

Partnership for the Assessment of Risks from Chemicals

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WP2 – T2.3



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e.g. version 1	Date 20/12/2023	Authors of D/AD	First compiled version for review by PARC T2.3 partners.
e.g. version 2	Date 20/01/2024	T2.3 partners	Draft version with comments provided by partners
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Abstract

This is the first deliverable on the exit strategy of PARC. It summarises the outcomes of a survey that was sent to PARC National Hubs (NHs) about the different activities of PARC that need to be sustainable at the EU level. A sustainable activity is defined as an activity that can be continuously delivered at a consistent quality and level of performance, providing a stable and reliable foundation for coordinating and expanding joint work at EU level. Ensuring sustainability requires coordinated systems, governance and infrastructure across several dimensions such as financial, management, technical and data management aspects.

The specific aim of this first survey on the exit strategy was to ask the NHs which PARC activities should be sustainable at EU level. Out of the 29 NHs of the countries participating in PARC, 20 filled out the survey. In those NHs, some answers were from individuals and not from the NH as a whole, hence they were not included in the analysis and results that are shown here. A majority of the responding NHs identified Human Biomonitoring as the activity that should be sustainable with the highest priority. However, other activities have also been identified by a significant number of NHs as requiring a sustainable framework in Europe: Toxicology (through a European Toxicology Programme), environmental monitoring activities, Data storage and analysis, detecting emerging substances and safe and sustainable by design approaches. Chemical substance prioritisation for additional studies on exposure and hazards was also considered important at the EU level.

Proposals were made on the optimal frameworks for the sustainability of these activities: a central European coordination (e.g. an EU agency), national nodes, harmonised laboratory networks, and data sharing and storage. Based on comments from the NHs and individual partners, different schemes were built for PARC activities and will be further discussed with the Work Package (WP) and task co-leaders, as well as with the PARC Governing Board (GB), in order to further develop the options and prioritise them. These initial proposals are in line with ideas developed in the commission's "one substance, one assessment" project currently under discussion.

The current limitation of the first survey regarding the exit strategy is that most NHs had not started to discuss the exit strategy and several of them did not have the time to reach a consensus among the partners. However, the positive outcome is that this has elicited such discussions within the NHs and this is critical at a time when the "one substance, one assessment" legislative package has been put forward by the European Commission.

While this deliverable should be considered as a first step, additional deliverables are needed to fully develop the different options for exit strategy and the initiatives that are taken to develop these options and eventually to implement them.

Key Words

- Human biomonitoring: Human biomonitoring (HBM), HBM Surveys, HBM4EU, biomarkers, libraries, cross-sectional, longitudinal, bio-banking, population representation, regulatory effectiveness, real-life mixtures
- Human Health: health effects, Health Impact Assessment (HIA), indicators, effects biomarkers, health outcome, molecular epidemiology, exposure-effects analysis, toxicity, human health risk assessment
- Risk: risk management, weight of evidence, risk mitigations, risk communication, risk reduction,
- SSbD: waste, Safe-and-Sustainable- by- Design (SSbD), safe by design, innovative

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Acronyms

COPHES - European coordination action on human biomonitoring

DEMOCOPHES – COPHES pilot study

ECHA - European Chemicals Agency

EFSA - European Food Safety Authority

ESBIO - Expert Team to Support BIOmonitoring in Europe

EEA - European Environment Agency

EURL ECVAM - EU Reference Laboratory for alternatives to animal testing

EU - European Union

HES - Health Examination Survey

HBM - Human Biomonitoring

HBM4EU - Human Biomonitoring for Europe European joint Programme co-funded under H2020

LIFE+ Programme - The Financial Instrument for the Environment and for Climate Action

MS - Member State

NAMs - New Approach Methodologies

NH - National Hub

NHCP - National Hub Contact Point

NORMAN - Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances

PARC - Partnership for the Assessment of Risks from Chemicals

WP - Work Package

1. Introduction

PARC includes a variety of activities that support chemical risk assessment in Europe and subsequent risk management measures. Its wide scientific spectrum includes toxicology, hazard assessment, human biomonitoring, environmental monitoring and safe and sustainable by design approaches as well as tools to detect emerging risks.

Several of these activities have been funded in the past through dedicated research programmes that were, however, limited in time and scope. One of these previously implemented initiatives is HBM4EU which has paved the road towards a robust human biomonitoring programme in Europe and parts of PARC will follow up on the expertise and results generated within this project, i.e. the involvement of National Hubs (NHs) for every participating country. NHs involve the relevant national scientific experts, national ministries, partners, research entities and other stakeholders to develop collaboration and contribute to the development of synergies with related national/EU initiatives.

Other activities of PARC also build on previous expertise. For example, the NORMAN network has developed a solid expertise in environmental monitoring that is invaluable for the current activities of PARC. In the hazard assessment and toxicology field, a large number of programmes such as those of the ASPIS cluster and those devoted to endocrine disruptors (EURION cluster) have also developed activities that are extremely useful for those developed in PARC. In the Safe by Design field, previous projects, in particular on nanomaterials, prepared for the activities currently in progress in PARC.

All those activities are obviously needed for the chemical policy process in Europe, in particular with the implementation of the EU's Chemicals Strategy for Sustainability towards a toxic-free environment¹. However, these activities cannot only rely on a series of projects limited in time. A sustainable framework could ensure effective long-term support of the chemical policy in Europe.

We define a sustainable activity as an activity that can be continuously delivered at a consistent quality and level of performance, providing a stable and reliable foundation for coordinating and expanding joint work at EU level. Ensuring sustainability requires coordinated systems, governance and infrastructure across several dimensions such as financial, management, technical and data management aspects. In this deliverable the focus is on sustainable frameworks at the European level. Obviously the national level is also important and will be addressed in later reports.

The political agenda is critical for securing PARC activities and including sustainable frameworks into the EU legislation. This will highly depend on the commitment of the new commission to implement the green deal, in particular the zero pollution plan and the chemical strategy for sustainability. For these reasons, it is wise to have several options for each of the PARC activities.

One of PARC's objectives is to create a sustainable high-level network for chemical risk assessment. The sustainability of successful PARC activities, tools and networks needs to be investigated and discussed with all PARC participants and notably PARC's National Hubs (NHs). Indeed, countries involved in PARC have established or extended NHs. These hubs develop collaboration and contribute to ensuring PARC's activities are aligned with national activities. There are no prescriptive rules and the construction is based on country needs; however, relevant ministries, research entities and other stakeholders are involved. A National Hub Contact Point (NHCP) is nominated for each NH and the NHs are coordinated by the National Hub Co-ordinators ensuring that the needs of the NHs are fed into PARC.

To address this exit strategy of PARC activities, as a first step we surveyed the NHs for their opinions on the activities that should become sustainable and on initial ideas as to the right

¹ [Chemicals strategy - European Commission \(europa.eu\)](https://ec.europa.eu/chemicals/strategy)

operational frameworks for such activities. **This deliverable presents the results of this first survey and makes specific proposals that will be the basis for future discussions on the exit strategy of PARC.** Although this was not planned originally, additional deliverables are needed to update on the progress in defining the best suited sustainable frameworks and the strategy to achieve such goals, taking into account the political context. While this deliverable should be considered as a first step, additional deliverables are needed to fully develop the different options for exit strategy and the initiatives that are taken to develop these options and eventually to implement them. At this stage, only the sustainability of large thematic areas is considered (e.g. HBM, toxicology). In the future, the sustainability of specific projects developed in PARC could be specifically addressed (e.g. how to further developed the NAM projects).

2. Methods

A survey was carried out under Task 2.3 'Sustainability' and sent to all National Hub Contact Points (NHCPs) for completion (the survey is included in the annex to this report).

The exit strategy preparation for the PARC activities that are most relevant to risk assessment is a critical objective of Task 2.3. It is in line with the EU's Chemicals Strategy for Sustainability and aims at developing a framework ensuring the sustainability of tools, networks, and activities developed within PARC.

The aim of this first survey on the exit strategy was to ask the NHs which PARC activities should be sustainable at EU level. It also aimed at developing some options for the most relevant management and technical operational systems to continue carrying out those activities in the long term.

Sustainable activities are defined as activities, infrastructures, skills, data hubs, etc. that are carried out on a regular basis by a nominated organisation (or organisations) with secured European and/or national funding. In some cases, such activities can be legally embedded.

The survey was prepared by task 2.3 partners and sent to the NHCPs. They initially had one month to fill in the survey, in May/June 2023. NHCPs, NH members and scientific and health institution members filled in this survey. In some cases, the NHCP completed the survey on behalf of the NH, in other cases partners filled in the survey on behalf of themselves. This depended on the capacity of the NH to reach a consensus within the imparted time. Several comments from the NHs and individual partners were sent, making it crucial to summarise the answers in an executive summary.

Prior to the survey, the NHCPs participated in a 45-minute workshop on sustainability during the 1st NHCPs meeting in Riga, Latvia in April 2023. The survey and the basics of sustainability were briefly discussed.

The final version of the questionnaire was translated from a shared Word document to an online survey made with the REDCap tool. The survey is still available here: <https://survey-insa.minsaude.pt/redcap/surveys/?s=JJMYKKLWYF>. The list of questions from the survey are in the [Annexes](#).

The responses were collected and exported in an Excel document from the REDCap survey. They were then divided in two sets: all responses and only NH responses. The responses were then processed and displayed in both a Word document for the open text responses and a Power Point presentation with infographics for the quantitative responses.

3. Results

3.1. NH participation

A total number of 28 answers were expected from the NHCPs of the 29 participating countries. A total number of 37 answers from 24 countries were received. 20 answers came from NHs. In addition, the Norwegian and German NHs (Norwegian Institute of Public Health; German Environment Agency; German Federal Institute for Risk Assessment (BfR)) answered but as 4 different individuals. Those 4 answers were considered as individual answers as they did not represent the NH point of view as a whole. The reasons for these individual responses are that they were not yet able to give a common response to this survey. This was not unexpected since few NHs started thinking about the exit strategy already in year 1 and 2 of PARC. One of the aims of the survey was also to trigger such a discussion.

12 other responses came from other organisations than NH and are listed here:

Table 1. Other responses not from NH

<i>Country</i>	<i>Institute</i>
<i>France</i>	BIOMAE - Biomonitoring Aquatic Environnement
<i>France</i>	WECF France - Women Engage for a Common Future
<i>France</i>	Ametra06 - Association pour la Médecine du Travail)
<i>France</i>	Comité Scientifique Pro Anima
<i>France</i>	PETA Science Consortium International E.V.
<i>France</i>	ANSES – French Agency for Food, Environmental and Occupational Health & Safety
<i>Germany</i>	Rwth Aachen, Institute For Occupational, Social And Environmental Medicine
<i>Portugal</i>	FMUL - Lisbon School Of Medicine
<i>Sweden</i>	SLU – Swedish University of Agricultural Sciences
<i>Switzerland</i>	ETH Zürich – Swiss Federal Institute of Technology
<i>Switzerland</i>	Unisanté
<i>Switzerland</i>	FOEN - Federal Office for the Environment

For the NHs that responded individually, they were not included in the below table as they did not represent a NH response. At this stage, we consider the results of the survey as indicative and the figures and tables presented below should not be considered as representing the opinion of all NHs but only of those who responded. However, we took into consideration the opinions of the individual organisations in our discussion of future frameworks for the exit strategy.

Table 2. NHs that filled in the survey (not including individual responses)

Institute	Country
Environment Agency Austria	Austria
Flemish Department of Environment and Spatial Planning	Belgium
Croatian Institute of Public Health	Croatia
State General Laboratory - Ministry of Health (SGL/MOH-CY)	Cyprus
National Centre for Toxic Compounds, RECETOX, Masaryk University	Czech Republic
Danish Environmental Protection Agency	Denmark
Estonian Health Board	Estonia
Finnish Institute of Occupational Health	Finland
National Public Health Center	Hungary
University of Iceland (UI)	Iceland
Ministry of Health	Israel
National Public Health Surveillance Laboratory	Lithuania
Laboratoire Nationale de Santé	Luxembourg
Nofer Institute of Occupational Medicine	Poland
Portuguese Environment Agency	Portugal
Slovak Medical University	Slovakia
National Institute of Public Health	Slovenia
Instituto de Salud Carlos III	Spain
Swedish Food Agency	Sweden
UK Health Security Agency	United Kingdom

3.2. PARC activities that should be sustainable

Prioritisation/ranking of three PARC activities that should be sustainable

A list of PARC activities was prepared and provided in the survey. The NHs were asked to select and rank the first three activities that should be sustainable. Please note that toxicology was split into three items in this list (NAM-based risk assessment, NAM development, computational toxicology). In figure 1A the three items were grouped together under toxicology for the sake of clarity. In figure 1b the distribution of the votes for the three items of toxicology is displayed.

Survey Question 4: In your opinion, what are the 3 most important activities to be sustainable?

The activities to choose from were:

- Access to data (environmental, human biomonitoring, risk assessment data of chemicals, etc.);
- Environmental monitoring (not already available);
- Toxicology: Development and implementation of NAM-based risk assessment strategies;
- Prioritization processes for substances;
- Human biomonitoring;
- Non-targeted screening;
- Capacity for data storage;
- Toxicology: NAM development;
- Computational toxicology;
- Toolbox and models enabling the application of a safe and sustainable by design (SSBD) approach;
- Other chemical data flows

When an activity is not mentioned in a priority line (1; 2 or 3), it is because it has received 0 vote.

Figure 1. PARC activities that should be sustainable. Each NH listed and ranked 3 priorities that should be sustainable. Note that Toxicology is the combination of three activities that are detailed in figure 1B

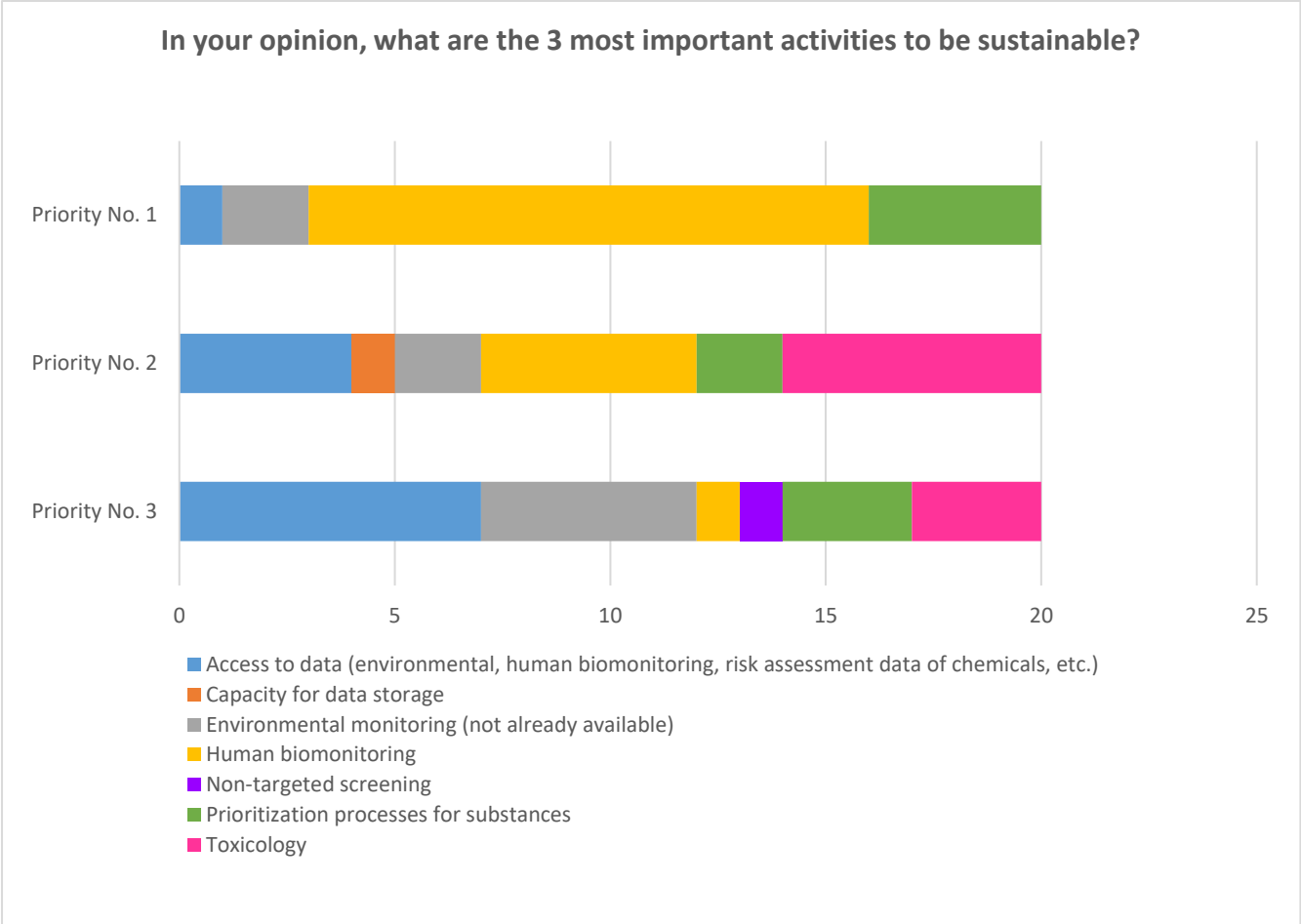


Table 3. Detailed votes for PARC activities that should be sustainable. Each NH listed and ranked 3 priorities that should be sustainable (summarised in figure 1)

Priority	Rank	Activity	# votes
Priority No. 1	1	Human biomonitoring	13
	2	Prioritisation processes for substances	4
	3	Environmental monitoring (not already available)	2
	4	Access to data (environmental, human biomonitoring, risk assessment data of chemicals, etc.)	1
Priority No. 2	1	Toxicology/hazard assessment: Development and implementation of NAM-based risk assessment strategies	6
	2	Human biomonitoring	5
	3	Access to data (environmental, human biomonitoring, risk assessment data of chemicals, etc.)	4
	4	Environmental monitoring (not already available)	2
		Prioritisation processes for substances	2
		Capacity for data storage	1
Priority No. 3	1	Access to data (environmental, human biomonitoring, risk assessment data of chemicals, etc.)	7
	2	Environmental monitoring (not already available)	5
		Prioritisation processes for substances	3
	3	Toxicology/hazard assessment: Development and implementation of NAM-based risk assessment strategies	3
	4	Human biomonitoring	1
	Non-targeted screening	1	

The following activities did not receive any vote for any of the priorities:

- Toxicology: NAM development
- Computational toxicology
- Toolbox and models enabling the application of a SSBD approach
- Other chemical data flows

The answers to this question show that HBM is very clearly ranked first. In fact, the large majority of NHs ranked HBM either first or second. Toxicology is ranked second but closely followed by access to data. The latter is ranked third and is closely followed by environmental monitoring. The three activities in which data are produced and that received most of the votes are HBM, toxicology and environmental monitoring. Concerning toxicology, all the votes went to the item “Toxicology: Development and implementation of NAM-based risk assessment strategies”. There is also obviously a need to further develop access to data as a service.

Other activities that received few votes were the prioritisation process of substances and non-targeted screening.

Human Biomonitoring sustainability

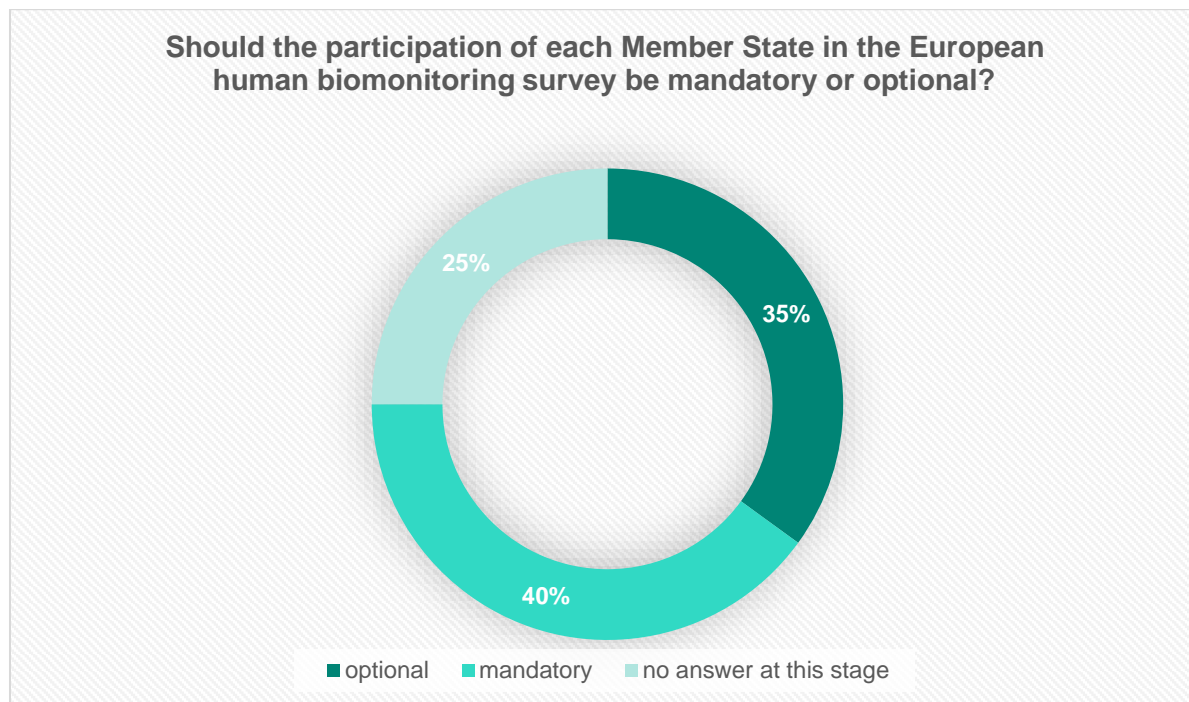
HBM: Confirmation of the high priority of HBM sustainability

Survey Question 1: the HBM4EU sustainability task concluded that a sustainable human biomonitoring framework in Europe is a high priority. Do you agree with this conclusion?

The aim of this question was to confirm the importance of HBM sustainability as already supported by HBM4EU. 100% of NHs agreed that a sustainable human biomonitoring framework in Europe is a high priority, demonstrating a clear support to the high priority given to HBM sustainability in Europe that was put forward by the HBM4EU sustainability task (WP6 in HBM4EU).

Survey Question 2: Should the participation of each Member State in the European human biomonitoring survey be mandatory or optional?

Figure 2. Answers to the question: should the participation of each Member State in the European human biomonitoring survey be mandatory or optional?

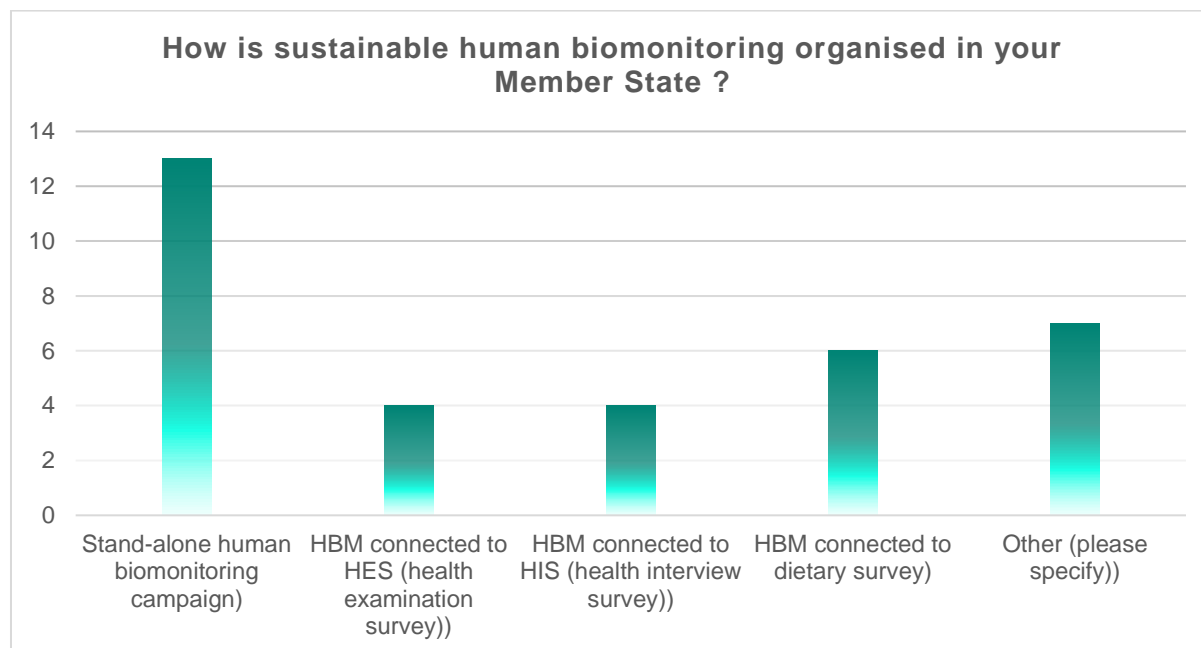


There are different opinions among the NHs concerning the mandatory or optional participation of a Member State (MS) to a human biomonitoring survey in Europe. This question needs to be further discussed and developed among partners in task 2.3 and with NHs in the future. This question should be addressed during the meetings with the NH Co-coordinators and NHCPs organised within task 2.3. This is also a question that should be ultimately addressed by policy makers.

The aim of the following question was to learn whether the HBM surveys were associated with other surveys.

Survey Question 7.2: How is sustainable human biomonitoring organised?

Figure 3. Proportions of the different organisations of HBM in Member States



While several MS have a stand-alone HBM survey, many others couple HBM with other surveys including dietary and/or health surveys. While this is a relevant question that needs to be addressed when building a sustainable HBM in Europe, the next table shows that very few MS have sustainable HBM in place i.e. carrying out HBM surveys on a regular basis.

HBM: Recurrence frequency of surveys in MS

Next, we asked the NH about the frequency of the HBM surveys in their countries.

Survey Question 7.3. What is the recurrence frequency (e.g. regular 2-year cycles, 4-year cycles, irregular)?

Table 4. Recurrence frequency of HBM surveys in the different MS (e.g. regular 2-year cycles, 4-year cycles, irregular)

Country	Answer
Austria	irregular
Belgium	Until now the FLEHS studies were organised in 4-5 years cycles: FLEHS I (2002-2006), FLEHS II (2007-2011), FLEHS III (2012-2015), FLEHS IV (2016-2020), and currently ongoing FLEHS-5(2022-2027).
Croatia	irregular
Cyprus	N.A.
Czech Republic	From 1994 to 2010 the population groups were monitored yearly. From 2014 to 2020 in 3 - 5-year intervals. Then, due to SARS-CoV-2 epidemic and lack of resources the regular cycles have been interrupted.
Denmark	No relevant input
Estonia	No recurrence

<i>Finland</i>	HBM connected to HES is conducted 3-7 years, not that regularly and depends if get funding. Dietary survey is part of HES so the HBM part related to dietary is done if it gets funding. Surveys performed by THL to update Finnish reference values for occupational exposure are not regularly done but made when needed
<i>Hungary</i>	N.A.
<i>Iceland</i>	5 y or only done once
<i>Israel</i>	4 years
<i>Lithuania</i>	Irregular
<i>Luxembourg</i>	irregular (see above)
<i>Poland</i>	irregular
<i>Portugal</i>	N.A.
<i>Slovakia</i>	N.A.
<i>Slovenia</i>	varies, majority is irregular
<i>Spain</i>	Stand-alone campaigns
<i>United Kingdom</i>	Not relevant

Table 5. Individual responses and not NH responses to question 7.2

Country	Organisation	NH or not	Answer
<i>France</i>	AMETRA06	Not NH	it depends on the level of exposure
<i>France</i>	Comité scientifique Pro Anima	Not NH	10-year cycles
<i>France</i>	Anses	Not NH	foreseen: continuous sampling
<i>Germany</i>	German Environment Agency	NH	Human ESB: Annually; GerES: cycles (1985-1986; 1990-1992; 1997-1999; 2001-2002; 2003-2006; 2013-2017; CORONA GAP; 2023-2024)
<i>Germany</i>	RWTH Aachen, Institute for Occupational, Social and Environmental Medicine	Not NH	irregular
<i>Norway</i>	Norwegian Institute of Public Health	NH	4 years cycles
<i>Portugal</i>	FMUL - Lisbon School of Medicine	Not NH	Irregular
<i>Sweden</i>	Swedish Food Agency	NH	It varies between 1-7 years depending on the study.
<i>Switzerland</i>	Unisanté	Not NH	pilot study currently

Table 4 shows a very large diversity of HBM activities in the different MS and that very few MS have a regular HBM survey. Note however that some MS who do have a regular HBM survey such as Germany and France are not listed because they did not fill the surveys as NHs (only certain organisations of those MS filled the survey or provided comments). Yet the results of the survey are that a small number of MS have a regular HBM survey organised at the national or regional levels, some have surveys that are targeted or organised by institutions depending on funding. This highlights the importance of the harmonised surveys carried out within HBM4EU and PARC, the role of financing from EU (DEMOCOPHES, HBM4EU and now PARC) in supporting such activities at a larger scale in Europe and the relevance of a sustainable HBM survey at the EU level.

Survey Question 1.1. What do you think is the most relevant way/operational system to achieve HBM sustainability?

In this section, the surveyed hubs were allowed to provide free answers to the above question. A large number of answers were given. We provide here statements resulting from several answers to this question. These conclusions are in fact in line with those of the HBM4EU sustainability WP (WP6) deliverables, indicating a stability of these opinions.

- Several organisations and NHs suggested that there was a need for a legal Framework governing HBM studies in Europe
- A laboratory network gathering the analytical laboratories is also required. The actual organisation of the network has to be determined.
- The system can be inspired by the food monitoring system.
- Some suggested that this framework should be within the responsibility of the European Environment Agency (EEA) in close collaboration with the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) and the agencies of the Member States
- Concerning the funding, a combined national & EU funding was suggested
- The following items were considered important to be incorporated in the programme:
 - Central prioritisation of chemicals to monitor (to the example of: Water Framework Directive Watch list)
 - Good balance between European alignment and national/regional priorities
 - Quality guarantee concerning chemical analysis
 - Harmonised data analysis and reporting

All these points can constitute the basis for a proposal that can be discussed within PARC, with the Commission and with Member States.

Other PARC activities not including HBM

In this section, questions were asked about PARC activities not including HBM. This helped us having more details on the priorities excluding HBM.

Survey Question 3. Which other PARC activities, in your opinion, should be sustainable (excluding HBM)?

Figure 4A. Selection of PARC activities to be sustained. NHs voted for different activities that they thought should be sustainable. Toxicology combined three different activities (see figure 4B)

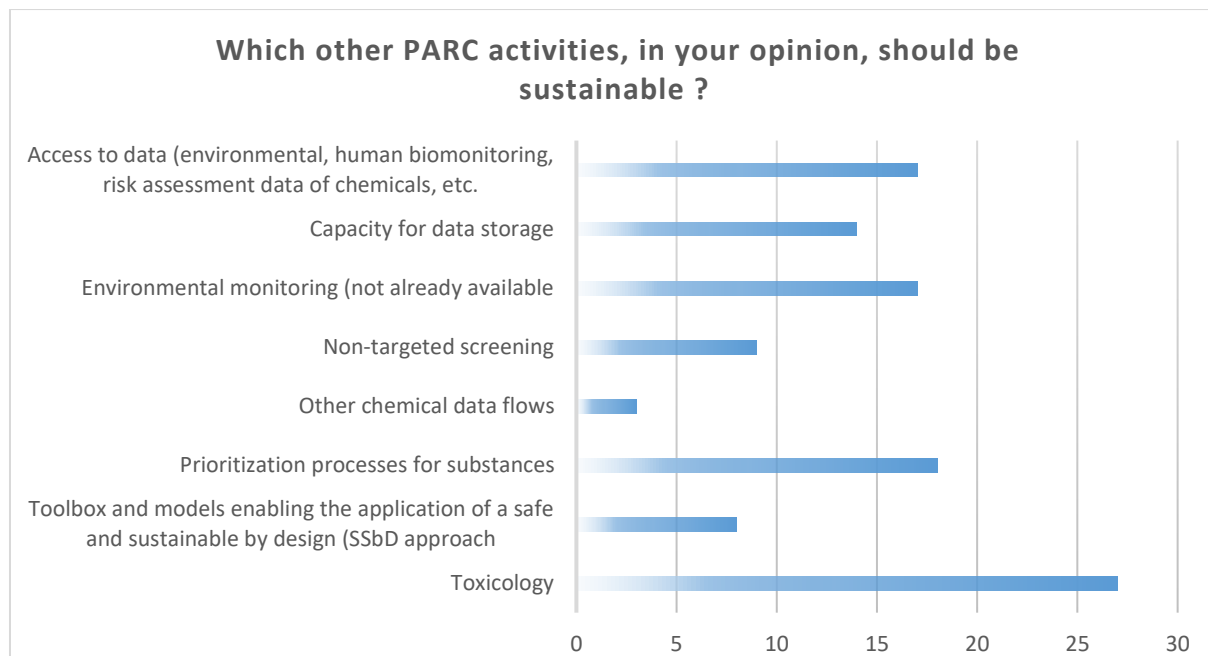
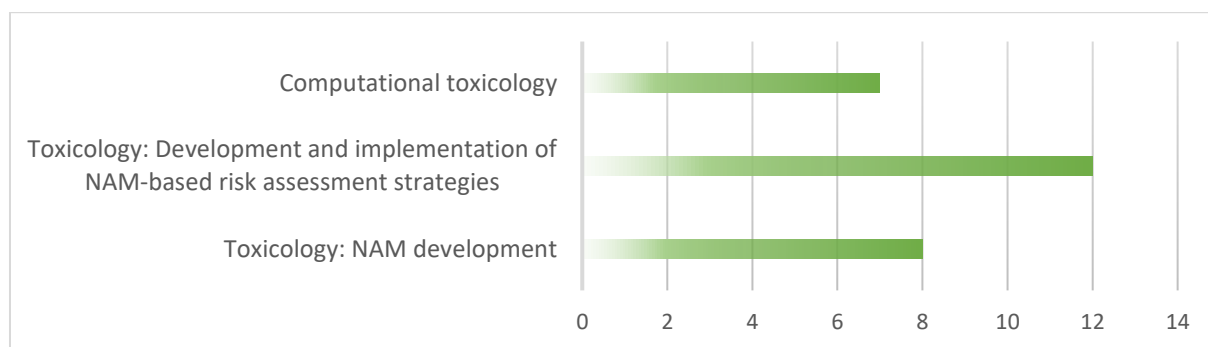


Figure 4B. Selection of PARC activities to be sustained in toxicology. Toxicology (hazard assessment) was split into different sub-activities.



Exclusion of HBM from these questions allowed a better survey of the priorities concerning other activities in PARC. Toxicology, environmental monitoring, capacity for data storage and access to data as well as the prioritisation process received a significant number of votes. There have been a large number of comments from the NHs and individual organisations concerning the different activities and the fact that they were not described in sufficient details. However, this was the first survey on the exit strategy and its main goal was to collect some general ideas that will allow further elaboration of the proposals. A compilation of those comments on the different activities is summarised below. At this stage, they do not constitute consensus conclusions but rather comments that can be helpful to fuel additional discussions and surveys.

- **HBM:** most comments were in favour of a sustainable legally-embedded framework for HBM in Europe.

- **Prioritisation:** when comments were made, they were in favour of prioritisation of chemicals at the European level. However, prioritisation could be carried out within each of the activities (HBM, environmental monitoring, toxicology and may not need an independent organisation (indeed different substances may be prioritised for the different activities).
- **Environmental monitoring:** we received several answers to the question on the most relevant media for environmental monitoring. There was not a general agreement, some highlighting water, air (including indoor air), soil, food. There are already monitoring activities concerning some of the media (food, water, external air, as well as biota and sediments). Several comments highlighted the need for additional monitoring activities of soil, indoor air, biota while also mentioning the additional development of monitoring of drinking water and wastewater. A couple of partners found that the survey was too focused on human monitoring and not enough on environmental monitoring. Globally, while environmental monitoring was deemed important for many partners, there was no clear consensus on the preferred media.
- **Toxicology (hazard assessment):** several answers highlighted the importance of different aspects of toxicology and its contribution to chemical risk assessment. In the survey including HBM, the only activity that was supported was the development of risk assessment strategies based on NAMs (figure 1). When HBM was excluded, other toxicology activities were selected such as NAM development per se and computational toxicology. There was also some support for computational toxicology and the development of new tools. As compared to HBM, the answers in the case of toxicology are still vague, but some partners agreed that sustainable toxicology activities in support of chemical risk assessment were needed.
- **Data storage and access to data:** this was also highlighted by some organisations. Some linked this objective to other activities such as HBM or environmental monitoring. However, there was some support to consider data storage and accessibility as an important objective.
- **Non-targeted screening:** there was less mention of this activity at this stage and it was linked to the other activities such as HBM and environmental monitoring.
- **Safe and sustainable by design:** we received few comments on this subject. Additional clarifications are needed before the NHs and organisations can provide a clear opinion.

Preferred operational systems for PARC activities (not including HBM)

Survey Question 5: What, in your opinion, is the most relevant operational system and host for each of the following activities?

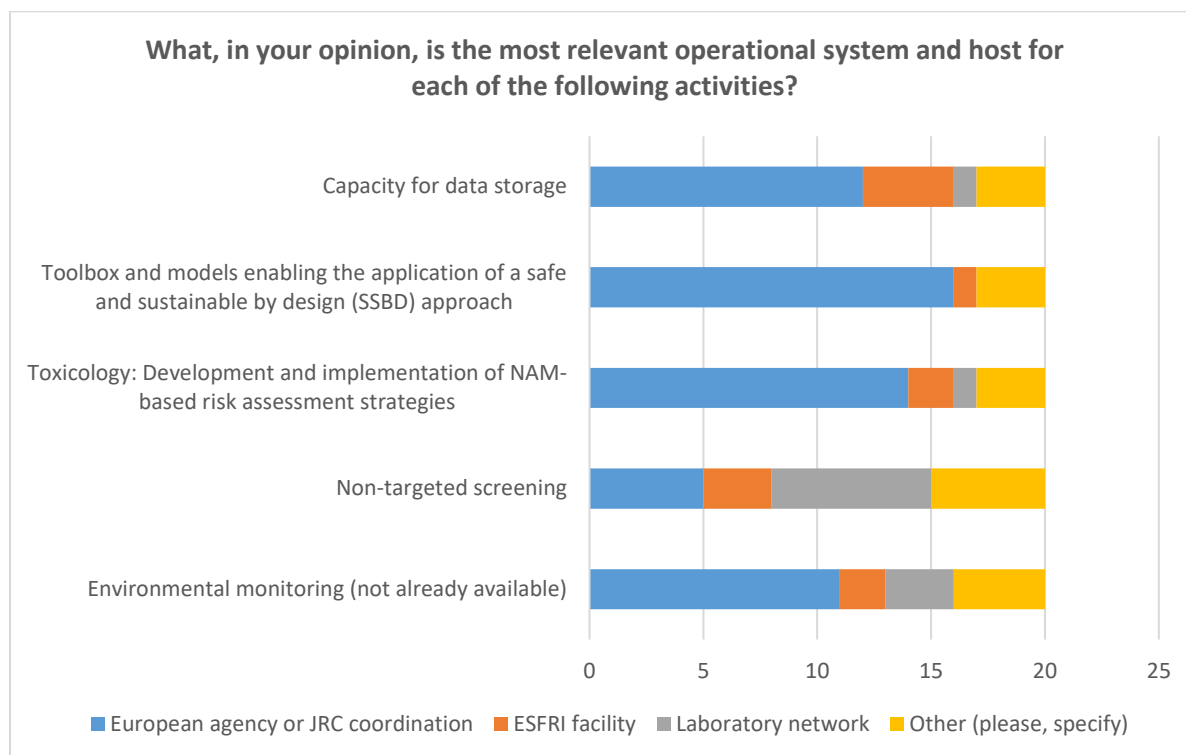


Figure 5. Opinion regarding the most relevant operational system and host for each of the following activities

The survey suggested different operational systems that could ensure the sustainability of PARC activities. The NHs answers were diverse depending on the activities. There was a clear support for a central European coordination for almost all activities but different solutions depending on the activities. Coordination by a European agency or JRC was preferred for data storage, SSBD toolbox and toxicology. There was also some support for an ESFRI (also a European coordination framework²). Concerning non-targeted screening and environmental monitoring the answers were split between the different options (European agency or JRC, laboratory network, ESFRI).

4. Discussion

First, it is important to emphasise the limitations of the survey. We received 37 answers to the survey coming from different organisations across the PARC participating countries. Out of these, 20 were from NHCPs (coordinating a NH response). However, even in the latter case, some NHCPs indicated that their answers were a compilation of the answers from different members of their hub rather than a consensus answer from the hub. The main reasons are that:

² ESFRI: European Strategic Forum for Research Infrastructures. A number of Research Infrastructures (RI) are on the roadmap of the ESFRI. They are constituted of national nodes and some of these are on the roadmap of their own ministries. An ESFRI can ultimately become an ERIC (European Research Infrastructure Consortium) which is a legal entity. For example, the exposome RI EIRENE is an ESFRI while the biobank RI BBMRI is an ERIC

- 1) when the survey was sent in May 2023, we were at the end of the first year of PARC or early second year and most NHs were focused on initiating activities and not on reflecting on the exit strategy, so it was felt that the survey came too early in the process;
- 2) there was not enough time for the NHs to reach a consensus on questions (despite the fact that the deadline for the survey was extended a couple of times, giving a total period of 12 weeks to respond);
- 3) some questions were found to be unclear;
- 4) because some partners are more interested in biomonitoring and others in toxicology, it may have been difficult to reach a consensus and it may be useful in the future to ask for priorities in each of the fields.
- 5) the focus here was on the sustainability of global thematic areas rather than on specific projects that have been developed within PARC.

Taking into account the challenges some countries had, the answers of the first survey should be considered rather as initial thoughts that will help to build and develop suggestions for exit strategy scenarios, because experiences from other projects showed that these issues should be addressed early on.

We (task 2.3 partners) understand the difficulties to answer some of the questions and to have a consensus on an exit strategy, which is a complex issue. However, we believe that it is not too early to address this question, as some of the solutions for an exit strategy require a long time for preparation, in particular any attempts to influence EU legislative developments, such as the one substance one assessment proposal which has already been published and will be considered under the next policy cycle. The experience in HBM4EU also showed that these issues should be addressed early on. We do not consider the answers to the survey as final positions from the different NHs and organisations but rather as initial thoughts that will help us build and develop suggestions for exit strategy scenarios.

Concerning the diversity of activities in PARC, first it seems difficult at this stage to imagine a single sustainable operational system that addresses all the activities of PARC. While it may be desirable to keep the connections between the different activities, it is likely that the different activities may require different sustainable frameworks but a coordination between these frameworks would be useful. Indeed, risk assessment requires contributions from exposure sciences and toxicological sciences as well as computational skills. The challenge will be to further develop these activities and to maintain the connection between them.

Second, there is a clear difference between the stages of the reflection on the exit strategy of the different activities, some being more advanced than others. In particular, the discussions on HBM sustainability are more advanced than for the other activities because they started with HBM4EU and because of the discussions initiated by the EC DG ENV on the data generation mechanisms, as well as the three recent legislative proposals by the Commission on “one substance, one assessment”, put forward on 07/12/2023 (https://ec.europa.eu/commission/presscorner/detail/en/IP_23_6413). The “Proposal for a Regulation establishing a **common data platform on chemicals**, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals - COM(2023) 779 final” includes –in its article 6, the collection, hosting, and maintenance, by the European Environment Agency (EEA), of human biomonitoring data generated within the territory of the EEA’s member and cooperating countries. Other activities of PARC are also impacted by the proposed legislative package, including data storage and access through the Common Data Platform on Chemicals to be established and managed by the European Chemicals Agency (ECHA) (article 3 and article 5 on Data flows for the purpose of the common data platform), environmental occurrence and sustainability data (articles 5 and 13) and Early warning and action system for emerging chemical risks (article 19) and

observatory for specific chemicals with potential contribution to emerging chemical risks (article 20).

While the sustainability of HBM and data storage and access may progress rapidly, the efforts of task 2.3 to identify relevant exit strategies for the other PARC activities should be pursued actively as well. In this regard, there are some opportunities that could help developing sustainable activities. For example, the development of the Commission Roadmap to phase out animal testing in the regulatory arena which is still in the earlier stages, could represent an important opportunity. The Commission's legislative proposals for the "one substance, one assessment" process in the EU is also an important opportunity.

From the different feedback that we received from the survey, it seems that the NHs and organisations would like to work more actively on precise proposals and make their comments based on that. The comments made by several organisations have helped us in elaborating some proposals that are presented below. For these reasons, we believe that this survey, although some felt it was premature, was very helpful to initiate a reflection and discussions on the exit strategy. We also believe it was a timely action because of the different initiatives at the EU level, namely the Commission's legislative proposals for the "one substance, one assessment" process in the EU, as mentioned earlier.

PARC activities are meant to provide new and high-quality knowledge that can support policies. It is crucial to identify with the different stakeholders the best framework for the sustainability of these activities. This obviously includes the PARC GB that needs to discuss these issues, for example following a presentation of the major conclusions of this deliverable. These science-policy links are illustrated by the legislative proposals put forward by the Commission on 07/12/2023 of the "one substance, one assessment" process. These links are also highlighted in several recent publications concerning various PARC activities including HBM (Lobo-Vicente et al, 2023), toxicology (Mehta et al, 2023; Schubauer-Berigan, 2023), exposure science and SSbD (Fantke et al, 2022) and all highlighted in the PARC strategy article (Marx-Stoelting et al, 2023).

5. Conclusion and Perspectives for future activities of task 2.3

The survey allowed task 2.3 to gather initial thoughts on the sustainability of PARC activities. Our reflections should be further developed in light of the "one substance, one assessment" legislative proposals of the Commission, which address a number of activities of PARC. Furthermore, within task 2.2, the future for next generation risk assessment is currently discussed (NGRA route) including the use of new methodologies and this should feed into task 2.3 work on the exit strategy and sustainability.

The way to make progress at this stage is to make specific proposals that could constitute the basis for further discussions and comments with PARC partners, with the Governing Board and with the Commission, EU agencies and JRC. The following sustainability frameworks for each of the main PARC activities are proposed for discussion.

Clearly this section goes beyond the outcomes of the first survey discussed in this deliverable but it is inspired by some of the open text comments received from NHs or partners in this survey and it could constitute the basis for our future discussions and activities in the task. In particular, several of these areas touch on current or potential roles of agencies. The aim of task 2.3 is to reach out to these agencies to discuss these options.

The options for sustainability are not limited to those discussed below (and mentioned by the NHs). Obviously international organisations such as the Organisation for Economic Co-operation and Development (OECD), international societies or industry-supported programmes could offer some alternatives and should be discussed with stakeholders in the future.

1. Human Biomonitoring (HBM)

- A comprehensive framework for HBM at the European level should be precisely defined and should include a process for chemical prioritisation, survey harmonisation and planning, questionnaires and sample collection, analytical assays and data storage and interpretation. The role of the different organisations (EU level or MS) should be clearly stated.
- It is suggested that this precise framework for HBM could be embedded in the legislation (for example, within the legislative proposals on “one substance, one assessment” put forward by the Commission on 07/12/2023, in particular on a common platform for chemical data³) and an associated budgetary contribution should be made available to MS).
- A central coordination at the EU level by an EU agency would be optimal (depends on the outcome of the legislative proposals put forward by the Commission on 07/12/2023 on sharing activities among EU agencies in the area of chemicals). Central coordination (EU level) includes global planning for the surveys, harmonisation, data collection, data exploitation at the European level.
- Involves national nodes who will provide the data (harmonised procedures). Mandatory participation or not is still an open question and would depend on a legislative framework setting reporting requirements against policy targets.
- Laboratory network with harmonised procedures for analytical assays. The HBM laboratory network could be organised for this purpose on a stand-alone basis or as part of a European ESFR/ERIC, e.g. EIRENE (WP9). A sustainable QA/QC programme should be established with a central coordination. There are several similar organisations in Europe, e.g. for Genetically Modified Food and Feed or in the area of public health and infectious diseases⁴.
- The foreseen activities are mostly dedicated to targeted quantitative assays but they could involve untargeted assays for emerging substance detection (the detection of emerging substances is also an item of the proposed “one substance, one assessment” legislative proposals).
- Data storage, protection and quality and Data analysis should be clearly described (WP7).
- The work on HBM sustainability will be carried out in close collaboration with WP4 (task 4.1).
- It is also important to consider the international development outside the EU, for example make linkages/synergies with regularly recurrent requirements for reporting of HBM data under the Stockholm Convention and Minamata Convention on exposure to certain chemicals, or with the recent establishment of the HBM Partnership under the World Health Organization as one of the outcomes of the 7th ministerial conference on Environment and Health held in Budapest 5-7 July 2023.

³ In the legislative proposal on Common Platform for Chemical data art 23 " The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it the new Union acts under which relevant chemicals data is generated or submitted." This may leave an option for a legal obligation to generate HBM data

⁴ <https://gmo-crl.jrc.ec.europa.eu/NRLs#inline-nav-2> ; https://health.ec.europa.eu/medical-devices-vitro-diagnostics/eu-reference-laboratories-eurls_en

2. Environmental monitoring

- Comprehensive environmental monitoring should complement currently available monitoring schemes (water, air, soil, food) performed by MS and collected and analysed by EU agencies (EEA and EFSA) to whom MS have a legal obligation to transmit data. Any extension should follow the same pattern of organisation, and synergies shall be used to enhance collaboration and efficiency. Significant extensions are likely to be very difficult as they will require thematic legislation and additional resources in Member States and centrally.
- Some NHs and/or partners suggested that more focus is needed on soil, indoor air, drinking and wastewater, biota, in addition to currently available monitoring.
- The specific matrix/matrices to be monitored should be clearly defined in accordance with regulatory needs and any associated data gaps.
- Ensure central coordination at the EU level by an EU agency (depends on the outcome of the legislative proposals put forward by the Commission on 07/12/2023 on sharing activities among EU agencies). Central coordination (EU level) includes global planning for the survey, harmonisation, data collection, data exploitation at the European level.
- Involves national nodes who will provide the data (harmonised procedures).
- Laboratory networks for analytical assays are needed. Should they be dedicated to each matrix or global, part of an ESFRI/ERIC? It is suggested to follow the type of organisation for other networks in Europe (see above).
- Activities are mostly dedicated to targeted quantitative assays but could involve untargeted assays for emerging substance detection (the detection of emerging substances is also an item of the proposed “one substance, one assessment” legislative proposals).
- Data storage, protection and quality and Data analysis should be clearly described (WP7).
- This work should be carried out in close collaboration with task 4.2.
- Linkages to international networks and activities should be also taken into account, including the global multilateral environmental agreements such as the Stockholm Convention on POPs, Minamata Convention on Mercury or upcoming Plastic Treaty.

3. Data storage and access

- Critical for all PARC activities. For certain activities such as HBM, data storage and access should take into consideration the General Data Protection Regulation (GDPR).
- Should be established at the European level.
- Planned in the “one substance, one assessment” legislative proposal⁵: Common Data Platform for a one-stop shop access to data on chemicals which will subsume existing platforms such as IPCHEM.
- Collaboration with ESFRI/ERIC, e.g. EIRENE.
- Collaboration with WP7.

⁵ Proposal for a Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals - COM(2023) 779 final

4. Toxicology

- The proposal is to develop a permanent “European Toxicology Programme”, based on PARC activities (WP5 and WP6), supporting risk assessment in the EU, inspired at least partially by the US National Toxicology Programme and by previous proposals for an inter-agency EU toxicological programme (EU-TP)⁶.
- Activities could include: Methods development in experimental and computational toxicology needed for risk assessment; New Approach Methodologies (NAM) development and validation; Adverse Outcome Pathway (AOP) development (in collaboration with AOP-wiki); computational studies including artificial intelligence (AI); targeted studies addressing a critical question and not available through industry-commissioned studies.
- A central European coordination is preferred and several possibilities should be discussed: EU agency, JRC, ESFRI/ERIC This central organisation will coordinate the activities of national nodes.
- There must be a close interaction with EU Reference Laboratory for alternatives to animal testing (EURL ECVAM), EPAA (European Partnership for Alternative Approaches to Animal Testing), and Chemicals 2.0 proposal (Bergrenn and Worth, 2023). It is critical to ensure coordination and complementarities.
- Within PARC, close collaboration with WP5, WP6 as well as WP8, 9 and 7.

5. Safe and sustainable by design and early warning

- Complies with the Commission’s proposed legislative texts on “one substance, one assessment”: “early warning and action system and a framework of indicators”.
- Still at an early exploratory stage.
- Cooperate with EU initiatives in this field.
- Close interaction with Toxicology programme and non-targeted screening activities.
- Collaborate with WP8.

⁶ EU-TP, April 2019

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First survey on the exit strategy

This survey is carried out under Task 2.3 'Sustainability'. It is sent to all National Hub Contact Points (NHCPs) for completion by 15/06/2023.

The preparation of the exit strategy for the PARC activities that are most relevant to risk assessment is a critical objective of Task 2.3. It is in line with the Chemicals Strategy for Sustainability and aims at developing a framework ensuring the sustainability of the tools, networks and activities developed within PARC. The National Hubs (NHs) will be involved in the preparation of the exit strategy from the start of the partnership and in the different steps leading to the identification of the relevant frameworks for sustainability through different surveys and meetings. Other PARC bodies will also be strongly involved, such as the Governing Board and the Management Board, as well as the European Commission.

The aim of this first survey on the exit strategy is to ask the NHs which PARC activities should be sustainable at EU level. It also aims at developing some options for the most relevant management and technical operational systems to carry out those activities in the long term.

Sustainable activities are defined as activities that are carried out on a regular basis by a nominated organization (or organizations) with secured European and/or national funding. In some cases, such activities can be legally embedded.

Considering the design of PARC and the experiences from the HBM4EU project that made the implementation of a framework for a sustainable human biomonitoring in Europe a high priority, we have set up this survey to ask for your expertise and opinion on the activities that should also be sustainable. PARC covers a wide range of activities related to risk assessment. In this survey we have taken into consideration the recommendations formed in the HBM4EU project and we request you, on one hand, to confirm these conclusions concerning human biomonitoring and, on the other hand, to prioritize the other PARC activities that need to be sustainable.

Please be aware that this is the first in a series of surveys and discussions concerning the exit strategy and it will help us frame the following activities.

We ask all NHCPs to complete this survey in consultation with their NH members. One form should be submitted per country. In case more than one form needs to be submitted, please contact us. The collected information will be treated confidentially according to the requirements of the General Data Protection Regulation (GDPR). Data obtained from this survey will be saved and stored by the Portuguese National Institute of Health Doctor Ricardo Jorge (INSA) during the implementation and up to 5 years after the end of the PARC project. The data will be processed and analysed by Task 2.3 partners.

This survey should take you approximately 15 min to complete (but requires discussions within the NH before completion).

Thank you for taking the time to complete it.

If you have any questions, please contact us.

Task 2.3 co-leaders:

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Tamás Szigeti (szigeti.tamas@nnk.gov.hu)

Your name

* must provide value

Name of your institute

* must provide value

The country that you are representing

* must provide value

Your e-mail address

* must provide value

1. The HBM4EU sustainability task concluded that a sustainable human biomonitoring framework in Europe is a high priority. Do you agree with this conclusion?

* must provide value

- Yes
 No

reset

2. Should the participation of each Member State in the European human biomonitoring survey be mandatory or optional?

* must provide value

- mandatory
 optional
 no answer at this stage

reset

3. Which other PARC activities, in your opinion, should be sustainable? (Select all options that apply)

- Prioritization processes for substances
 Environmental monitoring (not already available)
 Non-targeted screening
 Toxicology: NAM development
 Toxicology: Development and implementation of NAM-based risk assessment strategies
 Computational toxicology
 Toolbox and models enabling the application of a safe and sustainable by design (SSbD) approach
 Capacity for data storage
 Access to data (environmental, human biomonitoring, risk assessment data of chemicals, etc.)
 Other chemical data flows

4. In your opinion, what are the 3 most important activities to be sustainable?

(One selection allowed per column)

	Priority No. 1	Priority No. 2	Priority No. 3	
Prioritization processes for substances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Human biomonitoring	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Environmental monitoring (not already available)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Non-targeted screening	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Toxicology: NAM development	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Toxicology: Development and implementation of NAM-based risk assessment strategies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Computational toxicology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset

Toolbox and models enabling the application of a safe and sustainable by design (SSBD) approach	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Capacity for data storage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Access to data (environmental, human biomonitoring, risk assessment data of chemicals, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Other chemical data flows	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset

4.1. Please explain your decision on the selection of the first priority.

* must provide value

Expand

5. What, in your opinion, is the most relevant operational system and host for each of the following activities?

	European agency or JRC coordination	Laboratory network	ESFRI facility	Other (please, specify)
Environmental monitoring (not already available) * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-targeted screening * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Toxicology: Development and implementation of NAM-based risk assessment strategies * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Toolbox and models enabling the application of a safe and sustainable by design (SSBD) approach * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Capacity for data storage * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Abbreviations:

JRC - Joint Research Center (https://joint-research-centre.ec.europa.eu/index_en)

ESFRI - European Strategy Forum on Research Infrastructure (<https://www.esfri.eu/>)

6. We have already asked you in a previous survey (First survey for mapping the needs of the National Hubs) to identify those activities that are already sustainable at national level.

Please provide further details on how the sustainability of each activity is ensured in your country (e.g. please specify the legal framework, funding scheme, type of organizations responsible for implementing, etc.).

If you have no information to provide please write NA (non applicable).

(Please note that specific questions were formulated for human biomonitoring in Question No.7.)

6.1. Prioritization processes for substances

* must provide value

Expand

7.7. If you would like to share further information on human biomonitoring, please provide it here.

Expand

8. If you have any suggestions or comments on the questions or in general, on the exit strategy, please describe it here.

* must provide value

Expand

THANK YOU FOR COMPLETING THE SURVEY!

Submit

Save & Return Later

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