Hazard assesment of chemicals: Regulatory landscape and critical needs - an ECHA perspective

New approach methodologies workshop:

Towards an animal free regulatory system for industrial chemicals

31 May – 1 June 2023

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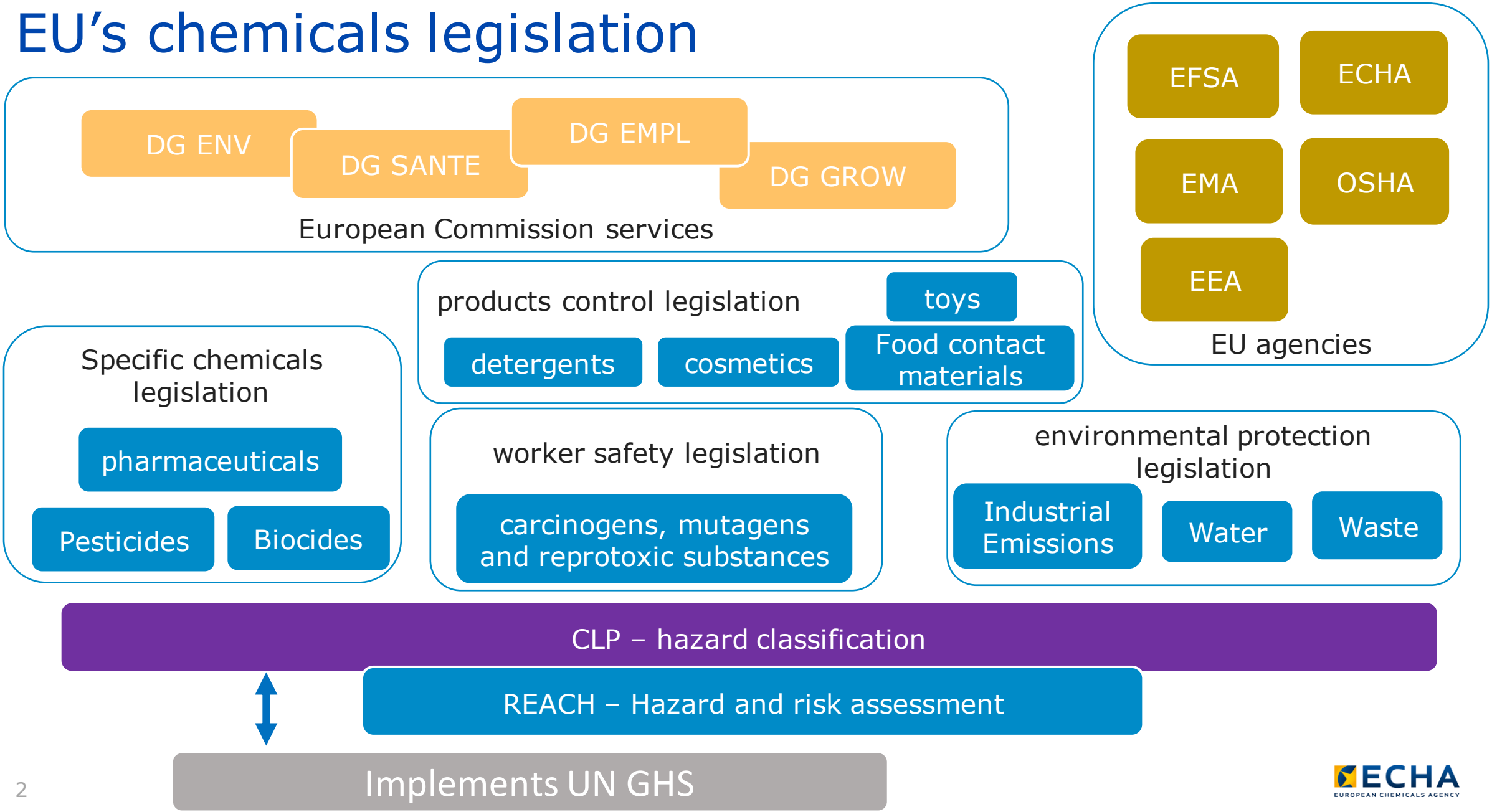
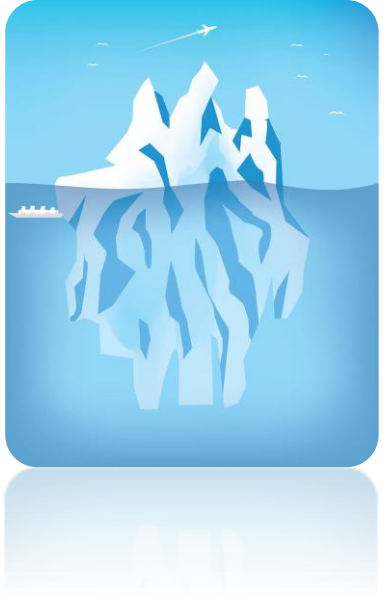
European Chemicals Agency

EU's chemicals legislation



REACH journey



Goals

- Protection of human health and environment
- Competitiveness and innovation of EU industry
- Animal testing as a last resort

Standard information requirements

- per tonnage band, including higher tier animal testing to explore long-term effects of chemicals
- OECD guideline studies as the 'benchmark' expressed in different annexes of the regulation – adaptations/waivers possible
- Requirements are the basis for risk assessment, including classification and labelling (CLP ≈ GHS)

Registration deadlines - 2010, 2013 and 2018 – build the database

>~2015 focus on '**compliance**', fill data gaps

> 2023 – the journey continues - enable faster **risk management**

Key elements of the current regulatory system

Substances of concern are identified based on their classification

- Defined hazard classes with clear corresponding criteria to allow consistent classification (implementing GHS)
- Based on adverse effects (e.g. effects on reproduction, endocrine disruption)
- Require derivation of safety levels / thresholds

Quality data for decision making

- reliable, comparable and re-usable, allowing mutual acceptance of data (MAD) between different EU legislations and at international level

Reverse of burden of proof

- Authorities are not required to intervene by default
- Separation of duties (avoid duplication of work by authorities and industry)

Standard information requirements

- Predictability and legal certainty for both industry and authorities
- Feasibility from workload and enforcement perspective

Article 117.3 Report 2023 edition

What is the report about?

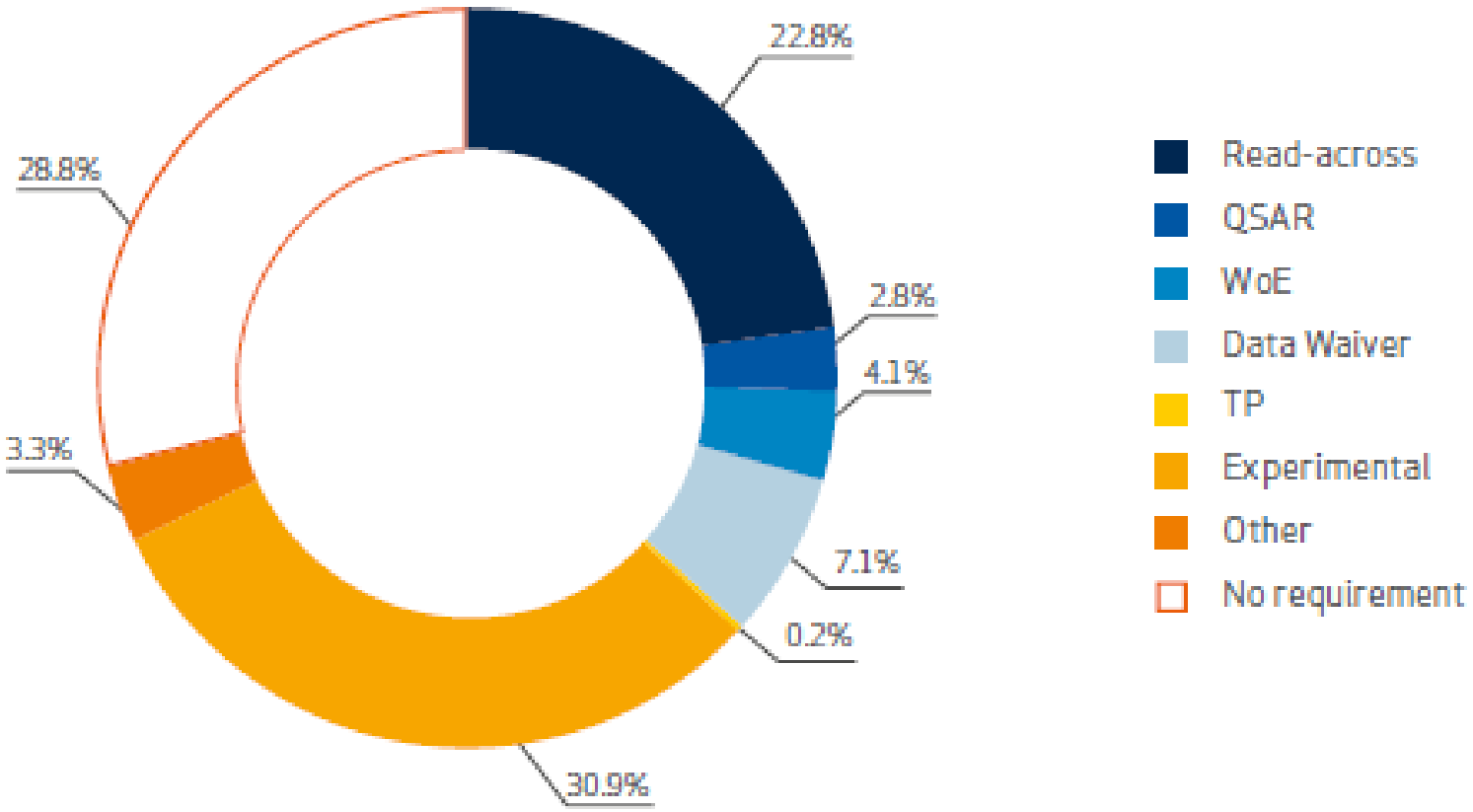
- → Legal obligation - animal testing as the last resort
- → Report on the status of implementation and use of **non-animal test methods** used to generate data in **REACH registrations**

2023 edition includes

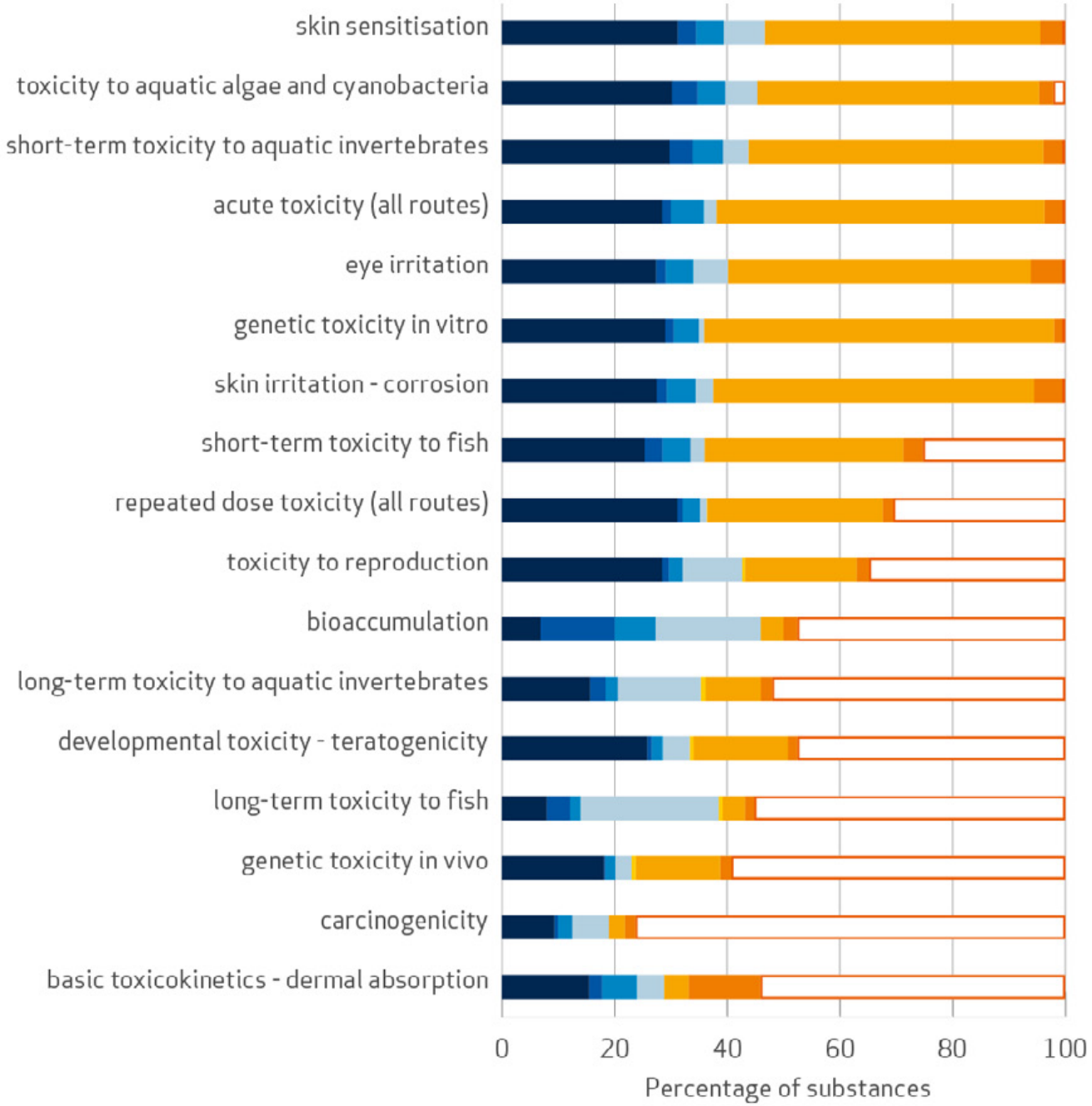
- → Data analysis of current REACH database, the same way as in previous editions
- → Additional analysis of newly registered substances (last 3 years)
- → ECHA's activities to promote NAMs and our contribution to the on-going debate on transitioning towards full replacement of animal testing for industrial chemicals

ADAPTATIONS USED MORE THAN EXPERIMENTAL STUDIES

READ-ACROSS IS STILL THE MOST COMMONLY USED ADAPTATION



Options used to fulfil the information requirements in the REACH registration database (2009 – 2022)



There are relatively few differences between the approaches registrants used to fulfil the information requirements in 2022 compared to past years (2019 and even 2016)

When additional information is required at higher tonnage bands registrants gradually use more adaptations

Frequency of the different options to fulfil the information requirements for the 12439 substances in the scope of the 5th edition of the report

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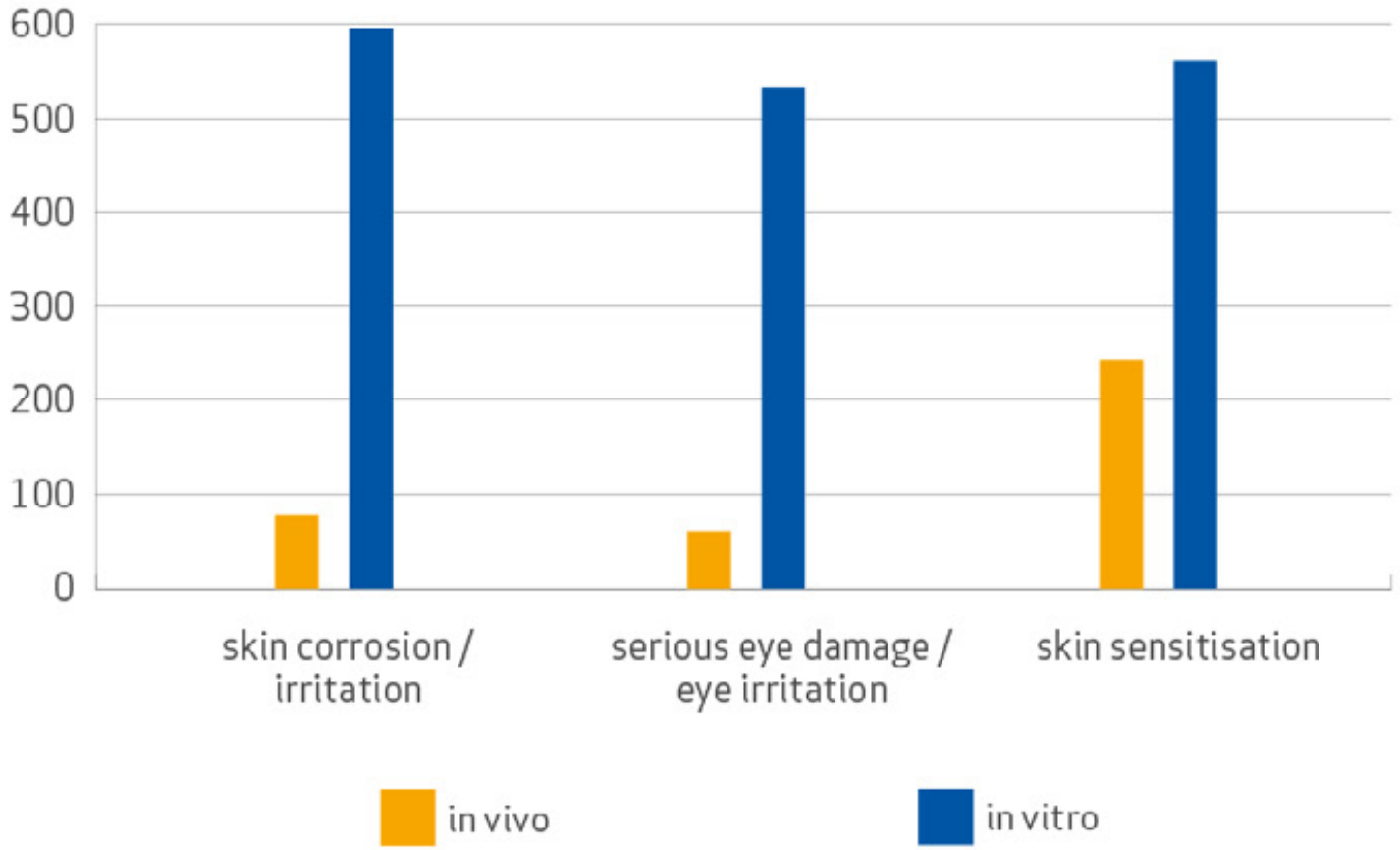
ALTERNATIVE METHODS INTRODUCED RECENTLY CONTINUE TO BE WIDELY USED



Occurrence of studies over the years 2019 - 2022 for the endpoints skin irritation/corrosion, serious eye damage/eye irritation and skin sensitisation

IN VITRO STUDIES HAVE BEEN PRIMARILY GENERATED UNDER REACH

ABOUT 90% OF STUDIES FOR SKIN IRRITATION/CORROSION, SERIOUS EYE DAMAGE/EYE IRRITATION CONDUCTED OVER THE LAST 3 YEARS ARE PERFORMED IN VITRO

ECHA's ongoing activities for the development and promotion of alternative methods

Several (inter-related) workstreams

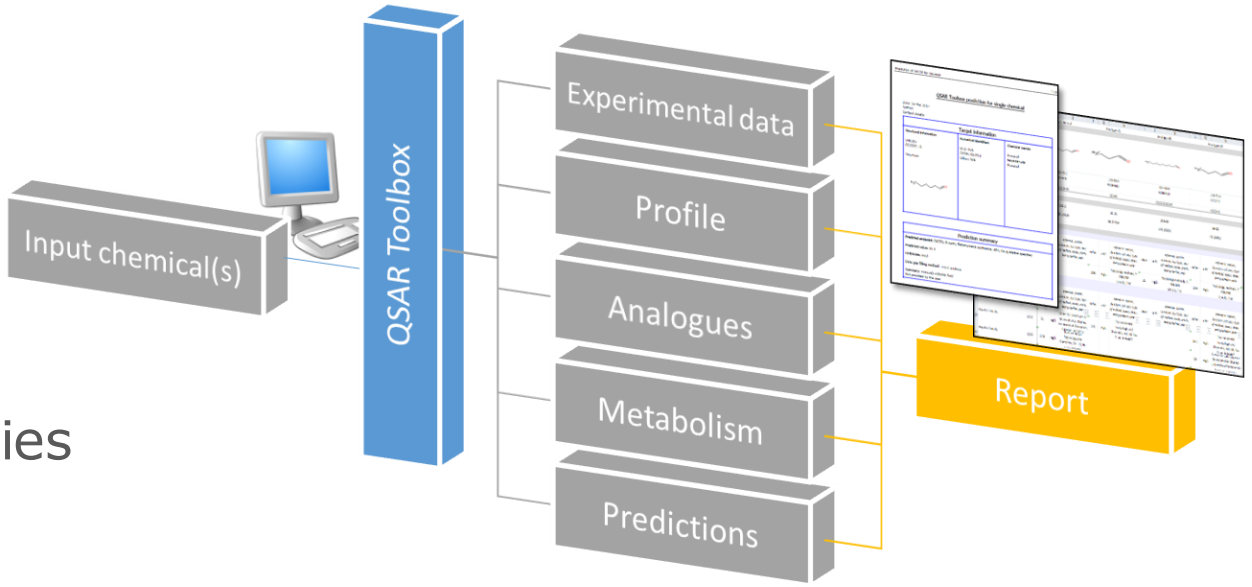
1. Use of alternative methods in ECHA's processes
   - ✓ **Grouping**
2. Input to harmonisation and reporting
   - ✓ **RAAF**
3. Computational methods and data availability
   - ✓ **QSAR toolbox**
4. Translation of NAMs into regulatory applications
   - ✓ **Skin sensitisation**
5. Organisation of trainings and promotion of proper use in the regulatory context
6. Interactions with sister agencies and key stakeholders
   - ✓ **EPAA, APCRA, EFSA**

OECD QSAR Toolbox: more than predictions

The QSAR Toolbox is a free software application that supports (eco)toxicologists in performing reproducible and transparent chemical hazard assessment using **non-animal methods**

Key functionalities:

- retrieve experimental data
- profiling properties of chemical
- simulate metabolism
- identify analogues and build categories
- predict properties



Co-developed by ECHA and OECD with 3rd party contributions

QSAR TOOLBOX

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Priorities for 2023 – few highlights

Step up our efforts on NAMs

- **NAM Workshop**:

  "**Towards an animal free regulatory system for industrial chemicals (31 May- 1 June)"**

  - Focus on NAMs for hazard assessment
  - Our contribution to the ongoing debate

- **Increase co-operation** across legislation within Europe (e.g. EFSA) and outside Europe (US EPA, Health Canada) through platforms such as EPAA and APCRA

- Stronger **involvement in scientific projects** which will address key aspects for regulatory acceptance (e.g. APCRA, EU research programmes ASPIS, PARC, etc.)

- Internal capacity building

Towards a full replacement of animal testing – how to progress faster?

- **Key questions to be addressed**
  - How a new approach can cover the most relevant effects and diseases of concern for the society (e.g. CMR, immunotoxicity, EDs, etc.)
    - Address higher tier endpoints
  - How to ensure a similar or better level of protection for human health and environment.
- **Identify and address the critical needs**
  - to enable research and policy choices
- **Concerted efforts of all stakeholders needed**
  - increased collaboration and co-operation
  - ECHA committed to play an active role

Thank you

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