Partnership for the Assessment of Risks from Chemicals

PARC NGRA*route*

A roadmap for making EU chemicals legislation NGRA-ready

Matthias Herzler

EC roadmap workshop

Brussels, 2023-12-12

PARC

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About PARC Task 2.2

https://eu-parc.eu
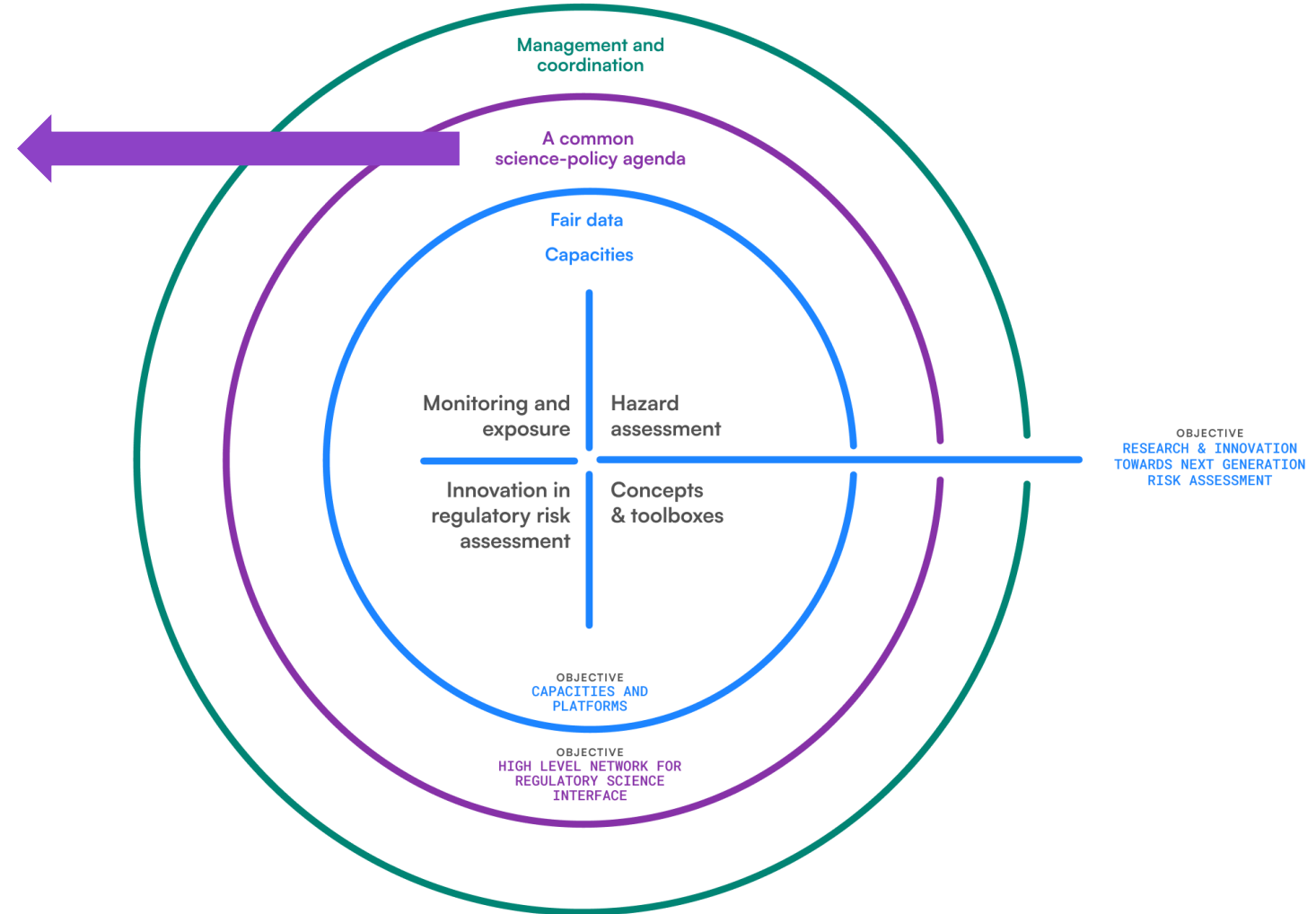
WP 2 – A common science-policy agenda

Task 2.2 – Knowledge management and uptake into policy

Two main activities:

NGRA roadmap **NGRA*route***

Online platform PARCopedia **.eu**

Uptake into policy - vision for NGRAroute

*"By April 2025, NGRAroute will provide a **concrete and applicable roadmap proposal for implementing NGRA as the default approach** to chemical risk assessment in EU chemicals legislation."*

Default approach:

- **Mandatory application of NGRA** framework first (incl. existing data, RAx)
- New testing *in vitro* as far as possible
- New *in vivo* testing only as **last resort if NGRA** not yet applicable

This concept, if implemented in the legislation, would allow for maximum flexibility.

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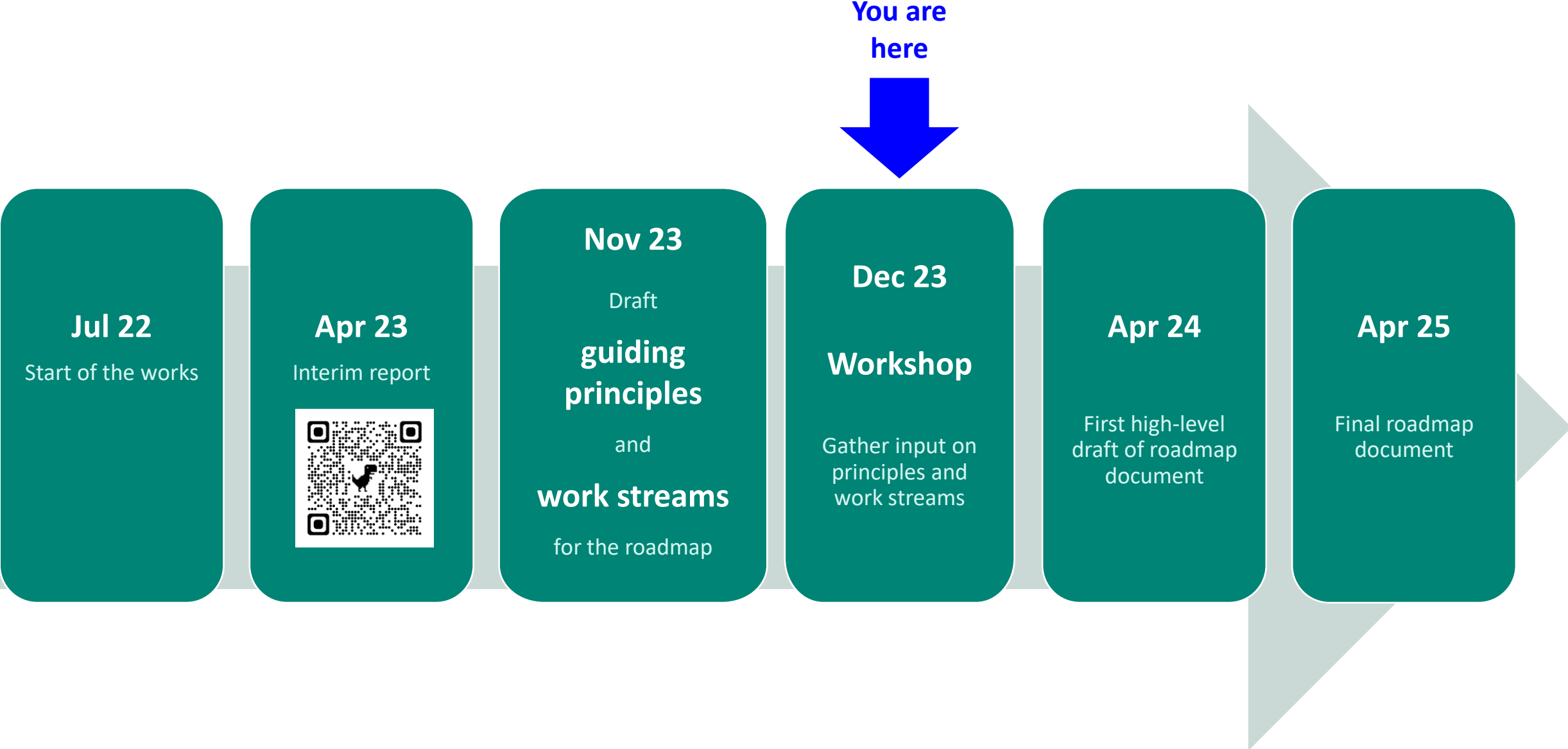
Why a roadmap like NGRAroute?
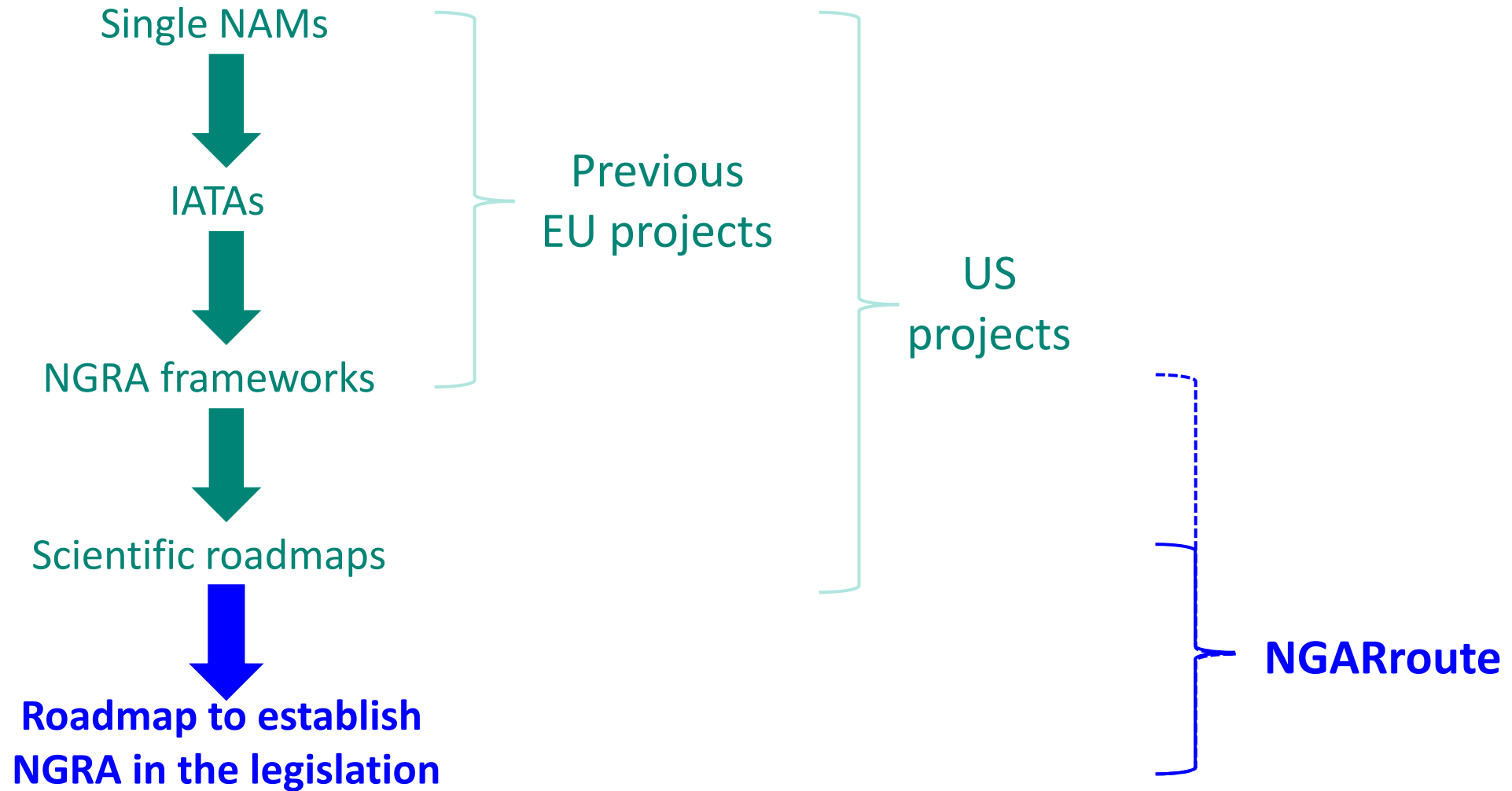
Why under PARC?

- 24 **EU MS, agencies** (except EMA) and **COM** are present.

- MS and academic **Affiliated Entities** also represent most other major **EU projects** on the matter (e.g. ASPIS cluster projects).

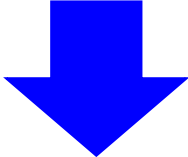- **SYNnet** to integrate external partners (e.g. EPAA)

Scope of the roadmap

–   The activity is meant to provide, by April 2025, a **roadmap proposal** to make European chemicals legislation **NGRA-ready**

–   In scope: **all European chemicals legislation** with a risk (i.e. hazard and/or exposure and/or risk) assessment component of their own.

–   For **human health** and **environmental** risk assessment

Timeline

You are here

Jul 22
Start of the works

Apr 23
Interim report

Nov 23
Draft
guiding principles
and
work streams
for the roadmap

Dec 23
Workshop
Gather input on principles and work streams

Apr 24
First high-level draft of roadmap document

Apr 25
Final roadmap document

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Why guiding principles?

Guiding principles are useful to

– foster broad **consensus** on fundamental questions (instead of getting lost in the details) early on

– **define** political, scientific and regulatory **boundaries** of NGRA and the further roadmap work

– help **structure** further work and **focus** discussions (cf. OECD (Q)SAR validation principles).

We have now drafted **"10 guiding principles for an NGRA framework to be established in EU chemicals legislation"**

1. First version circulated for comments within PARC in summer, 2nd round in autumn of 2023

2. Third version as **background document** for discussion today (13:30 – 17:00), along with some **preliminary conclusions** and proposed **work streams for future work**

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Draft guiding principles – policy implementation
for an NGRA framework to be established in European chemicals legislation

1. The framework ensures a **high and transparent level of protection** for human and environmental health that meets the overarching policy targets.

2. The framework relies on **new *in vivo* testing in sentient animals only as a last resort** and only until a full replacement is possible.

3. The framework allows for a **resource-efficient** assessment of a large number of chemicals within an **appropriate time-frame**.

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Draft guiding principles – scientific development
for an NGRA framework to be established in European chemicals legislation

4. The framework uses **state-of-the-art methodology** for modelling, testing and assessment with **high scientific relevance** to the protection targets, i.e. human health and the environment.

5. The framework provides a **high and transparent level of confidence**, in particular when concluding on the **absence** of relevant hazard, exposure and/or risk.

6. The framework is capable of **integrating multiple lines of evidence from a wide range of data, information and knowledge sources** in a highly **reproducible** way.

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Draft guiding principles – regulatory acceptance
for an NGRA framework to be established in European chemicals legislation

7. The framework is **applicable** to all chemical **hazard, exposure and risk assessment workflows** required by legislation.

8. The framework covers all relevant **pathways and endpoints** of **regulatory interest** and ideally is able to address also **new and emerging areas** of chemical risk assessment.

9. The framework allows for the assessment of single **substances** and their **transformation products**, **groups** of substances, intentional and unintentional **mixtures** and **articles** across all relevant **routes of exposure**.

10. The framework allows for **risk assessment of real-life exposure levels and durations** across all relevant **routes of exposure**.

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Preliminary conclusions for the further work

Four tentative work streams

For more information, see background document for the afternoon sessions

1. **The framework ensures a high and transparent level of protection for human and environmental health that meets the overarching policy targets.**

Work stream	Preliminary conclusions
Scientific development	Methodology to **define and determine** the achieved protection level in a transparent and scientifically robust way needs to be established. **Probabilistic** hazard/exposure/risk assessment methodology should be explored to that end[5].
Regulatory acceptance	Standardisation of methods is needed to ensure **consistency between assessments** with respect to protection levels across different classes of substances within and across regulatory sectors.
Policy implementation	The desired protection level needs to be **specified explicitly** in the legislation or associated guidance. In the current risk assessment framework, the protection level is often intransparent: while it is believed to be high overall, hazard/exposure/risk might be under- or overestimated on a case-by-case basis, resulting in an insufficient or excessive protection level, both with potentially detrimental consequences for society. It is also noted that "protection level" includes several **qualitative and quantitative components**, i.e. it would need to be specified which part of the population shall be protected against which effects, and to which extent.
Change management	Changing from an implicit, intransparent assumption to an **explicit, transparent and data-based statement of the protection level** will come with an increased responsibility for risk managers, as they need to decide on **what residual risk for human health and the environment may be tolerable** if exposure cannot be avoided completely. The benefits of transparency, consistency and accountability should be highlighted, but specifically the latter may not be popular. Furthermore, **communication to the public** that "safety" does rarely mean "zero risk" would need to be increased. On the other hand, people are familiar with this experience in many other aspects of life and in the long run, such communication is seen to improve the understanding of chemical safety in the population.

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Work stream tasks

Build **networks**

– **Projects** – **authorities** – **policy makers** – **social scientists/communciation experts**

– Involve EU **regulatory bodies**, experts from **PARC**, other **activities** (EU and worldwide), **supranational organisations** (OECD, WHO, UN), EU **regulatory** and **policy-making** bodies

– Identify **key players to be addressed for implementing** the necessary changes

Analyse **state of the art** and identify **concrete research questions** to be answered

– short (before completing roadmap) – medium – long term

Define **specific and concrete goals** and **steps** to be taken, detailed **work plan**

Work streams – tasks

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This will be discussed in more detail in session #2 this afternoon

How can this even work?

— We **know enough** to **start working!**

— A **co-operative structure between work streams and networks** needs to be set up.

— **PARC Task 2.2 can help** with the coordination.

But we also need a **true co-operative spirit**, work and knowledge sharing instead of **territorial claims of individual initiatives** and an **openness for debate** as well as **compromises!**
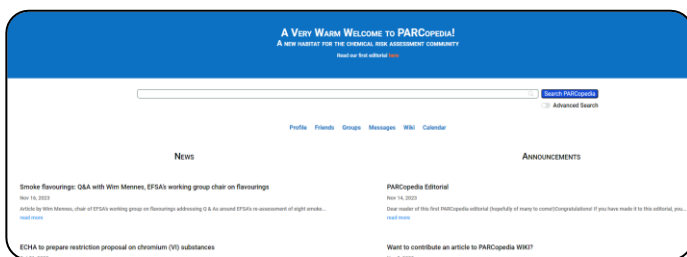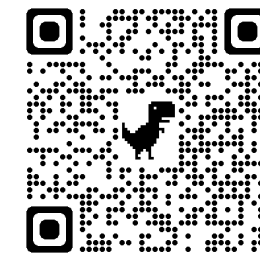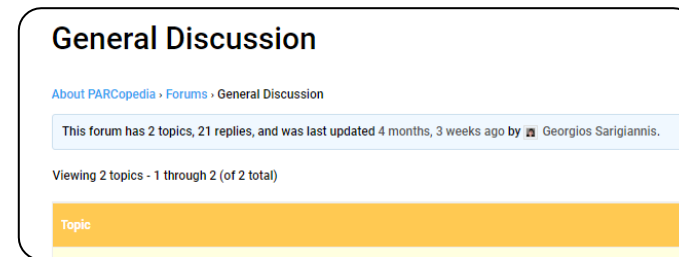
A new co-operative space for the risk assessment community
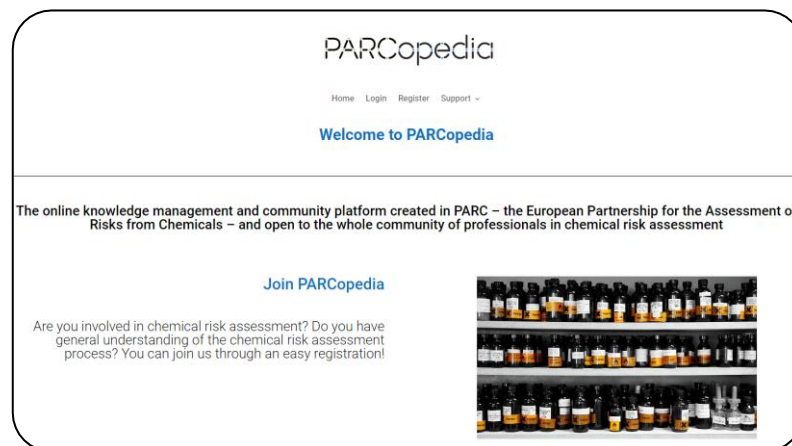(launched 15 November 2023)

https://parcopedia.eu

The new **knowledge management** and **community** platform created for **chemical risk assessment professionals** in and beyond **PARC.**
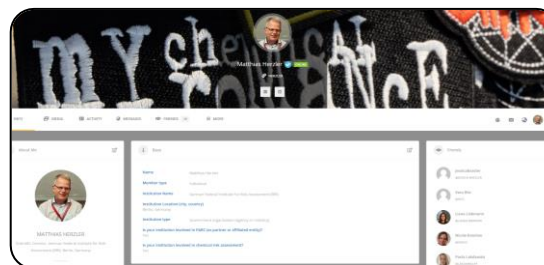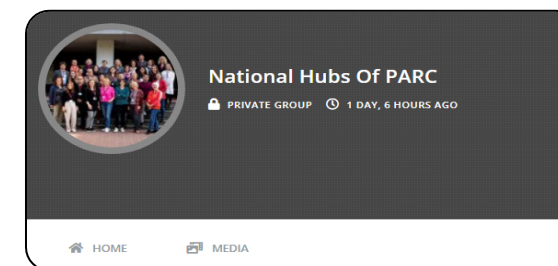
News, events, jobs

Discussion fora

WIKI

Personal profiles

Public and private groups

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SHARE!

EXPLAIN!

MEET!

HELP THE COMMUNITY!

DISCUSS!

ENJOY THE ~~SILENCE~~ SCIENCE!

HELP THE COMMUNITY!

PRESENT YOUR WORK!

STAY IN TOUCH!

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Thank you for your attention!

Matthias Herzler

On behalf of the PARC Task 2.2 team

PARCopedia.eu: @herzler

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P-A-R-C
Partnership
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