Regulatory uptake of new approach methodologies: balancing reduced animal use and health & environment protection

Perspectives from health and environment NGOs

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ECHA workshop, New approach methodologies workshop: Towards an animal free regulatory system for industrial chemicals, 31st May 2023

Health and Environment NGOs' perspectives

Position paper

Recommendations for working towards human health and environmental protection, while gradually replacing animal testing

Context

The REACH and CLP regulations are complementary to each other and aim to improve the protection of citizens and the environment against the threats from hazardous chemicals. Revision of both regulations is required to achieve the goals of the CSS. The foreseen revision of the CLP would be a major step forward with the inclusion of the new hazard classes for endocrine disrupting chemicals and persistent chemicals that either bioaccumulate in organisms or are mobile in water and pollute our drinking water. However, revision of the REACH Annexes is also needed to ensure that the information to identify these serious hazard properties becomes available, to enable companies to fulfil their obligations regarding safe use, and authorities to identify the substances of most concern such as chemicals causing cancer, infertility, or disruption of our hormonal systems. This information can then be used for increased risk management under REACH, as well as for other sectoral legislation.

We call on the EU authorities to:

1. Update the standard registration requirements under REACH to enable an effective identification and regulation of hazardous chemicals in line with the commitments of the CSS
2. Work towards a gradual transition to hazard identification based on NAMs in the future, as a foundation for the regulatory control of harmful chemicals
3. Implement the precautionary approach[4] to increase health and environment protection and reduce animal testing

In this position paper, the NGO recommendations for improving protection of health and the environment, while gradually replacing animal testing are further elaborated.

1. **Standard information requirements under REACH should allow for effective identification and regulation of hazardous chemicals as committed in the CSS**

The standard information requirements under REACH should allow for a swift identification of the hazardous properties of all harmful chemicals. However, the current information requirements under REACH are not sufficient for the identification of serious, long-term hazards. For example, they do not enable the identification of all carcinogens or chemicals that affect our hormonal systems. The European Environment Agency (EEA) reported in their 2020 outlook[5] on the European environment about the unknown territory of chemical risks in Europe. Over 22.000 chemicals were registered under REACH and placed on the EU market. Only 500 of these chemicals were well characterised with respect to their hazards and exposure.

Joint NGO letter to European Commission & position paper, 27th February 2023

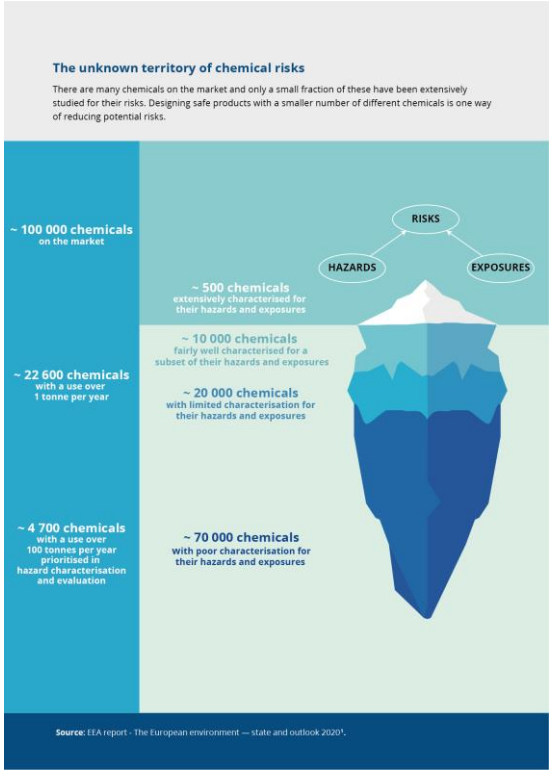
Regulatory context and market reality

- Significant **data gaps** on chemical substances already on the market:
  - A health & environment protection challenge
  - A barrier to the delivery of EU chemicals and product regulations

- Current **high level of evidence for regulatory identification, classification, regulation & reversed burden of proof** (on regulators)

- Lack of **availability of validated & regulatory accepted NAMs across endpoints of concern**

- **Transition to NAMs already underway**

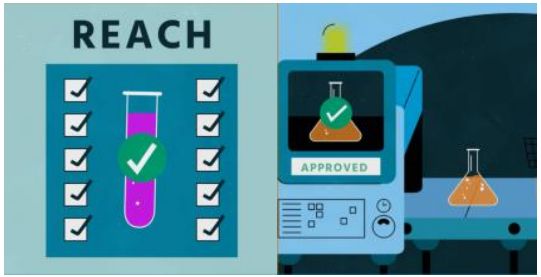


Main NGOs' recommendations

1. **Update the REACH information requirements** in line with CSS commitments

2. Commit to a **gradual transition to NAM-based hazard identification**, as a foundation for the regulatory control of harmful chemicals

3. Implement the **precautionary approach** to achieve both reduced reliance on animals & increased protection



NGOs' recommendations in details (1/2)

1. **Update the REACH information requirements**
   1. Current loopholes regarding **endpoints of high concern** (ED, carcinogenicity…)

   ⇒ REACH currently not delivering on 'no data, no market' & protection goals (REACH review conclusion)

   2. **NAMs in progress for those endpoints & in vivo studies still necessary for knowledge building** (immunotoxicity, ED, prediction of transgenerational effects)

   3. Keep flexibility for **regular updates of the REACH annexes** in line with scientific progress

2. Commit to a **gradual transition to NAM-based hazard identification**, as a foundation for chemicals' regulatory control
   1. **Allow validated & acceptable NAMs** for hazard identification & regulation of harmful chemicals as soon as available
   2. Promote **group assessments** for classification, SVHC identification, restrictions – based on read-across & *in silico* methods

NGOs' recommendations in details (2/2)

3. Implement the **precautionary approach** to achieve both reduced reliance on animals & increased protection

    1. **Adapt the level of evidence** required to identify, classify and regulate a chemical of concern: reducing animal use & speeding up assessments

    2. **Make better use of all the available evidence in a precautionary way**
        1. NAMs, academic data, info from structurally-related chemicals, *in vivo* data
        2. Early indication of concern should allow **precautionary** hazard identification & risk management measure
        3. **When in vivo tests necessary, use them in a more efficient way**:
            1. Data sharing
            2. Specific attention on study design for adequate dosing & potential use of results across endpoints to avoid studies' repetitions (current protracted identification discussions in e.g. ECHA EDEG)

Final considerations to achieving a gradual transition to NAMs

- **Clarify priorities of regulatory goals**:
  - Urgency = identify & regulate chemicals of concern **faster, more protectively for human health and the environment**
  - Keep in mind that **animal protection importantly includes protection of wildlife & domestic animals**
  - Put animal use for chemical safety testing in perspective **w/ other uses** (e.g. pharma, research)
  - Make regulatory system **less burdensome to take action on indications of concern** (burden of proof currently is on regulators)

- **Take a holistic & flexible approach**:
  - A **package** of measures across stakeholders: New science uptake, update in scientific practices, changes in regulations
  - Allowing **flexibility for real-life updates of information requirements** based on scientific progress
  - Gradual transition **not a 1-to-1 in vivo test methods' replacement** – approach will have to be adapted depending on endpoints looked at
  - Leaving room for **expert judgement** in chemicals' assessments

Thank you!

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Additional resources:

HEAL, Q&A on animal testing (2023)

ChemTrust, Chemical safety testing as part of a stronger REACH, protecting health & environment, promoting alternative methods (2023)

Chemsec, Chemical safety and animal welfare. What is at stake? (2023)

Joint NGOs' letter to the European Commission and position paper (2023)

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