

From Mapping the Needs to Setting PARC Priorities

90th EFSA Advisory Forum meeting

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PARC



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About the partnership

Members

≈ 30 countries
>200 organisations
3 EU agencies

Organisation

9 Work Packages (WPs)
2022-2029

Funding

€400 million budget



Co-funded by
the European Union



Structure



<https://eu-parc.eu>



Social media



European Partnership for the
Assessment of Risks from
Chemicals (PARC)



eu_parc



PARC.chemicals



Parc_chemicals

Prioritisation rounds in PARC

ROUND 1



ROUND 2

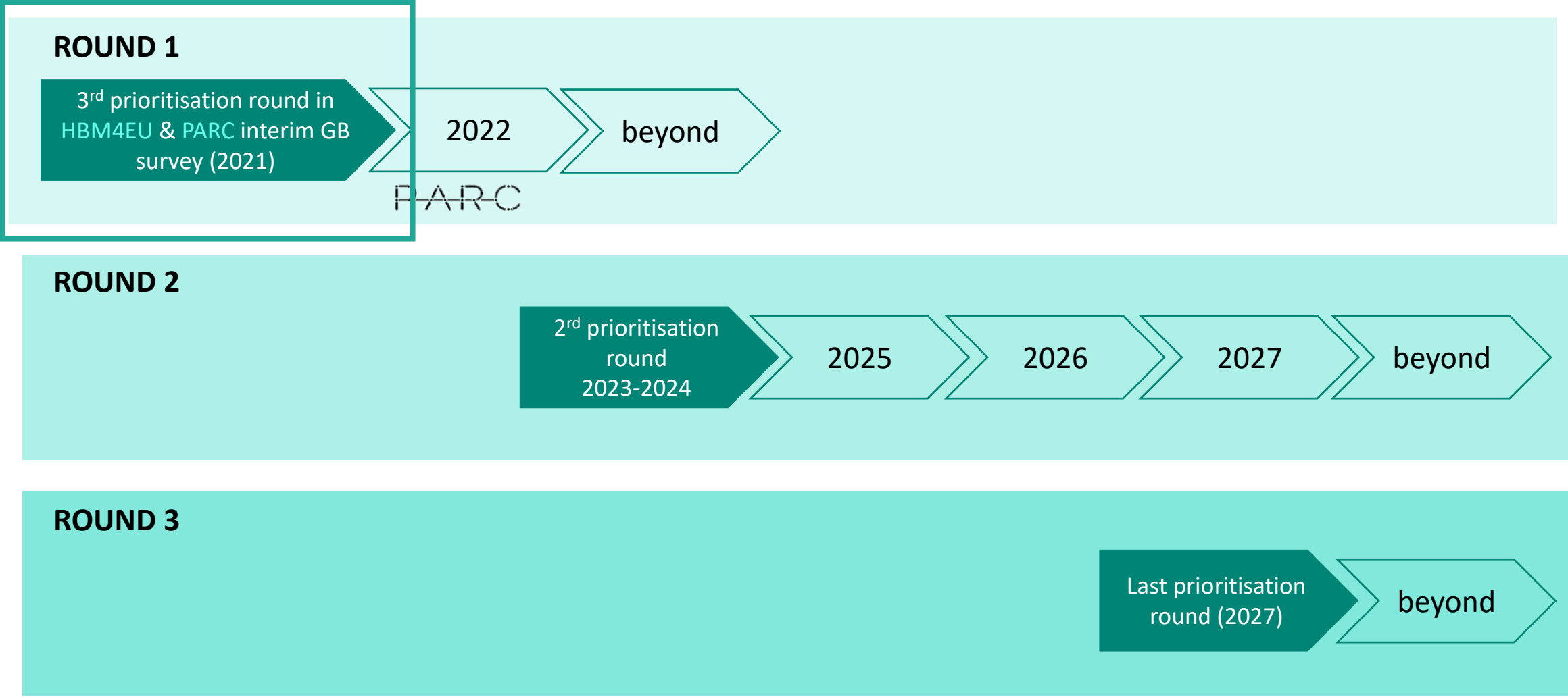


ROUND 3



GB: Governing Board

Prioritisation rounds in PARC



GB: Governing Board

Third Prioritisation in HBM4EU

HBM4EU processes that fed into PARC

1. Identifying priorities for new knowledge, tools and methods to be produced

Why?

To inform the 1st 3-year strategic plan – for inclusion in our proposal due May 2021

When?

June 2020 until May 2021

Who?

The PARC Steering Group, relevant national bodies, EU institutions, interested stakeholders

2. Identifying substances for human biomonitoring activities

Why?

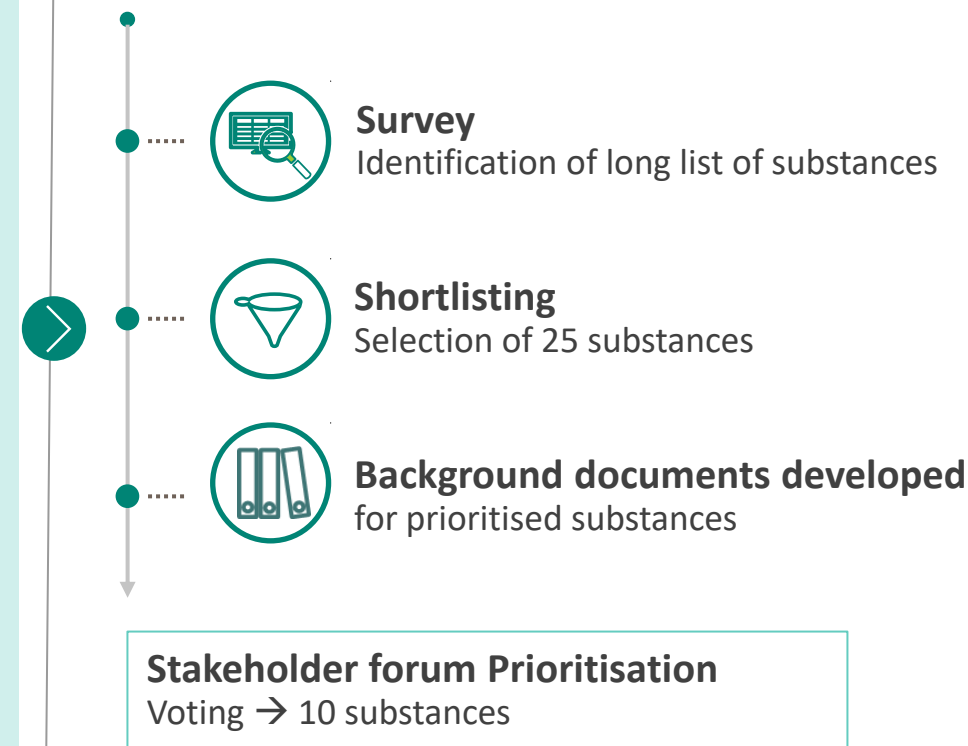
To produce a shortlist of substances together with background documents to feed into PARC

When?

June 2020 until May 2021

Who?

HBM4EU National Hubs,
EU Policy Board,
HBM4EU Stakeholder Forum



PARC interim Governing Board survey

Initial priorities selection

- Based on survey conducted in 2020
- Discussion with interim WP co-leaders and PARC Interim MB
- Identification of initial priorities



Issues identification following alignment with GSB and GB

01/12/2020

- Presentation of priorities to GSB and PARC interim GB
- Identification of issues
- Identification of input need from the GB in each WP



Governing Board survey

15/01/2021

- Survey sent to GB covering:
 - Substances
 - Endpoints
 - Suggestions
- One answer collected per GB member
- Compilation of results



WP: Work Package
MB: Management Board

GB: Governing Board
GSB: Grant Signatory Board

Substances prioritisation criteria- 1st round

1 Policy and Regulatory Relevance

- ✓ Discussions with agencies (e.g.: SCCS, ECHA, EEA, EFSA, etc.)
- ✓ Regulatory needs identified by PARC WPL/TL according to their WP/Task objectives
- ✓ “Chemical Strategy for Sustainability” and the “Strategic Research and Innovation Plan for Safe and Sustainable Chemicals and Materials”

2 Partnership: Synergy and Alignment

- ✓ Interactions and crosslinks with other WPs or Tasks within PARC
- ✓ Scientific activities done outside PARC
- ✓ Third round of Prioritisation done under HBM4EU
- ✓ Methods, endpoints and substances prioritised in the PARC interim GB’s survey

3 Practicality: Feasibility and Technicality

- ✓ PARC partners’ interests, their capacities and resources
- ✓ Available data and knowledge gaps
- ✓ Hazardous properties and characteristics of substances

WPL: Work Package Leader
TL: Task leader
GB: Governing Board

Substances/Groups prioritised - 1st round

| Substances/Group of substances | WP4 – Monitoring & Exposure | WP5 – Hazard Assessment | WP6 – Innovation in regulatory RA |
|--------------------------------------------------|-----------------------------|-------------------------|-----------------------------------|
| Biocides | ✓ | ✓ | ✓ |
| Pharmaceuticals/Hazardous medicinal products | ✓ | | ✓ |
| Veterinary pharmaceuticals | | | ✓ |
| Plant protection products | ✓ | ✓ | ✓ |
| PFAS | ✓ | | ✓ |
| BPA, BPA analogues, BPA alternatives, Bisphenols | ✓ | ✓ | ✓ |
| Natural Toxins | | ✓ | ✓ |
| Metals | ✓ | | ✓ |
| Mercury | ✓ | | |
| Arsenic | ✓ | | |
| Phthalates | ✓ | | |
| Flame retardants | | | ✓ |
| Endocrine Disrupting Compounds (EDC) | ✓ | ✓ | ✓ |
| Metabolic Disrupting Compounds (MDC) | | ✓ | |
| Emerging chemicals | ✓ | | |
| Mixtures | ✓ | ✓ | ✓ |
| Food contact material | | ✓ | ✓ |
| Cosmetics | ✓ | ✓ | ✓ |
| PBT/vPvB | | | ✓ |

RA: Risk assessment

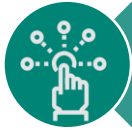
Methods prioritisation criteria- 1st round



Methods and Endpoints prioritised in PARC Governing Board's Survey



“Strategic Research and Innovation Plan for Safe and Sustainable Chemicals and Materials”



The interaction and crosslinks with other WPs or Tasks within PARC



Discussions with regulatory agencies



Initiatives outside PARC



Existing available data

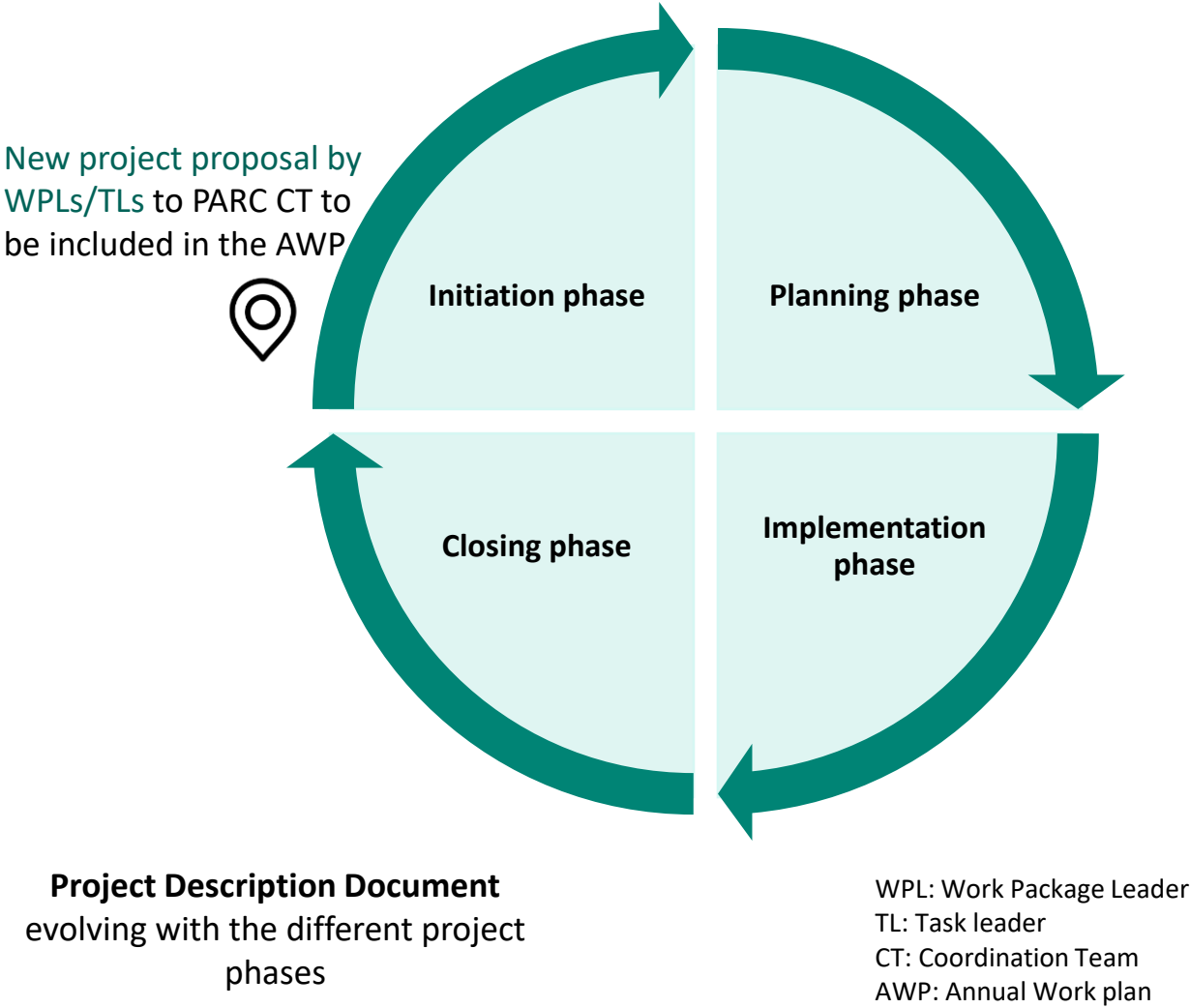


Expression of interest from partners, resources


WP: Work Package


Project Review Process


A project life cycle



Project reviewing criteria

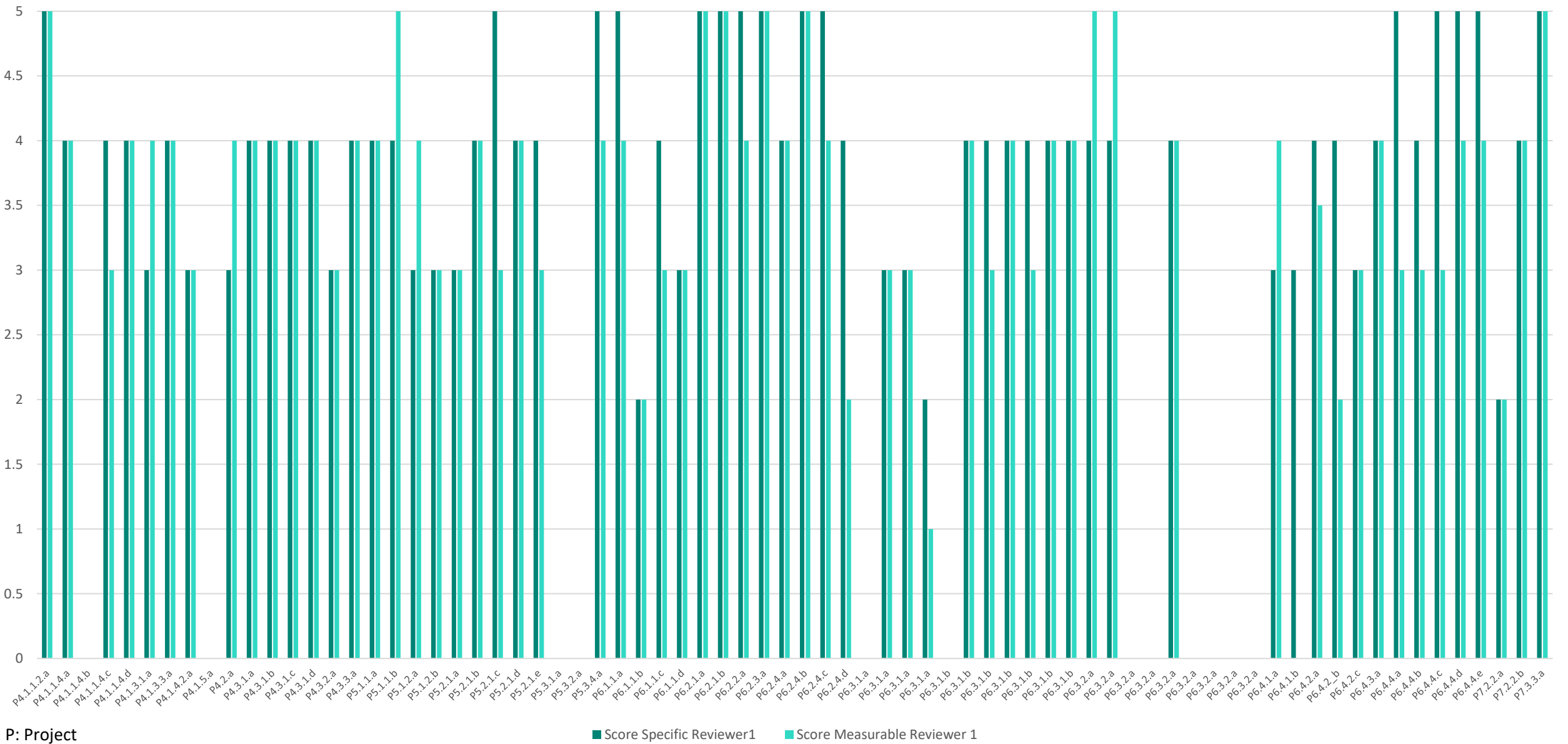
- **Specific**

Does the proposed project indicate and explain which specific regulatory (National/EU) process or outcome will benefit in a tangible manner and does it explain how it fits into the bigger picture of regulatory challenges?
- **Measurable**

Does the submitted project explain how it addresses the regulatory challenge (quantitatively/qualitatively) and which tangible benefits can be expected?
- **Scoring range from 1 to 5:**

1 = completely not
5 = completely yes

Feedback on the scoring of Year 1 projects

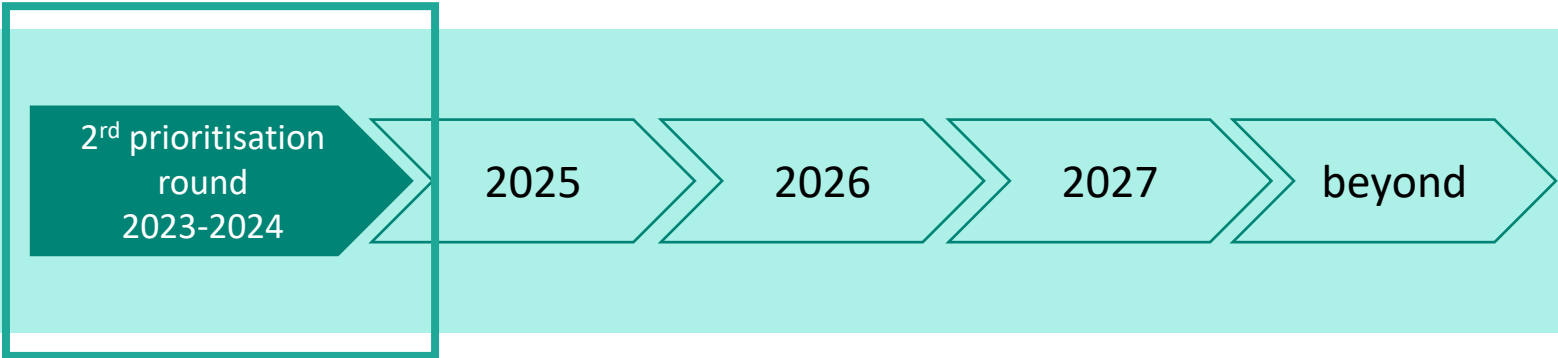


Prioritisation rounds in PARC

ROUND 1



ROUND 2



ROUND 3

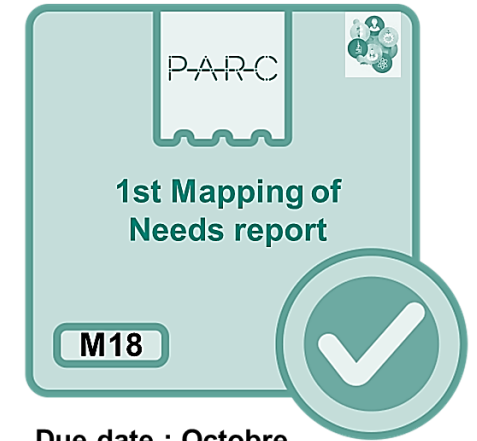


GB: Governing Board

Second Prioritisation round

Prioritisation process

- 1 Mapping of needs
- 2 Prioritisation of activities based on specific criteria
- 3 Preparation of background document



Due date : Octobre 2023

Improving the 1st prioritisation round

- **3 Online Focus Group Discussions:** 3rd – 9th of May 2023
Total of 13 participants: WP/ Task/ Project Leaders from WP 4, 5 and 6
- Online discussion with WPLs 4-5-6 and 8 on May 10, 2023



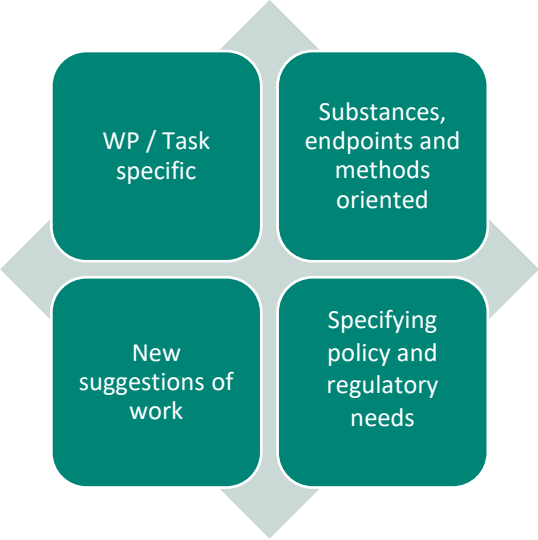
- Lessons learned
- Survey shaping

WPL: Work Package Leader

Mapping of Needs

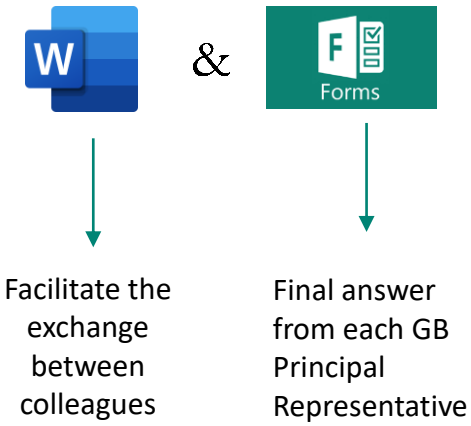
Survey preparation

Survey sent to **WPLs, TLs, Task 2.1 partners and GB chairs** on May 30 for feedback on the choice of questions: deadline June 8.



Survey filling

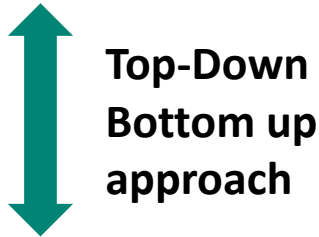
Survey sent to the Governing Board on June 13.
One response per GB Principal Representative. **Deadline: August 25**



Results' Discussion

Discussion of the results during with:

- Task 2.1 partners
- Management Board
- Governing Board
- Joint-session GB & MB (November 15)



Other consultations

National Hubs
Stakeholder Forum
International Board

**NEXT
STEPS**

WPL: Work Package Leader
TL: Task leader
GB: Governing Board
MB: Management Board

Mapping of Needs Survey Participation

Excellent response rate: 26 out of 30

| | | | | | |
|-------------------------------------|---------------------|-------------------------------------|------------|-------------------------------------|----------------|
| <input checked="" type="checkbox"/> | European Commission | <input checked="" type="checkbox"/> | Germany | | Netherlands |
| <input checked="" type="checkbox"/> | Austria | <input checked="" type="checkbox"/> | Greece | <input checked="" type="checkbox"/> | Norway |
| <input checked="" type="checkbox"/> | Belgium | <input checked="" type="checkbox"/> | Hungary | | Poland |
| <input checked="" type="checkbox"/> | Croatia | <input checked="" type="checkbox"/> | Iceland | <input checked="" type="checkbox"/> | Portugal |
| <input checked="" type="checkbox"/> | Cyprus | <input checked="" type="checkbox"/> | Ireland | <input checked="" type="checkbox"/> | Slovakia |
| <input checked="" type="checkbox"/> | Czech Republic | <input checked="" type="checkbox"/> | Israel | <input checked="" type="checkbox"/> | Slovenia |
| <input checked="" type="checkbox"/> | Denmark | <input checked="" type="checkbox"/> | Italy | <input checked="" type="checkbox"/> | Spain |
| <input checked="" type="checkbox"/> | Estonia | | Latvia | <input checked="" type="checkbox"/> | Sweden |
| <input checked="" type="checkbox"/> | Finland | | Lithuania | <input checked="" type="checkbox"/> | Switzerland |
| <input checked="" type="checkbox"/> | France | <input checked="" type="checkbox"/> | Luxembourg | <input checked="" type="checkbox"/> | United Kingdom |

Input through discussions at the Governing Board meeting



Mapping of Needs Survey Results (example)

Work Package 4: Monitoring and exposure.

Task 4.1: Human biomonitoring (for the general population)

| Substances / Groups <u>nominated > 3 times or by the EC</u> | Nomination |
|---------------------------------------------------------------------------------------------------|------------|
| Micro plastic and Nano plastic | 9 |
| Nanomaterials, Micro (& Nano) particles | 6 |
| Natural toxins, including Mycotoxins, Marine biotoxins and Freshwater biotoxins | 5 |
| Flame retardants (FR) | 4 |
| Lead | 3 |
| Benzophenones and other UV-filters | 2 |
| Mineral oil saturated hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH) | 2 |
| A shift of focus from already regulated chemicals to the substances used as substitutes for these | 2 |
| Volatile Organic Compounds (VOC) | 2 |
| Vitamins (A, D) from diet/various sources (e.g. supplementation) and products | 1 |



Long wish lists

Key Areas of Regulatory Challenge (KARC)



Link to
[KARC ECHA KARC \(europa.eu\)](https://echa.europa.eu/karc)



Identification of KARC

Extraction of the needs

Have for every need:

- PARC Scope: Yes / No
- Which WP(s)/ Task(s) Concerned
- Already addressed within PARC: Yes / No
- Already planned for the next AWP(s)
- Should be included in the next AWP(s)
- Could be included in the next AWP(s)
- Not Possible to include: Why?

To be filled in by Work
package or Task co-
leaders

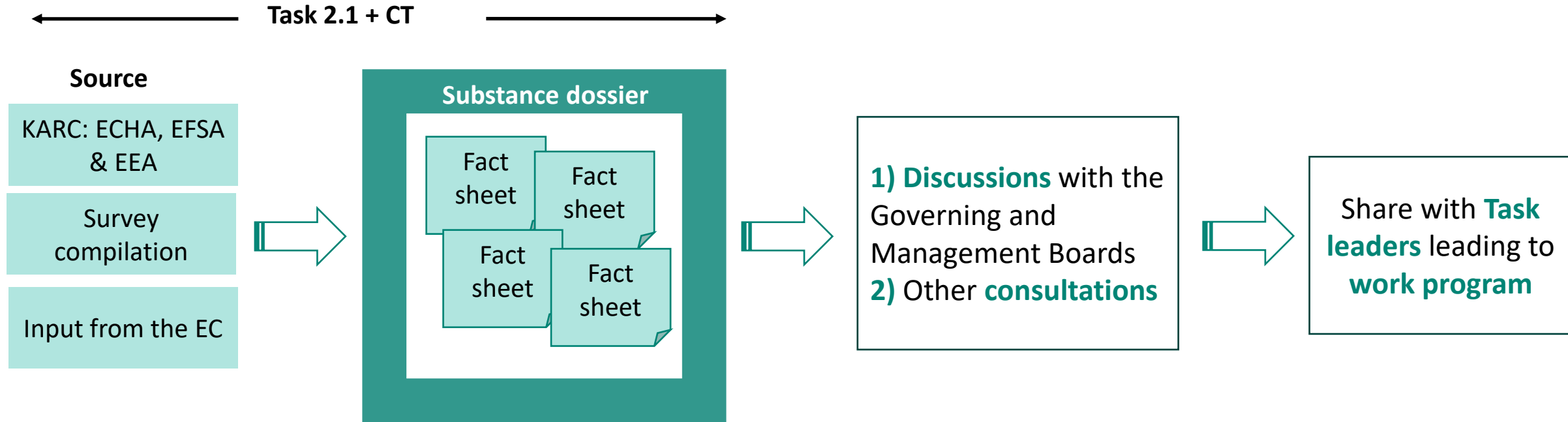
Four areas:

- Provide protection against most harmful chemicals
- Addressing chemical pollution in the environment
- Shift away from animal testing
- Improved availability on chemical data

- Why is the topic of relevance?
- Where does it fit in the regulatory landscape?
- What is the short- and long-term impact?

WP: Work Package
AWP: Annual Work Plan

Refining the Survey's Results



- Have **dossier for each substance** (the ones nominated **more than 3 times**)
- Elaborate **fact sheet for each clear need** + ask for clarification
- Have special background colour for the ones nominated by the **EC**
- Could be used as **background document**

- Ensure **alignment** and make links with the **KARC** identified by ECHA, EFSA, EEA
- Ensure **alignment** with national needs

- Elaborate the next **Annual work plan** and Project Portfolio

CT: Coordination Team

Fact sheet example: Micro & Nano plastics

| | |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Research question | Impregnation data, useful for estimating population exposure. |
| Objectives | <ul style="list-style-type: none">• Document the health impacts of micro plastics on humans.• Measure effect markers (e.g. obesogen associated markers).• Identify sources of human exposure to micro plastics. They might be added intentionally or non-intentionally and might be released as such or in the form of degradation product. RC could help define biodegradability criteria and review existing standards on micro plastics. Research on chemical interactions, mobility etc.• ADI levels and MRL levels for drinking water as well as for food products. |
| Regulations | <ul style="list-style-type: none">• Relevant for REACH restriction: The MS and EC should adopt a European restriction targeting micro plastics intentionally added in a large number of uses within the framework of the REACH regulation (this restriction, which would restricting the use of intentionally added micro plastic particles to consumer or professional use products of any kind, is currently being examined by the European Parliament and the Council).• Broad range of legal acts in addition to REACH: cosmetics regulation, food contact material regulation, POPs regulation, drinking water regulation as well as EU chemical strategy for sustainability and potentially also Zero Pollution Action Plan (water and soil actions). |
| Timeframe to deliver the results | |
| Concerned WP | Task 4.1; Task 4.2 |
| Identified by EU agencies KARC | ECHA regulatory key challenges 2.4.2.1 |
| Initiatives outside PARC addressing this need | |
| Nomination | Norway, Israel, EC, Luxembourg, France, Croatia, Ireland, Czech Republic, Austria → Total: 9 |

Key messages for a better prioritisation process

① Have a transparent prioritisation process

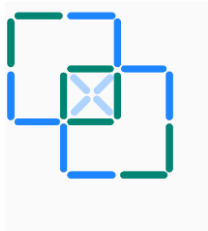
② Avoid only working with topics that are already extensively explored

③ Ensure alignment and synergy with other EU projects and initiatives

④ Ensure alignment and synergy between the WPs

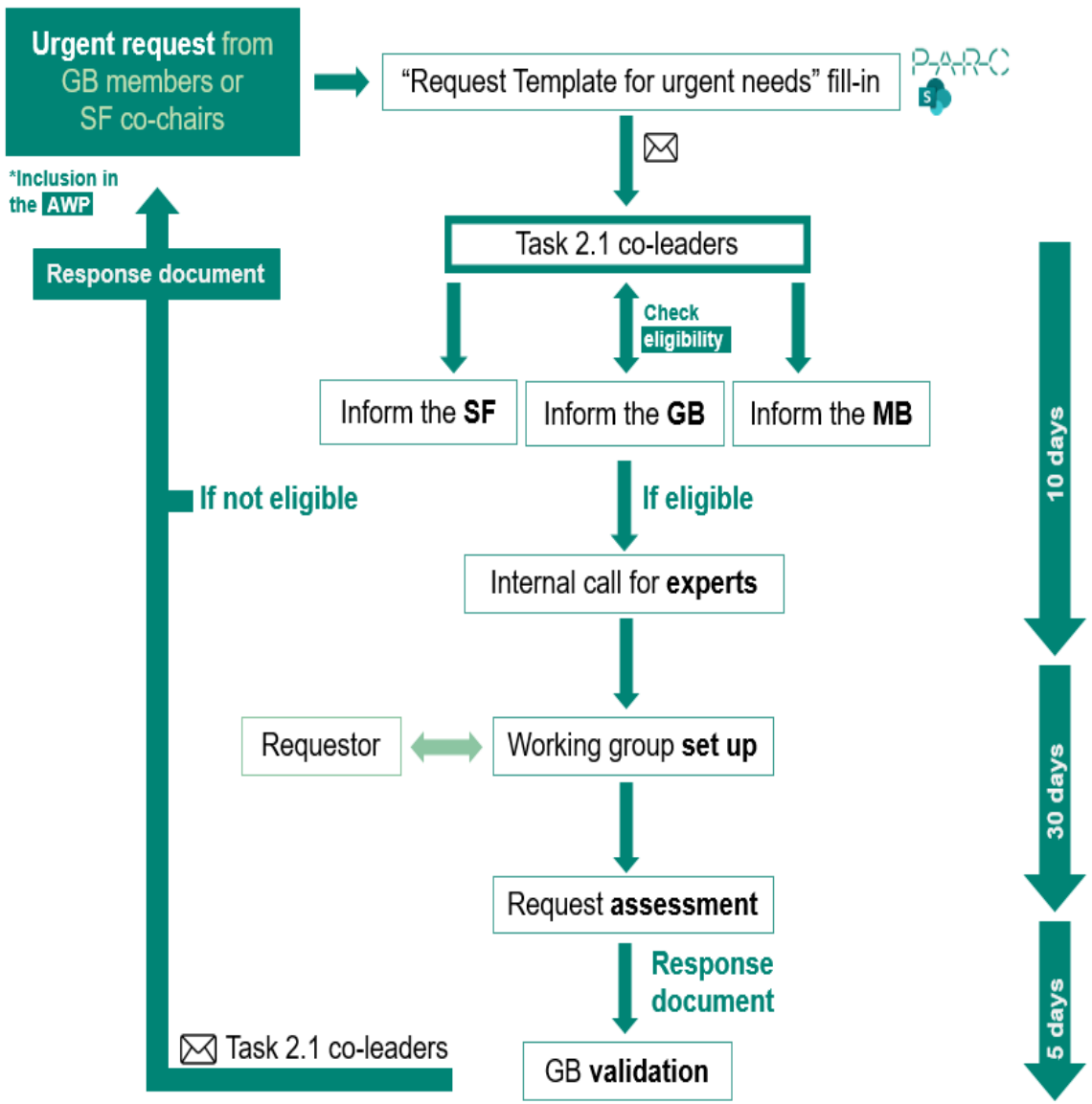
⑤ Utilise the partnerships to the fullest in term of matchmaking projects/activities with partners

⑥ Fulfil short-term and long-term policy needs in chemical RA



WPs: Work packages
RA: Risk Assessment

Rapid Response Mechanism



The request should be “eligible”:

- ✓ Covering PARC’s scope of research: a substance, an endpoint or a method related to human or environmental health
- ✓ Addressing a Health concern (causes significant risk in humans or in the ecosystem)
- ✓ Addressing a Regulatory challenge
- ✓ Cannot await a future prioritisation round
- ✓ Excluding an emergency situation (mandate being assigned to SCHEER)
- ✓ No other initiative is more appropriate to meet this need

The request should be “feasible” in terms of:

- ✓ Resources
 - ✓ Partners availability
 - ✓ Skills
 - ✓ Deadlines
- GB: Governing Board
SF: Stakeholder
MB: Management Board
AWP: Annual Work Plan



Task 2.1 co-leaders:

ANSES, ECHA, EFSA

Task 2.1 Partners:

EEA, EAA, BfR, DGS, UBA, GCSL, ISS

Thank you for your attention!



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