Partnership for the Assessment of Risks from Chemicals

Deliverable D2.13

Title: 2nd Mapping of Needs Report

WP 2 – T2.1



Partnership for the Assessment of Risks from Chemicals

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[1] PU = Public
PP = Restricted to other programme participants (including the Commission Services)
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2	18/11/2025	Reviewers, Task 2.1 partners and NH CP comments	Suggestions for improvement
3	19/12/2025	Authors of the Deliverable	Final version

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Abstract

The priorities for the first half of PARC were mainly shaped by the legacy of the previous European project, HBM4EU (Human Biomonitoring Initiative in Europe), and also by key policy documents such as the Commission's "Chemical Strategy for Sustainability", the "Zero Pollution Action Plan" and the "Strategic Research and Innovation Plan for Safe and Sustainable Chemicals and Materials". Additional factors included regulatory needs identified by Workpackage co-leaders (WPLs) and Task Leaders, discussions with EU-agencies, the hazardous properties of substances, available data and knowledge gaps, partners' interests and capacities, interactions with other PARC Workpackages (WPs) or Tasks , and relevant scientific activities outside of PARC (see deliverable 2.1). Also, since the WPs cover different topics, the prioritisation criteria and the factors taken into account were not the same for all of them.

This deliverable describes the second prioritisation round, which helped define the needs and priorities for the second half of the Partnership (years 4 to 7). PARC's priorities, for years 4 to 7, have been set considering the initial needs expressed by the Governing Board Principal Representatives (GBPRs) in 2023. These needs have been extensively discussed with WPLs, and later with other PARC parties. Initially, topics for which at least 3 needs were expressed by GBPRs in a task were retained, and all the needs expressed by the EU agencies (ECHA, EFSA, EEA) or the European Commission were selected. For each topic, e.g. a substance, (eco)toxicological endpoint or method, a dedicated factsheet was created. In a second step, topics and specific needs were discussed with the Management Board, Task 2.1 (Priority Setting) partners and Chemical and Methodology Leaders (where applicable). Then, a consultation phase began, mainly involving the consultation of the National Hubs, Stakeholder Forum, and International Board. Finally, the GBPRs were asked to select 15 needs of interest from the long list of approximatively 90 needs. The result was a list of ranked needs and the definition of the 17 top needs, i.e., those that received at least 6 votes. The complete list of needs, whose regulatory relevance was assessed in more detail by Task 2.1, was communicated within the PARC consortium. Thereafter, those selected by the consortium will be translated into projects for the coming years of the Partnership, ensuring a top-down <-> bottom-up approach. Project proposals will then be assessed via the project review process established in Task 2.1, ensuring the regulatory context, consistency, intra-PARC collaboration, timing and specificity.

Key Words

Prioritisation round, new priorities, policy need, regulatory needs, regulatory relevance, mapping of needs, KARC.

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Acronyms

CL: Chemical leader[1]
CRA: Chemical Risk Assessment
D: Deliverable
EC: European Commission
ECHA: European Chemicals Agency
EEA: European Environment Agency
EFSA: European Food Safety Authority
GB: Governing Board
GBPR: Governing Board Principal Representative
IB: International Board
KARC: Key Areas of Regulatory Challenge
MB: Management Board
ML: Methodology leader
NH: National Hub
PDD: Project Description Document
RRM: Rapid Response Mechanism
SF: Stakeholder Forum
T: Task
TL: Task Leader
WP: Workpackage
WPL: Workpackage leader

In this deliverable, PARC WPs and Tasks will be mentioned several times, therefore, for easier reading and understanding, please find below titles of these corresponding Tasks and WPs (2-4-5-6):

WP2: A common science-policy agenda
-Task 2.1: Priority setting
-Task 2.2: Knowledge management and uptake into policy
-Task 2.3: Sustainability and exit strategy
WP4: Monitoring and Exposure
-Task 4.1: Human Biomonitoring
-Task 4.2: Environmental and Multisource Monitoring
-Task 4.3: Innovative methods and tools for monitoring and surveys
WP5: Hazard Assessment

[1] PARC has a strong team of leading experts that have taken on the pivotal roles of Chemical Leader (CL) or Methodology Leader (ML) for priority substances/methods within PARC. CL or ML have an overview of the chemical or methodology within all PARC projects and help connecting and advancing those projects, to contribute to evidence-based decisions by policy makers, and to help communicate and disseminate new scientific discoveries to the wider public. The contact list of CLs and MLs is available on the PARC website: link.

-Task 5.1: Toxicity testing addressing data gaps of Concern
-Task 5.2: Innovative methods and tools for toxicity testing and modelling
-Task 5.3: Quantitative Systems Toxicology and development of new AOPs and PBPK

WP6: Innovation in RA

-Task 6.1: Integrated Approaches to Testing and Assessment of Chemicals
-Task 6.2: Integrative exposure and risk assessment
-Task 6.3: Review of risk assessment methodologies
-Task 6.4: Transposing results to regulatory risk assessment methodologies

For more information on the PARC WPs, please consult the PARC webpage (link).

1. Introduction

Under WP2, titled 'A common science policy agenda', the primary objective is to establish strong and effective connections between the research community and the regulatory system to foster innovation and enhance protection. Consequently, Task 2.1, 'Priority Setting', is responsible for mapping needs and prioritising activities within PARC, as well as ensuring a robust project review process.

This deliverable deals with the second prioritisation round that was conducted in view of defining the needs and priorities for future activities for the second part of PARC (i.e., years 4 to 7). This process, led by Task 2.1, started in June 2023 and a first deliverable D2.4 "1st Mapping of Needs report" submitted in February 2024, outlines the initial stages of this process, principally the needs mapping survey and the compilation of feedback, as well as an overview of the proposed next steps. The present deliverable presents the steps taken since that first deliverable and also the results obtained to date. Indeed, since then, the topics, i.e., substances, methods and effects, have been classified and extensively discussed, needs have been assessed, a consultation phase has also taken place and included the Stakeholder Forum (SF), the National Hubs (NHs), the International Board (IB) and the Governing Board (GB). In this prioritisation round, the EU agencies in PARC (ECHA, EFSA, and EEA) and the European Commission (EC) were actively involved, either by expressing regulatory-relevant needs they had identified or by contributing during the consultation and needs assessment phases.

As mentioned above, the end goal of this exercise was to feed the Partnership's workplan for future years while addressing relevant needs in the chemical risk assessment (CRA) field. Indeed, the different WPs in PARC include activities and tasks, and these tasks, in turn, include various projects. PARC projects undertaken under different WPs can sometimes complement each other and cover different aspects of the same need / topic. There are also WPs with transversal activities, such as WPs 7, 8 and 9. WP 7 ensures that data and associated information are Findable, Accessible, Interoperable, and Reusable (FAIR) and, WP9 aims to facilitate the establishment and maintenance of the capacities needed to address current, emerging, and novel challenges in chemical hazard, exposure, and risk assessment. WP 8 supports the development and consolidation of new concepts and tools that address key challenges of the Chemicals Strategy for Sustainability. WP 7 and WP 9 are more reliant on the priorities of other WPs and WP 8 is closely linked to the EC priorities. Therefore, throughout this deliverable, focus was only made on the needs related to WPs 4, 5 and 6 as the mapping of needs exercise only focused on these 3 WPs for the definition of future projects to be implemented.

Furthermore, as in previous prioritisation rounds, an evaluation was conducted to determine possible improvements for the next round and to identify the main strengths. For the first round, this was achieved through Focus Group Discussions, as described in the publication by Permana et al. (2025)[2]. In the second round, a questionnaire was shared with the involved PARC bodies, and the results are presented in this deliverable.

2. Prioritisation process overview

The second prioritisation process involved several steps that are detailed below and presented in Figure 1. Several PARC bodies were involved in this process, which was essential to accomplish the work and to reach a broad consensus given the scale of the Partnership and the importance of including all stakeholders. Particular weight was given to entities with greater regulatory authority and relevance in setting priorities (GB and EU agencies), while also ensuring that bodies ultimately responsible for implementation had their say in the process (Management Board (MB) and Task Leaders (TLs)).

[2] Collecting perspectives on project prioritisation process in the EU co-funded multinational partnership for the assessment of risks from chemicals (PARC) through focus group discussion (https://doi.org/10.1186/s12302-024-01041-1)

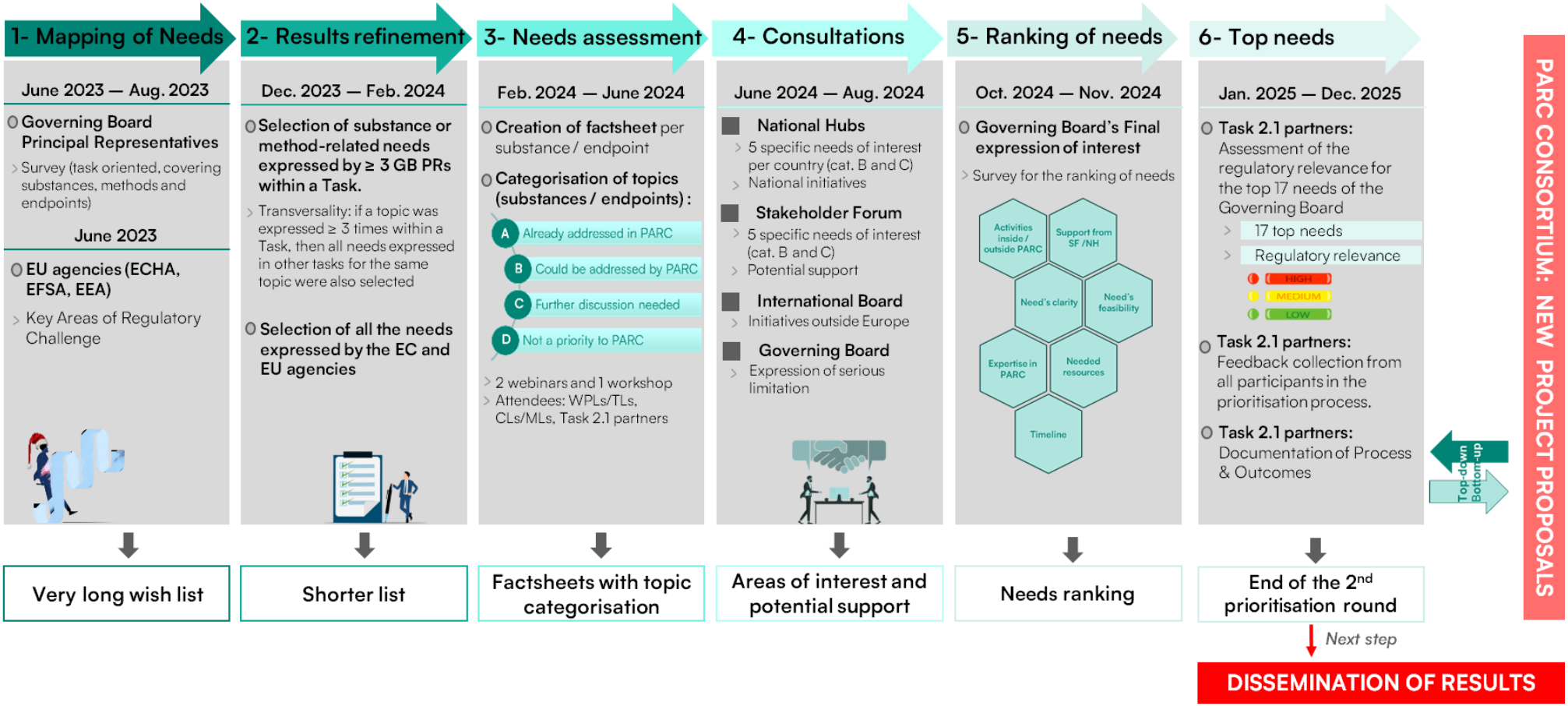


Figure 1: Overview of the different steps of the second prioritisation process of PARC

2.1 Involvement of the different PARC bodies

As will be shown in the following sections, different PARC bodies were involved in this process; an overview of their participation in the different steps of the process is presented in Figure 2. Indeed, certain steps required the participation of multiple bodies simultaneously. This collaboration, coordinated under Task 2.1, was essential to ensure the robustness of the overall process.

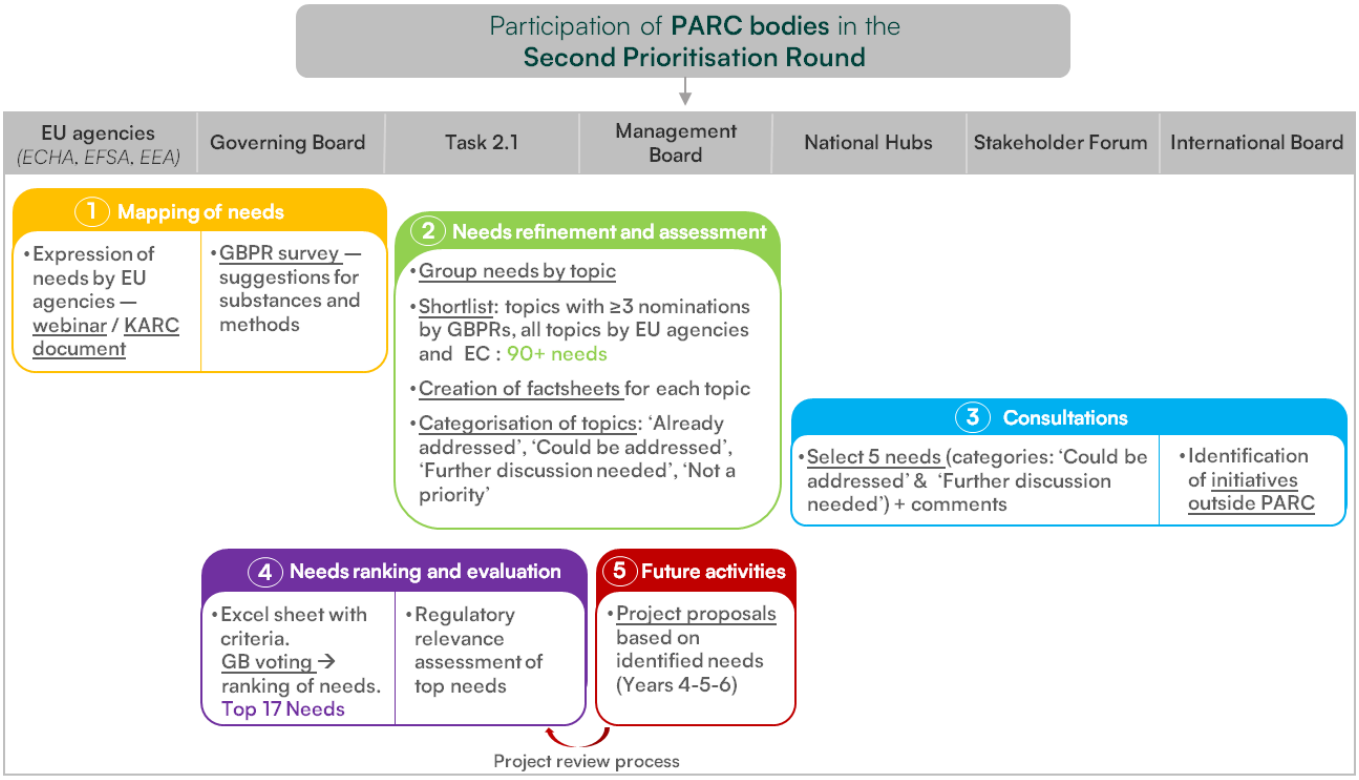


Figure 2: Overview of the involvement of different PARC bodies in the 2nd prioritisation round of the Partnership

2.2 Mapping of needs and results refinement

As described in D2.4, Governing Board Principal Representatives (GBPRs) expressed needs they have identified through the "Mapping of Needs" survey that was prepared by Task 2.1 and shared with them on 13 June 2023. By 25 August 2023, feedback had been received from the EC and the following 25 countries: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Luxembourg, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

The survey was Task oriented; it was possible to suggest new substances / methods / endpoints to be addressed by a PARC Task, specifying the regulatory / policy need for each. This was done for Tasks of WPs 4, 5 and 6. However, at the end of the questionnaire, GBPRs had the opportunity to provide suggestions for WPs 7, 8 and 9; the compilation of these suggestions is presented in Appendix 1.

The example below shows one of the survey questions related to Task 4.1. For more details on the questionnaire, please refer to D2.4, in the appendix (link).

Task 4.1: Human biomonitoring
Substances / groups of substances currently addressed under Task 4.1 on human biomonitoring for the **general population** are: *biocides, pharmaceuticals/hazardous medicinal products, plant protection products, PFAS, BPA/BPA alternatives/BPA analogues/Bisphenols, metals, mercury, arsenic, phthalates, emerging chemicals, mixtures.*
In your opinion, are there other additional substances / substances groups that should be addressed under Task 4.1 for years 4 to 7 of PARC?

- No

- Yes
  - Please add your suggestion (you can add up to 3 suggestions, start with the high priority one)
  - Kindly explain the regulatory/policy need for every suggestion otherwise your request will not be taken into account (If possible, specify the regulation reference + which process, if possible, e.g.: REACH restriction, classification, development of methods for endpoints for the information requirement, BPR, surface and drinking water …)

As a first step, the suggested needs were organised by grouping all needs related to a specific topic (such as a particular substance or group of substances, methods, or endpoints) under a single task. For each topic, the total number of proposals received, under each task, was then counted (see D2.4). The list of suggested needs was then shared with the MB and Task 2.1 partners to agree on the appropriate subsequent actions.

To assess the needs, a refinement step was needed and consisted in shortening the long list of needs by selecting topics nominated at least 3 times by GBPRs under a task, and all topics expressed by the EU agencies (ECHA, EFSA, EEA) in PARC or the EC. Indeed, as previously mentioned, the EC has filled in the questionnaire and expressed some needs. Also, these EU agencies organised a webinar on 14 June 2023 to express their areas of interest to PARC Workpackage co-leaders (WPLs) and TLs. During this webinar, ECHA presented the Key Areas of Regulatory Challenge (KARC) document which were also published in 2023 (link to the report). EFSA and EEA also shared their requirements during the webinar. Among other topics, EFSA's focus was on the further development of NAMs, while the EEA focused on the need for data to support the CSS indicators.

During the selection of needs, the transversality between the different Tasks and WPs was also considered. For example, for a specific selected topic, which received 3 nominations by GBPRs under a Task or nominated by the EC or one of the EU agencies, all the suggested needs related to that topic in other Tasks or WPs were also kept for the shortened list.

It is important to note that at this stage, some needs were very specific while others were very broad and some required clarifications. Also, the grouping of substances or some topics still needed to be discussed and better shaped.

2.3 Needs assessment

Factsheets were drafted for each selected topic. The factsheets document was considered as a working document and evolved throughout the process (final version available on the SharePoint: link[3]). For each topic, the factsheets included the suggestion, the objectives, the regulatory question, the concerned WP/ Task and the number of nominations, according to the information provided in the survey or in the KARC document.

For the needs related to nanomaterials and micro- or nanoplastics, the MB decided to start by mapping out what is already ongoing on these topics outside PARC and then, evaluate how PARC could contribute. Thus, chemical leaders (CLs) were appointed by Task 2.2 (Knowledge Management and uptake into policy) to prepare a state-of-the-art review (for further information please see section 3.7). No factsheets were therefore included for the needs on nanomaterials and micro- or nanoplastics.

To assess the needs, two webinars and one workshop were prepared and organised by Task 2.1.

The webinars were held on the 21st of February 2024 and on the 1st of March 2024 and ran for 2 hours each. Participants mainly included Task 2.1 partners, WPLs, TLs/CLs and methodology leaders (MLs) (when applicable). The purpose of organising two webinars, both having the same objective, was to allow maximal participation and accommodate the differing availabilities. The main agenda items of both webinars were to:

1/ Discuss how the KARC identified by ECHA in 2023 are addressed in PARC, and in cases where they are not, whether they could be or are planned to be addressed by PARC.

[3] Please note that the SharePoint link only works for PARC partners who are granted access to the SharePoint. As factsheets were used as working document, they were not made public. However, the document can be made available upon request to the PARC coordination team: parc@anses.fr.

Prior to the webinar, an extraction of the KARC needs was made and shared with the WPLs, TLs and T2.1 partners who were asked to complete the document by indicating:

a- if the need is in the scope of PARC,

b- which WP is concerned and

c- if the need is already addressed or is planned to be addressed in the upcoming annual workplans.

During the meeting, the different needs were discussed and the input from the participants were simultaneously added to the document.

2/ Discuss the needs identified from the GB survey. At that time, 31 factsheets were already drafted for the different topics. The collaborative platform 'Klaxoon' was used to ensure proactive input from all participants and gather the different views regarding the expressed needs. During the meeting, an overview of the various factsheets was carried out where participants could add their insights and provide comments either by adding them to coloured notes on the 'Klaxoon' board or by asking for the floor. Comments provided orally were added to the Klaxoon notes by the moderator to ensure the board was always complete and brought together all input. Figure 3 is a screenshot from the 'Klaxoon' board regarding "Benzophenone and UV filter" where only 1 need was nominated, by the EC, under Task 4.1. The screenshot shows some feedback provided by WP4 co-leaders and Task 4.1, 4.2 and 4.3.

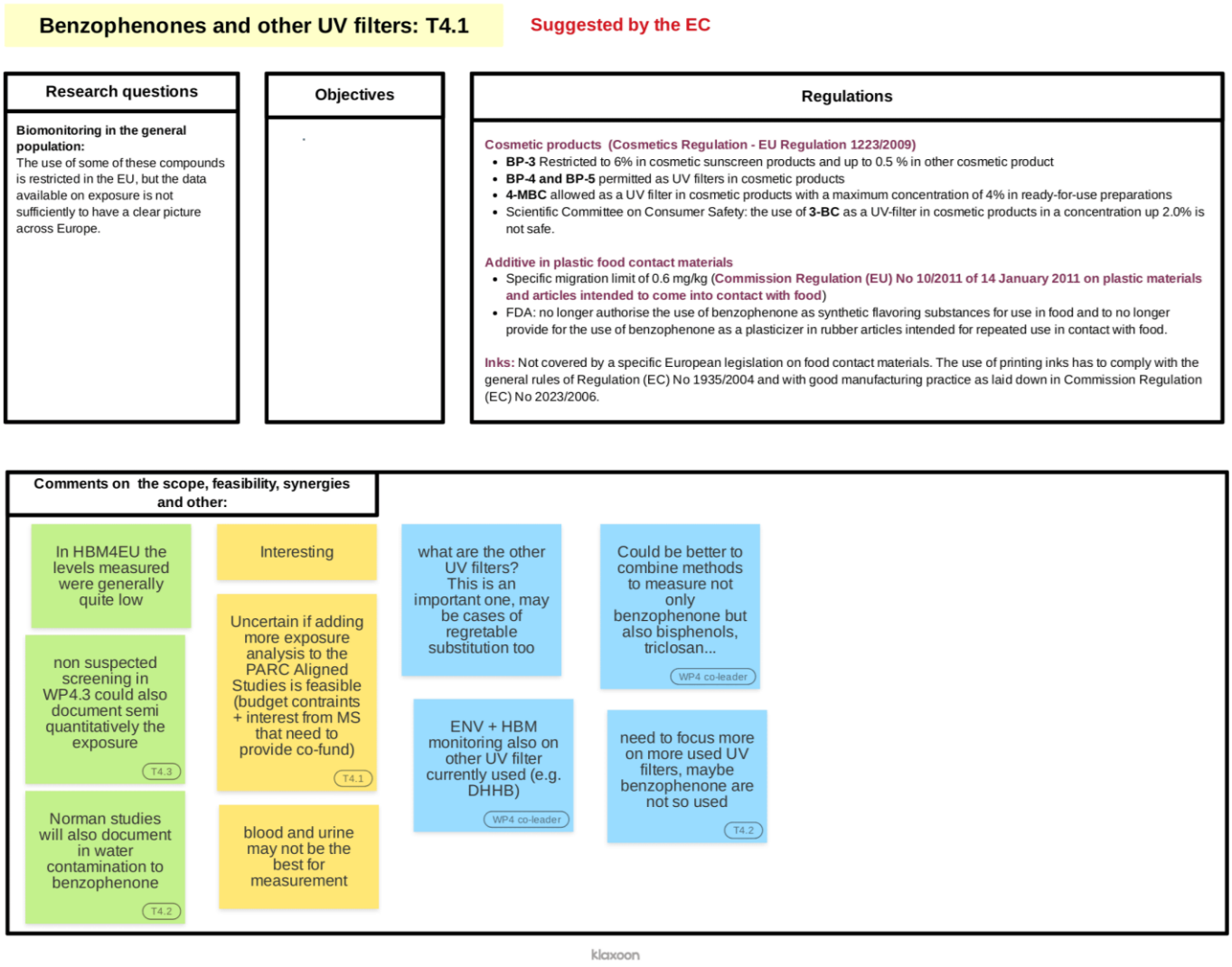


Figure 3: Screenshot from the 'Klaxoon' board on the topic "Benzophenone and UV filter".
(In this figure, there is no colour coding; the added notes have random colours.)

These two webinars were essential to prepare for the workshop on PARC Future activities which was planned on the 11th and 12th of March 2024.

The workshop was hosted by ANSES (France), online participation was also possible. In total, around ten PARC MB members participated in person, along with around fifty other online participants. Discussions focused mainly on the needs and the capacity of the various WPs to integrate new activities, taking into account the resources and work already underway (e.g., projects that will be extended). The PARC EU agencies had also introduced the workshop by reminding their areas of interest. Furthermore, EEA prepared seven new factsheets representing topics that are of interest to them.

The discussions at the workshop were very fruitful, and resulted in the classification of **topics** into four categories:

- **Category A:** 'Already addressed in PARC': this category includes topics that are addressed by PARC *via* some of its projects. Thus, project IDs[4] of the projects addressing this topic have been added to the related factsheets. It should be noted that even if a topic is addressed in PARC this do not imply that all identified needs expressed under this topic are addressed in PARC (i.e., needs expressed under this topic could be fully addressed, partially addressed or even not yet addressed in PARC). Even though some of the needs in this topic are already addressed by PARC, they were still included in the factsheet to support the continuation of the work in the upcoming years.
- **Category B:** 'Could be addressed by PARC': this category includes topics that are not yet addressed in PARC but are in the scope of the partnership. It will be important to check if there is expertise in the PARC consortium to address this topic and partners willing to put resources for this activity.
- **Category C: '**Further discussion needed': this category includes topics for which it is not yet clear whether they can be addressed by PARC or whether they are not a priority for PARC and thus, need further discussions.
- **Category D: '**Not a priority for PARC': this category includes topics not directly in the scope of PARC or for which there is limited added value from PARC. It could also imply that methods or tools currently available to address these needs are not available and would take too much time or resources to be ready for PARC to add value to the question.

It is also important to mention that, throughout these steps, it was possible for WPLs, TLs or Task 2.1 partners to identify topics or needs, from the long list, that were not initially selected and include them in the factsheet or create new factsheets (e.g., the factsheet on Biodiversity that was later added to the list). It was however not possible to nominate additional needs than the ones suggested by the GBPRs or the EU agencies or modify the nominated needs.
It was also possible to group some topics that were not initially grouped (e.g., the grouping of 'Chemicals leaching from plastics and rubber tyres' with 'Para-phenylenediamines like 6PPD and its metabolite 6PPD-Quinone'). Indeed, merging topics and merging needs was possible throughout the whole process, in order to refine the factsheets.

The factsheets were updated taking into account the discussions and the input from the different partners during the webinars and the workshop. Therefore, additional sections were included:

- Timeframe to deliver results: this section mentions if there is a specific policy agenda that impacts the relevance of the results.
- Feasibility discussion: this section summarises the discussions during the webinar and the workshop on the feasibility of addressing the need under PARC (in terms of available expertise and resources).
- Related project inside PARC: this section lists IDs of the projects addressing the topic, for the topics already addressed in PARC.
- Related activities outside PARC: this section lists the activities outside PARC that are related to this topic to avoid duplication of work.

The new version of the factsheets was then shared with the MB and Task 2.1; the categorisation of the topics was also presented at the physical MB meeting on the 13th of May 2024 at Hall in Tirol, Austria. During this meeting the next steps of the consultation phase were also discussed. A similar presentation was also made at the GB

[4] Each PARC project has a project ID created as follow: P<x.y.z.zz.i>_Y<n>_<Project Acronym>_<Project Manager Institute Acronym>, *x: WP number, y: task number, z: activity number, zz: sub-activity number, i: letter from a-z for project incrementing, n: Starting Year number*

meeting on the 15th of May 2024 in Austria to gather the members' initial views on the process. Positive feedback was received on the planning and the next steps.

Overall, the discussions and the assessment of the needs were key for the next phase of this prioritisation round: the consultations of different PARC bodies.

2.4 Consultations

Once the list of needs by topic and the categories were established, a new consultation phase began, mainly involving the consultation of the NHs, the SF, the IB and the GB.

This sub-section describes the purpose and approach used for each of the consultations that have taken place between June and August 2024.

- **Consultation of the National Hubs**
  Consultation: NHs were asked to select 5 needs of interest from the topic categories B and C ('Could be addressed by PARC' or 'Further discussion needed') to support their inclusion in future PARC activities. NHs were also asked to indicate national initiatives addressing the needs expressed in the factsheets for the topic categories A, B and C.
  Shared documents: The factsheets and a supportive document detailing the process of the mapping of needs and the different steps to date as well as the expectations from the consultation was shared to support this step.
  Method: During a NH Contact Points (NHCPs) meeting on the 4th of June, 2024, a presentation on the overall process and an introduction of the consultation phase was made. The feedback from the NHs on their 5 needs of interest was collected using an online form 'Response form for the consultation of National Hubs on the PARC Future Activities'. To gather feedback from the NHs, the best option would have been to submit one response per country by completing the response form. This option requires the implication and coordination by the NHCPs and the discussion of the priorities within the NH organisations. It was later agreed that, in cases where the NH was not able to provide a single response, each partner of the NH could response to the questionnaire individually. In this case, Task 2.1 compiled the feedback of the different organisations from this NH and considered the top 5 selected needs. Moreover, in the event of equivocal results and the inability to decide on top 5 needs, Task 2.1 approached the corresponding NHCP to finalise the choice.

- **Consultation of the Stakeholder Forum**
  Consultation: SF members were asked to select 5 needs of interest from the topic categories B and C in order to support their inclusion in the future PARC activities. SF members were also invited to provide any comments or additional information related to the needs (in the categories 'Already addressed in PARC', 'Could be addressed by PARC' or 'Further discussion needed') and indicate if they can provide support (standard/data).
  Shared documents: The factsheets and a supportive document detailing the process of the mapping of needs and the different steps to date as well as the expectations from the consultation was shared to support this step.
  Method: The feedback from each SF member was collected throughout an online form 'Response form for the consultation of Stakeholder Forum on the PARC Future Activities'. At the end of this consultation phase, a meeting with the SF members was held in order to provide, if possible, one answer on behalf of the SF regarding their 5 needs of interest (based on the most frequently selected needs).

- **Consultation of the International Board**
  Consultation: IB members were asked to inform PARC about any initiative outside Europe that could provide support to some of these nominated needs.
  Shared documents: The factsheets and a supportive document detailing the process of the mapping of needs and the different steps to date as well as the expectations from the consultation was shared to support this step.
  Method: Task 2.1 approached the contact point of the IB, which distributed the consultation request to the various members. Afterwards, a meeting was planned to discuss with the various board members about the list of needs and gather their feedback on current initiatives to avoid duplication of effort.

- **Consultation of the Governing Board**

GB members were asked to first identify some serious limitations in the suggested activities for the second half of PARC or any strong disagreement with the suggested categorisation of needs. They were also asked to indicate, if possible, for the different needs (except the ones classified as not a priority for PARC), the ideal timeframe to deliver the results according to the policy agenda. GB members could provide their input directly on the factsheets.

2.5 Ranking of needs

Task 2.1 co-leaders prepared an Excel sheet to facilitate the reviewing of the needs. In the Excel sheet, each row represents a specific need, with the following information organised in columns:
a) main topic
b) topic category (options: already addressed, could be addressed, to be discussed, not a priority)
c) need ID (format: Topic.NeedNumber)
d) brief description of the need
e) whether the need is addressed in PARC (yes, no, partially)
f) related Task
g) countries that initially nominated the need
h) clear relevance to PARC (yes, no, partially, unsure)
i) related activities within PARC
j) related activities outside PARC
k) feasibility
l) availability of expertise within the current PARC consortium
m) expected timeline for concrete results within PARC activities (short-term: 1-2 years, mid-term: before PARC ends, long-term: after PARC ends)
n) level of extra resources needed (if already budgeted in PARC, then “low”; if not budgeted and development of analytical methods, NAMs, or IATA is required, then “medium” or “high”)
o) support from SF members (number of supporters who responded)
p) support from NHs (number of supporters who responded)

The table was reviewed and completed by the MB.

A final column was left blank for GB members to place a mark beside the 15 needs they are most interested in supporting. Indeed, on 18 October 2024, GBPRs were requested to select 15 needs of interest from a list of approximately 90. To ensure the process was clearly understood, Task 2.1 organised two Q&A sessions on 29 and 30 October 2024 to address any questions related to the process or the needs.

Results from the voting were presented during the GB meeting on 13 November 2024 where final approval of the ranked needs was obtained. The result was a shortlist of the 17 top needs, those that received at least 6 votes.

2.6 Top needs

The regulatory relevance of the top priorities (i.e., the ones that received at least 6 votes from the GB) was assessed by Task 2.1 partners. Three levels of regulatory relevance were assigned to the various needs: high, medium, or low. For the 6 participating Task 2.1 partners, if a particular need fell outside the mandate of their institution, it was not evaluated.
Task 2.1 partners are currently organising the dissemination of the results of this prioritisation round so that they are accessible to all stakeholders of PARC, as well as to initiatives outside PARC that may wish to address relevant regulatory needs.

3. Results

3.1 Topics overview

Selected topics for which factsheets were created are presented in Figure 4. For this overview, topics were divided based on whether they represent chemical groups, endpoints, or tools/methods. However, some needs within the topics may span multiple categories, involving chemicals, endpoints, and tools simultaneously. To sum up, factsheets were drafted for twenty-two chemical groups, classified either by chemical structure, usage, complex mixtures, environmental fate or are material-related; as well as for five endpoints and six tools/methods. Of the twenty-two chemical groups, twelve were already addressed in PARC, seven were new topics requiring further discussion, and three were deemed low priority. Among the five endpoints and six tools/methods, one endpoint and two tools/methods represented new topics, while the remainder had previously been covered in PARC.

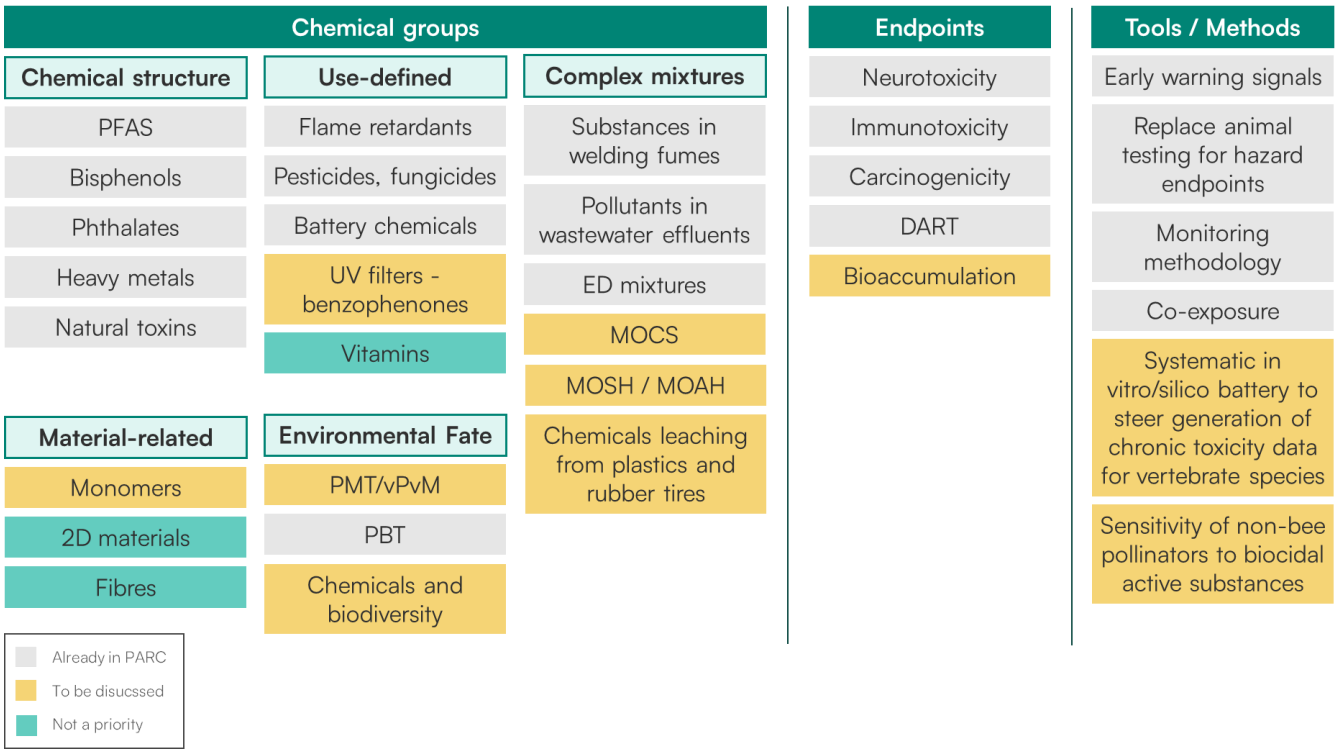


Figure 4: Overview of the topics (chemical groups, endpoints and tools / methods) selected following reduction of the long wish list of needs
Abbreviations: DART: Developmental And Reproductive Toxicity; PMT/vPvM: Persistent, Mobile and Toxic; very Persistent and very Mobile; PBT: Persistent, Bioaccumulative and Toxic; MOCS: More than One Constituent Substances; MOSH / MOAH: Mineral Oil Saturated / Aromatic Hydrocarbons

As previously explained, nanomaterials and micro- or nanoplastics were treated separately and were not included in the factsheets.

3.2 NH consultation

In total, 21 NH countries (out of 29 consulted) completed the online form expressing their top 5 needs of interest. As mentioned in section 2.4, countries were provided the flexibility to choose between submitting a single national response or individual NH member responses, depending on the feasibility of reaching a consensus at the country level. Feedback was received from the following NH countries: Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Israel, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland, United Kingdom.

Among these countries, compilation was made for Germany, Denmark, Switzerland and Belgium, indeed, several responses were received from their NH members; corresponding NHCPs were consulted about the results.

It is important to mention that, after having started the consultation phase, a request came from the German GB representative suggesting to ask NHs if they support the inclusion of Brominated Flame Retardants in the PARC Aligned Studies. Indeed, this need was included in the factsheet of 'Flame retardants', a topic categorised as 'already addressed in PARC' for which NHs did not have the option to vote for. Therefore, a question on this was subsequently added to the online form shared with the NHs.

Table 1 presents the results of this consultation; grey lines represent the topics (the ones from the categories 'Could be Addressed by PARC' and 'To be discussed') and the white lines represent the specific needs expressed for the different topics, for which the total number of votes from the different countries is indicated.

Table 1: Overview of the feedback received from NHs on their top 5 needs of interest

Topics / needs	Number of votes
Benzophenones and UV filters	
Collection of exposure data across Europe	9
Bioaccumulation	
Development of new methods and assessment approaches to evaluate the bioaccumulation potential of super hydrophobic substances which used to be overlooked due to the assumption that they are non-bioaccumulative	1
Improvement of assessment of secondary poisoning and man *via* environment specially for mixtures	1
Most bioaccumulation assessment are currently done on aquatic animals however certain substances are not bioaccumulative in aquatic animal but in air-breathing organism. Risk assessment method is needed	2
Rapid contaminant screening assay adapting a biophysical assay to classify drug molecule mammalian plasma membrane permeability, matching organism lipid/ sterol composition to published data, in order to address knowledge gaps in understanding bioaccumulation and biological effects of contaminants of emerging concern	2
Characterisation of More than One Constituent Substance (MOCS)	
Characterisation of MOCS	7
Chemicals and biodiversity	
Expand protection of biodiversity by the use of NAMs	1
Investigate on how to better address the effects of chemicals on biodiversity	3
Methods to assess the effect of chemicals on biodiversity	5
Use monitoring data (in the absence of human biomonitoring) to inform about the exposure levels of chemicals mixtures and potential threats on ecosystem services or biodiversity	3
Chemicals leaching from plastics and rubber tyres	
Close data gaps on chemicals leaching from plastics on human health, including non-intentionally added substances to plastics	10
Environmental monitoring on fate and behaviour of tyre additives	5
Human biomonitoring and exposure pathways	7
Chromium	
Environmental and multisource monitoring: Cr (III) toxic for aquatic organisms	1
Methods capable of distinguishing exposure to Cr(VI)-substances from exposure to other Cr-substances (Cr(III), Cr(0))	5
Mineral oil saturated hydrocarbons (MOSH) and Mineral Oil aromatic hydrocarbons (MOAH)	
Close data gaps	2
Human biomonitoring	5
Monitoring in food	1
Monomers of Polymers and biodegradable polymers	
Close data gaps on polymers and biodegradable polymers (environment)	2
Development of knowledge and methodologies to support hazard assessment of Polymers including rubbers	4

New methods to evaluate potential of PFAS polymers and precursors to form stable terminal PFASs	5
Persistent Mobile and Toxic substances (PMT)/ Very persistent and very mobile substances (vPvM)	
Development of approaches based on monitoring field data enabling persistence, long-range environmental transport and/ or bioaccumulation assessment	6
Innovative tools and methods for toxicity testing of chronic aquatic and soil toxicity	3
Monitoring in soil, water and biota	7
Review of the impact of new CLP hazard classes, including PMT and vPvM, on the procedure and the methodologies to derive environmental limit values	4
Sensitivity of non-bee pollinators (NBP) to biocidal active substances	
Data generation to evaluate the acute contact and oral toxicity in arthropod pollinators and compare the sensitivity between NBPs and honey bees. There is currently no method to assess toxicity in NBP as research is focused on bee.	3
Inclusion of Brominated Flame Retardant in HBM	**21**

All NHs were in favour of including brominated flame retardants in the Human Biomonitoring studies in PARC (21 votes in total).

Needs that received highest support from the NHs are:

- Closing data gaps on chemicals leaching from plastics on human health, including non-intentionally added substances to plastics (10 votes),
- Collecting exposure data across Europe for benzophenone and UV filter (9 votes),
- The characterisation of MOCS (7 votes),
- Human biomonitoring and exposure pathways for Chemicals leaching from plastics and rubber tyres (7 votes),
- Monitoring PMT/vPvM substances in soil, water and biota (7 votes).

Number of votes for all the needs were included in the factsheets and in the document sent to the GB to guide their final voting. France and Denmark's NHs also provided some feedback on the factsheets, which was considered when relevant.

It is important to note that the grouping of topics and the factsheets evolved throughout the whole process. Therefore, some needs were merged with others and some needs were moved under other topics, for example the needs expressed for chromium, which were later on grouped under the topic 'heavy metals'. Please refer to section 3.1 for the final grouping of topics for which factsheets were created.

3.3 SF consultation

Nine out of 15 SF members answered the survey providing their top 5 needs of interest, presented in Table 2:

- CHEM Trust
- Cosmetics Europe
- Eurometaux
- European Chemical Industry Council, Cefic
- European Environmental Bureau, EEB
- European Network for Environmental Medicine, EnvMed Network
- Food Packaging Forum
- Plastics Europe
- SMEunited

Table 2: Overview of the feedback received from the SF on their top 5 needs of interest

Topics / needs	Number of votes
Benzophenones and UV filters	
Collection of exposure data across Europe	4
Bioaccumulation	

Improvement of assessment of secondary poisoning and man *via* environment specially for mixtures	1
Characterisation of More than One Constituent Substance (MOCS)	
Aggregated exposure from Mixtures in view of MOCS	3
Characterisation of MOCS	2
Chemicals and biodiversity	
Development of a (Next Generation Risk Assessment) NGRA	2
Methods to assess the effect of chemicals on biodiversity	1
Use monitoring data (in the absence of human biomonitoring) to inform about the exposure levels of chemicals mixtures and potential threats on ecosystem services or biodiversity	1
Chemicals leaching from plastics and rubber tyres	
Close data gaps on chemicals leaching from plastics on human health, including non-intentionally added substances to plastics	2
Environmental monitoring on fate and behaviour of tyre additives	1
Human biomonitoring and exposure pathways	4
Chromium	
Methods capable of distinguishing exposure to Cr(VI)-substances from exposure to other Cr-substances (Cr(III), Cr(0))	2
Mineral oil saturated hydrocarbons (MOSH) and Mineral Oil aromatic hydrocarbons (MOAH)	
Human biomonitoring	2
Monitoring in food	1
Monomers of Polymers and biodegradable polymers	
Close data gaps on polymers and biodegradable polymers (environment)	2
Development of knowledge and methodologies to support hazard assessment of Polymers including rubbers	1
Monitor the implementation of the requirement to register polymers under REACH (when it happens)	4
New methods to evaluate potential of PFAS polymers and precursors to form stable terminal PFASs	1
Persistent Mobile and Toxic substances (PMT)/ Very persistent and very mobile substances (vPvM)	
Innovative tools and methods for toxicity testing of chronic aquatic and soil toxicity	1
Monitoring in soil, water and biota	2[5]
Review of the impact of new CLP hazard classes, including PMT and vPvM, on the procedure and the methodologies to derive environmental limit values	6

The number of votes for all the needs were included in the factsheets and in the document sent to the GB to guide their final voting.

A meeting was held on 16 September 2024 during which results were presented to the different SF members. The objective of the meeting was to have a consensus on the top 5 priorities of the SF of PARC which were selected as follows:

- Review of the impact of new CLP hazard classes, including PMT and vPvM, on the procedure and the methodologies to derive environmental limit values
- Collection of exposure data across Europe (Benzophenones and UV filters)
- Human biomonitoring and exposure pathways (Chemicals leaching from plastics and rubber tyres)
- Monitor the implementation of the requirement to register polymers under REACH (when it happens)

[5] A total of 4 votes was previously counted for this need; indeed, European Environmental Bureau had voted 3 times for this one. This was later corrected.

- Monitoring in soil, water and biota (PMT/vPvM)

Task 2.1 members also attended an SF meeting on 13 March 2025 to update them on the prioritisation round and the upcoming steps. The SF requested to have an opportunity to be involved in the final steps and express where they could provide support when the final needs are selected.

3.4 IB consultation

The IB was asked to identify initiatives outside of Europe for the different factsheet topics. Written input was received on behalf of five IB members, out of 15 consulted[6], from:

- Belgium, **University of Antwerp**: suggesting that PARC mainly supports upcoming policies by addressing plastics treaty, pesticide reduction strategy and, the increased use of metals in batteries and electronics.
- Canada, **Health Canada**: highlighting some initiatives in the field of pesticides and fungicides, NAMs, Endocrine Disruptors mixtures and human biomonitoring, also requesting to address the refinement of current methods for Burden of Disease (BoD) estimations.
- The United States:
  - **Center for Disease Control and Prevention (CDC)**: highlighting some examples on initiatives related to PFAS and major research areas of the NIEHS (National Institute of Environmental Health Science) strategic plan for 2025-2029.
  - **Johns Hopkins University**: highlighting the importance of integrating Artificial Intelligence (AI) and Human Exposome Project (HEP) methodologies into the research framework of PARC.
  - **Yale University**: highlighting the role of PARC in linking mechanistic studies with health outcomes, developing methods to assess risks from Real-Time exposure NIEHS Strategic Plan; the importance of connecting PARC with schools of Public Health to enhance risk assessment training and, the incorporation DNA repair assessment in PARC's future activities. The benefits of connecting with the National Institute of Environmental Health in China was also mentioned.

Complete feedback is reported in Appendix 2.

An IB meeting took place on 23 September 2024 during which the 2nd prioritisation round process was presented together with the preliminary results and overview of the next steps. Some IB members provided recommendations for key collaborators within their networks with specific expertise in the focus areas. Due to the large number of items, IB members refrained from providing contacts for each individual item. The activities of PARC as well as the IB institutes are very broad, resulting in challenges for each IB member to inventory all potentially overlapping activities. Also, many agencies within any IB member's networks may already have connections within PARC.

Similarly to the SF, it was agreed to inform the IB of the refined topics and deadline for submission of new comments and contributions.

3.5 GB ranking of needs

As mentioned in sections 2.4 and 2.5, GB members were initially consulted in view of identifying serious limitations regarding the needs and their input was requested regarding the ideal timeline for delivering the results. Feedback on the factsheets was received from the EC, Austria, Belgium, Denmark, France, Germany, Sweden and UK. The factsheets were updated taking into account the comments received, when relevant.

Later on, the GB was consulted in view of ranking the needs. Feedback was received from 20 GBPRs (out of 30 consulted) from the following countries on their top 15 needs of interest[7]. Some GBPRs voted for fewer than 15 needs; in such cases, the number in brackets shows how many needs they actually voted for: EC, Austria (9), Cyprus

[6] The list of IB members and their involvement in PARC are available on the PARC website: link.
[7] Latvia and Portugal did not provide written feedback but expressed their needs of interest on the Klaxoon board during the GB meeting (13 November 2024).

(6), Denmark, Estonia (14), France, Germany, Hungary, Israel, Italy, Latvia (4), Lithuania (14), Luxembourg, Netherlands, Norway, Portugal (14), Spain, Sweden, Switzerland, United Kingdom.

During the GB meeting on 13 November 2024, results of the consultation were presented and discussed. The voting of the GB helped in ranking the 90+ needs and shortening to the list of top needs (i.e., needs that received at least 6 votes) to focus and review their regulatory relevance.

Appendix 3 lists the various topics and needs, the countries that initially proposed them, the corresponding PARC Task, the feasibility of the needs, and the support of the NHs, SF, and the GB vote[8]. The needs are listed by topic and ordered as indicated in Table 3.

Table 3: The list of topics selected following PARC's second prioritisation round

N°	Topic
1	Natural Toxins
2	Flame Retardants
3	Heavy Metals
4	Benzophenones and UV Filters
5	Mineral Oil Hydrocarbons (MOSH/MOAH)
6	Vitamins
7	Substances in Welding Fumes
8	Battery Chemicals
9	PFAS
10	Bisphenols
11	Phthalates
12	Pesticides/Fungicides
13	Persistent Mobile Toxic/very Persistent very Mobile (PMT / vPvM) Substances
14	PBT Substances
15	Pollutants in Wastewater Effluents
16	Methods for Early Warning Signals (EWS)
17	Monomers of Polymers, Biodegradable Polymers
18	Chemicals Leaching from Plastics and Rubber Tyres
19	2D Materials
20	Developmental and Reproductive Toxicity (DART)
21	More than One Constituent Substance (MOCS)
22	New Approach Methods (NAMs) for Replacing Animal Testing
23	Fibre Toxicity
24	Neurotoxicity
25	Immunotoxicity
26	Endocrine Disruptor (ED) Mixtures
27	Co-exposure to Multiple Chemicals
28	Bioaccumulation
29	Chemicals and Biodiversity
30	Sensitivity of Non-Bee Pollinators (NBP) to Biocidal Active Substances
31	Monitoring Methodology
32	Carcinogenicity
33	Validation of Systematic *In Vitro*/Silico Testing for Chronic Toxicity

[8] When shared with the GB, the table also included information on the extra resources needs, the available expertise in PARC, the related activities in PARC and outside the Partnership; however, to avoid overloading the table in this deliverable, it has been simplified by removing the above-mentioned information.

3.6 Top needs and their regulatory relevance assessment

After having identified the top needs through the GB voting, Task 2.1 partners, particularly, ECHA, EFSA, EEA, EAA (Environment Agency Austria), GCSL (General Chemical State Laboratory – Greece) and ISS (Italian National Institute of Health) assessed their regulatory relevance taking into account the policy agenda at the EU level. This is presented in Figure 5 (below), which includes the topics, specific needs, need IDs (which are referenced in Table 5 in Appendix 3), and the number of votes received by the GB, followed by the partners' assessment of regulatory relevance. There is a colour code for topics, which are highlighted in yellow when they are not already addressed in PARC and in pink when they are already addressed in PARC. In addition, for regulatory relevance, there are six boxes: the one at the top left represents the assessment by ECHA, the one in the middle by EFSA, the one at the top right by EEA, and in the row below, from left to right, the assessments by GCSL, ISS, and EAA. The assessment colour code is green, orange, and red for high, middle, and low levels, or grey when the need falls outside the scope of the agencies.

3.7 Microplastics and nanoparticles

As mentioned earlier (section 2.3), during the needs mapping exercise, several needs were raised regarding microplastics and nanoparticles. However, following discussions with the MB, it was agreed to address these two topics separately by appointing CLs to assess the work currently ongoing on these two topics outside PARC and how PARC can add value. CLs have therefore been appointed and tasked with conducting a state-of-the-art review. In April 2024, Dorte Herzke (Norwegian Institute for Air Research - NILU) was appointed as CL for microplastics and Iseult Lynch (University of Birmingham- UoB) for nanomaterials; they provided corresponding reports in April 2025. The following is a brief preview of the conclusions:

- For microplastics (link to the report[9]), there are several research gaps, including for plastic chemical where PARC partners can contribute, but also in terms of current assessment methods where there is a lack of methods for human samples, therefore, the harmonisation of analytical methods for human tissues is needed. Potential synergies are possible with EU and international initiatives. It would be relevant if PARC can implement harmonised methods for the determination of micro- and nanoplastics and support intercalibration exercises and workshops for reliable and sensitive methods and, contribute to filling knowledge gaps as identified by the CUSP cluster (European research cluster to understand the health impacts of micro- and nanoplastics).

For nanomaterials (link to the report[10]), CLs will use one additional year to conduct a review on the methods for nanomaterials detection in the human biomonitoring studies and develop, within 2 years, a framework for the evaluation or the extension of PARC NAMs to nanomaterials. Meanwhile, CLs might suggest, new projects in the upcoming years to develop a tiered approach to identify nanomaterials mechanistic deviations from baseline toxicity, as a basis for grouping, read-across and establishment of sets of nanoforms to support regulatory implementation.

[9] This SharePoint link is internal to PARC partners as this report is not intended for public access.
[10] This SharePoint link is internal to PARC partners as this report is not intended for public access.

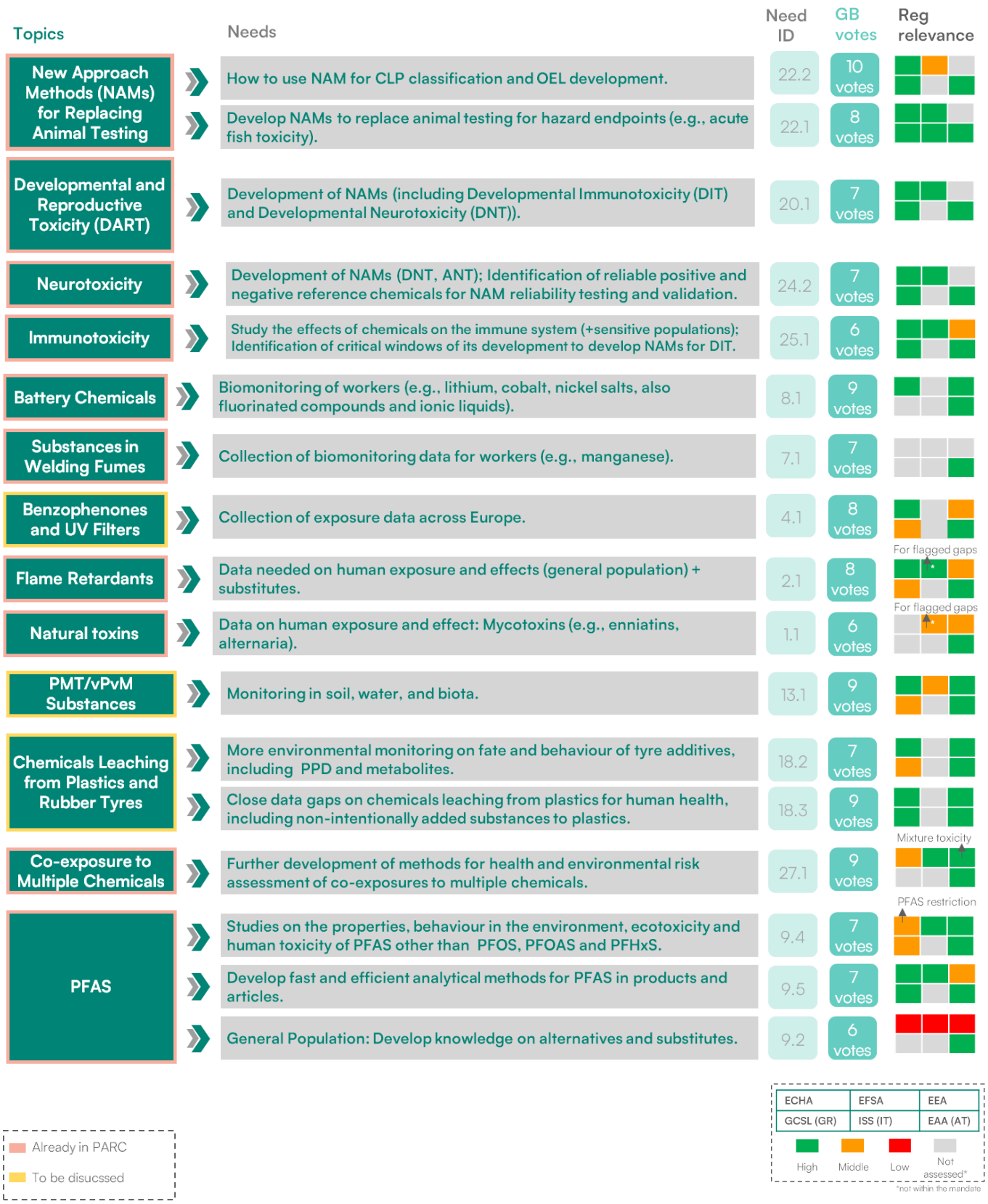


Figure 5: Top 17 needs following GB voting and assessment of regulatory relevance by Task 2.1 partners

Abbreviations: ANT, Adult Neurotoxicity, **CLP**: Classification, Labelling and Packaging, **DIT**: Developmental Immunotoxicity, **DNT**: Developmental Neurotoxicity, **OEL**: Occupational Exposure Limit, **PDD**: p-phenylenediamines, **PFAS**: Polyfluoroalkyl substances, **PFHxS**: Perfluorohexane sulfonate, **PFOA**: Perfluorooctanoic acid, **PFOS**: Perfluorooctane sulfonate, **PMT/vPvM**: Persistent Mobile Toxic / very Persistent very Mobile

4. Discussion

Strengths, limitations and lessons learned from this 2nd prioritisation round:

Concerns identified during the first prioritisation round of PARC and summarised in Figure 6 were considered in the current round. A key strength of this process was the active involvement of EU agencies and the European Commission, particularly in mapping needs and, more broadly, throughout the process. Furthermore, the engagement of the GB, and the consultation of various PARC bodies (NHs, SF and IB) has also strengthened the process. The planning of webinars and workshops facilitated productive discussions beyond written feedback, with Q&A sessions and introductory meetings prior to the consultation providing clearer guidance on expectations. Notably, these aspects represented improvements over the first round.

During the initial round, the need for clearer research questions and more effective grouping of needs was highlighted; while these challenges persisted, they were addressed through consultations and requests for clarifications. Additionally, in this round, efforts were made to avoid duplication of work and to consider the work continuation by regularly consulting the MB, reviewing ongoing projects, identifying "low-hanging fruits", and documenting ongoing activities both within and outside PARC for each identified need.

Considerations and Approaches	Concerns	Opportunities and Solutions
Criteria 1: Policy and regulatory relevance		
• Discussion with agencies • Identification of regulatory needs by PARC Work package Leaders & Task Leaders • Chemical Strategy for Sustainability and Strategic Research and Innovation Plan for safe and sustainable chemicals and materials	• Unclear research questions from the regulatory bodies • Different understanding of priority timeline: Policy (preparatory) Vs. Regulatory (immediate need)	• Conducting workshops and question-mapping exercises • Increasing involvement of EU agencies that are already within PARC
Criteria 2: Partnership: Synergy and alignment		
• Third prioritisation round under HBM4EU • Prioritisation form the PARC interim Governing Board survey • Synergies with other projects inside and outside PARC	• Avoiding duplication of work • Ensuring continuation of work	• Annual project review and mapping • Inter-EU project coordination • Collaboration through PARCopedia and SYNnet
Criteria 3: Practicality: Feasibility and Technicality		
• Partners' interests and resources • Available data and knowledge gaps • Hazardous properties of substances	• Missing out on partners that are capable but have no funding • Only working with topics that had been already well explored • Unclear view on who should drive the nomination of projects	• Mixing of Top-down ↔ Bottom-up approach of prioritisation • Opening up to new partners

Figure 6: Key concerns from the first prioritisation rounds, suggested opportunities and solutions
**This figure was inspired by the publication of Permana et al. (2025)*[11]

A number of challenges appeared throughout this process. It was indeed challenging to determine the time needed for the different steps of this prioritisation round. This was especially true when it came to providing a response per country, as reaching agreement on the submitted answer often required a considerable amount of time. Also, some of the expressed needs were very broad and difficult to assess. Moreover, the process took place over a period of a year and a half, thus the regulatory relevance may have changed between the nomination and the end of the prioritisation process (e.g., two updates were made for the KARC between the start and the end of PARC's prioritisation round). In addition, even though categorising the topics helped focus on specific needs during the consultation phase, especially with the NHs and SF, it caused some confusion. Indeed, GB members tended to vote more for topics not yet covered by PARC to include them in future years, even though some already covered topics were still important. Although this bias was addressed and clarified during the two Q&A sessions, it persisted to some extent.

[11] Collecting perspectives on project prioritisation process in the EU co-funded multinational partnership for the assessment of risks from chemicals (PARC) through focus group discussion (https://doi.org/10.1186/s12302-024-01041-1)

It is also relevant to pinpoint that participants had different scientific backgrounds and, while evidence / regulatory-based feedback was expected from those providing input (whether from the MB, the SF, the NH or the GB), this was not consistently met by all contributors. That is all the more reason why feedback from the different consultations was weighted differently, with the greatest weight given to the GB in the final voting step, given that GB members have the closest regulatory viewpoint.
Also, throughout the whole process, it has been reminded that, due to limited resources, in terms of personnel and funding, PARC cannot address all identified needs. For this reason, other calls and initiatives exist across the EU and were pointed out for the different topics of this prioritisation round (non-exhaustive list).
In addition, it should be mentioned that with the changes in regulations, the advanced technologies in the chemical world and industries and, the discovery of new emerging compounds, research needs always evolve. On the other hand, the needs mapping and prioritisation exercise can only identify and prioritise current needs, without necessarily predicting needs that may arise in the future and are unknown at the moment. However, if new needs are identified, it is therefore always possible to activate the Rapid Response Mechanism (RRM)[12] of PARC. This mechanism is designed to address urgent needs that are not on the priority list, even if they are identified outside the yearly window for submitting new projects.

A final prioritisation round of PARC will run in Year 6 of the Partnership for legacy considerations. This round will be conducted in close collaboration with Task 2.3 "Sustainability" as both activities are interconnected. Ideally, this prioritisation round would support the EU-HBM survey under the OSOA (One Substance, One Assessment) package. Feedback is therefore needed at the end of this process to identify areas for improvement for the final round. A survey was sent to PARC bodies that participated in this mapping of needs / prioritisation process (EU agencies, GB, MB, NH, SF and T2.1 partners).
The survey comprised 5 sections: **1/** General feedback, **2/** Process Effectiveness, **3/** Outcomes and Communication, **4/** Participation & Engagement, **5/** Suggestions for Improvement. The questions are presented in Appendix 7.
SF and NH participants were asked to respond only to sections 4 and 5. In contrast, the GB, MB, and T2.1 partners completed all sections of the questionnaire.

In total, 52 answers were received, 14 from the GB (including the EC), 12 from the MB (including EEA), 8 from the SF and 17 from the NHs. An overview of the results is presented hereafter.

Sections 1 & 2: General satisfaction (feedback from GB and MB)
The majority of the GB and MB expressed satisfaction (46%) or neutrality (35%) regarding the overall process. No notable differences were observed between GB and MB responses. In contrast, 4 GB and MB members (15% of respondents) reported being unsatisfied with the process.

Process effectiveness (feedback from GB and MB)
Overall, 58% of respondents considered the process effective, and some (8%) had even rated it as very effective in establishing priorities. A smaller share (27%) however found it only slightly effective. Two respondents (one MB and one GB) indicated that the process was below their expectations.
The schedule for this prioritisation round was deemed appropriate by all respondents except for one GB member who considered the timing not appropriate.
The majority of respondents considered the process somewhat, mostly, or even fully consistent and objective; only 8% of respondents (one GB member and one MB member) considered it to be mostly inconsistent and subjective.
According to the survey respondents, all relevant voices were heard during the process (more specifically the consultation phase); however, some feedback indicated that national priorities were given less weight than those put forward by EU agencies (which is indeed true as described above). In addition, a few respondents felt that the process was framed primarily from a risk assessment and safety perspective, rather than from the standpoint of identifying new policy directions and their regulatory consequences; this is however open to discussion because the initial needs mapping was based on inputs from both EU agencies and the GB. Some participants also pointed out that reaching a joint opinion was challenging, given the diversity of backgrounds and expertise, and the lack of

[12] The deliverable D2.5 'Rapid Response Report' (link) provides more details on the mechanism and, a news item on the PARC website (link) briefly reports the activation history of this mechanism to date.

sufficient detail, such as a clear specification of the need and its underlying rationale - it had already been acknowledged that the clarity and level of explanation for different needs were not always consistent.
While most respondents did not consider any steps of the process to be unnecessary, a small proportion indicated that certain steps could be reconsidered: the creation of factsheets (11%), the categorisation of topics (11%), and the consultation of NH, SF, or IB bodies (4%). All respondents agreed on the necessity of GB voting. One suggestion was that the GB could validate the voting results of other bodies (NH and SF) or adjust them at a higher level of aggregation. Another recommendation was to assess regulatory relevance much earlier in the process, rather than, as in this round, conducting that assessment only at the end and only for the top priority needs.

Section 3: Outcomes and Communication (feedback from GB and MB)
Only 35% of respondents expressed confidence in the outcomes of the prioritisation round, while 54% were neutral and 12% were not confident (2 MB members and 1 GB member). Indeed, given that projects addressing the identified needs and the final results for future activities are not yet clearly visible, neutrality was the dominant view.
Some respondents noted that some priorities were missing explaining that the overall process was perceived as favouring familiar topics which made it more difficult to address novel or less obvious topics. It was mentioned that experts in some of the top topics could have been consulted to provide a deeper understanding of the current state of the art. Some felt the perspective taken was too focused on present issues rather than future challenges. There was also concern over a strong bias towards health-related topics, with insufficient emphasis on chemicals, biodiversity, or bioaccumulation. From a policy standpoint, questions were raised about how to position chemical and product safety within the EC's current focus on competitiveness. Respondents also called for greater attention to hazard assessment, artificial intelligence, and Next Generation Risk Assessment (NGRA).
Regarding communication, 54% of respondents found the information on the prioritisation process and outcomes to be effective, 31% were neutral, and 15% considered it ineffective (3 GB members and 1 MB member).

Section 4: Participation & Engagement (feedback from GB, MB, FS and NH)
Overall, the purpose of this prioritisation round was generally perceived clear by participants. Only one respondent (SF member) indicated that the purpose was unclear.
Regarding expectations, 10% of respondents found them to be very clear and highly effective; 71% considered the expectations and the communication about what was required from them to be mostly clear. However, 20% (including respondents from GB, MB, NH, and SF) felt that expectations were mostly unclear.
It was pinpointed that different countries adopted varying approaches and interpretations of the instructions. Participants also highlighted difficulties in following the progress of projects and understanding what is still needed, given the large scale of the Partnership and its portfolio of over 100 projects. Furthermore, the process itself evolved during implementation ("developed along the way"), which led to many requests in favour of having the entire procedure clearer and more transparent from the start, with visibility on each stage from the outset. For example, the GSB was initially expected to be consulted specifically but ultimately was not, as the NH consultation took place. Some respondents suggested making the status update of the prioritisation process more accessible, including information on what had been proposed and the corresponding decisions taken. Finally, it remains unclear to some participants how the inputs from the SF and NH influenced the overall process.
Regarding engagement, 61% of respondents felt they had sufficient opportunities to contribute and share their views, while 34% believed these opportunities were insufficient, and 5% (1 NH member and 1 SF member) reported having very limited chances to contribute. In terms of how their input was valued, 49% agreed that their contributions were considered, 45% were neutral, and 6% (from MB, SF, and NH) felt their input was not considered.

Section 5: Suggestions for Improvement (feedback from GB, MB, FS and NH) – Some respondents indicated that the process was good and effective in setting priorities for the second half of the Partnership and had no suggestions for improvement for the next round, whereas others made a number of suggestions. These suggestions concerned the starting point of the process (the mapping of needs), the consultation phase, the communication, and some remarks for the third prioritisation round of PARC. An overview is presented in Table 4.
The feedback and perspectives gathered will be taken into account constructively to improve next prioritisation round. The process was indeed not straightforward, given the diversity of the Partnership, the different tasks and WPs it includes, as well as the different bodies involved whose voices needed to be heard. For the next round, we

now have a clearer understanding of how to strengthen communication, build on what worked well, and address areas requiring improvement.
Taken together, the process was effective in generating a list of priority topics and needs, although additional improvements can still be made in the future.

Table 4: Suggestions, lessons learned and pathways for improvement for the next prioritisation round

Mapping of needs - process	Consultation	Communication	3rd prioritisation round
• Define the process design from the start. • Make an overview of the most important policy developments, have it approved by the GB and then discuss priorities for PARC. • Organise a workshop for the GB to discuss and outline the needs, approximately 20 most pressing needs for the future. • Provide a better view of what is already in the pipeline (projects and activities). • Have a contact person for every proposal: share more details on the needs with the consortium (specific needs with clear connections to regulatory processes). • Have more specific questions instead of a wish list. • Make the link with the Early Warning Systems in WP8. • Consider a horizon-scanning / Delphi type method to look for emerging issues. • Provide clear answers for the different proposals (especially when not selected), in order to increase trust in the outcomes.	• Avoid repeating work in different bodies: specify which body makes which preliminary or final decisions, at which point. • Rather than conducting consultations sequentially, consult the various PARC boards and EU Agencies in parallel, thereby shortening the process. • Have more explicit decision from the GB. • Present the needs in a way that it is processable and easy to evaluate for the respective group. • Carry out live surveys during meetings to ensure common understanding of the ultimate goals and ensure that votes are made with the full picture in mind. This can be followed by written feedback. • Give more time to Member States (PARC includes a lot of competences so there is need to collect views). • Include more environmental experts (as they are less consulted, environmental toxicology topics are underrepresented). • Consider the regulatory relevance of the need as key criterion for inclusion in the list of needs. • Have clear transparent criteria to help facilitate the selection of top needs. This would ensure that all bodies approach the exercise with a shared and harmonised vision. • Improve the consultation surveys design. Surveys had a fixed set of questions / options, providing participants limited opportunity to suggest different priorities or different ways to address them. • Use an online platform for each NH, with options for shared access and interaction between hubs. This would enable greater cross-fertilisation of ideas and support more dynamic brainstorming. It may also help align and harmonise the priority list across countries.	• Be shorter and more precise in the communication. • Present the prioritisation process with an explanation of expected input; organise Q&As. • Have an online tool where all involved bodies can exchange views (e.g., private PARCopedia groups). • Share the results of all PARC bodies in view of having more transparency and explain how the feedback contributed to setting final priorities. • Lay out how the answers will be aggregated to a final decision.	•Attention not to jeopardise the completion and finalisation of currently ongoing projects. •Feasibility within PARC should weigh less or not at all, since the 3rd prioritisation concerns activities after PARC. •Have a process as participatory as possible - partners providing input *via* NHs but also *via* Consortium Meeting 2026 and *via* WP discussions. •Ensure a more consistent and transparent approach to grouping priorities - for example, avoid separating categories that overlap substantially (e.g., herbicides, fungicides, and pesticides), and clarify the relationship between new and former priorities such as reproductive toxicants and EDCs, given that many substances belong to both categories. •Refer to PARC Ethics considerations.

How can these needs contribute to the PARC project portfolio?

The complete list of needs was shared with the PARC consortium. The needs selected by the consortium will be translated into projects for the upcoming years of the Partnership (years 5, 6 and 7), ensuring a top-down ↔ bottom-up approach. Then, throughout the project review process of submitted projects' proposals, Task 2.1 will ensure the link between the high-level priorities and the activities that will be implemented in PARC. In fact, given that a project must have clear regulatory relevance, WPLs have been instructed to mention in the summary of the project description document (PDD) which specific need, among the 17 priority needs, the project addresses.
Moreover, during the MB physical meeting on 3 February 2025, Task 2.1 presented the top 17 priorities and the preliminary assessment of their regulatory relevance. During this meeting, MB members were also given the floor to indicate if they plan to address some of the needs and have completed a table on this after the meeting. The feedback received from WPs 4-5-6 is presented in Appendix 4. Indeed, many activities are already ongoing or planned to address these top needs.

Furthermore, it is important to mention that, as this prioritisation process was already underway when projects for the 4th year of PARC were submitted (i.e., in September 2024), the WPLs had already taken into account certain needs from the long list and, in particular, from the KARC document shared by ECHA, in order to propose projects for the 4th year of the Partnership. An overview of the Y4 submitted projects and the topic(s) they addressed is presented in Appendix 5. It is also worth mentioning that ethical approval for Aligned Studies has already been obtained in many countries. In some cases, the approval and consent forms specify the chemicals analysed, making it difficult to add new ones now, even if they are prioritised.

Do these needs reflect the PARC EU agencies research priorities?

As PARC aims to fill data gaps and address needs considered to be of high regulatory importance, the needs expressed in the KARC by ECHA were carefully considered. Therefore, at the end of this prioritisation process, an evaluation was conducted to determine which projects align with the different needs expressed in the KARC 2023 document or, alternatively, the initiatives outside the Partnership that might be linked. This overview is presented in Appendix 6; it does not intend to give the impression that no further work is needed to meet research needs expressed in the KARC, but was produced with the aim of establishing useful links between PARC projects that are related or potentially address the needs. Furthermore, ECHA's KARC is updated every year; indeed, since its first release in 2023, two webinars were held in 2024 (link) and in 2025 (link) highlighting the updates. If necessary, PARC may review this mapping to evaluate how its projects and activities address the updated needs in the KARC.

EFSA, on the other hand, has released, in April 2025, an editorial on the research & innovation needs that can support EFSA's regulatory science in the coming years (DOI: 10.2903/j.efsa.2025.e220401, link). This editorial was not available during the mapping of needs and was therefore not taken into consideration. However, it might be worth looking into whether some of these needs can be addressed in PARC or whether some already are. Furthermore, it should be noted that, EFSA did present some relevant areas of research during the first webinar organised by EU agencies in 2023 (see section 2.1) but also in 2024 and 2025 during WP6 meetings / webinars. EFSA also contributed to the reviewing of factsheets and participated in the assessment of the regulatory relevance of the top 17 needs. In addition, EFSA is actively involved in WPs 4-5-6-7 and 8, in areas mainly related to New Approach Methods, aggregated exposure, kinetic modelling, mycotoxins, PFAS, new emerging risks *etc*. EFSA is also co-leader in Task 2.1 and plays important role in the project review process, ensuring the regulatory link of ongoing projects in PARC.

The EEA was involved in the prioritisation and prepared seven new factsheets representing topics that were of interest to their areas of work as well as providing input to the Factsheets' document and the assessment of top 17 needs. EEA also focused on the need for data to support the CSS indicators during the webinar on June 14, 2023 on research needs, coordinated by the three EU agencies (see section 2.1).

5. Conclusion

This second prioritisation round resulted in a list of over 90 needs, from which 17 were identified as top priorities. This list will inform project proposals for Years 5 to 7 of PARC. This prioritisation exercise, conducted over a year and a half, was made possible through consultations with the various PARC bodies (NHs, SF, GB, MB, IB, Task 2.1) *via* both meetings and written feedback. The participation of the EC and EU agencies significantly enhanced the process, especially with the EU-regulatory links. While this round was built upon the lessons learned from the initial prioritisation, opportunities for further improvement were identified. The next steps involve determining an effective dissemination strategy (through publication on the PARC website but also other journals) as these results will provide valuable guidance for the scientific community in developing project calls.

List of the top 17 needs from this 2nd prioritisation round (receiving at least 6 votes from the GB):

- How to use New Approach Methods (NAMs) for Classification, Labelling and Packaging (CLP) classification and Occupational Exposure Limit (OEL) development.
- Develop NAMs to replace animal testing for hazard endpoints (e.g., acute fish toxicity).
- Development of NAMs for Developmental and Reproductive Toxicology (DART), including developmental immunotoxicity (DIT) and developmental neurotoxicity (DNT).
- Development of NAMs for neurotoxicity (including DNT, and adult neurotoxicity (ANT)); identification of reliable positive and negative reference chemicals for NAM reliability testing and validation.
- Study the effects of chemicals on the immune system (+sensitive populations); identification of critical windows of its development to develop NAMs for DIT.
- Biomonitoring of battery chemicals in workers (e.g., lithium, cobalt, nickel salts, also fluorinated compounds and ionic liquids).
- Collection of biomonitoring data for workers for Substances in Welding Fumes (e.g., manganese).
- Collection of exposure data across Europe for Benzophenones and UV Filters.
- Data needed on human exposure to Flame Retardants and effects (general population) + substitutes.
- Data on human exposure and effect of Mycotoxins (e.g., *enniatins, alternaria*).
- Monitoring Persistent Mobile Toxic/very Persistent very Mobile (PMT/vPvM) Substances in soil, water, and biota.
- More environmental monitoring on fate and behaviour of tyre additives, including p-phenylenediamines (PPD) and metabolites.
- Close data gaps on chemicals leaching from plastics for human health, including non-intentionally added substances to plastics.
- Further development of methods for health and environmental risk assessment of co-exposures to multiple chemicals.
- Studies on the properties, behaviour in the environment, ecotoxicity and human toxicity of PFAS other than Perfluorooctane sulfonate (PFOS), Perfluorooctanoic acid (PFOA) and Perfluorohexane sulfonate (PFHxS).
- Develop fast and efficient analytical methods for PFAS in products and articles.
- Develop knowledge on alternatives and substitutes of PFAS, for the general population.

Appendices

Appendix 1: Suggestions for WPs 7, 8 and 9, for the second half of PARC

WP7: FAIR Data
Task 7.1 FAIR Data policy and implementation
Task 7.2 Data Libraries
Task 7.3 Innovative analyses

- Have one system for all European projects.
- Develop and integrate bioinformatic approaches.
- Develop tools, applications, interfaces for "online" analysis of data (Task 7.3).
- Address GDPR (General Data Protection Regulation) issues.
- Make sure data/information from within different legislations are integrated through a feed-back mechanism. For example, data on surface water levels of pesticides (repeated exceedance of environmental quality standards (EQS) indicate need of systematic refinement of assessment or enforcement process) produced within the Water Framework Directive (WFD) should be used to validate and when needed fine tune the different components of the Plant Protection Products (PPP) assessment machinery.
- Support the development of a FAIR Environment and Health Registry (FAIREHR), as proposed by the 'Europe Regional Chapter of the International Society of Exposure Science' (ISES Europe) human Biomonitoring working group (Zare Jeddi et al., 2023). FAIREHR plans to offer the preregistration of studies on exposure sciences and environmental epidemiology using HBM (as a starting point) across all areas of environmental and occupational health globally. The registry is proposed to receive a dedicated web-based interface, to be electronically searchable and to be available to all relevant data providers, users and stakeholders.
- Organise workshops focused on informing and engaging the stakeholders at national and European (perhaps also international) levels during the development phase. To ensure that data and analytical tools are 'FAIR', resources should be allocated for the propagation and education in these databases and tools with a friendly user interface to facilitate information transfer among agencies and among people.
- Make a link with the Task on sustainability in PARC.
- After execution of other PARC tasks, evaluation is needed to identity gaps.

WP8: Concepts and toolboxes
Task 8.1 Safe and sustainable by design (SSbD)
Task 8.2 Scientific and technical basis for an Early warning system (EWS) on chemical risks
Task 8.3 Integrative models

SSbD:

- Ensure that an operational SSbD toolbox is developed by the end of PARC, with application in each of the 5 innovation stages identified in the stage gate approach (idea, design and planning, experimental testing, prototyping, validation).
- Ensure optimal synergies with IRISS (the International SSbD Network) and with new projects from Horizon Europe developing SSbD tools and models.
- Be in touch with other WPs in PARC, specifically involved in monitoring chemicals, in the attempt to define possible prioritized substances that may be of interest for the 8.1.2 toolbox operationalization and the focus of 8.1.3 future case studies in PARC. Substances can include: bisphenols, phthalates and substitutes (adipates, terephthalates, DINCH), metals, Chromium with co-exposure from nickel, and manganese, mycotoxins, aldehydes, endocrine disruptive chemicals, pesticides, limonene, pesticides and biocides, ethanol.
- Further consider ongoing case studies in projects internal and external to PARC and be in touch with them to develop possible cooperation.
- Have case-studies to test the toolboxes in real life with companies from different countries and industry-fields including green technologies.
- To collect opinion from stakeholders on the SSbD framework structure and needs, as well as on the toolbox developed under 8.1.2 activity, according to an iterative process. This may be helpful to implement suitable

SSbD case studies where to address the effective operationalization of the EC framework and that of the toolbox. Exchange of opinions with stakeholders may be also important to identify critical aspects in the operationalization of the 8.1.2 toolbox and to translate the preliminary developments in qualitative and quantitative outputs that may be generalized to different SSbD application contexts.

- Gathering feedback on the EC SSbD framework applicability and effectiveness may be helpful also to implement the framework in future years (e.g. applied methodology; needs for simplicity; expertise requirements; framework goals in different application settings as well in different stages of the framework application) and to overcome barriers to the operationalization of the SSbD framework (high costs, difficult application in small-medium enterprises contexts, needs for great resources; lack of knowledge; inadequate regulation; not sufficient communication; lack of guidance documents).
- Interlinkage of WP8 and WP7 for data needs for the SSbD tools.
- Include Small and medium-sized enterprises (SMEs) into the development of the SSbD toolbox so the tool will also be implementable by SMEs. Include also approaches for the design phase when data are more scarce (e.g. using validated NAMs).
- Have online guides and tools that support various stakeholders wishing to transition to more SSbD approaches relative to their current modes of operation.
- SSbD should be part of the training activities in academic institutions that provide training in chemical safety.
- Evaluate whether it is possible to further develop the concept and criteria for SSbD substances into something like a guidance for the definition of a "positive list" of substances with rather favorable or beneficial properties (e.g., low toxicity, easily degradable, medium mobility, etc.), which would make their use more preferable and safer for industrial applications.
- Generally, for the application of the SSbD framework, robust and reliable NAMs will play a pivotal role as they will enable to address some of the SSbD criteria in a simple, faster and more cost-effective manner as compared to traditional test methods often applied in a regulatory context. To identify which of the available or upcoming NAMs may be included in the SSbD toolbox currently developed in 8.1, a systematic analysis needs to be conducted, which requires a closer collaboration of Tasks 5.2, (6.3?) and 8.1. For the individual NAMs that are selected for inclusion in the SSbD toolbox, such an analysis should also consider which cut-off values are appropriate for the respective NAM to decide whether an investigated chemical/material can be considered as SSbD, or not.
- It is important to include costs (and cost of inaction) in the work with SSbD and circular economy issues. Socioeconomic aspects related to e.g., substitution should also be considered.
- Evaluate in PARC whether it is possible to provide the professional user with a risk assessment tool that considers the specific needs and uses under different regulations and would allow him to estimate and assess the aggregated risk of his applications. This might raise the awareness of unsustainable uses and might trigger the application of additional or permanent (e.g., buffer strips, treatment plant, compliance with REACH obligations, etc.) RMM (risk mitigation measures), or delays in application or emissions.
- Combine toolboxes as maintenance in the future will be a challenge.

EWS:

- Ensure collaboration with WP4 for development of tools for EWS. Include clear understanding how (assessment of) advanced materials and the applicability of existing (and tools presently developed under PARC) tools are part of this system.
- Develop tools to support in the peak identification of HR-MS without having to upload (make available) the HR-MS results, in combination with validation of HR-MS predictions *via* target analysis enable the development of NTS in monitoring programs.
- Closing data gaps in the exposure assessment of substances (e.g., pesticides and pharmaceuticals) by establishing an early warning system on a field scale.
- An exit strategy for EWS is needed, also including a systematic structure for actions within EU to handle new and/ or emerging risks identified.
- Scientific and technical basis for evidence-based application / prioritisation under the Water Framework Directive.

Other expressed suggestions:

- As more and more sophisticated functions are incorporated in articles and materials, by using for example biocides or nano to make advanced materials, it is important to know how these compounds are released or emitted from the materials. This may have impact on the occupational exposures but also on the exposure of the general population either the end users of *via* contamination of the indoor environment (air, dust...).
- Develop suggestions how existing data gaps can be filled. Evaluate whether regulation needs to be changed to fill these data gaps (e.g., request of more use data under REACH).
- Clarification of data requirements for sustainability, their robustness and level of specification/detail (several aspects of sustainability are still subject of research and discussion).
- Foster the collaboration between PARC and JRC.
- Further, work is needed on the comparability of (eco)toxicological endpoints in the product environmental footprint and the principles of (eco)toxicological assessments in EU regulations like CLP/REACH/BPR/PPPR (e.g., ED properties etc.).
- Support for the 3Rs (ASPA in the UK - Animals (Scientific Procedures) Act 1986) implementation – a roadmap for validation of NAMs and basis for decision-making as to when a NAM can replace an animal test.
- After execution of the tasks, an evaluation is needed to identify gaps.

WP9: Building infrastructural and human Capacities
Task 9.1 Laboratory networking
Task 9.2 Building exposure monitoring capacities
Task 9.3 Joint activities – harmonization
Task 9.4 Training

Laboratory networking:

- It would be good to link an early warning monitoring system on a field scale with existing well-established laboratory networks.
- Ensure the sustainability of the laboratory network and capacities built along PARC.

Building monitoring exposure capacities:

- Development of standardized and harmonized protocols for establishing biobanking facilities to assist countries in establishing their own biobanks.
- The International Organization for Standardization, in illustrating the requirements for biobanking (ISO 20387:2018), stresses the concept of biobanks being legal entities driving the process of acquisition and storage together with some or all of the activities related to collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data.
  Although biobanks were established within HBM4EU the funds for further development seem not be allocated in PARC. We propose that funds are allocated to further development of biobanks. Besides informed consent, quality of sample collection, transport, aliquoting, laboratory analyses, short and long-term storage, reuse of HBM samples and health data, personal, environmental and dietary history data, there are also rights of volunteers/patients and responsibility of researchers to inform the participants of new results based on the reuse of samples and/or data. EU member states have national laws concerning medical confidentiality, which apply to the professionals handling information relating to their patients' medical histories. Although participants in HBM PARC studies are predominantly healthy volunteers, it is expected that with the development of effect biomarkers new information and knowledge may provide insight into early effects. It is crucial that the participants are aware of any emerging risk to health which were not known at the time they had consented to their personal, health and biological samples to be used/reused for research. Therefore, long-term traceability is to be assured in order to act appropriately according to emerging information and knowledge.
- Ensure a link with PARC Task on sustainability: good alignment with WP 4, 7, etc.
- Investigate how monitoring networks can align (methodology), how data can be shared transparently across EU, ensure post-PARC infrastructure of data collection …
- Build synergies with other ongoing EU projects (i.e., EHEN) to comprise their knowledge/capacities into the library of capacities with regulatory relevance.

Joint activities – Harmonization:

- Explicit reference to the importance of expert knowledge and capacity in supporting regulatory assessments – work according to Test Guidelines and Good Laboratory Practices and most important their participation in the process of developing those.
- SSbD capacity building.
- Address sustainability of the NAM infrastructure.
- Have a regular collaboration among WP4 (both human AND environmental), WP7 and WP9. Outcome of WP9 is important for sustainability/exit strategy in PARC.
- Environmental protection could be more strongly embedded as there is a strong biomonitoring focus. Mapping of the Water Framework Directive monitoring and long-term observations of environmental health.
- The need to exchange experience on research funding in PARC, when no open calls are included, remains. In previous discussions, a specific activity on peer-to-peer learning on how partnerships can be supported from funding agencies requiring open calls without the classical ERA-NET approach was agreed. Sweden see that it is still important to include this proposed activity in the Partnership in order to be able to exchange experience and find workable ways to enable participation from relevant researchers in PARC.
- Make explicit how interdisciplinary the activity may be due to the wide nature of chemicals and to include complex materials (also on nanoscale).

Training: Training and capacity building at national levels are instrumental for sustainability.

- Once methodologies are developed in WP5, training how to apply and asses these NAMs and conduct NGRA should be performed jointly with WP5 and 6. As it can be expected that these projects will deliver first results important for WP9 after 3-4 years, respective trainings should be planned starting in year 4.
- Training programs on the new tools (WP8), new analytical methods and tools, NAMs, etc. developed under PARC should be planned for interested PARC partners and external organizations and stakeholders, including industry, regulators and policy-makers to ensure their wide dissemination and improve their acceptance.
- Dedicated training for SSbD toolbox developed within PARC that will be used also by other interested parties (like industrial partners and SMEs).
- Organise a specific training for Member State risk managers (policy makers), at a higher level on more basic understandings of AOP networks & IATA & other new risk assessment methodologies.
- The different surveys, which are used as instruments for collecting feedback, should be carefully designed to capture the needs and should be complemented with more interactive tools (e.g., online or physical meetings).
- For the training network, bring the experiences and actual needs from regulatory scientists *via* Webinars to students, academic researchers, etc. - and vice versa. Improve the involvement of regulatory scientists from member state authorities and ECHA/EFSA in the tasks/projects to get more relevant results and start their regulatory implementation, for example *via* joint project/task leads of academic and regulatory scientists.
- Train public health scientists – especially in toxicology as there are few dedicated study programs that will produce next generation toxicologists.

Appendix 2: Feedback from the IB consultation

Input from Thomas Hartung (Johns Hopkins University)

- **Artificial Intelligence (AI) Integration:** AI represents a transformative technology that can significantly enhance the analytical capacity and predictive capabilities within environmental health research. However, the documents provided suggest a lack of emphasis on AI in PARC's proposed activities. Given the complexity and volume of data involved in assessing risks from chemicals, AI could play a pivotal role in several key areas:
  - Data Integration and Analysis: AI can be employed to integrate heterogeneous data sources, including environmental monitoring, biomonitoring, and experimental data. This can facilitate the identification of patterns and correlations that are not easily discernible through traditional statistical methods.
  - Predictive Modeling: Machine learning algorithms can improve the prediction of chemical toxicity, exposure patterns, and health outcomes, thereby enhancing the risk assessment process. AI-driven models can also help simulate the impact of regulatory interventions and predict long-term outcomes.
  - Early Warning Systems: AI can support the development of real-time monitoring and early warning systems for environmental hazards, a potential future activity highlighted in your documents.
- Internationally, there are several initiatives where AI is being effectively integrated into environmental health research. For example, the United States Environmental Protection Agency (EPA) is actively using AI for predictive toxicology under the ToxCast program.

- **Human Exposome Project (HEP):** The Human Exposome Project aims to map the totality of environmental exposures throughout an individual's life and their impacts on health. The project is highly relevant to PARC's goals of understanding the comprehensive impact of chemical exposures on human health.
  - Global initiatives like the U.S. National Institutes of Health's (NIH) exposome-related projects and the European Human Exposome Network offer potential collaboration opportunities.

- **International Initiatives Supporting PARC's Activities**: In addition to AI and HEP, several international initiatives outside Europe could support PARC's future activities:
  - Precision Medicine Initiative (USA): This initiative could provide insights into individual susceptibility to chemical exposures based on genetic and environmental data.
  - The Global Burden of Disease (GBD) Project: Collaborating with GBD could enhance PARC's ability to quantify the impact of chemical exposures on public health at a global scale.
  - OECD's Extended Advisory Group on Molecular Screening and Toxicogenomics: This group focuses on integrating molecular data into regulatory frameworks, aligning with PARC's goal of innovation in regulatory risk assessment

- **Conclusion and Recommendations**:
  - To ensure that PARC remains at the forefront of CRA and public health protection, I strongly recommend **integrating AI and HEP methodologies into its research framework**.
  - Additionally, **establishing strategic collaborations with international initiatives focused on AI, exposome research, and data integration** will provide significant support to PARC's activities and enhance its global impact.

Input from Douglas Haines (Health Canada)

- **WP4: Monitoring and exposure**
  - Public health aspects of risk assessment and risk management of chemicals in PARC have not been identified in your consultations and documents. In particular, the burden of disease (BoD) (e.g., incidences, DALYs, etc.) estimated at the population level from exposures to chemicals and changes in the burden of disease expected or achieved as a result of policy decisions may be useful information.

- Efforts could include **applying and refining current methods for BoD estimations**, developing new methods, using microsimulations for estimating impacts of risk management options, etc.
- The field of ambient air pollution and health is an example where these types of approaches have successfully been developed and applied.

- **Pesticides, fungicide**
  - Pesticides are stringently regulated in Canada to ensure they pose minimal risk to human health and the environment. Under authority of the Pest Control Products Act, Health Canada:
    - registers pesticides after a stringent, science-based evaluation that ensures any risks are acceptable;
    - re-evaluates the pesticides currently on the market on a 15-year cycle to ensure the products meet current scientific standards; and promotes sustainable pest management.
- **NAMs**
  - For the Existing Substances Program, data generated from NAM-based approaches were increasingly used to support grouping and read-across, prioritization, and assessment of the potential for risk from data-poor substances under the Chemicals Management Plan (CMP), which is the Canadian analogue to PARC.
  - NAM data may be substituted in place of traditional data when the NAM is determined to provide a scientifically valid measure of the endpoint under investigation that is deemed sufficient for risk assessment.
  - Currently available cell-based NAMs, may lack complete biological analysis for systemic toxicity endpoints; Improved computational models and more complex tissue-based NAMs (for example, microphysiological systems).
- **ED mixtures**
  - Health Canada and Environment and Climate Change Canada maintain active scientific research programs that contribute internationally to advancements in the field of EDs through various research activities, including the development of toxicity test methods through OECD.
- **Human biomonitoring**
  - Canadian biomonitoring dashboard
  - 39 chemicals measured in blood or urine detection rates over 50% in the Canadian population

Input from Greta Schoeters (U. Antwerp)

- **Suggestion not to disperse activities further but to focus on being able to support upcoming policies such as**
  - plastics treaty (make sure that we get a good view on e.g., exposure to plastic compounds and the drivers of toxicity),
  - pesticide reduction strategy (make sure that you cover the most used pesticides and the drivers of toxicity),
  - increased use of metals in batteries and electronics.
- **Selection of compounds**
  - PARC should not go to different chemical classes,
  - PARC should ensure to provide solid arguments to underpin in a coherent way (exposure, toxicity, risk) a few upcoming policies to make the difference and promote science informed policy decisions.

Input from Antonia M. Calafat (CDC)

- **Initiatives in the USA that might provide support for some of the PARC activities**
  - None of them can provide financial support to PARC
  - Federal government efforts, and mainly regarding exposure assessment where agencies from various parts of the federal government work together, each within its area of expertise and using its own funds/resources, to address overarching goals,

- Recent examples (of the many areas of interest in PARC) of initiatives related to PFAS, emerging contaminants, and military exposures:
  - National-Emerging-Contaminants-Research-Initiative
  - PFAS strategic plan
  - The PACT Act, a law that expands health care and benefits for Veterans exposed to burn pits, Agent Orange, and other toxic substances
- **NIEHS Strategic Plan**
  - NIEHS conducts and funds research focused on environmental exposures of special interest and concern for public health, ranging from widespread chemical exposures; non-chemical stressors including social determinants of health; and exposures related to climate change and human activities that impact the environment.
  - NIEHS draft 2025-2029 strategic plan names six major research areas:
    - Exposomics;
    - Precision Environmental Health;
    - Mechanistic Biology and Toxicology;
    - Data Science and Computational Biology;
    - Environmental Health Disparities,
    - Environmental Justice, and Health Equity; and
    - Climate Change Impacts on Human Health.

Input from Vasilis Vasiliou (Yale University)

- **Linking Mechanistic Studies with Health Outcomes**
  - PARC has a unique opportunity to strengthen the connection between mechanistic studies and health outcomes.
  - Linking cellular and molecular mechanisms directly to the onset of diseases such as diabetes and neurodegenerative disorders, to uncover critical insights into how environmental contaminants may trigger or exacerbate these conditions.
  - This approach could significantly inform both prevention and treatment strategies.
- **Developing Methods to Assess Risks from Real-Time Exposure NIEHS Strategic Plan**
  - Development of advanced methodologies to assess risks from real-time exposure to environmental factors:
    - understanding the immediate and long-term health impacts of ethanol use and abuse requires real-time data and analysis,
    - By integrating wearable technology or biomarkers to continuously monitor exposure levels, PARC could enable more accurate and dynamic risk assessments.
- **Connecting PARC with Schools of Public Health to Enhance Risk Assessment Training**
  - Cultivate the next generation of scientists specializing in risk assessment.
  - Enhance educational outcomes but also ensure that emerging scientists are well-versed in the intersection of environmental epidemiology and risk assessment.
  - Ensure that public health decisions are informed by the latest research and methodologies.
- **Incorporating DNA Repair Assessment in PARC's Future Activities**
  - Inclusion of DNA repair toxicity in PARC's risk assessment framework.
  - Understanding how chemical exposures affect DNA repair mechanisms is vital, as these processes are crucial for maintaining genomic stability.
  - Disruption of DNA repair by chemicals can lead to mutations, genomic instability, and an increased risk of cancer and other diseases. Therefore, I recommend that PARC incorporates DNA repair assessment into its future activities.
    - Mechanisms of DNA Damage and Repair: DNA repair inhibition into its risk assessment processes developing and validating new biomarkers for DNA repair inhibition, which, when combined with traditional genotoxicity tests, would provide a more comprehensive evaluation of a chemical's carcinogenic potential.

- Developing High-Throughput Screening (HTS) Assays: Specifically assess the impact of chemicals on DNA repair pathways. These assays could rapidly identify chemicals that pose a risk to genomic stability, allowing for their prioritization in further testing.
- Interdisciplinary Research Collaboration: PARC could foster collaborations between toxicologists, molecular biologists, and epidemiologists to study the effects of chemicals on DNA repair in both in vitro and in vivo systems.
- Policy Development and Advocacy: PARC should advocate for the inclusion of DNA repair inhibition as a standard endpoint in CRA guidelines.
- Education and Training: PARC could support the training of new scientists in the field of DNA repair and CRA.

- **Connecting with the National Institute of Environmental Health in China**
  - PARC establishes connections with the National Institute of Environmental Health in China.

Appendix 3: Overview of the topics and needs, the nominations and support from the SF, NHs and the GB

Table 5: The refined list of topics and needs selected following the mapping of needs; SF, NHs and GB support

Main Topic	Topic category	ID Topic. Need	Need Description	Need already addressed in PARC	Related Task	Initial Nomination	Clear relevance for PARC	Feasibility	Support from SF	Support from NHs	GB votes
1. Natural Toxins	Already addressed	Need 1.1	Data on human exposure and effect: Mycotoxins (e.g., enniatins, alternaria).	Yes	T4.1	Norway, Belgium, Germany, Italy, Portugal	Yes	Not included in the HBM studies in T4.1. Need to check if analytical methods for natural toxins addressed in WP5 are available for human matrices.	Not included in the survey to the SF	Not included in the survey to the NH	**6**
1. Natural Toxins	Already addressed	Need 1.2	Data gaps on other natural toxins (e.g., DAS, citrinin, patulin, Cyanotoxins).	Partially	T5.1	Germany, Italy, Portugal, Norway	Yes	•Partners are willing to contribute. •Important to select the priorities based on exposure (from food analysis, HBM data - check the MCRA software-, total diet study results across Europe).	Not included in the survey to the SF	Not included in the survey to the NH	**5**
2. Flame Retardants	Already addressed	Need 2.1	Data needed on human exposure and effects (general population) + substitutes.	Partially	T4.1, T6.2	Belgium, EC, Denmark, Czech Republic, Sweden, Denmark	Yes	•Task 4.1: Availability of samples and resources, cofounding and funding from PARC. Until now not included in Aligned Studies in T4.1. •T6.2: HBM studies results are available for mixture risk assessment of mixtures in task 6.2. No kinetic models or sources of exposure is available but can be part of Y5-Y7 project proposal.	Not included in the survey to the SF	21 (supporting inclusion in the Aligned studies)	**8**

2. Flame Retardants	Already addressed	Need 2.2	Biomonitoring in workers.	Partially	T4.1 (workers), T6.2	Sweden	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
2. Flame Retardants	Already addressed	Need 2.3	Environmental levels: water, air, soil, biota, food. More data on occurrence of PBDE in infant formula + breast-fed infants.	Partially	T4.2	Belgium, EC, Sweden, Denmark	Yes	Environmental data available from monitoring programmes. Data will likely be generated in P4.2.c_Y3_Human exposure (Human exposure to organic contaminants from non-food environmental sources). Technically feasible.	Not included in the survey to the SF	Not included in the survey to the NH	**2**
2. Flame Retardants	Already addressed	Need 2.4	Data gaps on PBDE toxicokinetics, body burden, and transfer to the foetus.	Partially	T5.1	EC	Yes	Should be addressed by Industry under REACH. T4.1: Availability of samples and resources, cofounding and funding from PARC. Until now not included in Aligned Studies in T4.1. It is feasible to do, methods are existing but not yet widely used in the EU.	Not included in the survey to the SF	Not included in the survey to the NH	**1**
2. Flame Retardants	Already addressed	Need 2.5	Health impact assessment of flame retardants.	No	T6.2	Belgium, Spain	Yes	These activities are planned in Y5-Y7 project T6.2.	Not included in the survey to the SF	Not included in the survey to the NH	**2**
3. Heavy Metals	Already addressed	Need 3.1	Lead: Follow-up data on the impact of the recent REACH restriction.	Yes	T4.1, T6.2	Cyprus, Finland, EC, Latvia	Yes	There is already extensive data on Lead and it is already regulated. More than just exposure data, additional data is required for source tracking to better reduce exposure to lead (not only through food but	Not included in the survey to the SF	Not included in the survey to the NH	**5**

								also through the environment).			
3. Heavy Metals	Already addressed	Need 3.2	Data on general population exposure to lead, mercury, cadmium, and nickel.	Partially	T4.1, T6.2	Slovakia	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**2**
3. Heavy Metals	Already addressed	Need 3.3	Lead, arsenic, cadmium, and iodine levels in specific seaweed species.	Partially	T4.2, T6.2	EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
3. Heavy Metals	Already addressed	Need 3.4	Risk-benefit assessment of fish consumption (e.g., exposure to heavy metals).	Yes	T6.4, T6.2	Germany	Yes	Yes T6.2 health impact for the risk side. Risk benefit is based on burden of disease models.	Not included in the survey to the SF	Not included in the survey to the NH	**2**
3. Heavy Metals	Already addressed	Need 3.5	Data on Cr(III) toxicity in aquatic environments.	No	T4.2, T6.2	EC	Yes	Yes T6.2 (occupational studies are in MCRA) ready for mixture interpretation.	0	1	**1**
3. Heavy Metals	Already addressed	Need 3.6	Methods to distinguish exposure to Cr(VI) from other chromium substances.	No	T4.3	EC	Partially	Yes	2	5	**1**
4. Benzophenones and UV Filters	Could be addressed	Need 4.1	Collection of exposure data across Europe.	No	T4.1	EC, Portugal	Yes	•T4.3 could address common benzophenone in human matrices (in small scale suspect screening). •T4.2 could address benzophenone in the environment. However, data generated would likely be semi-qualitative or qualitative. Potential budget constrain.	4	9	**8**

5. Mineral Oil Hydrocarbons (MOSH/MOAH)	To be discussed	Need 5.1	Human Biomonitoring on MOSH tissue concentrations; development of biomarkers of exposure.	No	T4.1	EC, Slovenia	Yes	• T4.3: Should check if there are analytical methods available.	2	5	**1**
5. Mineral Oil Hydrocarbons (MOSH/MOAH)	To be discussed	Need 5.2	Contribution from environmental sources and food.	No	T4.2	EC	Yes	Mineral oils are usually very complex mixtures and not analysed as individual compounds. The most common used method is an online coupled LC-GC-FID, which cannot be seen as standard in analytical labs.	1	1	**0**
5. Mineral Oil Hydrocarbons (MOSH/MOAH)	To be discussed	Need 5.3	Toxicity of MOAH (genotoxicity, carcinogenicity) TK, immunotoxicity, neurotoxicity of MOSH.	No	T5.1	EC	No	Should be addressed by Industry under REACH.	0	2	**0**
6. Vitamins	Not a priority	Need 6.1	Biomonitoring of vitamins (A, D) across populations.	No	T4.1	EC	No	x	Not included in the survey to the SF	Not included in the survey to the NH	**2**
7. Substances in Welding Fumes	Already addressed	Need 7.1	Collection of biomonitoring data for workers (e.g., manganese).	Partially	T4.1 (workers)	Sweden, EC, Croatia, Austria, France, Latvia	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**7**
7. Substances in Welding Fumes	Already addressed	Need 7.2	Test compounds for innovative methods.	No	T5.2	Finland	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**

7. Substances in Welding Fumes	Already addressed	Need 7.3	Support the setting of occupational limit value for welding fumes under the CMR-Directive.	No	T6.2, T4.1, T4.2	Finland	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
8. Battery Chemicals	Already addressed	Need 8.1	Biomonitoring of workers (e.g., lithium, cobalt, nickel salts, also fluorinated compounds and ionic liquids).	Partially	T4.1 (workers), T6.2	Sweden, EC, France, Portugal, Austria	Yes	•It would be valuable to focus specifically on new generation batteries used e.g., in electrical vehicles. There are various metals used in these including cobalt, nickel, manganese and lithium. In addition, there are organics, including fluoropolymers (which in combustion result in the release of HF and non-polymeric PFASs). There isn't much information on the occupational exposure during the life-cycle of this kind of batteries or e.g., recommendations on the most suitable biomarkers etc… •T6.2: occupational data will be generated and interpreted partly in T4.1 and 6.2.	Not included in the survey to the SF	Not included in the survey to the NH	**9**
9. PFAS	Already addressed	Need 9.1	Monitoring of PFAS-related chemicals using SS/NTS and PFAS sum analysis.	Partially	T4.1 (workers), T6.2	EC, Ireland, Austria, France, Denmark, Germany	Yes	Yes (T4.1). T6.2: might be further explored not used yet.	Not included in the survey to the SF	Not included in the survey to the NH	**5**
9. PFAS	Already addressed	Need 9.2	General Population: Develop knowledge on alternatives and substitutes.	No	T4.1, T6.2	Denmark	Yes	Yes	Not included in the survey to the SF	Not included in the	**6**

										survey to the NH	
9. PFAS	Already addressed	Need 9.3	Environmental monitoring and data gathering, fate and behaviour study in the environment; methods for the detection in the air.	Partially	T4.2, T6.2	EC, Denmark, Austria	Yes	Yes T6.2: occupational studies/health impact and aggregated exposure are in MCRA, ready for mixture interpretation.	Not included in the survey to the SF	Not included in the survey to the NH	**1**
9. PFAS	Already addressed	Need 9.4	Studies on the properties, behaviour in the environment, ecotoxicity and human toxicity of PFAS other than PFOS, PFOAS and PFHxS.	Partially	T5.1	Finland, Switzerland, France, EEA	Partially	For substance groups that industry has to work at, like PFAS, PARC should not start additional work in T5.1.	Not included in the survey to the SF	Not included in the survey to the NH	**7**
9. PFAS	Already addressed	Need 9.5	Develop fast and efficient analytical methods for PFAS in products and articles.	Yes	T6.4	Sweden	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**7**
9. PFAS	Already addressed	Need 9.6	Release of PFAS combustion products from waste incineration plants.	No	T5.2	EC	Yes	For substance groups that industry has to work at, like PFAS, PARC should not start additional work in WP5.	Not included in the survey to the SF	Not included in the survey to the NH	**2**
10. Bisphenols	Already addressed	Need 10.1	Workers: Biomonitoring data from workers to assess current safety measures.	Partially	T4.1 (workers), T6.2	EC, Ireland, Austria	Yes	Yes T6.2: occupational data will be generated and interpreted partly in T4.1 and 6.2.	Not included in the survey to the SF	Not included in the survey to the NH	**5**
10. Bisphenols	Already addressed	Need 10.2	Workers: Measurement co-exposures to chemicals including chemical families such as bisphenols.	Partially	T4.1 (workers), T6.2	Italy	Yes	Yes T6.2: occupational data will be generated and interpreted partly in T4.1 and 6.2.	Not included in the survey to the SF	Not included in the survey to the NH	**0**

10. Bisphenols	Already addressed	Need 10.3	Workers: Collection exposure data on alternative of bisphenols used in production process as bisphenols are being more tightly regulated.	No	T4.1 (workers)	Denmark	Partially	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
10. Bisphenols	Already addressed	Need 10.4	Monitoring of non-intentionally added substances (NIAS), associated to bisphenols, e.g., cyclo-di-BADGE in food & other environmental media as appropriate.	Yes	T4.2	Belgium	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
10. Bisphenols	Already addressed	Need 10.5	Collection of epidemiological data on the carcinogenicity of BPA including genotoxic carcinogenesis.	No	T5.1	Hungary	Partially	WP5: no epidemiologist in WP5 . WP6: For genotoxic effects epidemiological data should be available, availability of data should be checked.	Not included in the survey to the SF	Not included in the survey to the NH	**0**
10. Bisphenols	Already addressed	Need 10.6	Use bisphenols and its alternative as a test compound for innovative methods.	Yes	T5.2	Germany, Hungary	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
11. Phthalates	Already addressed	Need 11.1	Workers: Biomonitoring data collection from workers to assess effectiveness of current health protection measures.	Yes	T4.1 (workers), T6.2	EC, Austria, France	Yes	Yes (T4.1). T6.2: occupational data will be generated and interpreted partly in T4.1 and 6.2.	Not included in the survey to the SF	Not included in the survey to the NH	**2**

11. Phthalates	Already addressed	Need 11.2	Phthalate alternatives (e.g., for DEHP) in medical devices, especially for vulnerable populations.	No	T5.1	Belgium	Partially	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
11. Phthalates	Already addressed	Need 11.3	Phthalates use in future PARC case studies (toolbox operationalization).	Partially	T8.1	Italy	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
12. Pesticides/ Fungicides	Already addressed	Need 12.1	Workers: Data on worker exposure to pesticides and fungicides.	No	T4.1 (workers), T6.2	EC, France	Yes	Not defined yet	Not included in the survey to the SF	Not included in the survey to the NH	**2**
12. Pesticides/ Fungicides	Already addressed	Need 12.2	General population exposure data on pesticides.	Partially	T4.1, T6.2	Ireland	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
12. Pesticides/ Fungicides	Already addressed	Need 12.3	Methods for the detection of pesticides substances in air/deposition.	Partially	T4.3, T6.2	Austria	Yes	No	Not included in the survey to the SF	Not included in the survey to the NH	**0**
12. Pesticides/ Fungicides	Already addressed	Need 12.4	Closing data gaps of concern for pesticides.	No	T5.1	Norway	No	For substance groups that industry has to work at, like PFAS, PARC should not start additional work in T5.1.	Not included in the survey to the SF	Not included in the survey to the NH	**0**
12. Pesticides/ Fungicides	Already addressed	Need 12.5	Alignment of dietary exposure calculation approaches (incl. food consumption survey data, toxicological reference values and MRLs/indicative	Yes	T6.3, T6.2	UK	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**4**

			levels) across regulatory silos (pesticide/biocides/ vet meds/food contaminants).								
12. Pesticides/ Fungicides	Already addressed	Need 12.6	Environmental risk assessment.	Yes	T6.4	EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
13. PMT/vPvM Substances	Could be addressed	Need 13.1	Monitoring in soil, water, and biota.	Partially	T4.2	Switzerland, EC, UK, Luxembourg, Denmark, Germany	Yes	Yes	2	7	**9**
13. PMT/vPvM Substances	Could be addressed	Need 13.2	Chronic aquatic & soil toxicity (endpoint for innovative tools and methods for toxicity testing).	No	T5.2	Belgium	Yes	Yes	1	3	**2**
13. PMT/vPvM Substances	Could be addressed	Need 13.3	Review of the impact of new CLP hazard classes (PBT, vPvB, PMT, vPvM, EDC) on the procedure and methodologies to derive environmental limit values (such as EQS).	No	T6.3	Luxembourg	Yes	Yes	6	4	**5**

14. PBT Substances	Already addressed	Need 14.1	Development of approaches based on monitoring field data enabling persistence, long-range environmental transport and/or bioaccumulation assessment (+ case study on siloxanes).	Partially	T4.2	EC	Yes	Yes	0	6	**3**
15. Pollutants in Wastewater Effluents	Already addressed	Need 15.1	Monitoring pollutants in wastewater effluents + Diffuse pollution.	Yes	T4.2	EC and EEA	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**2**
16. Methods for Early Warning Signals (EWS)	Already addressed	Need 16.1	Develop methods for Early Warning Systems to detect emerging chemical risks.	Yes	T8.2, T4.3	EC, EEA, EFSA	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**5**
17. Monomers of Polymers, Biodegradable Polymers	Could be addressed	Need 17.1	Understanding polymer's bioavailability - Biodegradable polymers (environment).	No	T5.1	Switzerland, EC, UK, Portugal	Yes	Yes	2	2	**4**
17. Monomers of Polymers, Biodegradable Polymers	Could be addressed	Need 17.2	Monitor the implementation of the requirement to register polymers under REACH (when it happens).	Partially	T6.3	UK	Partially	Not defined yet	4	0	**0**
17. Monomers of Polymers, Biodegrada	Could be addressed	Need 17.3	KARC. 2.4.1. Polymers including tire rubber: Development of knowledge and	No	T5.1	EC	Partially	Yes	1	4	**3**

ble Polymers			methodologies to support hazard assessment.								
18. Chemicals Leaching from Plastics and Rubber Tyres	Could be addressed	Need 18.1	Data on the impact of chemicals leaching from plastics and rubber tyres on human and environmental health. Monitoring of various PPD and their respective quinones is required to estimate the exposure and potential risks for human health.	No	T4.1	Austria, Norway, Finland, Denmark, Portugal	Yes	Based on the results of exploratory work on the expertise in PARC a new activity /project could be designed to address this need.	4	7	**5**
18. Chemicals Leaching from Plastics and Rubber Tyres	Could be addressed	Need 18.2	More environmental monitoring on fate and behaviour of tyre additives, including PPD and metabolites.	Partially	T4.2	Austria, Norway, Finland, Denmark, Portugal	Yes	Yes	1	5	**7**
18. Chemicals Leaching from Plastics and Rubber Tyres	Could be addressed	Need 18.3	Close data gaps on chemicals leaching from plastics for human health, including non-intentionally added substances to plastics.	Partially	T5.1	Norway, Portugal	Partially	Yes	2	10	**9**
18. Chemicals Leaching from Plastics and Rubber Tyres	Could be addressed	Need 18.4	Integrative exposure and risk assessment of PPDs+ quinones: para-phenylenediamines (PPDs e.g. 6PPD and	Partially	T6.2	Austria	Yes	Yes	0	0	**2**

			its metabolite 6PPD-Quinone).								
19. 2D Materials	Not a priority	Need 19.1	Provide some data in particular ability to span across the family and different morphologies effectively (incl. grouping approaches).	No	T5.2	EC	Partially	x	Not included in the survey to the SF	Not included in the survey to the NH	**0**
20. Developmental and Reproductive Toxicity (DART)	Already addressed	Need 20.1	Development of NAMs (including developmental immunotoxicity and developmental neurotoxicity).	Partially	T5.2, T6.2	Norway, Germany, UK, France, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**7**
20. Developmental and Reproductive Toxicity (DART)	Already addressed	Need 20.2	Development of IATAs.	No	T6.1	Norway	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**4**
21. More than One Constituent Substance (MOCS)	To be discussed	Need 21.1	Methods to characterize the effects of complex substances (MOCS) on health and the environment. Applicability of NAMs developed to MOCs (e.g., Essential oil).	No	T5.2	Czech Republic, EC	Yes	Yes	2	7	**4**

21. More than One Constituent Substance (MOCS)	To be discussed	Need 21.2	Aggregate exposure from 'Mixtures' in view of MOCS; what would be the CLP classification according to the use of data based on the MOCS themselves or on individual components.	No	T6.2	EC	Yes	Not sure PARC has the expertise on these chemicals.	3	0	**1**
22. New Approach Methods (NAMs) for Replacing Animal Testing	Already addressed	Need 22.1	Develop new approach methods (NAMs) to replace animal testing for hazard endpoints (e.g., acute fish toxicity).	Partially	T5.2	EC, Sweden, Denmark, Norway, Austria, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**8**
22. New Approach Methods (NAMs) for Replacing Animal Testing	Already addressed	Need 22.2	How to use NAM for CLP classification and OEL development.	Yes	T6.1, T6.3 and T6.4	Sweden, Denmark, Norway, Austria,	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**10**
22. New Approach Methods (NAMs) for Replacing Animal Testing	Already addressed	Need 22.3	In vitro -in vivo extrapolation & uncertainty.	Yes	T6.4	Belgium, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**2**
22. New Approach Methods (NAMs) for Replacing Animal Testing	Already addressed	Need 22.4	Read across, Protection of biodiversity.	Yes	T6.4	EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**

23. Fibre Toxicity	Not a priority	Need 23.1	A systemic approach to addressing (persistent) fibre toxicity with consideration on parameters contributing to different adverse outcomes, and possibility to use them in regulatory context (i.e., beyond WHO fibre paradigm).	No	T5.2	EC	Partially	x	Not included in the survey to the SF	Not included in the survey to the NH	**0**
24. Neurotoxicity	Already addressed	Need 24.1	Workers: Add some effect biomarkers in the HBM studies for workers.	No	T4.1 (workers), T6.2	Switzerland	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**2**
24. Neurotoxicity	Already addressed	Need 24.2	Development of NAMs (DNT, ANT); Identification of reliable positive and negative reference chemicals for NAM reliability testing and validation.	Partially	T5.2	Belgium, Israel, Spain, UK, Portugal, Czech Republic, Austria, Denmark, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**7**
24. Neurotoxicity	Already addressed	Need 24.3	IATA development, including for ecotox species (e.g., fish, daphnids, earthworms etc.).	No	T6.1	Belgium, Israel, Spain, UK, Portugal, Czech Republic, Austria, Denmark, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**4**
25. Immunotoxicity	Already addressed	Need 25.1	Study the effects of chemicals on the immune system, particularly in sensitive populations	Yes	T5.2, T6.2	EC, DK	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**6**

			(e.g., children); Identification of critical windows of development of the immune system to develop a NAM based battery to assess developmental immunotoxicity.								
25. Immunotoxicity	Already addressed	Need 25.2	IATA development for environmental assessment (e.g., fish, daphnids, earthworms etc.).	No	T6.1	Belgium, Spain, Germany, UK, Portugal, Czech Republic, Austria, DK, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**4**
25. Immunotoxicity	Already addressed	Need 25.3	Review of risk assessment methodology for chemical products with limited social benefit but has high and unnecessary exposure (e.g., fragrance for washing).	No	T6.3	Germany, Belgium	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**0**
26. Endocrine Disruptor (ED) Mixtures	Already addressed	Need 26.1	Study the effects of exposure to endocrine disruptor (ED) mixtures on human health and the environment.	Yes	T6.2	Belgium, EC, Czech Republic, Austria	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**4**
27. Co-exposure to Multiple Chemicals	Already addressed	Need 27.1	Further development of methods for health and environmental risk assessment of co-exposures to multiple chemicals.	Yes	T6.2	EC, Portugal	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**9**

28. Bioaccumulation	To be discussed	Need 28.1	To address the knowledge gaps in understanding bioaccumulation and biological effects of Contaminants of Emerging Concern (CECs), a rapid contaminant screening assay.	No	T5.2	Ireland	Yes	Not defined yet	0	2	**1**
28. Bioaccumulation	To be discussed	Need 28.2	Development of non-vertebrate methods to predict the bioaccumulation potential of surfactants and ionisable substances as well as of organo-metals and superhydrophobic chemicals.	No	T5.1	Austria, EC	Yes	Yes	0	1	**1**
28. Bioaccumulation	To be discussed	Need 28.3	Bioaccumulation in air breathing organism.	No	T5.2	EC	Unsure	Not defined yet	0	2	**1**
28. Bioaccumulation	To be discussed	Need 28.4	Improvement of assessment of secondary poisoning and man *via* environment specially for mixtures.	Yes	T5.2	EC	Unsure	Yes	1	1	**3**
29. Chemicals and Biodiversity	To be discussed	Need 29.1	Understand the impact of chemicals on soils biodiversity.	Partially	T4.3	UK	Yes	No	0	0	**2**
29. Chemicals and Biodiversity	To be discussed	Need 29.2	Exposure levels of chemical mixtures and potential threats to ecosystem	Partially	T4.2	Ireland, EC	Yes	Collaboration needed with biodiversity expertise in PARC.	1	3	**2**

			services or biodiversity.								
29. Chemicals and Biodiversity	To be discussed	Need 29.3	Methods to assess the effects of chemicals on biodiversity.	Partially	T5.2	France, EC, Ireland	Yes	Yes	1	6	**5**
29. Chemicals and Biodiversity	To be discussed	Need 29.4	Investigate how to better address the effects on/risks to biodiversity loss.	Partially	T6.4	Germany, EC	Yes	Not defined yet	0	3	**1**
29. Chemicals and Biodiversity	To be discussed	Need 29.5	Further development of a NGRA, which has already been initiated in collaboration with WP2.2.	Partially	T2.2	Austria	Yes	Not defined yet	2	0	**3**
30. Sensitivity of Non-Bee Pollinators (NBP) to Biocidal Active Substances	To be discussed	Need 30.1	Data on the sensitivity of non-bee pollinators to biocidal active substances.	No	T5.2	EC	Partially	Need to check if this should be under the remit of industry. Could be interesting to develop a method to assess hazard and exposure.	0	3	**0**
31. Monitoring Methodology	Already addressed	Need 31.1	Further harmonization of HBM: Continue the work to harmonize and mature approaches for human biomonitoring in the EU.	Yes	T4.1	EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**2**
31. Monitoring Methodology	Already addressed	Need 31.2	Harmonisation exercises for Non-Target Analyses in environmental and human biomonitoring: In order to identify	Yes	T4.3	Austria, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**2**

			emerging substances which may be of high regulatory priority and also to implement this into an early warning system.								
31. Monitoring Methodology	Already addressed	Need 31.3	Development of a European database in which all approved/registered substances (REACH, biocides, PPPs, pharmaceuticals).	Partially	T6.2	Germany	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
31. Monitoring Methodology	Already addressed	Need 31.4	Investigate how monitoring networks can align (methodology), how data can be shared transparently across EU, ensure post-PARC infrastructure of data collection …	Yes	T9.2	Belgium	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
32. Carcinogenicity	Already addressed	Need 32.1	High-throughput harmonized methods for genotoxicity and non-genotoxic carcinogenicity.	Partially	T5.2, T6.1	Portugal	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**1**
32. Carcinogenicity	Already addressed	Need 32.2	Develop AOPs and IATA for non-genotoxic carcinogenesis, including for the environment.	Partially	T6.1, T5.2	Norway, Germany, Portugal, EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**4**
32. Carcinogenicity	Already addressed	Need 32.3	Review of risk assessment methodology for chemical products with limited social	Partially	T6.3, T6.1, T5.2	Germany	Yes	Yes. See also need 25.3 on immunotoxicity.	Not included in the survey to the SF	Not included in the survey to the NH	**1**

			benefit but has high and unnecessary exposure (e.g., fragrance for washing). Non-genotoxic carcinogenicity as endpoint.								
33. Validation of Systematic In Vitro/Silico Testing for Chronic Toxicity	Already addressed	Need 33.1	Develop systematic in vitro/in silico models to predict chronic toxicity in vertebrate species.	Partially	T5.2, T6.1	EC	Yes	Yes	Not included in the survey to the SF	Not included in the survey to the NH	**3**

Appendix 4: MB feedback on the top 17 needs

Table 6: MB feedback on the top 17 needs and their potential inclusion in PARC's future activities

Topic	Need	Need ID	Task	Already addressed in Y1-Y3	Planned in Y4	Planned for the future years	Comment
New Approach Methods (NAMs) for Replacing Animal Testing	How to use NAM for CLP classification and OEL development.	22.2	T6.1, T6.3 and T6.4	**T6.4** Status of integration and use of NAMs in the EU regulatory risk assessment landscape (has started a landscaping). **P6.4.2.b_Y1**_NGRApractice_VKM_NIPH (Next Generation Risk Assessment Applied in Practice).	• **P6.4.2.b_Y1_** NGRApractice_VKM_NIPH will be extended. • **P6.4.2.d_Y4**_RegulatoryNAMs_ISS (Demonstrating the applicability of NAMs for specific regulatory processes through a series of case studies).	The projects will continue.	
	Develop new NAMs to replace animal testing for hazard endpoints (e.g., acute fish toxicity).	22.1	T5.2, T6.1	**T5.2**: Assay development started for **5 prioritised endpoints** (Immunotoxicity, Developmental neurotoxicity, Nongenotoxic carcinogenicity, endocrine disrupting chemicals, metabolism disrupting chemicals).	+Developmental and reproductive toxicity (**DART**) added as a priority. **Regulatory readiness** project initiated in Y4.	**T6.1:** Y5-Y7: IATA for carcinogenicity (genotoxic/non-genotoxic carcinogens). Y5-Y7: IATA for metabolic disruption.	For T5.2, more or less activities will continue until the end of PARC; for T6.1 additional projects will be submitted. Regulatory readiness project may need additional capacities.
				T6.1: IATA development for genotoxicity, liver fibrosis and thyroid hormone system disruption, plus workflow for human relevance assessment of AOPs and associated NAMs.	• **P6.4.2.d_Y4**_RegulatoryNAMs_ISS. • **P6.1.1.c_Y1**_IATA-GENTOX_Sciensano (IATA for Genotoxicity) • **P6.1.1.d_Y1**_IATA_STOT_UL-LACDR (IATA for systemic target organ toxicity) • **PARC_P6.1.1.e_Y4**_FISH-THSD_UAntwerpen (An AOP network-based approach for assessing thyroid hormone system disruptors in fish) • **P6.1.1.f_Y4**_HumanRelevance_RIVM (Workflow for Human Relevance Assessment of AOPs and Associated NAMs).		

Developmental And Reproductive Toxicity (DART)	Development of NAMs (including developmental immunotoxicity and developmental neurotoxicity).	20.1	T5.2	Not in Y1-Y3 for T5.2.	Y4: start of NAM development in T5.2: **P5.2.1.f_Y4_DART-ED_DTU** (Developmental and reproductive toxicity – Endocrine disruption).	Y5-Y7: Continue work of Y4.	May need more budget to succeed.
Neurotoxicity	Development of NAMs (DNT, ANT); Identification of reliable positive and negative reference chemicals for NAM reliability testing and validation.	24.2	T5.2	Yes, in Y1, DNT work improving the **developmental neurotoxicity *in vitro* battery**. **P5.2.1.e_Y1_DNT-ANT**_UFZ_IUF_NIPH (Neurotoxicity)	Y4: continue DNT-IVB + improve regulatory readiness. Addition of **ANT (adult neurotoxicity)**.	**T5.2**: Y5-Y7: Continue work of Y4 + improve readiness. Case study endpoint in **T6.2** projects: real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-Y7 and project kinetics external to internal exposure Y5-Y7. With focus on new HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	
Immunotoxicity	Study the effects of chemicals on the immune system (+sensitive populations); Identification of critical windows of its	25.1	T5.2, T6.1, T6.2	**T5.2**: Immunotoxicity *in vitro* battery focusing on the development of NAM and immunosuppression. • **P5.2.1.g_DIT-NAM**_Inserm (Developmental Immunotoxicity – NAM development) • **P5.2.1.d_Y1_Immunotox**_Inserm (Immunotoxicity)	Y4: Continue work of Y1-Y3 and improve regulatory readiness.	**T5.2**: Y5-Y7: continue work for Y4 and improve readiness. **T6.1:** results achieved may/will feed into the IATA for carcinogenicity.	

	development to develop NAMs for DIT.					Case study endpoint in **T6.2** projects: real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-Y7 and project kinetics external to internal exposure Y5-Y7. With focus on new HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	
Battery Chemicals	Biomonitoring of workers (e.g., lithium, cobalt, nickel salts, also fluorinated compounds and ionic liquids).	8.1	T4.1 (workers), T6.2	•HBM4EU partially covered in e-waste study. •PARC is covering battery recycling: **P4.1.1.4.d_Y1_OccupWaste**_ENSP_TTL (Occupational survey in the wate management sector). No data yet on new batteries in electrical vehicles.	**T6.2**: battery chemicals (interpretation of generated occupational data).	Case study chemicals in T6.2 projects: real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-y7 and project kinetics external to internal exposure Y5-Y7. With focus on new HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	

Substances in Welding Fumes	Collection of biomonitoring data for workers (e.g., manganese).	7.1	T4.1 (workers)	•PARC is doing more analysis and will use the HBM4EU data in 6.2.3 in mixture assessment and 6.2.1 in aggregated exposure assessment. •Candidate topic for future HBM occupational study.	Yes, under occupational studies.	Case study chemicals in T6.2 projects: real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-y7 and project kinetics external to internal exposure Y5-Y7. With focus on new HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	
Benzophenones and UV Filters	Collection of exposure data across Europe.	4.1	T4.1	There is some "recent" UV-filters (benzophenones) data from HBM4EU in adults. (https://hbm.vito.be/eu-hbm-dashboard; publication: 10.1016/j.ijheh.2023.114119). Moreover, these data will be further explored in association with metabolism (BMI & effect markers) and asthma & allergy as part of PARC project **P4.1.4.2.a_Y1_DataAnalysisHBM4EU**_VITO (further analysis of the data generated within HBM4EU).	No	No	•T4.3 could address common benzophenone in human matrices (in small scale suspect screening). •T4.2 could address benzophenone in the environment. However, data generated would likely be semi-qualitative or qualitative. Potential

							budget constrain.
Flame Retardants	Data needed on human exposure and effects (general population) + substitutes.	2.1	T4.1, T6.2	• **P4.1.1.4.d_Y1_OccupWaste_**ENSP_TTL where waste management workers exposure to flame retardants is studied (Brominated (BDE-47, BDE-153, HBCD, γ-HBCD) and OPFRs metabolites (BCEP, BCIPP, BDCIPP, DPHP) analyses are included in the waste management study). There is some "recent" flame retardant data from HBM4EU in children. (https://hbm.vito.be/eu-hbm-dashboard; publication: 10.1016/j.ijheh.2022.114070; 10.1016/j.ijheh.2023.114119; 10.3390/toxics11110878)	**T4.1**: not planned **T6.2**: **P6.2.1.a_Y1_SourcetoDose**_VITO (Developing, performing and validation of source to dose modelling including selected case studies): Case study on flame retardants	**T4.1**: not planned Case study chemicals in T6.2 projects: real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-y7 and project kinetics external to internal exposure Y5-Y7. With focus on new HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	
Natural toxins	Data on human exposure and effect: Mycotoxins (e.g., enniatins, alternaria).	1.1	T4.1	There is some "recent" mycotoxin (deoxynivalenol) data from HBM4EU in adults. https://hbm.vito.be/eu-hbm-dashboard; publication 10.1016/j.ijheh.2023.114119). Publication on exposure levels & determinants submitted; new analyses on exposure-effect in association with BMI part of **P4.1.4.2.a_Y1_DataAnalysisHBM4EU**_VITO.	No	No **T6.2**: Y5-Y7 will include some mycotoxin HBM data (national projects and aligned study Portugal).	
PMT/vPvM Substances	Monitoring in soil, water, and biota.	13.1	T4.2	No.		Could be addressed in Y5-Y7 after identification of data gaps and resources required.	It does not make sense to measure PMT in biota (only in water and soil). UBA and

							RIVM are partners of ZeroPM that addresses PMT, WP4 may only refer to ZeroPM if they have sufficient data and does not tackle this need (PMT) remaining open questions could be tackled.
Chemicals Leaching from Plastics and Rubber Tyres	More environmental monitoring on fate and behaviour of tyre additives, including PPD and metabolites.	18.2	T4.2	No.		Relevant and could be addressed by T4.2 in Y5-Y7 after identification of data gaps and resources required.	Relevant to do environmental monitoring for tyre additives.
	Close data gaps on chemicals leaching from plastics for human health, including non-intentionally added substances to plastics.	18.3	T5.1	No	Project lead by NIPH initiated: **P5.1.1.d_Y4_PlasticLeach**_NIPH (Hazard characterisation of leachable chemicals present in plastics). Discussion ongoing for the proposal of TG+ studies.	Y5-Y7: continue TG+.	
Co-exposure to Multiple Chemicals	Further development of methods for health and	27.1	T6.2 T6.4	**T6.4** • **P6.4.1.a_Y1_OPREMIXCS1**_BRUNEL_RWTH (Optimizing regulatory risk assessment and	• **P6.4.1d_Y4**_REMIX_UBA_EAWAG (Options to assess and regulate mixtures) starting in May 2025 • **P6.4.1.c_Y3**_Skinsenmix_RegionH	6.4 (REMIX and Skinsens) projects will continue.	

	environmental risk assessment of co-exposures to multiple chemicals.			management of chemical mixtures in Europe) (Finalised in April 2025). • **P6.4.1.b_Y1_MONAMMIXCS2**_UFZ (Dealing with unknown mixtures in regulatory risk assessment through the use of monitoring data and NAMs) (Finalised in April 2025). • **P6.4.1.c_Y3_Skinsenmix**_RegionH (Skin sensitization – effect of mixtures, current practices and gaps).		Method development and European Harmonisation in 6.2 project real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-Y7 and project kinetics external to internal exposure Y5-Y7. With focus on new HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	
PFAS	Studies on the properties, behaviour in the environment, ecotoxicity and human toxicity of PFAS other than PFOS, PFOAS and PFHxS.	9.4	T5.1	No.	Y5: Discussion with **EFSA**, ECHA and EEA on relevant of TG+ needs (PFNA, PFHxS, PFBA).	**T5.1:** Y5-Y7: TG+ studies. Relevant for **T4.2** to address environmental behaviour of PFAS. Case study chemicals in **T6.2** projects: real-life mixtures Y5-Y7, project burden of disease Y5-Y7, project aggregated exposure Y5-Y7 and project kinetics external to internal exposure Y5-Y7. With focus on new	May need more budget to succeed.

						HBM data from WP4 or elsewhere, with more focus on end-user (Agencies, Regulators).	
	Develop fast and efficient analytical methods for PFAS in products and articles.	9.5	T6.4	No.	Yes, **P6.4.3.b_Y3_ENFORCE**_KEMI (New methods to support the ENFORCEment of chemicals in consumer articles): Analytical workflow and individual methods for compliance testing of PFAS and additives in plastics.	**P6.4.3.b** will continue.	
	General Population: Develop knowledge on alternatives and substitutes.	9.2	T4.1, T6.2	**P4.1.1.2.a_Y1_GenHBMSurvey**_VITO: (General population human biomonitoring survey): PFAS analysis is included in teenagers and adults, bisphenols and phthalates are in all age groups (Bisphenol A alternatives are included, alternative plasticizers such as DINCH and others are included).	T4.1: A new project will measure PFAS for children (**P4.1.1.3.b_Y4_PFASChildren**_SpF).	No	

Appendix 5: 2nd prioritisation round feeding projects for Year 4

Table 7: Year 4 projects in relation to topics selected for the 2nd prioritisation round of PARC

Project ID	Project Title	Addressed topic(s)
P5.2.a_Y4	Regulatory readiness of NAM	NAMs for replacing animal testing
P6.4.2.d_Y4	Demonstrating the applicability of NAMs for specific regulatory processes through series of CSs	NAMs for replacing animal testing, Carcinogenicity, DART, In vitro/ silico battery to generate chronic tox data for vertebrates
P6.1.1.f_Y4	Workflow for Human Relevance Assessment of AOPs and Associated NAMs	NAMs for replacing animal testing
P5.3.1.b_Y4	Fostering the use of omics for grouping and read-across in risk assessment	NAMs for replacing animal testing
P5.2.1.g_Y4	Developmental Immunotoxicity - NAM development	NAMs for replacing animal testing, DART, Immunotoxicity
P5.2.1.h_Y4	Sexual dimorphism associated to susceptibility to hepatotoxicity of environmental contaminants	NAMs for replacing animal testing
P5.2.1.f_Y4	Developmental and Reproductive Toxicity - Endocrine Disruption (DART-ED)	NAMs for replacing animal testing, DART
P5.3.4.b_Y4	In vitro methods to assess respiratory uptake & toxicity	NAMs for replacing animal testing, In vitro/ silico battery to generate chronic tox data for vertebrates, PFAS, ED mixtures
P6.1.1.e_Y4	An AOP network-based approach for assessing thyroid hormone system disruptors in fish	NAMs for replacing animal testing
P6.4.2.e_Y4	Establishment of readiness criteria for AI/ML-based tools used in risk assessment	NAMs for replacing animal testing
P5.1.2.c_Y4	TG+ Microplastic bioaccumulation data gaps and applicability of in vitro bioaccumulation assessment methods (env)	NAMs for replacing animal testing
P4.1.1.3.a_Y4	PFAS in Mother Milk: pregnancy and postnatal health	PFAS
P4.1.1.3.b_Y4	Description of PFAS Exposure in early life in European countries (PFAS in children)	PFAS
P4.1.1.3.c_Y4	Time patterns of internal human exposure to environmental pollutants in Europe.	PFAS
P4.2.d_Y4	Volatile siloxanes in the European environment - towards robust data in support of regulatory action	PBT
P5.1.1.d_Y4	Hazard characterization of leachable chemicals present in plastics	Chemicals leaching from plastics
P6.4.1.d_Y4	Options to assess and regulate mixtures	Co-exposure from multiple chemicals, Chemicals and biodiversity;
P4.1.3.1.b_Y4	Derivation of Health-based Indoor Air Guideline Values	Chemicals leaching from plastics, Co-exposure from multiple chemicals

Appendix 6: PARC's answers to the KARC

The KARC document (2023 version) is organised into four main areas:
1/ Protection against the most harmful chemicals
2/ Addressing chemical pollution in the environment
3/ Reducing reliance on animal testing
4/ Improving the availability of chemical data
Each area comprises specific topics and sub-topics.

As PARC has, to some extent, based its prioritisation on this document, it was relevant to assess, for every KARC topic, if a corresponding topic was selected by PARC during its second prioritisation round and if this topic is already addressed in PARC or not. Also, for each KARC sub-topic or need, it was relevant to identify if specific needs were highlighted in PARC's second prioritisation round, check if they are already addressed in PARC, partially addressed or not, as well as related PARC projects and relevant activities outside of PARC.
An overview of this evaluation is presented in Figure 7 followed by a zoom-in on how each area is specifically addressed in PARC.

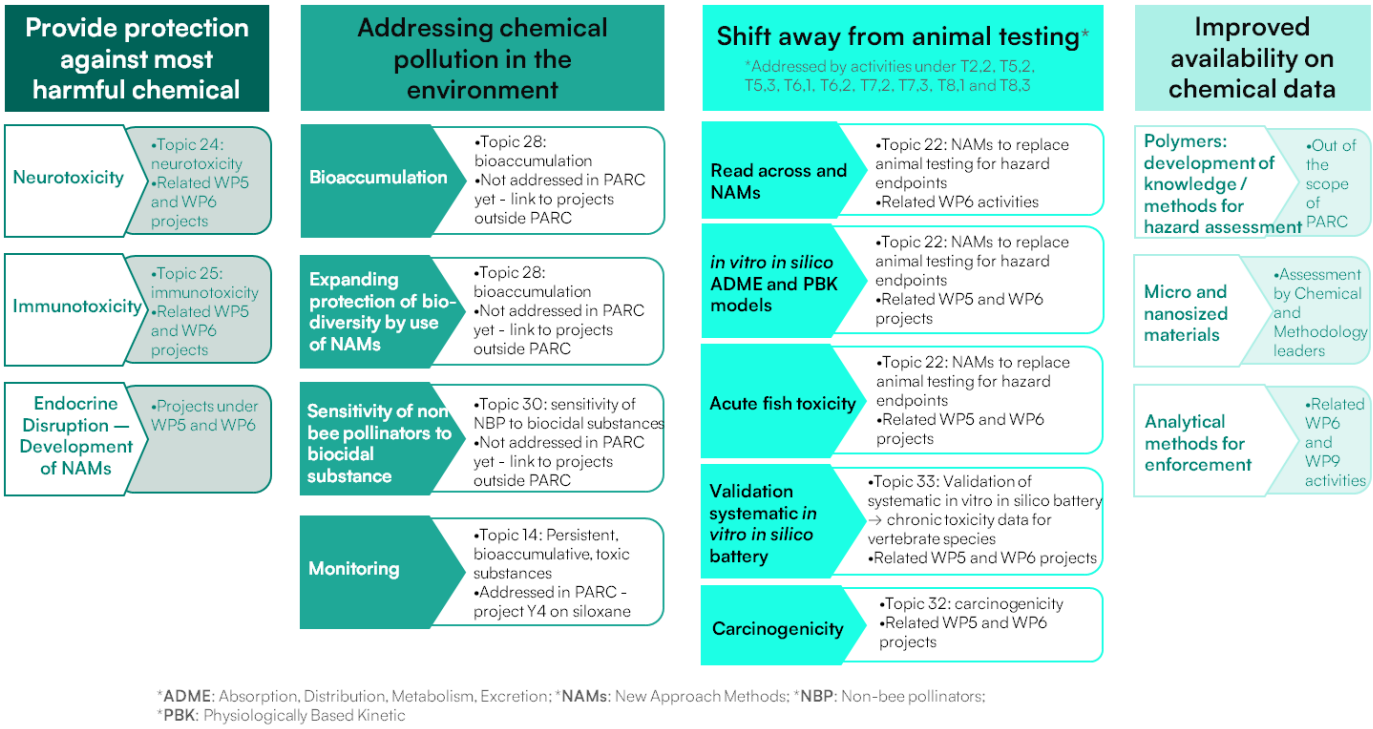


Figure 7: Assessing PARC's Response to Key Areas of Regulatory Challenge

It is important to note that this mapping does not mean that the identified needs in the KARC have been fully addressed by PARC and thus, that there is nothing left to do in these areas. It is simply intended to provide an overview of the existing connections and ongoing activities that may be relevant or useful.

1. Provide protection against most harmful chemicals

1.1 Neurotoxicity

How is this topic addressed in PARC?
This topic corresponds to the Factsheet 'Neurotoxicity' (N°24) and is already addressed in PARC.

1.1.1. Research on new AOPs, further development of existing AOPs and establishing their interlink with NAMs

Related activities within PARC:

•Project under **WP5** (Hazard Assessment):

- P5.3.2.a Y1 AOPDevelopment Inserm (project title: AOP development), this project is about the development of comprehensive Adverse Outcome Pathways (AOPs) that cover mechanisms underlying regulatory relevant Adverse Outcomes such as neurotoxicology, but also immunotoxicology, non-genotoxic carcinogenesis, endocrine disruption and metabolic disruption.

•Project under **WP6** (Innovation in Risk Assessment):

- P6.4.2.d Y4 RegulatoryNAMs ISS (project title: Demonstrating the applicability of NAMs for specific regulatory processes through series of Case Studies), this project will test then demonstrate how a NAM-based approach for regulatory hazard and Risk Assessment (RA) of chemicals can work and could be implemented in several regulatory frameworks (targeted endpoints are neurotoxicity, endocrine disruption, and carcinogenicity).

1.1.2. Identification of reliable positive and negative reference chemicals for NAM reliability testing and validation

Need 24.2 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Development of NAMs (DNT, ANT); Identification of reliable positive and negative reference chemicals for NAM reliability testing and validation.

Need already addressed in PARC: Partially

Related activities within PARC:

•Projects under **WP5** (Hazard Assessment):

- P5.2.1.e_Y1_DNT-ANT_UFZ_IUF_UU (project title: Neurotoxicity), objective is to build second generation NAMs to fill the gaps on developmental and acute/adult neurotoxicity.
- P5.2.a Y4 RegNAMs ANSES (project title: Regulatory Readiness of NAMs), output is to expand ReadEDTest to assess methods for some endpoints prioritised within WP5 (e.g., non-genotoxic carcinogenicity, immunotoxicity, developmental and acute neurotoxicity) and organize independent peer-review of the readiness of NAMs developed under WP5.

•Projects under **WP6** (Innovation in Risk Assessment):

- P6.4.2.d Y4 RegulatoryNAMs ISS (see previous explanation)
- P.6.3.1.b Y1 EffectRA BPI CS15 DNT SU (project title: Evaluation of conclusions drawn in guideline-compliant developmental neurotoxicity studies), this case study will follow regulatory process of the assessment of DNT in plant protection products (PPP), biocides, food contact material and REACH.

Related relevant activities outside PARC: *OECD. EURION Cluster: ENDpoiNTs. ASPIS Cluster: ONTOX, Precisiontox and RiskHunter. H2020 Panoramix. US-EPA for common data analysis and DNT IVB assembly. ATHLETE project of the European Human Exposome Network (EHEN) cluster. EFSA Brain Health Consortium led by NIPH-NO.*

1.1.3. The Developmental neurotoxicity (DNT) in vitro testing battery: further validation and refinement by increasing data density and by developing new tests to fill data gaps, using reference control substances identified

Need 24.2 (see above)

1.1.4. Early-stage development of a NAM battery dedicated to Adult Neurotoxicity (Alzheimer, Parkinson)

Need 24.2 (see above)

1.1.5. Addressing the known data gap presented by current DNT/ANT NAMs regarding toxicological information on metabolites

Need 24.1 (Task 4.1: Human Biomonitoring - workers): Add some effect biomarkers in the Human Biomonitoring studies for workers.

Need already addressed in PARC: No, but there are some activities that can be related.

Related activities within PARC:

•Project under **WP6** (Innovation in Risk Assessment) - Task 6.2 (Integrative exposure and risk assessment): 3 case studies using HBM data and understanding the neurotoxic effects.

- P6.2.4.c Y1 HIACaseStudies UU-IRAS (project title: Case studies on health impact assessment):
  - Mixtures of metals and neurodevelopment and/or nephrotoxicity
  - Mixture of chemicals in outdoor air and immunotoxicity (e.g asthma) and/or neurodevelopmental effects
  - Mixtures of pesticides and neurotoxicity, reproductive toxicity and developmental effects, nephrotoxicity

Related relevant activities outside PARC: *National Italian project: PRIN2017 'Endocrine disruptors: investigation of the effects on the immune and nervous systems (EDoNIS)' Ref N. 2017MLC3NF.*

Need 24.3 (Task 6.1: Integrated Approaches to Testing and Assessment of Chemicals): IATA development, including for ecotox species (e.g., fish, daphnids, earthworms etc.).

Need already addressed in PARC: Partially

Related activities within PARC:

•Project under **WP5** (Hazard Assessment):

- P5.2.1.e Y1 DNT-ANT UFZ IUF UU (see previous explanation)

Related relevant activities outside PARC: *Not identified.*

1.2 Immunotoxicity

How is this topic addressed in PARC?

This topic corresponds to the Factsheet 'Immunotoxicity' (N°25) and is already addressed in PARC.

1.2.1 Identification of critical windows of development of the immune system

Need 25.1 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Study the effects of chemicals on the immune system, particularly in sensitive populations (e.g., children); Identification of critical windows of development of the immune system to develop a NAM based battery to assess developmental immunotoxicity.

Need already addressed in PARC: Yes

Related activities within PARC:

•Projects under **WP5** (Hazard Assessment):

- P5.2.1.g_Y4_DIT-NAM_INSERM (project title: Developmental Immunotoxicity – NAM development), this project will firstly identify the critical developmental windows and process to support NAM development (non-lab); secondly there will be NAM development (lab-based).
- P5.2.1.d_Y1_Immunotox_Inserm (project title: Immunotoxicity), outcome is the development of NAMs for some immunotoxicity areas (organ-related immunotoxicity with a focus on respiratory toxicity and sensitization, immunosuppression, cellular immunotoxicity):
  - Characterisation of *in vitro* systems relevant for respiratory immunotoxicity.
  - Immunosuppression and response to vaccination.
  - *In vitro* systems to assay key events in the immune system function or dysfunction.
- P5.2.a_Y4_RegNAMs_ANSES (see previous explanation)
- P5.3.2.a_Y1_AOPDevelopment_Inserm (see previous explanation)

•Project under **WP6** (Innovation in Risk Assessment):

- P6.2.4.c_Y1_HIACaseStudies_UU-IRAS (project title: Case studies on health impact assessment): includes case studies with immunotoxicity endpoints based on HBM data:
  - Mixture of PFAS and immunotoxicity
  - Mixture of chemicals in outdoor air and immunotoxicity (e.g., asthma) and/or neurodevelopmental effects

Related relevant activities outside PARC: *EHEN Cluster projects on immune effects of the exposome: Hedimed and Eximious. ASPIS projects including ONTOX, RISKHUNT3R, PrecisionTox. Polyrisk, Aurora, VHP4Safety. EFSA (sensitization). National Italian project: PRIN2017 'Endocrine disruptors: investigation of the effects on the immune and nervous systems (EDoNIS)' Ref N. 2017MLC3NF. EU funded exposome projects.*

1.3 Endocrine Disruption - Development of NAMs

Is this topic addressed in PARC?
This topic and its subtopics are already addressed in PARC.

1.3.1 Development of NAMs

•Projects under **WP5** (Hazard Assessment):

- P5.2.1.b_Y1_MD-EDC-BfR (project title: Metabolic Endocrine Disruption), this project will focus on NAM development allowing to answer key regulatory needs. (There is a close collaboration with Goliath project).
- P5.2.1.c_Y1_EDThDisruption_DTU (project title: Endocrine disruptors – Thyroid hormone system disruption), this project aims to fill some gaps by gaining more mechanistic knowledge on THSD (Thyroid hormone system disruption) for targeted NAM development.
- P5.2.a_Y4_RegNAMs_ANSES (see previous explanation)
- P5.2.1.f_Y4_DART-ED_DTU (project title: Developmental and Reproductive Toxicity - Endocrine Disruption), this project will address current gaps in ED identification related to DART by characterising new mechanistic knowledge to support the development of NAMs and refine AOPs.

•Projects under **WP6** (Innovation in Risk Assessment):

- P6.1.1.e_Y4_FISH-THSD_UAntwerpen (project title: An AOP network-based approach for assessing thyroid hormone system disruptors in fish), this project will increase the use of NAMs to allow the identification and characterisation of THSD (complementary to OECD and JRC work).
- P6.1.1.f_Y4_HumanRelevance_RIVM (project title: Workflow for Human Relevance Assessment of AOPs and Associated New Approach Methodologies), this project will establish harmonized workflow for assessing human relevance of AOPs and NAMs that are related to key events and key events relationships.

1.3.2 Endocrine Disruption - Expansion of OECD toolbox to other non-EATS (non- Estrogen - Androgen - Thyroid - Steroidogenesis) modalities

•Projects under **WP5** (Hazard Assessment):

- P5.2.1.b_Y1_MD-EDC-BfR (see previous explanation)
- P5.2.1.f_Y4_DART-ED_DTU (see previous explanation)
- P5.3.2.a_Y1_AOPDevelopment_Inserm (see previous explanation)
- P5.2.a_Y4_RegNAMs_ANSES (see previous explanation)

•Projects under **WP6** (Innovation in Risk Assessment):

- P6.1.1.b_Y1_IATA-ED_UAntwerpen (project title: IATA for Endocrine disruption), this project will deliver IATAs for endocrine disruption; thyroid hormone system disruption and anti-androgenic adverse effects will be prioritised for IATA development.
- P6.1.1.e_Y4_FISH-THSD_UAntwerpen (see previous explanation)

1.3.3 Endocrine Disruption Risk Assessment

•Projects under **WP6** (Innovation in Risk Assessment):

- P6.1.1.f_Y4_HumanRelevance_RIVM (see previous explanation)
- P6.3.1.b_Y1_EffectRA_BPI (project title: Review of effect-specific risk assessment)
  - Case Study 10_ED-Cosmetics_VUB: Evaluation of RA approaches used for cosmetic ingredients with endocrine-disturbing concern.
  - Case Study 17_ED-in vitro_BPI: Use of non-guideline *in vitro* studies for ED assessment. This CS will develop a complementary document for risk assessors, including illustrative examples on the scientific criteria for consideration of data from non-validated *in vitro* methods for ED assessment across legislation.

- Case Study 18_ED-classes_BPI: New hazard classes and test requirements for endocrine disruption. This CS will focus on the added value of NAMs to delineate human/ population relevance aspects that are critical in deciding on classification of chemicals (category 1 or 2 of ED properties) under the upcoming CLP criteria.

- P6.4.2.d Y4 RegulatoryNAMs ISS (see previous explanation)

- Not addressed in Task 6.2 (Integrative exposure and risk assessment) yet but should be explored in period 2026-2029. HBM data on endocrine disrupting chemicals are being organized in the MCRA software. They are not part of the interpretation yet. Health Impact data (DALYs) for EDC should be further explored.
- WP4 (Monitoring and exposure): EDC monitoring campaign – can bring evidence for RA.

2. Addressing chemical pollution in the environment

2.1 Bioaccumulation

How is this topic addressed in PARC?
This topic corresponds to the factsheet 'Bioaccumulation' (N°28) and is not yet addressed in PARC, however, there are some related activities.

2.1.1. Development of non-vertebrate methods to predict the bioaccumulation potential of surfactants, ionisable substances and organometals

Need 28.2 (Task 5.1: Toxicity testing addressing data gaps of Concern): Development of non-vertebrate methods to predict the bioaccumulation potential of surfactants and ionisable substances as well as of organo-metals and superhydrophobic chemicals.

Need already addressed in PARC: No yet

Related activities within PARC: None

Related relevant activities outside PARC:

- UBA report (Bioaccumulation of ionic compounds - Deriving of alternative screening criteria from experimental studies)
- Fraunhofer IME (Bioaccumulation studies in aquatic organisms, particularly fish)

2.1.2. Development of new methods and assessment approaches to evaluate the bioaccumulation potential of super hydrophobic substances (kow>8)

Need 28.2 (see above)

2.1.3. Bioaccumulation potential in air-breathers (e.g., terrestrial mammals)

Need 28.3 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Bioaccumulation in air breathing organism.
Most bioaccumulation assessment are currently done on aquatic animals; however certain substances are not bioaccumulative in aquatic animal while being bioaccumulative in air-breathing organism. A RA method is needed.

Need already addressed in PARC: Not yet

Related activities within PARC: None

Related relevant activities outside PARC: LRI project (Cefic) 'ECO41: Enhanced Screening Methods to Determine Bioaccumulation Potential of Chemicals in Air-Breathing Species' (Canada)[13].

2.1.4. How to improve assessment of secondary poisoning and man via environment

Need 28.4 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Improvement of assessment of secondary poisoning and man via environment specially for mixtures.

Need already addressed in PARC: Yes

Related activities within PARC:

•Project under **WP4** (Monitoring and Exposure):

- P4.3.3.b Y2 EO2-Sentinel animals ONIRIS (project title: Proof-of-concept of innovative sampling and High-Resolution Mass Spectrometry (HRMS) based / Effect Directed Analysis (EDA) screening methods for exploring chemicals of emerging concern in sentinel animal species)

•Project under **WP6** (Innovation in Risk Assessment):

- P6.3.2.a Y1 ToolsRA SU (project title: Review of tools criteria and methods used in risk assessment)
  - Case Study 4_SecPoisoning_INERIS: Assessment of the approaches used to address secondary poisoning under current chemical regulations and identification of possible improvements needed to achieve an adequate protection of wildlife

Related relevant activities outside PARC: NORMAN. PrecisionTox. EFSA. TerraChem.

2.2 Expanding protection of biodiversity by use of NAMs

How is this topic addressed in PARC?
This topic corresponds to the Factsheet 'Chemicals and Biodiversity' (N°29) and is not yet addressed in PARC, however, there are some related activities.

Need 29.1 (Task 4.3: Innovative methods and tools for monitoring and surveys): Understand the impact of chemicals on soils biodiversity.

Need already addressed in PARC: Partially

Related activities within PARC:
•**Activity 6.4.4**: System approach for landscape-based environmental risk assessment (ERA) of pesticides (Doi: 10.1016/j.envint.2024.108999)

[13] If needed, it is possible, to get in touch with the project's leader through the International Board of PARC.

Related relevant activities outside PARC: Methodology leader report (on-going).

Need 29.2 (Task 4.2: Environmental and Multisource Monitoring): Exposure levels of chemical mixtures and potential threats to ecosystem services or biodiversity.

Need already addressed in PARC: Partially

Related activities within PARC:

•P4.2.a Y1 ENVMonitoringSpilotSurvey INERIS AU (project title: Establishment of overall process of environmental and multisource monitoring with the help of a pilot study addressing PFAS and endocrine disruptors). One of the aims of the project is to promote efficient overall protection of biodiversity by ensuring that the environmental and multisource monitoring is designed based on complete and up-to-date information, answering the identified regulatory needs. EDCs will include a variety of different classes of chemicals, among which are pesticides.
•P6.4.4.b Y1 PPPEXPCS2 RPTU (project title : Reduce complexity of models for predicted environmental concentrations of plant protection products while ensuring their predictive capacity), this project aims at investigating if the predictions in the exposure part of the ERA carried out in the context of authorisation of PPP under regulation can be simplified, improved in predictive potential and validated by maintaining the level of protection required.

Related relevant activities outside PARC: Methodology leader report (on-going).

Need 29.3 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Methods to assess the effects of chemicals on biodiversity.

Need already addressed in PARC: Partially

Related activities within PARC:

•Activities under **WP6** (Innovation in Risk Assessment):

- **Activity 6.4.4** (Risk assessment to support and promote efficient overall protection of biodiversity): The activity aims at better assessing effects on overall biodiversity and the possibility to simplify (i.e., less resource demanding) the methods used for the ERA of PPP without compromising the level of protection to be ensured by the assessment. PARC will evaluate and improve the current ERA for PPP looking into methods for possibly making exposure and effect assessment simpler and more efficient, benchmarking RAs, as well as "validating" ERA using monitoring data and landscape level models.
  Benchmarking and validation of new as well as existing prospective ERA tools and methods is a central theme of Activity 6.4.4. The activity therefore has the potential to provide development of NAMs for ERA in PARC with validation for ecological relevance. Mapping and coordination of efforts with PARC and relevant external projects will be required. To this end a project proposal has been scoped in collaboration with WP2 (Strengthening Collaboration for Next-Generation ERA (NG-ERA): A Horizon Europe PARC Platform and Process for Governance of Scientific Coordination.)
- **Activity 6.4.1** (Develop regulatory relevant approaches and methods for chemical mixtures), the project P6.4.1.d Y4 RE-Mix UBA Eawag (project title: Options to assess and Regulate MIxtures), initiated in Y4, aims to understand the long-term impact of chemical mixtures on biodiversity and ecosystem functions by leveraging lake sedimentary archives, paleoecotoxicology and AI-based

forecasting and the other will investigate how NAMs can be applied in European freshwaters monitoring. More could be included and new project on protection of biodiversity is planned but so far neither budget nor partners are set.

Related relevant activities outside PARC: Methodology leader report (on-going).

2.3 Assessing the sensitivity of non-bee pollinators (NBP) to biocidal active substances

How is this topic addressed in PARC?
This topic corresponds to the Factsheet 'Sensitivity of non-bee pollinators (NBP) to biocidal active substances' (N°30) and is not yet addressed in PARC.

Need 30.1 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Data generation to evaluate the acute contact and oral toxicity in arthropod pollinators and compare the sensitivity between NBPs and honeybees. There is currently no method to assess toxicity in NBP as research is focused on bee.

Need already addressed in PARC: No yet

Related activities within PARC: None

Related relevant activities outside PARC:

- EU Pollinators Initiative
- EFSA non-target arthropod project (AENEAS) (advancing the ERA of non-target arthropods).
- NORMAN network. LIFE APEX consortium. PollinERA. WildPosh. SYBERAC.

2.4 Monitoring

2.1.5. Development of approaches based on monitoring field data enabling persistence, long-range environmental transport and/or bioaccumulation assessment.

This sub-topic corresponds to the Factsheet 'Persistent bioaccumulative and toxic (PBT)' (N°14) and is not yet addressed in PARC, however, there are some activities related.

Need 14.1 (Task 4.2: Environmental and Multisource Monitoring): Development of approaches based on monitoring field data enabling persistence, long-range environmental transport and/or bioaccumulation assessment (+ case study on linear and cyclic siloxanes).

Need already addressed in PARC: Partially

Related activities within PARC:

•Project under **WP4** (Monitoring and Exposure):

- P4.2.d_Y4_Siloxanes_AU_INERIS (project title: Volatile siloxanes in the European environment - towards robust data in support of regulatory action), this project will first evaluate the technical feasibility of generating environmental data and, if possible, have a monitoring campaign focusing on environmental samples

Related relevant activities outside PARC: EMEP (European Monitoring and Evaluation Programme), AMAP (Arctic Monitoring & Assessment Programme), AnMAP (Antarctic Monitoring and Assessment Programme).

3. Shift away from Animal Testing

How is this topic addressed in PARC?
This topic corresponds to the Factsheet 'NAMS to replace animal testing for hazard endpoints (including acute fish toxicity)' and is already addressed in PARC.

- **Task 2.2: Knowledge management and uptake into policy - NGRAroute**

PARC is contributing to the elaboration and operationalisation of the EU roadmap. The roadmap will outline the path to expand and accelerate the development, validation and implementation of non-animal methods as well as means to facilitate their uptake across legislations.

- **WP5** (Hazard Assessment):
  - Task **5.2** (Innovative methods and tools for toxicity testing and modelling) and Task **5.3** (Quantitative Systems Toxicology and development of new AOPs and PBPK)
- **WP6** (Innovation in Risk Assessment):
  - Task **6.1** (Integrated Approaches to Testing and Assessment of Chemicals) and Task **6.2** (Integrative exposure and risk assessment)
- WP7 (FAIR Data)
  - Task **7.2** (Data Libraries) and Task **7.3** (Innovative analyses)
- WP8
  - Task **8.1** (Safe and sustainable by design (SSbD)) and Task **8.3** (Integrative models)

3.1. Read across and NAMs: Development of case studies

Need 22.4 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Read across and NAMs, protection of biodiversity: Development of case studies

Need already addressed in PARC: Yes

Related activities within PARC:

- Activities under **WP6** (Innovation in Risk Assessment)
  - Task 6.1 IATA projects
  - Task 6.4 (T6.4 Transposing results to regulatory risk assessment methodologies):
    - Activity 6.4.1: Develop regulatory relevant approaches and methods for chemical mixtures (4 projects).
    - Activity 6.4.2: Facilitate the regulatory acceptance and use of new methods (5 projects).

Related relevant activities outside PARC:

- EPAA (European Partnership for Alternative Approaches to Animal Testing), PARERE at EURL ECVAM Network for Preliminary Assessment of Regulatory Relevance, which includes validation of NAMs for regulatory purposes.
- OECD, regarding ongoing projects in the field of harmonization and regulatory acceptance of NAMs (incl. update GD 34) and development of the Adverse Outcome Pathway Wiki.

- EFSA OPenFoodTox (in silico models).

3.2. In vitro/in silico ADME and Physiologically-Based Kinetic models

Need already addressed in PARC: Yes

•Project under **WP5** (Hazard Assessment):

- P5.3.4.a Y1 PBK Kinetics Fraunhofer (project title: PBK models and quantitative systems toxicology), this project will establish PBK models informed by NAM data and integrate PBK models with AOPs as a basis for quantitative systems toxicology. The goal is to establish a framework for the application of qIVIVE-PBK models in a regulatory setting

•Projects under **WP6** (Innovation in Risk Assessment):

- P6.2.2.a Y1 PBPK INERIS AUTH (project title: refinement and development of PBPK models for human risk assessment), this project PBPK models will be refined / developed to address population sub-group sensitivities, integrating multiple exposure routes and sources and interpreting HBM data.
- P6.2.3.a Y1 RealLifeMixtures RIVM (project title: New risk assessment and exposome methodologies for to reduce exposure and risk of real-life mixtures), one of the objectives of this project is to develop hazard and kinetic information on prioritised substances

3.3. Acute fish toxicity

Need 22.1 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Develop new approach methods (NAMs) to replace animal testing for hazard endpoints (e.g., acute fish toxicity).

Need already addressed in PARC: Partially

Related activities within PARC:

•Project under **WP5** (Hazard Assessment):

- Task 5.2: Innovative methods and tools for toxicity testing and modelling (5 projects Human Health, 1 project (22 partners) NAMs Environment).

• Project under **WP6** (Innovation in Risk Assessment):

- P6.4.2.d Y4 RegulatoryNAMs ISS (see previous explanation)

Related relevant activities outside PARC: EURION cluster; ASPIS cluster, ENKORE cluster.

3.4. Validation of a systematic in vitro/silico battery to steer generation of chronic toxicity data for vertebrate species

How is this topic addressed in PARC?

This topic corresponds to the Factsheet 'Validation of a systematic in vitro/silico battery to steer generation of chronic toxicity data for vertebrate species' (N°33) and is already addressed in PARC.

Need 33.1 (Task 5.2: Innovative methods and tools for toxicity testing and modelling): Develop systematic in vitro/in silico models to predict chronic toxicity in vertebrate species.

Need already addressed in PARC: Partially

Related activities within PARC:

•Projects under **WP5** (Hazard Assessment):

- P5.2.1.e_Y1_DNT-ANT_UFZ_IUF_UU (see previous explanation)
- P5.2.1.a_Y1_NGTXCs_INRAE (project title: Non-genotoxic carcinogens), this project will improve the knowledge of the relationship between a range of different substances specific for distinct AOPs that lead to cancer (investigation with innovative NAMs)
- P5.2.1.h_Y4_SDHEPATOX_ANSES (project title: Sexual dimorphism associated to susceptibility to hepatotoxicity of environmental contaminants), this project will contribute to the improvement of *in vitro* methods for assessing chemical induce hepatotoxicity by integrating sexual dysmorphism parameters in different hepatic cell models
- P5.3.1.a_Y1_SystemsToxicology_UL-LACDR (project title: Systems toxicology approaches for mechanism-based chemical safety assessment), this project will help evaluate mechanistic data for a quantitative hazard characterization through news NAMs, thus supporting the RA AOPs framework. Innovative in silico methods and bioinformatic approached will also be validated, for quantitative hazard assessment

•Projects under **WP6** (Innovation in Risk Assessment):

- Task 6.1 IATA projects
- P6.4.2.d_Y4_RegulatoryNAMs_ISS (see previous explanation)

Related relevant activities outside PARC:

- ENDpoiNTs and other projects within the EURION cluster. In ENDpoiNTs, a battery of assays (in silico, in vitro and in vivo) are developed that detect ED-induced DNT.
- ONTOX, Precisiontox and RiskHunter of the ASPIS cluster.
- H2020 Panoramix.
- US-EPA for common data analysis and DNT IVB assembly.
- ATHLETE project of the EHEN.
- ENKORE cluster

3.5. Carcinogenicity

How is this topic addressed in PARC?

This topic corresponds to the Factsheet 'Carcinogenicity' (N°32) and is already addressed in PARC.

3.5.1. Improve the detection of carcinogens including those that act through a non-genotoxic mode of action

Need 32.2 (Task 5.2; Task 6.1): Develop AOPs and IATA for non-genotoxic carcinogenesis, including for the environment.

Need already addressed in PARC: Partially

Related activities within PARC:

•Projects under **WP5** (Hazard Assessment):
- P5.3.2.a_Y1_AOPDevelopment_Inserm (see previous explanation)
- P5.2.1.a_Y1_NGTXCs_INRAE (see previous explanation)

•Project under **WP6** (Innovation in Risk Assessment):
- Under T6.1, a project (Y5-7) aimed at an IATA for carcinogenicity is being developed, in which both genotoxic and non-genotoxic mechanisms will be included.

Related relevant activities outside PARC: OECD Expert Group on IATA for non-genotoxic carcinogenicity; OECD Advisory Group on Emerging Science in Chemicals Assessment; RISK-HUNT3R.

3.5.2. Development of Adverse Outcome Pathways (AOPs) for specific modes of genotoxic or mutagenic action

Need 32.2 (see above)

Related activities within PARC:

•Project under **WP6** (Innovation in Risk Assessment):
- P6.1.1.c_Y1_IATA_GENTOX_Sciensano (project title: IATA for Genotoxicity), the project focuses on the development of IATAs for genotoxicity in view of moving towards the assessment of genotoxicity without the use of animals.
- Under T6.1, a project (Y5-7) aimed at an IATA for carcinogenicity is being developed, in which both genotoxic and non-genotoxic mechanisms will be included.

4. Improved availability on chemical data

4.1. Polymers: Development of knowledge and methodologies to support hazard assessment:

This topic is out of the scope of PARC.

4.1.1. Interpretation of polymer's bioavailability

4.1.2. Assessment of polymer's stability to degradation under environmental conditions

4.1.3. Polymer bioavailability; assessment and relevance for human health hazard assessment

4.2. Micro-and nano-sized materials:

Assessment to be conducted by the Chemical Leaders that were appointed to make a state-of-the-art and see how PARC can have an added value:

- For microplastics, there are several research gaps, including for plastic chemical where PARC partners can contribute, but also in terms of current assessment methods where there is a lack of methods for human samples, therefore, the harmonisation of analytical methods for human tissues in needed. Potential synergies are possible with EU and international initiatives. It would be relevant if PARC can implement harmonised methods for the determination of micro- and nanoplastics and support intercalibration exercises and workshops for reliable and sensitive methods and, contribute to filling knowledge gaps as identified by the CUSP cluster (European research cluster to understand the health impacts of micro- and nanoplastics).
- For nanomaterials, CLs will use one additional year to conduct a review on the methods for nanomaterials detection in the human biomonitoring studies and develop, within 2 years, a framework for the evaluation or the extension of PARC NAMs to nanomaterials. Meanwhile, CLs might suggest, new projects in the upcoming

years to develop a tiered approach to identify nanomaterials mechanistic deviations from baseline toxicity, as a basis for grouping, read-across and establishment of sets of nanoforms to support regulatory implementation.

4.2.1. Improve toxicity assessment for micro- and nano-sized materials (e.g., nanomaterials or microplastics) and investigate the long-range transport, uptake and toxicity for humans and other organisms

4.3. Analytical methods for enforcement:

Related activities within PARC:

- Project under **WP6** (Innovation in Risk Assessment):
  - P6.4.3.b Y3 ENFORCE KEMI (project title: New methods to support enforcement of chemicals in consumer articles), this project will evaluate the applicability of methods of chemical identification for use in enforcement of chemical safety.
- WP9 (Building Infrastructural and human capacities)
  - Task 9.1 Laboratory networking, including 4 transversal activities contributing to exchange of information about development and validation of analytical methods.

Appendix 7: Feedback survey on the 2nd prioritisation round of PARC

Informed consent

Thank you for participating in the recent prioritisation round of PARC. Your feedback is essential to help us understand what worked well, what could be improved, and how we can refine the process for future rounds.

I hereby agree to participate in this survey. I acknowledge and agree to the processing of my contact information for the mapping of needs. I will not be asked for any information that identifies me personally. There will be no personal benefit from my participation, other than contributing to science.

(ANSES, represented by its Director General, is responsible for processing personal data in the framework of the preparation and the implementation of the European Partnership for the Assessment of Risks from Chemicals. ANSES collects professional personal data (name, organisation and organisation address, professional email address and phone number) that are used for the different communication needs during the preparation and the implementation of the Partnership. The ANSES Data Protection Officer is the ANSES Director of the Legal Affairs Department (saisine-daj@anses.fr). The data are kept during the preparation, the implementation and up to 5 years after the end of the Partnership. In accordance with the provisions of REGULATION (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation - GDPR) and the amended French Data Protection Act of the 6th of January 1978, you have the right to access, rectify, limit and in some cases delete your personal information. You may also, for legitimate reasons, oppose the processing of your personal data. The personal information collected from you in the framework of the Partnership and its implementation is transmitted to the persons involved in the Partnership. You can access your personal information by contacting PARC@anses.fr. If you consider, after having contacted us, that your rights arising from the French Data Protection Act are not respected, you can make a complaint to the CNIL (Commission Nationale de l'Informatique et des Libertés - the French Commission on Data Protection).)

Contact details (for everyone)

- Name of your organisation:
- Country:
- E-mail address:
- What is your involvement in PARC?
  Options: Governing Board (GB) - Management Board (MB) - National Hub (NH) - Stakeholder Forum (SF)- EU agency
- What PARC Workpackage are you involved in? (*for MB only) - one possible answer

General feedback (for Task 2.1, EU, MB and GB)

- How satisfied do you feel about the overall prioritisation process?
  Scale: Extremely unsatisfied - Unsatisfied - Neutral - Satisfied - Very Satisfied)

Process Effectiveness (for Task 2.1, EU, MB and GB)

- Do you feel the process used for this prioritisation round was effective in helping establish future PARC activities?
  Scale: Not effective - Below expectations - Slightly effective - Effective - Very effective
- Was the timeline for the prioritisation round appropriate and well-managed?
  Scale: No - Somewhat - Yes
- How consistent and objective do you think the prioritisation process was?
  Scale: Completely inconsistent and subjective - Mostly inconsistent and subjective - Somewhat consistent and objective - Mostly consistent and objective- Fully consistent and objective
- Were all relevant voices heard and considered in the process?
  Scale: No - Yes
  If anything was missed, please specify:
- Were there any parts of the process that felt unnecessary?
  Scale: No - Yes: The creation of factsheets -The categorisation of Topics into 4 categories - The consultation of either the NH, SF or IB - The voting from the GB- Other
  Please indicate what other part of the process, if any, was unnecessary from your point of view
- What do you think was necessary and worked well?
  Options: Nothing - The creation of factsheets -The categorisation of Topics into 4 categories - The consultation of either the NH, SF or IB - The voting from the GB - Other
  Please indicate what other part of the process, if any, was necessary from your point of view

Outcomes and Communication (for Task 2.1, EU, MB and GB)

- How confident are you in the outcomes of this prioritisation round (i.e., does the final list of priorities reflect the most important needs)?
  Scale: Not confident - Neutral - Confident
- Are there any priorities you believe were missed or underemphasised? Please mention them (Open text)
- How effective was the communication regarding the prioritisation process and outcomes?
  Scale: Ineffective - Neutral - Effective

Participation & Engagement (for everyone)

- How clear was the purpose of the prioritisation round for you?
  Scale: Unclear - Somewhat clear - Very clear
- Did you know what was expected from you in this process and was the communication clear and effective?
  Scale: Not at all (unclear expectations and poor communication) - Mostly unclear (expectations and communication were confusing) - Mostly clear (expectations and communication were clear and effective) - Completely clear (expectations and communication were very clear and highly effective)
  If *anything was specifically unclear, please specify:*
- Do you feel you had sufficient opportunity to contribute or share your views?
  Scale: Very limited opportunity - Some opportunity, but not enough - Sufficient opportunity
- Do you feel your input was valued and considered?
  Scale: Disagree - Neutral - Agree

Suggestions for Improvement (for everyone)

Were there any tools or methods you think could have been used to make the process more effective and increase trust or transparency in outcomes? Do you have any suggestions for improving the process in view of the third prioritisation round? (Open-ended)