Partnership for the Assessment of Risks from Chemicals

Deliverable D2.12

Title: Exit Strategy Plan 2

WP2 – T2.3



Work package	WP2 - A common Science Policy Agenda
Task	T2.3- Sustainability
Dissemination level [1]	PU = Public
Lead Beneficiary/ Responsible AE	INSERM (FR)
Contributing Participants	ANSES (FR), UBA (DE), BfR (DE), AUTH (EL), BPI (EL), EEA (EU), EFSA (EU), EAA (AT), NCPHP (HU), NIJZ (SI), GCSL (EL), INSA (PT), MU (CZ), SpF (FR), DOMG (BE), FMUL (PT)
Responsible author(s)	Robert Barouki /INSERM/ Robert.barouki@u-paris.fr
Co-authors	Tamás Szigeti /NPHC/ szigeti.tamas@nnk.gov.hu Réka Kakucs kakucs.reka@nngyk.gov.hu Ana Virgolino /FMUL/ avirgolino@medicina.ulisboa.pt Osvaldo Santos /FMUL/ osantos@medicina.ulisboa.pt Adrienne Pittman/ANSES/ adrienne.pittman@anses.fr Beata Janasik /NIOM/ beata.janasik@imp.lodz.pl Ľubica Murínová /SZU/ lubica.murinova@szu.sk Kateřina Šebková /MU/ katerina.sebkova@recetox.muni.cz Jana Klánová /MU/ jana.klanova@recetox.muni.cz Lukáš Pokorný /MU/ lukas.pokorny@recetox.muni.cz Katja Leicht /BfR/ katja.leicht@bfr.bund.de Maria João Silva /INSA/ m.joao.silva@insa.min-saude.pt Sónia Namorado /INSA/ sonia.namorado@insa.min-saude.pt Nicole Bandow /UBA/ nicole.bandow@uba.de Marike Kolossa-Gehring/UBA/marike.kolossa@uba.de Till Weber /UBA/ till.weber@uba.de Hanna Schulz /UBA/ hanna.schulz@uba.de Ovnair Sepai /UKHSA/ ovnair.sepai@ukhsa.gov.uk Karen Van Campenhout /DOMG/ karen.vancampenhout@vlaanderen.be Maja Mampaey/ DOMG/ maja.mampaey@vlaanderen.be Loïc Rambaud/SpF/ loic.rambaud@santepubliquefrance.fr Sébastien Denys /SpFrance / sebastien.denys@santepubliquefrance.fr Clémence Fillol / SpF/ Clemence.fillol@santepubliquefrance.fr Xavier Coumoul/Inserm/ xavier.coumoul@parisdescartes.fr Michel Samson/Inserm/ michel.samson@univ-rennes.fr Daniela Zanini-Freitag /EAA/ Daniela.Zanini-Freitag@umweltbundesamt.at Wojciech Wasowicz wojciech.wasowicz@imp.lodz.pl Milena Horvat milena.horvat@ijs.si Denis Sarigianni sarigiannis@eie.gr Spyros Karakitsios spyros.karakitsios@gmail.com Kiara Aiello-Holden/ BfR/ Kiara.Aiello-Holden@bfr.bund.de And all the participants in the workshop – see page 9
Internal Reviewers[2]	Joana Lobo Vicente /EEA/ Joana.Lobo@eea.europa.eu Maria Uhl /EAA/maria.uhl@umweltbundesamt.at
External Reviewers[3]	PARC Management Board

Due date of deliverable	31/08/2025
Actual submission date	10/10/2025

Technical reference

[1] PU = Public
PP = Restricted to other programme participants (including the Commission Services)
RE = Restricted to a group specified by the consortium (including the Commission Services)
CO = Confidential, only for members of the consortium (including the Commission Services)
[2] WP/task co-leader(s) from the same WP
[3] Independent Reviewers that should not be part of the task related to the Additional Deliverable/Deliverable or part of projects related to the Task

Document history

Version	Date	Reviewer name/Institutions	Short description of changes
version 1	Date 25/08/2025	Authors of D	First compiled version for review by PARC T2.3 partners.
version 2	Date 05/09/2025	T2.3 partners	Draft version with comments provided by partners
version 3	Date 25/09/2025	MB reviewers	Final version with comments provided by reviewers
version 4	Date 09/10/2025	T2.3 and WP2 co-leaders	Final version for submission

“Funded by the European Union. Views and opinions expressed are, however, those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.”

Abstract

This is the second deliverable on the exit strategy of the Partnership for the Assessment of Risks from Chemicals PARC. It summarises the outcomes of a workshop on sustainability involving PARC's T2.3 members and the Management Board, held in February 2025. It also takes into consideration discussions with WP leaders and the Management Board (MB) before and after the meeting, as well as a survey of the National Hubs (NHs).

The workshop's aim was to discuss options for sustainable exit strategies for PARC activities, focusing on their long-term sustainability and how to continue overarching European coordination and linking of the activities that should be sustainable. A further goal was to identify viable options that will form the basis of continued discussions with the PARC boards: (MB, Grant Signatories Board (GSB), and Governing Board (GB)) and the NHs.

There is a general agreement that at least some PARC activities need to be continued after the project's ending, through sustainable frameworks, given that PARC's activities enhance the European Union's regulatory framework for chemicals and its research and risk assessment capacities, ensuring that Europe remains at the forefront of chemical safety while fostering economic growth and sustainability. PARC created a hub of excellence that brings together network creation, co-design, and implementation of activities supporting improved regulatory chemical risk assessment in Europe.

In light of the diversity of activities in PARC, it seems difficult to imagine and propose a single sustainable operational system that encompasses all the thematic components of PARC (e.g., monitoring and exposure, hazard assessment, development of methods/models, etc.), although the risk assessment of chemicals provides the overarching framework. The solutions for sustainability of each activity may be different, and the strong co-design link established in PARC between the scientific and policymaking communities should be pursued and leveraged to enhance coordination of next generation chemical risk assessment in Europe.

Yet, there is clearly a need for a global post-PARC overarching EU coordination of the activities which should continue), integrating three key sets of actors: EU and national agencies (ensuring regulatory oversight, guidance, and policy alignment), infrastructures (supporting essential activities), and researchers (addressing knowledge gaps).

The considerations and initial sustainability options and frameworks discussed during this workshop provided the basis for on-going discussions and development of PARC's exit strategy. PARC's sustainability is a recurrent item on the agendas of PARC's MB, GB, and GSB meetings, as all are key actors in the shaping and implementation of the strategies. Further actions for integrated sustainability solutions will be explored more concretely with the wider network and national agencies – in particular the GSB and the GB but also NHs throughout 2025 and 2026. Also the PARC Stakeholder Forum and the International Board have been and will be consulted.

Key Words

- Environment and health, environmental health
- Human biomonitoring: Human biomonitoring (HBM), HBM Surveys, HBM4EU, biomarkers, libraries, cross-sectional, longitudinal, bio-banking, population representation, regulatory effectiveness, real-life mixtures
- Environmental monitoring: non-targeted screening (NTS), suspect screening, effect-based methods, soil, water, biota, Early Warning System (EWS), biodiversity
- Human Heath: health effects, Health Impact Assessment (HIA), indicators, effects biomarkers, health outcome, molecular epidemiology, exposure-effects analysis, toxicity,

human health risk assessment, exposome, exposomics, Adverse outcome pathways (AOP), systems toxicology, digital models, PBPK
- Risk: risk management, weight of evidence, risk mitigations, risk communication, risk reduction, (regulatory) risk assessment, new approach methodologies (NAMs), fill data gaps, NGRA, use of AI,
- SSbD: Safe-and-Sustainable-by-Design (SSbD), safe by design, waste, green chemistry, innovation
- Data: FAIR (Findable, Accessible, Interoperable, Reusable) data, artificial intelligence (AI), reuse, open access, common data platform on chemicals,
- Infrastructure and capacity: laboratory networks, European infrastructures, EIRENE (Research Infrastructure for EnvIRonmental Exposure assessmeNt in Europe)
- Stakeholder, synergies

Table of contents

Technical reference ____ 3

Document history ____ 3

Abstract ____ 4

Key Words ____ 4

Table of contents ____ 5

Authors and Acknowledgements ____ 6

Acronyms ____ 6

1. Introduction ____ 8

2. Methods ____ 9

3. Results from the February 2025 workshop on the PARC exit strategy ____ 10

3.1. Discussion on WP4: Human biomonitoring (HBM) and environmental monitoring ____ 10

3.1.1. Key sustainability goals for WP4 ____ 10

3.1.2. Current status ____ 10

3.1.3. Summary of needs ____ 11

3.1.4. Action points for WP4 ____ 11

3.2. Discussion on WP5: Hazard assessment ____ 11

3.2.1. Key discussion points for WP5 ____ 11

3.2.2. Action points for WP5 ____ 12

3.3. Discussion on WP8: Safe and Sustainability by Design (SSbD), Early Warning System (EWS), risk modelling platform ____ 13

3.3.1. Key discussion points for WP8 ____ 13

3.3.2. Action points for WP8 ____ 13

3.4. Discussion on WP6: Regulatory risk assessment ____ 14

3.4.1. Key discussion points for WP6 ____ 14

3.4.2. Action points for WP6 ____ 14

3.5. Discussion on WP7: FAIR helps make information in chemical risk assessment sustainable ____ 14

3.5.1. Key discussion points for WP7 ____ 15

3.5.2.Action points for WP7 16
3.6. Discussion on WP9: Infrastructural and human capacities 16
3.6.1.Key discussion points for WP9 16
3.6.2.Action points for WP9 16
3.7. Other activities and general issues 16
3.8. Conclusion on overarching coordination and linking of the sustainable activities 17
3.9. Follow-up action points from the workshop (summary) 17
4. Discussion and perspectives for future activities of Task 2.3 19
5. Conclusion 20
Annexes 21
Annex 1: P4.1.5 note on EU-wide HBM feasibility 21
Annex 2: Note from DG RTD on phasing-out strategies for European Partnerships 22

Authors and Acknowledgements

Authors: Robert Barouki, Tamás Szigeti, Adrienne Pittman Réka Kakucs, Ana Virgolino, Osvaldo Santos, Beata Janasik, Ľubica Murínová, Kateřina Šebková, Jana Klánová, Lukáš Pokorný, Katja Leicht, Maria João Silva, Sónia Namorado, Nicole Bandow, Till Weber, Hanna Schulz, Ovnair Sepai, Karen Van Campenhout, Maja Mampaey, Loïc Rambaud, Xavier Coumoul, Michel Samson, Daniela Zanini-Freitag, Wojciech Wasowicz, Milena Horvat, Denis Sarigiannis, Spyros Karakitsios, Kiara Aiello-Holden

Thank you to the reviewers: PARC MB

Acronyms

AI - Artificial intelligence
AOP - Adverse Outcome Pathway
ECHA - European Chemicals Agency
EFSA - European Food Safety Authority
EEA - European Environment Agency
EC – European Commission
EHEN - European Human Exposure Network
EIRENE – Environmental Exposure Assessment Research Infrastructure
EU - European Union
EWS - Early Warning System
FAIR - Findable, Accessible, Interoperable, Reusable
HBM - Human Biomonitoring
HBM4EU - Human Biomonitoring for Europe - European joint Programme co-funded under Horizon 2020
IPCHEM - Information Platform for Chemical Monitoring
IHEN - International Human Exposure Network
JRC - Joint Research Centre
MS - Member State
NAMs - New Approach Methodologies
NEXUS - Network for EXposomics
NGRA - Next-Generation Risk Assessment

NH - National Hub
NHANES - National Health and Nutrition Examination Survey
NHCP - National Hub Contact Point
NTP - National Toxicology Program
OECD – Organisation for Economic Co-operation and Development
OSOA - One Substance, One Assessment
PARC - Partnership for the Assessment of Risks from Chemicals
RRM - Rapid Response Mechanism
SSbD – Safe and Sustainable by Design
TG – Test Guideline
WP, WPL - Work Package, Work Package co-Leaders

1. Introduction

The rationale for sustaining PARC activities has been thoroughly outlined in the Partnership for the Assessment of Risks from Chemicals (PARC) proposal, which justified the establishment of a dedicated task (Task 2.3 'Sustainability'). Long-term continuation is essential to monitor environmental and human contamination, accelerate knowledge on chemical toxicity, implement early warning systems, and develop methods for safer chemical innovation. These goals ultimately aim to enhance the health protection of European citizens, while also improving European competitiveness and contributing to a truly One Health approach.

In PARC, a sustainable activity is defined as an activity that can be continuously delivered at a consistent quality and level of performance, providing a stable and reliable foundation for coordinating and expanding joint work at European Union (EU) level. Ensuring sustainability requires coordinated systems, governance and infrastructure across several dimensions such as financial, management, technical and data management aspects and different scales (national, European or international levels).

According to the Regulation (EU) 2021/695 establishing Horizon Europe, it is stated that European Partnerships are required to submit a strategy for "phasing-out" from Horizon Europe programme, (this refers to discontinuation of funding from Horizon Europe, with possible continued transnational funding by national or other EU programmes or through private investment, as indicated in Annex III of the Regulation). PARC has initiated discussions on its exit strategy from the start. Through surveys, launched as early as the 1st year of PARC (see D2.9 "1st PARC exit strategy plan and sustainability report"), and follow-up targeted meetings and workshops with the different Work Packages (WPs) and governance boards of PARC, initial thoughts and possibilities for the sustainability of PARC activities are reflected upon and developed, as activities progress. In light of the diversity of activities in PARC, it seems difficult to imagine a single sustainable operational system that encompasses all the thematic components of PARC (e.g., monitoring and exposure, hazard assessment, development of methods/models, etc.) although the risk assessment of chemicals provides the overarching framework. While it may be desirable to keep the connections between the different activities, it is likely that the different activities may require different sustainable frameworks, and a coordination between these frameworks would be needed. Likewise, the strong co-design link established in PARC between the scientific and policymaking communities should be leveraged and pursued. There is also a clear difference between the maturity levels for the exit strategy of the different activities, some being more advanced than others.

PARC's T2.3 workplan planned for a first specific workshop on sustainability with T2.3 members and the PARC Management Board (MB), which was carried out in February 2025. **This deliverable presents the results of the workshop and delves into specific proposals. These proposals will be the basis for future discussions and development on the exit strategy of PARC, with, not only the specific WPs, but also the different boards of PARC, including the Governing Board (GB) and Grant Signatory Board (GSB), as well as the National Hubs (NHs) and relevant EU-hub members, planned over 2025 and 2026.**

Although the Grant Agreement does not specify coordinated phasing out strategies for the European Partnerships, in July 2025, the EC sent a note from DG RTD to the attention of European Partnerships on the subject of "Phasing-out strategies: framing the future of each European Partnership" (see Annex 2). This note aims to help frame the exercise and provides a common timeline and guidance for the development of the phasing-out strategies; European partnerships will benefit from support from DG RTD. PARC's T2.3 activities are in line with this request and will benefit from this process.

2. Methods

A first survey to identify the different activities of PARC that need to be sustainable at the EU level was carried out under Task 2.3 'Sustainability' and sent to all National Hub Contact Points (NHCPs) for a response by 15/06/2023. The results are analysed in D2.9 first Exit Strategy Plan (https://www.eu-parc.eu/deliverables). This first survey on the exit strategy highlighted which PARC activities the National Hubs (NHs) identified as needing to be sustainable at the EU level. It also developed initial thoughts and options for the most relevant management and technical operational systems to continue carrying out those activities in the long term. These formed the basis for further, more targeted discussions, with the WP co-leaders (WPLs), the 3 EU agencies (European Chemicals Agency (ECHA), European Food Safety Authority (EFSA), European Environment Agency (EEA)) involved in PARC, and, more recently, the JRC, on the exit strategy.

On 4 and 5 February 2025, an in-person workshop on the PARC exit strategy, with PARC MB members and Task 2.3 partners, was organised in Copenhagen (Denmark), hosted by the EEA, back-to-back with a PARC MB meeting.

The workshop's aim was to discuss options for sustainable exit strategies for PARC activities, focusing on their long-term sustainability and how to continue overarching European coordination and linking of the sustainable activities. An overview of the initial survey on the exit strategy which targeted NHs in 2023, was presented and highlighted that many had faced challenges in expressing a commitment to final strategies since the survey was at an early-stage or due to lack of national consensus. This feedback that was provided in the questionnaire and presented in D2.9 formed the basis for the workshop discussions. The workshop aimed to identify viable options rather than reach consensus immediately. The process was structured to focus on individual tasks and work packages (specifically each R&I activity/WP) before discussing how to seek broader overarching strategies to maintain overarching coordination and link between the activities and how they feed into each other. This process aimed to ensure tailored solutions for each activity rather than a one-size-fits-all approach. Discussions also addressed the need for overarching, integrated European coordination to support sustainability. A follow up process was discussed with the MB during the meeting, engaging the WP and activity leaders to continue each WP/activity discussion over the coming months and identify more clearly activities that should be sustained and how.

The workshop facilitators were Robert Barouki (INSERM) and Tamás Szigeti (NCPHP) (Task 2.3 Co-leaders) and they were supported by note-takers from T2.3 partners, including Joana Lobo Vicente (EEA), Adrienne Pittman (ANSES), Maja Mampaey (DOMG), Sónia Namorado (INSA), and Till Weber (UBA).

Workshop participants (physical presence):

- Basile Cazalis de Fondouce (ANSES)
- Adrienne Pittman (ANSES)
- Gilles Rivière (ANSES)
- Christophe Rousselle (ANSES)
- Pascal Sanders (ANSES)
- Spyros Karakitsios (AUTH)
- Kiara Aiello-Holden (BfR)
- Maja Mampaey (DOMG)
- Karen Van Campenhout (DOMG)
- Maria Uhl (EAA)
- Safia Korati (ECHA)
- Joana Lobo (EEA)
- Roser Gasol (EEA)
- Claudia Heppner (EFSA)
- Eugenia Dessipri (GCSL)
- Susana Pedraza-Diaz (ISCIII)
- Sónia Namorado (INSA)
- Robert Barouki (Inserm)
- Lina Wendt-Rasch (KEMI)
- Jana Klanova (MU)
- Tamás Szigeti (NCPHP)
- Mirjam Luijten (RIVM)
- Sébastien Denys (SpF)
- Clemence Fillol (SpF)
- Marike Kolossa-Gehring (UBA)
- Nicole Bandow (UBA)
- Till Weber (UBA)
- Iseult Lynch (UoB)
- Stijn Baken (VITO)
- Jos Bessems (VITO)

3. Results[1] from the February 2025 workshop on the PARC exit strategy

3.1. Discussion on WP4: Human biomonitoring (HBM) and environmental monitoring

WP4 representatives discussed the sustainability goals for HBM and the integration of environmental and multisource data. They recalled past efforts towards sustainability in HBM and the challenge of ensuring continuity without gaps. They insisted on the need to have a fully sustainable HBM system in Europe immediately after the end of PARC activities and thus avoid periods of time with no activity at all. Initial intentions to implement an Article 185 initiative[2] (Treaty on the Functioning of the European Union) solution for sustainability, which eventually shifted due to strategic changes at the Commission level, were recalled from HBM4EU and the importance of a legal framework to embed monitoring in Europe, be it HBM or environmental monitoring, was highlighted.

3.1.1. Key sustainability goals for WP4

- Extending HBM and providing environmental and multisource data for regulatory purposes.
- Creating a foundation for a sustainable legally-embedded European HBM system.
- Supporting the 'One Substance, One Assessment (OSOA)' approach, which highlights the need for sustainable HBM in Europe, including a common data platform.
- Ensuring sustainability and further development of innovative methods such as non-targeted and suspect screening in conjunction with targeted analysis.
- Providing HBM guidance values for chemicals of concern.
- Maintaining a permanent Rapid Response Mechanism (RRM) to address urgent environment and health issues and that could also support the EWS.

3.1.2. Current status

- T4.1 - Human biomonitoring: The first report on sustainable HBM programmes will be delivered around April 2026 (end of Y4 of PARC), detailing strengths and weaknesses across European programmes. Since the Copenhagen meeting, amendments from the European Parliament for the "Common data platform" legislative proposal were put forward for discussion. These included amendments under article 21 "data generation mechanism"[3] establishing a legal framework for regular HBM surveys in Europe. The process is being closely followed by PARC and will be clearer by the end of 2025[4].
- T4.2 - Environmental and multisource monitoring: The existing Water Framework Directive is a potential model for frameworks in other media. Ongoing legislative efforts, such as the proposed EU Soil Directive may provide useful regulatory frameworks as examples for other domains, including the HBM field. There is a need for coherent monitoring systems in soil, air, and other environmental compartments. Case studies addressing specific

[1] Themes and activities are listed by order of discussion during the workshop.

[2] Article 185 initiatives (Article 185s), promoted by the Commission in 2001 as an instrument to implement joint programming of research activities, are long term public-public partnerships (P2P) established on a voluntary basis by EU Member States that aim for scientific, managerial and financial integration of national research programmes at European level in a given field. They are established through the EU ordinary legislative procedure and require a Dedicated Implementation Structure (DIS)

[3] See page Procedure File: 2023/0453(COD) | Legislative Observatory | European Parliament

[4] https://www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-access-to-and-availability-sharing-and-re-use-of-chemical-data-(refit)

chemicals are needed to recommend future environmental monitoring and the integration of HBM with environmental monitoring.

- T4.3 - Innovative methods and tools for monitoring and surveys: Harmonisation of methods and the development of a network for non-targeted analysis are needed. Non-targeted analysis is considered valuable for identifying emerging substances and can be a component of an Early Warning System (EWS) approach. A dedicated infrastructure for storing, analysing and providing authorities with access to extensive raw data generated from non-targeted analysis is not yet available.
- The ambition would be to establish a sustainable monitoring platform/system (beyond PARC) that holistically covers chemical exposure in humans and ecosystems.

3.1.3. Summary of needs

- A legal foundation for HBM and reporting obligations similar to those for environmental monitoring (e.g., the EU Water Framework Directive). Finalisation of the legal foundation for soil monitoring.
- A sustainable solution for data storage beyond PARC, potentially building on existing initiatives such as the Information Platform for Chemical Monitoring (IPCHEM) and the proposed common data platform to ensure long-term availability of results.
- Improved linkage and interoperability of HBM and environmental and food monitoring data as well as with other data sources (health, social, etc.).
- Capacity to maintain and harmonise activities on non-targeted and suspect screening, possibly within the Environmental Exposure Assessment Research Infrastructure (EIRENE). Consider including such activities in routine biomonitoring in the future.

3.1.4. Action points for WP4

- Finalise the sustainability report by the April 2026 (end of PARC Y4).
- Evaluate possible coordination with EIRENE.
- Identify data sharing, visiting and federation solutions.
- Work with the EC and member states in the national hubs to explore regulatory pathways for embedding HBM within European regulation (see above for new developments since the meeting).
- Ensure contribution to risk assessment: strengthen the link between HBM and hazard assessment, ensuring guideline values are established.
- Ensure the sustainability of the laboratory network (including targeted and non-targeted screening) by involving NHs and European infrastructures.
- Responsible: WP4, WP7, WP9. Coordinate with Task 2.3 for sustainability issues.
- Timeline: End of 2025 for the report and ongoing for the other activities

3.2. Discussion on WP5: Hazard assessment

WP5 is committed to advancing Next-Generation Risk Assessment (NGRA) by integrating new approaches and methods for health assessment. The focus is on filling data gaps on poorly characterised contaminants and emerging hazards that are outside the scope of mandatory industry testing under current regulatory frameworks, while promoting innovative tools and technologies and the transition to non-animal New Approach methodologies (NAMs). The activities of WP5 are diverse, some of these (such as TG+ concept) are still at an early stage and the lessons learnt will be drawn towards the second half of PARC.

3.2.1. Key discussion points for WP5

- Improving the relevance of human testing by promoting regulatory acceptance of new approaches.

- Use of NAMs before market entry (ensuring robust hazard identification) and after market introduction (continuous monitoring and assessment) of regulated chemical substances.
- Validation of NAMs (national funding options for validation were mentioned, possible role of Joint Research Centre (JRC) in supporting validation efforts).
- Advancing *in silico* methods has been recognised as a top priority due to rapid improvements in capability and emergence of explainable artificial intelligence (XAI).
- Linking HBM to hazard assessment (development of HBM guideline values, development of effect biomarkers, broader adoption of HBM for regulatory purposes).
- Endpoint development: where OECD TGs exist further NAM development is not required, while other endpoints (e.g., developmental & reproductive toxicity, carcinogenicity) require continued input.
- Funding & sustainability: DG GROW, and DG ENV need to discuss financial support. EFSA's role in complementary efforts was highlighted. Potential for dedicated EU funding for data generation.
- Strengthening collaboration with the US (National Toxicology Program - NTP) to leverage expertise.
- Evaluation of TG+ (Test Guideline Plus)[5]: following initial studies carried out in PARC, further assessment is needed.

3.2.2. Action points for WP5

- Activities that should be sustainable within WP5 were identified:
  - Activities related to the identification of priorities in terms of development and validation activities related to NAMs for different hazards.
  - The TG+ concept as a tool to improve the acceptance of NAMs (i.e., omics) as well as generating data needed by the Agencies.
- Build on the work already initiated within WP5 to identify which frameworks would be needed at the European or inter-MS (or inter-agencies) levels to further develop what could constitute a "European hub of excellence in chemical risk assessment", bringing Toxicology to the forefront of science and innovation to continue providing a research and scientific basis for activities and policies that promote health and prevent disease and identifying substances that should be evaluated for potential effects. This entails refining scientific and policy priorities along the following directions:
  - Prioritise NAMs based on endpoints and regulatory impact.
  - Advance in silico methods as a priority for chemical risk assessment.
- Ensure contribution to risk assessment: strengthen the link between HBM and hazard assessment, supporting guideline values determination.
- Secure funding through national and EU-level initiatives, exploring agency-led and/or infrastructure-led sustainability options.
- Identify sustainable funding for pre-validation activities of prioritised NAMs (private/public sector?)
- Enhance collaboration of PARC partners with ECHA, EFSA, and US-based research programmes.
- Ensure balanced funding between environmental and human health activities.
- Responsible: WP5, in collaboration with EU agencies. Coordinate with Task 2.3 for sustainability issues.
- Timeline: Ongoing

[5] Test guideline (TG) required endpoints include histopathology or clinical chemistry. On top of that, additional parameters can be investigated (referred to as "TG+") like toxicokinetics, toxicogenomics of target organs, other NAM-based data.

3.3. Discussion on WP8: Safe and Sustainability by Design (SSbD), Early Warning System (EWS), risk modelling platform

WP8 presented the Safe and Sustainability by Design (SSbD) initiative, focusing on complementarity with green chemistry and the role of public-private partnerships for advancing sustainability. The political relevance of SSbD was highlighted particularly in light of the "Competitiveness compass" presented by the European Commission in January 2025, a new roadmap to restore Europe's dynamism and boost its economic growth. Developing capacities and leadership for safer chemicals represents a competitive advantage of European industry (chemical, pharmaceutical). Note that SSbD relies heavily on advances made by other WPs, in particular WP5 and WP7. The presentation also covered the early warning systems (EWS) and the development of the risk modelling platform.

3.3.1. Key discussion points for WP8

- The role of ECHA was discussed during the meeting, keeping in mind the EU's need for collaboration with industry to move forward on green and safer chemistry initiatives.
- How will the SSbD toolbox continue after PARC? The toolbox will remain available as an overarching platform. Since it is being developed in an open space, it could continue to exist beyond PARC, with free access for users. The SSbD toolbox is a voluntary approach, not mandated by legislation currently, and while it offers valuable guidance, its long-term sustainability requires further discussion, strong arguments, and a viable business model.
- There is certainly also a link between SSbD and NAMs. During the development phase of a new chemical substance, industry can use NAMs to test the safety of certain chemicals within the SSbD framework, which can in turn help boost the development of NAMs.
- Concerning sustainability, one option suggested was a centre supporting innovation covering SSbD and green chemistry, in collaboration with industry (public-private partnership). To avoid conflicts of interests, the core of the centre could be in one of the member states with little involvement in the chemical industry.
- EWS was highlighted as a key aspect of WP8, emphasising that EEA would be the main player in managing the EWS. The EWS is currently more advanced at the policy level. The technical aspects should be maintained and further developed with sustained funding from the EC. Access to sufficient data is crucial and requires strong linkages with WP7.
- The risk modelling platform should also be sustained. This would require European involvement (EEA, ECHA, JRC?) as well as a network of Member States (MS) similar to the European Environment Information and Observation Network (Eionet) or WHO collaborating centers.
- The role of EU infrastructures should be discussed as these can not only maintain PARC outcomes but contribute to further developing them.

3.3.2. Action points for WP8

- Continue to collaborate with industry, ECHA and JRC on SSbD.
- It is proposed that EEA takes the lead on EWS management, ensuring sustained funding from the EC.
- Start planning for the risk modelling platform options. WP8 and WP6 should engage in deeper discussions on case studies. Need to consult agencies on their approach; a workshop with regulatory agencies and infrastructures was proposed.
- Responsible: WP8, EEA, EFSA, ECHA. Coordinate with Task 2.3 for sustainability issues.
- Timeline: Ongoing

3.4. Discussion on WP6: Regulatory risk assessment

The umbrella of sustainable PARC activities and structures is regulatory risk assessment with the need for exposure and hazard assessment and the balance between innovation, and the use of NAMs in a functioning regulatory system.

There was consensus that future risk assessments need to combine human risk assessments with environmental health and biodiversity considerations.

For the development of future sustainable activities addressing impacts of chemicals on biodiversity, collaboration with other ongoing partnerships and research projects focusing on biodiversity should be pursued.

3.4.1. Key discussion points for WP6

- NAMs, while important for regulatory assessment, also need to be validated within an organised structure and with a clear scientific basis rather than by comparison to *in vivo* results. The validation process must remain flexible and able to adapt to ongoing developments, with clear boundaries yet to be fully defined.
- Maintaining the regulatory objectives is essential to ensuring continued impact of PARC's outputs. National regulatory organisations need to be encouraged to actively participate in the research and development related to the regulatory risk assessment process, with sufficient resources allocated to ensure their contributions. The involvement of agencies is crucial for the success of the initiative resulting in regulatory-relevant methods. Regulatory agencies' involvement in the prioritisation of knowledge gaps is essential. A close collaboration between regulatory agencies and research institutes is an important legacy of PARC that should be maintained and further developed.
- The importance of connecting toxicology and human biomonitoring activities was emphasised, as these two pillars are crucial for meaningful regulatory risk assessment.
- Environmental risk assessment also requires additional focus, with a special emphasis on synergies and integrating research with regulatory needs.
- Discuss with infrastructures such as EIRENE on their possible contribution.

3.4.2. Action points for WP6

- Secure a long-term platform for regulatory risk assessments and ensure collaboration between EU MS and EU bodies.
- Continue working on NAM integration within European risk assessment frameworks, including connections to the EWS and SSbD Toolbox when relevant.
- Prioritise the identification of gaps and synergies to address key challenges and further integrate research with regulatory needs.
- Continue building networks and collaboration with initiatives addressing environmental risk assessment of chemicals and/or biodiversity.
- Responsible: WP6, ECHA, EFSA, JRC. Coordinate with Task 2.3 for sustainability issues.
- Timeline: Ongoing.

3.5. Discussion on WP7: FAIR helps make information in chemical risk assessment sustainable

WP7 is responsible for making data Findable, Accessible, Interoperable, and Reusable (FAIR) in PARC. WP7 introduced "FAIRification" as a key method for ensuring knowledge preservation and reuse of data within chemical risk assessment and exposome research. If data is (FAIR), it is already sustainable and can be effectively integrated into broader initiatives. On this basis, WP7 indicated to be ready to contribute further to discussions on making PARC sustainable.

After the workshop in February 2025, WP7 has further developed and consolidated their vision on how FAIR data can contribute to sustainability. This is reflected in section 6 of Deliverable D7.3 (First report on data infrastructure, tools and services for FAIRification and reuse of chemical risk assessment data), and it was also discussed at the Annual WP7 meeting. The vision revolves around three pillars:

- FAIRification of information already ensures a degree of sustainability. FAIR principle F1 mandates the use of persistent (i.e. sustainable) identifiers, and FAIR principle A2 mandates the long-term availability of metadata. FAIR data is therefore one part of the answer to the question: "How will PARC ensure information in chemical risk assessment is made sustainable?" The FAIR infrastructure and FAIR skills created through PARC will therefore play a key role in ensuring the sustainability of PARC's activities.
- FAIR data increases data quality, trust in data, and AI readiness, according to a report from the Pistoia Alliance on the Business case for FAIR data in life sciences (https://marketing.pistoiaalliance.org/hubfs/FAIR%20Business%20Survey.pdf). All these factors fundamentally increase the sustainability of data, as they lower the barriers for successful reuse. Especially the AI readiness aspect ensures longer sustainability as AI-related technologies will increasingly be introduced in science in general and chemical risk assessment in particular
- A guarantee to sustainability is to maximally incorporate information (data, models) in existing initiatives (platforms, databases, tools, infrastructures…) with a long-term vision and funding. Therefore, PARC should maximally strive to leverage such initiatives, and deposit information in established repositories with clear sustainability models (e.g. EOSC, Elixir, NORMAN etc.). In WP7, the Chemical Risk Assessment Hub6 is developed with a long-term vision well beyond the horizon of PARC (via collaboration with EIRENE). Another good example of a long-lived resource is the Common Data Platform on Chemicals, which will soon even have a legal basis. WP7's role is to strengthen the link between FAIR data in PARC and such long-term external resources.
- Given the increasing attention globally to the broader domain of exposome research, integrating information into this broader context ensures long-term relevance. Exposome research aims to link health outcomes to both chemical and non-chemical exposure. Making information on chemical risk assessment interoperable with e.g. information on non-chemical exposure will ensure continued relevance, as it enables researchers to address research questions considered of high importance in the coming decade(s).

3.5.1. Key discussion points for WP7

- It was noted that data and models are key resources that need to be preserved for future use in chemical assessments and must be integrated with environmental research.
- FAIR data is a key enabler of machine-actionable approaches and modelling, essential for NGRA, EWS and SSbD.
- Close collaboration with key EU agencies like EEA, ECHA, and JRC is necessary for long-term sustainability, especially considering the Common Data Platform on Chemicals.
- Interactions and solutions should be coordinated with other programmes beyond PARC (e.g., exposome projects, EOSC, Research Data Alliance, Pistoria Alliance etc.).
- "Go Fair Foundation" is critical to ensuring a robust "FAIRification" process
- Infrastructures are also to be considered (such as EIRENE, ELIXIR[7]).

[6] https://marketing.pistoiaalliance.org/hubfs/FAIR%20Business%20Survey.pdf

[7] ELIXIR is an intergovernmental organisation that brings together life science resources from across Europe. These resources include databases, software tools, training materials, cloud storage and supercomputers (source: https://elixir-europe.org/about-us, consulted on 28/07/2025).

3.5.2. Action points for WP7

- Focus on data preservation through “FAIRification” across PARC activities and integrate chemical risk assessment into the broader exposome and life sciences research networks.
- Work on interoperability of data sets (e.g., by developing a minimum metadata standard) to support machine actionability.
- Coordinate sustainability efforts with agencies and other organisations, including the CDPC, EOSC and others, determining who will maintain key resources.
- Responsible: WP7, WP9. Coordinate with Task 2.3 for sustainability issues.
- Timeline: Ongoing.

3.6. Discussion on WP9: Infrastructural and human capacities

WP9 discussed the importance of sustaining infrastructure for laboratory activities, human capacity building and data sharing, particularly as it relates to human health and chemical exposures. Key aspects include coordinating laboratory networks, maintaining open-access data systems, and ensuring sustained training programmes.

3.6.1. Key discussion points for WP9

- There were concerns about the technical capacity and long-term funding for maintaining up to date laboratory networks after PARC.
- Strong connections between SSbD, EWS, the networks and risk assessments will be essential for long-term impact.
- The different laboratory activities of PARC should remain coordinated, including data generation, storage and sharing as discussed in WP7. Infrastructures such as the Research Infrastructure for EnvIRonmental Exposure assessmeNt in Europe - EIRENE can support both the coordination of laboratory work and the integration and accessibility of related data.
- A sustained training programme should be developed (European Life-science Infrastructure for Biological Information - ELIXIR, EIRENE, etc).

3.6.2. Action points for WP9

- Strengthen collaboration between NHs and EU institutions to ensure sustainable laboratory network information sharing and capacity building for chemical exposure monitoring.
- Investigate capacity of EIRENE and other European Research infrastructures to support PARC sustainability; this could already start with common projects between EIRENE and PARC.
- Responsible: WP9, WP7, EEA, EFSA, ECHA. Coordinate with Task 2.3 for sustainability issues.
- Timeline: Ongoing.

3.7. Other activities and general issues

The approaches developed and implemented in PARC (within WP2) to ensure science to policy translation, the mapping and prioritisation of regulatory challenges, the project review process and the PARC quality assurance processes are also important and needed in the long term, thus requiring sustainability solutions.

Other PARC activities and tools, including the knowledge management platform “PARCopedia” developed by WP2, require long-term sustainability strategies to maintain impact beyond PARC's lifetime.

The role and sustainability of the NHs should be brought to the GB for discussion.

The European Research Infrastructure EIRENE should be further discussed within PARC in relation to NHs, as it could provide one pathway for sustaining some PARC activities. In this context, possible extension of EIRENE should also be considered, especially given that Eastern European countries are currently underrepresented in EIRENE.

There is significant overlap between the stakeholder communities of PARC, International Human Exposure Network (IHEN), European Human Exposure Network (EHEN) and EIRENE. A joint outreach meeting to stakeholders could leverage these shared communities to enhance engagement, foster synergies, and strengthen alignment on key issues related to chemical risk assessment. A coordinated vision of the future of chemical risk assessment and exposome research should be developed and discussed with the EC.

3.8. Conclusion on overarching coordination and linking of the sustainable activities

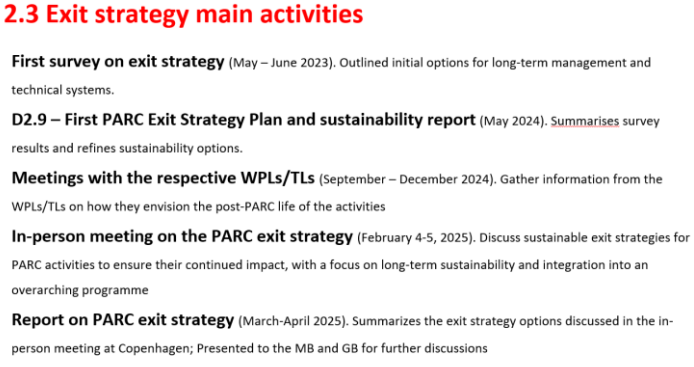
There is a general agreement that PARC activities need to be continued through sustainable frameworks. Furthermore, the entire process, network and structure created through PARC should also be sustained: PARC created a hub of excellence that brings together network creation, co-design, capacities, and implementation of activities supporting improved regulatory chemical risk assessment in Europe.

There is a need for an overarching post-PARC coordination of these activities, not to run the activities per se but rather to coordinate them and ensure their coherence and ambition, maintaining continued interaction between the biomonitoring and toxicology pillars and integrating three key sets of actors: EU and national agencies (ensuring regulatory oversight, guidance, and policy alignment), infrastructures (supporting essential activities to support the underpinning research excellence), and research institutions (addressing knowledge gaps and innovation). NHs and joint training programmes should ensure broad anchoring.

While overarching coordination would be useful, the solutions for sustainability of each activity may be different. This coordination would cover and integrate mandatory activities of (next generation) risk assessment (biomonitoring, filling gaps in exposure, hazard and risk assessment, data harmonisation and preservation, etc.) as well as research activities that are guided by a living science-to-policy dialogue. Articulation with other initiatives such as EIRENE, ELIXIR and IHEN and collaboration with international programmes or initiatives (such as the National Toxicology Program (NTP), the National Health and Nutrition Examination Survey (NHANES) and the Network for EXposomics (NEXUS) in the United States of America) should be implemented. Also the link to the science-policy panel on chemicals, waste and pollution prevention at UN-level should be further explored.

3.9. Follow-up action points from the workshop (summary)

Summary slides from the workshop and the basis for further discussions and follow-up actions:



Topic	Activities	Possible options and organisation
Human Biomonitoring	Regular HBM surveys	Legally-embedded; OSOA process as a first option
Environmental monitoring	Water, air, soil monitoring	Existing legislations
Toxicology (European Toxicology Programme)	TG+, NAM and *in silico* prioritisation	Inter-agencies, infrastructures, research programmes
Non-targeted screening	Discovery-oriented, emerging chemicals	Infrastructure, lab network, research programmes
Early warning systems	Environmental and human EWS	Agencies
SSBD	Safety and sustainability tests	Public-private, Agencies-JRC, centralised?
Data	Data storage and Fairification	Agencies, infrastructures
Infrastructures and capacities	Labs networks coordination, Data analysis, training	Infrastructures
National hubs and science to policy	National hubs, Prioritisation, PARCopedia, risk assessment and knowledge transfer	within overarching coordination + infrastructures
European chemical Risk Assessment overarching Coordination	Overarching activities in risk assessment; integrates and links activities below and global coordination	Inter-agencies, infrastructures, MS networks, research programmes

WP4 (Monitoring and Exposure):

- Finalise HBM sustainability report in April 2026. (P4.1.5a)
- Establish legal foundations for sustainable European HBM (taking into consideration very recent developments) (also see Annex 2 on P4.1.5 note on EU-wide HBM feasibility).
- Evaluate possible coordination with EIRENE.
- Identify solutions for data sharing and lab activities post-PARC.
- Timeline: End of 2025 and ongoing

WP5 (Hazard assessment):

- Optimise the work on development of NAMs and the TG+ studies (coordination and funding)
- Identify sustainable funding for pre-validation activities of prioritized NAMs
- Co-creation or work programme with agencies, infrastructures, other WPs (6, 8, 9)
- Timeline: Ongoing

WP8 (Concepts and Toolboxes: SSbD, EWS):

- Continue collaboration with industry for SSbD.
- EEA to manage EWS and secure funding from EC.
- Timeline: Ongoing

WP6 (Innovation in regulatory risk assessment):

- Secure regulatory risk assessment network and collaborate with MS and EU bodies.
- Timeline: Ongoing

WP7 (FAIR data):

- Make chemical risk assessment data sustainable through FAIRification
- Integrate FAIR information in existing resources with a long-term vision, such as the CDPC and the CRA Hub.
- Integrate it into broader exposome research.
- Timeline: Ongoing

WP9 (Building infrastructural and human capacities: infrastructural capacities):

- Strengthen infrastructure and data sharing systems with EU institutions and NHs.
- Timeline: Ongoing

WP2 (A common science-policy agenda: science to policy, prioritisation, knowledge management and sustainability):

- Communicate conclusions with MB, GB, EC, agencies, parliament, NHs/MS and the EC
- Oversee the overall progress of the activities and their overarching sustainable coordination and continued linking
- Timeline: Ongoing

4. Discussion and perspectives for future activities of Task 2.3

PARC was born out of two significant political ambitions: 1) to make the EU a model in chemical safety through research and innovation and 2) to demonstrate the feasibility of increasing the EU's competitiveness while protecting human health and the environment, in a One Health approach. Throughout PARC's lifetime (and even afterwards), the political context evolves and PARC's co-design approach involving regulators, risk assessors, researchers and policymakers makes the partnership uniquely flexible to address this evolving context and ensure its continued impacts.

PARC places a strong emphasis on innovation in several key areas critical for advancing chemical safety and risk assessment. The partnership focuses on biomonitoring and developing more effective methods for detecting chemical exposure in humans and ecosystems. PARC is also actively working on the advancement of NAMs in hazard and risk assessment. Additionally, PARC promotes the use of FAIR data to ensure that high-quality scientific data is widely shared and can be used for transparent and reproducible risk assessments. PARC recognises the importance of maintaining competitiveness in the chemical industry, particularly through initiatives like the SSbD. Together, these innovations aim to enhance the regulatory framework, ensuring that Europe remains at the forefront of chemical safety while fostering economic growth and sustainability.

PARC is deeply rooted in the science-to-policy perspective, bridging scientific research with regulatory decision-making to ensure the co-design of the results produced and to ensure that the outputs are not only scientifically sound but also relevant to policy and regulatory frameworks. By generating cutting-edge data and insights on chemical safety, PARC provides evidence-based recommendations that directly inform EU policies and regulations. Key actors from the regulatory and policymaking landscape are well integrated in PARC internal processes to ensure a co-design approach that constitutes a unique added-value of the PARC partnership.

Regarding the sustainability of successful PARC activities, the major proposals from the workshop concern ensuring overarching coordination in (next generation) risk assessment and linking of the HBM activities (involving the currently discussed legal proposal for data generation according to the OSOA framework) with the EU toxicology activities (e.g., focusing on emerging substances and make use of NAMs). Proposals were made among others for continuing the SSbD activities, ensuring sustainable laboratory infrastructures, and advancing the "FAIRification" of data, all of which aim at strengthening risk assessment capacities in Europe. It was clear during the discussions that the impact of PARC activities needs to be continued through sustainable systems. The entire process, network and structure created through PARC should also be maintained. It was suggested that a comprehensive, overarching framework and network would be needed to sustain the multidisciplinary interactions developed in PARC, which would link and coordinate all the proposed initiatives and continue the identification and prioritisation of future strategic research and innovation activities to support them. The potential roles of EU agencies, infrastructures and research programmes were also discussed. The outcomes of the workshop were presented to the GB at its meeting in April 2025 and further meetings are planned with the relevant actors in PARC including EU agencies and EC DGs over the second half of 2025-early 2026 to work together, based on the workshop results and further discussions within the WPs, on refining the proposed

options and identifying opportunities, viable pathways and timelines to achieve sustainability of certain activities. The support announced in July 2025 by DG RTD to European partnerships as part of the process for development of phasing-out strategies will be particularly useful and timely. PARC's T2.3 and Coordination team members will take part in this process.

PARC's sustainability is a recurrent item on the agendas of PARC's MB, GB and GSB meetings as all are key actors in the shaping and implementation of the strategies. It is also tightly linked to PARC's key results and indicator framework to support the sustainability of PARC's high impact activities. PARC's advisory bodies, the Stakeholder Forum and the International Board were also consulted and will continue to have the opportunity to provide feedback and identify potential solutions. Besides that, also other stakeholders will be involved.

PARC is also working together with the EU agencies to develop indicators/signals for the European indicator framework for chemicals.

Future activities planned to refine the exit strategy include meetings over the autumn 2025 between the MB with relevant key actors from the PARC EU Hub and GB chairs, and GB or GSB members, to discuss the preliminary options and possible frameworks that are currently being discussed at the EU level (e.g., the OSOA legislative proposal and the multi-annual financial framework). This will allow for exploring sustainability options and how MS can support them at the EU level, for the major successful activities undertaken in PARC, based on the findings and recommendations outlined in this deliverable. The goal is to identify viable pathways for sustaining PARC's scientific, regulatory, and infrastructural contributions and impacts beyond the project's partnership's lifetime and to identify further actions for integrated sustainability solutions to then be explored more concretely with the wider network and national agencies – in particular the GSB and the GB but also NHs, throughout 2025 and 2026.

5. Conclusion

Next Generation Chemical risk assessment requires contributions and innovation from exposure and toxicological sciences as well as computational skills and infrastructures. It also needs high quality FAIR data and metadata. The strength of PARC is bringing all these together in a truly One Health approach and steering these activities by prioritisation and ensuring regulatory relevance. Anchoring certain activities, such as EU-wide HBM, in a legal framework, and coordinating the efforts, could not only improve chemical risk assessment but also enhance its cost-effectiveness.

A challenge will be to further develop the activities and to maintain the connection between them.

The "strategy and options" discussed will evolve with the policy context, notably in light of the OSOA legislative proposals of the Commission which address certain activities of PARC.

Further options to ensure sustainability will be explored and synergies with other initiatives will be promoted with a view to maximising the implementation of EU and UN health and environmental protection goals.

Annexes

Annex 1: P4.1.5 note on EU-wide HBM feasibility

An Internal progress report of P4.1.5.a_Y1_SustainHBMSystem_VITO was prepared in May 2025 to provide initial feedback from leaders of Human Biomonitoring actions in PARC on the financial feasibility of an EU-Wide HBM programme under art. 21 of OSOA legal framework to the EC DGs.

This document is compiled by VITO, ISCIII, UBA, SPF and ANSES in their role as T4.1 co-leads, WP4 co-leads and PARC CT resp. together with the input of partners from PARC project P4.1.5.a_Y1_SustainHBMSystem. The document provides insights into considerations regarding the EU representativeness of a HBM study and its associated cost implications. It outlines major cost components and the necessary financial resources, serving as a basis to assess the feasibility of the proposed amendments. The information in this document has been compiled based on the knowledge available at hand, drawing from experience in national human biomonitoring (HBM) studies and EU-level research projects such as DEMOCOPHES, HBM4EU, and PARC, within the constraints of the available time. While every effort has been made to ensure accuracy and relevance, the findings and recommendations should be interpreted in the context of evolving insights and practical implementation challenges.

This report is an internal and available on request only.

Annex 2: Note from DG RTD on phasing-out strategies for European Partnerships

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH AND INNOVATION

Directorate G – Common Policy Centre
The Director

Brussels
RTD.G.4

NOTE FOR THE ATTENTION OF EUROPEAN PARTNERSHIPS

Subject: **Phasing-out strategies: framing the future of each European Partnership**

According to the Horizon Europe Regulation, European Partnerships are required to submit a phasing-out strategy. This note sets out the framework for the exercise: it explains the purpose and importance of phasing-out strategies, outlines the timeline and steps for their development, and provides guidance to support the preparation of sound and actionable strategies that support a meaningful transition beyond Framework Programme and EU funding.

1. CONTEXT

As part of their lifecycle and in line with the legal obligations set out in the Horizon Europe Regulation (Article 10.2(c) and Annex III.4(b)), each European Partnership is required to provide an ex-ante "exit-strategy and measures for phasing-out from the Programme".

Phasing-out in this context refers to a (possibly gradual) discontinuation of funding from the Framework Programme (FP). Continued transnational funding by national or other Union programmes, or through private investments, is entirely possible and desirable.

This process is not merely a compliance step. It is a critical forward-looking exercise to define how the partnership can transition beyond FP funding, capitalising on the momentum, knowledge, and collaboration built over time. It is an opportunity to articulate and communicate the partnership's clear and strategic vision on its future role and evolution, notably in view of the next Multiannual Financial Framework (MFF), such as possible transformations, merges, shifts in form or focus etc. It is also a strategic opportunity to secure the legacy of the partnership, to ensure the lasting impact of its results and position its community for the future.

The obligation of preparing a phasing-out strategy does not imply a mandatory phasing out of FP funding or discontinuation of the partnership under the next FP. However, failure to comply with this legal requirement may be considered a weakness when assessing the partnership's performance and future prospects.

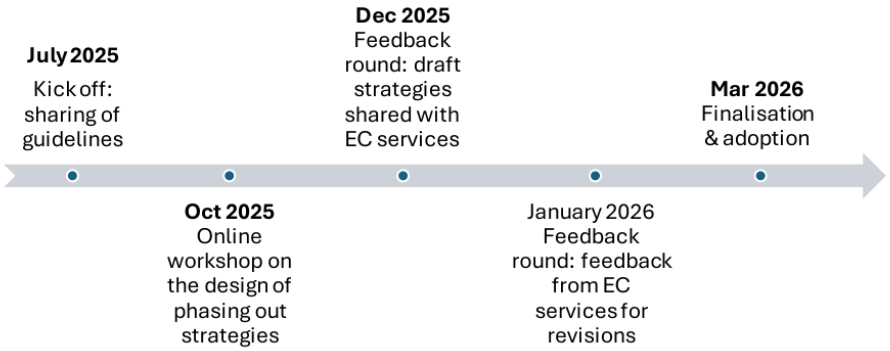
Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË – Tel. +32 22991111
Office: ORBN 02/135 – Tel. direct line +32 229-55614

Marion.JAMARD@ec.europa.eu

2. PROCESS

While the development of phasing-out strategies is in principle an ex ante selection criterion for partnerships (Horizon Europe Regulation Annex III, Art. 1(c[iv])), the timelines for latest adoption dates of the phasing-out strategies depend on the type of European Partnership ([1]), but will all be aligned for Q1 2026 to the extent possible for smoother coordination.

Tentative timeline:



Throughout the process of developing their phasing-out strategies, European Partnerships will be coordinated in thematic clusters and benefit from the guidance and support of the European Commission services (unit RTD.G.4 and the relevant thematic units). This collaborative setup will help ensure the elaboration of robust transition pathways, cross-fertilisation across strategies and alignment with broader strategic considerations.

This exercise is optional for Joint Undertakings and the KICs, as a specific processes for their phasing-out or financial sustainability strategies are already in place. They are however still welcome to share their knowledge with the partnership community and join the exercise if they wish to further refine their reflections, receive support, and benefit from cross-fertilisation with other partnerships.

3. GUIDELINES

The phasing-out strategy should be presented in a concise, strategic document of no more than three pages per scenario ([2]). It should offer clear reflections on how the partnership envisions its future, outlining concrete and realistic pathways forward.

In order to comply with the legal requirements, **each strategy must include at least one credible scenario that does not rely on continued funding from the EU Framework Programme.** While not mandatory, other options may also be explored ([3]), such as accessing other sources of public and/or private funding, consolidation with other

([1]) See the annex for details.

([2]) Underlying reflections, scenarios, analyses, etc, where appropriate, shall be made available in supplementary materials.

([3]) Keeping in mind the requirements in terms of conciseness and robustness.

initiatives, implementation via a different instrument, discontinuation, decreasing funding rates etc.

Please note:

- This is not a box-ticking exercise. All proposed scenarios should be credible, meaningfully developed, supported by actionable steps for implementation and indicators to track progress towards completion.
- This exercise is not about listing achievements or past performance, as these are already captured through the Biennial Monitoring Reports. However, the strategies developed through this exercise will inform and contribute to the content of future Biennial Monitoring Reports on partnerships.
- The status quo (i.e. continuing the partnership as it currently operates with Union funding) does not constitute a scenario.

The phasing-out strategy will be a practical, living document which may be regularly reviewed and updated post its adoption to take into account the progress made, maturation of the reflections and evolution of the policy context. The partnerships are invited to make it public to ensure that stakeholders interacting with the partnership will be able to adjust in a meaningful way to the future possibilities with or outside of the partnership and thereby ensure continuity in the field.

Checklist

There is no one-size fits all approach: each partnership may follow a different approach to develop its phasing-out strategy. However, all strategies should include a common set of key elements to ensure the robustness, consistent quality, and comparability.

The following will serve as a checklist for these minimum requirements:

Compulsory elements:	**Yes**	**Partly**	**No**
The strategy includes at least one credible scenario **without EU Framework Programme funding**.			
Each fully-fledged scenario proposes an **alternative implementation modality** to achieve the policy purpose of the partnership, and develops a realistic, **actionable** pathway and an indicative timeline.			
Each scenario includes **indicators** for assessing progress towards the phasing out (e.g. amount of funding from other sources, etc).			
The scenarios are **consistent** with the overall strategic orientation of the partnership and **coherent** with their policy context at the time (i.e. do not duplicate or contradict other existing or foreseen initiatives or plans).			

Other non-compulsory elements:

- Policy reflection on the benefits and drawbacks of each scenario.

ANNEX: LEGAL BASES & TIMELINES

Horizon Europe Regulation – applicable to all European Partnerships

Article 10

2. (c) European Partnerships shall: […] have a clear life-cycle approach, be limited in time and include conditions for phasing-out the Programme funding.

Annex III

1. (c) Ex ante demonstration of additionality and directionality of the European Partnership, including a common strategic vision of the purpose of the European Partnership. That vision includes in particular: […] exit-strategies and measures for phasing-out from the Programme.

4. (b) In the absence of renewal, appropriate measures ensuring phasing-out of the Programme funding according to the conditions and timeline agreed with the legally committed partners ex ante, without prejudice to possible continued transnational funding by national or other Union programmes, and without prejudice to private investment and on-going projects.

Implementation-type specific references and latest adoption dates of phasing-out strategies

Implementation type	Specific legal base	Timeline
Art. 187 (JUs)	Single Basic Act & EuroHPC Regulation	Q2 2025
Art. 185	Metrology & PRIMA Regulations	Not defined
EIT KICs	EIT KIC Partnership Agreements (financial sustainability strategies)	With the submission of the first Business Plan
Co-programmed	Memoranda of Understanding	1st Strategic Plan: before the interim evaluation of Horizon Europe (Q2 2025); 2nd Strategic Plan: 1 year after MoU signature (Q2 2026)
Co-funded	Individual Grant Agreements	Defined individually in the Grant Agreements or undefined