

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals
LEAD DG (RESPONSIBLE UNIT)	DG ENV B2, DG GROW F1
LIKELY TYPE OF INITIATIVE	Legislative proposal
INDICATIVE PLANNING	Q4 2022
ADDITIONAL INFORMATION	https://ec.europa.eu/environment/strategy/chemicals-strategy_en

The Inception Impact Assessment is provided for information purposes only. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

The [European Green Deal](#) sets a high ambition for a toxic-free environment leading to zero pollution. The [Chemicals Strategy for Sustainability](#) adopted on 14 October 2020 is the first delivery of the zero-pollution ambition. The objectives of the Chemicals Strategy for Sustainability are to better protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives. To this end the Strategy outlined a number of actions intended to increase the knowledge base and control of chemicals.

Chemicals are everywhere in our daily lives. They are fundamental for our well-being and high living standard and are important building blocks of key technologies to address future challenges. The REACH Regulation on Registration, Evaluation, Authorisation and Restriction of chemicals, together with the CLP Regulation on Classification, Labelling and Packaging of chemicals, are the key Union legislation for the assessment and management of chemicals. The REACH Regulation was last evaluated in 2018 (referred to as "latest [REACH Review](#)" below). It concluded that REACH is effective but that there are opportunities for further improvement, simplification and burden reduction. Following the evaluation, a number of non-legislative actions have been launched (some of them finalised, others still ongoing) to improve the implementation of REACH.

In addition, to deliver on the commitments made in the Chemicals Strategy for Sustainability, the CLP Regulation will also be subject to a targeted revision, along other sectoral chemical legislation.

Problem the initiative aims to tackle

The Chemicals Strategy for Sustainability recognises the need for a targeted revision of REACH to achieve its objectives by addressing the following problems that have been identified:

REACH is the most advanced knowledge base globally but there are still gaps in knowledge of many substances. The information required on critical hazard classes does not allow a sufficiently thorough hazard assessment, including for carcinogenicity, neurotoxicity, immunotoxicity and endocrine disruption. The same applies to intermediates, polymers, and substances in the lowest tonnage range, and no assessment of risks is required for non-threshold substances.

The registrants' safety assessments do not take combination effects of chemicals into account. Individual registrants are only responsible for their own substances and do not take into account that, in reality, humans and the environment are exposed to a plethora of different substances from different sources. Thus, securing safe use

of one substance is in itself not sufficient for protecting humans and the environment against combination effects.

The communication in the supply chains is inefficient. As identified and reported in the latest REACH Review, the communication up and down the supply chain on uses and necessary risk management measures lacks accuracy and clarity, which has a significant negative impact on the control of risks.

The evaluation of registration dossiers and substances is too complex and insufficient. The procedures for evaluation of registration dossiers and substances are complex, with several bottlenecks delaying the request for information from registrants and the conclusions on possible hazards and risks. In addition, the procedures are insufficient to ensure compliance of all registration dossiers.

The authorisation procedure is too heavy and inflexible. The authorisation process has imposed a heavy burden on both companies and authorities. A multitude of applications for the use of small quantities of substances, unclear criteria for authorisation and information gaps (in particular for uses where competitors have already implemented alternatives), as well as unclear information in applications (in particular from applicants up the supply chain and from only representatives) have led to prolonged discussions and delays in decision making. In many cases, this has placed EU-based companies at a competitive disadvantage compared to their non-EU competitors.

The current restriction process is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances. The normal restriction procedure, through specific risk assessment, puts a high burden on authorities to document unacceptable risk for health or the environment. Although REACH already enshrines the use of a generic approach (i.e. assuming that the use constitutes a risk) for restricting certain carcinogenic, mutagenic or reprotoxic (CMR) substances in consumer products, this procedure cannot be used for other critical hazard classes including persistent endocrine disruptors, persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances, immunotoxicants, neurotoxicants, respiratory sensitisers or substances that affect specific organs. Moreover, professional users are often using the same products as consumers, but much more frequently and during longer periods of time. Yet, they are unlikely to benefit from the same risk management as in industrial settings. Hence, they should get a level of protection at least at the level of consumers.

The control and enforcement is not equally effective in all Member States. Considerable differences exist between Member States depending on available resources and different policies leading to inconsistent effectiveness of controls. The increasing import of products from countries outside the EU, including by consumers' direct purchases through online portals, allows for import of goods that are not subject to the necessary controls to ensure compliance with EU law. These differences represent a risk for consumers and the environment and they negatively affect the competitiveness of compliant European industry.

Basis for EU intervention (legal basis and subsidiarity check)

The initiative concerns a targeted revision of an existing EU Regulation, which is based on Article 114 of the Treaty on the Functioning of the European Union that is harmonising provisions on chemicals at EU level in order to preserve the good functioning of the internal market. In line with the Regulation to be revised, the objectives of this initiative cannot be sufficiently achieved by the Member States alone, by reason of its scale and effects, and can therefore be better achieved at EU level. Therefore, the subsidiarity principle is respected.

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.

Revision of the registration requirements: Various options for revising the registration requirements for manufacturers and importers will be analysed, including increased information on hazards of concern, documentation of safe use, registration of certain polymers, and information on the environmental footprint.

Introduction of a Mixtures Assessment Factor (MAF): Options for addressing the risks of exposure to several

substances (combination effects) by introducing one of more MAFs in Annex I will be analysed.

Simplifying communication in the supply chains: Options for improving safety data sheets (information for downstream companies and workers on chemical risks and protective measures) will be assessed, including in particular harmonised electronic formats.

Revision of the provisions for dossier and substance evaluation: Various options will be considered for ensuring that registration dossiers are in compliance and that sufficient information for concluding on concerns is available. These include the possibility to revoke registration numbers for non-compliant registrations and to allow authorities to commission tests to obtain hazard information.

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.

Revision of provisions for control and enforcement: Options include establishing minimum requirements for national controls and enforcement, including stricter border controls; and establishing a European Audit Capacity to audit Member States enforcement.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

It is expected that some changes to the REACH Regulation will lead to increased costs for industry, including for SMEs, throughout the supply chains. This would be a result of the obligation to register certain polymers and the increased information requirements for the registration of substances, the introduction of new risk management measures and the changes to the companies' product portfolios following new restrictions or the phasing out of the use of Substances of Very High Concern subject to authorisation. The costs will most likely vary among operators depending on their position in the supply chain and their size. However, all operators will benefit of simplified, transparent and predictable provisions.

It is expected that changes will further incentivise innovation and substitution and that the European industry as a whole will rebound through the greening of the industry towards more safe and sustainable products and increased consumer confidence. In this respect, more information on the chemicals can be used for innovation purposes and the production of safe and sustainable chemicals and products for export, which might benefit the innovative industry investing in safe and sustainable solutions. Furthermore, imposing the same requirements for imported products as for domestic products would ensure a level playing field, thus alleviating the current disadvantage for EU industry.

The revisions and the reforms of the REACH Regulation are expected to impact the future mandate of the European Chemicals Agency and the income deriving from the fees payable to the Agency by duty holders.

Likely social impacts

The initiative will increase the protection of human health by reducing the exposure to hazardous chemicals, for citizens in general, and for workers and self-employed, including via the environment. Furthermore, better control and safer use of chemicals at workplaces will reduce the risk of occupational diseases and premature retirement of workers, as well as related health costs for society. In the short term, there may be job losses resulting from new legal requirements or increased costs for products using hazardous chemicals; however, in the long term this is expected to be compensated by growth in production of products using alternatives to the most hazardous chemicals.

Likely environmental impacts

An improved regulation of substances, including by generating more data, will support innovation initiatives towards substituting the most problematic substances. Moreover, more efficient restrictions of the most toxic, persistent, mobile and/or bioaccumulative substances in products for consumer use and professional use, except for uses essential for society, will further reduce the emissions of these substances, thus improving the environmental protection. Safer use of chemicals will result in reduced releases of hazardous substances to the environment, thus reducing the costs of environmental remediation that not acting would entail.

Likely impacts on fundamental rights
The initiative will improve the protection of consumers and the environment as enshrined in the Charter of Fundamental Rights of the European Union .
Likely impacts on simplification and/or administrative burden
Options for simplification of the REACH Regulation and reducing administrative burdens, especially for SMEs, will be analysed. For industry, it is anticipated that stricter registration requirements, in particular for substances at lower tonnages and for certain polymers, will increase the administrative burden and related compliance costs. This may to some extent be alleviated by increased use of alternative non-animal test methods. It is expected that improvement of tools for communication in the supply chains will reduce the administrative burdens. Simplifying the authorisations and restrictions processes will make these more transparent and predictable and, thus, reduce the administrative burden, although compliance with restrictions and authorisation conditions might lead to additional costs in the short term. For authorities, at EU as well as at Member State levels, the evaluation provisions may be clarified, thus reducing the administrative burden. Reduced administrative burden for authorities is also expected through streamlining and simplifying the restriction and authorisation processes.
D. Evidence Base, Data collection and Better Regulation Instruments
Impact assessment
An impact assessment will be carried out with the objective to identify and assess, both quantitatively and qualitatively, the economic, social and environmental impacts (positive and negative) of the various options. The impact assessment will be finalised and presented together with the Commission's proposal for revision of REACH by the end of 2022.
Evidence base and data collection
The Commission published its latest REACH Review in March 2018. The report was based on a number of studies carried out in the years preceding the reporting as well as stakeholder consultations, see: https://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm https://ec.europa.eu/environment/chemicals/reach/publications_en.htm https://ec.europa.eu/growth/sectors/chemicals/reach/review_en https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_article_138.pdf Since the latest REACH review, a number of studies have been completed (see links above) and further supporting studies will be carried out to expand the evidence base for the impact assessment. Additional evidence will be obtained from ECHA and through a stakeholder consultation as part of the impact assessment.
Consultation of citizens and stakeholders
The purpose of the present consultation is to obtain feedback on the proposed initiative from the main stakeholders, including competent authorities, businesses, NGOs, academia, individuals and other stakeholders and to gather evidence on the impacts that it would cause. For the proposed initiative: <ol style="list-style-type: none"> 1. The present Inception Impact Assessment is open for four weeks for public feedback 2. Targeted stakeholder consultations will take place as part of supporting studies and workshops 3. An open public consultation for 12 weeks is planned in all EU languages The launch of stakeholder consultation activities related to this initiative will be announced in the consultation planning that can be found at Have your say (europa.eu) . In addition, the Commission will set up a dedicated webpage (https://ec.europa.eu/environment/strategy/chemicals-strategy_en) to inform about the activities, studies and workshops related to the impact assessment.
Will an Implementation plan be established?
The initiative concerns revision of an existing Regulation, which applies directly in all Member States. No implementation plan will be established but, where necessary, existing guidance documents will be revised or new guidance documents will be developed by the European Chemicals Agency for Member States and other stakeholders.