



EU Chemicals Strategy for Sustainability

#ChemicalsStrategy
#EUGreenDeal



European
Commission

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Chemicals Strategy

- The EU's chemicals strategy for sustainability towards a toxic-free environment
- Published on 14 October 2020 as part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal
- Global chemicals production is expected to double by 2030
The already widespread use of chemicals will also increase, including in consumer products
- Many chemicals have hazardous properties which can harm the environment and human health
- [Chemicals strategy \(europa.eu\)](https://europa.eu/chemicals-strategy)

Chemicals Strategy for Sustainability: 5 building blocks

Boosting innovation

- Commission recommendation on safe and sustainable by design criteria
- Innovation and research financing
- Generic do no significant harm criteria for chemicals under taxonomy

Strengthening legislation for better protection

- CLP regulation
- **REACH**
- Cosmetics product regulation
- Toy safety directive
- Food contact materials legislation
- Food additives legislation
- Food contaminants legislation
- Communication on essential use criteria

Simplification & coherence

- Horizontal proposal on (re-)attribution of technical work on chemicals to EU Agencies
- **Horizontal proposal on improving access, sharing and re-use of chemical data**
- Proposal for a basic regulation of the European Chemicals Agency

Knowledge and science

- Research and innovation plan for chemicals
- Research funding
- European partnership for the assessment of risks from chemicals
- Indicator framework

Global

- Export ban on chemicals banned in the EU
- Proposal of new hazard classes to UN Global Harmonised System for Classification
- Funding for developing countries

REACH Revision: 3 main issues to address

1. Unaddressed risks

- Registration and testing requirements for some polymers
- New testing requirements to assess endocrine disruption
- Request more granular information on use and exposure
- Increase information requirements (use and exposure, low tonnage substances, and modify requirements for higher tonnage substances)
- Include additional hazard classes in the Substances of Very High Concern
- Lower the safe level of a chemical by certain factor to address risks of unintentional co-exposures (MAF)
- Set maximum tolerable level of risks for chemicals for which it is not possible to calculate a safe level
- Extend the requirements to conduct a Chemical Safety Assessment for low tonnage substances

2. Low efficiency of regulatory processes

- Extending the generic restrictions to additional hazard classes and to professional uses
- Simplification of the authorisation regime
- Introducing essential use concept and using it as a criterion for granting authorisation or derogation from restriction

3. Insufficient compliance

- Establish a **European Audit Capacity**
- Provide a **mandate to OLAF** on illicit chemicals
- Mandate ECHA to **revoke registration numbers** for persistently non-compliant registration dossiers
- Provide for the possibility for **access to justice**, **collective redress** and to **claim compensation** for damages related to non-compliance

REACH Revision - Registration

- More information on critical hazard properties (e.g., endocrine disruption, more information on low tonnage substances, mostly non-animal data)
- Registration of certain polymers of concern
- More information on use and exposure
- Mixture assessment factor => cocktail effect
- Update Annex XI on adaptations of standard testing requirements



REACH Revision - Evaluation

All registrations must comply with the legal requirements

- Revocation of registration numbers
- Improve procedures for filling of data gaps, incl. by group assessment and mandating testing
- Streamline substance evaluation procedures (hazard based)



REACH Revision – Reform authorisation and restrictions

Problems

- Restrictions have been introduced at a slow pace
- Authorisation system is complex, too slow and burdensome

Specific objectives

- Increase efficiency, speed up restriction and authorisation processes
- Further incentivise substitution

Changes under consideration:

- Earlier info on use & exposure
- Reform authorisation & restriction processes
- Introduce essential use concept
- Extend generic risk management approach

CSS Simplification & coherence: **Legislative proposal on chemicals data**

Proposal for a Regulation of the European Parliament and of the Council **establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals**

- Currently at end of interservice consultation – Commission adoption expected Nov – Dec 2023
- Ordinary legislative procedure with EU Council and Parliament

Objectives

- Develop a common data platform for chemicals data from multiple sources, including environmental sustainability-related data;
- Information in data platform is secure, of high quality, findable, accessible, interoperable and reusable;
- Enable commissioning of testing and monitoring of substances as part of the regulatory framework when further information is considered necessary;
- Keep records of studies commissioned or carried out in a chemicals regulatory context
- Establish a monitoring and outlook framework for chemicals

A gradual TRANSITION to animal-free chemical regulations:

- A societal expectation, but it cannot happen in one day
- Shifting to a **new safety PARADIGM**: we support the **Commission's Roadmap towards phasing out animal testing**, with short, medium and long-term objectives and deliverables
- **All stakeholders** need to be committed and agree on what is achievable

Actionable now:

- Initiate **MODERNISATION** of chemical regulations by progressive uptake of existing NAMs (eg read across, simple endpoints)
- Foster **REGULATORY ACCEPTANCE and confidence**, using state-of-the-art approaches and swifter validation (while maintaining robustness)
- Improve **USES & EXPOSURE information** : refined exposure metrics can help target testing needs
- Secure **INTERNATIONALLY harmonised** NAM methodologies and Mutual Acceptance of Data (MAD)

Potential to speed up the safety assessment of chemicals and to ACCELERATE INNOVATION: Can we use the full potential of AI / Big Data and the ECHA database as an EU advantage for innovators?

A Strategy for Replacement



REGULAR REVIEW
OF METHODS



DELETION OF
TEST METHODS



SET
MILESTONES



MONITOR
PROGRESS



ENHANCE REPORTING:
IMPLEMENTATION &
COMPLIANCE



STAKEHOLDER
INPUT



EXPERT
COMMITTEE



VALIDATION



COMMUNICATION



LEGISLATIVE
FLEXIBILITY



EDUCATION
& TRAINING



FUNDING



TRANSFORMATIVE
GOVERNANCE



ECHA's work to promote replacement of animal testing beyond the regulatory implementation

EPAA Annual Conference

Session 3: Impact of CSS on innovation and animal testing

15 November 2023

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1. EPAA conference 15 Nov 23 – Transition Roadmap - what about the science?
 - Use AI as co-pilot in safety science. AI outperforms animal studies (Hartung et al.)
 - Use of evidence-based procedures/systematic reviews is the best humans can do to accelerate the transition
 - Use of scientific evidence alone is **not sufficient to accelerate**.

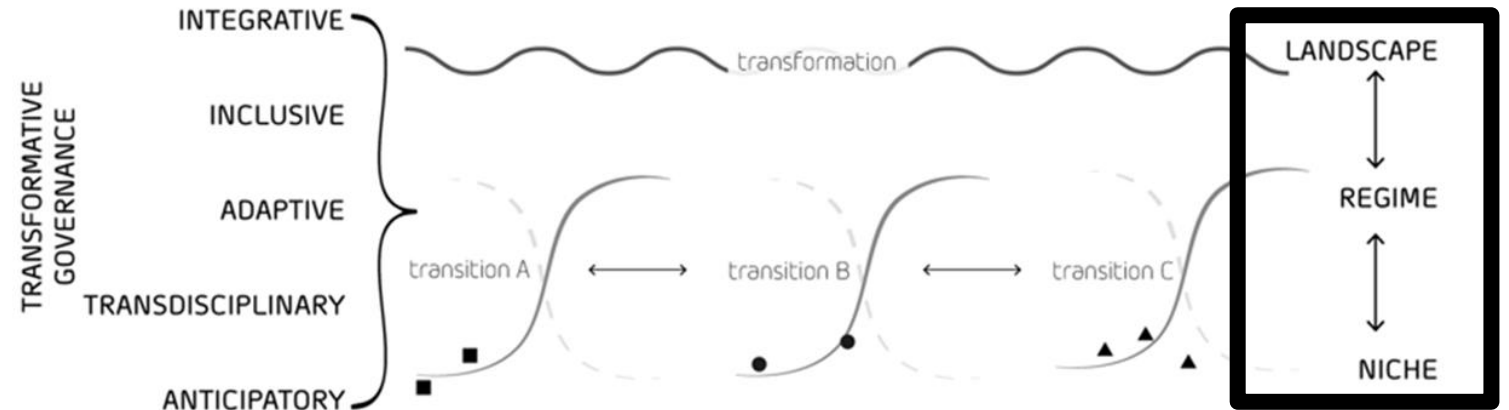
3. TRANSFORMATIVE GOVERNANCE INTEGRATES THE 3 LEVELS OF TRANSITIONS

NICHE: THE TECHNICAL LEVEL WITH INNOVATIONS - DEVELOPMENT OF NAMS SUCH AS AI, ORGANOIDS, NGRA

REGIME: THE “STATUS QUO”, WHERE REGULATIONS, INDUSTRY NORMS, AND PRACTICES SHAPE SYSTEMS - THE SAFETY ASSESSMENT SYSTEM

LANDSCAPE: SOCIETY AT LARGE, WHERE VALUES AND ECONOMIC INTERESTS MEET TO SHAPE NICHE AND REGIME LEVELS - ECI

2. Transition science (Geels 2011)



Visseren-Hamakers, I.J. Cashore, B., Loorbach, D., Kok, M., de Koning, S., Vullers, P. & van Veen, A. (2022). How to save a million species? Transformative governance through prioritization. In: Visseren-Hamakers, I.J. & Kok, M. (Eds.) Transforming Biodiversity Governance. Cambridge University Press.

1.) Considerations under the REACH revision:

- Replacing animal studies with non-animal studies/including new non-animal studies, e.g.:
 - Inclusion of non-animal methods as default for acute toxicity
 - Invertebrate test for bioaccumulation instead of study with fish
 - NAMs providing information on toxicokinetics/ADME
- Strengthen Annex XI (provisions for adapting information requirements)
- Foster the use of non-animal adaptations under Evaluation decisions

2.) Commitment of the Commission to work towards phasing out animal testing for chem. safety assessments:

- Communication COM (2023) 5041 replying to the European Citizens' Initiative 'Save cruelty-free cosmetics – Commit to a Europe without animal testing'

Action plan to replace animal testing	Analyses of how to improve acceptance, validation, organisation	Outreach and involvement of stakeholders
<ul style="list-style-type: none"> • Gap analysis • Short term measures / study replacements • Long-term measures • Development needs / research needs 	<ul style="list-style-type: none"> • Analysis of how to accelerate acceptance of methods + validation • Analyse need/feasibility of an advisory scientific committee • Analyse current landscape of working groups etc. providing advice on non-animal methods 	<ul style="list-style-type: none"> • Stakeholder involvement • Workshops • Strengthen collaboration of agencies and expert committees • Outreach to non-EU partners /international organisations – UN GHS • Increase impact in international forums

3.) Commission Workshop on the roadmap towards phasing out animal testing:

- 11/12 December, Brussels (hybrid)
- Further information: https://single-market-economy.ec.europa.eu/events/roadmap-phasing-out-animal-testing-chemical-safety-assessments-2023-12-11_en