Main outcomes from the ECHA NAM workshop and Key Areas of Regulatory Challenge report

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

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NEW APPROACH METHODOLOGIES WORKSHOP

31 MAY - 1 JUNE

Towards an animal free regulatory system for industrial chemicals

Towards an animal free regulatory system for industrial chemicals

The workshop aimed to discuss the critical needs within the current regulatory system by bringing perspectives from different stakeholders, and to explore opportunities to increase the use of NAMs in the short and long term.

→ Steering committee

- European Commission, DG Environment
- European Partnership for Alternative Approaches to animal testing (EPAA)
- European Chemical Industry Council - CEFIC
- PETA Science Consortium International
- ECHA secretariat

➢ **500 participants** (150 on-site)

Industry, Authorities, researchers and NGOs (environment and animal welfare)

→ Videos, presentations and background document available online

Some take-aways

- → Strong commitment from all stakeholders to move towards animal-free chemical safety assessment
  - Different expectations on how ready we are and how fast we can move
  - It is important to have goals to make progress
  - Communication and training play a role
- → Use of New Approach Methodologies is advancing for some, but not all, toxicological endpoints, and challenges remain
  - Confidence building in NAMs is required, e.g. using targeted case studies
  - We can do more with already ongoing testing and available data to accelerate the transition

Some take-aways

- → Regulatory context defines the readiness to apply NAMs
  - Mutual Acceptance of Data is essential to ensure global acceptance
  - There is not one recipe fits all
  - Legal and scientific certainty is critical
- → Targeted investment is required to facilitate NAM regulatory acceptance (including validation)
- → Quality and accessibility of data important to support informed regulatory decisions making and help developing test methods
- → Input into the dialogue is required from all stakeholders across sectors and geographical regions

- ➢ 72% of the participants felt more confident that we can move forward with the replacement of animal testing

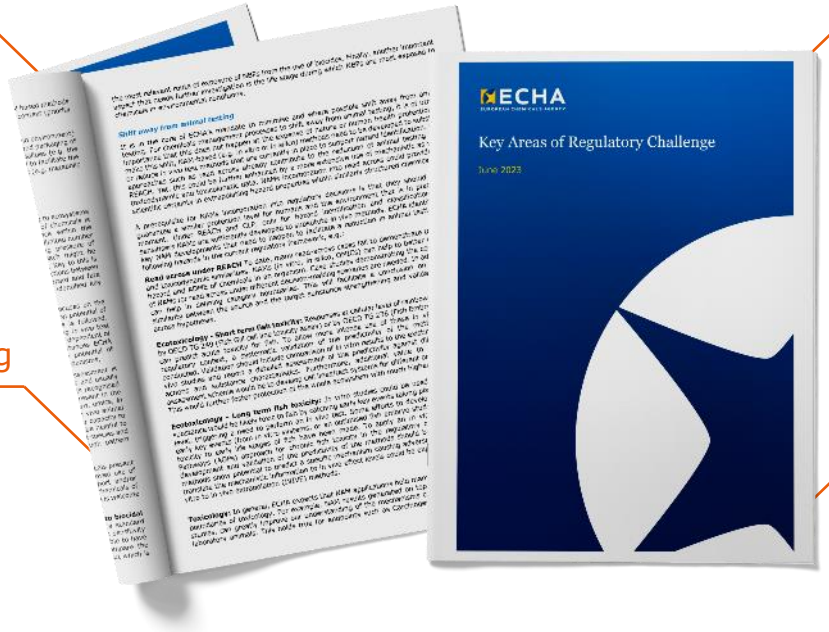
ECHA's Key areas of regulatory challenge

Increase collaboration between research and regulators

Key Areas of Regulatory Challenge (June 2023)

Provide protection against most harmful chemicals

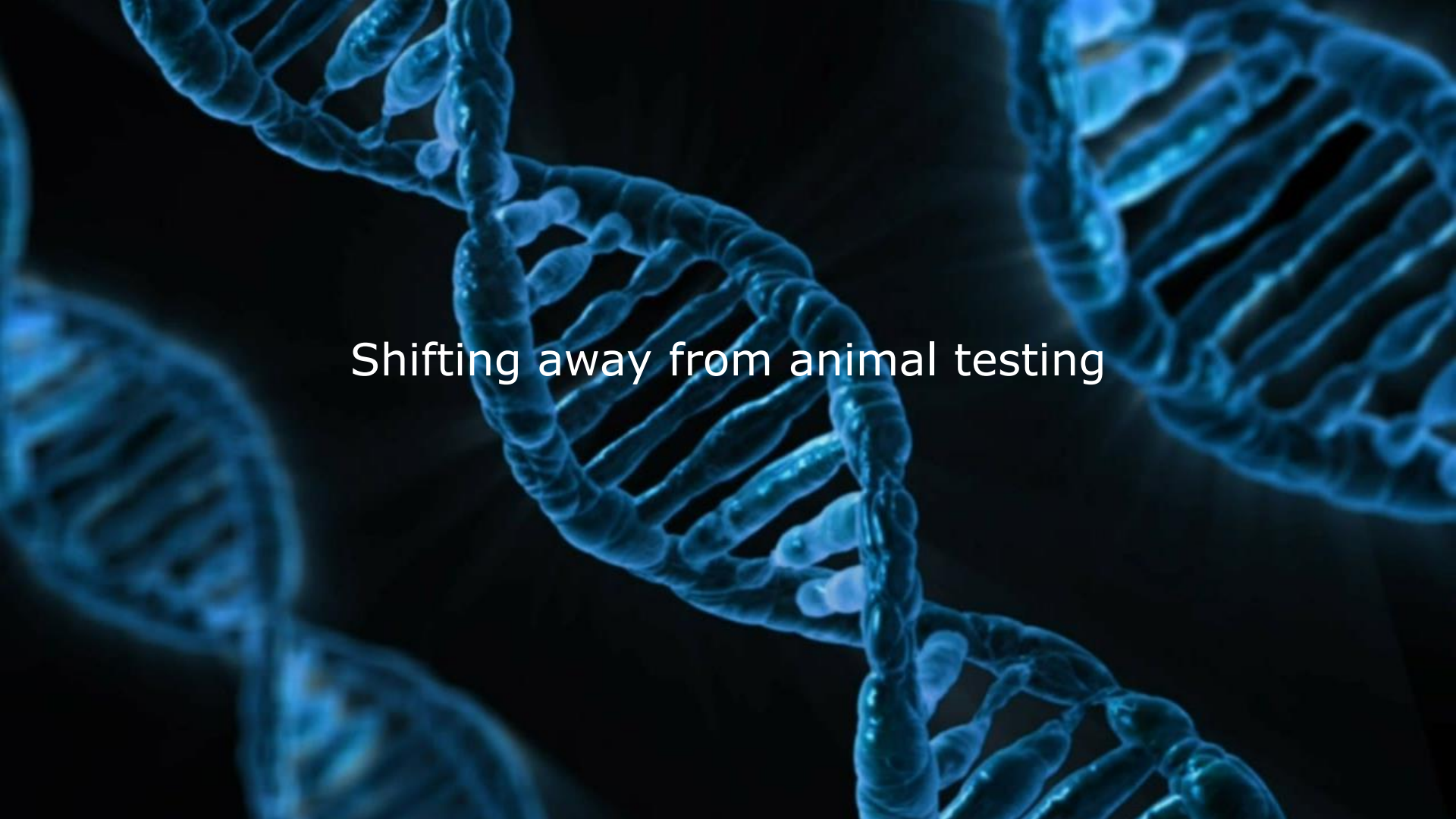
Addressing chemical pollution in the environment



Shift away from Animal Testing

Improved availability on chemical data

Update foreseen annually. Next version available in June 2024


Shifting away from animal testing

NAMs for animal free hazard assessment in three steps:

Step 1. Define

Identify critical needs for transition to animal free system to steer NAM development

Step 2. Demonstrate

Apply already available NAMs under current system

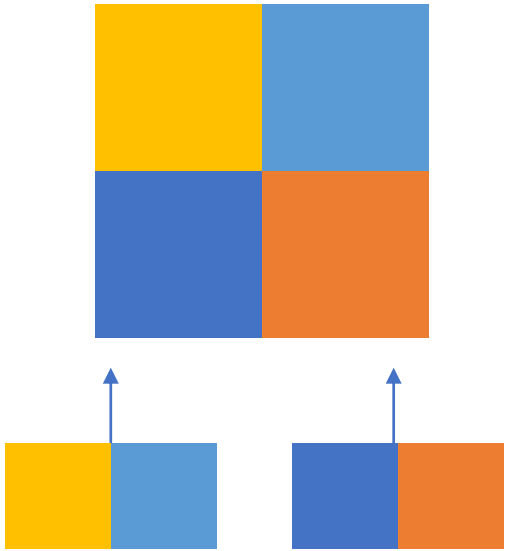
Step 3. Re-design

Re-think overall system to enable NAMs & **Redefine** main elements

Key area examples for NAM development

→ Read across and NAMS:

- **Challenge:** Read across is the most commonly used alternative approaches for filling data gaps (for repeated dose toxicity, developmental and reproductive toxicity endpoints). However, many fail to demonstrate sufficiently similar toxicokinetic and toxicodynamic properties.
- **Needs**: NAMs, in vitro and silico tools, can help to support the read across hypothesis by generating data on the kinetics and dynamics of different compounds and defining category boundaries. The development of case studies can facilitate the incorporation and understanding of NAMs for read across



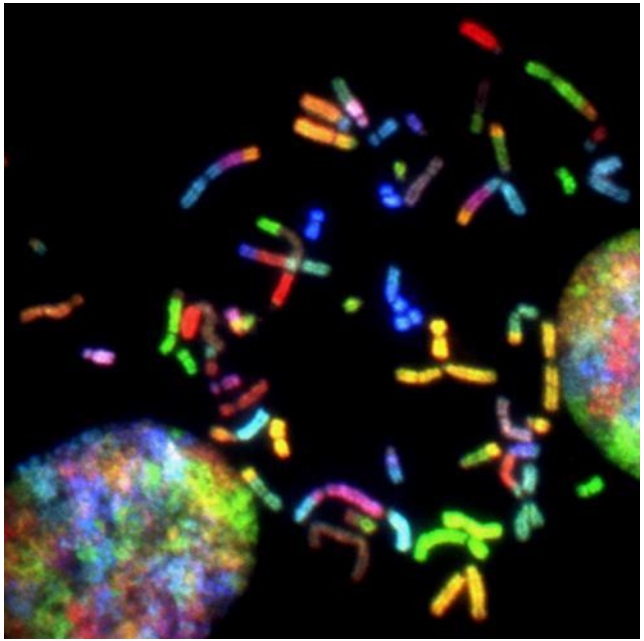
Key area examples for NAM development

→ Carcinogenicity:

Challenges: Identification of carcinogens relies on 2-year rodent assay. The study involves a large number of animal and takes a long time to get the results. At this rate, testing will continue for decades before currently unknown carcinogens are identified.

Needs:

1. Improve the detection of carcinogens including those that act through a non genotoxic mode of action.
2. Develop Adverse Outcome Pathways (AOPs) for specific modes of genotoxic or mutagenic action.

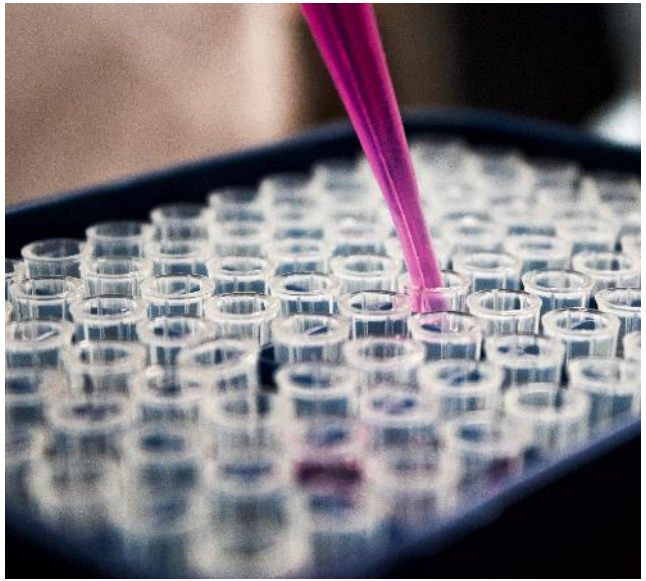


Key area examples for NAM development

→ In vitro/in silico ADME and Physiologically-Based Kinetic models:

Needs:

1. Catalogue what methods are currently available (and can be run by CROs) and can be used to predict ADME/TK properties
2. Characterise the performance of these methods and IVIVe modelling and how the performance is affected by a given chemical space?
3. Identify the current limitations and uncertainties related to ADME/TK methods?



Final remarks

- → ECHA is proactive to promote NAMs, and our activities in this respect are going beyond the regulatory implementation
- → Joint and focussed efforts are needed to fill the gaps
- → There is a need to agree on critical elements to be addressed for a transition to an animal test free system
- → NAMs can be utilised to refine, reduce and replace animal testing under the current system
- → Developing, agreeing and sharing criteria for NAMs in regulatory applications is a key for a wider acceptance
- → It is a collective effort and requires buy-in by all stakeholders, including the public

Thank you

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