

# Transitioning to “Next-Generation Risk Assessment” (NGRA)

Why, what, who, how, chances and challenges ... and what’s PARC got to do with it

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*The views expressed in this presentation are exclusively my own and do NOT represent an official position of the BfR or other German authorities.*

# Useful definitions

## „New Approach Methodologies“ (NAMs)

Methods not in routine use for Chemical Risk Assessment (CRA) when I started at BfR 21 years ago.

## „Next-Generation Risk Assessment“ (NGRA)

CRA framework helping us overcome the problems of „Past-Generation Risk Assessment“.  
It relies on NAMs (as above) and not on (new) traditional *in vivo* testing.

# Why do we need NGRA?

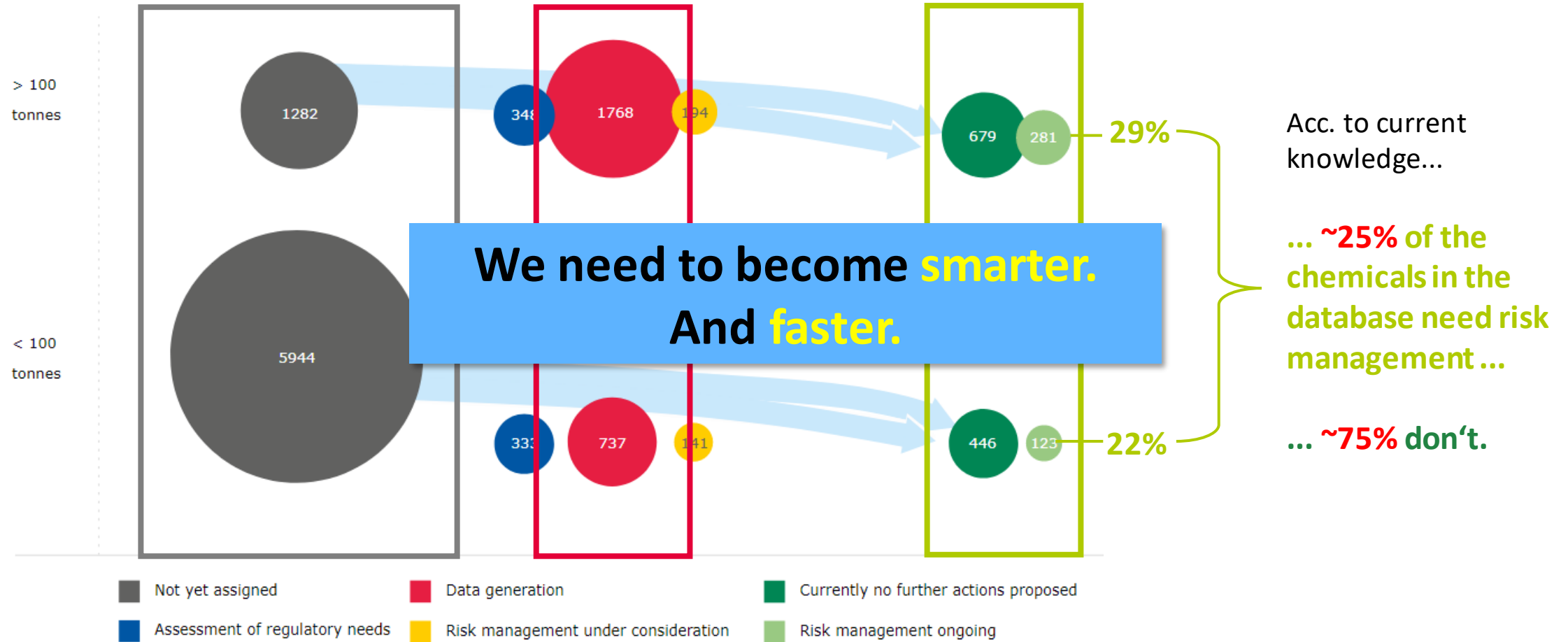
The current CRA framework **protects us well**, but there are problems\*:



\*cf. also EU Chemicals Strategy for Sustainability

# One figure to show them all... (source: ECHA website, last accessed 2023-05-26)

Figure: REACH chemical universe: substances with active registrations above 1 tonne/year.



# What we want from NGRA

high throughput,  
**speed**

early filter for  
**real concern**

full **quantitative** risk assessment  
(ideally probabilistic)

high and transparent level of  
**confidence**

comparable level of  
**protection**

improved knowledge about  
**use and exposure**  
(also cumulative, aggregate)

**species**-relevance,  
reflect **mechanistic** knowledge

**combination** effects

# Scientific challenges (non-exhaustive list...)

early biomarkers **in vitro** vs.  
real adverse effects **in vivo**

reliable identification of  
**low/no toxicity**

**quantitative RA**  
(qIVIVE/qAOPs...)

**integration**  
of diverse streams of evidence

**validation**  
(qualification)

**standardisation**  
(and translational capacity building)

Even if we do not have everything in place already,  
**WE CAN START** the **transition** right **NOW.**

# To do this, we need a new mindset\*!

## *Article 25*

### **Objectives and general rules**

1. In order to avoid animal testing **testing on vertebrate animals** for the purposes of this Regulation shall be undertaken **only as a last resort**. It is also necessary to take measures limiting duplication of other tests.

There are many reasons why REACH **Art. 25 (1)** has not become a real part of the REACH „DNA“ ...

### **On the side of the authorities:**

**Structural** (mandate, capacity), but also **mindset** issues have favoured an often **skeptical, passive attitude**, waiting for others to deliver fit-for-use NAMs.

\* (among other things...)

# And is this even really our job (as authorities)?



**YES, it is.** Due to our unique role and expertise, the **authorities** need to **take the lead**.

Some of us have been working on it for a while already ... and now there's the **Partnership for the Assessment of Risk from Chemicals.**



<https://eu-parc.eu>



**A** (first attempt to formulate the) **vision for a new mindset**  
(PARC Task 2.2, NGRARoute roadmap activity, interim report\*)



**“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” = first line of risk assessment**

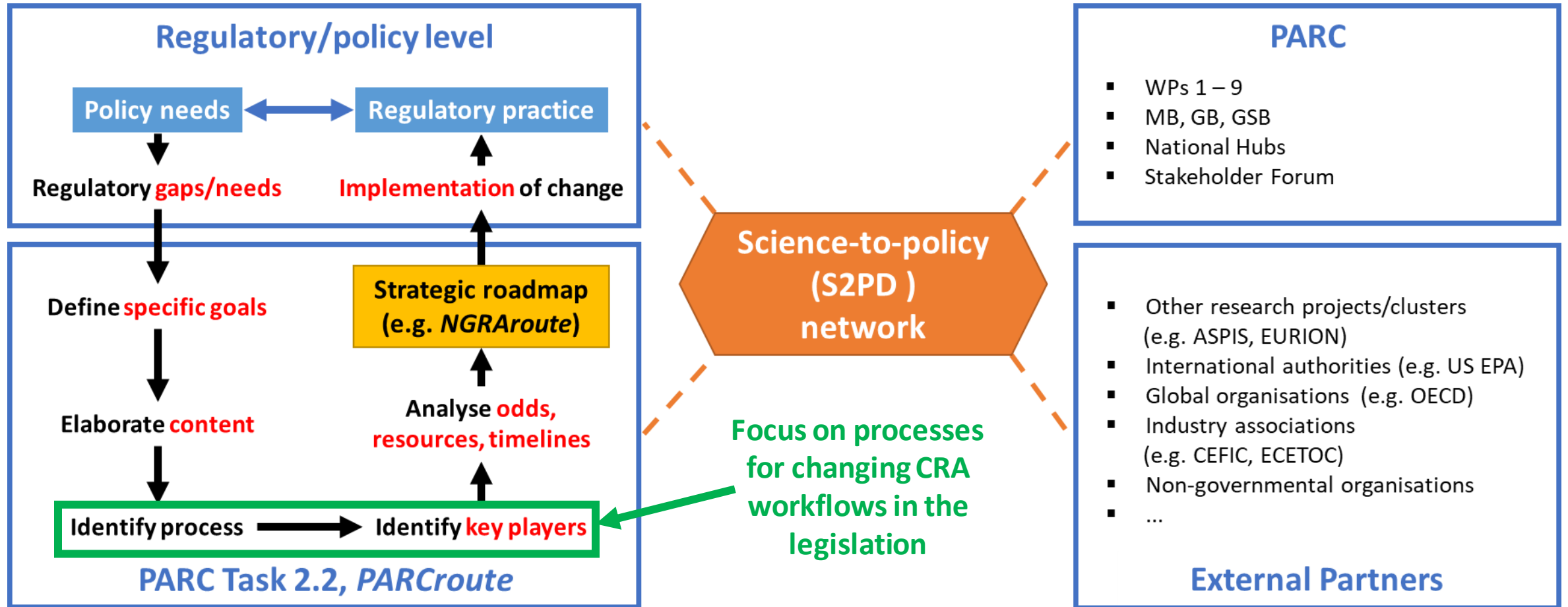
→ traditional in vivo testing only if:

a) NGRA is not (yet) practically feasible or b) the conclusions from NGRA are not sufficiently reliable

This is **NOT A REVOLUTIONARY APPROACH** → REACH Art. 25 (1)  
(cf. also REACH Annex VII, section 8.3 on skin sensitisation)

\* Currently under review by the European Commission, will be published on the PARC website after approval.

# ... and a strategy (PARC Task 2.2, NGRARoute interim report\*)



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# The challenges ahead require a collective effort



... need to establish **consensus** within a **broad and diverse community**

... **good understanding of new methods** required on all sides  
(researchers, risk assessors, risk managers, policy makers)

... need to **connect people** to **share** work,  
**exchange** ideas and **discuss** new approaches

... help prevent/overcome **language barriers**



Pieter Bruegel (the Elder): The Tower of Babel  
Source: Wikipedia, the free encyclopedia

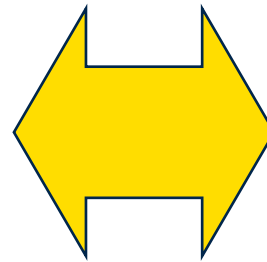
Coming November 2023...



# PARCopedia

An  
*online*  
*knowledge platform*

to *create and share knowledge* on  
chemical risk assessment (CRA)



A  
*community*  
*space*

for CRA professionals

to *connect* different disciplines, sectors and  
areas of work, in- and outside of PARC

# Features

- **Knowledge base** (“wiki”) covering all aspects of CRA
- **Special focus on NAMs and NGRA** as well as other innovative (PARC) content
- A **community space** made of profiles, blogposts and discussion groups

## YOU ARE INVITED...

... to *present* yourself and your work ...

... to *exchange* points of view, *share and comment* on what’s new in PARC(opedia) and CRA ...

... to *interact* with a lively, *interdisciplinary* community and help us *shape the CRA of tomorrow!*

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