Partnership for the Assessment of Risks from Chemicals

Phasing-out strategy: framing the future of European Partnerships – scenarios for the European Partnership for the Assessment of Risks from Chemicals (PARC)

Updated - March 2026

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Authors and comments

Authors: T2.3 partners and the PARC Management Board (MB) with contributions from task co-leaders and partners of the P4.1.5.a_Y1_SustainHBMSystem_VITO project on HBM sustainability.
Comments:
The exit strategy and phasing-out scenarios are strongly dependent on strategic and political support of the Member States and the active participation of the PARC Governing Board (GB) in this process. In line with this, the definition of priorities for the GB is important. A consultation process and preliminary validation by the PARC GB Chairs were carried out prior to the submission deadline for this revised version. However, as obtaining pre-validation of the strategy by the entire GB was not feasible within the available timeframe, this revised version was submitted in parallel to the EC and to the PARC GB on March 20th, 2026. Comments and feedback from the GB may be received, and the content of this document may be revised accordingly before the GB can adopt the strategy. The strategy is a living document and will be refined further.

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Introduction

According to the Horizon Europe Regulation, European Partnerships are required to submit a phasing-out strategy. Phasing-out in this context refers to the discontinuation of funding from the European Commission (EC) Framework Programme (FP). The requirement by the EC is that each strategy must include (at least one) credible scenarios that ensure the legacy of the achievements without relying on continued FP funding but rather on continued transnational funding by national &/or other European Union (EU) programmes, &/or through private investments.

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. PARC is generating many important scientific, regulatory outputs and is showcasing how transversal integration of the different components of chemical risk assessment is highly valuable for Next-Generation Risk Assessment (NGRA). For instance, the creation of a sustainable European framework for generating, harmonising, quality-assuring, managing and re-using human exposure data is highly relevant for future risk assessment and for evaluating the effectiveness of chemicals legislation. Similarly, testing strategies based on New Approach Methodologies (NAMs) are being developed for different health effects. Underlying capacities, data-sharing arrangements, FAIR data management, and shared access/visualisation platforms should be maintained beyond Horizon Europe funding.

Beyond its scientific outputs, PARC has established an invaluable collaboration network between risk assessment, public health and environmental protection agencies, regulators, research operators and academic scientists, a structured science-to-policy interface, a coordinated prioritisation mechanism and a co-creation process to solve emerging and urgent regulatory needs, and integrated approaches to chemical risk assessment. The Rapid Response Mechanism (RRM) established by PARC to swiftly and efficiently address urgent needs, enables PARC to respond dynamically to emerging challenges in human and environmental health, even when these fall outside its predefined priorities.
Preserving these systemic achievements is as critical as maintaining individual tools, resources or datasets. PARC significantly strengthens the European Union's chemical regulatory framework and its research and risk assessment capacities. There is broad consensus among PARC partners and the Governing Board (GB) that PARC activities need to be continued after the end of Horizon Europe funding, through sustainable frameworks. Maintaining these efforts is essential to ensure that Europe remains at the forefront of chemical safety while fostering economic growth, competitiveness 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. Given the **diversity of PARC's domains** (environmental and human monitoring, Early Warning System (EWS), hazard assessment, risk assessment, Safe-and-Sustainable by Design (SSbD), integrated modelling, data management, …), and the different long-term implementation frameworks (e.g. EU-wide HBM survey included in the **One Substance, One Assessment (OSOA) laws**, which entered into force in January 2026), sustainability cannot be achieved through a single, uniform model. Instead, the long-term legacy or continuation of critical activities is based on a **multi-scenario strategy**, combining distinct thematic sustainability frameworks under an overarching **European coordination structure or network**.
Across all domains, "sustainability" refers to **long-term, continuous, high-quality delivery or legacy**.
The sustainability vision relies on **three pillars**:

1. EU & national agencies (regulatory frameworks, policy or regulatory advice and alignment),
2. Infrastructures and services underpinning the scientific excellence and supporting the use of the results (tools and methods, result valorisation...),
3. Research institutes & academia (research & innovation, knowledge generation, capacity building).

As much as possible, the sustainability approach shall link to existing frameworks and activities related to chemical risk assessment and look to avoid duplication and minimise administrative or resources burden for participating organisations and countries.

In order to respond to the EC legal requirement, three phasing out scenarios **without Framework Programme** funding, reflecting different levels of ambition and integration (and budget), are proposed to be investigated: from (*i*) a (preferred) comprehensive continuation and expansion model (scenario A) in which further work on what was already initiated in each field of activity of PARC (e.g., monitoring and exposure, hazard and risk assessment, safe and sustainable by design, early warning systems, development of methods/models, etc..) depends on identified needs, varied funding streams and budgets available, to (*ii*) a middle scenario (scenario B) involving (adapted) continuation based primarily on public funding from the participating countries, to (*iii*) a model focused on solely preserving core achievements and ensuring legacy (scenario C). The three scenarios are briefly described in the core text:
- Scenario A: Continuation and expansion through multimodal funding and a variety of actors.
- Scenario B: (Adapted) Continuation through public funding from the partners and network of chemical risk assessors.
- Scenario C: Preserving core achievements and ensuring the legacy, with limited public funding.
For scenarios A and C, annexes 1 and 2 provide a description in more detail on the sustainability of the main domains and thematic activities.

The "strategy and options" discussed will evolve with the policy context, notably in light of the OSOA laws, which entered into force on 01/01/2026 and which address, or are relevant to, a number of activities of PARC and a deep analysis of what is covered, what could be partially covered within the OSOA laws still needs to be carried out as its implementation progresses, notably with the European agencies mandated for this implementation.

Thematic groups[1] (open discussion groups including PARC Management Board (MB), GB and International Board (IB) members, stakeholders including the PARC Stakeholder Forum and other PARC participants (e.g. methodology and chemical leaders) were launched in March 2026 to track, for chemical risk assessment, regulatory developments as well as developments in the field of research, innovation and competitiveness, and identify and seize opportunities for uptake of PARC results. These discussions will play a role in the further refinement of the phasing-out and sustainability strategy for PARC.

The different scenarios are hypothesis-driven and based on the projection of the current PARC activities. They take into account the available information on the implementation of the **OSOA** legislative framework, the development of the **Common Data Platform on Chemicals (CPDC)** and the implementation of the European roadmap for phasing out animal studies for chemical safety assessment as well as uncertainties regarding the future landscape for national and European policies and programmes. Downscaling and prioritising may take place to respond to these evolutions and to the identified needs, coverage and priorities of the possible funding streams and funders.

The process towards the development of the exit strategy, which includes these three phasing-out scenarios, is tracked in impact indicator 3 (on sustainability) of the existing PARC indicator framework[2]. Said indicator tracks, amongst others, (1) the number and characteristics of meetings held on the exit strategy, (2) the number and characteristics of the thematic subgroups in which the phasing out scenarios are under discussion, (3) the number and characteristics of parties that expressed an interest in participating in each thematic subgroup, and (4) the documents and deliverables published on the exit strategy.

[1] Thematic groups are open discussion groups including Management Board (MB), Governing Board (GB) and International Board (IB) members, stakeholders including the PARC Stakeholder Forum and other PARC participants (e.g. methodology and chemical leaders...). The themes covered are: overarching coordination, Data and infrastructure, NAMs and NGRA, human health risk assessment, environmental monitoring and risk assessment, HBM, SSbD.

[2] See: Indicators | Parc

Scenario A: Expansion through multi modal funding and with a variety of actors

Overarching Coordination Instrument on Chemical Risk Assessment

One of the main PARC achievements was the creation of a network of high-level expertise in chemical risk assessment, both covering the environment and human health. This network, which comprises national risk assessment and public health agencies, research institutions and EU agencies (EFSA, ECHA, EEA), ensures an overall alignment of activities leading to an improved risk assessment based on more and harmonised data and enhanced models that together will lead to the reduction of exposure to hazard chemicals in future. PARC is in capacity to prioritise the needs for research and innovation, to implement a portfolio of projects and activities addressing the regulatory needs and to report the results to different audiences from the citizen level to the policy level. The close hands-on collaboration where academic scientists and risk assessment and surveillance bodies and regulators have co-created the projects in PARC so that the results are directly applicable is a valuable achievement and advantage of PARC, which needs to be preserved. The steering hence implemented allows regulators to provide detailed input on how the research projects are designed, and not just on the overarching themes/topics.

Coordination is understood here as covering three distinct phases:
"Pre-coordination" - co-construction of relevant activities responding to common priorities in order to support current regulatory processes for assessing the risks associated with chemical substances and to address new challenges in chemical risk assessment in line with a shared strategic vision, including mapping, priority setting, identification of relevant links and complementarities.
"Coordination monitoring" - follow up of risk assessment activities, the interactions between different approaches in fields to improve chemical risk assessment and links between all relevant components, actors and/or networks as described above, ensuring the coherence and ambition and maintaining interactions, synergies and communication.
"Post-coordination" - assessing the quality, efficiency and impact of the co-construction and coordination of implemented activities to improve future processes and make sure the needs of the stakeholders in chemical risk assessment and in particular those of the agencies and regulators are still met.

This overarching coordination and network includes a number of transversal activities, such as coordination, prioritisation, science to policy, knowledge management and communication. It is responsible for the coordination of activities between all actors in chemical risk assessment and management of the co-funded budget, for the implementation of the common process of priorisation, science to policy production and creation and management of PARCopedia[3], national hubs (NHs), as well as communication through different channels, and collaboration with other projects.

The coordination of the different activities is focused on:

1. **Strategic Vision:** Maintaining a fit-for-purpose strategic vision through the regular update of PARC's Strategic Research and Innovation Agenda (SRIA)
2. **Priorities and needs:** Identifying priorities and areas where additional research is needed whether through national or European funding
3. **Science-to-Policy Dialogue**: Fostering dialogue with and between researchers, policymakers, the regulatory community and stakeholders, and developing strategic scientific uptake into regulatory processes
4. **Close collaboration between national and EU levels:** Bringing together the Ministries/EC DGs, national and EU regulatory agencies to steer the coordination and activities for the implementation of EU directives and regulations
5. **Collaboration with the private sector:** this could include development and validation of NAMs, co-production of FAIR data sets, case study libraries, input into relevant training data sets and training programmes, as well as cooperative projects for different industrial domains, considering potential conflicts of interest and with focus on priority substances defined in the EU with fitting environmental exposure levels and trainings that do not concern the regulatory context directly.

[3] PARCopedia is a community space to connect and share your ideas on chemical risk assessment, with professionals from different disciplines within the chemical risk assessment community.

6. **International Involvement:** Enhancing international collaboration by engaging with organisations like the **WHO, UNEP, and OECD** to strengthen alignment and support the EU's global leadership in chemical safety
7. **National Hub (NH) Coordination:** Providing central oversight and coordination for the **NHs**, which were essential to PARC's success.

This network, involving risk assessors and managers (equivalent to PARC's GSB, MB and GB) and continuing the close collaboration with researchers and scientists, would be maintained with the support of Member States and EU agencies. The role of identifying future needs and priorities and designing activities to address these could be done within a committee organised by e.g. one EU agency in which interested representatives from the network of risk assessment agencies could participate or it could be a "new" committee embedded within one of the EU agencies with participation nominated by each Member State. Where feasible and relevant, this could / should be aligned with the governance structure envisioned for the relevant EC roadmaps and strategy documents. This network will organise activities that could answer the policy needs identified and will be in charge to either financially support them directly or identify other funding sources. This will depend on the types of activities (see details below) and could include industrial partners in a tripartite configuration (under clear rules and conditions to be agreed upon). It should be noted that to ensure that post-PARC activities make newly generated data FAIR and invest in standards, each thematic activity creating (in the broadest sense) data should have a FAIR data strategy, and adhere to existing standards and should set aside sufficient funding for data management and FAIRification (at least 5%).

Implementation and governance modalities:

This overarching coordination will be established with a high-level steering board with EC/DGs and Ministries and a board consisting of national and EU agencies (which could include research funding agencies to ensure co-construction of the R&I needs and options for funding).

A memorandum of understanding (MoU) could provide the governance frame and define the way to support the coordination team in charge of the SRIA, organisation of governance and management meetings and communication. Robust governance provisions shall be foreseen and discussed to manage potential conflicts of interest, and to ensure impartiality, transparency and scientific independence in decision-making and implementation.

The programme of activities performed under the regulatory frameworks will be described and the regulatory needs for research activities will be co-defined and established by a prioritisation process and under coordination of the abovementioned board. Depending on the needs, priorities and engagement, research & innovation activities in support of the SRIA will be planned and carried out. These activities could be funded through different modes, which could include public funding through EU & national programmes and/or private funding. To ensure the connection with research initiatives at the national level of Member States, if relevant, transnational calls organised with national research funding agencies could be established, based on the list of priorities and national commitment.

If this scenario is chosen, discussions must be held with the PARC Governance boards (Governing Board (GB) and Grant Signatory Board (GSB)) as early as 2026 in order to define a clear, specific and cost-estimated value proposition, identifying the benefits, obligations, governance model and financial implications to establish a new contractual framework to which the partners would commit.

Pathway and indicators:

1st half of 2026: Adoption of the strategy by the PARC GB and consultation on the activities to be continued and expanded

- Adoption of the strategy
- Consortium meeting thematic sessions

2nd half of 2026: Initial consultation and identification of sustainable (legal) instruments and mechanisms and possible engagement / commitment from partners

- Number of consultation meetings
- Number of (legal) instruments and mechanisms reviewed
- Number of commitments secured from partners (e.g. number of partners willing to sign a MoU, the scope and level of financial contributions from each partner, and the specific activities they agree to support)

2027-2028: Definition of the implementation tool, governance and funding, establishment of the contractual implementation agreement (consortium agreement or memorandum of understanding…)

- Consensus on the most effective instruments for sustainable actions

- Statutes and governance rules drafted and approved
- Financial management system defined and initial funding secured

2027-2029: Mapping of research needs, transnational discussion about transnational calls via national research funding agencies

- Number of areas of activity where working programme is established.
- Number of formal collaboration agreements signed

2029: At the end of PARC as a Horizon Europe funded Partnership, start of the consortium and transfer of activities and assets from PARC to the new consortium

- Instrument formally established and legally recognised
- Resources allocated and responsibilities assigned

2029-onwards: Implementation of the activities in the context of the new consortium. (Within PARC, an indicator framework has been developed and could potentially be used as a basis to track the progress based on the abovementioned goals. Some suggestions include for e.g. Tracking of the prioritisation processes; Number & characteristics of policy briefs; Feedback on European policy processes; Tracking of the activities of the NHs...)[4]

Risk Identification and Mitigation Plan:

The risks identified below concern how the phasing-out process is conducted based on the present situation. Other risks related to the evolution of the landscape between now and the end of PARC can emerge. All scenarios have the same categories of risks but the mitigation strategies are different and reflect the specific risk in each category for the scenario.

Risk Category	Risk	Mitigation Strategy
Legal and Regulatory	Delays in obtaining legal approvals and signatures	Ensure legal experts are engaged in the discussions on the contractual format and legal instruments, maintain open communication and request continuous feedback on barriers, develop contingency plans and consensus meetings
Financial	Insufficient funding	Diversify funding sources[5], develop a robust transparent funding strategy, discuss the establishment of baseline funding to ensure support for some essential overarching activities to be sustained and ensure all actors specify funding possibilities, tailor the programme based on the actual commitment and reduce ambitions if there is not enough funding
Stakeholder engagement	Lack of engagement Difficulty in identifying the right stakeholders	Regular communication between PARC and committee's set-up at EU level for strategy implementation (OSOA, Roadmap for phasing out animal studies, ...), formal partnership agreements, regular update meetings and feedback loop
Operational and capacity	Lack of agreement within the PARC community Lack of engagement and delays in implementation of the phasing out process Insufficient capacity or resources to manage the phasing out process	Involvement of all interested partners by developing and co-creating the sustainable network, ensuring inclusiveness, collaboration and communication, detailed work plan for the phasing out process and in-house capacity and resource assessment to address all actions in the phasing-out strategy, using uncommitted budget to establish and engage interested participants in the thematic groups with dedicated contact points, establishment of a clear plan for the future and effective resource allocation, regular progress reviews in the different governance boards and other relevant arenas (including NHs)

Phasing out and sustainability options for the main domains and thematic activities:

Given the diversity of activities within PARC, the phasing-out strategy relies on a multi-operational system that incorporates all of PARC's thematic components, ensuring continued innovation and flexibility under the umbrella of NGRA in Europe. 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 will be pursued and leveraged through the overarching coordination and network created to enhance coordination of next generation chemical risk assessment in Europe. Annex 1 summarises the current on-going PARC activities and their sustainable implementation scenario under a multi-modal funding option and provides more details for each of the main domains and thematic activities.

[4] See: Indicators | Parc

[5] A constraint in this scenario is that the inability to assess potential FP funding opportunities may impede specific R&I activities, which could be significantly strengthened, and deliver higher value, through targeted FP contributions, that could be investigated in a scenario A bis.

Scenario B: (Adapted) Continuation through public funding from the partners and network of chemical risk assessors

Implementation and governance modalities

A **coordination structure and network of (national and EU) risk assessment and surveillance bodies** will be set up:

- To maintain a fit-for-purpose strategic vision for the future developments of chemical risk assessment in Europe, for example through the regular update of PARC's Strategic Research and Innovation Agenda (SRIA)
- To follow the progress of the different thematic activities implemented by the European and national Agencies
- To continue the feedback loop of contribution to the prioritisation of regulatory needs (substances/ endpoints, methods)
- To coordinate the maintenance of existing FAIR data standards, and coordinate the FAIR data strategy of the different activities
- Provide central coordination for the National Hubs at the national level with targeted central oversight
- To communicate the research needs identified by the consortium
- To enhance international involvement and support towards international organisations by engaging with international organisations involved in chemical risk assessment.

This network and coordination activity is maintained with the support of public funding from the participating countries and organisations. It would be valuable to preserve the active participation of national as well as EU authorities to continue collaboration around the prioritisation and co-creation of regulatory relevant research; continued funding and incentives (such as the possibility of prioritising and "influencing" research funded through different funding streams) are needed for this. The role of identifying future needs and priorities and designing activities to answer them could be done within this network with in-kind contribution from the partners and agencies (national and EU). To ensure the regulatory relevant co-creation is maintained, consultation and involvement of both regulators and researchers should be maintained in the steering of the SRIA and design of the research and innovation activities to support the SRIA.

A **memorandum of understanding** (MoU) should provide the governance frame and support the coordination team in charge of the SRIA, organisation of meetings and communication.

Continuing to answer prioritised needs within the domains and thematic activities:

This network will organise in-house activities that should address the policy needs identified, according to the PARC main domains and thematic activities (cf. PARC activities identified in scenario A annexe - 2nd column of the summary table), and will be in charge to financially support them directly - as currently within PARC co-funding equivalent to 200 M euros are provided by Member States for 7 years, we could anticipate that an equivalent budget could still be dedicated to support further work. However, this will depend on the types of activities and interest/priorities of the interested parties.

It should be noted, that to ensure that post-PARC activities make newly generated data FAIR and invest in standards, each thematic activity creating data should have a FAIR data strategy, and adhere to existing standards and should set aside sufficient funding for data management and FAIRification (at least 5%).

Limitations of the scenario: The activities implemented and their scope will depend on the priorities and capacities of the participating countries and organisations and may change over time. This scenario may in the end not be well balanced or not as inclusive as hoped, as some Member States may no longer be able to participate and funding may be secured only for a limited period or vary over time. For public research organisations (Institutes, Universities), the allocation of resources will vary and depend on the priorities of the teams, institutional strategies and national strategies for research funding.

***Pathway and indicators**:*
June 2026: Adoption of the strategy by the PARC GB and consultation on the activities to be continued
- Adoption of the strategy
- Consortium meeting thematic sessions
- Consultation of Member States on activities to be continued

2nd half of 2026: Initial consultation on possible engagement of Member states and identification of legal instruments and interest for engagement by thematic areas
- Number of consultation meetings
- Number of (legal) instruments and mechanisms reviewed
- Number of commitments secured from partners (e.g. number of partners willing to sign a MoU, the scope and level of financial contributions from each partner, and the specific activities they agree to support)

2027-2028: Definition of the implementation tools and funding, establishment of the consortium agreement
- Consensus on the most effective instruments for sustainable actions
- Statutes and governance rules drafted and approved
- Financial management system implemented and initial funding secured

2026-2029: Mapping of research needs, discussion about transnational collaborations between regulatory agencies with academic partners.
- Number of areas of activity where working programme is established.
- Number of formal collaboration agreements signed.

2029: At the end of PARC as a Horizon Europe funded Partnership, tart of the consortium and transfer of activities and assets from PARC to the new consortium
- Instrument formally established and legally recognised
- Resources allocated and responsibilities assigned.

2029-onwards: Implementation of the activities

Risk Identification and Mitigation Plan:
As for scenario A, the risks identified below concern how the phasing-out process is conducted based on the present situation. Other risks related to the evolution of the landscape between now and the end of PARC can emerge. All scenarios have the same categories of risks, but the mitigation strategies are different and reflect the specific risk in each category for the scenario.

Risk Category	Risk	Mitigation Strategy
Legal and Regulatory	Delays in obtaining legal approvals and signatures	Ensure legal experts are engaged in the discussions on the contractual and legal instrument, maintain open communication and request continuous feedback on barriers with authorities, develop contingency plans, dock onto existing committees and groups (e.g. Member States committee)
Financial	Insufficient funding	Develop a robust funding strategy, discuss the establishment of baseline funding to ensure support for some essential overarching activities to be sustained and ensure all participating countries specify funding possibilities
Stakeholder engagement	Lack of engagement Unbalanced engagement and coverage	Regular communication and regular update meetings, notably with EU steering teams. Stakeholder mapping and prioritisation review and transparent adjustment of work plan, outline the benefits of future overarching collaboration on chemical risk assessment
Operational and capacity	Lack of engagement and delays in implementation of the phasing out process	Detailed work plan for the phasing out process and in-house capacity and resource assessment, engagement of interested participants in the thematic groups with dedicated contact points, establishment of a clear roadmap for the future plans and effective resource allocation, dedicated project managers, regular progress reviews in the different governance boards and NHs

Scenario C: Preserving core achievements and ensuring the legacy with limited public funding

Overarching Coordination on Chemical Risk Assessment

The operational network created by PARC is maintained with the support of public funding from the participating countries. PARC partners and the Governing Board (GB) consider it important and valuable to maintain the discussion and active exchange between national as well as EU authorities. The role of ensuring the legacy of PARC's achievements and tools and of updating the Strategic Research and Innovation Agenda (SRIA) and continuing the exchange on common priorities, leading to identifying common future needs and priorities and potentially designing (well-aligned) activities to answer them, would require commitment within this network (and could be funded though in-kind contributions).

Concerning Knowledge management, PARC has organised webinars and training sessions through a close collaboration between EU and national agencies, universities and research institutes supported by the partnership. Part of the materials (video records, documents, software) will be accessible through the open science repository. On-site training contributes to capacity building and networking. National or EU support will be needed to sustain these activities.

PARC has implemented the collaborative platform PARCopedia to empower knowledge sharing and meaningful interactions among researchers, risk assessors, risk managers and policy makers. The platform supports interdisciplinary dialogue and the dissemination of best practices, scientific understanding and regulatory developments through a community-driven knowledge base and interactive features such as blogs, discussion group and event updates. The sustainability of the platform will be discussed and responsibilities transferred to a partner or a group of partners.

The coordination activity will require a modest, but stable funding base and a network of collaborating institutions. The budget required to cover personnel costs, meetings, workshops, and targeted expert activities is still to be defined but, further to experience, should be between 1 to 3 M euro per year.

In light of the diversity of achievements in PARC, the solutions for maintaining these may be different but would use existing solutions and infrastructures.

Limitations of the scenario: The strong co-design link established in PARC between the scientific, academic and policymaking communities is not actively pursued nor leveraged to enhance coordination of next-generation chemical risk assessment in Europe. Research and innovation activities are not implemented nor expanded upon. One risk with this scenario is to re-fragment activities that support transition to NGRA in Europe and to disconnect with research and innovation in academia.

Maintaining the legacy of the main domains and thematic activities:

In light of the diversity of activities in PARC, the solutions for preserving the core achievements and ensuring their legacy are different.

It should be noted, that to ensure that the FAIR data generated in PARC remains FAIR, PARC relies on resources with a long-term vision and funding and any newly generated data should have a FAIR data strategy, and adhere to existing standards and should set aside sufficient funding for data management and FAIRification (at least 5%).

Annex 2 summarises the current on-going PARC activities and their legacy phasing-out scenario under and provides more details for each of the main domains and thematic activities.

Pathway and indicators

- Identify and catalogue all PARC achievements that need to be maintained
- Discuss legal issues and ownership of PARC products
- Ensure they are accessible after the end of PARC and identify where they will be before the end of PARC

- Investigate possible implementation tools for the coordination activity with the PARC governance boards from June 2026 to the end of PARC (2029) and ensure the design is established in coherence with the implementation of European frameworks (OSOA, Phasing out animal testing, SSbD).

Risk Identification and Mitigation Plan:
As for scenario A and B, the risks identified below concern how the phasing-out process is conducted based on the present situation. Other risks related to the evolution of the landscape between now and the end of PARC can emerge. All scenarios have the same categories of risks but the mitigation strategies are different and reflect the specific risk in each category for the scenario.

Risk Category	Risk	Mitigation Strategy
Legal and Regulatory	Delays in obtaining legal approvals and signatures	Ensure legal experts are engaged in the discussions on the contractual and legal instrument, maintain open communication and request continuous feedback on barriers with authorities, develop contingency plans
Financial	Insufficient funding	Develop a robust funding strategy, discuss the establishment of baseline funding to ensure support for some essential overarching activities to be sustained and ensure all participating countries specify funding possibilities
Stakeholder engagement	Lack of engagement Unbalanced engagement and coverage	Regular communication and update meetings, notably with EU steering teams, stakeholder mapping and prioritisation review and transparent adjustment of work plan
Operational and capacity	Lack of engagement and delays in implementation of the phasing out process Insufficient capacity to manage the phasing out process	Detailed work plan for the phasing out process and in-house capacity and resource assessment, engagement of interested participants in the thematic groups with dedicated contact points, establishment of a clear roadmap for the future plans and effective resource allocation, dedicated project managers, regular progress reviews in the different governance boards and NHs

Annex 1: Details on the sustainability of the main domains and thematic activities from scenario A

Summary of the phasing out and sustainable implementation scenario under a multi-modal funding format for the main domains and thematic activities

PARC Domain / thematic activity	PARC activity	Phasing-out and sustainable implementation scenario
Human Biomonitoring (HBM) cornerstones	European aligned study	EU-wide HBM survey implemented within OSOA legislation article 21a. *Synergies with and contributions from national HBM initiatives will be crucial.* Network of HBM experts distributed in national hubs and WHO European Environment and Health Process (EHP) on HBM, which facilitates: • Expert exchange • networking Integrating toxicology in HBM to ensure that measured values are set into context.
	European laboratory network	Support to establish national /EU reference laboratories and network. Lab networks mapped by PARC and infrastructures (e.g. EIRENE) can support capacity building.
	Biobanking of samples	The European Research Infrastructure for biobanking and biomolecular resources (BBMRI) can support the infrastructure. MS with existing biobanks and sufficient capacities could provide this contribution to an EU-wide HBM study.
	Long term storage and accessibility of FAIR HBM data	Support from MS for FAIR data repositories that facilitates the controlled sharing of personal data, subject to the General Data Protection Regulation (GDPR) and the Common Data Platform on Chemicals (CPDC).
Research and innovation supporting HBM activities	Derivation of health guidance values	Agree on a shared programme for a network of national agencies &/or ECHA. Values included in the repository for HBM-GVs in the Common Data Platform on Chemicals (CPDC).
	Effect biomarkers in support of health impact assessment and AOP framework	This activity could be carried out within research infrastructures such as EIRENE but may be transferred to EU agencies when practical and policy relevance are established. And consider toxicology to ensure that biomarkers are set into context.
Environmental monitoring	Environmental studies to collect and structure sampling plan for a multi-media analysis taking into account existing monitoring frameworks and identifying data gaps, Data used for human exposure estimation, environment exposure (wastewater, waste management, pesticide risk assessment), for improving exposure models, EWS	Monitoring (sampling scheme and analytical work and data reporting and analysis) done through existing EU /National legal frameworks and workflows. The monitoring needed for Early Warning System (EWS) and for improving exposure estimates for risk assessment needs to be continued at the national level. New laboratory networks could be established (e.g. soil) to support the monitoring objectives (DIRECTIVE (UE) 2025/2360). Contributing to the Early Warning system protecting human health, the environment, wildlife and biodiversity.
Innovative sampling and analytical methods for HBM and	Development and validation of new methods adapted to different objectives, sharing of knowledge to	Research and innovation is performed at national levels. Collaborations on the new methodologies between laboratories working in the different

environmental monitoring	support the development of non-targeted analysis based on HRMS and bioassays to also feed into the Early Warning System.	monitoring areas established in PARC is necessary to harmonise analytical methodologies, chemical standards, reference items.
EWS (Early Warning System)	Development of computational framework to support early detection of chemicals of concern in human, environment, materials or products	The objective is to create a permanent, anticipatory EU-wide infrastructure to detect emerging chemical risks using integrated data and advanced analytics (AI/ML). A long-term operational authority can provide strong governance and regulatory relevance and research and innovation to support the development of the approach according to the OSOA objectives can be implemented to advance signal detection methods, data fusion, and mechanistic interpretation.
Hazard assessment with the integration of NAMs	Cooperative studies to assess the hazard of emerging contaminants, Development of NAMs (New Approach Methodologies) to characterise different endpoints (human, ecological) based on mechanistic knowledge (e.g. adverse outcome pathways or key characteristics). Development of testing strategies, such as integrated approaches for testing and assessment (IATA) or defined approaches, to combine NAMs in an intelligent and efficient manner.	R&I activities according to the set priorities, with national and EU dedicated funding or calls on the topic (excluding FP10) for the implementation of the roadmap for phasing out animal studies, including qualification and/or validation of NAMs, and development of testing strategies. Link to transnational initiatives such as EU Strategy for test method development and validation, which could be done in collaboration with CARACAL, exchange with public-private partnership like EPAA or PEPPER. Use of specific European infrastructures and collaboration with different European institutes (JRC-ECVAM[6]), collaboration with OECD and international initiatives (US, Japan, Korea). Implementation of a Inter-Agency Programme (EU Toxicology Initiative – EUTI), funded by Member States, is relying on a coordinated programme between EU agencies (ECHA, EFSA, EMA) and JRC. Such programme should focus on regulatory priorities, data-gap filling, roadmaps for validation and qualification of NAMs as well as the development of testing strategies for human health and the environment, in alignment with OSOA and the EC roadmap for phasing out animal studies in chemical risk assessment. These activities could be complemented, depending on the funding available, by a network of EU Research Infrastructures, embedding toxicology modules within existing research infrastructures to coordinate method uptake and data FAIRification. Some elements could be supported by industry and/or through the Competitiveness Fund[7] for the qualification and validation of NAMs. The future development will be in line with the implementation of the EU roadmap for phasing out animal studies in chemical safety assessment (human, environment, change).
Integrated Risk assessment	Development of integrative approach for exposure assessment, assessment of regulatory acceptance of approach based on the next generation risk assessment methodologies for human health and the environment Integration of HBM data, environmental data and academic data.	Activities will continue according to the objectives of OSOA to support risk assessment by national and EU agencies. The strategic relevance of the modelling platform requires its stabilisation within a clear governance structure. For the other activities, two complementary formats are possible: i) establishing an alliance where governance involves ECHA, EFSA, EEA, and JRC, ensuring

[6] EU Reference Laboratory for alternatives to animal testing (EURL ECVAM), part of the Joint Research Center (JRC)
[7] European Competitiveness Fund - European Commission

	Development and harmonisation of models between agencies in collaboration with academia. Platform of integrative modelling Development of methods for follow up of risk assessment and risk management through enforcement, feed-back loops and effectiveness analysis.	regulatory relevance and long-term maintenance and the PARC teams would serve as the principal scientific and computational integrators, advancing modelling workflows (PBK, mixture risk and aggregate assessment estimators, Machine-Learning-based predictors) and ensuring interoperability, and ii) enhanced steering and coordination of current EU modelling efforts, where EU agencies take a reinforced steering role to align modelling standards and infrastructure, while the national teams funded by the MS act as the central scientific integrator to ensure coherence. Research on the effectiveness of current risk assessment methodology needs to be continued at the national level as a part of a prioritisation and feed-back loop. Research and development to improve and facilitate enforcement needs to be conducted in close cooperation with national enforcement agencies, analytical labs and the ECHA forum. The development of the Next Generation of Environmental Risk assessment was initiated and should be implemented as a sustainable activity.
Safe and Sustainable by Design	Operationalisation of the tool boxes.	Developing and maintaining the SSbD toolbox as an open, European platform for end users (Start-up, SME, industry, regulatory agencies). To be supported by private funding in the context of the bioeconomy and the establishment of the EU Chemicals Innovation and Substitution Hubs
FAIR data	Development of FAIR data. Training and data management framework	All post-PARC activities must allocate at least 5% of funding to data management and FAIRification, consistent with the approach developed in PARC. This should be included in the funding allocated to the activities.
Catalogues / Training / Harmonisation	Activities performed in close collaboration with a network of universities	These activities should be developed to support the transition.

Human Biomonitoring

The key scenario is the **OSOA-Anchored HBM System**. The **One Substance, One Assessment (OSOA)** laws provide the main lever for establishing a **sustainable and legally embedded European HBM framework**. Under this frame, an **EU-wide HBM survey** will be mandated with Member States (MS) contributing harmonised national data into a common EU structure. This will be led by ECHA, and EFSA with the cooperation of the EEA. This medium-term framework creates the conditions for maintaining sufficient capacity for study design, sampling and analysis across Europe, building on experience and capabilities developed under PARC.

As PARC is actively building a sustainable and legally anchored HBM system supported by Member States, ensuring harmonised and coordinated practices, this work and materials could serve for the next planned OSOA HBM EU wide survey. Its work focuses on maintaining and expanding an EU-wide HBM network to guarantee high quality, state of the art fieldwork, while strengthening a network of leading European laboratories equipped to develop and refine analytical methods for both established and emerging biomarkers of chemical exposure. In collaboration with academia and research institution, research activities will be enhanced to develop innovative sampling and analytical methods for effect and exposure biomarkers.

It should be noted that further to a short survey questioning National Hubs (NHs) about upcoming HBM studies at national and/or regional level addressing the general population between 2028-2035, feedback from 21 out of 28 NHs of PARC, demonstrate broad interest and feasibility for aligning national HBM studies with a future EU-wide programme. Approximately 70% of responding countries have either planned activities or expressed clear willingness to participate in a coordinated effort. With timely coordination—particularly ensuring key information about OSOA is available ≥2-year in

advance — there is a strong basis to build an integrated, harmonised EU HBM system leveraging national initiatives.
PARC has also developed a robust Findable, Accessible, Interoperable and Reusable (FAIR) data infrastructure to secure long-term storage, accessibility, and efficient management of HBM data which could also serve the EU wide survey.
HBM-GVs could be derived based on a network of national agencies with or without EU contribution. National panels are already mandated to derive such values in some EU countries as well as RAC at ECHA level. A shared programme could be agreed and supported by these national fundings already in place. These values could then be included in the repository for HBM-GVs in the Common Data Platform on Chemicals (CPDC).
Indicators:

- numbers of Members States that are willing to participate and align their national programme with the EU wide survey
- number of institutions ready to participate to the derivation of new HBM-GV values or updates of previous ones

Budget: 40 million euros already dedicated within OSOA
Timeline: 4 years from implementation of OSOA (end of 2025) to do the EU wide HBM survey

Environmental monitoring
The data generated by the different monitoring frameworks are used by exposure modellers to identify the sources and the fate of the chemicals in the environment and along the food chain. The models are used to estimate the human exposure and the level of pollution of ecosystems. Different EI regulations implement chemical contamination in different media.
Within PARC several environmental monitoring campaigns have been done on different chemical families (PFAS, endocrine disrupters...) and different matrices (water, soils, air…). These studies allowed us to describe a background level of exposure in the European environment. New analytical methods and biomarkers of exposure or effects were also developed. With the collaboration with the NORMAN association PARC could benefit from prioritisation tools and a network already in place to monitor the environment.
Environmental monitoring will continue through **existing EU legal frameworks** (e.g. Water Framework Directive, Soils Monitoring Directive ...), focusing on integrating innovative methods (such as Non-Targeted Screening - NTS/ Suspect Screening) and ensuring FAIR (findable, accessible, interoperable and reachable) data flows into coordinated European monitoring. The sampling scheme and analytical work is structured according to the regulatory frameworks, data reporting and the analysis is performed through existing workflows (e.g.: EEA/Eionet data flows environmental monitoring, EFSA reports and national authorities and laboratory networks for food safety). New laboratory networks could be established (e.g. soil) to support the monitoring objectives.
Indicators:

- number of substances monitored in several environmental matrices
- number of studies using NTS/suspect screening

Early Warning System (EWS)
The objective is to create a permanent, anticipatory EU-wide infrastructure to detect emerging chemical risks using integrated data and advanced analytics (AI/ML). The EWS requires further scientific development to become a robust, anticipatory system capable of detecting emerging chemical risks across environmental and human exposure domains. Key needs include: (i) comprehensive, high-resolution datasets from environmental monitoring, HBM, non-targeted/suspect screening, effect-based methods, and contextual emission/use patterns; (ii) advanced AI/ML analytics for anomaly detection, pattern recognition, prioritisation algorithms, and automated signal classification; (iii) integration of innovative monitoring technologies and NAM-derived effect indicators that can support early interpretation of potential hazards; (iv) harmonised data-assessment strategies workflows for signal validation and signal prioritisation, uncertainty analysis, and escalation towards regulatory action; (v) interoperable digital tools and dashboards that allow real-time signal tracking, ingestion of distributed data streams, and transparent communication; and (vi)

methodological development to link early detection signals with mechanistic understanding and exposure–hazard interpretation, ensuring timely and actionable outputs.
A dedicated scientific partnership with a partner (or a group of partners) as the mandated operational host and long-term governance authority would unite MS monitoring networks, EU agencies, and scientific institutions to accelerate methodological development and strengthen EU-wide capacities for detecting emerging chemical risks. Work could be carried out on signal detection methods, AI/ML analytics, data-fusion strategies, and mechanistic interpretation tools that link emerging signals to exposure and hazard pathways, allowing strategic investments in advanced monitoring technologies, non-target screening, NAM-based effect indicators (to coordinate with toxicology), and high-quality data infrastructures. Also, if relevant, development of analytical methods and algorithms could be carried out within different EC programmes other than FP such as LIFE or through other funding streams, maybe including industry.
Ensuring the sustainability and long-term effectiveness of the Early Warning System requires an EU-level pathway that consolidates governance, strengthens scientific capacity, and integrates monitoring, analytical, and modelling infrastructures. The pathway proposed here builds on two foundational elements: (i) EEA as the mandated operational host and governance authority, ensuring regulatory anchoring, coordination with Member States, and continuity of data flows; and (ii) the teams identified in PARC as a central scientific and analytical hub, responsible for developing, validating, and advancing the methodological core of the EWS, from AI/ML signal detection and prioritisation algorithms to data-fusion techniques and mechanistic interpretation frameworks. Under this pathway, EEA coordinates data provision and QA/QC processes with MS monitoring networks, HBM initiatives, and environmental agencies, while the research team coordination leads the harmonisation of analytical strategies, the development of prioritisation dashboards, and the integration of signals with exposure and hazard knowledge bases. Complementary expertise from specialised laboratories, research infrastructures, and other EU agencies strengthens the system's capacity for early detection across multiple exposure domains. The Health Emergency Preparedness and Response Authority (HERA), is in charge of pandemic preparedness and should also be investigated as part of the solution.
Indicators:

- *Number of partners supporting these activities*
- *Number of member states funding these activities at national level*

Hazard Assessment: methodological developments (NAMs, NGRA)

With the publication of the EC roadmap for phasing out of animal studies for chemical safety assessment (expected in April 2026), an EU governance will be established to steer the transition towards next-generation risk assessment (NGRA), i.e. innovative approaches to chemical risk assessment that are mechanism-based. In this context, the goal is to maintain a pan-European network for developing, validating, and applying NGRA approaches that make use of New Approach Methodologies (NAMs). PARC has established a strong collaboration between regulatory agencies and academic teams for several health effects, both for human health and the environment. Numerous NAMs were either developed or further refined within PARC to move them closer to the validation step and/or use in a regulatory context. Also, testing strategies (e.g. IATA or defined approaches) that combine NAMs based on mechanistic knowledge were developed for prioritised health effects. Criteria and guidelines were also developed and tested to better report to the regulators, the results generated with these methods and to assess the validity of these data. Case studies addressing regulatory relevant problem formulations were also done to illustrate how NGRA could be used in different regulatory contexts (cosmetic, occupational field, CLP…) for a variety of endpoints (e.g. carcinogenicity, genotoxicity, endocrine disruption, immunotoxicity, neurotoxicity…)
The following activities would be interesting to pursue:

- Prioritise endpoints needing development of NAMs and NGRA, i.e. testing strategies
    - National and EU dedicated calls on the topic (excluding FP10)
- Implement NAMs by contributing to the EU validation strategy through
    - Public-private partnerships like EPAA or PEPPER

    - Collaboration with the different European (JRC-ECVAM[8]), OECD and global initiatives dedicated to validation of assays
    - The use of specific European infrastructures (extending EIRENE to toxicology may be an option)
- Support the implementation of the European roadmap on phasing out animal testing for chemical safety assessments by providing collaborative structures, leading activities to develop and implement an overarching, one-health-centered NGRA framework and other significant contributions to NAM use and NGRA implementation.
    - Test and evaluate NAM-based testing strategies for various health effects through case studies
    - Organise multi-stakeholder discussions to promote acceptance and implementation
- Improve the competitiveness of the EU market, as NGRA-based decision making will be more reliable, efficient and quicker and support EU industries in bringing new compounds to the market following the SSbD concept.

Indicators:

- Number of NAMs used in a regulatory context
- Number of validation activities performed
- Number of testing strategies acceptable for regulatory decision-making developed

Hazard Assessment: Filling data gaps

There are also some needs to fill data gaps for emerging chemicals of concern to support risk assessment by national and EU agencies and to support rapid risk assessment to support risk management decisions. PARC has performed many experimental studies to answer specific questions related to the toxicity of some compounds that were under scrutiny by the regulatory agencies at EU and/or national levels (bisphenols, PFAS, toxins…). The expert network built under PARC allowed to elaborate a comprehensive and efficient toxicological programme based on non-animal methods whenever possible, to cover these data gaps.

The further development of the computational models (QSAR, PBPK, qAOP) will contribute to fill the needs for the implementation of the roadmap for phasing out animal studies for chemical safety assessment.

The goal is to maintain a pan-European network for developing, validating, and applying NAMs and NGRA approaches. An **Inter-Agency Programme (EU Toxicology Initiative – EUTI)**, funded by Member States would rely on a coordinated programme between EU agencies (ECHA, EFSA, EMA) and JRC focusing on regulatory priorities, data-gap filling, roadmaps for validation and qualification of NAMs and the development of NAM-based testing strategies, and alignment with OSOA and the roadmap for phasing out animal studies in chemical risk assessment. This could be complemented, depending on the funding available, by a **Network of EU Research Infrastructures**. This involves embedding toxicology modules (NAM/IATA development, AOP building, PBPK models, integrated exposure and risk models) within existing research infrastructures, such as **EIRENE, ELIXIR, EOSC, and the EFSA TK Plate**, to coordinate method uptake and data FAIRification by academic research teams.

The inter-agency programme and EU infrastructure network are complementary rather than mutually exclusive and together contribute to improving risk assessment and maintain the EU's leadership in chemical safety assessment. Implemented in parallel, they can support a structured dialogue between academia, industry, Member States and EU authorities to advance the development and adoption of robust tests and computational models needed for risk assessment throughout the development stages (SSbD) until new chemicals, materials and products are placed on the market. These efforts range from early stages of research to end use, closing the innovation gap in order to drive sustainable and long-term growth and could potentially be funded/financed by industry and/or through newly created European competitiveness fund[9].

Indicators:

- Number of partners interested by the initiative
- Number of member states supporting the initiative

[8] EU Reference Laboratory for alternatives to animal testing (EURL ECVAM), part of the Joint Research Center (JRC)

[9] European Competitiveness Fund - European Commission

Risk Assessment methods improvement and integrated modelling

INTEGRATED HUMAN RISK ASSESSMENT

PARC works on hazard exposure data generation, and their combination in integrative risk and health impact assessment to consider multiple exposures (mixtures) via multiple sources and routes (aggregate exposure). In this way, PARC is providing (i) harmonised, high-quality datasets from environmental monitoring and human monitoring (HBM), new testing strategy based on NAMs and NGRA, product-use information, and emissions inventories, structured according to FAIR principles; (ii) advanced modelling approaches such as PBK models, multimedia fate models, probabilistic modelling of mixtures and aggregate exposure, machine-learning predictors, and mechanistic modelling frameworks incorporating systems toxicology; (iii) systematic integration of hazard data from in vivo, in vitro/in silico data, and exposure data from human and environmental monitoring into coherent probabilistic risk assessment; (iv) development of transparent model-evaluation protocols, variability and uncertainty quantification, validation schemes, and harmonised parameter sets to ensure regulatory confidence; (v) modular, interoperable modelling tools and computational environments that support scenario analysis, back-calculation, and forward-looking simulations; and (vi) sustained methodological innovation to link exposure, hazard, and sustainability considerations into unified, interpretable, and policy-relevant outputs.

The data and models developed in PARC were harmonised to be FAIR and were integrated in the ParcToolBox (MCRA) and enable to run harmonised case studies of integrated risk assessment as show cases (also relevant for the modelling platform).

These activities were aligned with the EFSA Roadmap on NAMs, mixture and aggregate exposure assessment. They benefit of the national or European supports for the development of tools (MCRA), EFSA-TK Plate and the work done by the exposome networks engaged in different national and European project.

INTEGRATED ENVIRONMENTAL RISK ASSESSMENT

PARC has also engaged some activities to develop the risk assessment for ecosystem and to estimated impact on the biodiversity. In close collaboration with other research programmes, PARC has launched recently a project to support the initiation and implementation of a next generation environmental risk assessment.

MODELLING PLATFORM

The strategic relevance of the modelling platform requires its stabilisation within a clear governance structure. As for the other activities above, two complementary formats that together support the EU's leadership in integrative modelling for chemical risk assessment are suggested and their scope and coverage would depend on the priorities and funding available by MS.

A Dedicated Scientific alliance for Integrated Modelling. This format establishes an alliance where governance involves ECHA, EFSA, EEA, and JRC, ensuring regulatory relevance and long-term maintenance. The PARC core team would serve as the principal scientific and computational integrators, advancing modelling workflows (QSAR, qAOP, PBK, mixture risk, aggregate exposure, ML-based predictors) and ensuring interoperability.

Enhanced steering and coordination of current EU modelling efforts. This alternative sees EU agencies taking a reinforced steering role to align modelling standards and infrastructure, while the national teams funded by the MS acts as the central scientific integrator to ensure coherence across fragmented efforts.

Implemented in parallel, they can facilitate structured engagement with industry to advance the development and uptake of the open, interoperable computational models and data repositories required for the pre- and post-market authorisation for new chemicals, materials and products, as well as for the assessment of emerging chemicals, contaminants and mixtures. Infrastructures, such as ELIXIR and EIRENE, are also important in this sector and shall be included.

Indicators:

- Number of national and EU agencies supporting the principles of a common computational platform
- National and EU computational platforms

Safe and Sustainable by Design

The political relevance of Safe-and-Sustainable-by-Design (SSbD) is highlighted particularly in light of the "Competitiveness compass"[10] the new roadmap to restore Europe's dynamism and boost its economic growth.

PARC is contributing to transition from concept to implementation, through:

- Integration of SSbD into formal EU policy instruments to ensure consistent execution;
- Incorporatation of SSbD in national and regional Innovation Hubs to provide direct support; and
- Providing scientific methodologies and data resources (including NAMs, AI/ML, and interoperable datasets) to facilitate robust, early-stage decision-making.

Further and continuous support to SSbD operationalisation through scientific development. The toolbox and the knowledge sharing portal will remain available as overarching platforms. Since the SSbD toolbox is being developed in an open space, it could continue to exist beyond PARC, with free access for users.

The SSbD framework is a key policy driver for development of NAMs and supports European competitiveness. During the development phase of a new chemical substance, industry can use NAMs to test the safety of certain chemicals within the SSbD framework without the requirement of formal validation as is usually the case for regulatory acceptance of NAMs. This would in turn help boost the development and wider acceptance of NAMs in safe chemical innovation.

PARC supports the development and operationalisation of an SSbD toolbox in collaboration with JRC and other EU and national projects (IRISS). The objective is to share the tools used for the safety assessment with industry and SME to help them in their development by an early assessment of the new chemicals.

The long-term plan is centred on maintaining the SSbD toolbox as an open, European reference platform. The recommended next steps include:

A) embedding SSbD within Innovation Hubs; (B) developing an SSbD data profile compatible with the Ecodesign for Sustainable Products Regulation (ESPR)/ Digital Product Passport (DPP) and Corporate Sustainability Reporting Directive (CSRD) frameworks; (C) integrating an SSbD schema and open Application Programming Interfaces (APIs) into the Common Data Platform for Chemicals (CDCP); (D) establishing a pre-regulatory sandbox for NAMs, AI, and ML applications; and (E) funding pilots for value-chain data sharing focused on substitution and design trade-offs. These measures will accelerate market entry for safer alternatives while minimising reporting complexities.

Indicators:

- Number of partners involved in SSbD
- MS support for national SSbD Innovative center

FAIR Data and Infrastructural Capacities

The EU's One Substance, One Assessment (OSOA) framework—introduced as part of the Chemicals Strategy for Sustainability and entering into force in 2026—aims to streamline and harmonise chemical safety assessments across more than 70 pieces of EU legislation. This major reform addresses long-standing fragmentation in chemical data and assessment processes by creating a centralised, cross-sectoral system for chemical information. The legislative package establishes a common data platform, managed by the European Chemicals Agency (ECHA), consolidating hazard, exposure, monitoring, and regulatory data previously dispersed across multiple agencies and legal instrument

To function effectively, the OSOA framework requires chemical data to be FAIR—Findable, Accessible, Interoperable, and Reusable.

The objective of this phasing-out strategy is to support science and regulation by enabling continued reuse of chemical risk assessment data. Making data Findable, Accessible, Interoperable, and Reusable (FAIR) should not be a standalone part of the PARC phasing out strategy. Rather, FAIR data is a strategy to secure the legacy of PARC. The phasing-out strategy for each of the main subdomains in PARC (human biomonitoring, environmental monitoring, and toxicology) must therefore include continued investment in FAIR data, and in the community-based standards, tools, and resources necessary to make data FAIR. This will enable federated analyses and trusted research environments in the future

[10] https://commission.europa.eu/topics/competitiveness/competitiveness-compass_en

FAIR data management is a core cross-cutting strategy to secure the long-term legacy of PARC.
The phasing-out strategy for each of the main subdomains (human biomonitoring, environmental monitoring, hazard assessment, integrative modelling) must therefore include continued investment in FAIR data, and in the community-based standards, tools, and resources necessary to make data FAIR. This will enable federated analyses and trusted research environments in the future.
The data strategy is based on two needs:

- ensure post-PARC activities have a data strategy and funding,
- continually assess whether the resources for depositing data have long-term vision and funding

The overarching coordination process must ensure that **all post-PARC activities allocate at least 5% of funding** to data management and FAIRification, consistent with the approach developed in PARC. This should be included in the MS funding allocated to the activities.
Indicators:

- Number of partners supporting the FAIRification
- Governance and funding for the implementation of the common data platform

Annex 2: Details on the sustainability of the main domains and thematic activities from scenario C

Summary of the current on-going PARC activities and their legacy phasing-out scenario

PARC Domain / thematic activity	**PARC activity**	**Legacy phasing-out scenario**
Human Biomonitoring (HBM)	The HBM data generated under PARC are kept by each data owner and also compiled in the VITO dashboard. Catalogues of laboratories and SOPs, templates, communication tools are developed. HBM-Guidance Values (HBM-GV) derived under PARC for general population or for workers	The data sets will be maintained after PARC with the support of national fundings and be available for reuse by the research community. HBM data will be integrated into the Common Data Platform for Chemicals (CDPC) hosted by the European Chemicals Agency (ECHA). The Personal Exposure and Health (PEH) Data Platform offers a solution for data harmonisation, FAIR data management, and clear data flows for human biomonitoring data to the CDPC. Data evaluation tools or methods developed in PARC shall be made available and maintained in this context, through open access platforms. The governance and coordination at EU level is supported by EU agencies according to their mandates.
Environmental monitoring	Environmental studies to collect and structure sampling plan for a multi-media analysis, Data used for human exposure estimation, environment exposure (wastewater, waste management) Development of new methods and biomarkers of effects.	In the different regulatory frameworks, the monitoring data generated will be made available on the CPDC or EFSA platforms. Monitoring data, generated under research national and transnational activities should be shared with the support of the NORMAN network or as FAIR data using open science platforms (e.g. Zenodo). The catalogues of Laboratories proficient for chemical analysis will be made available through Open access platforms and updated by partners or an infrastructure. Analytical capacity can be maintained and further expanded in close collaboration with existing monitoring networks. For joint method development, training, and interlaboratory comparisons, the designation of national focal points to coordinate monitoring activities within each Member State, or EU wide coordination (for example through an EEA Topic Centre), collaboration with existing networks such as NORMAN[11] can be implemented. The priorisation tool and methods to design futures studies will be made available for the research community and competent authorities. The priorisation process will be performed by National and EU agencies according to their mandates.
EWS (Early Warning System)	Development of computational framework to support early detection of chemicals of concern in human, environment, materials or products	Core components can remain accessible and interoperable under a stable European operator (EEA) with a reinforced steering role across MS to coordinate existing monitoring and risk-detection programmes.

[11] https://www.norman-network.net/

Hazard assessment	Cooperative studies to assess the hazard of emerging contaminants, Development of NAMs (New Approach Methodologies) to characterise different endpoints (human, ecological) based on mechanistic knowledge (e.g. adverse outcome pathways or key characteristics) Development of testing strategies, such as integrated approaches for testing and assessment (IATA) or defined approaches, to combine NAMs in an intelligent and efficient manner.	NAM-based testing strategies and associated case studies are published and available in open access platforms and some can move through existing processes based on the framework in the roadmap for phasing out of animal studies. Incorporation of NAMs and/or NAM-based testing strategies into already existing tools or guidance documents and participation in R&I projects. The data generated on questions relating to the toxicity of compounds are available in open access platforms and communicated to the relevant EU and/or national regulatory agencies.
Risk assessment	Development of integrative approach for testing and exposure assessment, assessment of regulatory acceptance of approach based on the next generation risk assessment methodologies for human health and the environment Integration of HBM data, environmental data and academic data. Development and harmonisation of models between agencies in collaboration with academia. Platform of integrative modelling Development of methods for follow up of risk assessment and risk management through enforcement, feed-back loops and effectiveness analysis.	Data generated accessible in open access platforms and the models, tools, algorithm developed have been incorporated into the PARC toolbox and/or other already sustainable tools like the Chemical Risk Assessment Hub, MCRA. They will be shared with the scientific communities through existing infrastructures. Coordination across the numerous EU-funded modelling initiatives already contributing to NGRA, exposure science, mixture assessment, and computational toxicology could be strengthened with EEA, ECHA, EFSA and JRC playing a reinforced steering role.
SSbD	Operationalisation of the tool boxes.	PARC has developed and released the PARC SSbD toolbox that will be maintained by Member States which are investing in it via national hubs. The activities are supported by national centers.
FAIR data	Development of FAIR data. Training and data management framework PARC CRA hub	Making data Findable, Accessible, Interoperable, and Reusable (FAIR) is a strategy to secure the legacy of PARC. PARC relies on resources with a long-term vision and funding. PARC's Chemical Risk Assessment Hub – a Catalogue of available resources for chemical Risk Assessment is being built for integration with the EIRENE catalogue of services and could be funded via EIRENE ERIC and related projects.

Human Biomonitoring (HBM)

The HBM data generated under PARC are kept by each data owner and also compiled in the VITO dashboard. These data sets will be maintained after PARC with the support of national fundings and be available for reuse by the research community. Critical steps are the entry into force of the OSOA legislation package early 2026, where a EU-wide HBM survey is planned.

It should be noted that further to a short survey questioning National Hubs about upcoming HBM studies at national and/or regional level addressing the general population between 2028-2035, feedback from 21 out of 28 NHs of PARC, demonstrate broad interest and feasibility for aligning national HBM studies with a future EU-wide programme. Approximately 70% of responding countries have either planned activities or expressed clear willingness to participate in a coordinated effort. With timely coordination—particularly ensuring key information about OSOA is available ≥2-year in

advance — there is a strong basis to build an integrated, harmonised EU HBM system leveraging national initiatives.
HBM data will be integrated into the Common Data Platform for Chemicals (CDPC) hosted by the European Chemicals Agency (ECHA) for EU-wide data sharing and storage. However, the specifics and data flows to the CDPC are to be established. The Personal Exposure and Health (PEH) Data Platform offers a solution for data harmonisation, FAIR data management, and clear data flows for human biomonitoring data to the CDPC. Data evaluation tools or methods developed in PARC should be made available in this context. These include:

- The catalogues of Laboratories proficient for chemical analysis will be made available through open access platforms.
- All SOPs, template for questionnaires, communication tools, will be made available under Open access platforms.
- HBM-Guidance Values (HBM-GV) derived under PARC for general population or for workers will be published and then made available for further use.

The governance and coordination at EU level is supported by EU agencies according to their mandates.

Environmental monitoring

Within PARC several environmental monitoring campaigns have been done on different chemical families (PFAS, endocrine disruptors...) and different matrices (water, soils, air…). These studies allowed us to describe a background level of exposure in the European environment. New analytical methods and biomarkers of exposure or effects were also developed. With the collaboration with the NORMAN association PARC could benefit from prioritisation tools and a network already in place to monitor the environment. The environmental and multisource monitoring activities developed under PARC are sustainably continued through the existing legal basis that ensures the long-term continuation, institutional stability, and financial sustainability of the monitoring activities beyond the Partnership and future Framework Programme funding. In the different regulatory frameworks, the monitoring data generated will be made available on the CPDC, EFSA platforms according to the recommended format. Monitoring data, generated under research national and transnational activities should be shared with the support of the NORMAN network or as FAIR data using open science platforms (e.g. Zenodo).
The catalogues of Laboratories proficient for chemical analysis will be made available through Open access platforms and updated by partners or an infrastructure. Analytical capacity can be maintained in close collaboration with existing monitoring networks, ensuring harmonised protocols and quality assurance. A clear governance and coordination mechanism is essential to coordinate activities for joint method development, training, and interlaboratory comparisons. This may include the designation of national focal points to coordinate monitoring activities within each Member State, EU wide coordination (for example through an EEA Topic Centre), collaboration with existing networks such as NORMAN[12] to promote joint method development, training, interlaboratory comparisons, pilot or proof-of-concept studies and innovation.
The priorisation tool and methods to design futures studies will be made available for the research community and competent authorities. The priorisation process will be performed by National and EU agencies according to their mandates.

Support to Early Warning System

Core components, such as signal detection algorithms, data ingestion pipelines, prioritisation dashboards, and governance protocols, must remain accessible and interoperable beyond PARC, under a stable European operator with a reinforced steering role across Member States that could be the European Environment Agency. Enhanced Coordination of Existing EU Monitoring & Risk-Detection Programmes would strengthen and harmonise existing fragmented initiatives,

Hazard Assessment: methodological developments (NAMs, NGRA)

All the NAMs, NAM-based testing strategies and associated case studies are published and available in open access platforms. Some of the NAMs developed will be further moved into a validation process via already existing validation process (e.g. PEPPER in France, EPAA, OECD…) based on the framework

[12] https://www.norman-network.net/

implemented in the roadmap for phasing out of animal studies. Protocols for NAMs and testing strategies developed will be incorporated in already existing tools or guidance documents that will be updated (e.g. note of Guidance of the SCCS, ScirapTool, OECD guidelines…). Collaboration with research and innovation projects with national and EU agencies will be ensured on a case-by-case basis by participating in the project boards or as partners.

Hazard Assessment: Filling data gaps

PARC has performed many experimental studies to answer specific questions related to the toxicity of some compounds that were under scrutiny by the regulatory agencies at EU and/or national levels (bisphenols, PFAS, toxins …). The expert network built under PARC allowed to elaborate a comprehensive and efficient toxicological programme based on non-animal methods whenever possible, to cover these data gaps.

All the data generated have been published and made available in open access platforms. Some of them were already communicated to the concerned EU and national agencies so that they could be incorporated into the data set used to assess these compounds.

Integrated Human Health Risk Assessment methods improvement and integrated modelling

All the data generated have been published and made available in open access platforms. The models, tools, algorithms developed have been incorporated into the PARC toolbox and/or other already sustainable tools like the Chemical Risk Assessment Hub, MCRA. They will be shared with the scientific communities through existing infrastructures. Coordination across the numerous EU-funded modelling initiatives already contributing to NGRA, exposure science, mixture assessment, and computational toxicology could be strengthened with EEA, ECHA, EFSA and JRC playing a reinforced steering role.

Safe and Sustainable by Design

PARC supports the development and operationalisation of an SSbD toolbox in collaboration with JRC and other EU and national projects. The objective is to share the tools used for the safety assessment with industry and SMEs to help them in their development by an early assessment of the new chemicals. SSbD is relevant to both public and private institutions and is in line with the competitiveness compass of the EC. PARC has developed and released the PARC SSbD toolbox that will be maintained by Member States which are investing in via national hubs. The activities are supported by national centers.

FAIR data

Making data Findable, Accessible, Interoperable, and Reusable (FAIR) is a strategy to secure the legacy of PARC. To ensure that the FAIR data generated in PARC remains FAIR, PARC relies on resources with a long-term vision and funding. PARC maximally strives to leverage existing long-term initiatives, and deposit information in established repositories with clear sustainability models. For each of the resources, the foreseen scenario for long-term funding is indicated. To ensure that post-PARC activities make newly generated data FAIR and invest in standards, each thematic activity creating data should have a FAIR data strategy and adhere to existing standards and should set aside sufficient funding for data management and FAIRification (at least 5%).

PARC data management plan (DMP) and tools developed to develop PARC project DMPs will remain accessible, as will the guidance and training support.

PARC's Chemical Risk Assessment Hub – a Catalogue (yellow pages) of available resources (monitoring and biomonitoring efforts, laboratory capacities and databases) for chemical Risk Assessment is being built for (compatibility etc.) integration with the EIRENE catalogue of services and could be funded via EIRENE ERIC and related projects.