European Partnership for the Assessment of Risks from Chemicals

PARC

Horizon Europe Partnership

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**PARC in a Nutshell**

**Status:** Co-funded European Partnership for Assessment of Risks from Chemical under Horizon Europe. Public partnership with almost 200 Institutions from 28 Countries.

**Started:** 1st of May 2022 for 7 years – Focus on components of Chemical Risk Assessment.

**Vision:** To establish a Science to Policy dialogue and interface to apply the long term visions of European policies (notably the Chemical Stategy for Sustainability) and to establish a hub of excellence en enabling the transition to the Next Generation Risk Assessment.
PARC in a Nutshell

A public-public Co-Funded European partnership

Under Horizon Europe Pillar II – Global challenges and Industrial Competitiveness Cluster 1 – Health

Nearly 200 organisations from 28 countries and 3 EU agencies: EEA, EFSA, ECHA

Coordinated by ANSES (France)

Estimated budget of over 400M€
PARC Environment

H2020 Clusters
Projects
Regulatory environment National/EU Agencies

Hazard
Exposure
Risk
Questions

Economic impact
Scientific impact
Data Methods Knowledge Capacities
Policy/societal impact

European Green Deal
EU Chemicals Strategy for Sustainability - Towards a toxic-free Environment
Zero pollution action plan
PARC GOVERNANCE

Governing Board
- Strategic role
- Taking into account the relative weight (PMs) of the countries
- Veto rights
- Integration of the EC

Grant Signatory Board
- Contractual management role
- Taking into account the relative weight (PMs) of the participating countries
- Opt out and Veto rights

National Hubs
- Input role
- NHCPs in each country
- 2 NH co-coordinators
- Resources allocated to NHCPs and NHC

PARC Advising bodies:
- International Board
- Stakeholder Forum
- Data and Ethics Protection Board

PARC Management bodies:
- Management Board
- Grant Signatory Board
- Coordinator Coordination Team

Main tasks: daily management, planning, and/or decide on activities and projects

PARC Executive bodies:
- Work packages 1-9

Main tasks: daily business, planning, and implementation of activities and projects
PARC structure

PARC Draft proposal « Concept Paper », 03/06/2020:

HORIZON-HLTH-2021-ENVHLTH-03-01: European partnership for the assessment of risks from chemicals (PARC) – Project 101057014
PARC boundaries

In

- **Chemical compounds**, including mixtures, toxins, nano, release from articles...
- **Human Biomonitoring**
- **New monitoring activities in environment**, new sampling and analytical methods
- **Priority knowledge gaps** for evidence-based chemical risk assessment as identified by risk assessors and risk managers and where research and innovation activities bring added value
- **Regulatory concern** that cannot be clarified under existing regulatory frameworks and which require independent and additional R&I activities (controversies, orphan chemicals (incl. toxins))
- **Innovative** analytical, testing and data analysis tools and methods
- **New risk assessment approaches** to develop more holistic risk assessment frameworks
  - Hazard and exposure assessment,
  - Risk assessment for mixtures

Out

**Biohazards** and noise, radiation, waves..

**Testing and information requirement under existing regulatory frameworks**
- REACH activities
- Part of marketing authorisation applications for chemicals or products
- Regulatory monitoring

**Questions without links to a regulatory/policy concern**
PARC activities: Priorisation Process

1. Mapping of needs
2. Policy questions (Substances, Methods)
3. Scoring and ranking
4. Task force 2.1 in support of MB
5. Review of the Project

- Proposed projects
  - WP3
  - WP4
  - WP5
  - WP6
  - WP7
  - WP8
  - WP9

PARC Project management Initiating Phase

- OK for planning
- Not approved

- EU Agencies
- PARC MB
- Governing Board
- MS Agencies
- Stakeholders

Ranking of priorities
**Priority setting**

**Project Priorisation**

**Knowledge Management**

- **WP2**: Environment Agency Austria (AT)
- **WP2**: European Environment Agency (EU)

**PARC Project management Initiating Phase**

- OK for planning
- Not approved

**Proposed projects Short project description,**

- WP3
- WP4
- WP5
- WP7
- WP8
- WP9

**Ranking of priorities**

- EU Agencies
- Governing Board
- MS Agencies
- PARC MB
- Mapping of needs
- Policy questions
- Substances
- Methods
- Scoring and ranking

**Task force 2.1 in support of MB**

**Review of the Project**

**This project**

- WP1
- WP2 (T.2.2)
- WP3

**Knowledge**

- Processing
- Data/information

**CLs MLs**

- PARCopeedia

**WP4, 5, 6, 8, 9**

**Uptake into policy**

- Policy makers
- Researchers
- General Public

**S2PDnet**

- Define improvement goal
- Identify regulatory gap/demand

**S2PDforum**

- Analyse odds, resources, timelines
- Strategic roadmaps (PARCroute)

**T2.2**

- Implementation of improvement
- Regulatory Key Players

**Regulatory practice**

**European Partnership for the Assessment of Risks from Chemicals – Biodiversa+ 19/09/2022**
WP3: Synergies, collaboration and awareness

- GSCL (GR) and INSA (PT)
WP4: Monitoring and Exposure

Monitoring chemicals in humans (internal exposure) and in the environmental and food compartments (external exposure).

4.1 Human Biomonitoring
Consolidate and further develop the human biomonitoring platform, generating and analysis of HBM data, and develop the network of qualified laboratories for biomarkers analysis.

4.2 Environmental Monitoring
Understand the presence of chemicals in the environment, their exposure to humans, considering multiple sources (e.g. air, water food, consumer products).

4.3 Innovative tools and methods
Develop innovative tools and methods to improve human, food and environmental monitoring schemes, contribute to an early warning detection of chemicals of emerging concern.
**WP5: Hazard Assessment** ➔ BfR(DE) and ANSES (FR)

**Work-streams**
- Substances oriented
- Endpoint oriented
- Regulatory oriented

**Human Health**

**Environment**

**5.1 Closing data gaps (TG+, in vivo)**
- Exposure, concern

**5.2 Innovative methods (in vitro)**
- Regulatory need & readiness

**5.3 Systems toxicology (in silico)**
- Data integration, modelling

- NAM data from TG study
- Need to confirm results in TG study
- Data input/request to improve modelling, AOPs
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- Human disease models
- PBPK

**Human Health**

**Environment**
WP6: Innovation in regulatory risk assessment

Protect human health and the environment; contribute to a non-toxic environment and a circular economy

Scientific basis for NGRA

- Quantitative AOP networks
- Mechanism-based IATAs, using New Approach Methodologies
- Multiple route exposure
- Unintentional mixtures and real-life exposure
- Health impact assessment
- Across regulatory silos

Regulatory science

- Driven by regulatory needs
- Determine feasibility, within existing legislations and in the future
- Efficiency of existing and emerging methods
- Data availability and quality
- Across legislations
- Regulatory acceptance

Generating the best science to answer regulatory questions

Ensure that science meets regulatory needs

KEMI (SE) and RIVM (NL)
PARC Purpose in the field of Alternative Approaches to Animal testing:

To engage in overcoming barriers to the usability of alternative (non-animal) assessment methods for regulatory purposes by providing test guidelines for certain endpoints and proof of the biological or toxicological relevance of the endpoints assessed for human health.

The functionality, applicability and relevance and, when possible, validation of new and existing in vivo, in vitro and in silico models will be addressed and their up-take by the regulatory system supported.

New Approach Methods:

NAMs: US EPA definition

Any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals

Next Generation of Risk Assessment (NGRA):

Use data from NAMs for risk assessment.

Tiered combinations of in silico tools, in vitro systems, organ models and Omics in conjunction with PB-PK and complex exposure models.

NAMs robust and acceptable for regulators
PARC activities and projects in relation with NAMs
WP5 Hazard assessment  /  WP6 Innovation in regulatory risk assessment

**Integrated Approach to Testing and Assessment**

- Endocrine disruptors
- Metabolic disruption
- Immunotoxicity
- Neurotoxicity (Acute, Development)
- Non Genotoxic Carcinogens
- Neurotoxicity (Acute, Development)
- Endocrine disruptors
- Metabolic disruption
- Immunotoxicity

**Knowledge (WP2)**
**Training (WP9)**
**QA/QC (WP9)**

**Case studies**

**WP8**
Concept & Toolboxes

Emerging Toxins
BPA Alternatives

OECD TGs  +  NAMs

Omics

FAIR (WP7)

Exposure modelling

**Co-funded by the European Union**
Collaborations with PARC

Industry

European Commission

Member States

Collaborations
Synergies

Stakeholder forum
- Industry
- NGOs

On going projects

Carcinogenicity of agrochemicals

QIVIVE (Quantitative in vitro to in vivo extrapolation)

PBK Modeling in safety assessment

Planned projects

Non genotoxic carcinogens

QIVIVE, PBPK modeling and System Toxicology, IATAs

Exposure modeling

Non Animal science in regulatory decisions for chemical safety

JRC

European Commission

Mutual Consultation

Exchange on case studies
FAIR Models/Data
Identification of gaps/needs

Mapping of resources
Training
WP 7 FAIR data

Data Policy
Data Management
FAIR data

All WPs that use data and/or produce data

WP7

Efficiency – Reuse and integration – Sustainability

VITO (BE) and UoB (UK)
WP8: Concepts and toolboxes

WP8 aims at supporting the development and consolidation of new concepts and approaches such as:

- **Safe and Sustainable by Design** chemicals, and their applications in materials and products (Task 8.1)
- Trans-regulatory approaches for **Early Warning Systems** for chemical risks, identification of information need (Task 8.2)
- **Integrative models** approaches for chemical exposure, hazard and risk assessment (Task 8.3)
WP9: Building infrastructural and human capacities

ISCIII (ES) and MU(CZ)

1. Identification and prioritization of needs and gaps

2. Building infrastructural and human capacities

3. Filling the needs, closing the gaps

4. Next-generation RA and sustainability beyond PARC

Task 9.1 Laboratory networking

Task 9.2 Building exposure monitoring capacities

Task 9.3 Joint activities (harmonization)

Task 9.4 Training

Stakeholders Policy

Sustainability

Priority setting

WP 3

Synergies, collaboration, communication, dissemination

WP 2

WP 4, 5, 6

R &I needs

WP 7, 8

Data FAIRification, harmonization, (re)use Models
Partnership contact details

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Merci pour votre attention!
How PARC will contribute to the Chemicals Strategy for Sustainability

By

• Establishing a permanent dialogue between regulatory risk assessors at EU and National level and the research community

• Consolidating EU networks and infrastructures involved in risk assessment of chemicals
  • Mapping of laboratories capacities and harmonisation of performances:
    - Human and Environmental Monitoring
    - Hazard assessment and characterisation
  • Strengthening a community of Risk assessors involved in a regulatory context

• Developing or promoting new innovative methods/ tools/ platforms that will support new generation risk assessment approaches
  • AOPs/IATAs
  • Exposure driven assessment: e.g. “real mixtures” identifications
  • (Re)use of data, FAIRNess of data
  • Modelling tools

• Direct support to the
  • Safe and Sustainable by Design approach
  • Early Warning System