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Proposal to Revise the REACH Authorization and Restriction Processes

This factsheet was developed as part of a series on evolving European Union chemical policies.

SUMMARY

- A key initiative within the Chemicals Strategy for Sustainability (CSS) is the targeted revision of the REACH Regulation.

- Among the various reform options that may be incorporated into the REACH Revision, which could come into force independently via comitology (a negotiated conference approach), or be published solely as communications for recommended practices, are the extension of the **Generic Risk Management Approach (GRA)**, the definition of Essential Uses (**Essential Use Concept - EUC**), the development of a **Mixture Assessment Factor (MAF),** and the increasing **Grouping of Substances**. The path toward legislative action (co-decision vs. comitology) on these initiatives is a pain point for the EU with some favoring the faster, executive route of comitology while many feel strongly that such impactful legislation should go through the ordinary legislative process of co-decision with multiple levels of review. These changes will be assessed in separate fact sheets, with this factsheet focusing on planned changes to REACH Authorization and Restriction processes.

- The legal revision proposal has yet to be published, but there is general favor for an approach that either clarifies and simplifies Authorization, keeping it separate from Restriction, or an approach that merges the Authorization and Restriction processes. An approach that removes the Authorization title from REACH is unlikely. Both favored approaches entertain a variety of specific reform options that are still highly debated.

- There is still no date set for the REACH revision and it has been deferred to the next term. Commission officials have confirmed that the REACH revision delay is a political issue, and the Commission has decided to work on preparing a better proposal for the next term, starting in the second half of 2024.

BACKGROUND & CONTEXT

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation entered into force in 2007 and has since continually adapted to reflect the growing knowledge of various chemicals and their characteristics. The commission is seeking to revise REACH in line with its Better Regulation Agenda, which aims to ensure evidence-based, transparent EU law-making based on the views of those impacted.

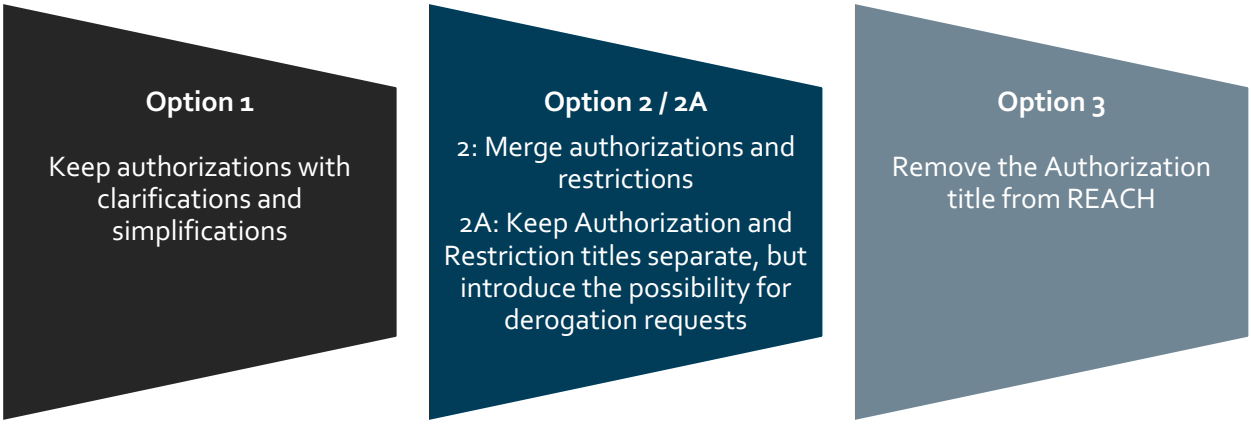
To implement the REACH Regulation, chemical substances that exceed 1 tonne of manufacture, import, or use per year per company must be registered with the European Chemicals Agency (ECHA). ECHA and the Member States then evaluate the information submitted by companies to determine whether a given substance poses risks to human health or the environment. To evaluate and improve the efficacy of REACH, the relevant national authorities of EU Member States and European Economic Area countries are required to submit a progress report on the operation of REACH every five years. The 2017 10-year progress report highlighted many of the shortcomings of the current REACH Regulation in practice and was a major impetus for the proposed REACH Revision as part of the REACH Refit Evaluation. These shortcomings included the Authorization process being too slow

in practice, and some design flows that have led to less-than-ideal outcomes regarding the substitution process and shortcomings in chemicals data.

The **Authorization process** of REACH applies to substances of very high concern (SVHCs) and **is carried out at the company-by-company level**. SVHCs are banned unless a company applies for an authorized use and that use is approved. The goal of Authorization is to progressively replace SVHCs with less dangerous substances or technologies where technically and economically feasible alternatives are available. The **Restriction process is carried out broadly at the EU level**. It limits or bans certain SVHCs across the entire EU if they are determined to pose an unacceptable risk to health or the environment.

DESCRIPTION

The focus of this factsheet is on the Authorization and Restriction elements of the REACH Revision. Despite the CSS pledge to implement the REACH Revision "in the most targeted way possible", through its impact assessment the Commission will consider three general options for the revision of Authorization under REACH, with a variety of sub-options for reforming the process that spans all three. While Option 3 centers around removing the Authorization title from REACH, most discussions in 2023 suggested it would likely be kept.



Sub-options to reform the Authorization and Restriction processes currently include the following:

- **Reform the Authorization process:**
    - Clarify and simplify provisions for authorization to address its current lengthy and resource-intensive process. For example, the number of individual and group application requests submitted as part of the Chromium VI authorization process far exceeded the predictions of the authorities in charge, significantly slowing the process timeline.
    - Allow national authorization for smaller applications.
    - Merge the REACH Authorization and Restriction processes into one and improve the interface with other pieces of legislation (complementing the One Substance One Assessment (OSOA) initiative under CSS).

- **Reform the Restriction process:**
    - Extend the Generic Risk Management Approach (GRA) beyond carcinogenic, mutagenic and reprotoxic (CMR) substances in consumer products to several other hazard classes and uses to include endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitizers and substances that affect specific organs. (An implicit extension of the GRA has already been applied to PFAS in the EU PFAS Proposal, by extending a vPvB hazard trait to the entire chemical class).
    - Extend the GRA to products marketed for consumer and professional uses, with the exception of those uses that are currently considered "essential" for society. For instance, the use of carcinogenic substances of categories 1A and 1B will no longer be possible in professional applications.
    - Change the default restriction process to be restrictions/bans with the possibility of derogations (e.g. PFAS Proposal).
    - Operationalize the essential use concept (EUC) in restrictions by creating criteria for granting derogations for chemical applications that are necessary for the health, safety, or functioning of society and there are no alternatives from a health and safety perspective.

- Prohibit the *import* of finished products containing substances subject to REACH authorization. Prohibit the manufacture/production for export of substances prohibited from use in the EU market.

- Strengthen incentives for substitution through supplementary fees to finance cooperation projects between users of SVHCs and alternative providers. For instance, the Commission is investigating the feasibility of initial notifications and annual fees for SVHCs in the Candidate List (list of substances of concern that could be subject to authorization), which would be used to fund ECHA activities on substitution or risk management-related activities in ECHA and Member States. Additionally, the Commission is considering further incentives for SME front-runners to share information on substitution solutions or technologies.

- Clarify the interface between REACH and EU Occupational Safety and Health legislation (OSH) to improve the coordination between the different legislations and differentiate them.

The Commission has noted that most stakeholders (Member States, Industry, and NGOs) favor combining the best elements of Options 1 and 2. Most likely, authorizations will remain, be updated, and simplified, and/or merged with restrictions. Member States (MSs) support the simplification of authorization and certain possibilities for joint authorizations/derogations for restriction where these make sense and can simplify the process (see **ANNEX I** for a more specific illustration of the options).

CURRENT STATUS

The proposal, originally slated for publication in November 2022, has been delayed multiple times. Even now, a concrete date for its release in 2024 has not been confirmed and it has not been included in the Commission's Work Program for this year. This new delay will affect the work of the European Parliament and Council and hinder the delivery of the final text before the next elections, despite previous requests from the European Parliament and stakeholders to have it published before the end of the summer. Denmark, the Netherlands, Norway and Sweden, have recently put pressure on the Commission to get an update on where the revision stands, highlighting its central role in the Green Deal policy rollout.

Public consultations to provide input into the Commission's process took place throughout 2021 and Q1 2022. Targeted consultations and surveys have also followed throughout Q2 2022 and, whenever it is published, the proposal will be presented together with an Impact Assessment.

The Commission has yet to decide whether most of the changes to the Annexes will be conducted through comitology (a mechanism used for the implementation of EU legislation, in which the Commission delegates implementing powers to committees composed of representatives from EU member states) or co-decision which includes multiple readings and levels of legislative review. In this case, trilogue negotiations between the European Parliament and Council could take 12 to 18 months if the institutions agree to limit the scrutiny to a coordinated single reading. However, without an expected date for the presentation of the proposal, it is difficult to predict when the proposal will be adopted.

IMPLICATIONS

The revisions could lead to a simplification of REACH through the application of the Essential Use Concept, which could increase efficiency and predictability, simplify, and speed up the decision-making process. Some within the Commission have called for the merging of the current authorization and restriction processes, claiming it is important to allow for bigger and more generic restrictions and derogations to make the restrictions feasible and reasonable. While individual authorizations could still be obtained, they would no longer necessarily be the norm. A merger of authorization and restriction could result in more generic restrictions, where derogations would be proposed by both the authorities and the industry (responsible for providing evidence) and subsequently evaluated through an authorization process. This is not possible under the current REACH. Coupling the above simplification options with the increasing interest in the adoption of the GRA and grouping of substances (e.g: the EU PFAS Restriction Proposal took this approach) envisaged within the revision, a larger number of substances could also become automatically subject to restriction. The REACH revision is expected to incorporate most of the CSS initiatives which will then be applied to further sectoral legislation. However, it is important to note that given its delays, other sectoral legislations (e.g., toys, food contact materials, or cosmetics) which were originally expected to adopt the new provisions applicable to them through REACH, have already moved forward, creating further challenges. As such, the REACH Revision will now need to consider these sectoral efforts and ensure there are no conflicts between them.

Several MEPs across all political groups represented in the European Parliament have raised concerns regarding the possibility of the European Commission carrying out fundamental changes to REACH and CLP through comitology (which would reduce their input into the process). The GRA, EUC, and MAF are among initiatives that could go through comitology rather than co-decision and there is heated debate regarding whether such impactful legislation should be made without going through the slower but more vetted co-decision process. European Parliament and Member States prefer to weigh in on these initiatives through co-decision.

The cross-party sentiment that many of these revisions should go through co-decision rather than comitology is where the similarities end. Several MEPs within the European People's Party (EPP) have called for a 'regulatory moratorium' while industry works to meet the EU's climate goals and reduce emissions. Some MEPs have been very vocal in favor of minimizing compliance costs for businesses, claiming that stricter rules under a revised REACH would hurt Europe's chemicals industry and have generally been pleased by the delays. However, some MEPs within the Renew party have emphasized that stakeholders, from industry to NGOs, supported a prompt and ambitious REACH revision and now feel like they have been waiting endlessly. Others have also expressed disappointment in the Commission's lack of action on chemicals through the REACH Revision, particularly given the EU Chemical Strategy for Sustainability, including criticism that the continued delay has intentionally favored short-term industry interests over public health.

The continued uncertainty as to what this revision will cover, especially considering the recent advancements of the CLP revision, brings into question the ability of the CSS to achieve its objectives. Although concerns raised by part of the chemicals industry have successfully slowed down an ambitious reform of the REACH legislation, this reluctance does not represent the broader consensus, since numerous companies agree that a substantial revision of the REACH regulations is necessary.

In general, the uncertainty in the REACH Revision and its continued postponement can make it challenging for companies and investors to formulate long-term plans; however, when enacted, an ambitious revision of REACH could present a clear advantage for alternative providers and progressive companies. The continued delay also complicates how the revision can be practically implemented, since it will now have to consider other legislative reforms that have moved ahead during the delay and ensure that it is aligned across sectors.

ANNEX I – POTENTIAL REACH REVISION POLICY OPTIONS

STEP	SUBSTANCES	BASELINE (no changes to REACH)	OPTION 1	OPTION 2A	OPTION 2	OPTION 3
Candidate list		CMR, PBT, vPVB substances + EIoC for other substances	Add ED, PMT, vPvM to hazard classes where no EIoC is necessary. Add requirements for downstream users to provide information on use, exposure, alternatives, and waste management. Add fees linked to this notification obligation linked to the SVHC use.			
Type of restriction applying by default (i.e., unless there is a derogation or authorisation)	SVHC on Annex XIV	Authorisation requirement/ Annex XIV	Authorisation requirement/ Annex XIV	Restriction/ Annex XIV bis	Restriction/ Annex XVII (integration of ex-Annex XIV)	None
	Other substances	Restriction/ Annex XVII	Restriction/ Annex XVII	Restriction/ Annex XVII		Restriction/ Annex XVII
Derogation proposed by authorities	SVHC on Annex XIV	Art 58(2) Only for uses where risks are properly controlled by other legislation	Art 58(2) Only for uses where risks are properly controlled by other legislation	Part of restriction proposal	Part of restriction proposal	n/a
	Other substances	Part of restriction proposal	Part of restriction proposal	Part of restriction proposal		Part of restriction proposal
Derogation of general applicability on industry request		None	None	Possible where foreseen in restriction	Possible where foreseen in restriction	None
Authorization	SVHC on Annex XIV	For substances in Annex XIV	For substances in Annex XIV	Possible where foreseen in Annex XIV bis, no upstream applications	Possible where foreseen in Annex XVII, no upstream applications	None
	Other substances	None	None	Possible where foreseen in Annex XVII		None

For factsheets and more information on European Chemicals Policies, please visit www.sustainablechemistrycatalyst.org/eu-chemical-policy.

AUTHORS

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