SRIA

2025

STRATEGIC RESEARCH & INNOVATION AGENDA

P-A-R-C

Co-funded by the European Union

STRATEGIC RESEARCH AND INNOVATION AGENDA (SRIA)

Abstract

The Strategic Research and Innovation Agenda (SRIA) of the Partnership for the Assessment of Risks from Chemicals (PARC) is a document that outlines the main objectives, challenges and expected impacts of the partnership. It also defines the details of the research priorities and activities that will be implemented by PARC throughout its duration (2022—2029).
The development of the SRIA is based on a co-creation process involving about 200 partners from 28 countries, including national agencies, universities, research organisations, ECHA, EFSA and EEA. It started from a comprehensive analysis of the current state-of-the-art, gaps and needs in chemical risk assessment, as well as on a wide consultation with relevant stakeholders.

The SRIA serves as a roadmap for PARC to achieve its goals and contribute to EU policies on chemicals.

ACRONYMS (A—Z)

AE	Affiliated Entity
AI	Artificial Intelligence
ASR/AWPs	Annual Summary Report / Work Plans
CA	Consortium Agreement
CL/ML	Chemical Leader / Methodology Leader
CRA	Chemical Risk Assessment
CSS	Chemicals Strategy for Sustainability
CT	Coordination Team
DEPB	Data and Ethics Protection Board
EC	European Commission
ECHA	European Chemicals Agency
ED/EDCs	Endocrine Disrupters / endocrine disrupting compounds
EDA	Effect-Directed Analysis
EFSA	European Food Safety Authority
EU	European Union
EWS	Early Warning System
FAIR	Findable, Accessible, Interoperable, and Reusable
GA	Grant Agreement
GB	Governing Board
GDPR	General Data Protection Regulation
GS	Grant Signatory
GSB	Grant Signatory Board
HBM	Human BioMonitoring
HBM GV	Health-based Guidance Values
IATA	Integrative Approaches to Testing and Assessment
IB	International Board
IPR	Intellectual Property Rights
JRC	Joint Research Centre
KARC	Key Areas of Regulatory Challenge
KPIs	Key Performance Indicators / Impact
MS	Member States
NAMs	New Approach Methodologies
NGRA	Next Generation Risk Assessment
NHs	National Hubs
NHCs	National Hub Coordinators
NHCPs	National Hub Contact Points
NTS	Non-Targeted Screening
OECD	Organisation for Economic Co-operation and Development
OO	Operational Objectives
PFAS	Per- and Polyfluoroalkyl Substances
PM	Project Manager
RA/RM	Risk Assessment / Risk Management
R&I	Research and Innovation
RRM	Rapid Response Mechanism
SDGs	Sustainable Development Goals
S2PD	Science-to-Policy Dialogue
SF	Stakeholder Forum
SO	Specific Objectives
SSbD	Safe-and-Sustainable-by-Design
SRIA	Strategic Research and Innovation Agenda
T/TL	Task / Task co-leaders
TRL	Technology Readiness Level
UNEP	United Nations Environment Programme
US-EPA	US Environmental Protection Agency
WHO	World Health Organization
WP/WPL	Work Package / WP co-leaders

REGULATORY RELEVANCE EUROPEAN GREEN DEAL ROADMAP CHEMICALS STRATEGY FOR SUSTAINABILITY STRATEGIC RESEARCH AGENDA POLICY

Table of Contents

EXECUTIVE SUMMARY

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Executive Summary

This SRIA presents the Partnership for the Assessment of Risks from Chemicals (PARC), its progression so far, challenges still to be met and how PARC will achieve its objectives to address current, emerging and novel chemical safety challenges and enable the transition to Next Generation Risk Assessment (NGRA), in line with the European Green Deal's zero-pollution ambition and in particular with the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (CSS).

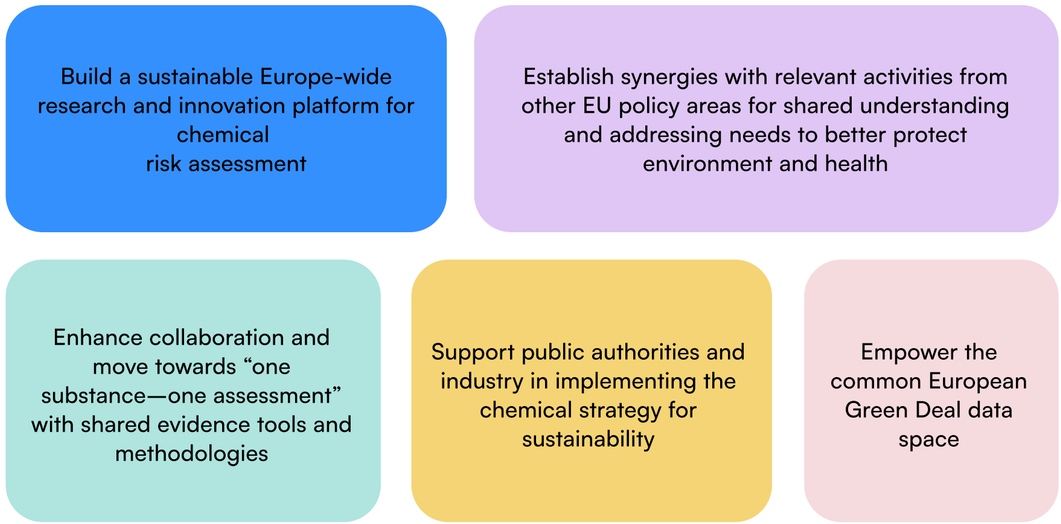
PARC is a large-scale research and innovation initiative co-funded by the European Commission under Horizon Europe. It brings together around 200 partners from 30 countries and European authorities, such as national agencies, public health agencies, academia, research organisations as well as the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environment Agency (EEA).

PARC provides an open collaborative space where all stakeholders including regulatory authorities, public agencies, research organisations and academia, collaborate and co-design research and innovation activities to improve chemical risk assessment data and methods applicable in the European regulatory context.

PARC covers all aspects of chemical risk assessment, such as hazard identification and characterisation, exposure assessment, including human and environmental monitoring.

It aims to address key challenges such as emerging risks, combined exposures, safe and sustainable design of chemicals, development of models and Early Warning System (EWS) data generation and management, and science-policy interface to ensure the protection of human health and of the environment from the potential hazards of chemicals.

The SRIA also presents PARC's strategic partnership impact pathways and showcases its contribution to scientific, societal and economic impacts. This mid-term update takes into account the evolving priorities and how PARC plans to address them as well as to report on the progress with concrete achievements and outputs.



Why an update of the SRIA?

The SRIA was first published in 2023 toward the beginning of the partnership. This initial version focused on how the partnership came about, its vision, and how it intended to achieve its objectives.

As the policy context has evolved since the start of the partnership and as PARC is intended to meet evolving regulatory needs, it is only natural that the SRIA also evolves to reflect policy developments at the national and EU level, as well as the achievements of PARC during its progression.

This revised SRIA integrates the need to balance ambitious green policies that constitutes PARC's roots (e.g. EU Green Deal, zero pollution and Chemical Strategy for Sustainability, etc.) with new priorities (e.g. industrial competitiveness, strategic autonomy, security, Artificial Intelligence, etc.) that frame high-level political and regulatory discussions.

In addition, this SRIA update comes at the mid-term of the partnership. This is a critical time for PARC as key scientific and regulatory contributions and milestones are being achieved and disseminated. It is also timely, as the discussion on how to make the partnership outputs and achievements sustainable beyond the current funding cycle, is underway.

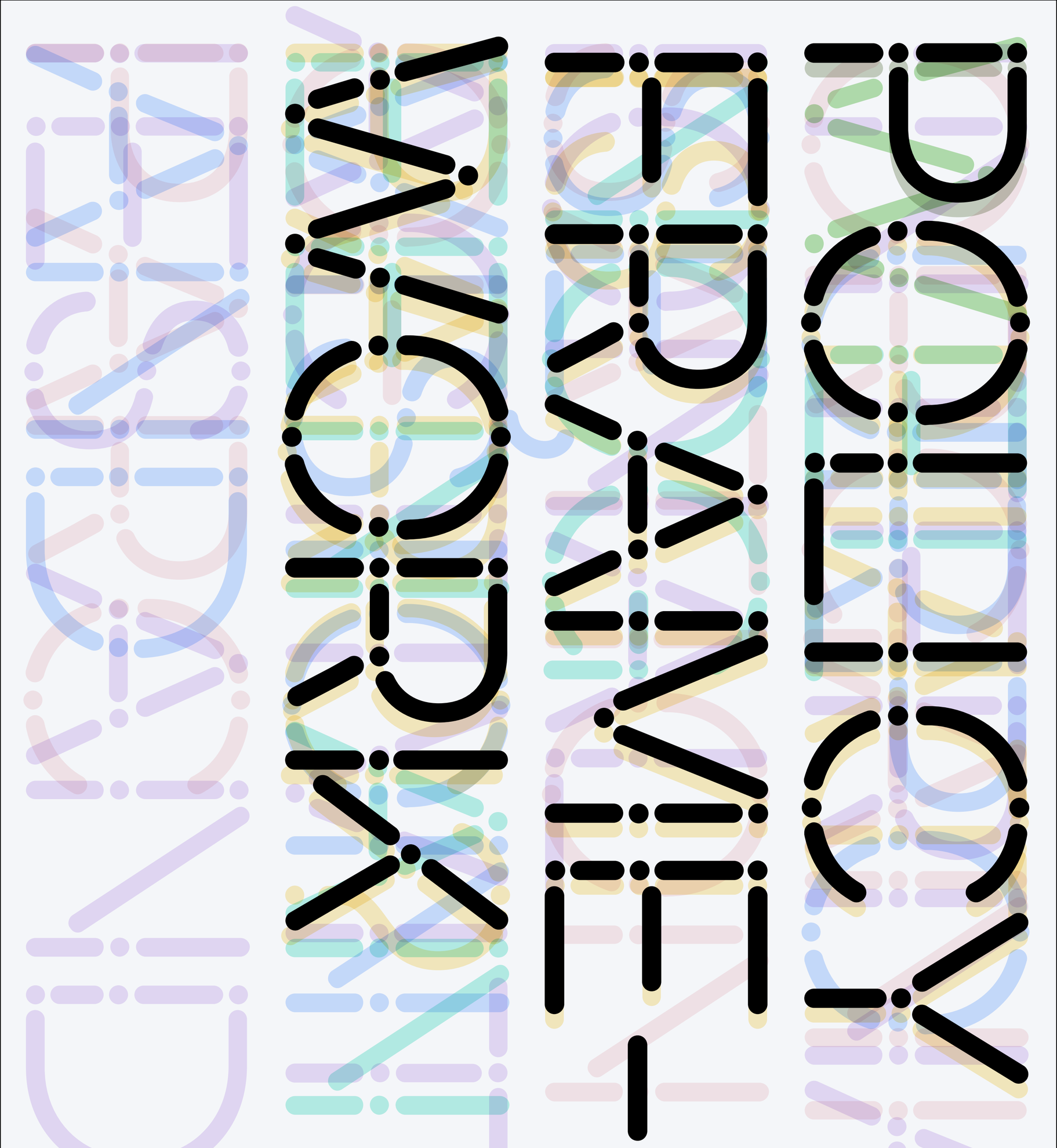
The SRIA will have a final update at the end of the partnership in which you may expect an increased focus on PARC's achievements, policy contributions, scientific outputs and sustainable takeovers of PARC activities beyond the lifetime of the partnership.

1. WHAT IS PARC?

1 What is PARC?

PARC is an EU-wide research and innovation partnership programme to support EU and national chemical risk assessment and risk management bodies with new data, knowledge, methods, networks and skills to address current, emerging and novel chemical safety challenges. This Partnership brings together ministries and national public health and risk assessment agencies, as well as research organisations and academia from almost all EU Member States. Representatives of Directorates-General of the EC and EU agencies involved in the monitoring of chemicals and the assessment of risks are also participating. Established under Horizon Europe, the EU's 2021—2027 Research and Innovation (R&I) framework programme, PARC is a co-funded European partnership, which started the 1st of May 2022 for 7 years with a budget of 400 million euros, co-funded 50% by the European Commission and 50% by Member States.

Fig. 1 — PARC Composition



2. POLICY FRAMEWORK

2 Policy framework

The Partnership for the Assessment of Risks from Chemicals (PARC) was born out of a significant political ambition: to make the European Union a model in chemical safety and demonstrate the possibility of increasing competitiveness while protecting health and the environment. PARC was conceived in 2020, started in 2022, and will continue until 2029. In the meantime, the political context has evolved and PARC's co-design approach with regulators, risk assessors, scientists and policymakers make the partnership uniquely flexible to address the evolving context. This section outlines the broad political context in which PARC is situated, starting with the broader political landscape and gradually narrowing down to the specific initiatives and frameworks that directly influence the partnership's work.

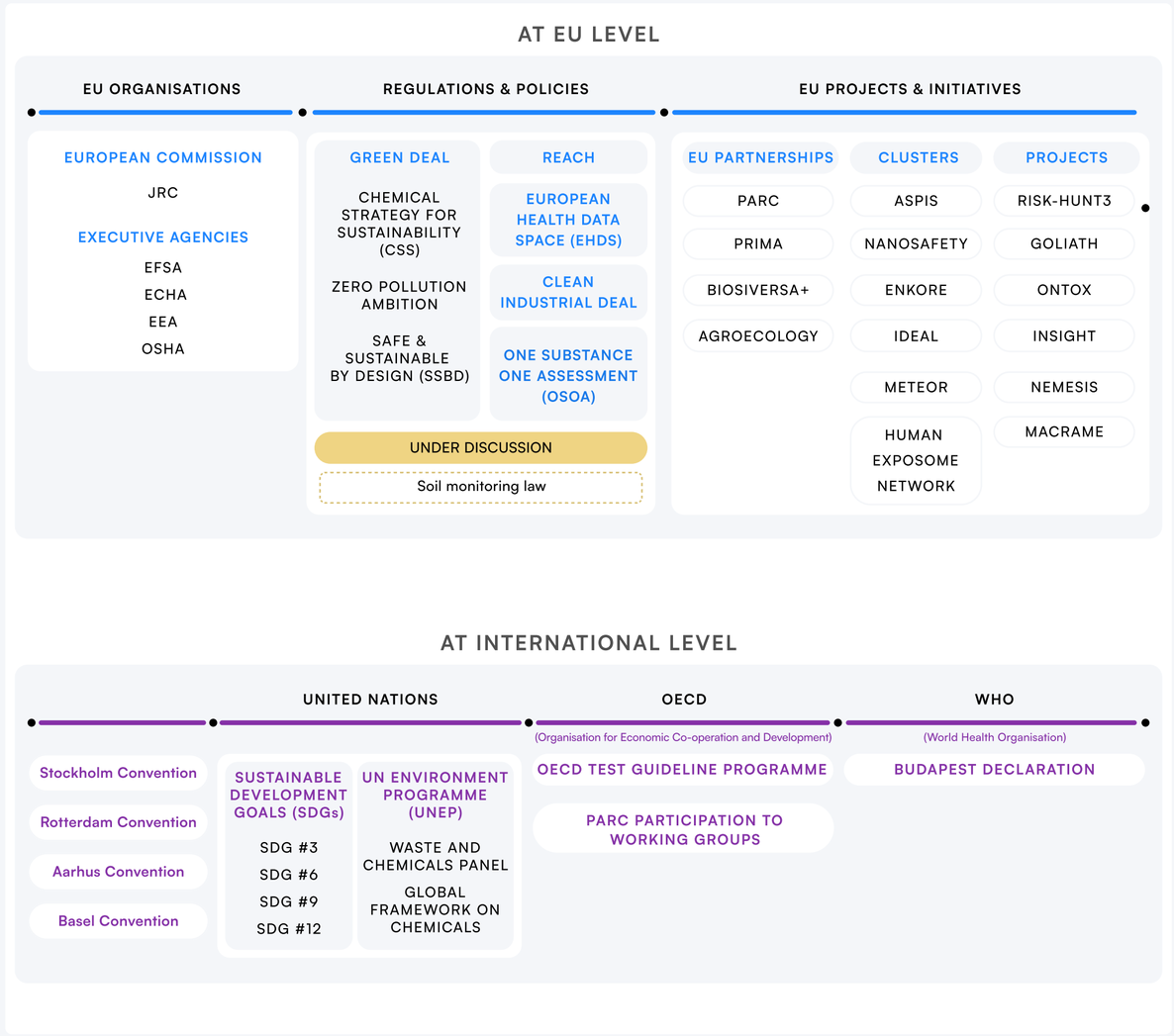


Fig. 2 — PARC Ecosystem

2.1 PARC and the Sustainable Development Goals (SDGs)

The United Nations Sustainable Development Goals[1] provide a global framework for addressing various challenges, including those related to chemicals and sustainable development.

PARC primarily addresses four Sustainable Development Goals (SDGs): Goal 3 (Good Health and Well-being), Goal 6 (Clean Water and Sanitation), Goal 9 (Industry, Innovation and Infrastructure) and Goal 12 (Responsible Consumption and Production).

On a lesser degree, PARC also indirectly contributes to UN SDG 14 (target 14.1 — reduce marine pollution), UN SDG 15 (target 15.5 — Protect biodiversity and natural habitats), SDG 16 (target 17.6 — Knowledge sharing and cooperation for access to science, technology and innovation; target 17.17 — Encourage effective partnerships).

Fig. 3 — Sustainable Development Goals

3: GOOD HEALTH AND WELL-BEING

Target 3.9 of this goal aims to substantially reduce risks to human health as a result of exposure to hazardous chemicals. By improving the risk assessment of chemicals, we can better understand their potential impacts on human health and take appropriate measures to mitigate these risks. This can include restricting the use of volatile organic compounds, limiting heavy metals in final products, and preventing the use of harmful ingredients such as carcinogens, mutagens, or reproductive toxicity.

6: CLEAN WATER AND SANITATION

Better chemical risk assessment can contribute to achieving UN SDG 6, which aims to ensure the availability and sustainable management of water and sanitation for all. Target 6.3 of this goal states that by 2030, we should improve water quality by reducing pollution, eliminating dumping, and minimizing the release of hazardous chemicals and materials. By understanding the risks associated with certain chemicals and by studying their fate in the environment, we can take steps to prevent their release into water bodies, thereby improving water quality.

9: INDUSTRY, INNOVATION AND INFRASTRUCTURE

Target 9.4 of UN SDG 9 calls for greater adoption of clean and environmentally sound technologies and industrial processes. By generating Findable, Accessible, Interoperable, and reusable (FAIR) data and models, by collaborating with research infrastructures, by working on harmonisation and standardisation and by developing training, we support innovation by industry. Improved chemical risk assessment will lead to enhanced safety and resilience in industrial processes through a better identification and mitigation of potential hazards associated with chemical use. It will also enable industries to adopt safer and more sustainable practices, which in turns will be a driver for innovation and competitiveness with the development of safer chemicals and alternative materials.

12: RESPONSIBLE CONSUMPTION AND PRODUCTION

Improved chemical risk assessment can support UN SDG 12, which promotes responsible consumption and production. Target 12.4 of this goal urges Member States to promote sustainable consumption and production in the manufacture, transport, use, and disposal of industrial goods, including through enforcement of environmentally sound management of chemicals and wastes throughout their life cycle. By developing and implementing the Safe and Sustainable by Design Approach, by providing training and guidance, PARC can contribute actively to this goal.

2.2 PARC and the Chemical Strategy for Sustainability of the Green Deal

PARC aligns closely with the European Union's Chemical Strategy for Sustainability (CSS) and the Green Deal agenda set by the President of the European Commission, Ursula von der Leyen. Announced in December 2019, the Green Deal aims to transform the EU into a climate-neutral economy by 2050, while the CSS, unveiled in October 2020, focuses on reducing harmful chemicals and promoting safer, more sustainable alternatives. PARC's focus on improving chemical safety and risk assessment directly supports these objectives.

Through its collaborative approach, PARC contributes to the EU's broader vision of achieving a toxic-free environment, one of the key pillars of the Green Deal. By fostering research and innovation in chemical safety, PARC helps to drive the transition towards a greener economy, where both human health and environmental protection are prioritized, while also enhancing competitiveness in the chemical industry.

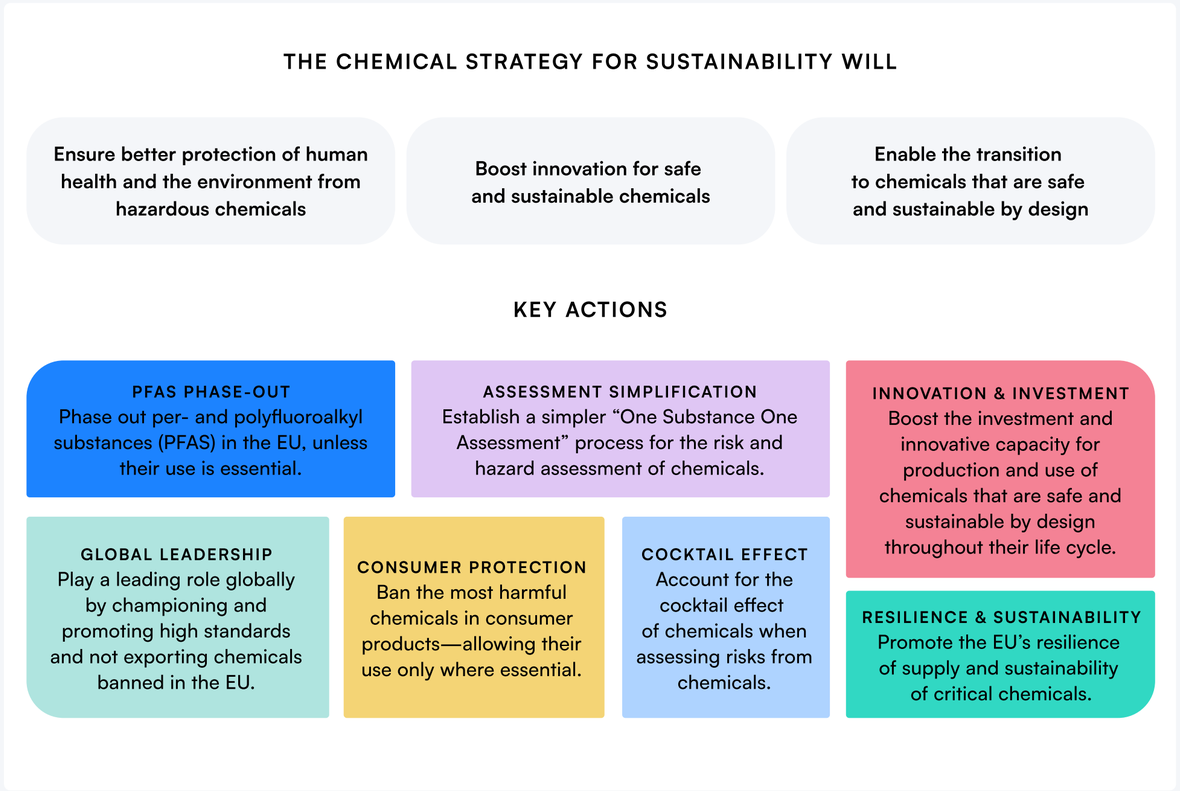


Fig. 4 — Chemical Strategy for Sustainability in brief

2.3 PARC in the evolving policy context: focus on strategic competitiveness

With the evolving context under the new European Commission, PARC plays a key role in supporting the EU's goals of competitiveness. Competitiveness should be enhanced by the efforts of all research communities to advance science and create an environment where innovation can thrive.

Both are needed to foster a favorable environment in which industries can innovate and grow. Together, research competitiveness and business competitiveness will enable the EU to enhance its resilience capabilities. As a partnership co-funded by Horizon Europe, PARC actively supports research and innovation. Moreover, as a partnership strongly focused on structuring an interface between science and public policy, PARC aligns with the new priorities set out by the European Commission for the 2024—2029 period.

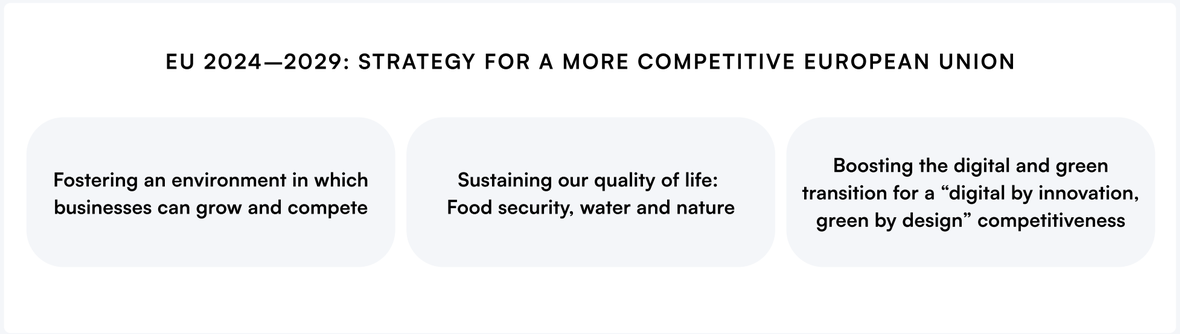


Fig. 5 — EU priorities for 2024-2029

As the Commission emphasises the importance of reducing dependency on external resources and improving our capacities of resilience, PARC's focus on chemical safety and innovation aligns with Europe's drive to strengthen its industrial base.

By advancing the development of safer and more sustainable chemicals, PARC helps foster a competitive chemical industry that is resilient and able to meet both regulatory standards and market demands.

At the same time, PARC contributes to strategic autonomy by promoting research and development within Europe, ensuring that the EU has control over the technologies and solutions critical to its economy.

PARC and Artificial Intelligence (AI) Act

Artificial Intelligence (AI) is a transformative technology that has the capacity to support numerous economic, environmental and societal processes including chemical risk assessment. If used wisely, it can bring many benefits. The use of AI systems in chemical risk assessment is already widespread and is foreseen to be a crucial technology to empower the Next Generation Risk Assessment (NGRA). Certain PARC activities are already exploring the potential use and applications of AI systems for chemical risk assessment.

For instance, AI can streamline knowledge harvesting (e.g. text-mining & natural language processing), multi-modal data analysis, predictive modeling (e.g. using Machine-Learning (ML) for Quantitative Structure-Activity Relationship (QSAR) models, system modelling, evidence-based reporting and support regulatory decision-making (while abiding to a 'human in the loop' approach)).

The AI Act (Regulation (EU) 2024/1689), which aims to regulate AI technologies to ensure safety, fairness, and transparency, could play a significant role in enabling PARC's efforts by laying down harmonised rules on AI and fostering the responsible use of AI in NGRA.

2.4 PARC in the risk assessment landscape: co-design and adaptability

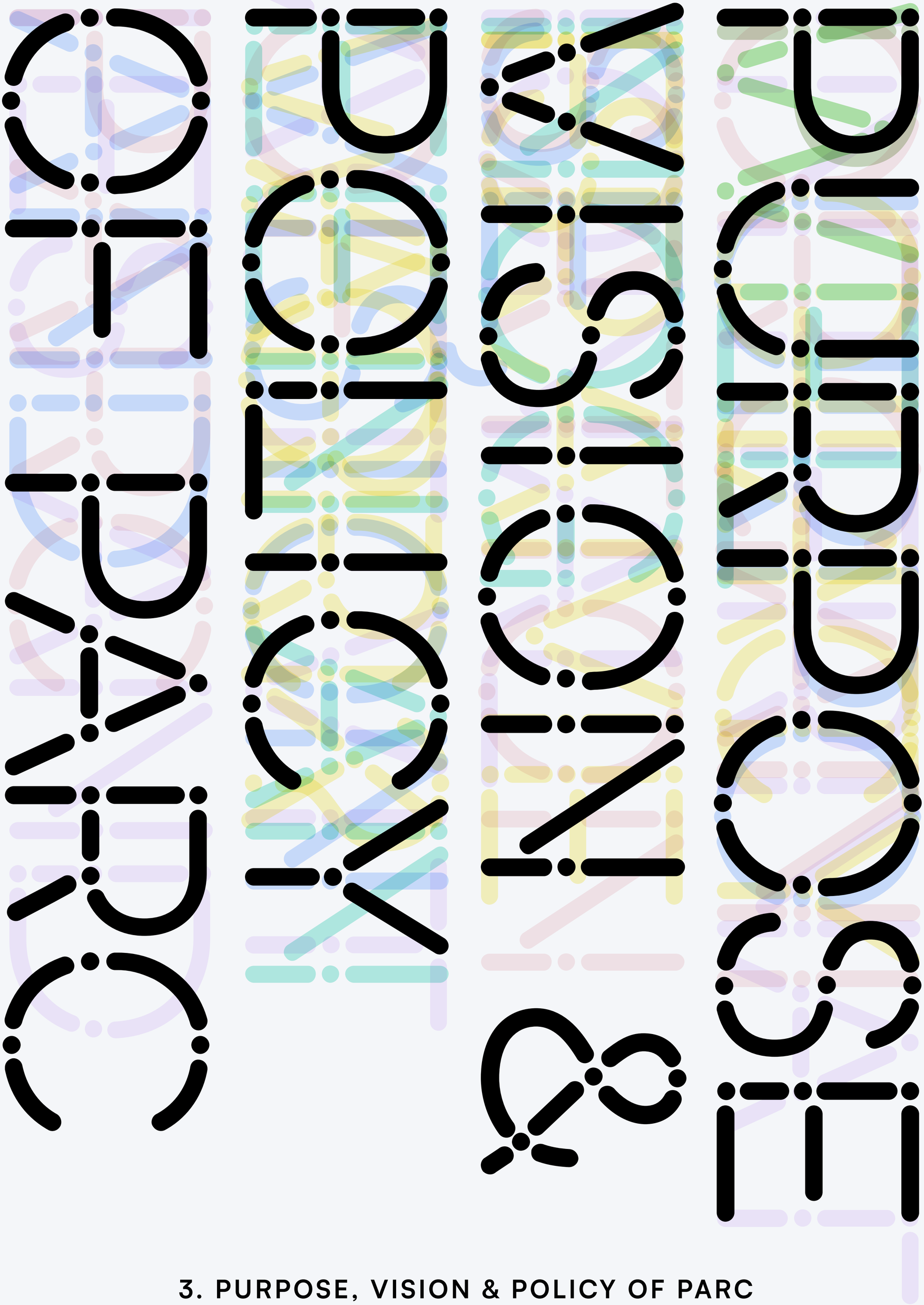
One of the core added-value activities of PARC is co-designing the next generation of risk assessment methodologies, drawing not only on the key areas of regulatory challenges (KARC) outlined by the European Chemicals Agency (ECHA) but also on broader concerns from various regulatory actors.

In practice, 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.

This is notably enabled by:

Direct involvement of EU regulatory agencies as PARC partners	Participation of regulators and policymakers in the prioritisation process	Consultation of stakeholders in the prioritisation process	Involvement of regulators as reviewers for project proposals as well as deliverable review	Organisation of regular meetings between PARC and regulatory agencies and policymaking bodies
ECHA EFSA EEA	See sections 6.2 and 6.3	Stakeholder Forum National Hubs International Board	+ project implementation follow-up	

Fig. 6 — Co-design and adaptability



3. PURPOSE, VISION & POLICY OF PARC

3 Purpose, vision and policy-contributions of PARC

PARC's vision is to address current, emerging and novel chemical safety challenges, to enable the transition to the Next Generation Risk Assessment, in line with the European Green Deal's zero-pollution ambition for a toxic-free environment, and to support EU competitiveness.

The guiding principles of PARC are the One Health approach, the science-to-policy interconnectedness and the innovation & competitiveness focus.

3.1 Vision of PARC

Fig. 7 — PARC Vision

3.1.1 One Health Approach

PARC is a partnership embedded in the One Health approach, which recognises the interconnectedness of human, animal, and environmental health. By focusing on the safety and sustainability of chemicals, PARC aligns with the One Health concept, acknowledging that chemical risks can affect not only human health, but also ecosystems and wildlife. This holistic approach ensures that risk assessments consider the broader impacts of chemicals across all domains, promoting a comprehensive strategy for safeguarding health and the environment. PARC's collaboration between scientific, regulatory, and industry stakeholders further supports the One Health vision by integrating diverse expertise to tackle the complex challenges of chemical safety.

PARC notably contributes through:

- Development of HBM aligned studies and occupational studies;
- Development of environmental studies in multiple matrices;
- Prioritisation of regulatory needs for human and environment safety;
- Development of common analytical standards and methods;
- Development of adverse outcome pathways based on biological knowledge at different levels of evolutionary trees;
- Organisation, harmonisation and structuring of research data to enable its effective re-use and integration for generation of One Health insights, modelling, SSbD, and beyond.

PARC's activities are aligned to the 6 recommendations on One Health Governance in the EU[1] (1. Definition of One Health, 2. Coordinated governance, 3. Policy coherence, 4. Education and knowledge sharing, 5. Transdisciplinary research, and 6. Integrated infrastructure for Prevention and Surveillance at the EU level).

[1] Scientific Advice Mechanism: One Health Governance in the European Union, Group of Chief Scientific Advisors, Scientific opinion No 16 November 2024.

3.1.2 Science to Policy perspective and regulatory relevance of the results produced

Biodiversity, water, food and health are all closely interlinked, yet they are often addressed in isolation. The One Health approach breaks down silos across disciplines and sectors and adopts an integrated perspective. It encourages research and innovation that explicitly examine the links and feedbacks between the different elements of the nexus. By its design and vision, PARC develops integrated risk assessment methods that consider the cumulative and cascading effects of chemicals across these different elements of the nexus.

PARC is deeply rooted in the Science to Policy perspective, bridging scientific research with regulatory decision-making to ensure that the co-design of the results produced — and 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. The partnership's work aims to translate complex scientific findings into actionable policy guidance that can enhance chemical risk assessments, improve public health protection, and support sustainable practices across industries. This direct link between science and policy ensures that PARC's outcomes are not only relevant but also influential in shaping the future of chemical regulation and public health safety in Europe.

3.1.3 Innovation and competitiveness

PARC places a strong emphasis on innovation in several key areas critical for advancing chemical safety and risk assessment. The partnership focuses on biomonitoring, developing more effective methods for detecting chemical exposure in humans and ecosystems. PARC is also actively working on the advancement of New Approach Methodologies (NAMs), which offer alternative, non-animal testing strategies that are faster, more cost-effective, and ethically sound. Additionally, PARC promotes the use of FAIR (Findable, Accessible, Interoperable, and Reusable) data to ensure that high-quality scientific data is widely shared and can be used for transparent and reproducible risk assessments.

The role of Artificial Intelligence (AI) in risk assessment is another key area, with PARC exploring how AI can enhance the accuracy and effectiveness of chemical risk evaluations. Finally, PARC recognises the importance of maintaining competitiveness in the chemical industry, particularly through initiatives like the SSbD, which encourages the development of sustainable, safe chemical alternatives. 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.

Evidence-based risk assessment of chemicals is crucial for competitiveness and innovation in European companies for several key reasons:

1. REGULATORY COMPLIANCE AND MARKET ACCESS

In the European Union, strict regulations govern the use and marketing of chemicals, such as REACH. Evidence-based risk assessments ensure that companies comply with these regulations, enabling them to access the European market without the risk of non-compliance penalties or product recalls. Meeting these standards can also provide a competitive advantage by making products safer and more trusted by consumers. PARC's role in refining, developing and applying all methodologies involved therefore is key also against the background of the robust perspective of the internal market.

2. CONSUMER TRUST AND BRAND REPUTATION

The potential of PARC as a lighthouse — platform displaying the principles and key developments in advancing risk assessment methodologies cannot be overrated. In an age where consumers are becoming increasingly concerned about safety, health, and environmental impact, state-of-the-art, evidence-based risk assessments help companies demonstrate that they are innovative and proactive in minimising risks. This fosters consumer trust and enhances the company's reputation. Companies that can provide transparent, science-backed evidence that their products are safe, tend to have a competitive edge in the marketplace.

3. INNOVATION AND SUSTAINABLE PRODUCT DEVELOPMENT

Risk assessments can drive and safeguard innovation by identifying potential hazards early in the product development process. By addressing these risks proactively, companies can design safer and more sustainable products that meet consumer expectations and align with regulatory standards. This innovation is essential in staying ahead of competitors, especially as industries move towards sustainable and circular economies.

4. COST EFFICIENCY AND RISK MITIGATION

The scientific endeavours within PARC in particular with a view towards subsequent validation processes are the backbone for the future of harmonised risk assessment methodologies. Evidence-based risk assessments allow European companies to identify risks and hazards before they become expensive problems. They can optimise the use of resources, avoid costly recalls or redesigns, and reduce potential legal liabilities. Additionally, early risk identification helps in securing insurance and reduces financial uncertainty.

5. GLOBAL COMPETITIVENESS

European companies that invest in evidence-based risk assessments may also gain a competitive advantage in global markets. As countries around the world adopt more stringent regulations around chemicals and environmental safety, companies that already adhere to rigorous European standards are better positioned to meet similar requirements elsewhere, ensuring smoother entry into international markets.

6. ALIGNING WITH EMERGING TRENDS

PARC is based on an interdisciplinary approach embracing also key elements of the multiple transformation addressed in the "Green Industrial Deal". With the increasing push towards sustainability, circular economy principles, and green chemistry, evidence-based risk assessment helps companies align with these emerging trends of innovation. By integrating risk assessments into their operations, companies can innovate in a way that is not only compliant with current regulations but also anticipates future regulatory changes and market demands for sustainable products.

7. ACCESS TO RESEARCH AND COLLABORATION OPPORTUNITIES

Evidence-based risk assessments encourage collaboration between businesses, regulators, and researchers, enabling companies to stay on top of the latest scientific advancements, generated and displayed by PARC. These collaborations can lead to new opportunities for product development, partnerships, and access to funding or grants, fostering innovation and growth in the competitive European marketplace.
In summary, PARC is establishing a solid basis for the future of evidence-based risk assessment thus ensuring that European companies are prepared to efficiently navigate the regulatory landscape, improve product safety, build consumer trust, and foster sustainable innovation—all of which contribute to long-term competitiveness in both local and global markets.

3.2 PARC Contribution to Policy

RISK ASSESSMENT

HUMAN MONITORING AND FOOD MONITORING

To verify the effectiveness of current measures, PARC has processed existing Human biomonitoring data with the MCRA tool to check if the exposure prediction based on food monitoring data can accurately predict the human internal dose. PARC partners have worked to develop a new module to perform this analysis at the national level to identify major contributing sources. In parallel, training on risk assessment are ongoing and information of risk management are upcoming.

ONE SUBSTANCE ONE ASSESSMENT (OSOA) INITIATIVE

The OSOA aims to streamline the evaluation of chemical substances by ensuring that all relevant data and assessments are considered through a single, unified process. This avoids duplicative assessments and promotes efficiency and consistency in regulatory decision-making. PARC supports this initiative by providing scientific expertise, research, and tools that enhance the risk assessment framework, facilitating the integration of various data sources, including environmental and health impact data. Both initiatives seek to reduce the burden on industry while ensuring that chemical safety assessments are robust, accurate, and transparent. By working together, PARC and OSOA contribute to a more effective regulatory system, enhancing chemical safety, protecting public health, and promoting sustainability across the EU.

NGRAroute - ROADMAP TOWARD NEXT GENERATION RISK ASSESSMENT

PARC is actively involved to bring forward the transition toward Next Generation Risk Assessment (NGRA). PARC is not only active in the ongoing discussions in close collaboration with the European Commission, but it also develops, refines and tests NGRA tools and processes.

To channel efforts, weigh on the discussion as well as to effectively promote the NGRA transition, PARC T2.2 ‘Knowledge management and uptake into policy’ had been developing a standalone roadmap proposal for the implementation of Next-Generation Risk Assessment as the default approach to chemical risk assessment in EU chemicals legislation.

In parallel, the European Commission initiated in 2023 the development of its own roadmap towards an animal-free regulatory system in response to the European Citizens’ Initiative (ECI) Save Cruelty-free Cosmetics - Commit to a Europe without Animal Testing”.

Given the complementary nature of the two initiatives and rather than duplicating efforts, the EC and PARC have joined efforts and pooled resources with PARC acting as a key facilitating framework to support and moderate the discussion in order to achieve a sound and realistic EC roadmap able to secure a broad support across the whole chemical risk assessment community.

PARC contribution to NGRA policy development has proven concrete with:

- Heavy involvement of PARC T2.2 members in the dedicated working groups set up by the European Commission (WGs on Human health, Environmental Safety Assessment, Change Management)
- Attendance to EC “Workshop on a roadmap for phasing out animal testing in chemical safety assessments” with active PARC participation (December 2023, October 2024)
- Participation in NGO-initiated roundtable (June 2024)
- Drafting 10 ‘guiding principles for the development of a future overarching NGRA framework’
- Engagement with stakeholders during multiple commenting rounds in the development of NGRAroutes
- Attendance to Animal-Free Chemical Safety Assessment Conference (March 2025)

TOOLS & RESOURCES

SAFE AND SUSTAINABLE BY DESIGN APPROACH

A key element of the PARC’s SSbD approach is the development of a toolbox, which will give guidance to the users about functionality, chemical safety, environmental sustainability and socio-economic aspects.

The SSbD toolbox developed within PARC features a structured collection of tools to be applied to address the different steps to the EC SSbD framework appropriately and reliably. It will serve as an important tool in supporting the EU Green Deal ambition including the Chemical Strategy for Sustainability by providing assistance in assessing the safety and sustainability of chemicals throughout their entire life cycle.

Its scope covers inter alia chemical safety over the life cycle, product sustainability aspects (including environmental life cycle assessment (E-LCA), economic (Life Cycle Costing-LCC), social life cycle assessment methodologies (S-LCA)) and functionality of chemicals in a product. By that, it aims to support designers, developers, and risk assessors of chemicals and materials from industry, academia and governments in applying and assessing SSbD of chemicals and materials.

The toolbox will be designed in such a way that it enables (re-)design and assessment at the different stages of the innovation process.

Acquiring input from and work with industry, academia and regulatory community is key to both the toolbox-development and reflecting on the practical aspects of making SSbD operational. Stakeholder perspectives will feed into on how safety and sustainability assessments can be best integrated in new chemicals and materials development, and translated into toolbox features, interface and workflows as well as new tool development.

SHIFT AWAY FROM ANIMAL TESTING

In close collaboration with on-going programmes, PARC supports development of new approach methodologies for several endpoints and collaborate with international organisations for further uptake. NAMs have the potential to become a major component of regulatory risk assessment, however, their actual implementation is challenging. PARC is designed to address many of the challenges that exist for the development and implementation of NAMs in modern CRA.
PARC’s proximity to national and European regulatory agencies is envisioned to ensure that all the projects that are initiated within PARC agree with actual regulatory needs. One of the main aims of PARC is to develop innovative methodologies that will directly aid chemical hazard identification, risk assessment, and regulation/policy.

OPEN AND FAIR DATA TO SUPPORT THE DIGITAL TRANSITION

Reflecting the push towards Open Data and the Green and Digital Transitions, PARC is investing significant effort into development of workflows to enable PARC data to be made FAIR — Findable, Accessible, Re-usable and Interoperable, and as open as possible but as protected as needed (i.e., for personal data from HBM studies for example). A key focus is on machine actionable data, which is structured and organised to be understandable by computers, which is critical to maximise the potential of Artificial Intelligence to support chemical risk assessment.
PARC’s mapping of the current use of AI in all aspects of its work, including in modelling, NGRA and the SSbD Toolbox, and how these uses of AI within PARC map to the AI Act’s risk levels is providing important insights for regulation and risk assessment and is feeding into ongoing discussions at the PARC, member state and EU levels best practice and risk management of AI.

SCIENCE TO POLICY

PARC & PREVALIDATION OF METHODS

The process of developing a method is guided by scientific knowledge, technical resources and constraints to produce results (detection, quantification, observation of effects) and support their interpretation (contribution of knowledge, monitoring, control, diagnosis, dose-effect relationships, toxicokinetics, toxicodynamics, etc.). From initial development by a scientific team to use by scientific communities within a regulatory framework, the development process is an iterative process of technical description, optimisation and validation in order to identify and characterise sources of variability, qualify performance criteria (error rate, measurement uncertainty) and acceptance criteria for an assay, series of assays, modelling and assessment (internal quality control, external quality control). Within the partnership, we support the scientific partners in developing robust methods that are relevant to monitoring activities, hazard characterisation and risk assessment within the regulatory framework, with the aim of recognition at international level (OECD validation, ISO/CEN standardisation). PARC supports the pre-validation stages, developing the scientific communities, sharing data and knowledge and training in good experimental, development and reporting practices.

3.3 Indicators of success

While the following actions are not finalised at the mid-term of the partnership, we can already point out 'indicators of success' that show how PARC is helping shape and improve the chemical risk assessment policy-context.

Indicator 1

National Hubs

The National Hubs (NHs) in PARC have strived to achieve their goals in key areas:

- **Two-way Communication: NHs facilitate effective communication between national stakeholders and PARC scientists, ensuring that national needs and priorities are integrated into the partnership's objectives.**
- **Prioritisation and Training: NHs play a crucial role in prioritising chemicals of concern and tailoring training programs to meet national needs.**
- **Sustainability and Development: The National Hub Contact Points and Coordinators support the continuous development of NHs through peer-to-peer learning processes in online and face-to-face meetings, fostering the growth of the NHs from the beginning of the partnership.**
- **Integration and Expansion: Many NHs were initially established under the European Human Biomonitoring Initiative (HBM4EU) and have since expanded to include broader aspects such as environmental exposure and risk assessment. The NHs have also taken on responsibilities for communication and dissemination of PARC outputs.**
- **Challenges: NHs face challenges like reaching consensus at the national level and ensuring their input is valued. Efforts are being made to address these challenges and enhance the integration of NHs into PARC.**

Overall, NHs are key players in PARC, contributing significantly to the harmonisation of national and European priorities in chemical risk assessment.

Participation in PARC general population aligned studies

The aim of the PARC aligned studies is to measure concentrations of environmental pollutants in the European population and to obtain comparable data across different EU countries

The study covers three age groups

Children	Adolescents	Adults
6—11 years	12—17 years	18—39 years

Targeting the following substances

Children	Adolescents	Adults
Bisphenols	Bisphenols	Bisphenols
Phthalates	Phthalates	Phthalates
Pesticides	PFAS	PFAS
Metals	Pesticides	Pesticides
	Arsenic species	Metals

Studied in

Children	Adolescents	Adults
14 countries	11 countries	20 countries

The (target) number of participants is

Children	Adolescents	Adults
± 3250	± 2610	± 4750

Legend general population study

Countries involved in following studies

- Only children
- Children & adults
- Children & adolescent
- Only adolescent
- Adolescent & adults
- Only adults
- Children & adolescent & adults

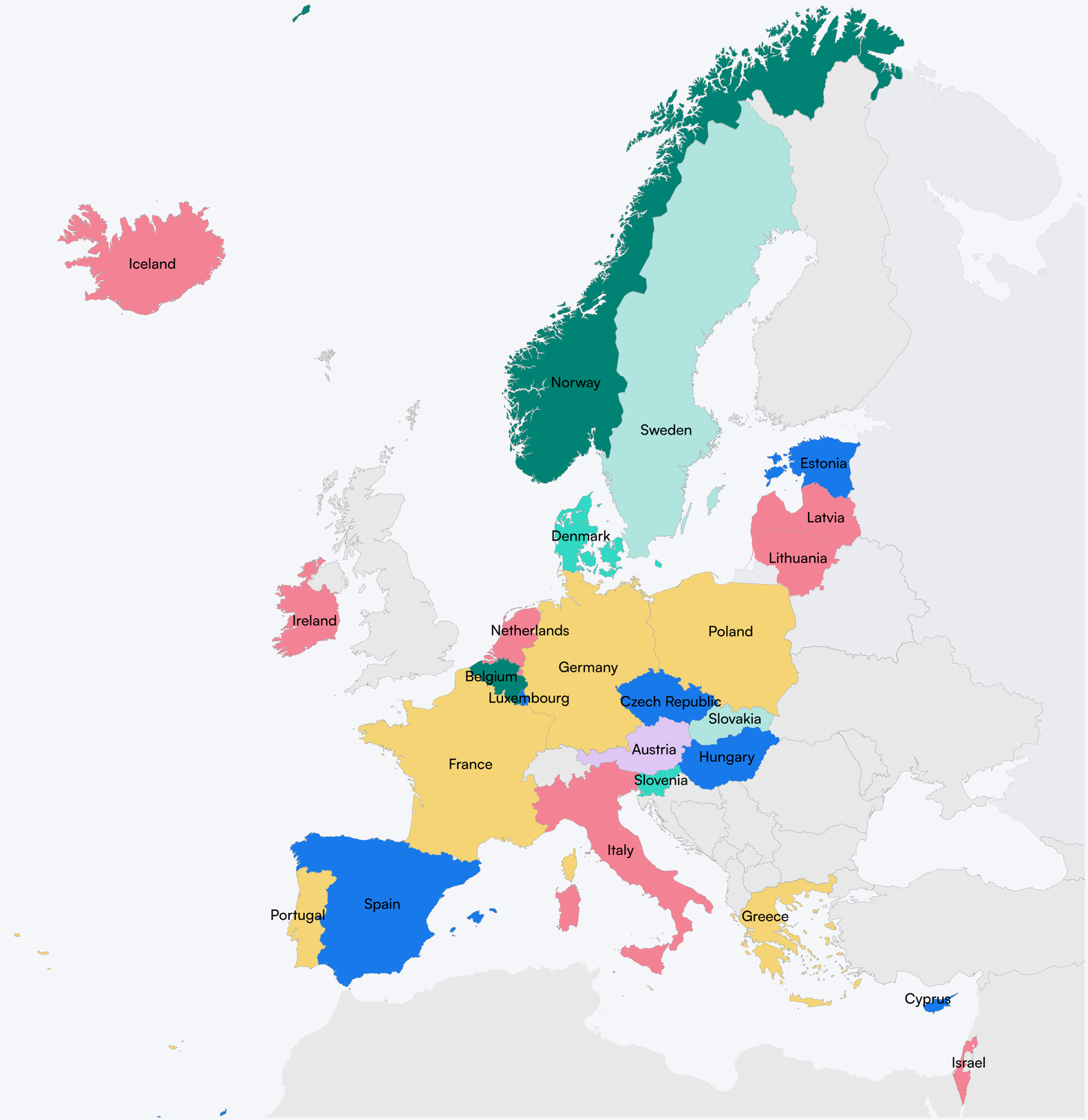


Fig. 8 — PARC Aligned Studies

Indicator 2
Aligned Studies

The work in the PARC Aligned Studies continues the journey towards a harmonised Human Biomonitoring (HBM) system in Europe, initiated by HBM4EU. Building on the lessons learnt from HBM4EU, PARC has implemented several improvements compared to the HBM4EU Aligned Studies. These enhancements include: a shorter sampling period to facilitate synchronised sampling across countries with harmonised questionnaires, a selected set of biomarkers for all studies to analyse, allowing further exploration of mixture exposure, and the definition of exclusion criteria for studies not targeting the general population.

Leveraging the already established network of researchers and laboratories, as well as the existing study designs, protocols and prioritisation of chemical substances developed in HBM4EU, the PARC Aligned Studies were able to commence swiftly. In the future, data generated from HBM4EU and PARC will be further explored to address new research questions, and the synthesis of experiences from both EU projects will be integrated into policy advisory for a sustainable European HBM system. The PARC Aligned Studies (see fig. 6) encompass the design, planning, and implementation of HBM studies for the general population across three age groups, children (6—11 years), adolescents (12—17 years) and adults (18—39 years), with a sample size ranging from 150—300 participants per country per age group. A total of 25 European countries, plus Israel, are participating in these studies, analysing over 100 exposure biomarkers in urine, blood and hair samples, and collecting harmonised data on habits and lifestyles. This takes up the mantle of HBM4EU's aligned studies with six additional countries (Austria, Latvia, Lithuania, Estonia, Ireland and the United Kingdom).

The aim of the PARC Aligned Studies is to measure concentrations of environmental pollutants in the European population and to obtain comparable data across different EU countries. The resulting HBM data is valuable for evaluating policies, assessing the impact of regulatory measures to reduce pollution, and identifying priorities.

Fig. 9 — Participation in PARC general population aligned studies

Several additional research topics are integrated into the framework of the PARC Aligned Studies. These topics, referred to as “add-ons,” are optional, meaning that not all studies will contribute to them. The following three add-ons are further developed:

- Implementation of effect biomarkers
- Collection of personal environmental samples
- Application of Non-Target Screening /suspect screening (NTS/SS) on human biomonitoring samples.

Milestones achieved so far are the definition of general criteria, including the harmonisation of questionnaires, the development of a general study design and the definition of a Quality Assessment/ Quality Control (QA/QC) programme for chemical analysis as well as common practices as part of the QA/QC and harmonisation for the pre-analytical phase. Also, work was done in the preparation of supporting materials, such as data transfer material and ethics approval. Of the 49 studies, 30 have obtained their ethics approvals, 17 have started their fieldwork and 4 have finalized the sample collection and interviews.

In the frame of infrastructures and human capacities, the HBM laboratory network from HBM4EU project has been updated and consolidated. In addition, PARC has set up the air laboratory network and continues working on the other environmental domains. Guidance documents have been draft to secure quality assurance and quality control procedures in PARC, and three in person training courses have been held.

Indicator 3

Progressing towards 80% of PARC data being Findable, Accessible, Interoperable and Re-usable

There is a significant disconnect between the ambition to make data FAIR versus the ability to make data FAIR — the original FAIR principles, as laid out in the seminal paper in 2016 intentionally avoided telling the community how to make their data FAIR, instead focusing on what FAIR data should consist of. Indeed, working on FAIR has been described as flying the plane while still building it, which reflects that the tools and resources needed to make data FAIR are built by the research communities interested in making their data FAIR. Thus, several of the FAIR principles require community consensus on what vocabularies to use and whose definition of a specific term is best, and what we mean by minimum and rich metadata (data that describes a dataset) — what is the minimum information others would need to re-use your data, such as knowing what the dataset is about and why it was generated, versus the optimal additional information (rich metadata) that could include information on data quality relative to current standards, or uncertainty in the measurements and other information that support users to understand the fitness of the data for their re-use purpose.

Within PARC, we have been focusing so far on building consensus within three main research communities — human biomonitoring, chemicals in the environment, and toxicology, with a subsequent step being then to ensure cross-community (or cross-domain) harmonisation (interoperability). PARC is feeding into the JRC-led activities around increasing the re-use of research data for chemicals risk assessment, and the metadata templates developed for PARC data will be integrated into the set of OECD Harmonised Templates.

The process that we have undergone in PARC has been to first train an internal set of FAIR facilitators, who have in-depth knowledge of the FAIR principles, and the tools and resources currently available, and the skills to develop new FAIR Enabling Resources and Tools where gaps are identified. To date over 20 PARC FAIR facilitators have been trained, and as part of this training, a wide range of PARC-specific FAIR Enabling Resources have been developed, including metadata templates, vocabularies and ontologies, data schema to help organise and structure data, machine-actionable data management plans and more. A specific focus is also on providing user-friendly interfaces for these tools that enable data generators (experimentalists) to work with them without needing to programme or to have technical skills, and workflows that align with how experimentalists currently work to maximise the uptake of these tools and workflows. These will increasingly be rolled out to PARC partners over the coming months, alongside additional training in PARC FAIR data approaches.

The challenges have been greater than initially foreseen, but the rewards will be enormous, and the opportunity for PARC to support other projects and initiatives, and provide the roadmap and best practice is exciting. Our next challenge is to optimise the tracking of data re-use so that we can demonstrate in real terms the benefits of making data FAIR for individuals, organisations, projects and partnerships, and for the European Agencies.

4. ORGANISATION OF PARC

4 Organisation of PARC

4.1 Project-based approach

To ensure the delivery of PARC operational outcomes by the different work packages, some of the R&I activities in PARC are done through projects grouped and organised under the tasks within the PARC Work Packages. In this way, the Participants contribute to PARC through their involvement in projects and their participation in cross-cutting transversal activities. The regulatory/policy relevance at EU and/or national levels is paramount for PARC projects.

This is ensured first by rooting the project proposals to the regulatory needs, and secondly by the active involvement of regulatory actors all along the project lifetime (review process, follow-up and deliverable review).

Over 100 projects are in the PARC project portfolio. Each year, new projects are selected through a dedicated review process.

4.2 Structuration in Workpackages

The partnership is organised according to nine work packages (WP) with a strong focus on the science-policy interface. The cross-cutting WPs (WP1, WP2, WP3, WP7, WP8, WP9) implement their tasks and activities along the 7 years while the research and innovation WPs (WP4, WP5 and WP6) also implement some through projects supporting their main task activities. WP7 has a few dedicated projects in close collaboration with other WPs.

WP1: MANAGEMENT AND COORDINATION

WP1 is in charge of the overall coordination, including the administrative and financial management of the Partnership, the monitoring of the implementation of the activities, their follow-up through reporting, the development and monitoring of Key Performance Indicators (KPIs), the organisation of PARC governance meetings and the Intellectual Property Rights, Data and Ethics activities.

WP2: A COMMON SCIENCE-POLICY AGENDA

WP2 establishes a cross-disciplinary network to set priorities for R&I in chemical risk assessment. WP2 set up a common agenda at the science-policy interface through a prioritisation process, making available PARC knowledge and actively promoting its regulatory consideration, also working towards the sustainability of the network.

WP3: SYNERGIES, COLLABORATIONS AND AWARENESS

WP3 ensures the development of synergies and collaborations with external initiatives. WP3 is in charge of stakeholder relations and international cooperation and develop appropriate tools for the communication and dissemination of the results of PARC.

WP4: MONITORING AND EXPOSURE

WP4 performs monitoring and measuring exposure both in humans and in the environment, taking into account the different sources, chemical fates and exposure pathways, working on necessary innovative analytical methods and tools.

WP5: HAZARD ASSESSMENT

WP5 contributes to the consideration of new approaches and methods of Hazard Assessment (HA) and provide data to fill gaps in knowledge on poorly characterised contaminants or new emerging hazards. WP5 aims also to promote the use of innovative methods and tools and contribute to integration of new technologies.

WP6: INNOVATION IN REGULATORY RISK ASSESSMENT

WP6 contributes to the development of regulatory workable and effective RA methods for human health and the environment, including adverse outcome pathways (AOPs) and integrated approaches to testing and assessment (IATAs), to support regulatory processes, transition to a circular economy and relevant policy-related strategies. Review of existing regulatory assessment systems is carried out to prioritise research and facilitate the uptake of new approaches.

WP7: FAIR DATA

WP7 strengthen exchange and reuse of research and regulatory data. For this, WP7 will interact with all the WPs to facilitate the access, storage and analysis of data, and the interfacing with the modelling and analysis tools developed by the WPs 4, 5, 6 and 8. It will work on data and metadata harmonisation and the Fair Data Policy. Further, it will develop innovative tools for analysing increasing amounts of data and their uncertainty.

WP8: CONCEPTS AND TOOLBOXES

WP8 makes available concepts and toolboxes in the form of integrative models, concepts and tools for the assessment of SSbD and the concept of EWS. WP8 works closely together with the different WPs and external communities working on these concepts.

WP9: CAPACITIES

WP9 support the development of both laboratory capacities and networking in the different fields of activities, by identifying existing and to be developed networks, supporting the implementation of standardisation approaches, evaluation of the reproducibility of performances and their monitoring (QA/QC) and setting up training for the Partnerships' members and the risk assessors and managers communities.

FOR MORE INFORMATION
You can find more details on the tasks from each Work Packages in the Annex 2 of the SRIA.

5. GOVERNANCE IN PARC

5 Governance in PARC

The Governance structure of PARC consists of a Management Board (WP co-leaders) and a Grant Signatory Board supported by a Coordination Team and strategically steered by a Governing Board. The PARC consortium is supported and advised by an International Board, a Stakeholder Forum and a Data and Ethics Protection Board. The National Hubs and EU Hub also support and advise PARC.

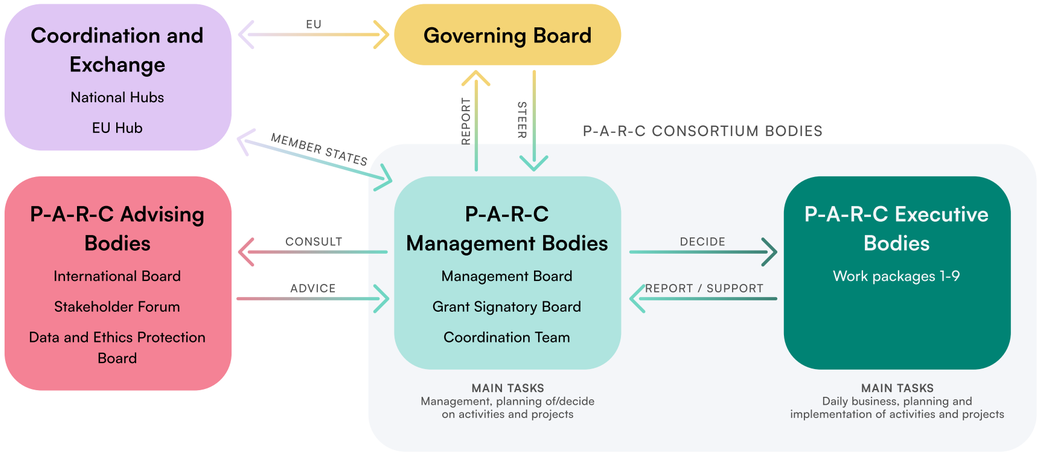


Fig. 10 — PARC Governance

GOVERNING BOARD (GB)

The GB is the overarching body of PARC that provides the highest-level strategic steering of the Partnership through continuous dialogue by its members with the implementation bodies to align PARC activities with activities undertaken at the European, national and international levels. The GB represents the national ministries or equivalent competent authorities of all participating countries (including, when applicable, countries of Associated Partners), and the relevant European Commission's Directorate Generals.

GRANT SIGNATORY BOARD (GSB)

The GSB manages the contractual implementation of PARC both on the scientific and administrative levels. It has an important role, in collaboration with the MB and GB, in the provision of input in the PARC orientations and priorities, and for the identification of synergies, resources and capacities between Participants. The GSB members are national or EU agencies in charge of chemical risk assessment or equivalents, e.g. national agencies dealing with chemicals aspects of environmental or health policies. The GSB members bring their network of scientists with whom they cooperate at national level into the Partnership as Affiliated Entities.

MANAGEMENT BOARD (MB)

The MB is the operational body that supports the Coordinator in the day-to-day implementation of the Grant Agreement based on the Description of Action and Annual Work Plans. The MB includes the Coordinator and the Work Package co-leaders.

EU HUB

An EU Hub has been set-up including the EC DGs (ENV, GROW, RTD, SANTE, JRC) and the three European agencies (ECHA, EFSA, EEA) involved in PARC. Work progress will be followed, through this EU hub, by other interested EU organisations.

COORDINATION TEAM (CT)

The Coordinator is the legal entity acting as the intermediary between the Parties, including their Affiliated Entities and Represented Associated Partners, and the Granting Authority. The Coordinator is responsible for the scientific and administrative management of the Programme. The Coordinator is supported by the CT for the administrative management and by the Deputy Coordinator and the MB for the scientific management. The CT ensures the secretariat of the GB, GSB and MB. The Coordinator, in addition to its responsibility as a Party, performs tasks assigned to it as described in the Grant Agreement and the Consortium Agreement.

NATIONAL HUBS (NH)

Countries involved in PARC establish and extend the NHs created to develop collaboration and contribute to ensuring PARC's activities are aligned with national activities. There are no prescriptive rules and the construction is based on country needs; however, relevant ministries, research entities and other stakeholders are involved. The NHs are coordinated by the National Hub Co-Coordinators ensuring that the needs of the NHs are fed into PARC.

INTERNATIONAL BOARD (IB)

The IB contributes to the science-to-policy dialogue, identification of synergies & collaborations, contribution on open science, new approaches. The IB includes individual experts from other international chemical risk assessment platforms, scientific advisory boards and scientific societies, and experts in related EU and international institutions and activities.

STAKEHOLDER FORUM (SF)

The SF provides the opportunity for stakeholders to share their vision on how to improve chemical risk assessment in Europe, collect recommendations and develop synergies at the EU and international levels. The SF includes representatives from relevant NGOs, industry/business associations, employer & worker representative bodies, health professionals and consumer organisations.

DATA AND ETHICS PROTECTION BOARD (DEPB)

The DEPB supports the MB in these matters, ensuring PARC's actions take these into account, reviewing all related documents as well as established processes for the management of contractual and regulatory requirements.

6. ACHIEVING THE VISION

6 Achieving the Vision: Activities, results and expected impacts

In the wide range of activities foreseen in PARC, past (regulatory) experiences as well as scientific and technological advances required for transitioning towards next generation risk assessment (NGRA) are taken into account. PARC is addressing challenges related to the implementation of NAMs for chemical risk assessment, thereby overcoming challenges associated with substance-by-substance risk assessment, and substantially reducing negative impacts on human health and biodiversity.

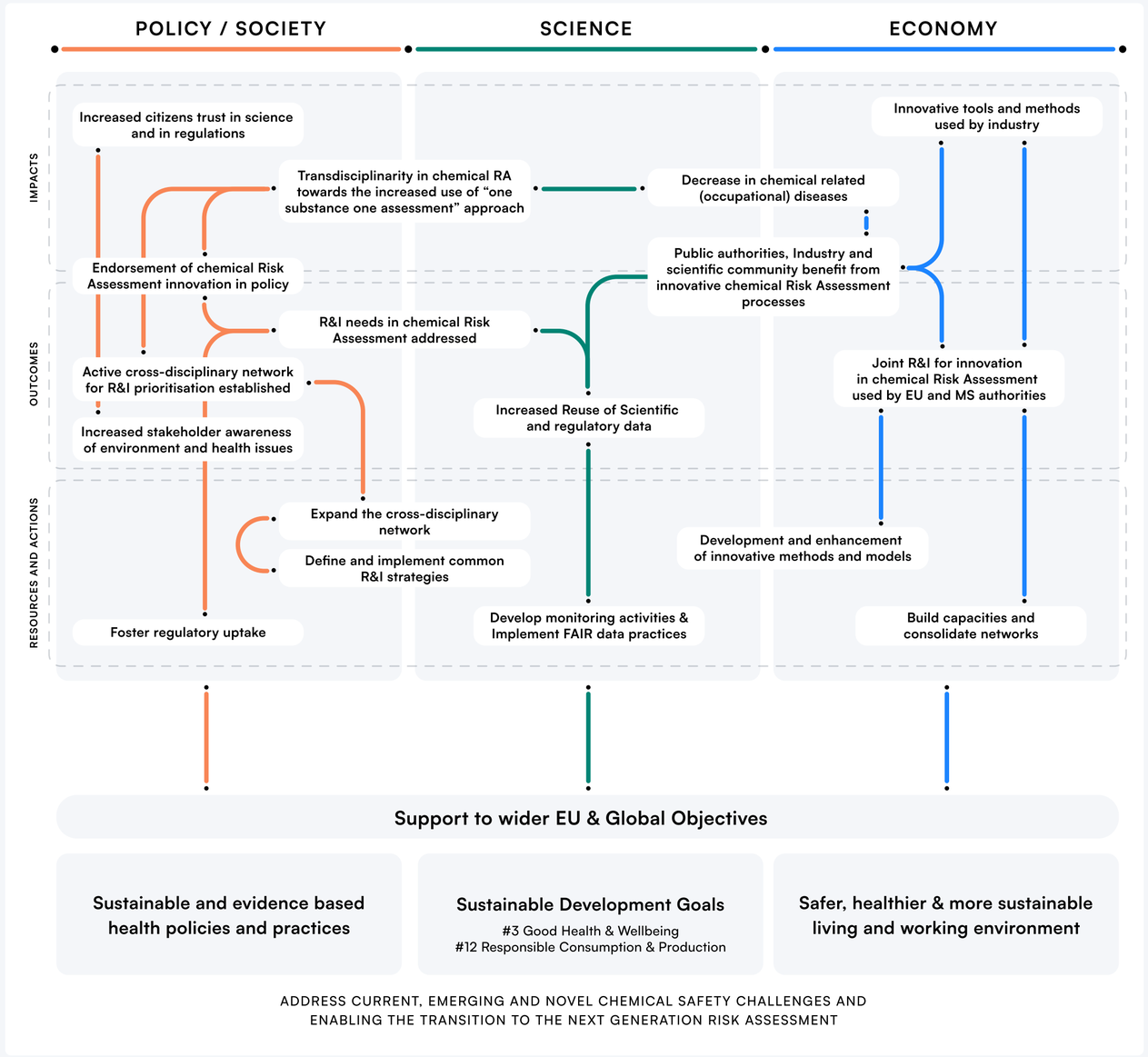


Fig. 11 — PARC's pathway to impact

6.1 PARC Specific Objectives and Operational Objectives

PARC's general objective and the lasting impacts we are looking to achieve is to consolidate and strengthen the EU's Research and Innovation capacity for chemical risk assessment to protect human health and the environment. Three Specific Objectives (SO) and 13 Operational Objectives (OO) have been defined:

Specific Objective 1
Policy and Societal Impact

EU and national risk assessors and regulatory entities come together with the scientific community in a cross-disciplinary network to set priorities for research and innovation in chemical risk assessment.

Four cross-cutting Work Packages in charge of management and coordination (WP1), establishment of a common science policy agenda (WP2) and development of synergies, collaborations and awareness (WP3) and capacities (WP9) collaborate with all partners to achieve the following operational objectives (OO).

WHAT HAS BEEN ACHIEVED SO FAR?

001.

HIGH LEVEL REPRESENTATION

Set up and operate a high-level group of EU and national representatives.

- The **PARC governance bodies** (Governing Board (GB), Management Board (MB), Grant Signatory Board (GSB)) have been interacting through **regular meetings and consultation** to steer and manage the Partnership.
- **Collaboration agreements & exchanges** with like-minded initiatives have been implemented (OECD, WHO, JRC, etc.)
- PARC has grown with the **inclusion of new countries** (Ireland, Montenegro) and **new partners**.

002.

SUSTAINABLE NETWORK

Expand a long-term sustainable network of National Hubs (NH).

- **National Hub Contact Points** (NHCP) have been identified for each country participating in PARC and NHCP meetings have been organised to share experience and best practices.
- **National Hubs** have been set-up and National Hub meetings have been organised in participating countries.
- **Annual online survey** has been developed and launched to develop a baseline for the NHs to identify the existing knowledge gaps, requests, suggestions and expertise and to address some specific requests arising from the WPs.

003.

RESEARCH & INNOVATION STRATEGY

Define common strategies and prioritisation processes for regulatory knowledge in chemical risk assessment.

- A transparent and multi-stakeholders **prioritisation process** has been implemented and led to the **co-identification of priority substances and endpoints** for PARC activities in the second half of the partnership.
- A **Rapid Response Mechanism** (RRM) has been set-up and successfully tested to address emerging concerns raised by stakeholders. This ensures that PARC can be responsive and swiftly integrate targeted activities in its workplan.
- **100+ research projects** (incl. case studies) have been approved and initiated in Y1-Y4 to respond to regulatory needs.

004.

REGULATORY UPTAKE

Foster the integration of PARC knowledge into chemical risk assessment and regulatory frameworks.

- PARC research outputs have been shared in over **200 PARC scientific papers** published in open-science manner.
- PARC is **known and acknowledged** by regulators & the scientific community; the partnership, its activities and its results are regularly presented to EU agencies, national ministries, EC DGs as well as in scientific conferences. PARC is also **working closely with regulators to ensure that results** are taken into account (e.g. Close collaboration led to the identification of Key Areas of Regulatory Challenges (KARC)).
- **Chemical Leaders** (CLs) and **Methodology Leaders** (MLs) have been appointed to **summarise PARC results** in dedicated communication materials for policymakers (e.g. policy briefs, state-of-the-art).

005.

EU & INTERNATIONAL COOPERATION

Promote collaboration across European programmes and strengthen EU leadership in global chemical risk research.

- PARC contributes to facilitate the uptake and use of **Next Generation Risk Assessment** (NGRA) approaches in regulatory processes (ex: PARC's feedback to the EC for the preparation of the roadmap for phasing out animal in chemical safety assessments).
- A **Synergy Network (SYNet)** has been established to set-up collaboration opportunities and facilitate knowledge sharing with like-minded activities (ex: EURION, ASPIS, etc.).
- PARC proactively seeks **collaboration and interaction** with **European and international bodies** (JRC, OECD, WHO, etc.).

006.

COMMUNICATION & PUBLIC AWARENESS

Ensure transparent dissemination, public access, and citizen understanding of chemical risk assessment results.

- Dedicated **communication tools, strategy as well as materials** are available (website, social networks, etc.) to synthesise PARC outputs in key messages adapted to the audience.
- The **Stakeholder Forum** composed of private sector actors as well as civil society NGOs has been established to facilitate PARC's outreach and ensure interaction with outside stakeholders.
- **National Hubs** are also continuously leveraged to promote exchange and dissemination at the national level.
- The **Indicator framework** has been set-up and is updated yearly to ensure a transparent monitoring of the progress of the partnership.

Specific Objective 2
Scientific Impact

European and national risk assessment entities and their scientific networks carry out a joint research and innovation programme to respond to the agreed priorities in chemicals risk assessment.

WHAT HAS BEEN ACHIEVED SO FAR?

007.

ANNUAL WORK PROGRAMMES

Develop and implement yearly research and innovation work programmes

- PARC has established a **portfolio of projects** (100+) approved through a clear and rigorous review process to ensure alignment with priorities identified during discussion between scientific and regulatory key actors.
- Each year, new projects are reviewed and included in PARC works program.

008.

MONITORING CAPACITY

Extend the HBM4EU platform and integrate data for regulatory purposes

- PARC has launched a **HBM general population survey with EU wide coverage** by aligning and harmonising national and/or regional HBM studies across Europe. Additional HBM occupational surveys are also performed.
- Based on the HBM data collected, **add-on studies using innovative methods are performed** (use of suspect screening, non-targeted screening, effect directed analysis, innovative sampling approaches, etc.).
- HBM platform developed under HBM4EU has been expanded with the setup of **PARC HBM laboratory network**.
- Pilot studies for **environmental monitoring** have started (PFAS in freshwater, endocrine-disruptors, etc.).
- PARC actively contributes to the discussion on the **new European monitoring programme** under development.

0010.

FAIR DATA & ADVANCED ANALYTICS

Implement FAIR data practices and boost innovation in data analysis for risk assessment

- PARC promotes **data harmonisation** and **data exchange** between different actors (scientific community, health agencies, regulators, policy-makers) to ensure transparency and data re-use.
- PARC produces **high-quality data** and ensures their **accessibility**, **interoperability** and **usefulness** in line with FAIR data approach.

0012.

MODELS & INNOVATIVE TOOLS

Develop advanced models, concepts, and tools for chemical risk assessment

- PARC has set-up **collaboration** with the JRC and the European Commission to perform stakeholders consultation and trainings (e.g. SSbD, NGRA roadmap, etc.).
- PARC actively **develops** and **refines models** as well as **innovative concepts** to support risk assessment.

Specific Objective 3
Economic Impact

European risk assessors, their scientific network and the wider stakeholder community have access to the R&I capacities required to implement innovative chemical risk assessment and communicate transparently to citizens and impacted stakeholders.

WHAT HAS BEEN ACHIEVED SO FAR?

009.

TOOL DEVELOPMENT FOR REGULATORY UPTAKE

Facilitate PARC results use in regulatory RA and support standardisation processes.

- PARC has established a **portfolio of projects** (100+) approved through a clear and rigorous review process to ensure alignment with priorities identified during discussion between scientific and regulatory key actors.
- Each year, new projects are reviewed and included in PARC works program.

0011.

ANALYTICAL & TOXICOLOGICAL NETWORKS

Consolidate and develop networks of laboratories and research centers

- PARC **consolidates** already existing HBM, analytical, toxicological and fit-for-purpose **networks of laboratories and research centers**.
- PARC has mapped out and maintain a **first inventory of air quality monitoring laboratories**.

0013.

CAPACITY BUILDING

Develop and implement training and exchange programmes in chemical risk assessment.

- PARC is developing and carrying out **training and exchange programmes in chemical risk assessment** tailored to the training needs identified (and frequently updated).
- PARC also **identify and promotes external training opportunities** such as events and online resources on relevant topics.

6.2 Prioritisation process

Priorities of PARC for years 4 to 7 have been set considering the initial needs expressed by the GB Principal Representatives (GB PRs) in 2023; through the 'Mapping of Needs Survey'. These needs have been extensively discussed with WPLs, and later, within the NHs to ensure synergy with their national needs as well as the SF — further explanation below.

Initially, topics for which at least 3 needs were expressed by GB PRs in a task were retained, and all the needs expressed by the EU Hub were selected. For each topic, e.g., a substance, endpoint or method, the needs and research questions were listed, as well as the regulatory context and the related projects within PARC or initiatives outside PARC.

In a second step, the needs were classified into different categories: (a) Already addressed in PARC, (b) Could be addressed by PARC, (c) Further discussion needed, (d) Not a priority to PARC.

Once this comprehensive list of needs by topic and the categories were established, a new consultation phase began, mainly involving the consultation of the NHs and the SF, who were asked to highlight their top 5 priorities from categories b and c. The IB also informed us about initiatives outside PARC in line with the topics, avoiding duplication of work.

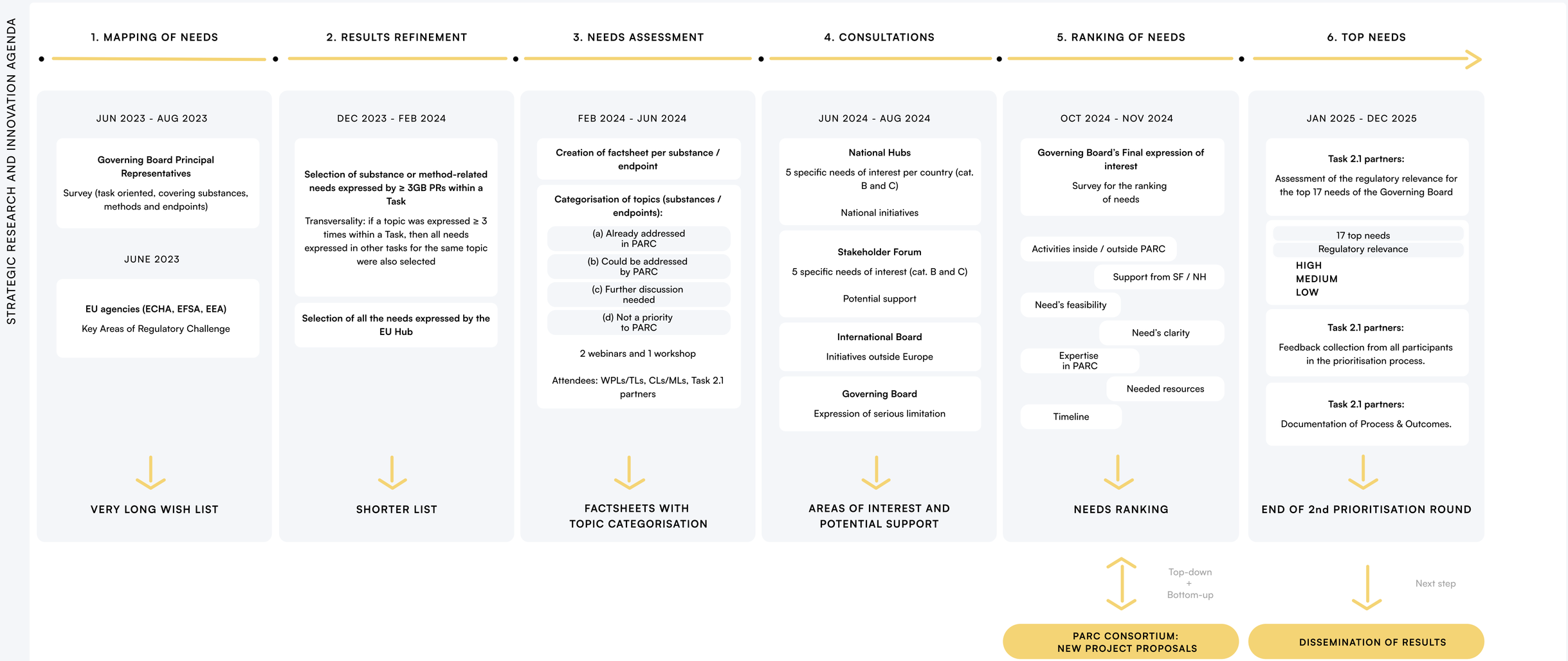


Fig. 12 — Overview of PARC's second prioritisation round

The 90 needs were finally ranked based on the support of the GB PRs. The 17 top needs that received at least 6 votes are listed in the table below.

TOP 17 PRIORITIES FOLLOWING THE GB CONSULTATION

TOPIC	NEED	TASK(S)*	GB VOTES
New Approach Methods (NAMs) for Replacing Animal Testing	How to use NAM for CLP classification and OEL development.	T6.1 T6.3 T6.4	10
Developmental and Reproductive Toxicology (DART)	Develop new approach methods (NAMs) to replace animal testing for hazard endpoints (e.g., acute fish toxicity).	T5.2	8
	Development of NAMs (including developmental immunotoxicity and developmental neurotoxicity).	T5.2	7
Neurotoxicity	Development of NAMs (DNT, ANT); Identification of reliable positive and negative reference chemicals for NAM reliability testing and validation.	T5.2	7
Immunotoxicity	Study the effects of chemicals on the immune system (+sensitive populations); Identification of critical windows of its development to develop NAMs for DIT.	T5.2 T6.2	6
Battery Chemicals	Biomonitoring of workers (e.g., lithium, cobalt, nickel salts, also fluorinated compounds and ionic liquids).	T4.1 (workers) T6.2	9
Substances in Welding Fumes	Collection of biomonitoring data for workers (e.g., manganese).	T4.1 (workers)	7
Benzophenones and UV Filters	Collection of exposure data across Europe.	T4.1	8
Flame Retardants	Data needed on human exposure and effects (general population) + substitutes.	T4.1 T6.2	8
Natural toxins	Data on human exposure and effect: Mycotoxins (e.g., enniatins, alternaria).	T4.1	6
PMT/vPvM Substances	Monitoring in soil, water, and biota.	T4.2	9
Chemicals Leaching from Plastics and Rubber Tyres	More environmental monitoring on fate and behaviour of tyre additives, including PPD and metabolites.	T4.2	7
Co-exposure to Multiple Chemicals	Close data gaps on chemicals leaching from plastics for human health, including non-intentionally added substances to plastics.	T5.1	9
	Further development of methods for health and environmental risk assessment of co-exposures to multiple chemicals.	T6.2	9
PFAS	Studies on the properties, behaviour in the environment, ecotoxicity and human toxicity of PFAS other than PFOS, PFOAS and PFHxS.	T5.1	7
	Develop fast and efficient analytical methods for PFAS in products and articles.	T6.4	7
	General Population: Develop knowledge on alternatives and substitutes.	T4.1 T6.2	6

*See annex for tasks description

These research questions selected by the consortium are being translated into projects for the coming years of the partnership (including Year 4), ensuring a top-down ↔ bottom-up approach.

6.3 Rapid Response Mechanism process

The Rapid Response Mechanism (RRM) is a process established to effectively tackle rapidly-emerging regulatory challenges and ensure that PARC remain adaptable and aligned with new regulatory needs. It is complementary to the standard planning of activities and prioritisation process and contributes to the OO2, OO3 and OO4.

Concretely, it is designed to increase responsiveness and ensure that urgent needs for information in the EU policy community and at national level in human health or Environmental health concerns can be addressed in a timely and transparent manner.

This mechanism can be activated by the Governing Board members, Stakeholder Forum members, National and European Hub members (via Governing Board representative). For instance, it has been activated on PFAS and MnHexP and the needs have been integrated in PARC activities.

Once activated, the PARC partnership quickly assesses the request and — if judged relevant — integrates ad-hoc activities in the PARC workflow, through a dedicated PARC activity/project, or the integration of the issue in an existing PARC project.

6.4 Indicator framework

To adequately track and report on the progress of PARC towards the Strategic Objectives and Operational Objectives exposed above, PARC T1.3 has designed an indicators framework formulated in three levels which feed into each other: (i) output indicators, (ii) outcome indicators and (iii) impact indicators.

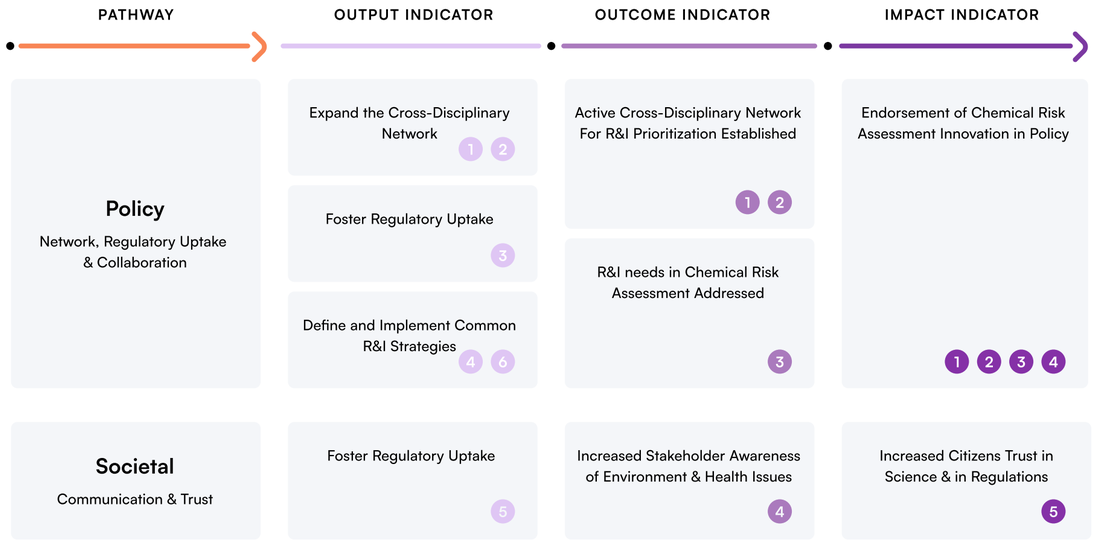
Fig. 13— PARC's indicator framework

Essentially, the output indicators are an instrument to monitor the progress during the PARC project. Outcome indicators are used as an instrument to monitor the societal, political, scientific and economic effect of PARC resulting from the output indicators. To monitor the impact of PARC on policy, science and society in the broad sense, impact indicators are used.

The data for the indicators is updated on a yearly basis and shared on the PARC website to ensure transparency and to facilitate monitoring for stakeholders.
In addition, the indicator framework is organised through impact pathways which align with the three Specific Objectives (i) Policy and Societal impact, (ii) Scientific impact and (iii) Economic impact (see Fig. 12).

FOR MORE INFORMATION
You can find more details & numbers on the indicator framework on the PARC Website

POLICY AND SOCIETAL IMPACT



SCIENTIFIC IMPACT

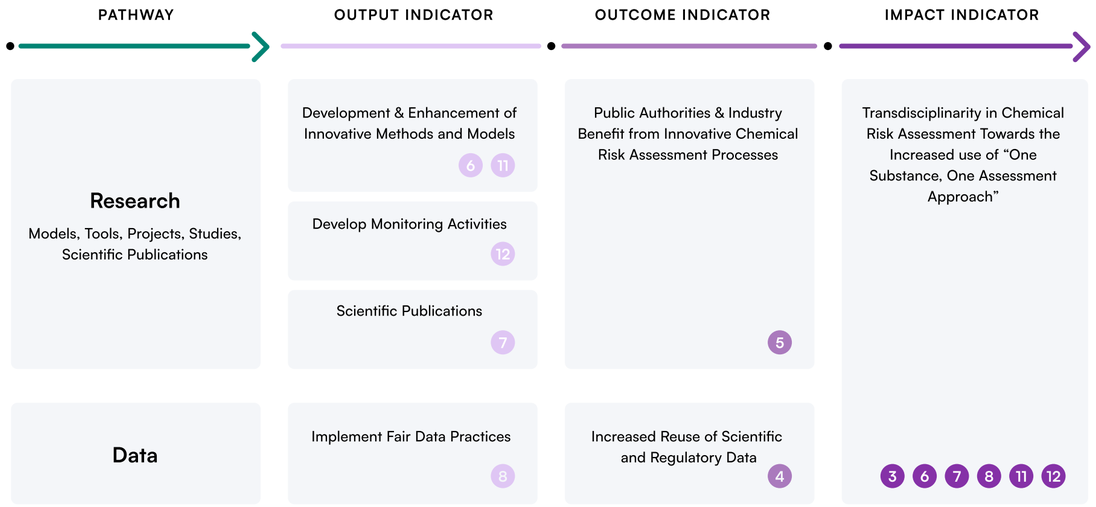


Fig. 14— PARC Impact pathways

ECONOMIC IMPACT

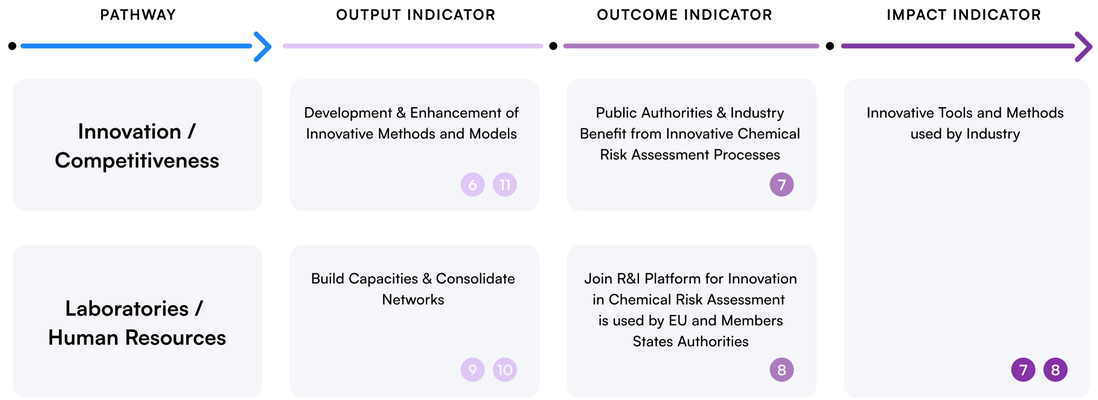


Fig. 14— PARC Impact pathways

6.5 Sustainability of PARC activities and "exit strategy"

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

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.). 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 useful. Likewise, the strong co-design link established in PARC between the scientific and policymaking community should be leveraged. There is also a clear difference between the stages of the reflection on the exit strategy of the different activities, some being more advanced than others.

Through surveys, launched as soon as the 1st year of PARC, and targeted meetings and workshops with the different WPs and governance boards of PARC, initial thoughts and possibilities for the sustainability of PARC activities are reflected upon and developed as activities progress. Anchoring certain activities, such as an EU-wide European Human Biomonitoring programme, in a legal framework, and coordinating the efforts, could not only improve chemical risk assessment but also enhance its cost-effectiveness.

Chemical risk assessment requires contributions from exposure sciences and toxicological sciences as well as computational skills and infrastructures. It also needs high quality-data and metadata. The strength of PARC is bringing all these together in a truly One Health approach. A challenge will be to further develop the activities and to maintain the connection between them. The "options" discussed evolve with the policy context, notably in light of the "one substance, one assessment" legislative proposals of the Commission, which address a number of activities of PARC.

7. INTERNATIONAL ACTIVITIES AND SYNERGIES

7 International activities and synergies

PARC actively contributes to fostering connections among international stakeholders including governmental bodies, academic institutions, research organisations, industry leaders, and non-governmental organisations.

7.1 Building International Networks

The regulatory framework for chemicals is established through international frameworks supporting chemical risk assessment and protection of human health and the environment through international treaties. PARC is firmly committed to engaging at the international level, collaborating with global initiatives and organisations to shape the future of chemical risk assessment. By leveraging its multidisciplinary expertise, PARC is positioned as a key enabler in the development of robust international networks, cutting-edge tools, data management practices, and the establishment of trends in global chemical risk assessment practices. PARC is contributing notably to facilitate the uptake and use of NGRA approaches in regulatory processes. In the different domains of PARC, methods and approaches will be applied in case studies, proficiency tests will be supported, and collaboration and interaction will be pro-actively sought with European and international bodies (e.g. EC—Joint Research Centre (JRC), Organisation for Economic Co-operation and Development (OECD) and World Health Organization (WHO)). This will allow for the characterisation of the NGRA approaches in terms of regulatory relevance, reliability and domain of application and move them forward on the path of standardisation.

The impact of undesirable chemicals on human health and ecosystems is a major international concern, and the UNEP has set up a “Science-policy Panel to Contribute Further to the Sound Management of Chemicals and Waste and to Prevent Pollution”. By establishing research and innovation activities in the fields of human and environmental monitoring in close collaboration with those involved in food safety monitoring, the PARC partnership is strengthening collaboration between laboratory networks and exposure monitoring specialists working within different regulatory frameworks with the same objectives of providing early warning, monitoring trends and analysing the health impacts of management and prevention measures. PARC is also collaborating with the exposome initiatives as well as initiatives in the field of environment to provide a better understanding of the fate of chemicals and support international policy initiatives.

PARC will also contribute to the activities of the Inter-governmental Science-Policy Platform on biodiversity and ecosystem services (IPBES) in close collaboration with other EU partnerships by sharing data, models and knowledge, on the field of research and development of safer and more sustainable chemical alternatives, chemicals monitoring and risk assessment.

7.2 SYNnet approach

The impact of PARC is boosted through the dissemination of outcomes produced and by fostering synergies and collaborations with other initiatives at national and international level. PARC is promoting the establishment of effective and efficient collaborations with other relevant scientific and/or regulatory initiatives. PARC has been structured to foster both formal synergies and informal collaborations via various channels. PARC has signed a specific collaboration agreement with the Joint Research Centre to advance scientific knowledge for the Assessment of Risks from Chemicals in the framework of PARC and to ensure that the results obtained are useful to support policy-making and the development and implementation of EU regulation. In particular, the JRC provides added value regarding such aspects as supporting harmonisation and standardisation of emerging approaches, promotion of research results, and interfacing with the regulatory community.

SYNnet

Discussions and collaboration on where and how PARC contributes to the CSS indicator framework have been implemented. PARC has identified the promotion of cooperations with other R&I initiatives as one of its operational objectives. To further support its mission, PARC has established SYNnet, a network designed to facilitate collaboration and knowledge sharing with other initiatives focusing on environmental, food, and human health issues and organisations working in the field of chemical risk assessment. Our aim with SYNnet is to advance R&I in chemical risk assessment through establishing official synergies. SYNnet helps identify interested external activities, establish synergies, and track the progress and outcomes of the collaborations.

SYNnet collects expressions of interest from external initiatives and mediates the dialogue between these initiatives and PARC relevant activity co-leaders, promoting the establishment of collaborations. Furthermore, a mapping of the external activities working in related areas is performed and workshops with selected external initiatives are organised. Two workshops have already taken place, in which the ASPIS Cluster, the partnership BioDiversa+, the NORMAN Association, and the projects from the EURION, ENKORE and Green Deal clusters were represented.

Dedicated scientific meetings, designated SYNnet Forums, are also organised back-to-back with relevant scientific events to promote dialogue and knowledge sharing among scientists, promote the establishment of synergies and disseminate the results and outcomes of the collaborations established. Two SYNnet Forums have already been organised back-to-back with the SETAC Europe 2024 Meeting and with the EEMGS 2024 Meeting.

The synergies with external activities and the network mapped with SYNnet are promoted through PARC's website.

PARC collaborations with existing H2020 clusters, such as EURION and ASPIS, and national research projects through the scientists participating in these projects have facilitated the uptake of results and the identification of complementary research to be performed by PARC projects. Moreover, available tools previously developed have been selected to support further activities in different PARC projects.

PARC has also established effective collaborations in the conceptualisation and operationalisation of the concept of safe and sustainable by design approach, including through supporting the SSbD bootcamps.

7.3 International Board

Composed of high-level experts in the various fields of chemical risk assessment from all over the world, the board brings together a wealth of scientific and regulatory knowledge and experience to help shape PARC's international collaborations and maximise innovation and competitiveness. The board meets at least three times a year, thus facilitating the exchange of ideas and best practices, ensuring that PARC's work remains at the forefront of global scientific and policy developments. The IB contributes to the science-to-policy dialogue, identification of synergies & collaborations, contribution on open science, new approaches. The IB includes experts from other international chemical risk assessment platforms, scientific advisory boards and scientific societies, and experts in related EU and international institutions and activities.

7.4 Practical contribution to international initiatives

Through participation of PARC's scientists in global forums, such as the United Nations Environment Programme (UNEP), the Organisation for Economic Co-operation and Development (OECD), the World Health Organisation's EHP Partnership on Human Biomonitoring, PARC ensures that the European perspective on chemical risk assessment is aligned with global priorities and policy frameworks. These collaborations enhance the exchange of knowledge and support the harmonisation of risk assessment methodologies across borders.

PARC plays a significant role in supporting the UNEP Science-Policy Panel on Chemicals and Waste, with its work directly contributing to the panel's efforts in advancing global chemical safety and waste management. PARC's research and innovations in chemical risk assessment feed into the panel's mission by providing scientific evidence, tools, and methodologies that inform policy decisions. Through this collaboration, PARC supports UNEP in its goal to promote sound chemicals management and sustainable development worldwide. By aligning its work with the panel's priorities, PARC strengthens the integration of science and policy, ensuring that chemical risk assessment approaches are robust, evidence-based, and aligned with global sustainability objectives.

Other important initiatives that PARC scientists are contributing to include the Exposome Moonshot forum, which will (i) create a public-private partnership of key constituents to support strategies to propel the field forward through innovation, education, and legislation; (ii) develop a conceptual framework and the technical innovations necessary to establish the Human Exposome Project and its governance; and (iii) develop an actionable roadmap towards realization and integration of tools and datasets across industries. Several PARC partners are involved in shaping the roadmap and the framework.

7.5 Setting Global Trends in Chemical Risk Assessment

PARC plays a pivotal role in setting the direction for future research and innovation in the field of chemical risk assessment. By engaging with international scientific communities and leading collaborative research projects, PARC is helping to shape the global agenda on emerging chemical risks and the development of new risk assessment models. This includes advancing the use of new alternative methodologies, promoting the integration of environmental and health risk considerations, and supporting the development of data-sharing platforms that enhance global regulatory capacity.

FAIR Initiatives: Global Contribution through RDA and CoDATA

On the FAIR (Findable, Accessible, Interoperable, and Reusable) side, PARC is actively contributing to global activities through its participation in the Research Data Alliance (RDA) and the CoDATA Cross-domain Implementation Framework. These international initiatives play a crucial role in advancing global data sharing practices and interoperability across research domains. By engaging with the RDA and CoDATA, PARC helps to foster the development of standards and best practices for managing research data, ensuring that data related to chemical risk assessment is accessible, reusable, and aligns with global frameworks for cross-domain data integration. This collaboration strengthens PARC's position in promoting FAIR data principles and supports the broader global research community in achieving greater data transparency and cooperation.

8. ANNEX

Annex 1 - Projects table (Y1-Y4*)

Legend

- Started Y1
- Started Y2
- Started Y3
- Planned start Y4

PROJECT ID	PROJECT FULL TITLE	DURATION
P2.1.a_Y3_MnHexP-RRM_UBA	[RRM] Mono-n-hexyl phthalate, extent of exposure and potential sources	M29-M76
P4.1.1.2.a_Y1_GenHBMSurvey_VITO	PARC General Survey (PARC Aligned Studies)	M1—M81
P4.1.1.3.a_Y4_PFASMothermilk_LNS_BPI	PFAS in Mother Milk: pregnancy and postnatal health	M37—M81
P4.1.1.3.b_Y4_PFASChildren_SpF	Description of PFAS Exposure in early life in European countries: study on young children (6—11y)	M37—M81
P4.1.1.3.c_Y4_TimePatternEU_VITO	Time patterns of internal human exposure to environmental pollutants in Europe	M37-M72
P4.1.1.4.a_Y1_OccupFeasability_TTL	Feasibility study to evaluate occupational exposure in general surveys	M1-M29
P4.1.1.4.b_Y1_SentinelSystem_KULeuven	Assessment of exposure to substances of high concern in the working population through a sentinel surveillance system: Mapping and preparation of proof-of-concept	M1-M36
P4.1.1.4.d_Y1_OccupWaste_ENSP_TTL	Occupational survey in the healthcare sector	M1-M48
P4.1.1.4.c_Y1_HealthCareSurvey_TTL_SRU	Occupational survey in the waste management sector	M1-M48
P4.1.3.1.a_Y1_DerivationofHBM-GVs_UBA	Derivation of health-based HBM guidance values (HBM-GVs)	M1-M81
P4.1.3.3.a_Y1_RoadmapLinkingHBMhealth_SpF_VITO	Derivation of Health-based Indoor Air Guideline Values	M37-M81
P4.1.3.1.b_Y4_Health-based-IA-GV_LNS_NCPHP	Roadmap to explore the links between prioritized chemical substances exposure	M1-M52
P4.1.4.2.a_Y1_DataAnalysisHBM4EU_VITO	Further analysis of the data generated within HBM4EU	M1-M48
P4.1.5.a_Y1_SustainHBMSystem_VITO	Preparation of a sustainable monitoring and surveillance system for Europe	M1-M66
P4.2.a_Y1_ENVMonitoringPilotSurvey_INERIS_AU	Establishment of the overall process of environmental and multisource monitoring with the help of a pilot study addressing PFAS and endocrine disruptors	M1-M42
P4.2.a_Y1_ENVMonitoringPilotSurvey_INERIS_AU	Applications of a framework for priority setting in environmental and multisource monitoring	M13-M36
P4.2.c_Y3_Human exposure_INERIS_AU	Human exposure to organic contaminants from non-food sources	M25-M72
P4.2.d_Y4_Siloxanes_AU_INERIS	Volatile siloxanes in the European environment — towards robust data in support of regulatory action	M25-M72
P4.3.1.a_Y1_T01-Concept Paper_MU	Global collective definition and prioritisation of main concepts, approaches and objectives associated to innovative methods undertaken in task 4.3 (inventories, selection/prioritisation, shared knowledge and visions among environmentalfood-HBM communities)	M1-M12
P4.3.1.b_Y1_T02-QAQC_WR	QA/QC requirements for HRMS and EDA-based screening approaches in environmental, food and human matricesv	M37-M60
P4.3.1.c_Y1_T03-EWStools_SLU	Illustrating the usefulness of innovative (self-)sampling combined with integrated suspect/NTS/EDA approaches as a contribution to early warning system and harmonized framework from environment-food-human	M1-M60
P4.3.1.d_Y1_T04-Data Processing Workflow_EHESP	Establishment of necessary advanced data processing methodologies and bioinformatic tools for NTS. Identify gaps / necessary methodological improvements for retrospective use of NTS HRMS data (digital sample freezing platform) and EU capacity in terms of centralized data repository	M1-M60
P4.3.2.a_Y1_H01-Perinatal exposure_INRAE	Proof-of-concept of innovative sampling and HRMS based / EDA screening methods for exploring human perinatal exposure to chemicals of emerging concern	M1-M48
P4.3.2.b_Y2_H02-Occupational exposure_INRS	Proof-of-concept of innovative sampling and HRMS based screening methods for exploring occupational exposure to chemicals of emerging concern	M13-M60
P4.3.2.c_Y3_H03-Complementary developments_JSI-Uantwerpen	Complementary developments regarding the application of HRMS based / EDA screening methods on human samples	M25-M72

PROJECT ID	PROJECT FULL TITLE	DURATION
P4.3.3.a_Y1_E01-Wastewater based epidemiology_UFZ-UBATH	Mining chemical information from wastewater treatment plants for I. human community (wastewater fingerprinting for community wide human exposure assessment) and II. environmental exposure assessment (screening of wastewater treatment plant effluents to assess the release of Chemicals of Emerging Concern into the water cycle).	M1-M48
P4.3.3.b_Y2_E02-Sentinel animals_ONIRIS	Proof-of-concept of innovative sampling and HRMS based / EDA screening methods for exploring chemicals of emerging concern in sentinel animal species	M13-M60
P4.3.4.a_Y2_F02-Food items exposure_ANSES	Complementary developments regarding the application of HRMS based/EDA screening methods on food samples	M13-M48
P5.1.1.a_Y1_Toxins_BfR_UNIVIE	Hazard characterisation of the mycotoxins enniatins and Alternaria toxins in order to close data gaps and improve risk assessment for human health	M1-M48
P5.1.1.b_Y1_BPA_HumTox_BfR	Hazard assessment of bisphenol A alternatives to close data gaps of concern for human health and improve their risk assessment	M1-M54
P5.1.1.c_Y3_TG+ EnnB1_ANSES	TG+ Enniatin B1	M25-M60
P5.1.1.d_Y4_PlasticLeach_NIPH	Hazard characterization of leachable chemicals present in plastics	M37-M81
P5.1.2.a_Y1_NaturalToxinsAqua_UGent	Toxicity assessment of naturally occurring toxins on aquatic organisms	M1-M36
P5.1.2.b_Y1_BPAalternatives_BPI_MU	BPA alternatives and associated mixtures (data gaps and NAM development)	M1-M48
P5.1.2.c_Y4_TG+MP_ANSES	TG+ Microplastic bioaccumulation datagaps and applicability of in vitro bioaccumulation assessment methods (environment)*	M37-M60
P5.2.a_Y4_ RegNAMs _ANSES	Regulatory readiness of NAMs	M37-M81
P5.2.1.a_Y1_NGTXCs_INRAE	Non-genotoxic carcinogens	M1-M60
P5.2.1.b_Y1_MD-EDC_BfR	Metabolic Endocrine Disruption	M1-M48
P5.2.1.c_Y1_EDThDisruption_DTU	Endocrine disruptors — Thyroid hormone system disruption	M1-M48
P5.2.1.d_Y1_Immunotox_Inserm	Immunotoxicity	M1-M48
P5.2.1.e_Y1_DNT-ANT_UFZ_IUF_NIPH	Neurotoxicity	M1-M48
P5.2.1.f_Y4_DART-ED_DTU	Developmental and Reproductive Toxicity - Endocrine Disruption (DART-ED)	M37-M81
P5.2.1.g_Y4_DIT-NAM_INSERM	Developmental Immunotoxicity - NAM development	M37-M81
P5.2.1.h_Y4_SDHEPATOX_ANSES	Sexual dimorphism associated to susceptibility to hepatotoxicity of environmental contaminants	M37-M60
P5.3.1.a_Y1_SystemsToxicology_UL-LACDR	Systems toxicology approaches for mechanism-based chemical safety assessment	M1-M48
P5.3.1.b_Y4_grOMICS_UL-LACDR	Fostering the use of omics for grouping and read-across in risk assessment	M37-M81
P5.3.2.a_Y1_AOPDevelopment_Inserm	AOP Development	M1-M48
P5.3.4.a_Y1_PBK_Kinetics_Fraunhofer	PBK models and quantitative systems toxicology	M1-M48
P5.3.4.b_Y4_RESUPT_RIVM	In vitro methods to assess respiratory uptake & toxicity	M37-M81
P6.1.1.a_Y1_HumanRelevance_RIVM	Workflow for Human Relevance Assessment of AOPs and Associated New Approach Methodologies	M1-M36
P6.1.1.b_Y1_IATA-ED_UAntwerpen	Integrated Approaches to Testing and Assessment (IATA) for Endocrine Disruption	M1-M36
P6.1.1.c_Y1_IATA_GENTOX_Sciensano	Integrated approaches to testing and assessment (IATA) for genotoxicity	M1-M48

*Includes projects foreseen for a start in Y4. Also includes case-studies.

Annex 1 - Projects table (Y1-Y4*)

Legend

- Started Y1
- Started Y2
- Started Y3
- Planned start Y4

PROJECT ID	PROJECT FULL TITLE	DURATION
P6.1.1.d_Y1_IATA_STOT_UL-LACDR	Integrated Approaches to Testing and Assessment (IATA) for Systemic Target Organ Toxicity	M1-M48
P6.1.1.e_Y4_FISH-THSD_Uantwerpen	An AOP network-based approach for assessing thyroid hormone system disruptors in fish (FISH-THSD)	M37-M81
P6.1.1.f_Y4_HumanRelevance_RIVM	Workflow for Human Relevance Assessment of AOPs and Associated New Approach Methodologies	M37-M81
P6.2.1.a_Y1_SourcetoDose_VITO	Developing, performing and validation of source to dose modelling including selected case studies	M1-M42
P6.2.1.b_Y1_Aggregate_Anses	Strategy for aggregate exposure from general life and occupational exposures	M1-M48
P6.2.2.a_Y1_PBPK_INERIS_AUTH	Refinement and development of PBPK models for human risk assessment	M1-M48
P6.2.3.a_Y1_RealLifeMixtures_RIVM	New risk assessment and exposome methodologies to reduce exposure and risk of real-life mixtures	M1-M48
P6.2.4.a_Y1_HIADataAvailability_VITO	Collection and generation of data for HIA of PARC priority chemicals	M1-M66
P6.2.4.b_Y1_HIAMethod_UU-IRAS	Improvement of health impact assessment methodologies	M1-M66
P6.2.4.c_Y1_HIACaseStudies_UU-IRAS	Case studies on environmental burden of disease, health impact assessment	M1-M42
P6.2.4.d_Y1_HIAIndicators_VITO	Development of a set of risk and health impact indicators	M1-M42
P6.3.1.a_Y1_SubstanceRA_SU	Review of substance-specific risk assessment	M1-M48
P6.3.1.a_Y1_SubstanceRA_SU_CS12_MethodOSOA_SU	Methods to identify coordination needs towards a 'one substance one assessment' approach	M1-M42
P6.3.1.a_Y1_SubstanceRA_SU_CS13_Plasticizers RA_UCL	Identification of differences and loopholes in the regulation of plastic additives	M1-M36
P6.3.1.a_Y1_SubstanceRA_SU_CS14_Biocides RA_SU	Identification of loopholes for substances with biocidal properties	M1-M42
P6.3.1.b_Y1_EffectRA_BPI	Review of effect-specific risk assessment	M1-M48
P6.3.1.b_Y1_EffectRA_BPI_CS9_SKINSENSIRISK_REGIONH	Skin sensitisation and risk assessment methodologies	M6-M54
P6.3.1.b_Y1_EffectRA_BPI_CS10_ED-Cosmetics_VUB	Evaluation of risk assessment approaches used for cosmetic ingredients with endocrine-disrupting (ED) concern	M8-M42
P6.3.1.b_Y1_EffectRA_BPI_CS11_GenotoxCarc_ISS	Analysis and evaluation of genotoxicity and carcinogenicity assessment across legislations, with a special focus on (Q)SAR based approaches.	M1-M48
P6.3.1.b_Y1_EffectRA_BPI_CS15_DNT_SU	Evaluation of conclusions drawn in guideline-compliant developmental neurotoxicity studies	M1-M48
P6.3.1.b_Y1_EffectRA_BPI_CS17_ED-in vitro_BPI	Use of non-guideline in vitro studies for ED assessments	M1-M48
P6.3.1.b_Y1_EffectRA_BPI_CS18_ED-classes_BPI	New hazard classes and test requirements for endocrine disruption	M1-M48
P6.3.2.a_Y1_ToolsRA_SU	Review of tools, criteria, and methods used in risk assessment	M1-M48
P6.3.2.a_Y1_ToolsRA_SU_CS1_CARB_SYKE	Comparative analysis of risk-based decision benchmarks in the EU regulatory framework	M1-M48
P6.3.2.a_Y1_ToolsRA_SU_CS2_RiskReduction_SU	Identification and review of methods for evaluating the effectiveness of risk assessment for reducing risk	M1-M36
P6.3.2.a_Y1_ToolsRA_SU_CS3_WorkplaceRA_TTL	Use of regulatory information in workplace chemical risk assessment	M1-M38
P6.3.2.a_Y1_ToolsRA_SU_CS4_SecPoisoning_INERIS	Assessment of the approaches used to address secondary poisoning under current chemical regulations and identification of possible improvements needed to achieve an adequate protection of wildlife	M2-M48
P6.3.2.a_Y1_ToolsRA_SU_CS7_REGPREP_EAWAG	Protecting the same ecosystem under different regulations: Differences and similarities of prospective and retrospective risk assessment for pesticides	M1-M48
P6.3.2.a_Y1_ToolsRA_SU_CS8_OccupReproDev_KI	A review of guidance values targeting occupational exposures to reproductive and developmental toxicants	M1-M48
P6.3.2.a_Y1_ToolsRA_SU_CS16_UncertaintyRA_ULUND	Practical challenges in using quantitative expressions of uncertainty in assessment	M1-M48
P6.3.2.a_Y1_ToolsRA_SU_CS19_DataGapFilling_DTU	Status of chemical data gap filling approaches across EU regulation	M13-M30
P6.3.2.a_Y1_ToolsRA_SU_CS20_Y3_PESTNAM_ISS	Understanding the implementation and use of NAMs in pesticide dossiers in both the HH and the environment	M25-M48
P6.4.1.a_Y1_OPREMIXCS1_BRUNEL_RWTH	Optimizing regulatory risk assessment and management of chemical mixtures in Europe	M1-M40
P6.4.1.b_Y1_MONAMMIXCS2_UFZ	Dealing with unknown mixtures in regulatory risk assessments through the use of monitoring data and NAMs	M1-M40
P6.4.1.c_Y3_Skinsenmix_RegionH	Towards establishing New Approach Methods in the risk assessment of skin sensitizing mixtures	M25-M72
P6.4.1.d_Y4_RE-MIX_UBA_Eawag	Options to assess and regulate mixtures	M37-M81
P6.4.2.a_Y1_LandscapingSurv_UNIBAS	Status of integration and use of New Approach Methodologies in the EU regulatory risk assessment landscape	M1-M36
P6.4.2.b_Y1_NGRApractice_VKM_NIPH	Next generation risk assessment applied in practice	M1-81
P6.4.2.c_Y1_NAMAM_UT	Landscape and readiness of computational new approach methods based on advanced AI and ML approaches for chemicals' next generation risk assessment	M1-M36
P6.4.2.d_Y4_RegulatoryNAMs_ISS	Demonstrating the applicability of NAMs for specific regulatory processes through a series of case studies	M37-M81
P6.4.2.e_Y4_READYAI_UNIBAS	Establishment of readiness criteria for AI/ML-based tools used in risk assessment	M37-M81
P6.4.3.a_Y1_SuProM_MU	A comprehensive review and application of databases and testing methods for SUbstances in PRoducts and Materials	M1-M36
P6.4.3.b_Y3_ENFORCE_KemI	New methods to support the ENFORCEment of chemicals in articles and chemical products	M25-M72
P6.4.4.a_Y1_CRNCS1_KEMI	Clarify regulatory needs — Transform EU strategies into regulatory useable research projects	M1-M81
P6.4.4.b_Y1_PPPEXPCS2_RPTU	Reduce complexity of models for predicted environmental concentrations of plant protection products while ensuring their predictive capacity	M1-M81
P6.4.4.c_Y1_PPPEFFCS3_UFZ	Reduce complexity of models for predictions of environmental effects of plant protection products while ensuring their predictive capacity	M1-M81
P6.4.4.d_Y1_PPPBENCHCS4_UDE	Benchmark ERA to support the transition towards a holistic paradigm	M1-M48
P6.4.4.e_Y1_PPPOSCS5_ISCIII	Quantify effects of PPP and other stressors through landscape risk assessment informing on environmental impact	M1-M81
P7.2.2.a_Y1_chemicals-in-environment_MU	Chemicals in the Environment data reuse	M1-M42
P7.2.2.b_Y1_HBMdatasets_VITO	FAIR and sustainable storage of human biomonitoring (HBM) datasets	M1-M48
P7.3.3.a_Y1_ALT-IST_IISPV	Alternative Predictive Testing Strategy for the Safety of Chemicals based on Integrative Systems Toxicology	M1-M60

*Includes projects foreseen for a start in Y4. Also includes case-studies.

Annex 2 - Work Packages and task descriptions

WP1
PARTNERSHIP MANAGEMENT AND COORDINATION

T1.1

OVERALL EXECUTIVE MANAGEMENT AND SUPPORT OF THE PARTNERSHIP

Setting up and implementing an effective management and governance framework for the PARC consortium in order to ensure that all actions are performed within the legal, ethical, financial and administrative rules and regulations and ensure the Partnership's progress, within the defined budget and abiding by the highest quality standards.

T1.2

SCIENTIFIC STEERING AND IMPLEMENTATION OF ANNUAL WORK PLANS

Guiding the PARC consortium and its activities in maintaining the course set out in the Description of Action, achieving milestones and producing the deliverables that have been agreed to.

T1.3

IMPACT EVALUATION AND MONITORING OF THE PERFORMANCE INDICATORS OF THE PARTNERSHIP

Set up the indicators framework and evaluating the impacts and performance through monitoring of the Partnership indicators.

T1.4

ETHICS FRAMEWORK

Setting the ethics framework to ensure that it abides by the contractual and regulatory requirements in this area and providing input to other WP co-leaders concerning ethics and data protection.

WP2
A COMMON SCIENCE-POLICY AGENDA

T2.1

PRIORITY SETTING

Coordinating the prioritisation process and providing inputs regarding regulatory processes and timelines to the PARC MB.

T2.2

KNOWLEDGE MANAGEMENT AND UPTAKE INTO POLICY

Supporting the strategic alignment of the work on the regulatory uptake of PARC results and developing a central knowledge management platform to act as PARC's information and knowledge broker.

T2.3

SUSTAINABILITY

Establishing and ensuring continuous dialogues with the NHCPs and supporting their progress, as well as providing assistance for capacity building and developing the exit strategy. The exit strategy will ensure a crosscutting and holistic long-term approach for R&I in chemical RA to: (1) support the ambitions of the Green Deal, (2) improve the sound management of chemicals and waste, (3) help meet the SDGs.

WP3
SYNERGIES, COLLABORATIONS AND AWARENESS

T3.1

BUILDING EFFECTIVE INTERACTIONS

Ensuring the representativeness of stakeholders from different sectors in the Stakeholder Forum and the formation of a high-level International Board and promoting effective interactions between PARC and both boards through the development of concerted and dynamic strategies, including follow up actions.

T3.2

COMMUNICATION, DISSEMINATION, AND AWARENESS

Developing and ensuring good and transparent external communication and dissemination to increase the visibility of PARC and the impact of the knowledge generated amongst policy-makers, scientists, citizens and other stakeholders at national, EU and international level, contributing to reinforcing the links between science-policy and with citizens.

T3.3

NETWORKING AND SYNERGIES

Establishing collaborations and synergies with other relevant scientific/ regulatory initiatives at national, EU and international level to increase mutual awareness and trust for the benefit of science and its translation into RA, RM and communication activities or tools

WP4
MONITORING AND EXPOSURE

T4.1

HUMAN BIOMONITORING

Further developing the human biomonitoring platform, generating new HBM data, and the network of qualified laboratories for exposure biomarker analysis created in HBM4EU.

T4.2

ENVIRONMENTAL AND MULTISOURCE MONITORING

Better understanding the presence of chemicals in the environment via multiple sources and the resulting exposure of humans and ecosystems in an integrated way.

T4.3

INNOVATIVE METHODS AND TOOLS FOR MONITORING AND SURVEYS

Developing robust, reliable and fit-for-purpose innovative tools and methods to improve or renew existing monitoring schemes, especially to support the exposure assessment for particularly vulnerable sub-populations and the early warning detection of chemicals of emerging concern.

WP5
HAZARD ASSESSMENT

T5.1

TOXICITY TESTING ADDRESSING DATA GAPS OF CONCERN

Investigating and closing data gaps identified by key stakeholders. Activities will be conducted in collaboration with tasks 5.2 and 5.3 as to make best use of biological matrices generated in the context of in vivo studies.

T5.2

INNOVATIVE METHODS AND TOOLS FOR TOXICITY TESTING AND MODELLING

Improving the current hazard characterisation paradigm by establishing comprehensive testing strategies that logically combine novel methods with well-established approaches, preferably in a tiered manner. By combining efforts from the tasks of the WP, the availability and applicability of new approach methodologies (NAMs) in RA will be promoted.

T5.3

QUANTITATIVE SYSTEMS TOXICOLOGY AND DEVELOPMENT OF NEW AOPS

Contributing to the improvement of mechanistic understanding of toxicity by analysing all available data and applying systems toxicology approaches. It will contribute to the development of AOPs and provide data for the improvement of Physiologically Based Toxicokinetic (PBK) models. It further aims at integrating relevant human disease models and developing concepts facilitating in vitro - in vivo extrapolation (IVIVE).

WP6
INNOVATION IN REGULATORY RISK ASSESSMENT

T6.1
INTEGRATED APPROACHES TO TESTING AND ASSESSMENT OF CHEMICALS

Delivering IATAs for a selected set of human health effects. The IATAs will be developed in close collaboration with relevant stakeholders and evaluated through dedicated case studies.

T6.2
INTEGRATIVE EXPOSURE AND RISK ASSESSMENT

Proposing innovative methods, tools and concepts and performing integrative risk and health impact assessments based on internal and external exposure of humans exposed to single chemicals and mixtures from multiple sources and routes for different living environments (including workplace).

T6.3
REVIEW OF RISK ASSESSMENT METHODOLOGY

Mapping and evaluating current methodologies employed in regulatory RA, including regulatory requirements determining the processes, to identify gaps and needs in methodological knowledge.

T6.4
TRANSPOSING RESULTS TO REGULATORY RISK ASSESSMENT METHODOLOGIES

Developing and fostering the uptake of innovative, effective and protective regulatory approaches and methodologies, including for groups of chemicals and chemical mixtures and developing a framework to address risks from chemicals in articles and materials on the EU-market.

WP7
FAIR DATA

T7.1
FAIR DATA POLICY AND IMPLEMENTATION

Developing and implementing a **PARC FAIR Data Policy** and the Data Management Plan.

T7.2
DATA LIBRAIRIES

Developing and implementing tools to make data generated in PARC available for reuse, and to enable access to and reuse of external data sources.

T7.3
INNOVATIVE ANALYSES

Introducing innovative analytical approaches in risk assessment to maximise use and insights from increasing amounts of open and FAIR data.

WP8
CONCEPTS AND TOOLBOXES

T8.1
SAFE AND SUSTAINABLE BY DESIGN

Supporting the operationalisation of the SSbD criteria and methodology developed by the EC and testing an SSbD toolbox to support the implementation of SSbD by the various users.

T8.2
SCIENTIFIC AND TECHNICAL BASIS FOR AN EARLY WARNING SYSTEM ON CHEMICAL RISKS

Identifying new and existing potentially hazardous substances and their sources to inform risk assessors and risk managers at an early stage of future challenges or emerging risk.

T8.3
INTEGRATIVE MODELS

Using the models developed under WP4, WP5, and WP6 and data of WP7 in a harmonised framework and implementing them in a functional open PARC tools network infrastructure.

WP9
BUILDING INFRASTRUCTURAL AND HUMAN CAPACITIES

T9.1
LABORATORY NETWORKING

Expanding laboratory capacities starting from the mapping of existing laboratory networks.

T9.2
BUILDING EXPOSURE MONITORING CAPACITIES

Mapping and cataloguing environmental (air, water/sediment, soil, biota, drinking water, food & feed) **monitoring networks** and identifying the gaps and opportunities for future alignment.

T9.3
JOINT ACTIVITIES - HARMONISATION

Strengthening capacities and laboratory procedures within and across domains and supporting a more uniform translation and implementation of the existing generic QA/QC principles from metrology and standardisation organisations.

T9.4
TRAINING

Supporting the organisation of trainings for the PARC members and the risk assessment/risk management communities in order to develop new or expand existing human capacities.

Annex 3 - List of PARC partners & National Hub Contact Point (NHCP) contact information

Note: Organisations that are represented in the Grant Signatory Board are highlighted in **bold**.

	PARC partners		National Hub Contact Point
Austria	• **Environment Agency Austria** • University of Vienna • Medical University of Vienna • Austrian Agency for Health and Food Safety • Austrian Institute of Technology GmbH • University of Gratz	• BioNanoNet Research Organisation mbH • University of Innsbruck • Medical University of Innsbruck • UMIT Tyrol	**Maria Uhl** maria.uhl@umweltbundesamt.at
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	PARC partners		National Hub Contact Point
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	PARC partners		National Hub Contact Point
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