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Chemical Regulations and  
Sustainability Symposium 2023



Chemical  
Business  
Association

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# EU REACH Revision, a status overview

## New Registration information and Evaluation requirements

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**Duration: 10 min**

# 1. Background

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# 1. Background

## Why the changes are being done

- Under the European Green Deal (2019) and the Chemicals Strategy for Sustainability “CSS” (2020) the European Commission aims to revise the rules governing the Registration, Evaluation, Authorisation and Restriction of chemicals in the EU, as currently set out in Regulation (EC) No 1907/2006 (REACH)
- This REACH Revision aims to further improve the protection of human health and the environment against hazardous chemicals and to encourage innovation to develop safe and sustainable alternatives

**Proposal for REACH  
revision was expected  
Q4 2023→Likely delayed**

# 1. Background

## Source

- The **European Green Deal** sets out the ambition to reach zero pollution for a toxic-free environment
- The **chemicals strategy for sustainability** tries to better protect people and the environment against hazardous chemicals and to encourage innovation to develop safe and sustainable alternatives
- Achieving these goals requires revising the rules governing the registration, evaluation, authorisation and restriction of chemicals in the EU

# 1. Background

## Update of REACH Annexes in 2021

- The REACH Revision is not to be confused to the changes already done in REACH annexes in 2021
  - The update of the REACH annexes clarified the information companies need to submit in their registrations
  - The law came into effect on 8 July 2021 and was applied from 8 January 2022.
- requirements for surface tension and water solubility of metals and sparingly soluble metal compounds;
  - requirements for *in vitro* testing for eye irritation and *in vivo* testing for skin or eye irritation;
  - requirements and adaptations for 28-day and 90-day repeated dose toxicity studies;
  - specific rules for adapting reproductive toxicity studies;
  - general rules for adaptation based on:
    - use of existing data;
    - weight of evidence;
    - substance-tailored exposure-driven testing; and
    - grouping of substances - in particular, those of unknown or variable composition, complex reaction products and biological materials (UVCBs);
  - new rules for adapting studies on fate and behaviour in the environment based on a low octanol-water partition coefficient;
  - new specific rules for adapting for dissociation constant and viscosity; and
  - additional requirements for human health and environmental testing to be performed at appropriately high dose levels.

**This was NOT REACH Revision!**

**Changes**

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## 2. Timelines

### Current situation



Source: [COM, „Have Your Say“ website](#)

<b>Objectives</b>	European Green Deal ambition to reach zero pollution for a toxic-free environment → Chemicals Strategy for Sustainability (CSS) announces actions to better protect people and the environment against hazardous chemicals and to encourage innovation to develop safe and sustainable alternatives → Achieving these goals requires revising the REACH rules
<b>Status</b>	<ul style="list-style-type: none"> <li>✓ Consultation on Impact Assessment (IA) concluded in 2022</li> <li>✓ Studies for IA mostly finalized</li> <li>✓ Regulatory Scrutiny Board positive opinion with reservations</li> <li>✓ COM is working to draft proposal as a priority</li> </ul>
<b>Next steps / time</b>	<ul style="list-style-type: none"> <li>➤ COM adoption of proposal <b>by latest Q4 2023</b>,</li> <li>➤ Transmission to European Parliament (EP) and Council (later 2023, or 2024) – COM schedule will determine whether current EP will tackle</li> <li>➤ Call for stakeholder feedback once the COM proposal is adopted</li> <li>➤ 2024-2025: Ordinary legislative procedure and Comitology for Annexes → REACH 2.0 could be in place as early as 2025</li> </ul> <p><b>However, very likely to be delayed even more.</b></p>



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### 3. New registration requirements

#### Summary

- New registration requirements for certain polymers of concern (covered in the previous presentation!)
- Update of existing registration dossiers to reflect enhanced information requirements
- Derived Minimal Effect Level (DMEL)
- Chemical Safety Report in all tonnage bands (incl. 1-10 tonnes per year)
- More strict requirements for intermediates

**Other revisions also;  
these are just the  
registration related**

### 3. New registration requirements

#### Impacts

Most, if not all, existing registration dossiers would need to be updated

Timeline to prepare lower tonnage band registration dossiers would go up

#### Pros & Cons

Enhanced safe use of chemicals

Much more information available for larger group of chemicals

### 3. New registration requirements

#### Mixture Assessment Factor

- One major initiative is the plan to introduce a mixtures assessment factor **MAF**
- A MAF would be applied to the assessment of substances and mixtures to make sure that the combination effects of chemicals (cocktail effects), and the combined exposure of humans and the environment from all relevant sources are taken seriously
  - MAF would work like other assessment factors used in REACH
  - It would multiply the value of the toxicity study (f.ex 2-100 times) **to make the hazard more severe**
- Echa has said it estimates that 20% of substances registered under REACH could be impacted
  - But could be much more!
- However, MAF has received criticism
  - Quote from [Chemicalwatch](#): “detailed risk calculations for all possible unintentional mixtures arising from use of the registered substance, as well as detailed exposure scenarios. However, ‘all possible unintentional mixtures’ would amount to a dizzyingly large set of combinations and permutations, making this approach essentially impossible, at least with the scientific methods and exposure data currently available”

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## 4. Evaluation

- The aim is to have a more unified system of how chemicals are regulated and evaluated
- When one agency assesses the substance, the same assessment will be the basis for regulatory measures across legislations

One substance,  
One assessment



## 4. Evaluation

### Tightening enforcement

#### *“Zero Tolerance Approach to Non-Compliance”*

- Enforcement is very scattered
  - ECHA does compliance checks
  - Member states are responsible for the actual enforcement
  - FORUM coordinates the work
- Extension of the scope of compliance check to all registered substances
- Give Echa the possibility to revoke registrations in case of non-compliance
- Reinforce EU capacities by establishment of a European Audit Capacity to audit enforcement activities in the Member States



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# New Registration information and Evaluation requirements

## Conclusions

- Proposal for REACH revision was expected Q4 2023
  - Probably only after the next mandate
- Changes are coming from European Green Deal and the Chemicals Strategy for Sustainability “CSS”
- Major changes would be:
  - Polymer registration
  - Updates to current dossiers and information requirements
  - CSR for lower tonnage bands
  - MFA
  - More strict intermediate registration conditions

***All this information is still highly speculative as the draft revision has not been published!***

***REACHLaw will monitor the situation and keep you updated on the changes***

# Thank You for Your Attention!

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