European Commission

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 hazard classification, labelling and packaging of chemicals
LEAD DG (RESPONSIBLE UNIT)	ENV.B2, GROW.F2
LIKELY TYPE OF INITIATIVE	Legislative initiative
INDICATIVE PLANNING	Q2 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 prejudge 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 Commission's European Green Deal[1] sets a high ambition for zero pollution leading to a toxic-free environment. One of the first deliverables is the Chemicals Strategy for Sustainability: Towards a Toxic-free Environment[2] adopted on 14 October 2020. The objectives of the strategy are to achieve a legitimate higher level of protection of citizens and of the environment against hazardous chemicals. It is also an opportunity to encourage innovation for the development of safe and sustainable alternatives and to promote the EU industry as a global frontrunner in the chemicals production and use.

In order to achieve these objectives, the Strategy *inter alia* includes the revision of Regulation (EC) No 1272/2008 on hazard classification, labelling and packaging of chemicals (the CLP Regulation). The CLP Regulation is the core piece of Union legislation for the hazard assessment of chemicals, stemming from the United Nations' global standard (GHS)[3], and sets out the hazard classification of chemicals and how to communicate those hazards to consumers and workers. The CLP Regulation together with the REACH Regulation on Registration, Evaluation, Authorisation and Restriction of chemicals are the key EU legislation on chemicals. In order to deliver on the commitments in the Chemicals Strategy for Sustainability, the REACH Regulation will also be subject to a targeted revision, along a number of pieces of sectoral chemical legislation.

Problem the initiative aims to tackle

The CLP Regulation aims at ensuring both a well-functioning single market for chemicals and a high level of protection of human health and of the environment. However, in a number of aspects, the Regulation has not kept up with scientific or technological progress, or with (on-line) market developments. In other aspects, the Regulation is ambiguous and allows for diverging interpretations. This hampers the well-functioning of the single market and inadequately protects human health and the environment. Topics identified include the following:

Incomplete information about hazards to human health and the environment. The CLP Regulation is in some respects unclear or incomplete on hazard identification, classification or the roles of different actors, in a way that could lead to insufficient information on chemical hazards available. Examples include: the absence of criteria and labelling requirements for chemicals for some health and environmental hazard such as endocrine disruptors; the absence or lack of clarity of classification or labelling for some products outside the scope of the current CLP regulation; the absence of specific provisions on the clear roles and for

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52019DC0640

[2] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

[3] https://unece.org/about-ghs

responsibilities of the various actors in the case of online sales.

Hindrance of the free circulation of chemicals in the internal market and/or undue administrative burden. This relates to, for example: the legal impossibility for companies to use multilingual fold-out labels for normally sized packaging; the practical impossibility for companies placing on the market mixtures in small containers to adhere to the CLP labelling rules.

Insufficient public resources and/or risk of inefficient use of them due to the absence of a mandate to the Commission or ECHA to initiate classification dossiers and of a prioritisation mechanism on the need to classify certain chemicals.

Basis for EU intervention (legal basis and subsidiarity check)

The initiative concerns a targeted revision of an existing EU Regulation falling under an area of shared competence of the EU according to Article 114 of the Treaty on the Functioning of the European Union. Approximately 543 € billion worth of chemicals are produced annually and move freely within the EU thanks in part to the CLP Regulation. Member States and industry benefit from a harmonised procedure for classification and labelling at EU level. Action at EU-level is necessary to increase the protection of human health and the environment while ensuring the free movement of chemicals in the internal market and enhancing competitiveness. In addition, this initiative is deployed in the context of the Chemicals Strategy for Sustainability, and is, therefore, aimed at boosting innovation for safe and sustainable chemicals. Tackling the measures at EU-level is thus more efficient and effective. It will not significantly change the balance between EU and national measures.

B. Objectives and Policy options

The impact assessment will consider a range of non-regulatory and regulatory measures compared to a baseline scenario. This analysis will quantify the costs and benefits of the changes to the CLP regulation or to its current implementation. It will also consider impacts stemming from the current existing sectorial provisions directly affected by the new hazard classes, such as endocrine disruptors in Biocides and Plant Protection Products Regulation.
The Baseline Scenario will take account of the rules and processes in place end of 2020, and under the assumption that the CLP regulation will be implemented as it stands.

The non-regulatory measures, in addition to the current implementation of the CLP regulation, will be considered, amongst which additional guidance and support measures, such as clarifications, technical assistance, training and financing more proposals for harmonised classification.

The measures that will be examined through options with different ambition levels could include, for example:

- introduce new hazard classes (such as endocrine disruptors) and corresponding criteria.
- introduce an obligation to provide information of some hazards on the label for products currently outside the scope of CLP.
- clarify the obligations to classify mixtures and some complex substances.
- introduce specific rules for online sales.
- introduce the possibility to submit proposals for and set harmonised environmental and safety values for some substances.
- require importers and downstream users to submit information on substances classified for physical effects or health hazards to poison centres and clarify obligations for distributors to submit such information, through an only representative or other means.
- introduce a mandate for Commission to request ECHA to develop new harmonised classification and labelling ('CLH') dossiers.
- allow multilingual fold-out labels.
- introduce tailored labelling rules where there is not enough space on packaging.
- introduce a prioritisation mechanism for harmonising the classification of certain chemicals.
- simplify and reduce unnecessary administrative costs.

All opportunities provided by new digital tools will be explored (apart from digital labelling as already covered by another initiative[4]), and the chemicals industry following the Union regulatory framework should benefit from the technological progress.

The described objectives and policy options are preliminary and may evolve through the impact assessment.

[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Simplification-and-digitalisation-of-labels-on-chemicals-CLP-Detergents-Fertilising-Products-

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

The initiative is likely to improve the functioning of the single market for chemicals. The following other economic impacts on EU and non-EU companies placing on the market in the EU, in particular for SMEs, are also expected: the additional hazard identification, notification and the possible associated relabelling will increase costs compared to the baseline scenario. Divergence from the UN GHS global standards may affect hazard communication for exported EU- manufactured chemicals. However, if the new criteria will be accepted globally, EU companies will benefit from the earlier adoption.
Due to their limited resources, SMEs may need to outsource some actions and/or skills and hence experience greater impacts compared with larger companies.

Voluntary substitution of chemicals singled out as hazardous may also happen, hence leaving room to other (new) innovative and safer chemicals and increasing the need for investments and research. The European industry as a whole may rebound towards more safe and sustainable products and increased consumer confidence thanks to the technological progress.

The amendments to the CLP Regulation are expected to impact ECHA's income.

Likely social impacts

Adequately characterised and labelled chemicals will improve working conditions of workers or self-employed and consumer protection, when exposed to chemicals and reduce health costs for society. It will also raise consumer-awareness by improving the current labelling system.

Likely environmental impacts

Adequately characterised and labelled chemicals will help the protection of the environment, preservation of the quality of natural resources and protection of (fauna) biodiversity, thus reducing the need of environmental remediation.

Likely impacts on fundamental rights

The initiative is fully in line with Articles 31, 35 and 37 of the Charter of Fundamental Rights of the European Union[5], which respectively require that healthy and safe working conditions, a high level of human health and environmental protection and the improvement of the quality of the environment must be integrated.

Likely impacts on simplification and/or administrative burden

The foreseen changes aim at keeping the harmonised and well-functioning Single Market for chemicals while reducing administrative costs for Member States and some administrative burden for companies.

Regulatory burden for companies is likely to increase because of certain new requirements. However, the additional costs, such as relabelling ones, will be kept to the minimum thanks to the more flexible rules on labelling and an appropriate transitional period. Clearer definitions/rules and better harmonisation in a number of different aspects will also reduce the burden for companies and public administration.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will be carried out from May until December 2021.The objective is to identify and assess, both quantitatively and qualitatively, which effects (positive and negative) the various options are expected to have in terms of improved protection of human health and the environment, as well as the economic costs, the impact on the internal market and social impacts.

Evidence base and data collection

The Commission has already performed two fitness checks in the field based on a number of studies previously carried out, as well as comprehensive stakeholder consultations:

- Fitness check on the chemical regulations other than REACH, published in 2019[6].
- Fitness check on endocrine disruptors, published in 2020[7].

In addition, the Commission will carry out a supporting study to expand the evidence based for the impact assessment. Additional evidence will be obtained from ECHA and through a stakeholder consultation as part of the impact assessment, cf. below.

Consultation of citizens and stakeholders

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN ; https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1566802607995&uri=CELEX:52019SC0199R(01)

[7] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Executive_summary_FC_EDC.pdf

The following consultations are planned, in order to gather data on the problem definition, the possible solutions and their impacts. They will complement the information gathered under the development of the Chemicals Strategy for Sustainability[8]. The purpose of the consultation is to obtain feedback from the main stakeholders, including competent authorities, businesses, NGOs, academia, individuals and other stakeholders.

1. The present Inception impact assessment is open for four weeks for public feedback.
2. Targeted stakeholder consultations will take place as part of the supporting study.
3. Existing CLP-relevant fora will be used, such as the Commission's expert group Caracal, its subgroup on endocrine disruptors, and ECHA's enforcement forum, Helpnet network, and expert groups.
4. A 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 at Have your say as well as on the Commission webpage dedicated to the Chemicals Strategy for Sustainability.

Will an Implementation plan be established?

The initiative concerns revision of an existing Regulation, which applies directly in all Member States. An implementation plan will be established, based on the impact assessment performed. Where necessary, guidance documents will be revised or developed by ECHA for use by Member States and stakeholders.

[8] https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_synopsis.pdf