EU CHEMICALS STRATEGY FOR SUSTAINABILITY

OVERVIEW

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

SUMMARY

- Published on 14 October 2020, the European Commission's (EC) Chemicals Strategy for Sustainability (CSS) represented the first step towards the "Zero pollution ambition for a toxicfree environment" announced in the European Green Deal.
- The CSS includes over 70 actions to be implemented between 2021 and 2024 as part of the Commission's commitment to addressing harmful chemicals in consumer products; however, the recent Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Revision delay has impacted several of these actions, making their trajectory towards implementation uncertain.



European Commission Headquarters in Brussels, Belgium

- Several public consultations have been carried out to gather input on the REACH and Classification, Labeling, and Packaging (CLP) revisions, and the Commission contracted studies to feed into the Impact Assessments that are expected to inform the decision-making process.
- The CSS tries to strike a balance between protection of health and the environment and innovation and industry competitiveness.

BACKGROUND & CONTEXT

The Chemicals Strategy for Sustainability (CSS) was adopted in 2020 as a key policy initiative of the Green Deal and its components will likely have the largest direct impact on the chemical industry, among the many other initiatives of the Green Deal. While both the European Parliament and the European Council have shown support for the CSS and called for its timely implementation, the recent delay in the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation Revision (REACH Revision) has impacted several of the CSS actions to be implemented between 2021 and 2024, introducing considerable uncertainty regarding their timelines for implementation. Many CSS initiatives are broadly horizontal / crosscutting across many sectors (e.g. cosmetics, detergents, toy safety) and will require revisions to sectoral legislation to implement. With the timing of many of these initiatives and their related sectoral legislation coming out on disparate timelines, ensuring horizontal alignment will be challenging.

DESCRIPTION

The CSS is distributed across various proposals and includes a wide range of over 70 actions. Some of the prominent actions include:

- Banning the most harmful chemicals in consumer products,
- Phasing out the use of per- and polyfluoroalkyl substances (PFAS) in the EU,
- Requiring companies to substitute hazardous chemicals with safer alternatives,
- Supporting the development of new, safe, and sustainable chemicals.

The actions and investments outlined in the CSS are expected to apply a "toxic-free hierarchy" to chemicals management, with an overarching two-part goal of protecting human health and the environment from hazardous chemicals while also boosting innovation for safe and sustainable chemicals. The toxic-free hierarchy prioritizes "safe and sustainable by design" first, followed by efforts to minimize and control exposure to hazardous chemicals, and finally eliminating substances of concern and providing remedy for damage as a last resort (FIGURE 1).

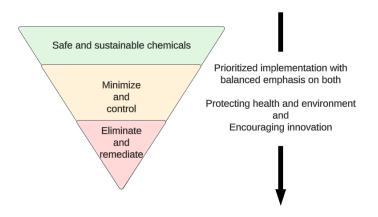


FIGURE 1. The toxic-free hierarchy for chemicals management, adapted from <u>The European Commission Communication on the</u> <u>Chemical Strategy for Sustainability COM/2020/667 final</u>.

The main proposals that comprise the CSS center around 6 core themes, outlined in FIGURE 2.

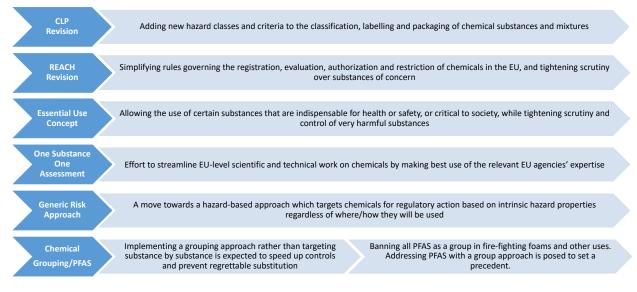


FIGURE 2. Core themes addressed in the Chemical Strategy for Sustainability.

These themes and the associated proposed changes and actions fall under three categories: **increased protection**, **innovation**, **and simplification**, and are laid out in **TABLE 1**. Data access and positioning Europe to be an international leader are also important parts of the plan.

TABLE 1. Summary of proposed changes and actions under the Chemical Strategy for Sustainability that fall under three broad categories. Many of these changes and actions are covered in more detail in separate spreadsheets that can be found at www.sustainablechemistrycatalyst.org/eu-chemical-policy.

Increased Protection	Innovation	Simplification	
 Reinforce REACH and clarify hazard classes under CLP to enhance communication to workers and consumers. Phase out the most harmful chemicals in specific consumer products: cosmetics, detergents, food contact materials, textiles. Establish an Essential Use Concept (EUC)¹ by setting criteria where most harmful substances will not be allowed until proven essential. Apply a Generic Risk Approach (GRA)² to chemicals management that targets chemicals based on intrinsic hazard properties regardless of how/where they will be used. 	 Shift to Safe and Sustainable-by- Design (SSbD)³ chemicals by establishing specific criteria for chemicals. Leverage the Research and Innovation (R&I) findings of the 2022 Strategic Research and Innovation Performance (SRIP)⁴ Report to feed into the Horizon Europe work program that supports R&I actions. Promote a global standard for chemicals management through international partnerships and cooperation with countries beyond the EU to support capacity-building, while preventing the export of hazardous chemicals banned in the EU. 	 Introduce the 'one substance one assessment' (OSOA)⁵ process (assessments proposed under one piece of legislation will be applicable for other pieces of legislation). Make targeted amendments to REACH and sectorial legislation⁶, to strengthen the governance of the European Chemicals Agency (ECHA) and increase the sustainability of its financing model. Update the REACH Restrictions Roadmap⁷ to group chemicals with similar features and in similar stages of the restriction process to streamline assessments and avoid regrettable substitutes. 	

The main proposals that comprise the CSS and hit on the 6 core themes are described below in TABLE 2.

TABLE 2. Main proposals that comprise the CSS.

Main Proposal	Description	Key Nuances and Implications
REACH Revision	Legal proposal to update the rules governing REACH to simplify processes and to tighten scrutiny over substances of concern.	Proposal was postponed to the next Commission taking office in Q4 2024 and is unlikely to be published before Q3 2025. The revision contains multiple actions, some of which create dependencies with implementation of other Green Deal initiatives. Additionally, initiatives like the EUC pertain to REACH and though they could be integrated into the REACH Revision, they may end up being implemented separately in other legislation as a result of the delay.
CLP Revision	Legal proposal to add new hazard classes to CLP regulations for chemical substances and mixtures.	Proposal was presented in December 2022. Implementation will trigger more communication of hazards via worker protections, packaging, labeling, transport, etc. and because CLP classification is also the basis for legislative provisions on the risk management of chemicals , it can trigger requirements under REACH, especially once the GRA is in place.

See Essential Use Concept (EUC) factsheet for more information.
 See Generic Approach to Risk (GRA) factsheet for more information.

6 See REACH Revision factsheet for more information.

³ See Safe and Sustainable by Design (SSbD) factsheet for more information.

⁴ See 2022 Strategic Research and Innovation Performance (SRIP) Report factsheet for more information. SRIP reports are bi-annual reports to analyze the EU's key research and development drivers, and performance in topics related to innovation. Though not explicitly part of CSS, the 2022 report elevated several CSS themes. ⁵ See One Substance One Assessment (OSOA) factsheet for more information.

⁷ See REACH Restrictions Roadmap factsheet for more information.

REACH Restrictions Roadmap	Staff working document to prioritize group restrictions on substances of concern targeted for the GRA (i.e. those with hazard endpoints like CMRs, EDs, PBTs, etc.) until the GRA is in place.	Published in April 2022, it will undergo multiannual planning until the new REACH and GRA are in place (2025–2027). Framed as a transparency and predictability tool, it is not legally binding and does not affect Member States' right to propose other restrictions. It does, however signal the planned move toward regulating full groups of structurally similar chemicals , targeting a wider range of their uses (industrial, professional, and consumer products), and highlighting prioritized alternatives ahead of regulatory action which gives marketplace time to adjust.
Safe and Sustainable by Design (SSbD)	Voluntary, non-regulatory framework to establish steps and criteria for assessing the safety and sustainability of chemicals and materials.	On December 8, 2022, the European Commission released a Recommendation introducing a voluntary European assessment framework for 'safe and sustainable by design' (SSbD) chemicals and materials. The framework defines "safe" as the absence of unacceptable risks and "sustainable" as a substance's ability to function without surpassing environmental boundaries. Objectives include promoting SSbD for a green industrial transition, guiding criteria development, driving innovation for safer and sustainable alternatives, and enabling comparative assessments. The SSbD Framework aims to position the EU as a global leader in safety and sustainability, emphasizing substitution of harmful substances and minimizing environmental impact.
One Substance One Assessment (OSOA) Process Implementation	Legal proposal to provide an ECHA Founding Regulation to clarify its tasks, financing model and governance to effectively carry out CSS initiatives. Legal proposal via an "omnibus regulation" to reallocate workflow across 5 agencies to streamline scientific and technical work on chemicals Legal proposals to revise sectoral legislation in order to ensure effective implementation of OSOA across sectors.	Nothing specific to watch from a chemicals perspective except to be aware that these planned internal changes in operations and reallocation of tasks to accommodate CSS will likely affect external operations, timing, points of contact at ECHA ⁸ , EFSA ⁹ , EMA ¹⁰ , EEA ¹¹ , and OSHA ¹² . For sectoral legislation, it's important to understand that once initiatives like the GRA and EUC are in place, their implementation will need to be specifically tackled in regulations for the relevant sectors (e.g. Cosmetics, Detergents, toy safety). The update of the Industrial Emissions Directives also proposes provisions to promote the use of safer chemicals and elimination of substances of very high concern as well as addressing emissions and reporting of PFAS from industrial plants.

As mentioned earlier, many of these initiatives are horizontal, cutting across several sectors and once implemented, will require amendments to sectoral legislation in all affected sectors. One example of this is the PFAS Restriction which is set to ban this group of chemicals and set a precedent for how chemical grouping may be implemented for other chemical groups. Sectoral legislation will be required to apply this to relevant sectors where PFAS are typically used. FIGURE 3 below illustrates how the cross-cutting horizontal initiatives within CSS (orange) will affect sectoral legislation (purple) as well as impact the implementation of other Green Deal initiatives relating to sustainable products (green) and investment opportunities (blue).

11 EEA: European Economic Area

 ⁸ ECHA: European Chemicals Agency
 ⁹ EFSA: European Food Safety Authority
 ¹⁰ EMA: European Medicines Agency

¹² OSHA: Occupational Safety and Health Administration

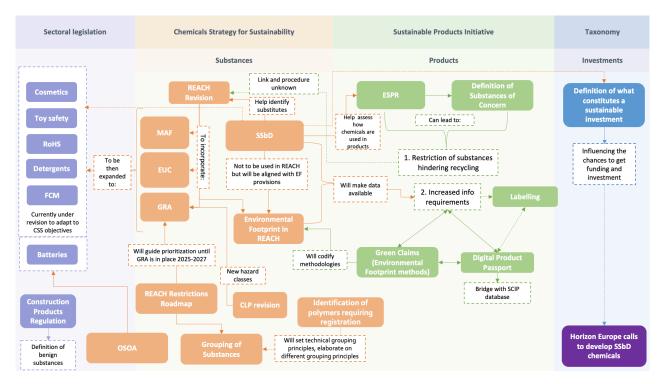


FIGURE 3. Relationship between cross-cutting initiatives within CSS (orange) and their impacts on other sectoral legislation (purple), sustainable product (green), and investment (blue) initiatives within the Green Deal.

CURRENT STATUS

With the REACH Revision delayed in Q4 2023 and the new mandate of the European Commission approaching, uncertainties arise regarding how certain CSS initiatives will be implemented across different pieces of legislation and sectors, particularly those with REACH Revision dependencies. **TABLE 3** below provides a current status of CSS initiatives and what to expect in the context of the REACH Revision delay.

TABLE 3. Current statuses of various CSS initiatives, with particular focus on those impacted by the REACH Revision delay.

CSS Initiative	Form	Next Steps & Remarks	Timing
Develop EU Safe and Sustainable-by- Design (SSbD) criteria for chemicals	Commission Recommendation	Ongoing technical work by EU services for criteria definition and first case studies. 5 th stakeholder workshop planned for December 2023. Guidance report expected in Q1 2024. SSbD is not a regulatory action but will act as a complement to REACH. It is intended as a driver for better chemistries and intends to offer predictability and incentives to investors. Thus, it will not result in new obligations for companies.	Adopted in December 2022
REACH Restrictions Roadmap (prioritization of CMRs, PBTs, etc.)	Staff Working Document (REACH implementation)	The Roadmap is regularly reviewed and updated by the European Commission. It will continue to be used until the REACH Revision enters into force, which does not provide the sufficient predictability for users and manufacturers, as substances listed in the Roadmap would be subject to the same complexities of current authorizations and restriction processes.	Roadmap published in April 2022

Expand the Generic Approach to Risk Management (GRA) beyond REACH Revision and apply to Food Contact Materials (FCM), cosmetics, and toys	Legal Proposal – Fragmented per file	REACH Revision and FCM revision are delayed. Toys and Cosmetics legislation is in progress. It would group uses, hazard and exposure data into a few use scenarios based on worst case assumptions, thereby often overestimating risk. It would fail to consider the importance of critical substances for essential uses and ignore well established low-risk manufacturing processes. Uncertainties remain as the GRA is a key action of the REACH Revision which has been delayed. It also depends on the introduction of new hazard classes under the CLP.	Next Commission 2024
Operationalize the Essential Use Concept (EUC) and develop criteria for implementation	To be integrated in the REACH Revision or published separately. To be implemented in other legislation.	Study by Consultancy WSP completed in March 2023 to support the Commission in defining the EUC. DG ENV working on final changes. Delays in the publication of the EUC leads to uncertainties for several sectors which do not know if their uses will be derogated or not. This could drive investments away from Europe in the short term.	Q1 2024
Proposal to revise the REACH authorization and restriction processes	Legal Proposal (REACH Revision – codecision)	Part of REACH Revision and Impact Assessment. Until the revised authorizations and restrictions processes come into force, substances listed in the SVHC list would be subject to current REACH processes, creating a lot of uncertainties for users. The simplifications a reform would bring also rely on the Essential Use Concept that has not been yet published.	Next Commission 2024
Proposal to amend REACH Article 68(2) to include professional users	Legal Proposal (REACH Revision – codecision)	Part of REACH Revision and Impact Assessment.	Next Commission 2024
Update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH legislation on cosmetic products, food contact materials (FCM), plant protection products, and biocidal products	REACH Revision – Comitology Biocidal Products Regulation (BPR) – Delegated Regulation Active substances and Plant protection – Commission Communications Legal Proposal – Revision Food Contact Materials Regulation Legal Proposal – Revision Cosmetic Products Regulation	REACH Revision delayed, FCM delayed, Cosmetics in progress. Consistency between the inclusion of the requirements under separate legislations is needed, in particular as these legislative proposals do not have the same timeline and might have different provisions when finally adopted. This relies on the new hazard classes introduced via the CLP delegated act. Endocrine Disruptors will also be prioritized for harmonized classification and labeling under the revised CLP regulation.	Next Commission 2024

Proposal to amend REACH Art. 57 to add endocrine disruptors, persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances to the list of substances of very high concern	Legal Proposal (REACH Revision – codecision)	Part of REACH Revision and Impact Assessment; Study launched; consultations ongoing.	Q4 2022
Introduce Mixture Assessment Factor(s) (MAF) in Annex I of REACH	Legal Proposal (REACH Revision – Comitology)	Could be launched separately to REACH Revision. The MAF may lead to unintended consequences in downstream legislation and compromise the ability to accurately assess the risk to consumers, and indirectly impact the availability of chemicals for which there is no risk. The MAF will be taken into account in the reformed authorizations and restrictions processes.	Unknown
Review of the definition of nanomaterial	Staff Working Document on the review of the Recommendation 2011/696/EU and a new Commission Recommendation (2022/C 229/01) on the definition of nanomaterial, replacing 2011/696/EU	Individual sectors are updating their internal definition according to the revised definition, in accordance with their own timetables. Nanoform definition expected as part of the REACH Revision proposal, now delayed.	Next Commission 2024
Proposal to amend CLP Regulation to give the Commission the mandate to initiate harmonized classification	Legal Proposal (CLP Revision)	Trilogue ongoing between EP and Council. The CLP revised regulation is expected to have various effects on REACH. For instance, harmonized classification being the starting basis to extend the generic approach to risk management. In addition, extension of data requirements under the REACH Revision needs to be made available for classification under the new CLP regulation. In summary, the two revisions are expected to work together.	Possible adoption before May 2024
Proposal to amend the CLP Regulation to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs and persistent and mobile substances, and apply them across all legislation	Legal Proposal (CLP Revision)	Proposal adopted but some parts may remain unclear due to delay in REACH restriction. CLP classification is also the basis for legislative provisions on the risk management of chemicals, meaning it can trigger requirements under REACH, especially relevant in light of the more generic approach to risk (GRA) to be extended in REACH. Until the new REACH is in place, new hazard classes would possibly trigger new authorizations and restrictions under the current procedure.	Adopted March 2024
Proposal at the UN GHS level to introduce, adapt or clarify criteria/hazard classes in line with the CLP Regulation	New Hazard Classes in GHS	Dependent on CLP Regulation Revision.	2022–2024

Proposals under the Stockholm Convention and the Basel Convention to address PFAS concerns at a global scale	Decisions from the COP and amendment of EU legislation, when relevant (i.e. POPs Regulation)	PFHxS inclusion in the Stockholm Convention to be discussed at next COP face to face meeting (foreseen in June 2022). A party is preparing a nomination dossier for C9-C14 PFCAs. Two parallel tracks are being taken on PFAS, as the most toxic group of PFAS are targeted at POP level and as the EU is proposing to restrict the whole group of substances with derogations under the 'universal' PFAS restriction. Coherence between these two tracks is critical to ensure predictability for businesses.	2023–2024
Horizontal proposal for reallocation of EU technical and scientific work on chemicals to the EU agencies (OSOA)	Legal Proposal	Roadmap and exploratory memorandum published. Originally announced for Q4/2022, then Q2/2023, it has not been tabled yet.	Unknown
Grouping of chemicals	Part of the REACH Restrictions Roadmap as well as being addressed under other aspects of REACH Revision	Use and acceptation of grouping of chemicals should be further facilitated. Grouping of substances rely on other measures in the REACH Revision (e.g., the identification of polymers requiring registration that will elaborate on grouping principles to be established, and the new authorization and restriction processes).	Next Commission 2024
Information on environmental footprint of chemicals	REACH Revision	Relates also to SSbD, which aims to minimize the environmental footprint of chemicals (4 th step of the sustainability assessment).	Next Commission 2024
Registration of Polymers	REACH Revision	Under the current REACH, polymers are exempted and not required to be registered, nonetheless it is envisaged in the revision. Registration will provide basic information on the quantities, uses, hazards and risks of polymers. The number of polymers to be identified for registration requirement is unknown until the REACH Revision is published.	Next Commission 2024
Registration of low volume substances	REACH Revision	Could lead to a merger of ANNEX VII & VIII.	Next Commission 2024
Proposal for a founding regulation for the European Chemicals Agency (OSOA)	Legal Proposal (new regulation)	Consultation September – October 2022. First expected to be published in July 2023, the proposal has been delayed since. The Belgian Presidency of the Council of the EU has committed to make it a priority once the Commission publishes it. The new proposal is expected to prepare ECHA for the complexities of the CSS implementation, which has already started.	Unknown
Ecodesign for Sustainable Products Regulation (ESPR) includes legal requirements on the presence of substances of concern in products ¹³	Legal proposal expected to use PFAS as a first example to set precedent	The Commission is expected to adopt its working plan setting priority products in Q1 2024. Work will continue at the technical level before the second trilogue, the date of which has yet to be set. The ESPR defines 'Substances of Concern' in products and can lead to the restriction of substances if they are hindering recycling activities. It can also prevent environmental claims under the Green Claims directive.	Adoption expected in Q1 2024

¹³ ESPR is not itself part of the CSS, but the CSS sets concrete actions that include requirements under ESPR.

For more factsheets and information regarding Green Deal initiatives that impact chemicals management, please visit www.sustainablechemistrycatalyst.org/eu-chemical-policy.

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This factsheet was developed through a collaboration between:

Sustainable Chemistry Catalyst | www.sustainablechemistrycatalyst.org

The Sustainable Chemistry Catalyst is an independent research and strategy initiative, based at the University of Massachusetts Lowell, that is focused on accelerating the transition to safer, more sustainable chemistry through research and analysis, and stakeholder engagement with scientists, policymakers, and commercial actors. The Catalyst works to understand barriers and opportunities to commercialization, identifies model solutions and strategies, develops methods to evaluate safer alternatives, and builds a community of expertise to support the transition to safer, more sustainable chemistries and technologies.



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