25 - 26.10.2023 | DAY 1

Chemical Regulations and Sustainability Symposium 2023

100 YEARS 1923 - 2023 Chemical Business Association

REACHLAW COMPLIANCE. SUSTAINABILITY.

Essential Use Concept & REACH Authorisation Reform

Essential Use Concept & REACH Authorisation Reform

Table of Contents

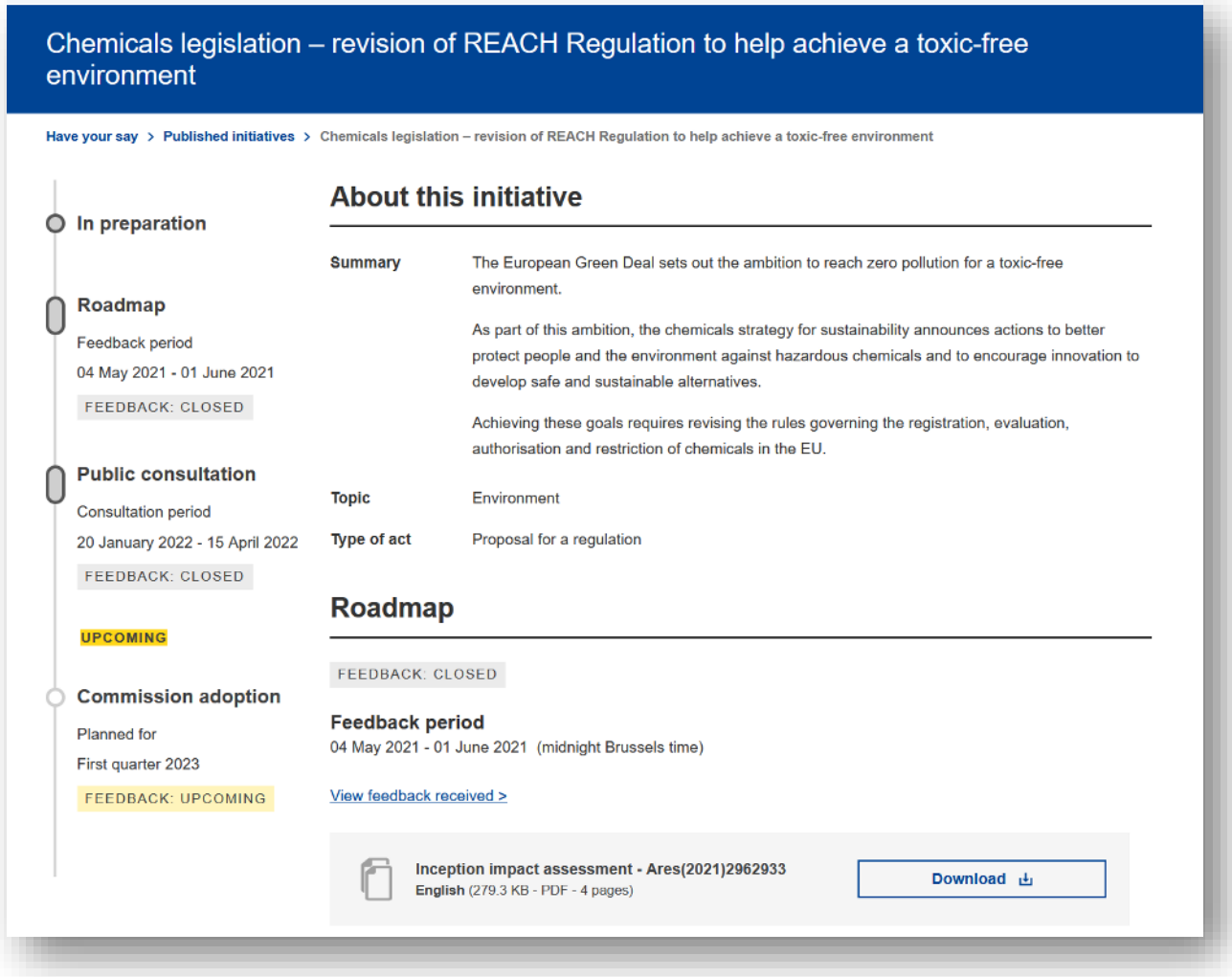
Duration: 20 mins

1. REACH revision
2. Current understanding of likely revisions
3. Essential use concept
4. Looking ahead

EU Green Deal
Chemical Strategy for Sustainability (CSS)

The European Green Deal sets a high ambition for a toxic-free environment leading to zero pollution. The Chemicals Strategy for Sustainability (CSS) adopted on 14 October 2020 is the first delivery of the zero-pollution ambition.

- ✓ need for a targeted revision of REACH to achieve its objectives



REACH revision inception impact assessment

Reform of authorisation & restriction processes

B. Objectives and Policy options

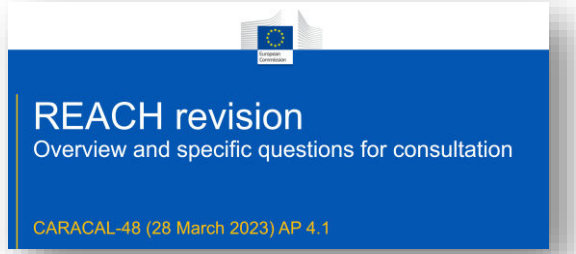
The overall objective of the initiative is to ensure that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation and a high level of protection of health and the environment, while preserving the internal market, as provided for in the Chemicals Strategy for Sustainability. To address the problems identified, a range of possible measures will be considered. The baseline situation consists of a continuation of the current provisions of the Regulation as of April 2021. An initial list of possible options to revise the REACH Regulation to fill gaps and to simplify and strengthen the legal provisions has been identified. For each option, various sub-options, including possible exemptions, may also be considered. The options and sub-options are not mutually exclusive, but can (and most likely will) be combined with each other. The options are preliminary and may evolve with the analysis.

Reforming the authorisation process: Options include clarifications and simplifications of the current provisions, national authorisation for smaller applications, removing the authorisation title from REACH, integrating the REACH authorisation and restriction systems into one and improving the interface with other pieces of legislation (complementing actions under the one-substance one-assessment action under the Chemicals Strategy)

Reforming the restriction process: Options include extending the generic risk approach to restrictions to endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs; extending the generic risk approach to products marketed for professional use; and operationalising the concept of essential use in restrictions, including the criteria for granting derogations.

Status of REACH revision

Estimated to be adopted in 2024-2025*



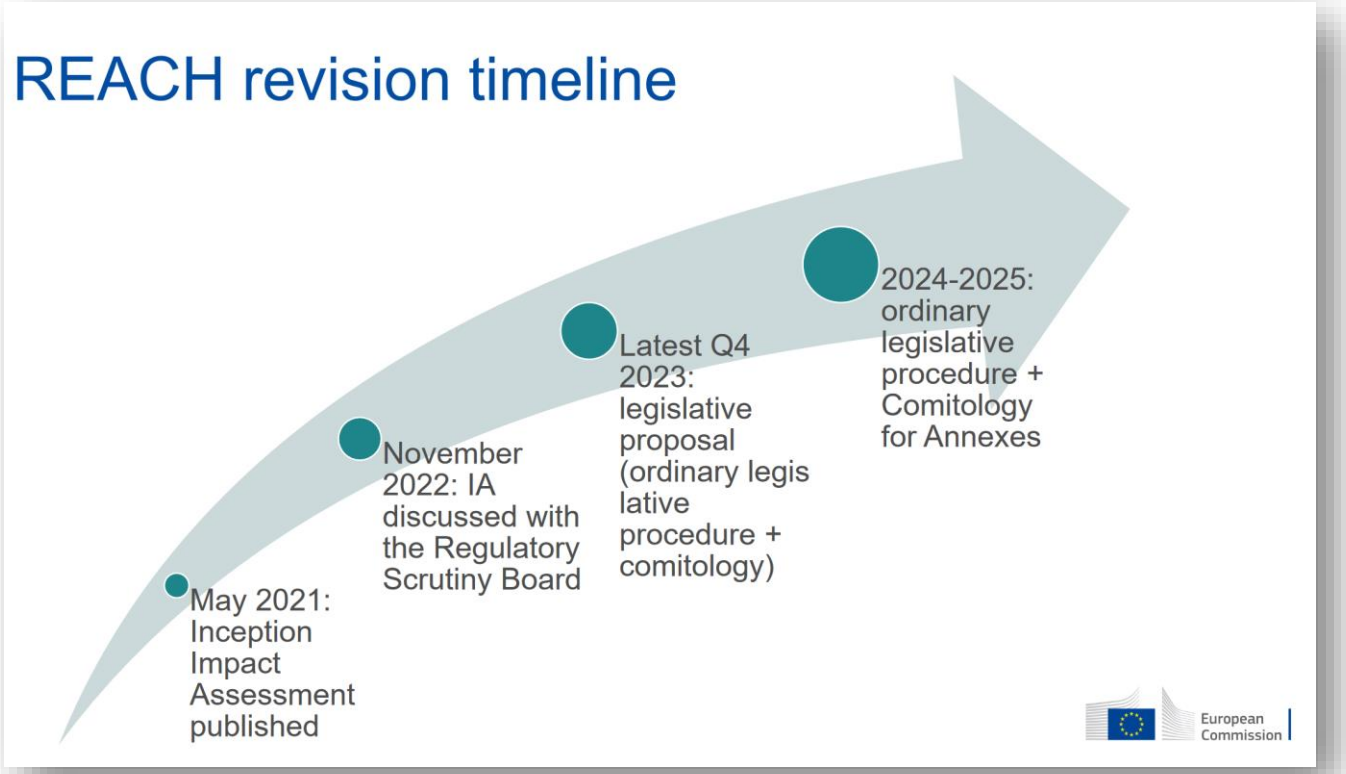
Revisions propsed have been costed in an impact assessment and submitted to Regulatory Scruntiny Board almost 1 year ago

Delays in release of legislative proposal

Current status is that is may be released in Q4 2024 *

* *Latest indication is that there will be more delays*

At the moment we have info on what the main changes are likely to be but not the details or implementation



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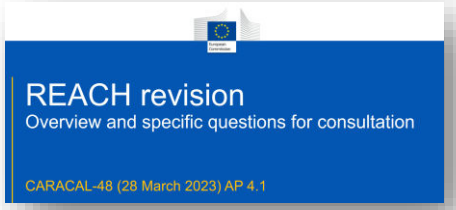
2. Current understanding of likely revisions
3. Essential use concept
4. Looking ahead

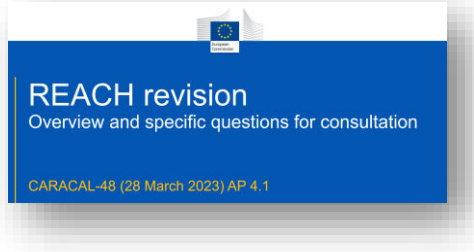
Authorisation and restriction changes
Generic risk assesment (GRA) & essential use concept



- Authorisation & restriction processes will be streamlined
- ”essential use” will be introduced

7. Extension of the **generic risk approach** (art. 68(2)) to the most harmful substances with derogations only for **essential uses** (to be defined in a stand-alone horizontal policy document)
8. **Authorisation and restriction reform** to streamline these regulatory tools and reduce the burden on companies and authorities

Reform in practice
Collect more information in registation files



- Earlier information on use, exposure and alternatives
  - For all substances covered by the registration dossier
  - For the most harmful substances -> more details in registration dossier
  - For substances of very high concern -> new notification scheme for downstream users
  - Further information on request e.g. for the preparation of a restriction proposal

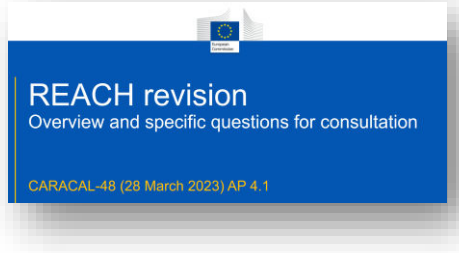
Reform in practice

Keep authorisation & restriction processes but adapt rules

- Both processes will remain but the rules will be adapt to simplify them
  - Exclude essential uses from the scope of the authorisation requirement
  - Adapt process and criterial for derogations under restrictions
  - Broad restrictons (GRA and grouped restrictions)
  - Limiting individual authorisation applications
  - Strenghtening the role of substitution plans

  - *Details are under discussion*

Reform in practice
Implement essential use concept



- Something new under REACH (already in place for greenhouse gases under the Montreal protocol)
  - Dergoatons from generic restrictions only for ”essential uses”
  - Additional criterion for derogations from specific restrictions and authorisation requirements
  - Simplification for clearly essential/non-essential uses to allow/not allow derogations
  - *Not a lot of detail available as yet on how this would be implemented in practice..*
  - *Latest indication is that guidance on essential use concept could be adopted before the end of the current EU Commission term*

What will this mean in practice?
Change is coming

- Current EU REACH process will change significantly
  - Aiming not to have applicant by applicant authorisations
  - Aiming to exclude uses that are ”essential”
  - Aiming to simplify process to allow sector wide authorisations
    - Concept sounds like the RoHS exemptions
  - Prioritisation criteria uses to recommend substances to be included on the authorisation list also likely to change
  - More synergy with restriction process

  - Changes likely to be adopted in ca. 2028
  - After this, EU REACH and UK REACH authorisation processes will be quite different

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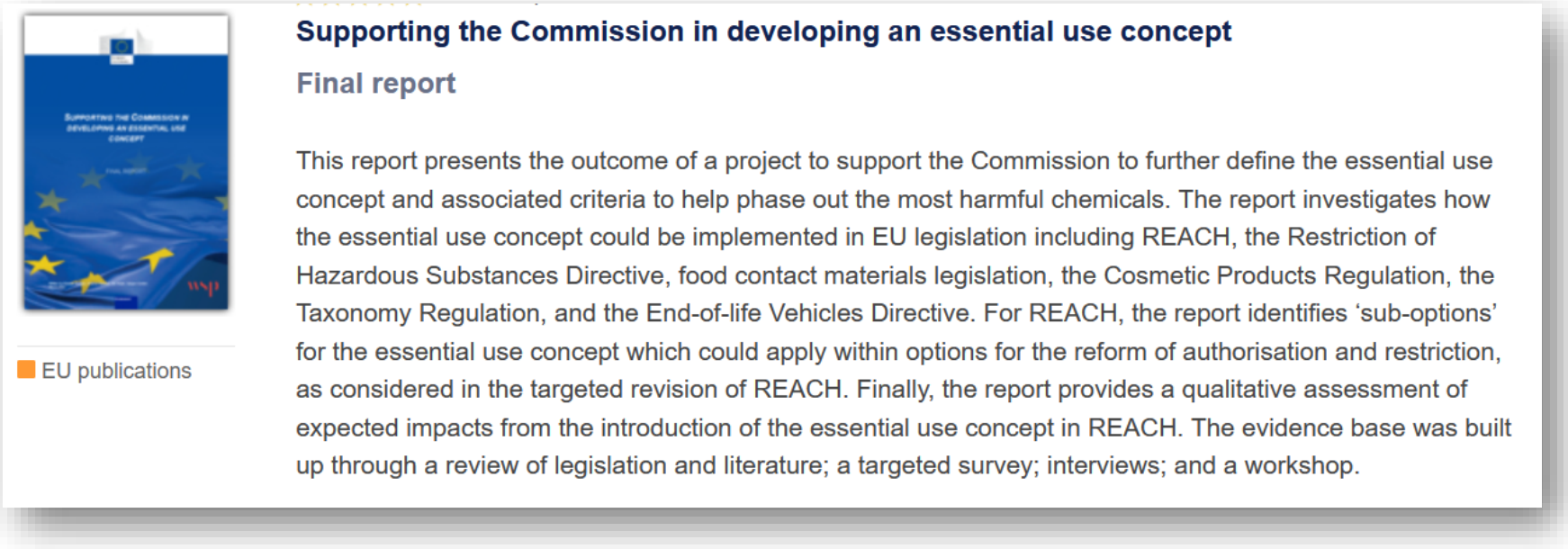
New EU REACH terminolgy
Essential use and the ”most harmful chemicals”

Looking at possible definitions and implementations



European Commission, Directorate-General for Environment, Bougas, K., Flexman, K., Keyte, I. et al., *Supporting the Commission in developing an essential use concept – Final report*, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2779/529713

Essential use concept
How has it been scoped

- Objective of the Chemicals Strategy for Sustainability (CSS): limit the use of the most harmful chemicals to uses which are essential for society

  These substances should only be allowed if the use is

  - necessary for health and/or safety;
  - AND/OR is critical for the functioning of the society;
  - AND there are no alternatives that are acceptable from the standpoint of the environment or human health

- A systematic tool for phasing out the uses of the most harmful chemicals in all non-essential uses while giving more time for the substitution in essential uses

Essential use
Why is the concept needed?

- REACH authorisation process is inefficient and burdensome, decision-making is slow, and it does not incentivise substitution enough
- The pace of restrictions is not sufficient, delayed implementation to address risks to human health and the environment and to ensure that the most harmful chemicals are banned
- Despite current provisions, emissions of and exposure to the most harmful chemicals continues

- The CSS sets actions to ensure consistent protection from the most harmful chemicals, which includes the development of essential use criteria

Essential use concept
Aims

- To allow systematic decision-making to facilitate the phasing out of the most harmful chemicals by only allowing them when their use is proven essential for society
- Bring more simplicity, transparency, predictability and efficiency in decisions, to speed up decision-making and reducing administrative burden
- Minimise essential uses, as well as their associated exposure and risks to human health and the environment as far as possible
- Encourage substitution of essential uses by requiring industry to demonstrate that appropriate effort is being made to substitute essential uses (substitution plan requirement)

Introduction
Proposed scope

- Only applicable to uses of the most harmful chemicals (as defined in the CSS):
  - CMR substances and endocrine disruptors (1st priority)
  - Persistent and bioaccumulative substances (PBT/vPvB) (1st priority)
  - Chemicals affecting the immune, neurological or respiratory systems
  - Chemicals toxic to a specific organ (repeated and single exposure, Cat. 1)
- Note: The purpose is not to assess whether a certain chemical is essential, or a specific sector is essential/non-essential
- Important: the essentiality of a use may evolve over time with changing wider societal needs or as alternatives become available

Essential use concept
Regulatory scope

Horizontal concept: The essential use criteria will be used for both generic (GRA) and specific (SRA) risk assessments in all relevant EU legislation (CSS)

- Focus on uses in **consumer products**, but intention to extend GRA also to **professional users**
  - Derogations from restrictions under GRA only for essential uses
- Could also be applicable for assessing derogations from any restrictions and authorisation applications
- Implementation under further EU legislation (e.g. RoHS, food contact materials, toys directive, cosmetic products) may vary

Essential use criteria
Taking a closer look

- The criteria must not be too generic as this would allow too many uses of the most harmful chemicals
- The criteria must also not be too narrow which could be short-sighted and lead to discrimination against products/sectors or failure to respond to changing societal needs
- WSP proposal: Essential use criteria to be further defined in horizontal guidance* to ensure consistency in the application of these criteria
- In addition, legislation-specific guidance on the implementation of the concept in practice

** latest indication is that this guidance may be adopted before the end of the current EU Commission term*

Essential use criteria
Necessary for health/safety

- Only uses upon which health and/or safety are dependent on are considered necessary
  - Preventing, monitoring or treating severe health issues
  - Sustaining basic conditions for human life and health (e.g. food, water, shelter/security but also environmental health)
  - Managing and preventing health crises and emergencies (e.g. disease outbreaks)
  - Personal safety (e.g. uses related to proper functioning of seat belts, PPE, life jackets)
  - Public safety (e.g. safety of public infrastructure, functioning of emergency services)
  - Addressing a danger to animal health which cannot be contained by other means

Essential use criteria
Criticality for the functioning of society

- Only uses upon which the functioning of society is dependent on should be deemed critical for the functioning of society
  - Providing resources or services critical for society
    - Uses required for the installation and maintenance of critical infrastructure, e.g. energy & transport
    - Uses needed for providing critical services, e.g. waste and water treatment, communication and healthcare infrastructure
  - Managing societal risks and impacts from natural and man-made crises and emergencies
    - E.g. repairing/preventing damage to infrastructure from natural disasters
  - Protecting cultural heritage
    - Uses related more to luxury than the preservation of cultural heritage including traditional crafts should not be considered critical
    - Assessment may require more political judgement compared to other, clearer elements
  - Running traditional and religious practices
  - Protecting and restoring the natural environment
    - Uses needed for reduction emissions of greenhouse gases or biodiversity loss, analysis, monitoring and remediation of pollutants in the environment

Essential use criteria
Lack of alternatives

- Alternatives (substances, materials, technologies, products or processes) must be acceptable from the standpoint of environment and health
- Current REACH definition: Alternatives must be suitable, i.e. the alternative must be safer, technically and economically feasible and available
  - "Safer" should mean that the alternative entails a lower chemical risk for human health and the environment from a life cycle perspective
  - Availability, technical and economic feasibility should be considered from a societal point of view rather than from the view of the applicant
    - Key consideration: Would a lower-performing alternative compromise the use in terms of health/safety or functioning of the society?
    - Defining the economic feasibility from a societal point of view would likely rely on political judgement

Essential use concept
Conditions for an essential use

- Industry must take all steps to minimize the essential use, emissions and exposure during all lifecycle stages
- Any decision on essentiality must be time-limited and subject to review after a specified time period or earlier if new information is available
  - This time period would be set based on the substitution plan and the expected duration of the essentiality for society
  - Possible additional requirements for monitoring schemes and reporting to demonstrate progress in R&D
- The derogation from restriction/authorisation decision should be contingent on industry demonstrating that appropriate effort to substitute is undertaken

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Looking ahead
Practicalities of implementation

- Likely transition periods between old and new REACH requirements
- REACH revision likely to be further delayed... Essential use concept guidance may be available next year
- Open Qs
  - Essential use concept implementation will need to have a regulatory body changeed with giving opinions and taking decisions on what is/is not ”essential”
  - This will be very challenging ...
    - A given chemical will have diverse uses in equally diverse sectors
    - Breath of compentence needed by the committee will be very broad
  - Will it really be able to fulfil the aim of ”simplification”?
  - Or will it be a new bottleneck?

Thank You for Your Attention!

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