental, consumer and occupational exposure pathways;
3. regulatory demand;
4. societal concern; and
5. technical feasibility (see Annex 2).

Single substances and substance groups will be scored by means of an adapted Delphi method involving the participation of experts from the task 4.2 partners (ANSES, UBA and VITO) in a dedicated workshop organized by ANSES in February 2017. Experts from task 9.1 (working on the best suited biomarkers, matrices and needs for new analytical methods), WP15 (mixtures) and WP16 (emerging substances) may also be invited. Knowledge gaps will be considered while scoring. This will be particularly relevant for category D substances that may have been placed on the market as substitutes for regulated chemicals of known concern.

The adapted Delphi method aims to reach a consensus between experts on proposed scores for each substance and substance group on the short list. The attributed scores will provide a ranking of the substances and groups of substances on the short list.

At the workshop, participants will also produce a list of possible partners who might take on the role of Chemical Group Leader for the top ranking substances. The interest of these partners in delivering on the role will then be explored in advance of the management Board meeting in March 2018.

8.4 Consultation on the background documents including the proposed scoring

The revised background documents including the scores will be sent to the National Hubs and the Stakeholder Forum for **consultation from mid-February to early-March 2018**. These actors will be asked to provide feedback on the documents and to comment on the scoring.

A joint meeting of the EU Policy Board and the HBM4EU Management Board will be held in mid-March to discuss the scores for the short list of substances and substance groups, and the proposed ranking. The background documents will be sent to the Management Board and EU Policy Board in advance of the meeting.

The meeting will allow for an informed exchange on the substances and groups that emerge as priorities. Responses to the consultation on the background documents and scores will be taken into account. The aim of the meeting will be to achieve consensus on a draft 2nd list of HBM4EU priority substances.

For each selected priority substance, the Management Board will be asked to consider which partners might act as **Chemical Group Leader** (CGL). Criteria guiding this decision include that the partner:

- Is part of a National Hub that nominated the substance of substance group for prioritisation under HBM4EU;
- Has proven experience in undertaking HBM work or research on the substance or group of substances; and
- Is willing to undertake the role of a CGL.

In cases where it is decided to continue work on a substance on the 1st list of priority substances, the Management Board will then be asked to decide whether the existing CGL should continue in their role.

8.5 Revision of the background documents and agreement on a 2nd list of HBM4EU priority substances

The background documents will then be revised by ANSES, VITO and UBA in the **second half of March 2018**, based on feedback from the consultation. On the basis of the revised scores, ANSES will produce the 2nd list of HBM4EU priority substances.

ANSES will then send the final 2nd list of HBM4EU priority substances to the Management Board and the EU Policy Board for a final approval. The Management Board will also be asked to approve the proposed CGL.

8.6 Proposal for a 2nd list of priority substances

The 2nd list of priority substances will be submitted to the European Commission as deliverable D4.5 under the HBM4EU project in early **April 2018**. The 2nd list of HBM4EU priority substances and proposed CGLs will then be submitted to the HBM4EU Governing Board for approval in **September 2018**.

9 Task 4.4 - Producing scoping documents

Once the 2nd list of HBM4EU priority substances and proposed CGLs is available, VITO will lead the production of scoping documents for each substance or group of substances together with CGLs and UBA. These scoping documents will identify the research priorities, with a focus on addressing key policy questions.

The scoping documents finalised by early June 2018 will then be translated into the 2019 HBM4EU Work Plan.

Annex 1 - Survey for nominating substances (Task 4.1)

The survey on nominating the substances launched in task 4.1 'Mapping of needs', as presented here below, is based on questions towards the five families of criteria and individual criteria, which were identified from the task 4.2 work on the prioritization methodology (detailed in Annex 2). Some of the initially suggested criteria were not included as such in the survey, in order not to overload the applicants with questions. Nevertheless, a number of free-text boxes allow the applicant to specify all relevant information in his possession that could be used against the prioritization criteria.

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 substances 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.

Annex 2 - Proposed prioritisation criteria

The identification of prioritisation criteria in the task 4.2 has been developed on the basis of the following:

1. Review of the scientific literature (SCOPUS and Pubmed databases) on existing methods and strategies aiming at the prioritisation of chemical substances in the biomonitoring field (see details in section 1 below). From this bibliography, biomonitoring studies focusing on the prioritisation criteria were extracted. These studies relate mainly to the following countries: France (ESTEBAN), Belgium (Flanders, FLEHS), Germany (GerES), Canada (CHMS) and the United-States (CDC-NHANES, California, Michigan, Minnesota). A summary of identified HBM programmes and their chemical prioritization process is available in Section 2 below.
2. Identification of prioritisation criteria in HBM programs of interest;
3. Selection of criteria that capture scientific evidence, regulatory demands, societal concerns and technical aspects;
4. Grouping of selected criteria into 5 “families”: ‘Hazards’, ‘Exposure’, ‘Regulatory’, ‘Public concern’ and ‘Technical’;
5. Specifying indicators for each criterion (if any), aiming to facilitate the scoring and ranking (see section 3 below for proposed groups of criteria, individual criteria and indicators).

Section 1 - Literature search (Pub Med and Scopus)

A selection of papers and other bibliographic documents resulted from a literature search (Pub Med and Scopus). The key words used are summarized in the following Table:

Data-bases	Key words
PubMed	-biomonitoring[Title/Abstract]) AND choice of substances[Title/Abstract] -((human biomonitoring[Title/Abstract]) AND choice of pollutants[Title/Abstract]) AND whole world[Title/Abstract] -(biomonitoring[Title/Abstract]) AND selection of pollutants[Title/Abstract] -(human biomonitoring[Title/Abstract]) AND How to select pollutants to evaluate[Title/Abstract -(human biomonitoring[Title/Abstract]) AND screening of pollutants[Title/Abstract] -(protocol selection pollutants[Title/Abstract]) AND human biomonitoring[Title/Abstract] -(protocol biomonitoring human[Title/Abstract]) AND USA[Title/Abstract] -((biomonitoring) AND whole world) -(implementation[Title/Abstract]) AND human biomonitoring[Title/Abstract] -(Prioritization of substances[Title/Abstract]) AND human biomonitoring[Title/Abstract]
Scopus	-(TITLE-ABS-KEY (biomonitoring) AND TITLE-ABS-KEY (choice of substance)) -((human biomonitoring[Title/Abstract]) AND choice of pollutants[Title/Abstract]) AND whole world[Title/Abstract] -(TITLE-ABS-KEY (human monitoring) AND TITLE-ABS-KEY (whole word)) -(TITLE-ABS-KEY (biomonitoring) AND TITLE-ABS-KEY (selection of pollutants))

	-(TITLE-ABS-KEY (biomonitoring) AND TITLE-ABS-KEY (concept of programme)) -(TITLE-ABS-KEY (biomonitoring) AND TITLE-ABS-KEY (screening of pollutants)) -(TITLE-ABS-KEY (protocol selection pollutants) AND TITLE-ABS-KEY (human biomonitoring)) -(TITLE-ABS-KEY (protocol biomonitoring human) AND TITLE-ABS-KEY (usa)) -(TITLE-ABS-KEY (biomonitoring) AND TITLE-ABS-KEY (whole world)) -(TITLE-ABS-KEY (implementation) AND TITLE-ABS-KEY (human biomonitoring)) -TITLE-ABS-KEY (prioritization of substances) AND TITLE-ABS-KEY (human biomonitoring)) -TITLE-ABS-KEY (concept of biomonitoring)

The selection criteria for articles were based on the content of the abstracts and the year of publication (the most recent were preferred). The references of articles and reports are quoted in the Table below:

References	Title	Country
Douglas A. Haines and al, 2016	An overview of human biomonitoring of environmental chemicals in the Canadian health Measures Survey: 2007-2019	Canada
Health Canada, 2010	Second Report on Human Biomonitoring of Environmental Chemicals in Canada: Results of the Canadian Health Measures Survey Cycle 1 (2007-2009)	
Health Canada, 2014	Overview of the Third Report on Human Biomonitoring of Environmental Chemicals in Canada. 1-8. Retrieved from http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/chms-ecms-cycle3/overview-vue	
Samuel P. Caudill and al, 2016	Confidence Interval Estimation for Pooled-Sample Biomonitoring from a Complex Survey Design	U.S.
Federal Register, 2002 a	Final Selection Criteria and Solicitation of Nominations for Chemicals or Categories of Environmental Chemicals for Analytic Development and Inclusion in Future Releases of the National Report on Human Exposure to Environmental Chemicals. (194).	
Federal Register, 2002 b	Proposed Criteria for Selecting New Environmental Chemicals or Categories of Chemicals for Analytic Development and for Inclusion in Future Releases of the National Report on Human Exposure to Environmental Chemicals. (54).	
Federal Register, 2003	Candidate Chemicals for Possible Inclusion in Future Releases of the National Report on Human Exposure to Environmental Chemicals. (189).	
Hermann Fromme and al, 2015	Persistent and emerging pollutants in the blood of German adults: occurrence of dechloranes, polychlorinated naphtalenes and siloxanes	Germany

L. Casteleyn and al, 2014	A pilot study on the feasibility of European harmonized human biomonitoring: strategies towards a common approach, challenges and opportunities.	Europe
Greet Schoeters and al, 2012	Concept of the Flemish human biomonitoring programme	Belgium
Nadine Frery and al, 2012	Highlights of recent studies and future plans for the French human biomonitoring (HBM) programme	France
C. Fillol and al, 2014	Prioritization of the biomarkers to be analyzed in the French biomonitoring program [*Biomonitoring* (Vol. 1, pp. 95-104)]	
Beatriz Perez-Gomez and al, 2012	BIOAMBIENT.ES study protocol: rationale and design of a cross-sectional human biomonitoring survey in spain	Spanish
Lucija Perharic and al, 2012	Development of national human biomonitoring programme in Slovenia	Slovenia
Reinhard Joas and al, 2011	Harmonised human biomonitoring in Europe: activities toward an EU HBM framework	Europe
Tamar Berman and al, 2011	Human biomonitoring in Israel: past, present, future	Israel
Roel Smolders and al, 2009	Applicability of non-invasively collected matrices for human biomonitoring	Belgium
PJ Boogaard and al, 2008	Biomonitoring as a tool in the human health risk characterization of dermal exposure	Netherlands
Mina Ha and al, 2014	Korean Environmental Health Survey in Children and Adolescents (KorEHS-C): Survey design and pilot study results on selected exposure biomarkers	Korean
Toshihiro Kawamoto and al, 2014	Rationale and study design of the Japan environmental and children's study (JECS)	Japan
California Department of Public Health, 2013	Report to the California Legislature	California
R-R. Room, 2008	Minnesota Department of Health Environmental Health Tracking and Biomonitoring Advisory Panel Meeting	Minnesota

The publication of 'Samuel P. Caudill, 2016, Confidence Interval Estimation for Pooled-Sample Biomonitoring from a Complex Survey Design', was excluded following a thorough reading because the biomonitoring approach was very statistical (not adapted to our case).

Section 2 - Overview of identified HBM programs and their chemical prioritisation process

HBM program	General description of the process
France	A comprehensive prioritization method was used to select the biomarkers to be monitored in the French national biomonitoring program (Elfe cohort - longitudinal study from childhood and Esteban cross sectional survey of the metropolitan population aged 6-74 years). The Delphi consensus method was used to prioritize biomarkers. The process relied on members of government agencies to validate an initial list of pollutants; on French speaking experts to establish the selection criteria; on French speaking and international HBM experts to rate the chemicals using a graded score; on French speaking experts to review, validate and establish a provisional final list; and on an "emerging risk" group of the National Environmental Health Plan (PSNE) to review, revise and recommend the final list.
Belgium (Flanders) FLEHS	A mathematical chemical selection process was carried out by using Delphi method. Prioritization of chemicals was based on international lists and expert advice by weighted scoring. A step-by-step procedure was implemented to first categorize criteria and later select and score the chemicals. Therefore scientific experts and the strategic advisory board for the minister of Environment, Health and Energy and the Socio-economic board (representatives of employers and employees) were asked to make recommendations.
Germany GerES	A prioritization concept was performed on bases of existing international lists and further information on hazardous chemicals and degree of exposure of the general public and expert judgments (government authorities, industry and science). The selection of chemicals is focused in a cooperation project between the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) and the German chemical industry association (VCI) to select new substances and develop new analytic methods since 2010.
Canada CHMS	A prioritization approach based on expert advice (workshop of experts), stakeholder consultations via questionnaire, and Health Canada regulatory program needs mandated by the Chemicals Management Plan was carried out. The process was adapted and evolved for each of the first three cycles of the CHMS.
U.S. CDC-NHANES	A participatory approach, led by the CDC, has been used in the United States via notices in the Federal Register to establish criteria for inclusion or removal of chemicals, and for the nomination of chemicals to measure in the biomonitoring program as part of the NHANES. An expert panel of outside reviewers and CDC scientists scored nominated individual chemicals or categories of chemicals using weighted criteria to categorize the chemicals into five priority groups.
Michigan	A prioritization approach based on expert and stakeholder interviews and meetings, and scoring against weighted selection criteria was followed to identify and select chemicals to biomonitor in Michigan residents.
California	The process for selecting chemicals to include in the California Environmental Contaminant Biomonitoring Program (CECBP) is specified in the Senate Bill 1379 Perata Biomonitoring.

	A Scientific Guidance Panel has been established under this legislation and has two major responsibilities: - Assembling a list of "Designated Chemicals" and recommending chemicals for addition to the Designated Chemicals list in addition to those identified in the law. - Recommending "Priority Chemicals" for inclusion in the CECBP. Priority Chemicals are selected from among the Designated Chemicals for biomonitoring in California. The program retains the final decision making authority regarding the inclusion of chemicals recommended by the Scientific Guidance Panel.
Minnesota	Through the advice of the Environmental Health Tracking and Biomonitoring (EHTB) advisory panel and in accordance with the EHTB statute (which directs Minnesota Department of Health to make recommendations for an ongoing biomonitoring program. Whether or not biomonitoring is conducted in the future is dependent on issue of feasibility, including whether the biomonitoring program receives additional funding. The (EHTB) program sought input from both the public and targeted state agencies.

HBM program	Detailed prioritization steps
France	(1) In 2009-2010 members of the Department of Health and Environment in the French Institute for Public Health Surveillance (InVS), various ministries (health, ecology and work) and other public health agencies validated a first set of pollutants (more than 100) on the basis of biomonitoring feasibility, relevance and existing regulations in air or water. The list was extended to pollutants that were of major interest for members of the working group (toxicity, prioritiy in terms of health, routes of exposure.) → 51 groups of biomarker (2) Evolving relevant criteria to prioritize 51 groups of biomarkers using Delphi consensus method - criteria definition: 11 French-speaking experts (3 toxicologists, 1 expert in occupational medicine, 3 epidemiologists, 1 expert in pollutant exposure, 1 expert from the chemical industry and 2 environmental NGOs) established a list of selection criteria for the Elfe and Esteban studies - 11 experts were asked to evaluate the eight criteria regarding their relevance 0-10 (via e-mail questionnaire) (3) 11 French-speaking experts and 10 international biomonitoring experts rated the 51 groups of biomarkers according to each of the criteria (0.8 if the whole group of biomarkers fitted the criterion, 0.6 if the answer was somewhat true, 0.4 if the answer was somewhat untrue and 0.2 if none of the biomarkers fitted the criterion) →provisory list (4) Meeting of the 11 French-speaking experts to discuss the ranking of each biomarker →new prioritized list of biomarkers in May 2011 (5) Prioritized list was slightly modified through "emerging risk" group of National Environmental Health Plan (PSNE) and finally presented by email to the members of the National Biomonitoring Program's Scientific council → final list
Belgium (Flanders) FLEHS	(1) Chemical selection based on available lists potential substances of interest were selected by screening available lists such as: - FLEHSII (Belgium) - WHO milk campaign - ENNS (France) - GerES (Germany) (2) Identification of criteria using Delphi method Experts of the centre for environment and health and of the E&H Flemish administrations working in environment and health followed a two stage approach: Stage 1: ranking of the evaluation criteria to give them a weighting factor

	Stage 2: scoring each pollutant for each criterium. For each substance 11 selected criteria were weighted through priority (1-5, meaning extremely high to very low priority), and for the criteria "costs" and "invasiveness" there were only three scores (1-high; 3-moderate and 5-low). The scored chemicals were then summed in two priority lists. (3) Expert advice The priority lists were sent via email for external advice to external scientific experts and to the strategic advisory board for the minister of Environment, Health and Energy and the Socio-economic board (representatives of employers and employees).This resulted in the final list. (4) Final approval The final list was ratified by the FLEHS steering committee.
Germany GerES	(1) Since 2010 a cooperation between BMUB and VCI is funded to establish new human biomonitoring methods and biomarkers for emerging substances (according to SVHC, REACH, NGO-Lists and expert advice ("list and pot approach")) (2) Based on the information of the "list and pot approach" 2010 the Federal Institute for Risk Assessment (BfR) extracted a list of 120 substances with either a potential health relevance or to which the general population might potentially be exposed to a considerable extent. As the aim of the BMUB/VCI Cooperation (Initiative) is to develop new HBM-methods (for about 50 substances in ten years), this list of 120 substances covered mainly substances for which no HBM-methods exist or the biomarker chosen is to be discussed → basic list (3) Twice a year a conference of 20 experts (government authorities, industry and science) discuss about the substances of the basic list or other new substances which enter into the focus of the scientists or general public. Each year a list of about 10 priority substances is built, about five substances are selected by an advisory board for which new HBM methods are developed. (4) Especially for GerES the BfR was asked in 2014 to prioritize (on the background of the basic list and expert advice) substances for this cross-sectional study on children (5) This GerES V list was then added by the substances which were already measured in GerEs IV. Afterwards the HBM-commission (25 experts) gave their advice for selection of chemicals for GerES V
Canada CHMS	CHMS Cycle 1 (2007-2009) (1) In 2003, Health Canada identified 220 initial candidate chemicals based on the NHANES National Report on Human Exposure to Environmental Chemicals. (2) An expert workshop was held in November 2003. Participants were asked to identify their greatest priority for biomonitoring. Through a voting process, this list was narrowed down to the top 10 chemicals or chemical groupings (e.g. PCBs as a group). (3) In 2006, the Government of Canada launched the Chemicals Management Plan (CMP) which provided additional funding for biomonitoring (4) The 2003 Expert Workshop Report was revisited to select additional chemicals identified at that workshop. In addition, further consultations were held within Health Canada to identify additional priority chemicals of relevance under the regulatory objectives of the CMP. (5) A final list of 91 chemicals or metabolites were selected and included in CHMS Cycle 1. CHMS Cycle 2 (2009-2011) 1) In Spring 2008, Health Canada initiated a consultation process to solicit nominations and select chemicals to include in the CHMS Cycle 2. 2) A questionnaire was the primary mechanism of consultation. The target audience was the CMP Stakeholder Advisory Council (academia, health and environment NGOs), the Canadian Environmental Protection Act (CEPA) Industry Coordinating Group, the CEPA National Advisory Committee, the Federal/Provincial/Territorial Committee on Health and Environment, and Health Canada regulatory programs. The notice was also posted on the Government of Canada's Chemicals Substances website for public access and nomination. 3) An initial list of 310 nominated chemicals were received. 4) 93 chemicals were selected using the selection criteria from cycle 1 and additional criteria listed below (45% of CHMS Cycle 1 chemicals were repeated and 55% new chemicals were measured in Cycle 2). CHMS Cycle 3 (2012-2013)

	(1) The selection of chemicals for Cycle 3 was very soon after the Cycle 2 selection was finalized and no new consultation process was undertaken. A new indoor environment component was added to the CHMS Cycle 3, namely an indoor air and a tap water component. The Cycle 2 nomination list was used and additional criteria listed below were applied. (2) 95 chemicals or metabolites were selected for Cycle 3.
U.S. CDC-NHANES	(1) CDC established proposed criteria for selecting new environmental chemicals or categories of chemicals for analytical method development and for selecting additional environmental chemicals or categories of chemicals to appear in future releases of the National Report on Human Exposure to Environmental Chemicals. (2) CDC posted a notice in the Federal Register (March 20, 2002) requesting public comments on its proposed criteria. (3) CDC posted in the Federal Register (October 7, 2002) the final selection criteria and weighting factors and solicited nominations for chemicals or categories of environmental chemicals for analytic development and inclusion in future releases of the National Report on Human Exposure to Environmental Chemicals. (4) CDC published the nominated chemicals solicited from the October 7, 2002 Federal Register notice on the CDC website. Using the selection criteria and the weighting factors described in the October 7, 2002 Federal Register notice, an expert panel of outside reviewers and scientists at CDC's National Center for Environmental Health, Division of Laboratory Sciences, scored nominated individual chemicals or categories of chemicals. On the basis of their final point score, chemicals were placed in one of five priority groups. Chemicals in Group 1 are more likely, but not guaranteed, to appear in future releases of the Report than are chemicals in the remaining groups.
Michigan	(1) Identification of local and national organizations that would have an interest on health and environment issues, and identification of individuals from these organizations to contact. Concurrently, a questionnaire was constructed to be administered via interview to these individuals soliciting their opinion as to which chemicals in the Michigan environment posed the greatest potential danger to health. (2) Interviews of the individuals identified above beginning with employees of the State of Michigan were carried out. These early interviews led to a modified questionnaire. Individuals from organizations outside of state government were then interviewed. (3) Through these interviews, a preliminary list of chemicals of concern for Michigan residents was created. (4) Stakeholders were selected and placed into two groups: i) Analytical Chemist Group and ii) Implementation Planning Group (academics, governmental authorities, industry) In three meetings, each moderated by a facilitator the stakeholder group defined the criteria for chemical selection and developed a priority list of chemicals to biomonitor.
California	(1) Designated Chemicals In the first stage of the selection process, chemicals of concern are considered for inclusion in a list of "designated chemicals". Only a "designated" chemical can be biomonitored. Designated chemicals are defined in the legislation as: 1. Those substances including chemical families or metabolites that are included in the Federal Centers for Disease Control and Prevention (CDC) studies that are known collectively as the National Reports on Human Exposure to Environmental Chemicals program; and 2. Those that have been adopted by the Program as "designated" according to the process laid out in the legislation. Further public participation activities were held and designed in part to elicit ideas on additional chemicals that should be "designated" within the meaning of the legislation. (2) Priority Chemicals There are more designated chemicals than can be biomonitored by the Program during its initial activities. The legislation sets out a process of picking "priority chemicals" for biomonitoring from those that have been designated. While the Program retains final decision-making authority, the Scientific Guidance Panel may recommend priority chemicals based on the additional criteria listed in the section below.

Minnesota	(1) Nomination of chemicals The first stage of this process was to solicit nominations for chemicals from the public and from state agency staff. Online survey An online survey was developed to provide an opportunity for members of the public to make recommendations for the types of chemicals that are important to them. The online survey was posted for four weeks. Respondents were asked to rank their five highest priorities from a list of different type of chemicals. State agency input Staff from seven state and regional agencies that potentially deal with environmental chemicals were contacted to provide input on priority chemicals. (2) Scoring process The next stage in the chemical selection process will be to score the nominated chemicals, along with the chemicals included in NHANES, using the selection criteria previously reviewed by the advisory panel. The scoring process will likely involve both internal and external experts. The recommendations made by the advisory panel will be reviewed by program staff in consultation with the commissioner of health.

HBM program	Criteria for prioritizing chemicals
France	1. hazardous properties to health, included by known or potential toxic effects of substances and their severity, especially carcinogenicity, reproductive toxicity, mutagenicity, neurotoxicity, immunotoxicity, and endocrine-disrupting effects 2. exposure characteristics This included: – nature of contamination sources (anthropogenic and natural) – characteristics of contamination (dispersive or confined) – potential human exposure and characteristics of the exposed population (general population, workers only or vulnerable populations: children, pregnant women, etc.) – possibility of multi-method/multiple sources of/multiple types of exposure (soil, air, water..) 3. social perception; reflected the level of public concern (Were exposure to the particular pollutant and its potential effects a concern for the public authorities? Were the dangers of this substance given media coverage?) 4. biomarker characteristics; included the meaning of the marker (i.e. does it reflect current exposure and/or the internal dose accumulated, and/or the biologically active internal dose?) and also took into account the sensitivity, specificity, and the intraindividual and/or inter-individual variability of the biomarker 5. results' interpretation; availability of information for interpreting the results: distribution of biomarker levels in a reference population; knowledge of the relationship between the biomarker level and external exposure and/or adverse effects; the toxicokinetics of the xenobiotic, and of the biomarker when not the xenobiotic itself (ideally integrated in a physiologically-based pharmacokinetic (PBPK) model); the individual and environmental factors that may influence the fate of the xenobiotic, in vivo analysis (co-exposures, food habits, genetic determinants, body mass index, etc.) logistic and analytical feasibility; sampling method's human invasiveness, the blood or urine sample volume required to analyze biomarkers, the conditions for collection (transport, storage, etc.), the availability of a validated assay method with sufficient information to analyze biomarkers, such as the existence of a detection limit and a quantification limit adapted for the interpretation, and the cost of analysis feasibility of prevention; availability of European or national regulations, the availability of a toxicity reference value (TRV), as well as the current feasibility of exposure reduction, taking into account its techno-economic and social implications, the possibility of supporting a predefined public health policy, etc. 6. contribution in terms of new knowledge in France, considering the gaps of knowledge at the national and international levels and the national specificities in terms of exposure, behavior, susceptibility to exposure, etc., the need for national data for harmonization and international comparisons

Belgium (Flanders) FLEHS	1. health effects (effects known humans/animals/in vitro) 2. size and group of exposed population 3. level of exposure (general population, specific sources) 4. existence of biomarker 5. perinatal exposure (placental transfer) 6. interpreted accountability of measurement 7. biological matrix: invasiveness 8. costs 9. social perception 10. contribution to new scientific knowledge for Flanders 11. possibility for prevention
Germany GerES	1. relevance of health effects (known or suspected health risks or effects) 2. high incidence and distribution of a measurable substance in children and youth (3-17 years), effecting the general population not only a group of people 3. Availability and feasibility of the method of analytical method for a cross-sectional population representative survey - biologic matrices (urine is preferred, blood is restricted) - operable method (background) - assurance of quality control (existing SOPs etc.) 4. sufficient sample size 5. relevance for environmental and health policy 6. costs
Canada CHMS	CHMS Cycle 1 (2007-2009) 1. Known or potential exposure in the Canadian population; 2. Known or suspected health risks or effects; 3. Data needs for public health or regulatory actions; 4. Data from other sources (are there adequate data already available); 5. Feasibility to include in a national survey (field collection, biological matrix requirement (blood or urine versus other matrix); 6. Existence of an appropriate laboratory analytical method; 7. Cost. CHMS Cycle 2 (2009-2011) Same selection criteria as CHMS Cycle 1 with new additional criteria: 1. Sources of exposure – data showing environment, food or consumer products as the main source; 2. Known or potentially vulnerable populations (e.g. age groups, sex); 3. International obligations.
U.S. CDC-NHANES	1. Independent scientific data which suggest that the potential for exposure of the U.S. population to a particular chemical is changing (i.e., increasing or decreasing) or persisting; 2. seriousness of health effects known or suspected to result from exposure to the chemical (for example, cancer, birth defects, or other serious health effects); 3. proportion of the U.S. population likely to be exposed to levels of chemicals of known or potential health significance; 4. need to assess the efficacy of public health actions to reduce exposure to a chemical in the U.S. population or a large component of the U.S. population (for example, among children, women of childbearing age, the elderly); 5. existence of an analytical method that can measure the chemical or its metabolite in blood or urine with adequate accuracy, precision, sensitivity, specificity, and speed 6. incremental analytical cost (in dollars and personnel) to perform the analyses (preference is given to chemicals that can be added readily to existing analytical methods).
Michigan	1. Health Effect (range 0 to 5.0) - Human health effect: 5.0 - Animal or other health effect: 4.5

	- Structural similarities to chemical with know adverse human health effect: 4.0 - None of the above: 0 2. Probability of Exposure (range 0 to 3.5) - Significant exposure: 3.5 - Bio-accumulation: 3.0 - None of the above: 0 3. Seriousness of Health Effect (range 0 to 2.5) - Effect occurs early in life (in utero): 2.5 - Cancer: 2.5 - Multigenerational: 2.0 - Early in life and multigenerational: 4.5 - Other: 1.5 - • None of the above: 0
California	Under Step 1, the Panel may recommend additional designated chemicals not included in the CDC program using the following criteria: 1. Exposure or potential exposure to the public or specific subgroups. 2. The known or suspected health effects resulting from some level of exposure based on peer-reviewed scientific studies. 3. The need to assess the efficacy of public health actions to reduce exposure to a chemical. 4. The availability of a biomonitoring analytical method with adequate accuracy, precision, sensitivity, specificity, and speed. 5. The availability of adequate biospecimen samples. 6. The incremental analytical cost to perform the biomonitoring analysis for the chemical. The Step 2 criteria to select Priority Chemicals are: 1. The degree of potential exposure to the public or specific subgroups, including, but not limited to, occupational subgroups. 2. The likelihood of a chemical being a carcinogen or toxicant based on peer reviewed health data, the chemical structure, or the toxicology of chemically related compounds. 3. The limits of laboratory detection for the chemical, including the ability to detect the chemical at low enough levels that could be expected in the general population. Other criteria that the panel may agree to.
Minnesota	1. Degree of exposure in the state population or sub-population of interest 2. Seriousness of health effects resulting from exposure 3. Adequacy of a method to detect the chemical (e.g. availability of adequate biospecimen samples; degree to which the chemical stays in the body long enough to be measured) 4. Interpretability of the result (e.g. availability of appropriate numbers for comparing the results; degree of information known about what different levels in the body mean) 5. Actionability based on the result (e.g. ability for public health action to be taken to stop the exposure; there is a need to assess the effectiveness of chemical exposure; degree of public concern) 6. Feasibility (e.g. cost; capacity) 7. Potential for information building

Section 3 - Proposed groups of criteria, individual criteria and indicators meant to be used for the scoring step for prioritizing substances

1/ Hazardous properties

➢ **Hazardous properties**		
Effect	*Classification*	*Indicator(s)*
Carcinogenic	IARC classification	1, 2A, 2B, 3 or 4
	CLP classification	1A, 1B or 2
	Knowledge gap	☑
Mutagenic	CLP classification	1A, 1B or 2
	Knowledge gap	☑
Reprotoxic	CLP classification	1A, 1B or 2
	Knowledge gap	☑
Specific Target Organ Toxicity (STOT)	Single exposure (STOT-SE)	1, 2 or 3
	Knowledge gap	☑
	Repeated exposure (STOT-RE)	1 or 2
	Knowledge gap	☑
Neurotoxicity		Yes, no or suspected
Immunotoxicity		Yes, no or suspected
Respiratory sensitization		Yes, no or suspected
Endocrine disruptor		Yes, no or suspected
Other specific hazardous properties	SVHC	Yes, no, under review or unknown
	Other classification(s)	xxx
	Emerging substance	xxx
Please complete with available information and identify any specific knowledge need ***+ add file(s)***		

2/ Exposure characteristics

➢ **Exposure characteristics**		
Criteria	*Sub criteria*	*Indicator(s)*
Extent of exposure	Geographical extent	Hotspots
		Regional
		Country (one or several)
		EU wide
		Unknown
	Duration of exposure	Acute
		Subchronic
		Chronic
		Unknown
	Level of environmental release (E-PRTR)	xxx
	Multisource exposure	Yes, no or suspected
Media of exposure	Air	Yes, no or suspected
	Water	Yes, no or suspected
	Food	Yes, no or suspected
	Soil	Yes, no or suspected
	Products (e.g. cosmetics, etc.)	Yes, no or suspected
	Other	xxx
	Knowledge gap regarding the external exposure	Yes/no
Exposure routes	Dermal	☑
	Inhalation	☑
	Oral	☑
	Trans placental	☑
Prevalence of exposure		Widespread use by workers
		Consumer use
		Unknown
Evidence of exposure from biomonitoring data	Availability of biomonitoring data	Yes/no – add references
Persistence and Bioaccumulation potential	PBT	Yes, no, under review or knowledge gap
	vPvB	Yes, no, under review or knowledge gap
Source of exposure	Natural	Yes, no or suspected
	Anthropogenic	Yes, no or suspected
Volume of production	ECHA database	0-10 tonnes *per annum*
		10-100 tonnes *per annum*
		100-1000 tonnes *per annum*
		>1000 tonnes *per annum*
		Unknown

3/ Regulatory status

➢ **Regulatory status**		
Criteria		*Indicator(s)*
Regulation(s)	Legal framework to regulate chemical in EU	Yes/no – add references
	Legal framework to regulate chemical at national level	Yes/no – add references
	Regulatory gap	Yes/no – add justification
Effectiveness of current environmental policy development and implementation	Environmental policy monitoring	Yes/no – add references
Effectiveness of current measures to minimize exposure to the substance or chemical group	Health policy monitoring	Yes/no – add references
Guidance values	Availability of a toxicity reference value	Yes/no – add references
	Biomonitoring guidance values	Yes/no – add references
	Availability of biomarker level in a reference population	Yes/no – add references
	Health impact or risk assessment	Title(s) + link(s)
Potential for exposure prevention or reduction	Human exposure from environmental sources (including products)	Title(s) + link(s)
	Occupational exposure	Title(s) + link(s)
Please complete with available information and identify any specific knowledge need ***+ add file (s)***		

4/ Public concern

➢ **Public concern/social perception**		
		Indicator(s)
Social perception and attitudes towards the substance or chemical group	Available data (surveys, *e.g.* Eurobarometers, etc.)	Title(s) + link(s)
	Lists (e.g. SIN List from Chemsec, NGO)	Title(s) + link(s)
Public information & knowledge	Media coverage	Yes/no or unknown
Please complete with available information and identify any specific knowledge need ***+ add file (s)***		

5/ Technical feasibility

➢ **Technical criteria**		
Criteria		*Indicator(s)*
Biomarker(s)		
Availability	Status	Available & used for HBM
		Available & used for research
		Not available – research need
Analytical method		
Availability	Status	Available & used for HBM
		Available & used for research
		In development but not yet implemented
		Not yet developed – research need
Performance	Estimated additional analytical effort needed	Not necessary
		Minor adaptation from existing methodological basis
		Major adaptation
		De novo development
Please complete with available information and identify any specific knowledge need ***+ add file (s)***		

Glossary of terms used in the different sections:

- Section on the 'Hazardous properties' family of criteria

Carcinogenic: ability of inducing tumours, increase tumour incidence and/or malignancy or shorten the time to tumour occurrence

IARC (International Agency for Research on Cancer) classification: Group 1: carcinogenic to humans; Group 2A: probably carcinogenic to humans; Group 2B: possibly carcinogenic to humans; Group3: not classifiable as to its carcinogenicity to humans; Group 4: probably not carcinogenic to humans. See http://monographs.iarc.fr/ENG/Classification/index.php/

CLP (Classification Labelling and Packaging) classification: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, introduced on the basis of the United Nations Globally Harmonised System (GHS). See Carcinogenic Mutagenic and Reprotoxic (CMR) categories from Annex IV of the CLP regulation: 1A (known to have CMR potential for humans, based largely on human evidence), 1B (presumed to have CMR potential for humans, based largely on experimental animal data) and 2 (suspected to have CMR potential for humans) on https://echa.europa.eu/regulations/clp/classification

Mutagenic: ability of causing a mutation, which is a permanent change in the genetic material of a cell or microorganism. See ECHA infocards on substances: https://echa.europa.eu/information-on-chemicals

Reprotoxic: ability of causing adverse effects on the reproduction and the reproductive system in animals or humans. ECHA infocards on substances: https://echa.europa.eu/information-on-chemicals

STOT (Specific Target Organ Toxicity): most substances producing systemic toxicity do not cause a similar degree of toxicity in all organs but usually produce the major toxicity to one or two organs[1]. These are referred to as target organs of toxicity for the substance. Two classes of target organ toxicity are defined Specific target organ toxicity - single exposure (STOT-SE) and Specific target organ toxicity - repeat exposure (STOT-RE)

STOT-SE (Specific Target Organ Toxicity - Single Exposure): specific, non-lethal target organ toxicity arising from a single exposure to a chemical (example of acute effect). Substances with a STOT-SE are classified into 3 categories: **Category 1** substances have produced significant toxicity in humans, or, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following single exposure ; **Category 2** substances, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following single exposure ; **Category 3** substances produce transient (short duration or temporary) target organ effects such as narcotic effects or respiratory tract irritation

STOT-RE (Specific Target Organ Toxicity - Repeat Exposure): specific target organ toxicity arising from repeated exposure to a substance or mixture (example of chronic effect). Substances with a STOT-RE are classified into 2 categories: **Category 1** substances have produced significant toxicity in humans, or, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure ; **Category 2** substances, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure

Neurotoxicity: ability of inducing adverse effects on the nervous system, which can result for example in confusion, fatigue, irritability, or other behavioral changes. Source of information, see: http://scorecard.goodguide.com/health-effects/chemicals-2.tcl?short_hazard_name=neuro&all_p=t

Immunotoxicity: ability of inducing adverse effects on the functioning of the immune system. Altered immune function may lead to the increased incidence or severity of infectious diseases or cancer, since the immune system's ability to respond adequately to invading agents is suppressed. Allergens, which are compounds that stimulate the immune system and can cause hypersensitivity reactions or allergies, are considered to be immunotoxicants. Source of information, see http://scorecard.goodguide.com/health-effects/chemicals-.tcl?short_hazard_name=immun&all_p=t

Endocrine disruptor: exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations ; a potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expressed to lead to endocrine disruption in an intact organism, or its progeny, or (sub) populations (World Health organization (WHO) International Programme on Chemical Safety (IPCS) definition**,** see http://www.who.int/ceh/publications/endocrine/en/). See also EU priority list: http://ec.europa.eu/environment/chemicals/endocrine/

SVHCs (Substances of Very High Concern): substances deemed very hazardous with respect to human health and the environment and which come under scrutiny for authorization or restriction under REACH. Human health concerns includes substances classified as Carcinogens Cat 1 & 2, Mutatoxic and Reprotoxic Cat 1 & 2, and substances with can interfere with the hormone system (endocrine disruptors). Substances which are of high concern to the environment include PBTs, vPvBs. See: https://echa.europa.eu/candidate-list-table

Respiratory sensitization: ability of inducing hypersensitivity of the airways following inhalation

[1] *Toxicology, the Basic Science of Poisons from* Casarett and Doull's

Emerging substance: substances that have been detected in the environment, but which are currently not included in routine monitoring programmes at EU level and whose fate, behavior and (eco)toxicological effects are not well understood

- Section on the 'Exposure characteristics' family of criteria

E-PRTR (European Pollutant Release and Transfer Register): Europe-wide register providing key environmental data from industrial facilities in European Union Member States and in Iceland, Liechtenstein, Norway, Serbia and Switzerland. Contains data reported annually by more than 30,000 industrial facilities covering 65 economic activities across Europe.
For each facility, information is provided concerning the amounts of pollutant releases to air, water and land as well as off-site transfers of waste and of pollutants in waste water from a list of 91 key pollutants including heavy metals, pesticides, greenhouse gases and dioxins. See http://prtr.ec.europa.eu/#/home

Multisource exposure: exposure to the substance through various media (e.g. air, water, soil, food, consumer products)

PBTs (Persistent, Bioaccumulative and Toxic): substances defined as toxic, persisting in the environment and bioaccumulating in food chains and, thus, posing risks to human health and ecosystems. PBTs transfer rather easily among air, water, and land, and span boundaries of programs, geography, and generations. See https://echa.europa.eu/

vPvB (very Persistent and very Bioaccumulative) substances: substances of very high concern, which are very persistent (very difficult to break down) and very bio-accumulative in living organisms. See https://echa.europa.eu/

Natural exposure: non-anthropogenic release of the substance

Anthropogenic exposure: release of the substance through human-made activities

Volume of production: tonnage manufactured and/or imported per year to the European Economic Area (EEA), which is published (or registered) on ECHA database (data may be claimed confidential and may not be available). See https://echa.europa.eu/

ECHA (European Chemicals Agency): EU agency which manages the technical, scientific and administrative aspects of the implementation of the EU regulation REACH. See https://echa.europa.eu/

Vulnerability: defined in this context as the diminished capacity of an individual or group to cope with, resist and recover from the impact of a natural or man-made hazard, depending from physical, economic and social factors for example[2]

Exposure routes: routes by which substances can enter the body, which in the case of environmental pollutants are dermal absorption, inhalation, ingestion (oral absorption) or transplacental transfer

Widespread use by professional workers: uses carried out in the context of commercial activities and assumed to take place in most towns of a certain size, by multiple actors each at low scale e.g. local garage, small cleaning businesses. They are also considered end-uses. The further fate of the substance corresponds to the fate as described for uses at industrial sites[3]

[2] http://www.ifrc.org/en/what-we-do/disaster-management/about-disasters/what-is-a-disaster/what-is-vulnerability/
[3] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Consumer use: all end-uses of the substance as such or in a mixture carried out by consumers can be reported under this life cycle stage. Uses by consumers are also considered to take place in a widespread manner[3]

Biomonitoring data: measurements of the levels of indicators of chemicals uptake (known as biomarkers) in biological matrices, as body fluids (e.g. blood, hair, saliva or urine) or tissues (e.g. hair, nails, fat, and bone)

- Section on the 'Regulatory status' family of criteria

Toxicity Reference Value (TRV): toxicological index used to qualify or quantify a risk to human health when compared with exposure. TRVs are established for a given critical effect, and are specific to a substance, a duration of exposure (acute, sub-chronic or chronic) and a route of exposure (oral, inhalation, etc.). Their derivation depends on available data on the substances' toxicological mechanisms of action and commonly accepted assumptions: a distinction is therefore made between "TRVs without a threshold dose" and "TRVs with a threshold dose"[4]. According to the (inter)national agencies deriving TRVs, TRVs with a threshold dose can be referred as:

Agency	Acronym	Name	Pathway
TRV in the general population			
ANSES	VTR	Valeur Toxicologique de Référence à seuil de dose	Oral & inhalation
	DJA	Dose Journalière Admissible	Oral
	DJT	Dose Journalière Tolérable	
	DHT	Dose Hebdomadaire Tolérable	
	DMT	Dose Mensuelle Tolérable	Oral & inhalation
ATSDR	MRL	Minimum Risk Level	Oral & inhalation
EFSA	ADI	Acceptable Daily Intake	Oral
	TDI	Tolerable Daily Intake	Oral
	TWI	Admissible Tolerable Weekly Intake	Oral
	TMI	Tolerable Monthly Intake	Oral
OEHHA	REL	Reference Exposure Levels	Oral & inhalation
RIVM	MPR	Maximum Permissible Risk level	Oral & inhalation
	ADI	Acceptable Daily Intake	Oral
	TCA	Tolerable Concentration in Air	Inhalation

[4] Anses website: https://www.anses.fr/en/content/trvs-toxicity-reference-values

	TDI	Tolerable Daily Intake	Oral
WHO	TCA	Tolerable Concentration in Air	Inhalation
	ADI	Acceptable Daily Intake	Oral
	TDI	Tolerable Daily Intake	Oral
	TWI	Admissible Tolerable Weekly Intake	Oral
Health Canada	ADI	Admissible Daily Intake	Oral
	TDI	Tolerable Daily Intake	Oral
	CA	Admissible Concentration in Air	Inhalation
US EPA	RfD	Reference Dose	Oral
	RfC	Reference Concentration	Inhalation
TRV in the workplace			
ACGIH	TLV-TWA	Threshold Limit Values - Time Weighted Average	
	TLV-STEL	Threshold Limit Values- Short Term Exposure Limit	
	TLV-C	Threshold Limit Value - Ceiling	
ANSES	VLEP-8h	Valeur Limite d'Exposition Professionnelle (8 heures)	
	VLCT-15 min	Valeur Limite Court Terme (15 minutes) (VLCT-15 min)	
	-	Valeur plafond	
Denmark	TWA-8h	Time Weighted Average-8h	
	STEL	Short TErm Limit	
DECOS	TWA-8h	Time Weighted Average-8h	
	STEL	Short TErm Limit	
DFG	MAK	Maximale Arbeitsplatzkonzentrationen	
NIOSH	REL–TWA	Recommended Exposure Level-Time Weighted Average	
	REL-ST	Recommended Exposure Level- Short-Term exposure limit	
	REL-C	Recommended Exposure Level – Ceiling	

OSHA	PEL-TWA	Permissible Exposure Level-Time Weighted Average
	PEL-STEL	Permissible Exposure Level- Short-Term exposure limit
SCOEL	TWA	Occupational Exposure Limit Time Weighted Average
	STEL	Occupational Exposure Limit Short Term Exposure Limit

According to the (inter)national agencies derivating TRVs, TRVs without a threshold dose can be referred as:

Agency	Acronym	Name	Pathway
ANSES	VTR	Valeur Toxicologique de Référence sans seuil de dose	Oral & inhalation
OEHHA	-	Oral Slope Factor	Oral
	-	Unit Risk Factor	Inhalation
WHO	-	Inhalation Unit Risk	Inhalation
	-	Oral Slope Factor	Oral
RIVM	CR	Excess lifetime cancer risk	Oral & inhalation
	MPR	Maximum Permissible Risk level	Oral & inhalation
Health Canada	$TD_{0,5}$	Tumorigenic Dose $_{0,5}$	Oral
	$TC_{0,5}$	Tumorigenic Concentration $_{0,5}$	Inhalation
US EPA	IUR	Inhalation Unit Risk	Inhalation
	OSF	Oral slope factor	Oral
	-	Drinking Water Unit Risk	Oral

Biomonitoring guidance values - provisional definition: represents a certain concentration or range of concentrations of a chemical or its metabolite in a biological medium (blood, urine, or other medium) that is consistent with an existing health-based exposure guideline, or associated with exposures that are consistent with general population exposure guidance values. Different types of biomonitoring guidance values exist, as for example:

Agency	Acronym	Name
Biological Guidance Values in the general population		
ANSES	VBR	Valeur Biologique de Référence
DFG	BAR	Biologische Arbeitsstoff-Referenzwerte

	BAT	Biologische Arbeitsstoff-Toleranzwerte
SCOEL	BGV	Biological Guidance Values
UBA	HBM-I or -II	Human biomonitoring value-I or -II
	BE	Biomonitoring Equivalent
Occupational Biological Guidance Values		
ANSES	VLB	Valeur Limite Biologique
SCOEL	BLV	health-based Biological Limit Value
ACGIH	BEI	Biological Exposure Indices
DFG	BAT	Biologischer Arbeitsstoff Toleranzwerte
	BLW	Biologischer Leit-Wert
	EKA	Expositionsäquivalente für Krebserzeugende Arbeitsstoffe
FIOH	BAL	Biological Action Level
HSL	BMGV	Biological Monitoring Guidance Value
SUVA	VBT	Valeur Biologique Tolérable

Potential for exposure prevention or reduction: feasibility of exposure prevention or reduction, e.g. availability of substitutes or alternative industrial process (taking into accounts technical, economic and social implications) from environmental sources (for the general population) and/or occupational settings (for workers)

Annex 3 - Information on Cadmium and Perfluorooctanoic acid against the prioritisation criteria

1/ Cadmium (CAS number: 7440-43-9)

Hazard			
Criteria	**Indicators**	**Result**	**Sources**
CMR (Carcinogenic/Mutagenic/Reprotox)	Harmonized classification (CLP)	**Category 1B**	https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/51061https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/51061
	Self-classification (CLP)		No data found
	Classification CIRC	**Group 1**	http://monographs.iarc.fr/FR/Classification/
	Classification NTP		No data found
Specific Target Organ Toxicity (Single Exposure)	Classifications STOT RE, SE		No data found
Specific Target Organ Toxicity (Repeated Exposure) *		**STOT RE 1**	https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/51061https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/51061
Immunotoxicity		**Yes**	Relevant publications (e.g. http://scorecard.goodguide.com/health-effects/chemicals-2.tcl?short_hazard_name=immun&all_p=t)
Neurotoxicity		**Yes**	Relevant publications (e.g. http://scorecard.goodguide.com/health-effects/chemicals-2.tcl?short_hazard_name=neuro&all_p=t **or** Grandjean P, Landrigan PJ. *Neurobehavioural effects of developmental toxicity* . Lancet Neurol. 2014 Mar;13(3):330-8. doi: 10.1016/S1474-4422(13)70278-3. Epub 2014 Feb 17. Review. PubMed PMID: 24556010)
Respiratory sensitization	Harmonized classification (CLP)		No data found
Endocrine disruptor potential	Identification SVHC	**Yes**	https://echa.europa.eu/candidate-list-table
	ED classification (Commission List)		No data found
Substances of possible concern for which there are knowledge gaps	i.e. substitutes with similar toxicological properties to known toxic substances for which we do not yet have toxicity data; to lend weight to knowledge gaps over known substances.		No data found

Exposure			
Criteria	**Indicators**	**Result**	**Sources**
Environmental exposure			
Extent of exposure	Geographical extent	**hotspot**	http://opac.invs.sante.fr/doc_num.php?explnum_id=5581
	Confined or Dispersive	**Widespread use by professional workers / consumer uses**	https://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdfhttps://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdf
	Level of environmental release (E-PRTR)		No data found
	Multi-sources/multipathway exposure	**Yes**	ECHA, "Inclusion of substances of very high concern in the candidate list", 17/06/2013
Media of exposure	Level of exposure in external media [air, water, soil, food, consumer products]	**Yes**	https://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdfhttps://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdf
	Knowledge gap regarding the external exposure (upstream compartments data)		No data found
Persistence and bioaccumulation potential	PBT (Persistent, Bio-accumulative, Toxic)	**SVHC**	Wcislo Eleonora and al, "Human health risk assessment in restoring safe and productive use of abandoned contaminated sites", 2016; https://echa.europa.eu/documents/10162/a048359b-de39-4b7e-8602-51272a55aeae (page 22):"equivalent level of concern" due to the adverse effects on kidney and bones, effects that depending on dose may be serious and even contribute to premature death, the continuous accumulation of cadmium in the body, [...] and high societal costs in terms of health care and shortening of life time and a decreased quality of life
	vPvB (very Persistent, very Bio-accumulative)	**SVHC**	
Source of exposure	Natural / anthropogenic	**Natural**	http://opac.invs.sante.fr/doc_num.php?explnum_id=5581
Production volume		**>1000**	https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.028.320https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.028.320
Human exposure			
Vulnerability	Sex	**Yes**	http://www.csst.qc.ca/prevention/reptox/Pages/fiche-complete.aspx?no_produit=4440
	Age	**Yes**	
	Social classes		No data found
	Preexisting Diseases	Yes	http://www.csst.qc.ca/prevention/reptox/Pages/fiche-complete.aspx?no_produit=4440
Target population	Newborn/children	**Yes**	http://www.csst.qc.ca/prevention/reptox/Pages/fiche-complete.aspx?no_produit=4440
	Adults	**Yes**	
	Pregnant women	**Yes**	
	Elderly		No data found
	Workers	**Yes**	https://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdfhttps://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdf
	Other group(s)		No data found
Exposure routes	Dermal	**Low**	INERIS, "Fiche de données toxicologiques et environnementales des substances chimiques-Cadmium et ses dérivés", 29/09/2011
	Inhalation	**Yes**	https://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdfhttps://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdf
	Oral	**Yes**	
	Transplacental	**Yes**	http://www.csst.qc.ca/prevention/reptox/Pages/fiche-complete.aspx?no_produit=4440
Evidence of exposure from biomonitoring data	Availability of biomonitoring data	**Yes**	https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

Regulatory status

Criteria	Indicators	Result	Sources
Regulation(s)	Legal framework to regulate chemical in EU	**Yes**	https://echa.europa.eu/documents/10162/22177693/what_is_an_infocard_en.pdf/4960b3a4-a84f-461d-926c-b4a683b2f98f
	Legal framework to regulate chemical at national level	**Yes**	No data found
	Regulatory gap	**No**	ECHA CoRAP: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
Effectiveness of current environmnental policy development and implementation	Policy monitoring (economic indicators…)	**Yes**	https://www.senat.fr/rap/l00-261/l00-261_mono.html#toc654
Effectiveness of current health policy development and implementation	Policy monitoring (economic indicators…)		No data found
Guidance values	Availability of toxic reference values	**Yes**	Wcislo Eleonora and al, "Human health risk assessment in restoring safe and productive use of abandoned contaminated sites", 2016
	Availability of biomarker level in a reference population (surveillance)	**Yes**	https://www.anses.fr/sites/default/files/files/CHIM2009sa0344Ra.pdf http://www.toxi.ucl.ac.be/biological_monitoring/biomarqueur/283
	Existing health impact or risk assessment	**Yes**	Wcislo Eleonora and al, "Human health risk assessment in restoring safe and productive use of abandoned contaminated sites", 2016
Potential for exposure prevention or reduction	Environmental exposure		No data found
	General population exposure		No data found
	Occupational exposure		No data found

Public concern

Criteria	Indicators	Result	Sources
Social perception and attitudes toward chemical compounds	Surveys (e.g. Eurobarometers)	**No**	Euro-barometers http://ec.europa.eu/public_opinion/flash/fl_361_sum_en.pdf
Public information & knowledge	NGOs' lists (ChemSec, ETUC…)	**Yes**	http://chemsec.org/business-tool/sin-list
	Media coverage / publications en specific substances		

Technical			
Criteria	**Indicators**	**Result**	**Sources**
Biomarker(s)			
Availability	1- Available & used for HBM 2- Available & used for research 3- Not available – research need	**Available & used for HBM**	http://opac.invs.sante.fr/doc_num.php?explnum_id=6864
Analytical method(s)			
Availability	1- available & used for HBM 2- available & used for research 3- in development but not yet implemented 4- not yet developed – research need	**Available & used for HBM**	http://opac.invs.sante.fr/doc_num.php?explnum_id=6864
Laboratory capacity	Sample analysis capability (nb/month)	**Function of the matrix**	
	Number of analyzed samples within an HBM context		
	Number of analyzed samples within a research context		
Performance (Estimated additional analytical effort needed)	1- Not necessary 2- Minor adaptation from existing methodological basis 3- Major adaptation 4- De novo development	**Not necessary**	Wcislo Eleonora and al, "Human health risk assessment in restoring safe and productive use of abandoned contaminated sites", 2016
Standards	Availability	**Yes**	ISO 5961:1994 Qualité de l'eau -- Dosage du cadmium par spectrométrie d'absorption atomique

2/ Perfluorooctanoic acid (CAS number: 335-67-1)

Hazard			
Criteria	**Indicators**	**Result**	**Sources**
CMR (Carcinogenic/Mutagenic/Reprotox)	Harmonized classification (CLP)	**Category 1B**	ECHA, "Member state committee support document for identification of pentadecafluorooctanoic acid (PFOA", 14 june 2013
	Self-classification (CLP)		No data found
	Classification CIRC	**Group 2B**	Agents classified by the IARC Monographs, volumes 1-117
	Classification NTP		No data found
Specific Target Organ Toxicity (Single Exposure)	Classifications STOT RE, SE		No data found
Specific Target Organ Toxicity (Repeated Exposure) *		**STOT RE 1**	ECHA, "Member state committee support document for identification of pentadecafluorooctanoic acid (PFOA", 14 june 2013
Immunotoxicity			No data found
Neurotoxicity			No data found
Respiratory sensitization	Harmonized classification (CLP)		No data found
Endocrine disruptor potential	Identification SVHC		No data found
	ED classification (Commission List)		No data found
Substances of possible concern for which there are knowledge gaps	i.e. substitutes with similar toxicological properties to known toxic substances for which we do not yet have toxicity data; to lend weight to knowledge gaps over known substances.		No data found

Exposure

Criteria	Indicators	Result	Sources
Environmental exposure			
Extent of exposure	Geographical extent	**Worlwide**	ANSES, "Note d'appui scientifique et technique de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relative aux composés perfluorés présents dans les eaux destinées à la consommation humaine", saisine n°2012-SA-0001, 17 janvier 2014
	Confined or Dispersive	**Widespread use by professional workers / consumer uses**	
	Level of environmental release (E-PRTR)	**Very high**	Kinani Said and al, "L'analyse des composés alkyle perfluorés-état de l'art et difficultés", janvier 2010
	Multi-sources/multipathway exposure	**Yes**	
Media of exposure	Level of exposure in external media [air, water, soil, food, consumer products]	**Yes**	
	Knowledge gap regarding the external exposure (upstream compartments data)		No data found
Persistence and bioaccumulation potential	PBT (Persistent, Bio-accumulative, Toxic)	**SVHC**	INRS, "Base de données Fiches toxicologiques-Acide perfluorooctanoïque et ses sels (PFOA et ses sels)", 02/2016
	vPvB (very Persistent, very Bio-accumulative)	**SVHC**	
Source of exposure	Natural / anthropogenic	**Anthropogenic**	Santé Canada, "L'acide perfluorooctanoïque (APFO) dans l'eau potable", 2 septembre 2016
Production volume		**10-100**	Rapport de 2010, mais en 2017 la substance n'est pas enregistrée dans REACH . RPS, "Analysis of the risks arising from the industrial use of Perfuorooctanoic acid (PFOA) and Ammonium Perfluorooctanoate (APFO) and from their use in consumer articles. Evaluation of the risk reduction measures for potential restrictions on the manufacture, placing on the market and use of PFOA and APFO", final report (20/12/2008-20/10/2009)
Human exposure			
Vulnerability	Sex	**No**	ECHA, "Member state committee support document for identification of pentadecafluorooctanoic acid (PFOA", 14 june 2013
	Age		No data found
	Social classes		No data found
	Preexisting Diseases		No data found
Target population	Newborn/children	**Yes**	ECHA, "Member state committee support document for identification of pentadecafluorooctanoic acid (PFOA", 14 june 2013
	Adults	**Yes**	
	Pregnant women		No data found
	Elderly	**Yes**	ECHA, "Member state committee support document for identification of pentadecafluorooctanoic acid (PFOA", 14 june 2013
	Workers	**Yes**	Afssa, "Avis de l'agence française de sécurité sanitaire des aliments relatif aux risques potentiels pour la santé humaine liés à la présence résiduelle d'acide perfluorooctanoïque (PFOA) dans les revêtements antiadhésifs des ustensiles de cuisson des aliments", 13 mars 2009
	Other group(s)		No data found
Exposure routes	Dermal	**No**	Afssa, "Avis de l'agence française de sécurité sanitaire des aliments relatif aux risques potentiels pour la santé humaine liés à la présence résiduelle d'acide perfluorooctanoïque (PFOA) dans les revêtements antiadhésifs des ustensiles de cuisson des aliments", 13 mars 2009
	Inhalation	**Yes**	
	Oral	**Yes**	
	Transplacental	**Yes**	INRS, "Base de données Fiches toxicologiques-Acide perfluorooctanoïque et ses sels (PFOA et ses sels)", 02/2016
Evidence of exposure from biomonitoring data	Availability of biomonitoring data	**Yes**	

Regulatory status

Criteria	Indicators	Result	Sources
Regulation(s)	Legal framework to regulate chemical in EU		No data found
	Legal framework to regulate chemical at national level		No data found
	Regulatory gap	**No**	ECHA CoRAP: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
Effectiveness of current environmnental policy development and implementation	Policy monitoring (economic indicators…)		No data found
Effectiveness of current health policy development and implementation	Policy monitoring (economic indicators…)		No data found
Guidance values	Availability of toxic reference values	**Yes**	INRS, "Base de données Fiches toxicologiques-Acide perfluorooctanoïque et ses sels (PFOA et ses sels)", 02/2016
	Availability of biomarker level in a reference population (surveillance)	**Yes**	http://bvs.mag.anses.fr/sites/default/files/BVS-mg-011-FLOCH-BARNEAUD.pdf
	Existing health impact or risk assessment	**Yes**	ECHA, "Member state committee support document for identification of pentadecafluorooctanoic acid (PFOA", 14 june 2013
Potential for exposure prevention or reduction	Environmental exposure	**Yes**	http://www.ec.gc.ca/ese-ees/451C95ED-6236-430C-BE5A-22F91B36773F/PFOA%20%26%20PFCAs_RMA_FR.pdf
	General population exposure	**Yes**	
	Occupational exposure	**Yes**	

Public concern

Criteria	Indicators	Result	Sources
Social perception and attitudes toward chemical compounds	Surveys (e.g. Eurobarometers)	**No**	Euro-barometers http://ec.europa.eu/public_opinion/flash/fl_361_sum_en.pdf
Public information & knowledge	NGOs' lists (ChemSec, ETUC…)	**Yes**	http://chemsec.org/business-tool/sin-list
	Media coverage / publications en specific substances		

Technical			
Criteria	**Indicators**	**Result**	**Sources**
Biomarker(s)			
Availability	1- Available & used for HBM 2- Available & used for research 3- Not available – research need	**Available & used for research**	Kinani Said and al, "L'analyse des composés alkyle perfluorés-état de l'art et difficultés", janvier 2010
Analytical method(s)			
Availability	1- available & used for HBM 2- available & used for research 3- in development but not yet implemented 4- not yet developed – research need	**available & used for research**	Kinani Said and al, "L'analyse des composés alkyle perfluorés-état de l'art et difficultés", janvier 2010
Laboratory capacity	Sample analysis capability (nb/month)		No data
	Number of analyzed samples within an HBM context		No data
	Number of analyzed samples within a research context		No data
Performance (Estimated additional analytical effort needed)	1- Not necessary 2- Minor adaptation from existing methodological basis 3- Major adaptation 4- De novo development	**Not necessary**	Kinani Said and al, "L'analyse des composés alkyle perfluorés-état de l'art et difficultés", janvier 2010
Standards	Availability	**Yes**	ISO 25101:2009 Preview Water quality -- Determination of perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) -- Method for unfiltered samples using solid phase extraction and liquid chromatography/mass spectrometry