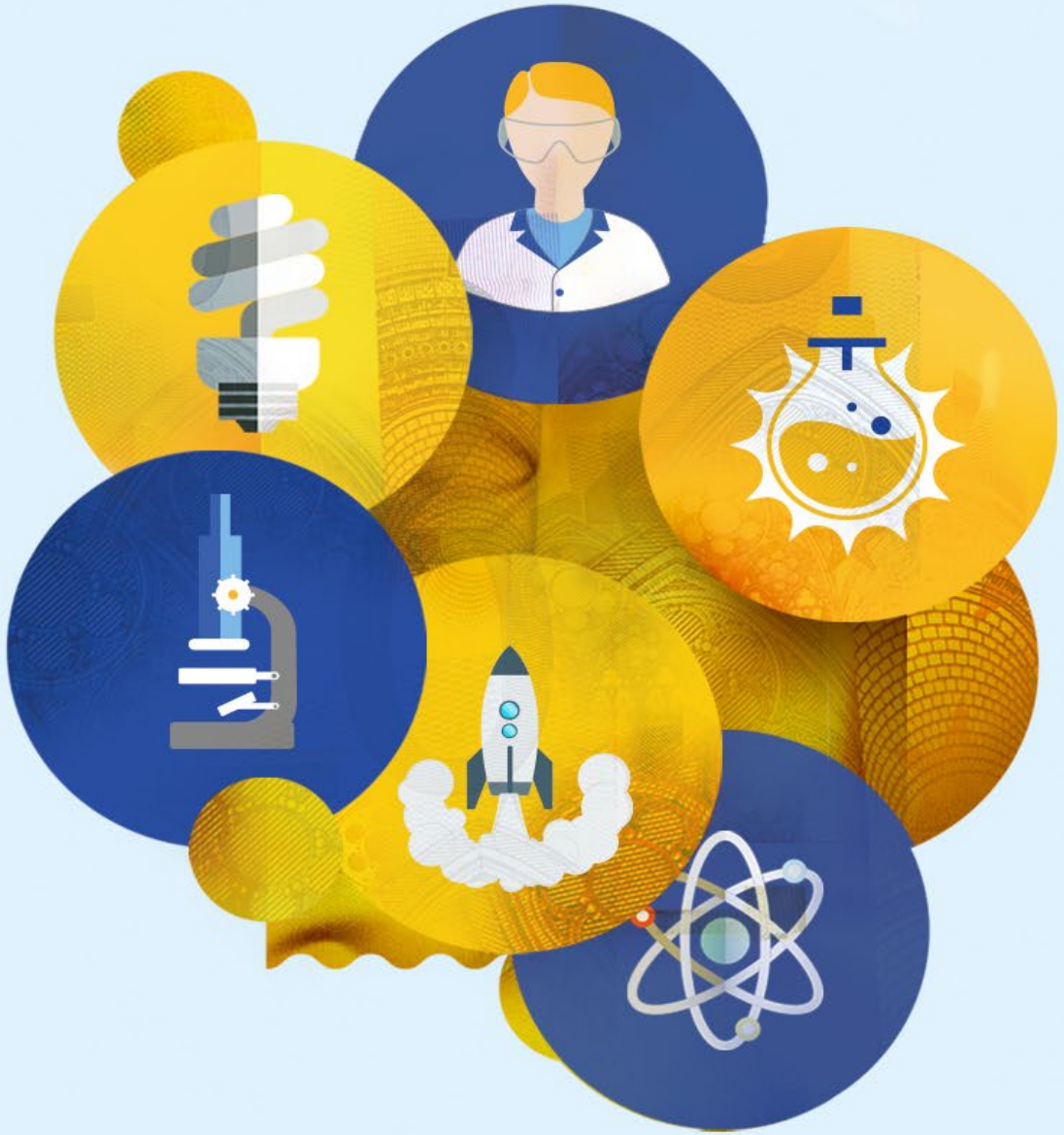
European Partnership for the Assessment of Risks from Chemicals

PARC

Horizon Europe Partnership

Christophe ROUSSELLE

Christophe.rousselle@anses.fr



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.

European Commission

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EUROPEAN PARTNERSHIPS STAKEHOLDERS FORUM

PARC in a Nutshell

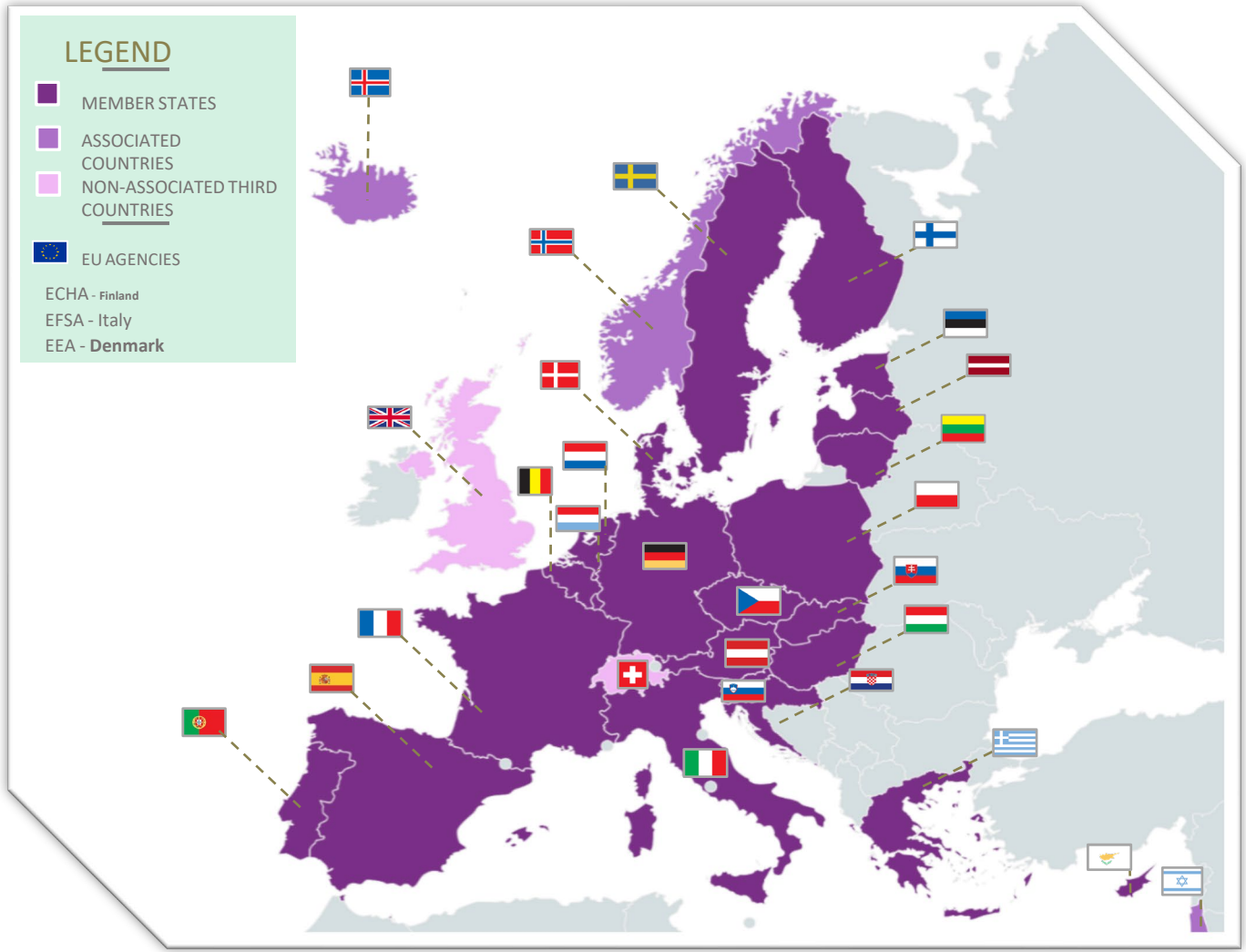
A public-public **Co-Funded European partnership**

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€**



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PARC Environment

H2020 Clusters

Projects

Regulatory environment
National/EU Agencies

Economic impact

Scientific impact

Data
Methods
Knowledge
Capacities

Policy/societal impact

PARC

Hazard
Risk
Exposure
Questions

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

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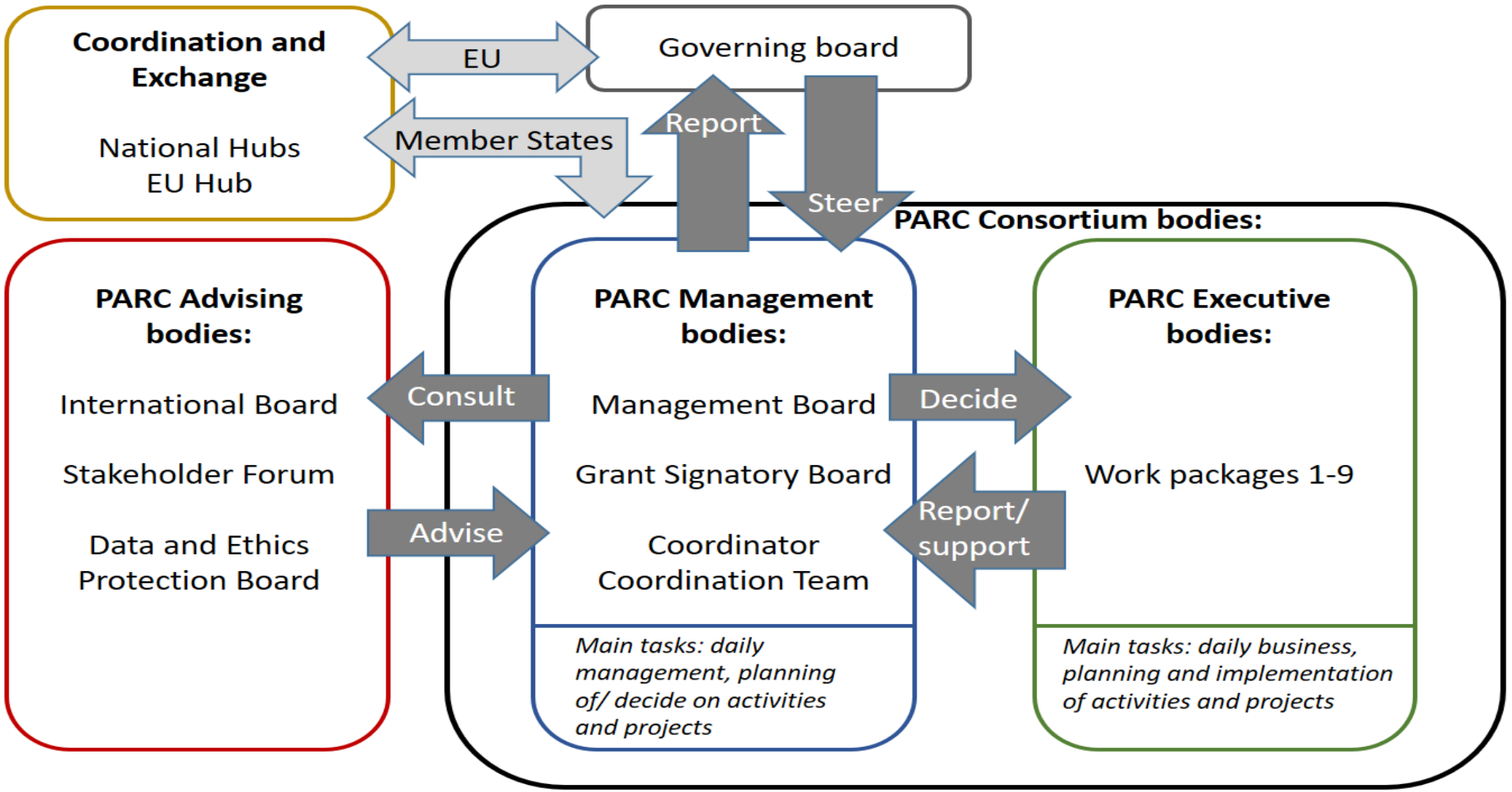
PARC GOVERNANCE



Governing Board

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

Grant Signatory Board

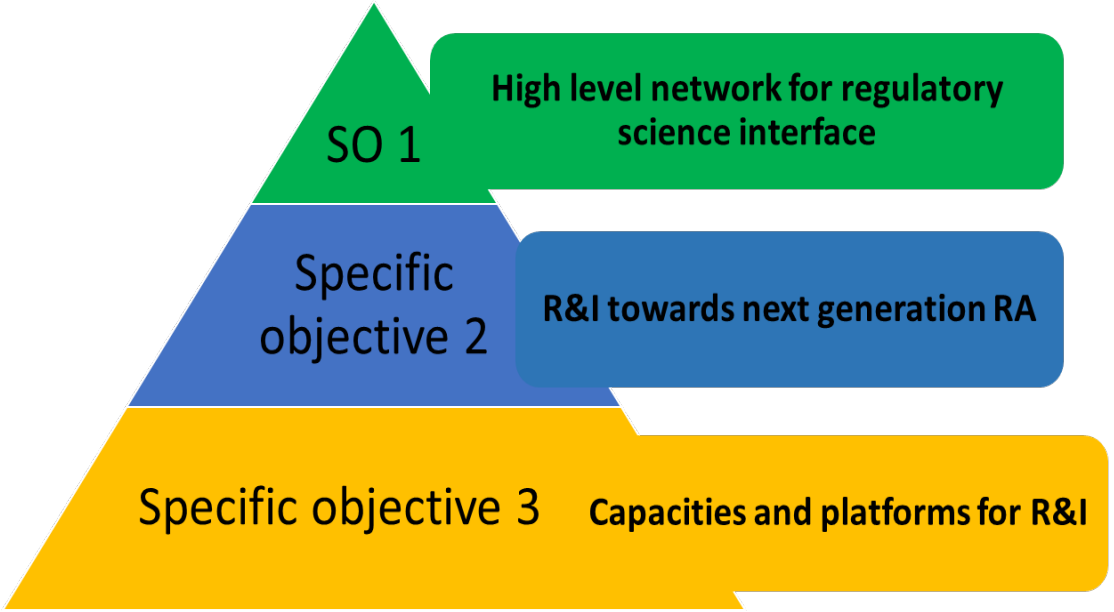
- Contractual management role
- Taking into account the relative weight (PMs)of the participating countries
- Opt out and Veto rights

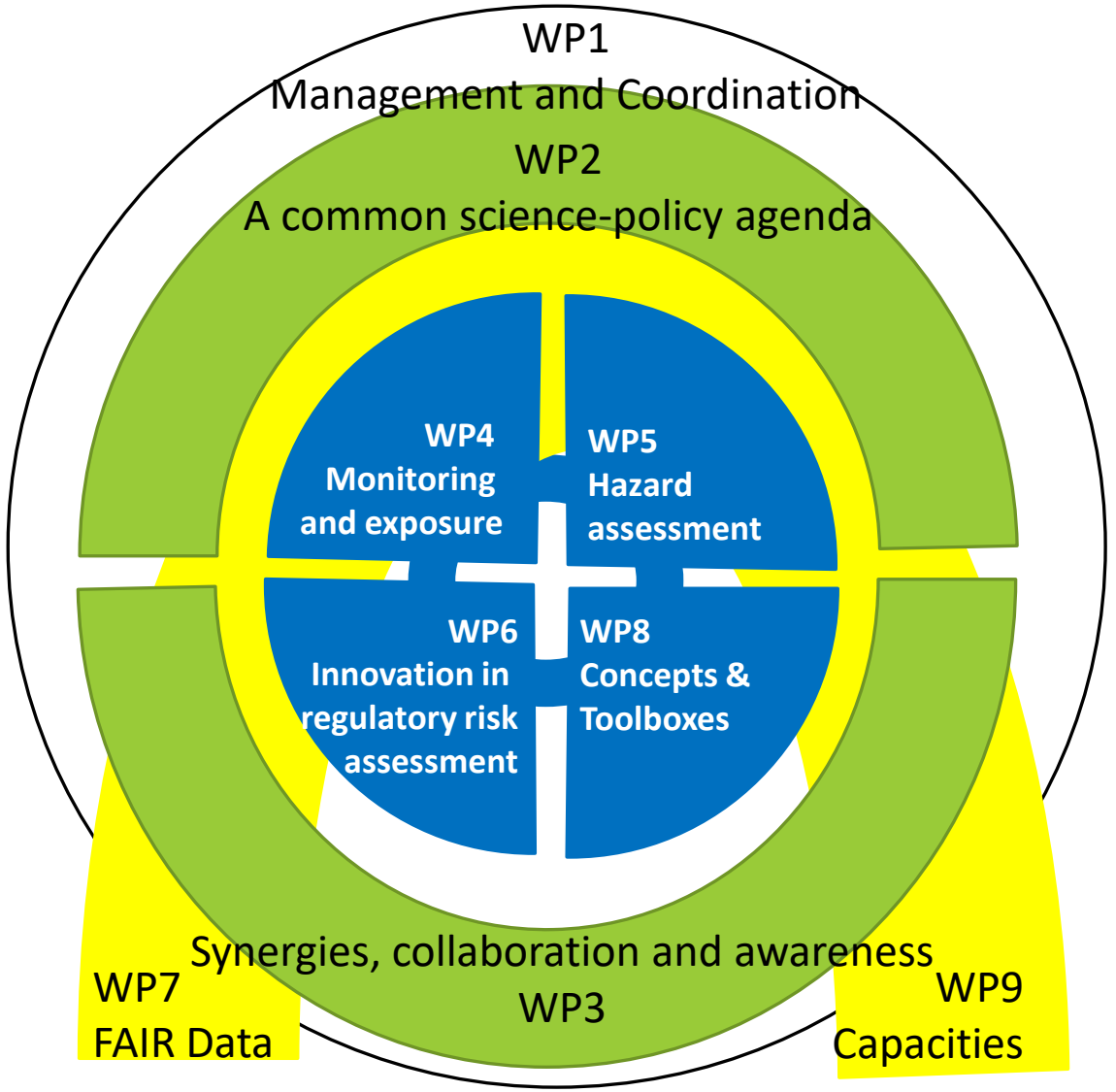
National Hubs

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

PARC structure

PARC Draft proposal « Concept Paper », 03/06/2020:
https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf





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 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

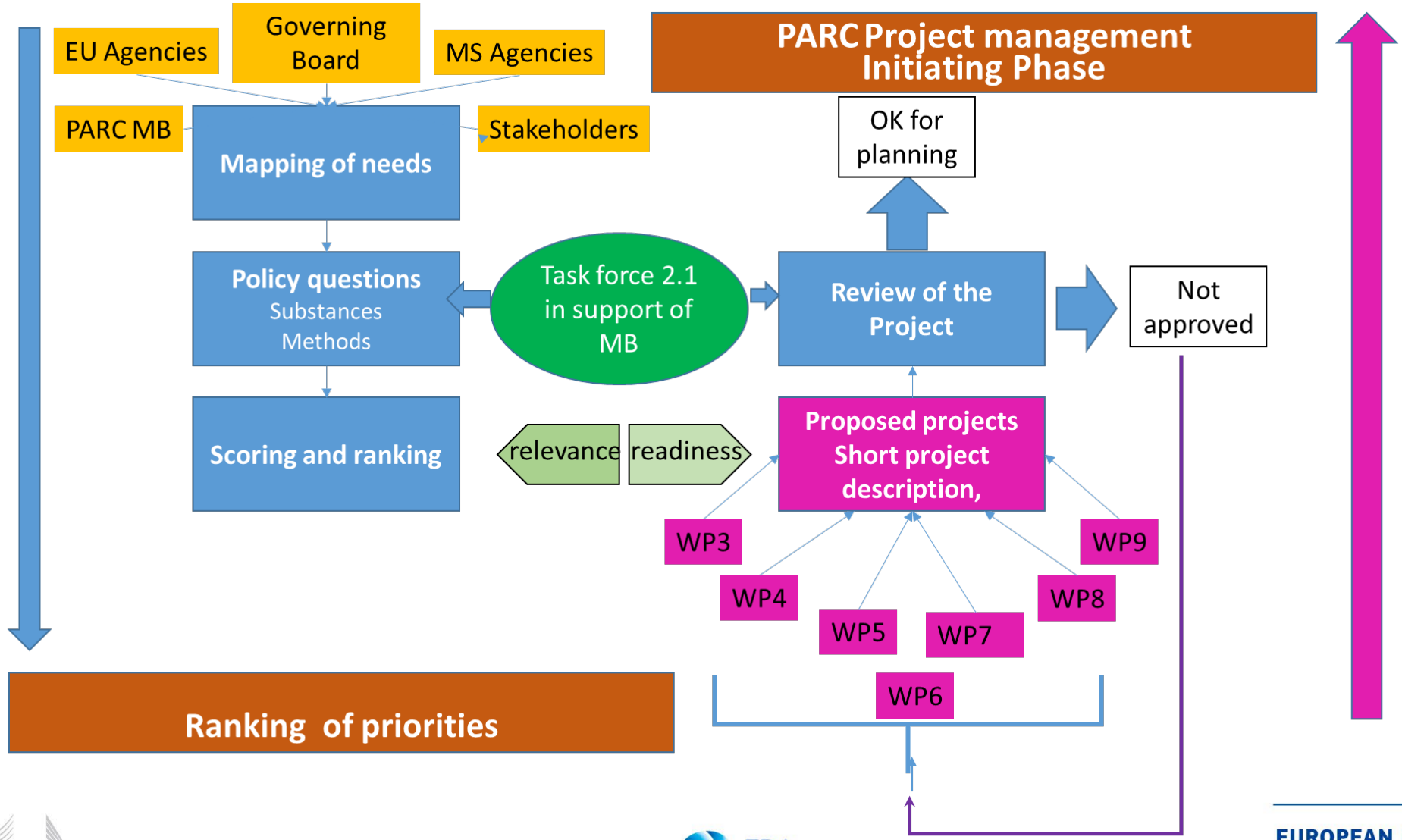
Biohazards and noise, radiation, waves..

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



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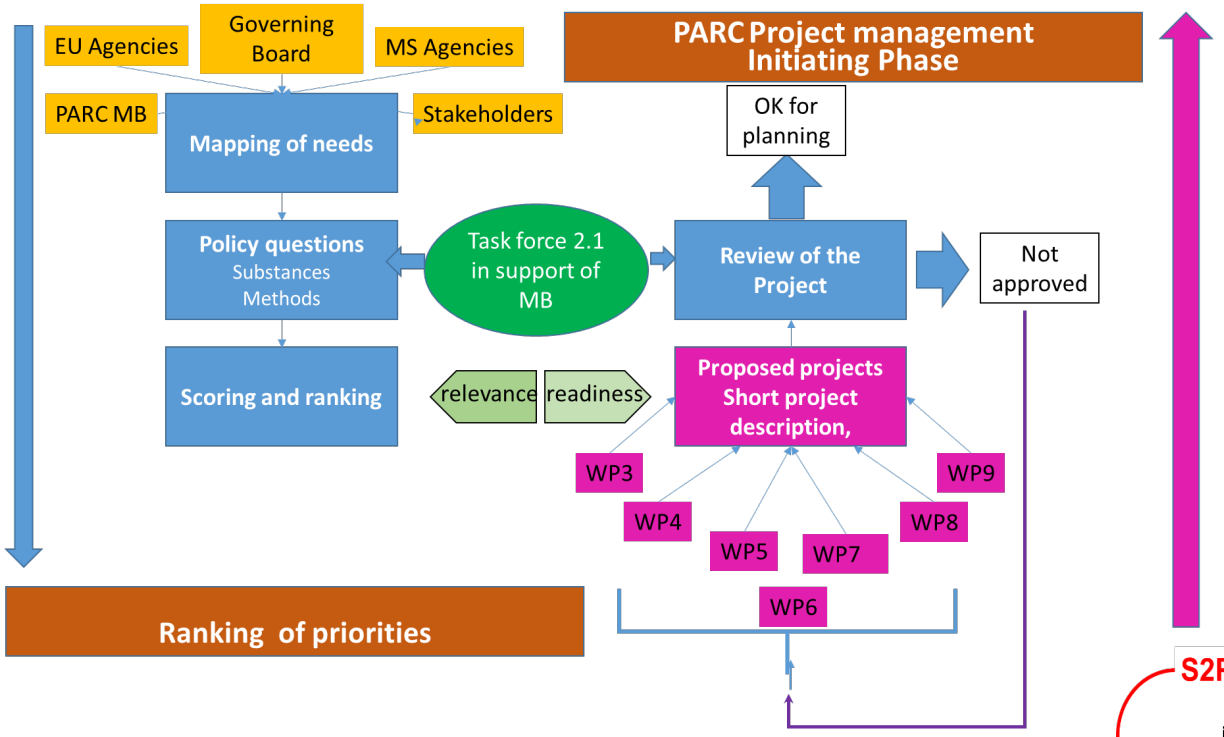
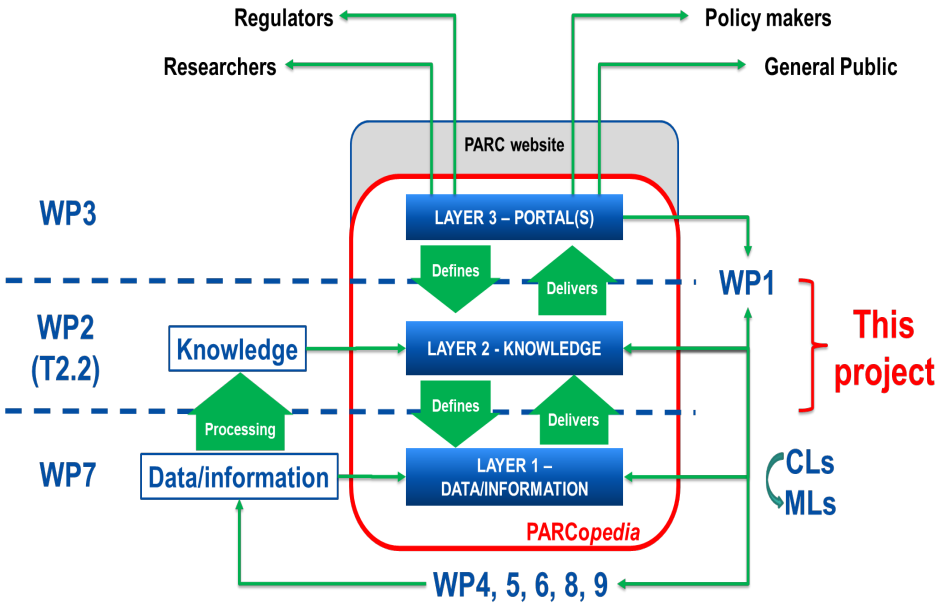
Priority setting

Project Priorisation

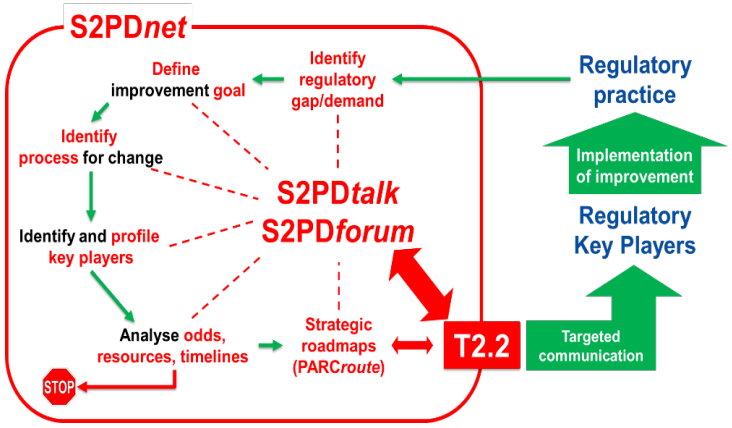
Knowledge Management





WP2

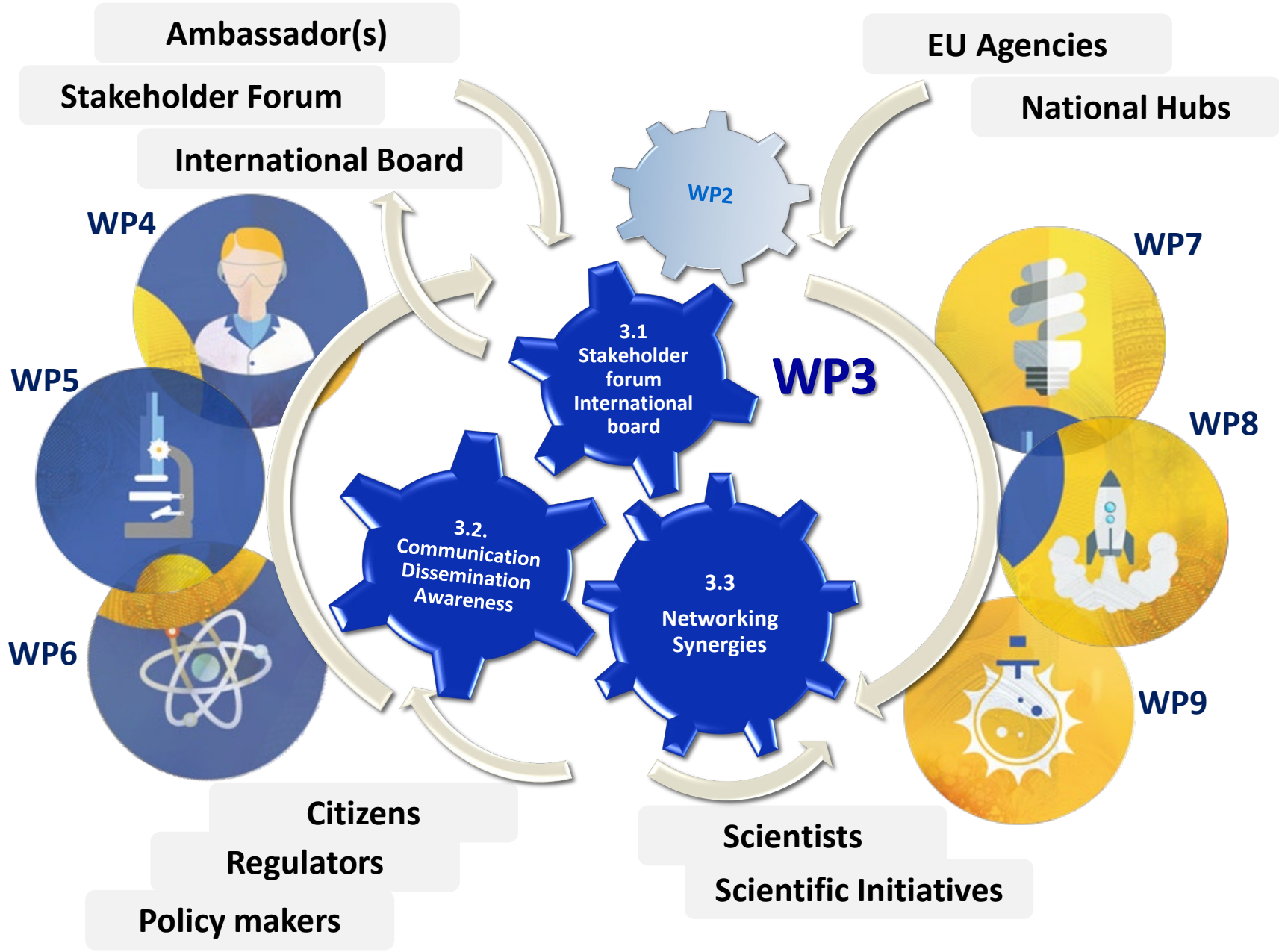
Environment Agency Austria (AT)
European Environment Agency (EU)



uptake into policy

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).

➢UBA (DE) and SpF (FR)

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

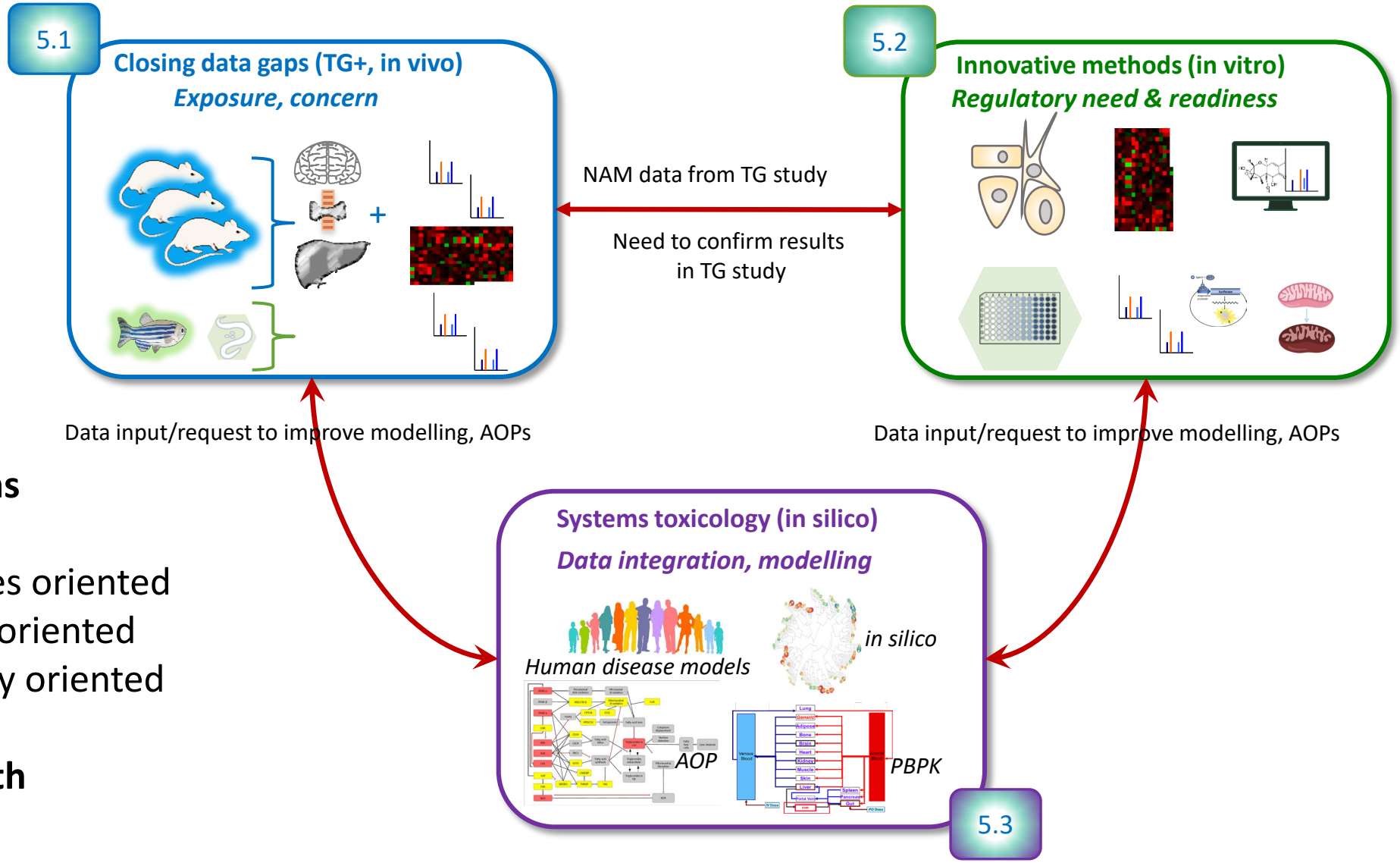
Understand the **presence of chemicals in the environment**, their exposure to humans, considering multiple sources (e.g. air, water food, consumer products)

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

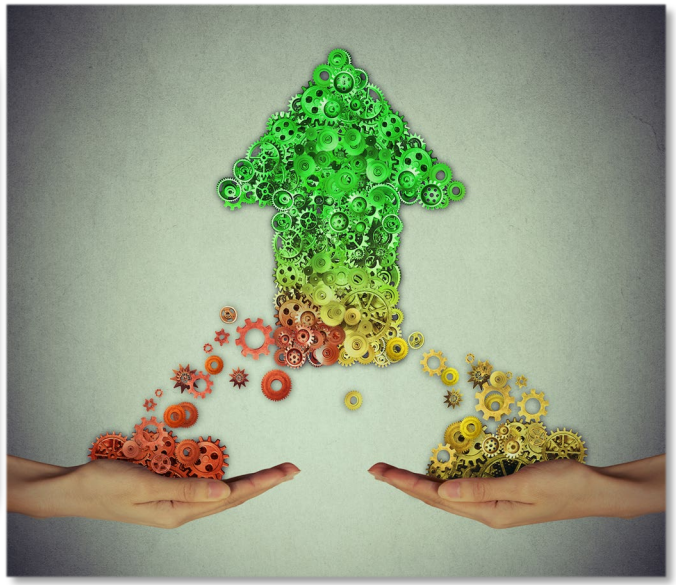
WP6: Innovation in regulatory risk assessment

➢KEMI (SE) and RIVM (NL)

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
Heatlh 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

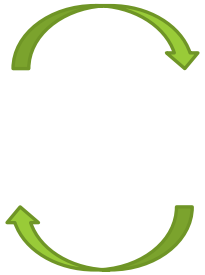
PARC Purpose in the field of Alternative Approaches to Animal testing:

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.

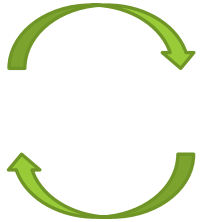
New Approach Methods :
NAMs:*US EPA definition*

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

Co-funded by the European Union

PARC activities and projects in relation with NAMs

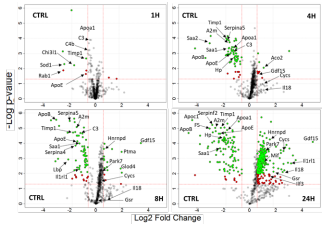
WP5 Hazard assessment / WP6 Innovation in regulatory risk assessment

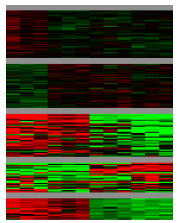
Emerging Toxins

BPA Alternatives

OECD TGs + NAMs

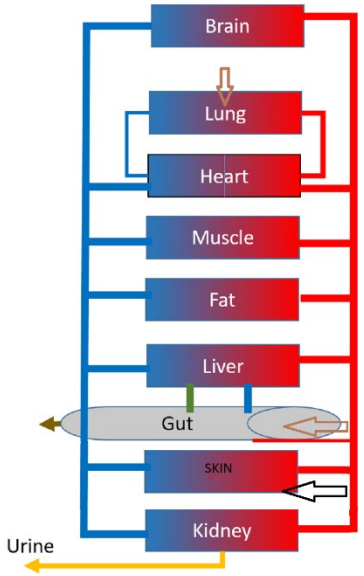
Omics



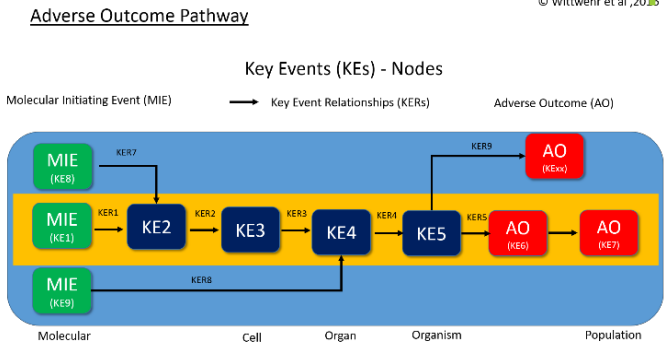


FAIR (**WP7**)

Integrated Approach to Testing and Assessment



Exposure modelling



Non Genotoxic Carcinogens

Neurotoxicity (Acute, Development)

Endocrine disruptors

Metabolic disruption

Immunotoxicity

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

Case studies

WP8
Concept & Toolboxes

Co-funded by the European Union

Collbaorations with PARC

Industry | European Commission | Member States

Collaborations
Synergies

The European Partnership for Alternative Approaches to Animal Testing

European Commission

JRC

PEPPER

Stakeholder forum
- Industry
- NGOs

On going projects

Carcinogenicity of agrochemicals

QIVIVE (Quantitative in vitro to in vivo extrapolation)

PBK Modeling in safety assessment

Non Animal science in regulatory decisions for chemical safety

Planned projects

Non genotoxic carcinogens

QIVIVE, PBPK modeling and System Toxicology, IATAs

Exposure modeling

Mutual Consultation

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

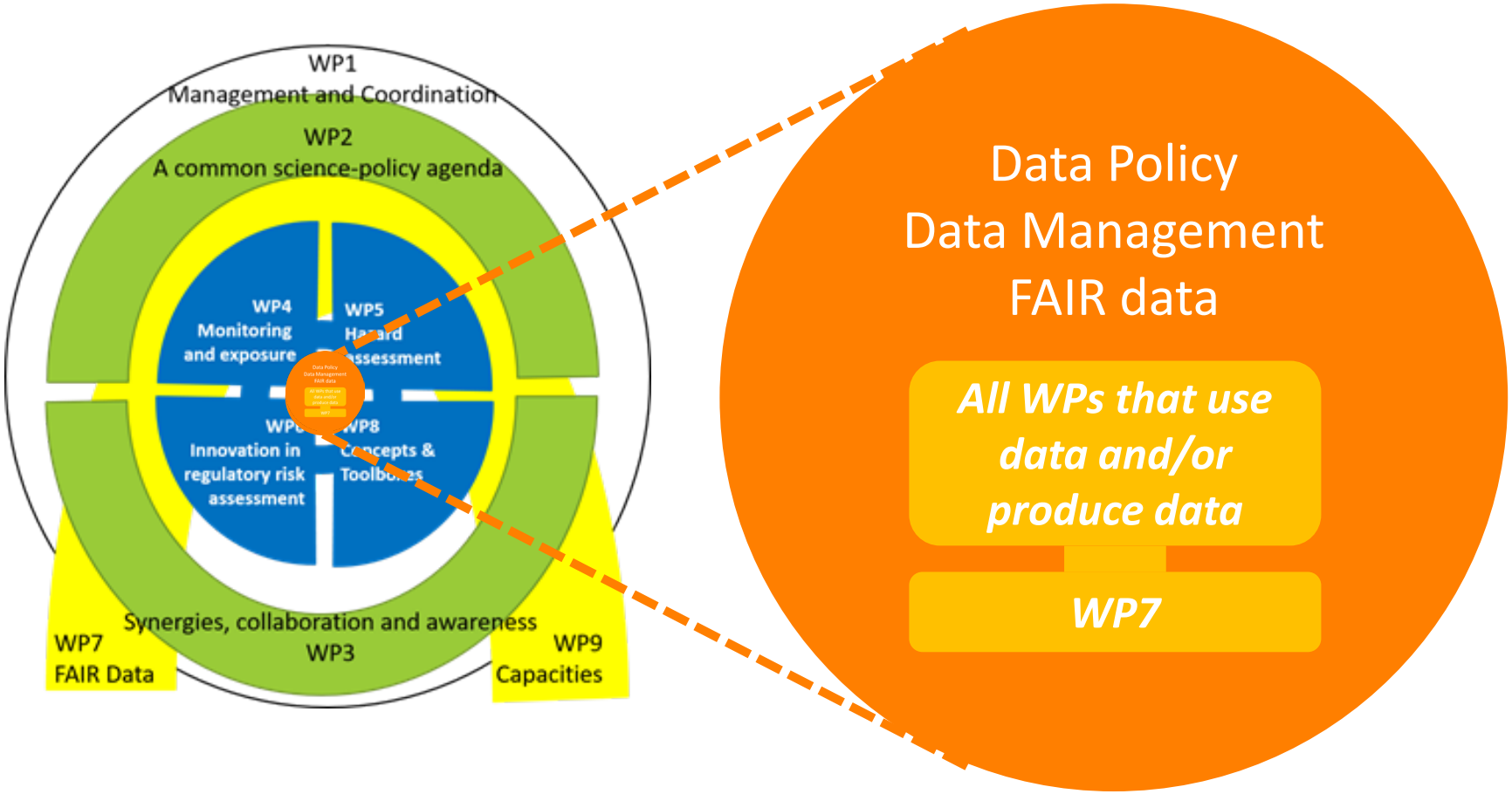
Mapping of ressources

Training

Co-funded by the European Union

WP 7 FAIR data

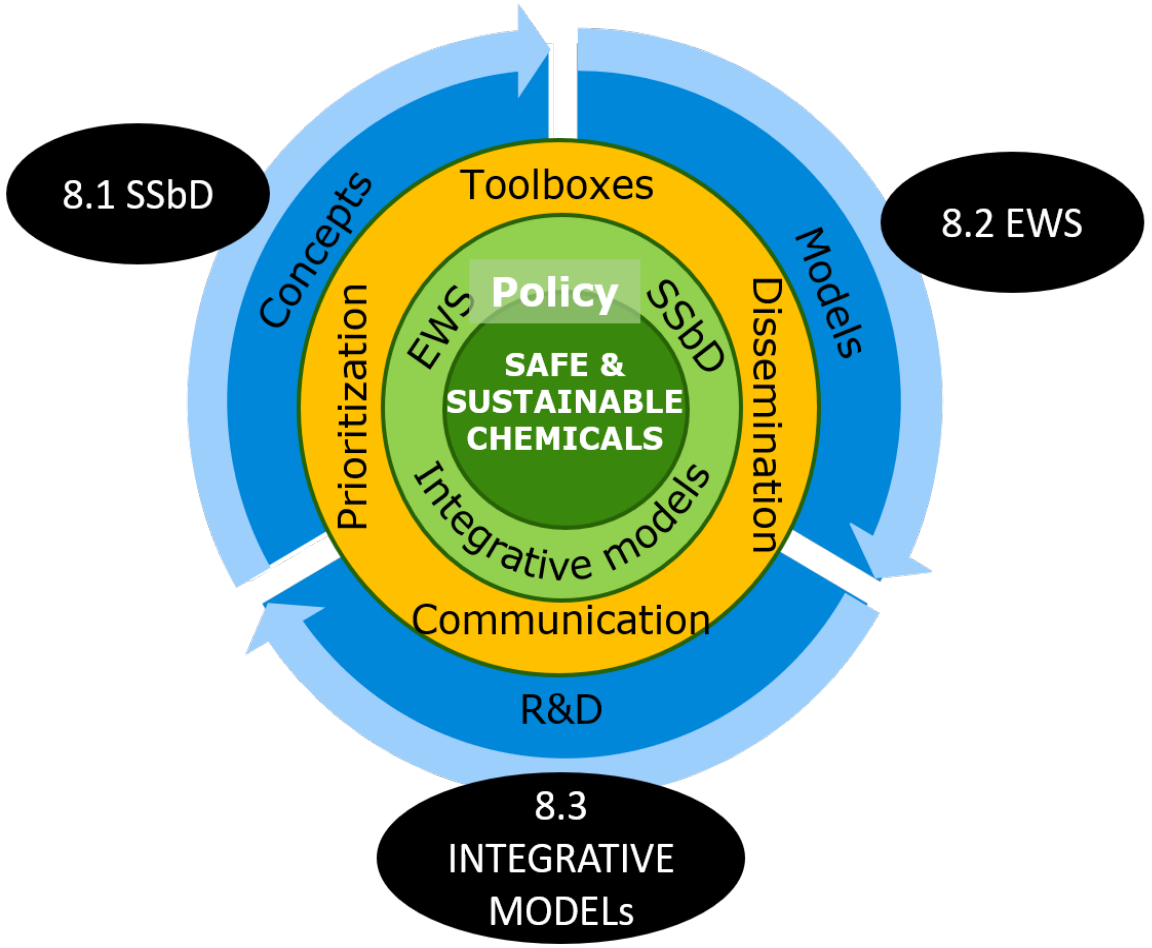
➢VITO (BE) and UoB (UK)



Efficiency – Reuse and integration – Sustainability

WP8: Concepts and toolboxes

➢AUTH (GR) and UniNa (IT)

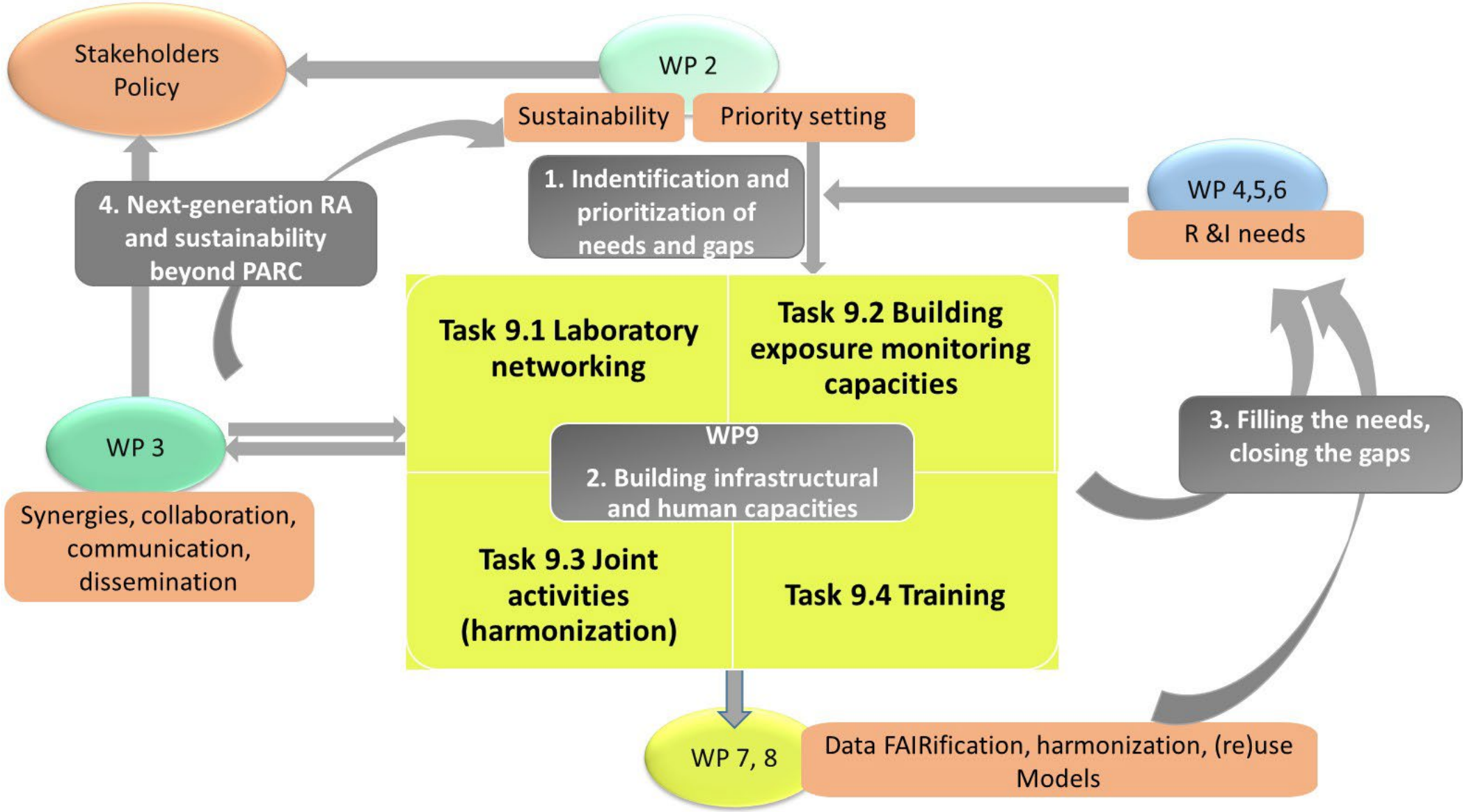


WP8 aims at supporting the development and consolidation of new concepts and approaches such as:

- **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)



Merci pour votre attention!

Partnership contact details

Coordination Team:

PARC: parc@anses.fr

Pascal Sanders: pascal.sanders@anses.fr

Christophe Rousselle: christophe.rousselle@anses.fr

Adrienne Pittman: adrienne.pittman@anses.fr

Philippine de Barbeyrac: philippine.debarbeyrac@anses.fr

Basile Cazalis de Fondouce: basile.cazalisdefondouce@anses.fr

Ronan Corfdir: ronan.corfdir@anses.fr

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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