European Partnership for the Assessment of Risks from Chemicals

PARC

Horizon Europe candidate Partnership

How can EPAA contribute?
27 October 2021

EPAA Annual Conference

Pascal Sanders, ANSES
Coordinator of PARC

parc@anses.fr
What is PARC?

• A public-public **partnership** under Horizon Europe

• 7 years partnership – 400 millions euros co-funded 50/50

• An initiative where the **European Union**, prepared with early involvement of **Member States and Associated Countries**, together with public partners (EU and National Risk Agencies, Universities, Public Research Organisations), commit to **jointly support the development and implementation of a programme of research and innovation activities in relation with the assessment of risk from chemicals**.

• Submitted 21/09/21 HORIZON-HLTH-2021-ENVHLTH-03-01
PARC Origins
« EU-TP » A Inter-Agencies European programme to perform toxicological studies for substances of concern for Public Health

Anses initiative launched in January 2017 with MS Agencies (BfR, DTU-Food, FSAO, RIVM, FPS, NFA) and discussed at different EU levels (DGs, EFSA, ECHA, JRC)

Research and innovation Roadmap

H2020 EJP for Human Biomonitoring
2017-2022
Co-fund with 150 Partners
Coordinator UBA

A Human Biomonitoring Platform
Science to Policy
Chemical exposure and human health

European Green Deal
EU Chemicals Strategy for Sustainability - Towards a toxic-free Environment
Zero pollution action plan
Number of participating countries: 28
Austria (AT), Belgium (BE), Croatia (HR), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Iceland (IS), Israel (IL), Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Netherlands (NL), Norway (NO), Poland (PL), Portugal (PT), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE), Switzerland (CH), United-Kingdom (UK)

Participating EU agencies/services:
3 agencies: EEA, EFSA, ECHA
and 5 DGs: DG R&I, DG ENV, DG SANTE, DG GROW and JRC

Pending countries for whom participating entities are still to be confirmed: 4
Bulgaria (BG), Cyprus (CY), Ireland (IE), Romania (RO)

Countries with which no contact has been achieved: 1
Malta (MT)
Horizon Europe Work Programme - HEALTH
HORIZON-HLTH-2021-ENVHLTH-03-01: European partnership for the assessment of risks from chemicals (PARC)
WP2: A common Science Policy Agenda (EAA(AU), EEA(EU))

WP3: Synergies, collaborations and awareness (INSA(PT), GSCL(EL))

Policy questions
Identify regulatory gaps/demands
Ranking of priorities

Project proposals
Projects Review

Knowledge management
Communication

Data collection

Regulatory Key players
Policy makers
Stakeholders
Researchers

General public

Task 2.1 Prioritisation
- Identify process for change
- Identify and profile key players
- Analyse odds, resources, timelines
- Build strategic roadmaps (PARCRoute)

Task 2.2 Knowledge management and uptake into policy

Task 2.3 Sustainability

Science to Policy Dialogue (SP2D)

European Partnership for the Assessment of Risks from Chemicals – EPAA 27 October 2021
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

Closing data gaps (TG+, in vivo)

Exposure, concern

Innovative methods (in vitro)

Regulatory need & readiness

Data input/request to improve modelling, AOPs

NAM data from TG study

Need to confirm results in TG study

Work-streams

- Substances oriented
- Endpoint oriented
- Regulatory oriented

Human Health

Environment

Systems toxicology (in silico)

Data integration, modelling

Human disease models

PBPK

AOP
WP6: Innovation in regulatory risk assessment

European Partnership for the Assessment of Risks from Chemicals – EPAA 27 October 2021

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
workers and general population
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)
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)

Findability
Accessibility
Interoperability
Reuse
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

- Task 9.1 Laboratory networking
- Task 9.2 Building exposure monitoring capacities
- Task 9.3 Joint activities (harmonization)
- Task 9.4 Training
- Data FAIRification, harmonization, (re)use Models

WP 3
Synergies, collaboration, communication, dissemination

WP 2
Sustainability
Priority setting

1. Identification and prioritization of needs and gaps

WP 4, 5, 6
R & I needs

4. Next-generation RA and sustainability beyond PARC

Stakeholders Policy

3. Filling the needs, closing the gaps

ISCIII (ES) and MU (CZ)
How EPAA can contribute?

A close collaboration is expected according our common objectives about 3Rs and shared challenges in EPAA action programme

• Address science and technology gaps
• Improve intra and inter sectorial collaboration and coordination
• Optimise translation from research to regulatory practice
• Facilitate acceptance of additional sources of evidence in the current regulatory framework
• Communicate scientific reality
• Educate the educated

Return of experience
Participation in stakeholder forum
Identification of needs, gaps
Industry case study reports
PARC case studies discussion
PARC proposal preparation roadmap

- **Proposal** submitted to the European Commission by the Coordination Team.

- **Evaluation** by the European Commission.
- **Preparation of the Consortium Agreement** in collaboration with all partners and eventual collaboration agreements with EU organisations.

- **Preparation of the Grant Agreement** in collaboration with all partners: verification of administrative information, revision of the budget and Description of Action (DoA) if necessary, signature of the administrative forms and preparation of the Kick-off meeting that will take place in March-May 2022 (TBC).

**March - May 2022 (TBC) : Launch of the Partnership and kick off meeting in France (under French presidency of the Council of the EU)**
Thank you for your attention!