ECHA
EUROPEAN CHEMICALS AGENCY

Bridging the gap between science and regulatory science in the EU: Regulatory perspective

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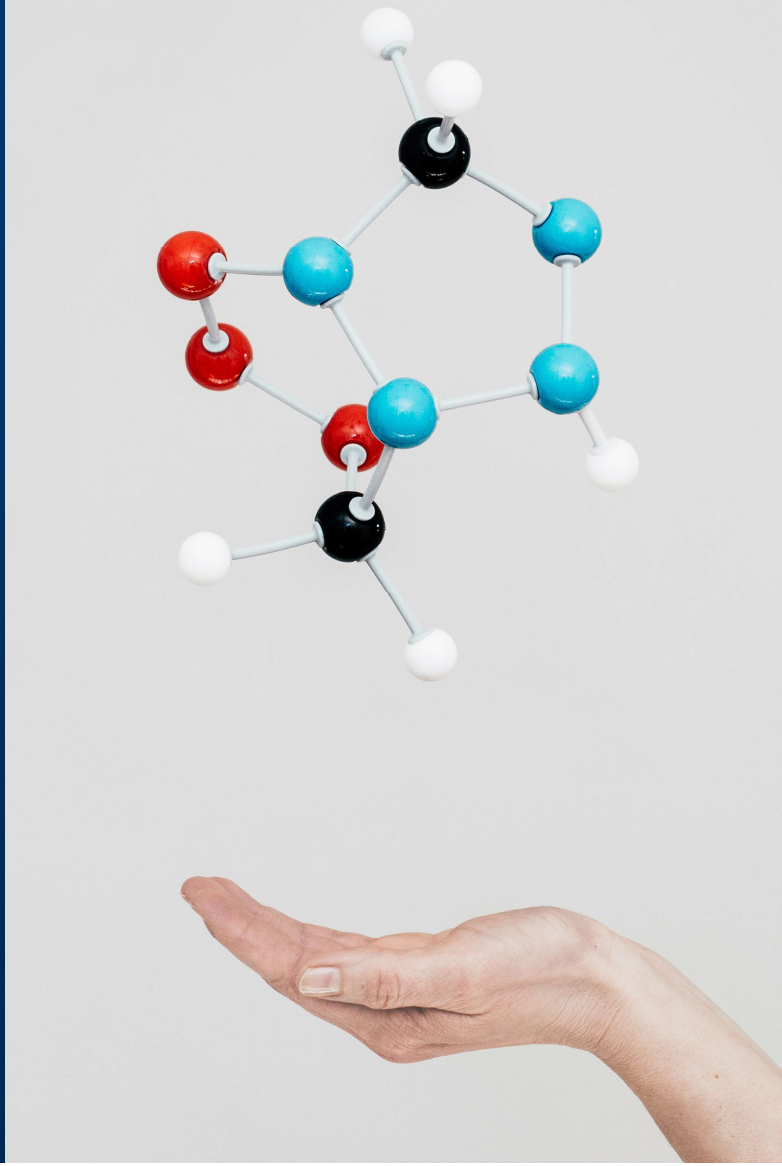


ECHA's Legal Basis

650 Staff
Helsinki, Finland

Legislation

REACH, CLP, Biocides, PIC, POPs, Waste Framework Directive, Drinking Water Directive, 8th Environmental Action programme, Cross-border Health Threats, Batteries

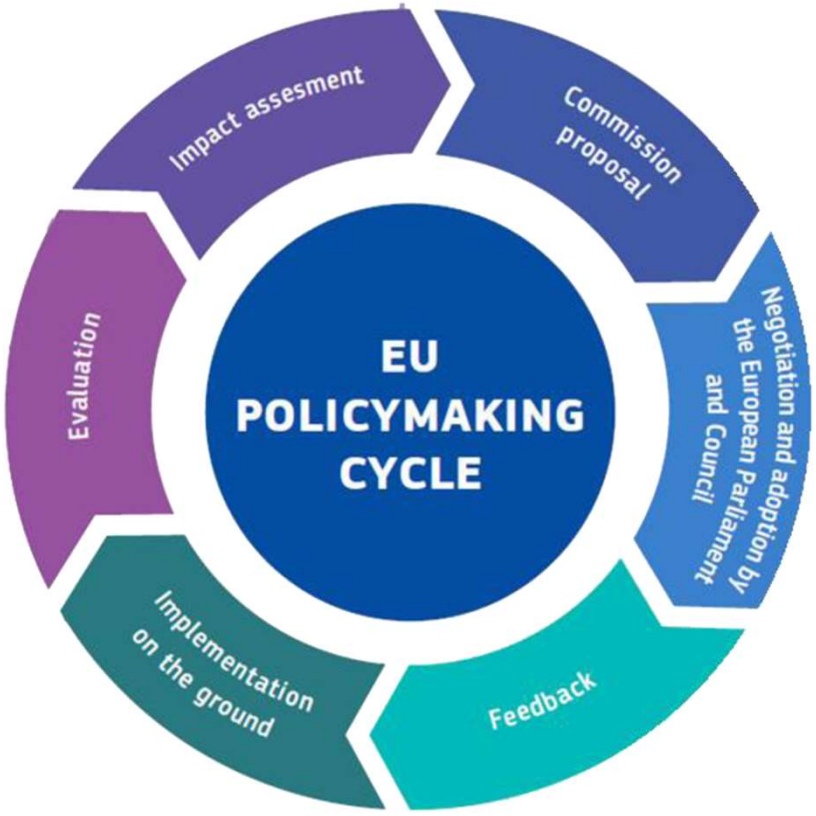
Specific tasks

EU Observatory for Nanomaterials, EU Chemicals Legislation Finder, Occupational Exposure Limits (OELs), Instrument for Pre-accession Assistance (IPA), IUCLID for EFSA, Partnership for the Assessment of Risk from Chemicals (PARC)

Implementing EU Regulation (1/2)

→ Regulation is a result of a policy cycle:
- Translation of a policy ambition into a legal framework
- Legal text sets out principles, rights, obligation etc
- Legal text is not 100% prescriptive

→ Applied science is essential in implementing regulation
- But technical annexes, prescribing e.g. 'how to fulfil obligations' are often prone to differences in interpretation



Implementing EU Regulation (2/2)

→ Science evolves ➔ so does regulation

- This development is part of 'policy cycle' review
- Review of regulation can be based on changes in scientific findings ➔ regulators need a reliable basis to make changes
- Cost benefit assessment
  - Key step in (re)drafting EU regulation
- Obviously, there is a delay between developing scientific reality and the changes in legal framework

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Regulatory challenges

→ When implementing EU regulation, you need to be a 'scientist with a legal brain'

→ Even the best scientific argument fails if there is no legal basis for it

→ So 'regulatory science' is what we work with as regulators
- Applying the 'best science' for a specific legal context
- Often working at the boundaries of current knowledge
- We need you as scientific community to help pushing these boundaries

Implementing EU Regulation: where science makes a difference

→ Key is to identify and characterise hazardous properties and exposure leading to risks for humans and the environment

→ Required in order to set appropriate risk management actions (e.g. Classification and Labelling, Authorisations, Restrictions, Occupational exposure limits) in order to manage safe uses of substances

You can help with models, methodologies, data

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Drivers for regulatory science

Chemical Strategy for Sustainability (CSS)

- Addressing chemical pollution in the environment
- Provide protection against most harmful chemicals
- Shift away from Animal Testing
- Data availability

Legal Requirements

- Changes in Regulations e.g. new hazard classes in CLP Regulation (ED, PMT/vPvM, PBT/vPvB) and new information requirements
- …

Advances in Science

- Ambition to further develop animal free methodologies
- Improved precision in analytics
- Partnership for the Assessment of Risks from Chemicals (PARC)

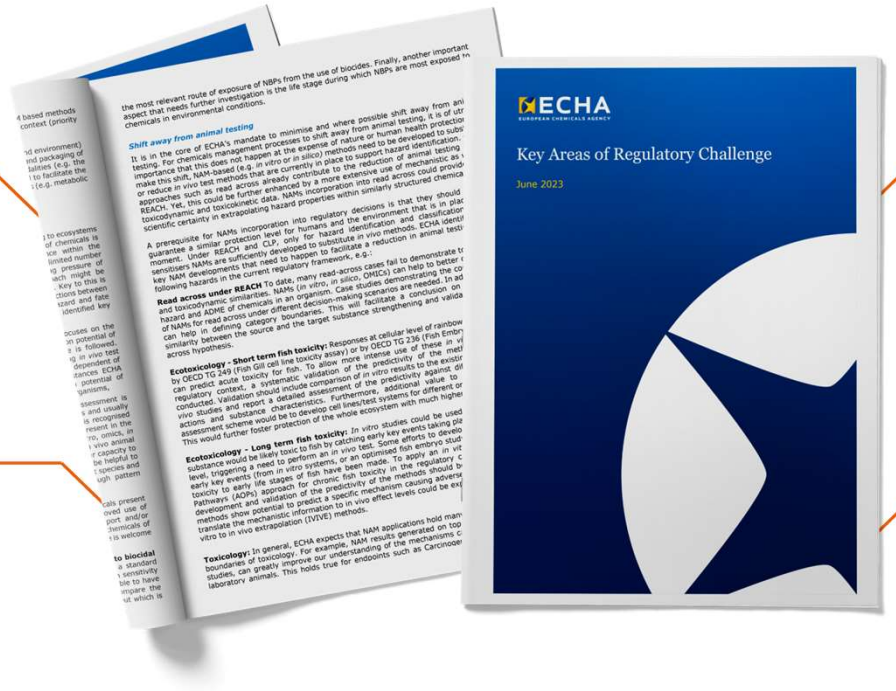
ECHA's Research needs

- → PARC was the trigger to initiate internal prioritisation of science areas where we face biggest challenges
- → Based on the structure of the Commission's Chemical strategy for Sustainability (CSS; Part of the Green Deal)
- → First ECHA attempt to illustrate what would be beneficial in terms of research and why

Key Areas of Regulatory Challenge (November 2023) CSS perspective

Provide protection against most harmful chemicals

Shift away from Animal Testing



Addressing chemical pollution in the environment

Improved availability on chemical data

ECHA PODCAST

ECHA's Safer Chemicals Podcasts:
Bridging the gap between scientific research and chemicals regulation

ECHA EUROPEAN CHEMICALS AGENCY

Zoom in: “Addressing chemical pollution in the environment”

→ Bioaccumulation

- Development of non-vertebrate methods to predict the bioaccumulation potential of surfactants, ionisable substances and organometals
- Improved bioaccumulation assessment for air-breathing organisms,
- Improve the assessment for secondary poisoning and man via environment specially for mixtures
- Development of new methods and assessment approaches to evaluate the bioaccumulation potential of super hydrophobic substances
- How to improve assessment of secondary poisoning and man via environment?

→ Monitoring

- Development of approaches based on monitoring field data enabling persistence, long-range environmental transport and/or bioaccumulation assessment.
- Case study 1: Environmental monitoring data for linear and cyclic siloxanes

→ Expanding **protection of biodiversity** by use of NAMs

→ Data generation for assessing the sensitivity of **non-bee pollinators** (NBP) to biocidal active substances

Conclusions

- → How to close ‘the gap’?
  - How to translate these needs better?
  - How to make you more familiar with EU regulatory needs?
- → How and where to keep a dynamic dialogue going between all stakeholders?
  - Structural need for this!
- → **Beware!** Talking about scientific uncertainties as regulators:
  - does not mean we are not able to do ‘our job’.
  - let ‘uncertainty’ not undermine the dialogue with stakeholders

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