Towards chemical safety assessments using solely non-animal methods: the PARC contribution

Workshop on the Commission roadmap towards phasing out animal testing for chemical safety assessments

Mirjam Luijten

11 December 2023

PARC

Co-funded by the European Union

What is PARC?

- A public-public **Partnership** under Horizon Europe
- 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 of chemicals.**

Public-Public

Co-Fund Budget
EU 50/50 MS,AC
400 M€

Started : 01/05/2022
Duration : 7 years

~200 Partners

29 countries

24 Member States: Austria (AT), Belgium (BE), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE), Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Netherlands (NL), Poland (PL), Portugal (PT), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE)
3 Associated countries: Iceland (IS), Israel (IL), Norway (NO)
2 Non-associated Third countries: Switzerland (CH), United Kingdom (UK)

3 European Agencies : European Environment Agency · efsa European Food Safety Authority · ECHA EUROPEAN CHEMICALS AGENCY

PARC

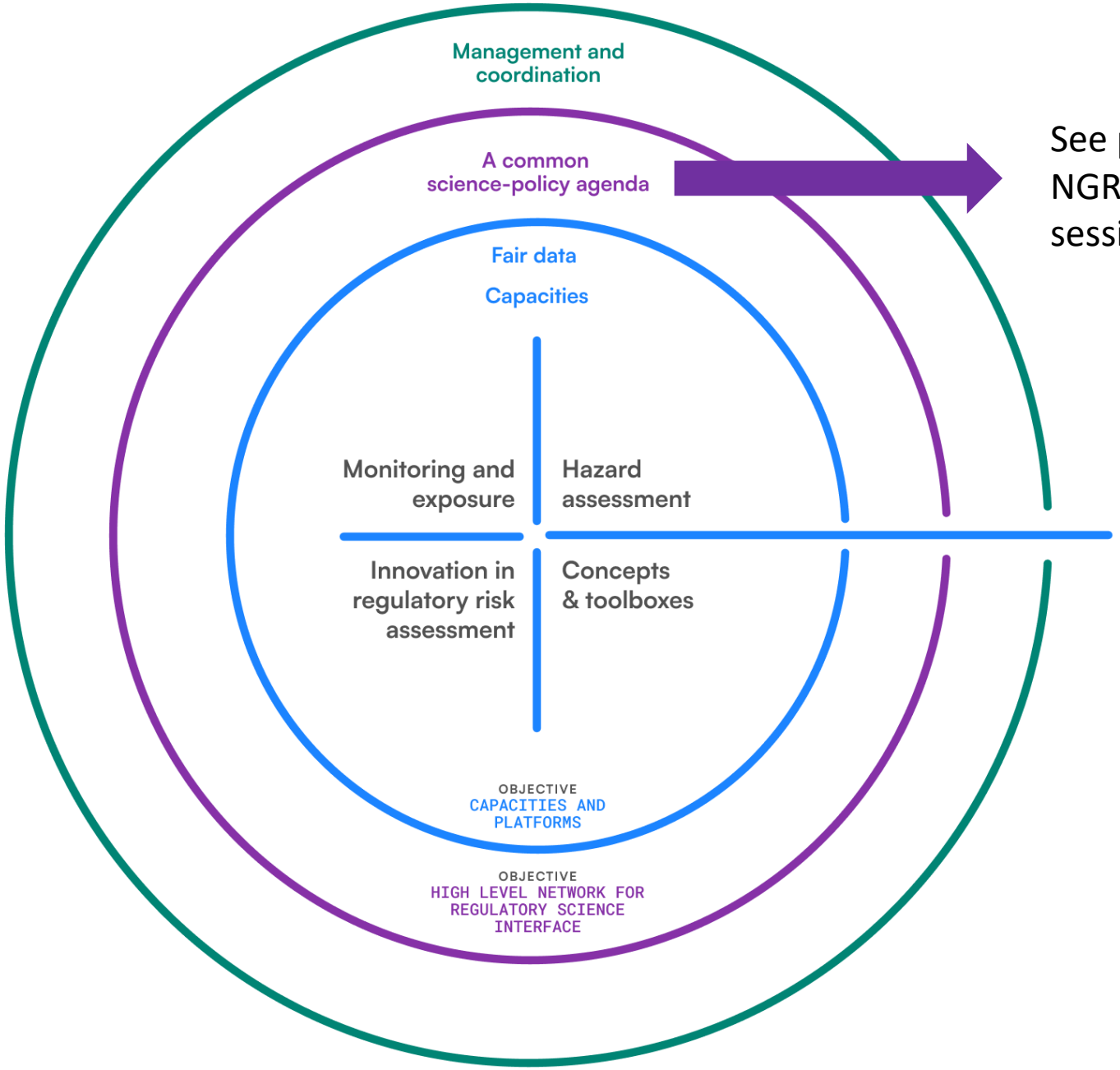
HORIZON EUROPE

Co-funded by the European Union

PARC Objectives

Global Objective

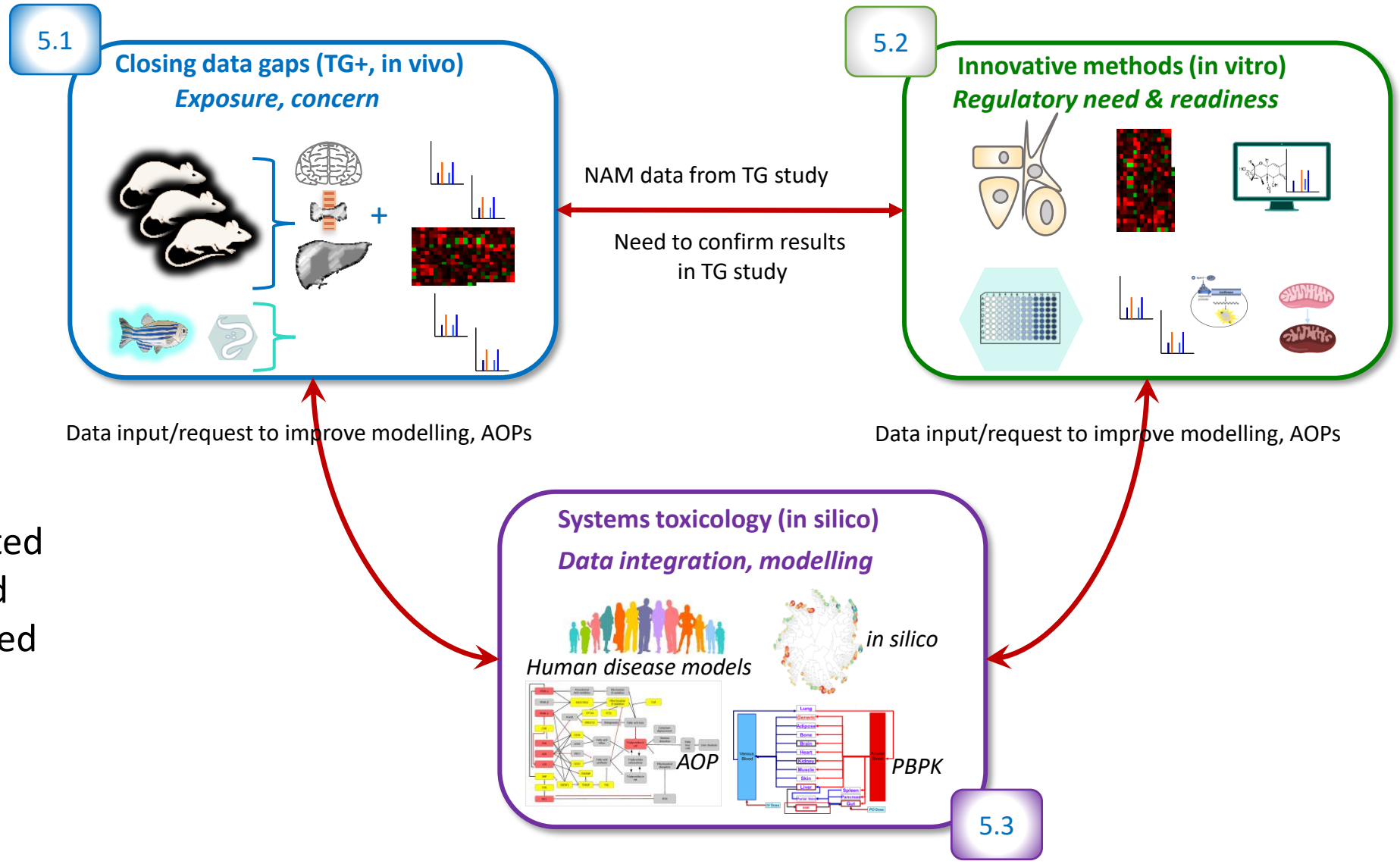
To consolidate and strengthen the EU's R&I capacity for **chemical risk assessment** to protect human health and the environment and to contribute to a non-toxic environment and a circular economy.



See presentation on NGRAroute in session 4, part 3

WP5 Hazard Assessment

➢BfR(DE) and ANSES (FR)

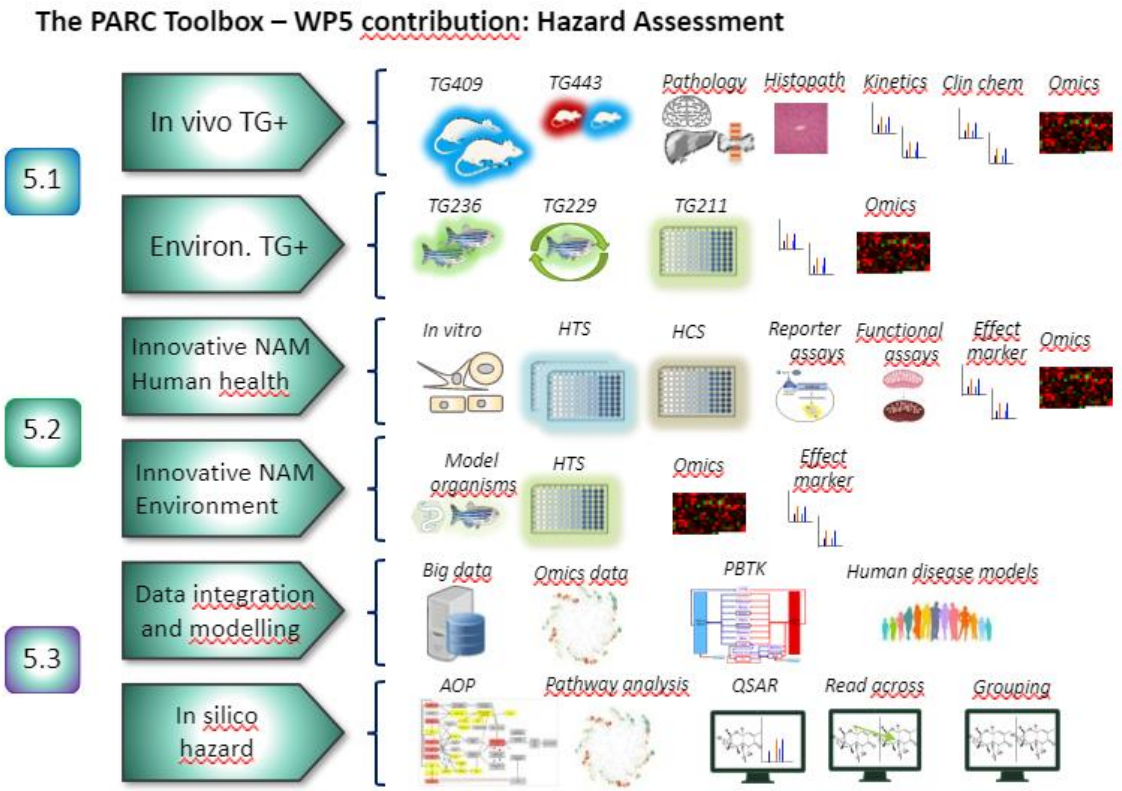


Work-streams

- Substances oriented
- Endpoint oriented
- Regulatory oriented

Human Health
Environment

WP5 Hazard Assessment



Substances

- Toxins
- Bisphenol A (BPA)
- Natural Toxins
- BPA alternatives

Methods

- Systems Toxicology
- AOP Development
- PBK/QST

Human health effects

- Non-genotoxic carcinogenicity
- Metabolic Endocrine Disruption
- Endocrine Disruption
- Immunotoxicity
- Neurotoxicity

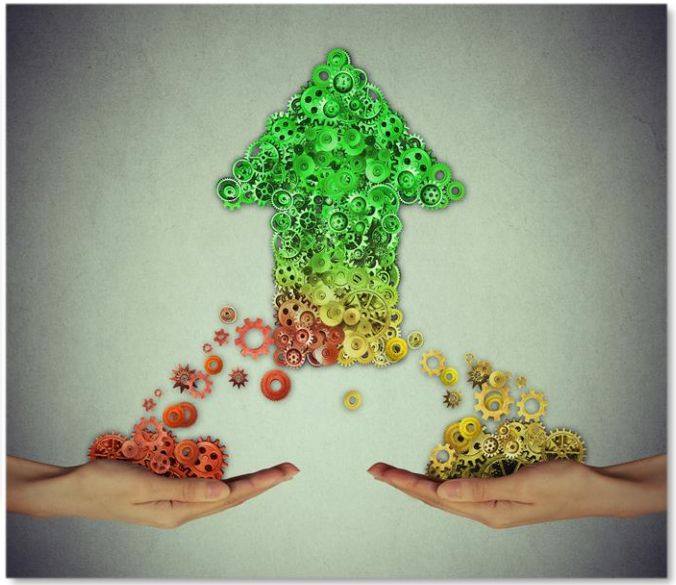
WP6 Innovation in regulatory risk assessment

➢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



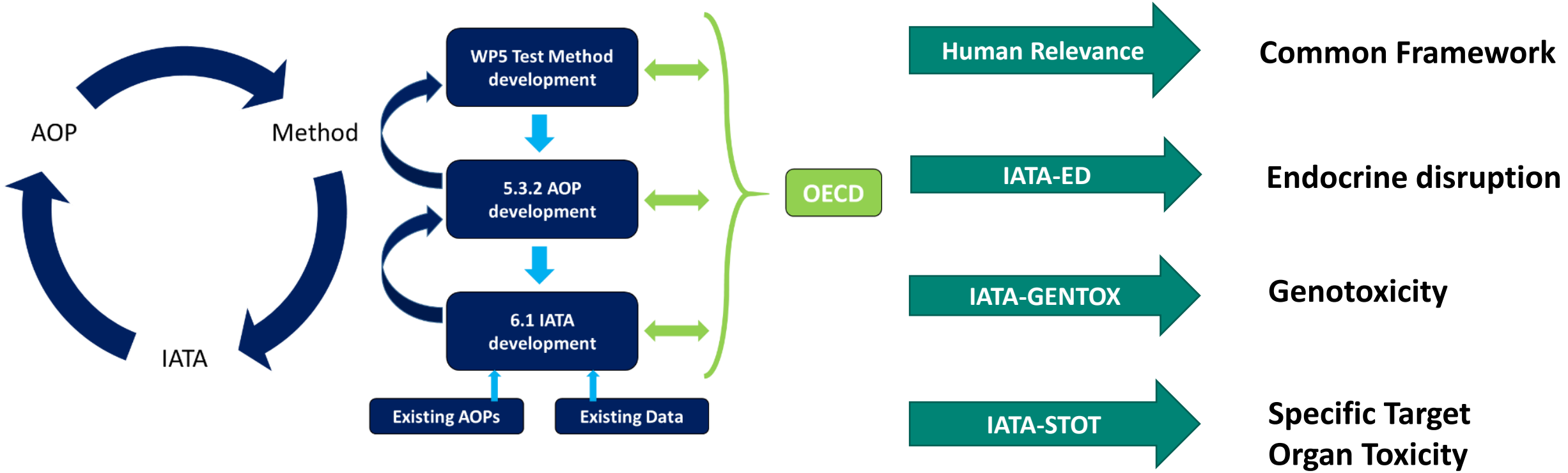
Regulatory science

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

T6.1 Integrated Approaches to Testing and Assessment



Towards chemical safety assessments using solely non-animal methods

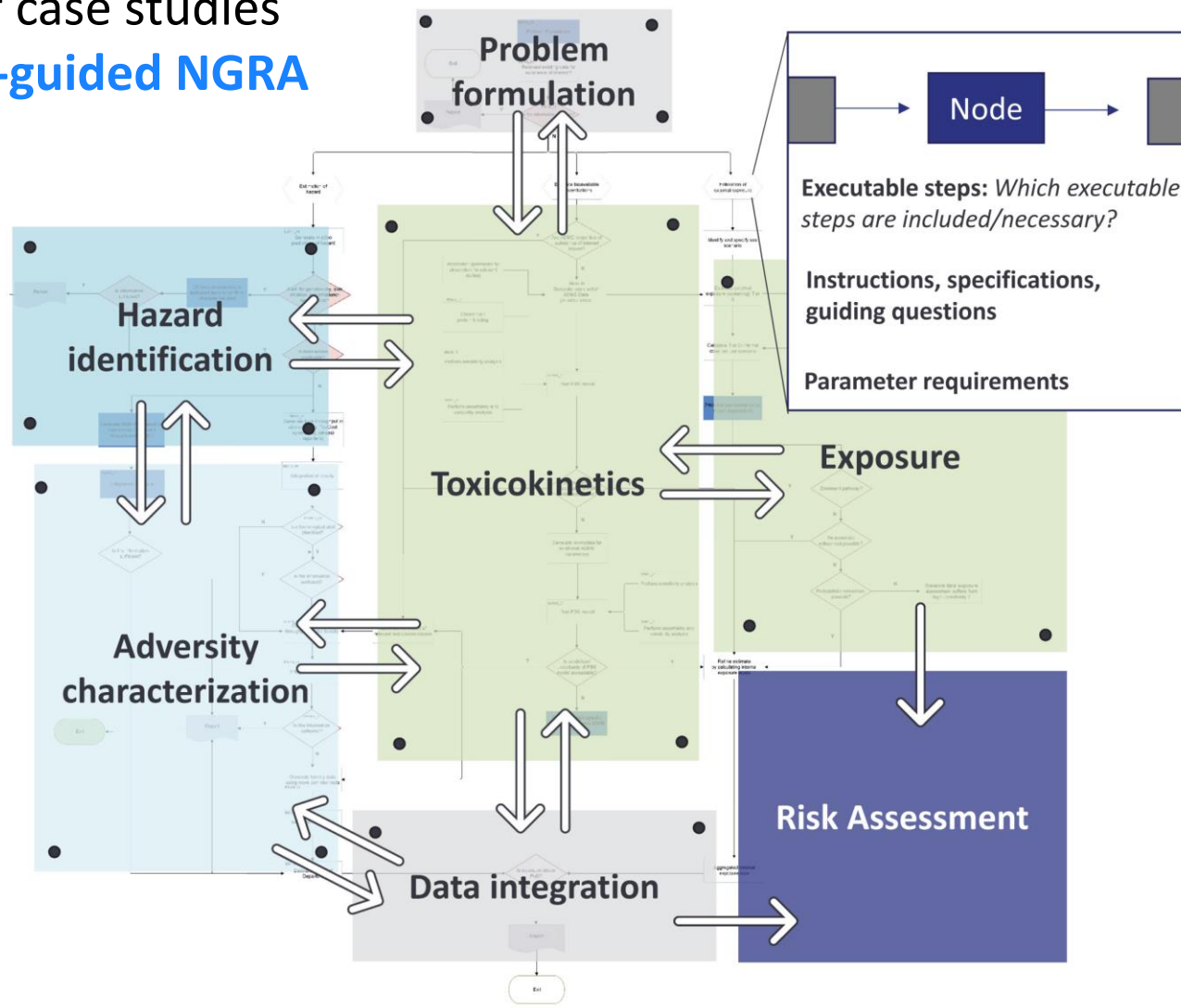
- Ensure regulatory readiness of NAMs and NGRA approaches – driven by WP2
- Leverage of existing NGRA concepts, knowledge and experience
- Join forces with initiatives external to PARC

Joint workflow for NGRA

- ASPIS aims to leverage the knowledge and insights gained from designing concepts and a large variety of case studies to **operationalize** NGRA, by developing a **well-guided NGRA workflow** for safety assessment of chemicals

- This workflow serves as **guidance** on **data generation** *and* **interpretation**

- **ASPA**, the **ASPIS-initiated alternative Safety Profiling Algorithm**:
  - Defines a tiered approach on what tools/methods to use
  - At which steps to obtain and evaluate data, incl. uncertainty assessment
  - How to put data into a context of a hazard or risk assessment scenario



Take home message

PARC has a lot to offer, including:

- Essential toxicity data, to overcome gaps in knowledge → enhanced protection of public health and the environment
- A diverse range of innovative NAMs, incl. NAMs that will have a high level of regulatory readiness
- IATAs for various health effects, incl. case studies demonstrating their applicability for different regulatory problem formulations
- A workflow for human relevance assessment
- Criteria for NAMs for regulatory use
- Contributions to (pre-)validation of NAMs in multiple ways

- PARC Website : www.eu-parc.eu

- PARC Contact: PARC@anses.fr
- Coordinator: Pascal.Sanders@anses.fr
- Deputy Coordinator: Christophe.Rousselle@anses.fr