

ENSURING A FUTURE-PROOF EU CHEMICALS POLICY

EEB proposals to ensure simpler, faster and bolder chemical policy goals

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The European Environmental Bureau (EEB) is the largest network of environmental citizens' organisations in Europe. It unites 185 civil society organisations from 41 countries, working for a better future where people and nature thrive together.

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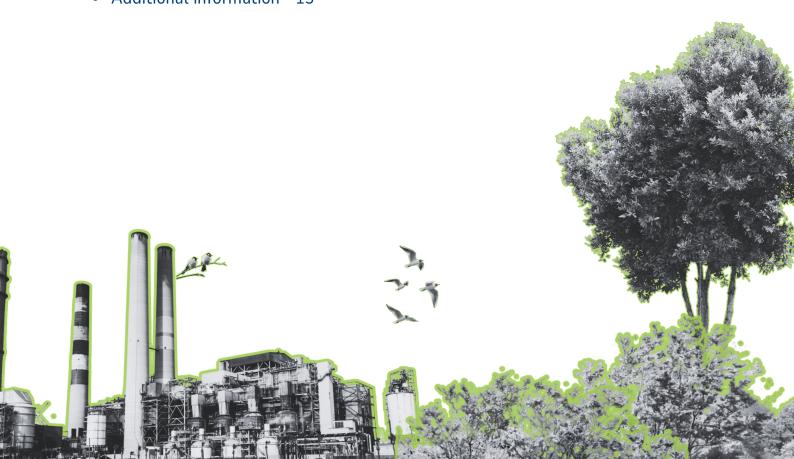
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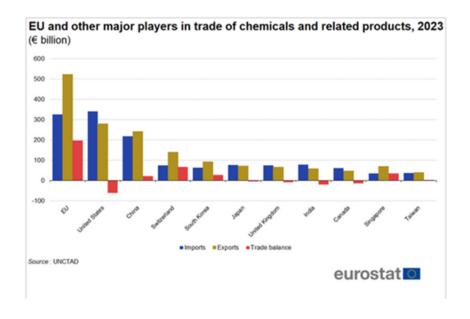
Environmental standards are key to EU competitiveness

We would like to thank the Commission for the opportunity to reflect on advancing EU chemicals policies towards a future-proof, toxic-free future. This progress will stimulate innovation in safer, more sustainable, more circular and climate friendly chemicals, materials, and technologies, ultimately catalysing the competitiveness of the EU economy through sustainability.

Just as the EU cannot compete with other regions' extremely low wages, it also cannot compete through dirty and toxic production processes. Deregulating chemical safety policies will not lead to increased competitiveness; instead, it will cause the EU to lose momentum to gain competitiveness through innovation towards safer and more sustainable products and processes.

In the last years, EU chemicals policies have made considerable progress in protecting people and the environment from the risks posed by hazardous chemicals, as highlighted by the latest REACH review or the Chemicals Strategy for Sustainability (CSS). For example, REACH has generated the most advanced knowledge base on chemicals in the world and set up scientific bodies to carry out the risk and hazard assessments of chemicals. The EU has also managed to reduce the risks to people and the environment for certain hazardous chemicals like carcinogens.

REACH has also demonstrated that strong environmental standards are crucial to the EU's competitiveness. According to Eurostat, the EU chemical industry has performed significantly better since the adoption of REACH. In 2022, EU chemical production sales reached a <u>decade high</u> of €872 billion—€335 billion more than in 2011—marking the highest recorded value. While there was a slight decline in 2023, with sold production of chemicals and related products growing from €537 billion in 2011 to <u>€785 billion in 2023</u>, the industry's overall economic growth remains substantial. Additionally, in Q2 2024, the EU chemical sector recorded the <u>largest trade surplus</u> of all industries at €59.3 billion, while EU chemical and pharmaceutical trade presented a <u>robust growth</u>. The EU had a growing trade surplus in chemicals and related products throughout the 2002–2023 period, from €55 billion in 2002 to €198 billion in 2023. Looking at the major international players in trade of chemicals and related products, EU is the largest exporter of chemical products, with a total trade of €848 billion.





However, despite the benefits of the EU chemicals policy framework for people, the environment and the economy, multiple assessments by authorities, academia, industry and civil society organisations (CSOs), including the Chemicals Strategy for Sustainability, have highlighted the need for further policy actions. Addressing the contribution of chemicals to the triple planetary crises, ensuring regulatory predictability, and promoting innovation toward safer and green alternatives are essential to maintaining Europe's competitiveness.

The flawed implementation of REACH has become burdensome for both authorities and industry. Meanwhile, the public and workers continue to be exposed to chemicals of high concern through everyday products, food, and water. On average, it takes two decades to assess and take action on the risks posed by chemicals. According to the synthesis report by the EEA and ECHA on the EU indicator framework for chemicals, "more work is needed to make chemicals safe and sustainable" as the overall use of the most harmful chemicals (in particular those that are carcinogenic, mutagenic and reprotoxic) is still growing.

The REACH Regulation's aim to ensure information on the risks of chemicals throughout the supply chain and create strong market incentives for safer and green chemicals has not been fully accomplished. Companies lack sufficient incentives to disclose the hazardous properties of chemicals or their uses in products and processes. According to the CSS, only one third of chemicals marketed in the EU fully meet the legal requirements on safety data. As a result, authorities are often doomed to work with incomplete or non-existent data, while downstream users lack the needed information to manage chemicals risks and innovate toward safer, more sustainable products. In addition, the many incentives for non-compliance have created an uneven playing field for companies, allowing free riders to block market access to frontrunners committed to innovative, safer and more sustainable practices and products. Therefore, the measures we propose below —regarding the implementation and revision of REACH, as well as other chemical policies— offer the opportunity to strengthen protections for people and the environment, while promoting innovation and competitiveness. As highlighted by the <u>EU's competitiveness compass</u>, this can be achieved by "bringing a real simplification on the ground and ensuring faster decision-making on important hazards".



Optimising REACH: reducing administrative burdens for SMEs while maintaining protection standards

To effectively reduce administrative burdens within the REACH framework—particularly for SMEs—it is crucial to identify opportunities where efficiency can be increased without compromising the high level of protection for people and the environment. By streamlining processes, applying new methods, and improving data management, it is possible to maintain strong regulatory standards while alleviating the burden on authorities and industry. The following measures provide actionable steps that can reduce administrative complexity across various REACH processes, such as Evaluation, risk assessment, Restriction, Authorisation, and providing information along the supply chain, while promoting innovation, enhancing predictability, and safeguarding public health and the environment.

Evaluation/Risk Assessment

- Grouping chemicals with similar properties allows authorities to fulfil their mandate of
 ensuring a high level of protection more effectively and with less burden, compared to a
 piecemeal substance-by-substance approach. This approach helps avoid regrettable
 substitution, enhances clarity and predictability for industry and prevents companies from
 making unnecessary investments in harmful or unsustainable alternatives.
- Applying a Mixture Assessment Factor (MAF) provides a practical and efficient approach to addressing risks from combined exposures. By increasing the risk characterisation ratio in chemical safety assessments, it helps identify potential risks that might otherwise be overlooked, thus simplifying the risk evaluation process.
- New assessment methods, new approach methods, or non-animal methods (NAMs) are widely used under REACH by many chemical companies in their registration dossiers to facilitate market access. NAMs that are considered acceptable by regulatory authorities should also be used for identifying and regulating the most hazardous chemicals, thereby improving the level of protection while gradually reducing animal testing and reducing the burden on both authorities and companies. EU risk assessments must be updated to align with 21st century science!
- The precautionary approach is the most cost-efficient way to enhance protection of health and the environment while reducing the burden on authorities and companies. Ensuring better use of existing data for hazard identification and taking precautionary action to phase-out the most harmful chemicals, will decrease the burden of evidence for authorities, while effectively minimising the need for animal testing. When hazardous properties are identified for a substance —based on evidence from structurally related chemicals, NAMs, academic data and other existing information this evidence should directly lead to a precautionary decision by authorities, avoiding lengthy and resource-intensive assessments.



Restriction

• Extending the Generic Risk management Approach (GRA) to cover all the most harmful chemicals in mixtures and in articles intended for the general public and professional users, as committed to by the CSS, allows authorities to fulfil their mandate of ensuring a high level of protection more efficiently. This is more effective than the standard restriction procedure, which involves separate, lengthy, and burdensome specific risk assessments. GRA streamlines the process, reduces administrative burdens, and accelerates decision-making, making it less resource-intensive for all parties involved.

Extending GRA to professional uses of substances and mixtures —notably those similar to consumer uses (e.g., professional paints or cleaning products) — simplifies the regulatory framework by addressing multiple use scenarios together, reducing complexity and avoiding duplicated efforts. This generic risk-based approach also enhances clarity and predictability for industry, as it establishes clear criteria for action, thereby preventing companies from investments in unsustainable and short-sighted alternatives.

Furthermore, extending the right to initiate actions under Article 68(2) to Member States would help distribute the workload, share it with the Commission, accelerate the process, and reduce the burden on the Commission. This would ultimately speed up regulatory action and improve overall effectiveness.

- **Grouping by default.** The scope of restrictions should, by default, cover groups of chemicals. This approach would reduce the burden of a substance-by-substance approach on authorities and all stakeholders.
- Ensuring early information on uses of chemicals and available alternatives will reduce the burden on authorities when preparing restriction dossiers or making decisions about the availability of alternatives. Existing use descriptors are too broad, making them not useful for authorities and stakeholders to identify potential alternatives. Improved data and a more specific reporting on chemical uses would enable supply chain actors to better identify and manage risks, leading to more targeted and efficient risk mitigation for companies.

Additionally, better and earlier information on availability of alternatives and/or the time needed to substitute would simplify the preparation of restriction dossiers and decision-making by authorities. This would also reduce the need for add-on calls for evidence, as more relevant risk-related information would become available to authorities upfront, streamlining the regulatory process and saving time and resources for all stakeholders.

• The Essential Use Concept should guide decisions on potential derogations, easing the burden not only for authorities preparing and deciding on dossiers but also for stakeholders as it would increase predictability. Time-limited derogations should only be granted to uses deemed essential, this is, those uses that are critical for society and for which it is demonstrated that no alternatives are available.



Authorisation

- Limiting the possibility to obtain authorisation to essential uses. This would significantly reduce the number of Applications for Authorisation (AfAs) that authorities need to assess and decide upon. Companies would have more predictability as they would have clear criteria for which uses applications are allowed and which are not. The burden on applicants would also be reduced, as they would only need to demonstrate the criticality of the use and the lack of alternatives, avoiding the need for burdensome socio-economic assessments.
- Worshipping the legal text, as well as <u>Court mandates</u> and <u>Ombudsman recommendations</u>, when implementing authorisations will significantly reduce the burden on companies applying for authorisations and authorities assessing and deciding on these applications. This can be achieved by:
 - Rejecting all applications that are not in conformity. Applications containing insufficient
 information, such as information on exposure scenarios and availability of alternatives for
 the use applied for, should be promptly dismissed.
 - Ensuring that the burden of proof lies with the applicants: it is up to applicants for authorisation to demonstrate that they have met the legal conditions for obtaining the authorisation by providing sufficient information. Authorities should make decisions based on the information provided and deny authorisations in cases where there is uncertainty, for example regarding the availability of alternatives.
- Encouraging joint AfAs for similar uses with similar exposure scenarios.
- Ensuring early information on uses and alternatives: ensuring early and reliable information on the uses of chemicals in the registration dossier as well as adequate (more specific and useful) use-descriptions in company applications for authorisation, will reduce the burden on authorities when assessing and deciding on availability of alternatives.

Information along the supply chain

- Developing a digital and centralised database of Safety Data Sheets (SDS) would reduce
 the burden on SMEs both in preparing SDS and assessing the risks of the products they use. A
 digital system, linked to ECHA's chemical database would facilitate accurate information on
 hazards and labelling, reducing the resources needed by SMEs. A centralised database of SDS
 would also make it easier for SMEs and workers to access accurate information, in their own
 languages, thereby reducing the process of understanding and controlling the risks associated
 with the products they use.
- 'Report only Once' through Digital Product Passports (DPP) would significantly streamline reporting processes and reduce administrative burdens by enabling companies to submit chemical content information only once, rather than repeatedly across various regulatory frameworks or new Substances of Concern being added to the DPP's reporting list. This centralised approach would ensure that all required chemical data are stored in a single, standardised format, making it easier for authorities, manufacturers, and downstream users to access and verify information. By reducing duplication and eliminating the need for multiple submissions of the same data, through for example SCIP database, REACH article 33 requirements or DPP, SMEs, in particular, would save time and resources, while also ensuring regulatory compliance in a more efficient manner.



Striking a Balance: streamlining REACH Authorisation and Restriction while ensuring strong health and environmental protection

Strict regulation, underpinned by clear and transparent processes, timelines, and deadlines, serves as a key incentive for companies to replace hazardous chemicals with safer alternatives. A more straightforward implementation of the existing REACH restriction and authorisation chapters would significantly streamline the regulation of the most hazardous chemicals, enabling quicker action and better protection for health and the environment. In contrast, voluntary schemes that allow companies to set their own o regulatory timelines will increase the complexity of these processes. This flexibility would therefore lead to delayed actions, increasing the burden on both authorities and industry stakeholders, especially on SMEs. Such schemes also risk weakening the predictability of the regulatory process, ultimately hindering progress towards a safer and more sustainable chemicals landscape.

Therefore, to effectively streamline both the authorisation and restriction processes while maintaining robust health and environmental protection, a straightforward implementation of these regulatory processes should be ensured, including by:

- Extending and making use of GRA. This enables a more efficient and comprehensive assessment of the most harmful chemicals, reducing the need for burdensome authorisations and Article 68(1) restrictions, helping to reduce the administrative burden on both authorities and industry, while enhancing protection for health and the environment.
- Grouping chemicals and uses for restriction and authorisation by default. By grouping chemicals and their uses together, the restriction and authorisation processes become more streamlined, reducing the need for separate, individual assessments of each substance or use scenario. This simplifies the regulatory framework and enhances predictability for industry, ensuring that health and environmental risks are still effectively managed and reducing the risk and the burden for companies to perform regrettable substitutions.
- Ensuring better and earlier information on hazards, uses and alternatives. Access to detailed, timely data on chemical hazards, usage patterns, and the availability of alternatives would significantly reduce the workload for authorities, making decision-making more efficient. This would also enable industry stakeholders to make better-informed decisions and promote innovation towards safer alternatives.
- Avoiding the possibility of exemptions, derogations, or authorisations of non-essential
 uses. Non-essential uses should not be allowed to request exemptions, derogations or
 authorisations. This would reduce the number of applications for authorisation and derogation
 requests that authorities need to assess, ensuring that resources are focused on the most
 critical uses. This would also provide more clarity and predictability for companies and reduce
 the overall regulatory burden.



 Removing adequate control route and replacing socio-economic assessments with Essential Use assessment. As supported by the study commissioned by the European Commission on the Essential Use Concept, among all the options studied, replacing the socio-economic route with the Essential Use Concept is the best choice. It provides the most predictable, costeffective, ambitious and coherent approach, delivers the greatest benefits for human health and the environment, enhances the competitiveness of companies producing safer and sustainable alternatives, and allows for a more systematic application. This approach would apply both to authorisations and derogations from restrictions, eliminating the need for the adequate control route under authorisation. As a result, all applications for authorisation and derogations from restriction would be assessed based on the Essential Use concept. This means that, instead of relying on lengthy, complex and resource-intensive socio-economic assessments, decisions would be guided by a chemical use not being critical for society and availability of alternatives, simplifying the decision-making process. This streamlined approach would not only enhance regulatory efficiency and reduce administrative burdens for authorities but also increase predictability and allow companies to prioritise the identification of safer substitutes and avoid unnecessary delays in the authorisation and restriction processes.



Future-Proofing EU Chemicals Policy: key steps for the next 20 years

As the European Union looks ahead, strengthening REACH and the chemicals policy framework to meet future challenges is essential to ensuring a high level of protection for human health and the environment while fostering innovation and competitiveness. By implementing the following key steps, the EU can modernise its chemical regulation framework, making it fit for the next two decades while maintaining its global leadership in chemicals management:

- Solve the data gap and update to 21st century science: Fill the chemical data gap by ensuring that companies provide under REACH comprehensive updated information on hazards, specific uses in products and processes, and exposure of chemicals and polymers. Make information readily available to authorities and all actors across the supply chain to enhance transparency and traceability of chemicals present in materials, products and waste.
- Speed up regulation of the most hazardous chemicals. Make safe products the easy choice: Use the available information to expedite the regulation of the most hazardous chemicals by adopting group-based approaches. Banning the most hazardous chemicals in uses aimed for the general public and in professional uses, as well as non-essential industrial uses. Leverage the recent successful revision of the CLP Regulation to streamline hazard identification requirements for EDCs and persistent and mobile chemicals. An ambitious, binding and transparent workplan to phase out most hazardous chemicals in articles aimed for the general public and professional users by 2033 should be published.
- Give REACH teeth, ensure industry liability: Strengthen REACH to ensure robust, dissuasive sanctions, including a revocation mechanism, and harmonised enforcement. Establish clear provisions to hold chemical companies accountable for any harm caused by their chemicals. Enforce financial responsibility on companies to cover the costs associated with monitoring, enforcement, and addressing adverse effects of their chemicals, including compensating affected individuals and communities, and remediating contaminated sites. Integrate the Polluter Pays Principle in the legal text.
- Mainstream intrinsically safe chemicals, materials and products, and promote substitution:
 mainstream inherently safe and sustainable chemicals, materials and products across all
 sectors of industry and daily life. Implement policies and economic instruments (including
 public procurement) that encourage the use of these alternatives while promoting substitution
 strategies. Strong regulatory incentives such as clear phase-out rules are best placed to give
 predictability to companies required to substitute and to suppliers of alternatives. Establish an
 EU wide substitution support centre to facilitate the transition to safer and more sustainable
 alternatives.



- Enhance authorities' accountability: Strengthen accountability mechanisms for the European Commission and Member State Competent Authorities responsible for chemical regulation. Empower and mandate authorities to duly consider the costs of inaction, take swift and decisive actions to address chemical risks and ensure timely compliance with regulatory requirements. Establish a clear process for authorities to take timely action following the identification and reporting of early warnings within the early warning and action system for emerging chemical risks.
- Empower citizens and establish compensation mechanisms: Provide citizens accessible information about chemical risks, opportunities for public participation in decision making processes, mechanisms for reporting pollution and access to justice. Introduce compensation mechanisms for victims of chemical pollution to provide redress for harm caused by exposure to hazardous chemicals, employing adapted burden of proof rules to give victims a real procedural chance at justice. Ensure that individuals and communities affected by chemical contamination have avenues for demanding action and seeking compensation and remediation.



Enhancing Knowledge in REACH: Strengthening risk management while boosting industry competitiveness

EU economic actors need reliable information on the hazards and uses of chemicals, including polymers, to be able to understand and manage the risks of their production processes and products. This information is essential for developing and marketing safe and sustainable products while ensuring investor and consumer confidence.

To address information gaps, the following actions should be taken:

Updating registration information requirements. All chemicals of high concern, as described in the <u>Communication on the essential use concept</u>, including polymers and CMRs marketed in low volumes, should be subject to registration requirements. Annex VII-X information requirements should be amended to ensure the identification of EDCs, mobile chemicals, and other substances with critical hazards, including effects on the nervous and immune systems. To limit waiving options and ensure that these hazards will be identified even for chemicals marketed, imported, and produced in low tonnages.

By obtaining more, better, and updated information on intrinsic hazards, registrants will be better equipped to conduct chemical safety assessments of their known uses. For downstream users, this will significantly simplify the process of identifying harmful chemicals and enable more effective risk management measures in the workplace, while also facilitating the identification of safer alternatives.

- Ensuring registration of polymers. Ignorance about polymers' compositions and their lifecycle risks hinder risk management, burdening authorities, industry, and other stakeholders as stunningly illustrated by the uPFAS restriction initiative, where Fluoropolymers are included in the scope. A better understanding of polymers will not only help companies identify materials that are more suitable for recycling or reuse but also support the development of more effective and efficient recycling technologies business models for a Circular Economy. A notification system for all polymers should be developed to be able to group these chemicals for a stepwise registration process, including those produced in very high volumes (>100.000 t/year).
- Ensuring compliance with registration information requirements and information obligations along the supply chain. REACH's reliance on voluntary compliance by companies has fostered a culture of widespread non-compliance, making it difficult for authorities and industry to manage risks effectively. Stricter enforcement of registration and supply chain obligations is essential to close these gaps, ensure that comprehensive data is available for risk management and decision-making and secure a level playing field for companies.



Ensuring Fair Competition and Consistent REACH Implementation Across the EU

To ensure fair competition between EU manufactured and imported products, and to achieve consistent implementation across the EU, it is essential to adopt measures that strengthen compliance, streamline decision-making, and align conditions for all market players. This will help create a fairer, more predictable regulatory environment, benefiting both EU industries and consumers, while fostering sustainable and safe products.

Key measures to ensure a level playing field include:

- Ensuring compliance with legal obligations, especially with information requirements. One of the main challenges for creating a level playing field is ensuring that both EU manufactured and imported products meet the same legal standards. Strict enforcement of registration and information obligations will ensure that all market players, both domestic and foreign, provide the necessary data for risk assessments and safety evaluations. This reduces the chances of non-compliant products entering the market and ensures that all products are held to the same safety standards.
- Speeding-up the implementation of the Restrictions Roadmap, ensuring same regulatory
 conditions for articles manufactured in the EU and for those imported. This should include
 all products, including those made from recycled materials. By aligning conditions for both,
 market distortions caused by regulatory differences between EU and imported products would
 be eliminated, promoting fairness and environmental responsibility.

Enhancing predictability for companies, including those using these chemicals or marketing safer alternatives. To encourage innovation and help EU industries compete on a level playing field, predictability in the regulatory process is critical. This can be achieved by speeding-up decision-making within the Commission, providing clear phase-out deadlines, and expediting the identification of substances of very high concern (SVHCs) and extending the use of GRA to include additional hazard categories, as committed to in the CSS. This will streamline risk assessments, reducing administrative burdens and enabling faster action on hazardous substances.



Strengthening REACH Enforcement: Tools and strategies for better collaboration across the EU

Effective enforcement of REACH is essential not only to protect of health and the environment, but also to create strong incentives for companies to comply with regulations. Robust enforcement ensures a level playing field, providing predictability for companies across the EU.

A key priority in improving enforcement is achieving harmonisation of enforcement across Member States. This will ensure that enforcement practices as well as legal and sanction frameworks are consistent and effective throughout the European Union. To achieve this, it is critical for Member States to establish common definitions and minimum criteria concerning their enforcement activities and ensure that the penalties provided are not only harmonised but also effective, proportionate, and dissuasive. Harmonisation will prevent discrepancies between how enforcement is carried out in different countries, ensuring fair competition, and strengthening the overall impact of REACH.

Improving transparency on enforcement actions, non-compliant companies and decisions is key to ensure protection, information, scrutiny, fair competition and incentives for compliance. The ECHA's Enforcement Forum should take a leading role in these efforts, guaranteeing harmonisation, transparency and offering guidance and oversight to ensure that enforcement practices are mandatory and aligned across EU. Additionally, ECHA can facilitate better collaboration among Member States, supporting and sharing information, resources, and best practices as well as setting mandatory standards for inspections and sanctions to ensure harmonisation.

Additional information

- From Risk to Resilience: Navigating Towards a Toxic-Free Future
- The Need for Speed Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections
- Waiting for REACH: The negative impacts of delaying reform of EU chemical laws



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