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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Delegations will find attached document SWD(2022) 436 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

{COM(2022) 748 final} - {SEC(2022) 452 final} - {SWD(2022) 434 final} -
{SWD(2022) 435 final}

A. Need for action

What is the problem and why is it a problem at EU level?

The problem addressed by the initiative is that the current version of the CLP Regulation insufficiently protects humans and the environment from intrinsic hazards of certain chemicals moving freely within the EU's single market. This problem manifests itself in three areas:

2. Hazardous chemicals are not comprehensively identified and classified. That is true in particular for chemicals that have endocrine disrupting ('ED'), persistent, bioaccumulative and toxic ('PBT'), very persistent and very bioaccumulative ('vPvB'), persistent, mobile and toxic ('PMT'), or very persistent and very mobile ('vPvM') properties, since there is currently no duty to systematically examine and classify such properties.
3. Member State Competent Authorities and the European Chemicals Agency ('ECHA') operate on the limit of their resources to prepare proposals (in the case of Member State Competent Authorities) and Opinions (in the case of ECHA) for harmonised classification and labelling of substances. As a consequence, they do not have the optimal tools to implement homogenous risk management measures for all hazardous chemicals. It also risks fragmenting the single market and un-levelling the playing field for companies operating on it.
4. The communication on chemical hazards is sub-optimal, which results in a lack of knowledge on hazardous properties of chemicals. This leads to a situation where consumers and businesses cannot base their purchase decisions on robust knowledge that enables them to minimise environmental and health risks, leading to potential exposure of consumers, workers and the environment to unnecessary risks. There is a high level of non-compliance with the CLP obligations in the context of e-commerce Information on hazardous mixtures submitted to poison centres for their emergency health response is insufficient in certain cases.

What should be achieved?

The three main objectives are:

1. To ensure that critically hazardous chemicals, including those with ED, PBT, vPvB, PMT and vPvM properties, are classified adequately and homogenously throughout the EU;
2. To make chemical hazard communication simpler for economic operators and more accessible and understandable for users of chemicals; and
3. To make sure that the rules on chemicals hazard classification and communication are applied equally by all relevant actors in the supply chain.

What is the value added of action at the EU level (subsidiarity)?

Action at EU level is crucial to preserve free movement of chemicals on the single market.

Different actions at national level would impose additional administrative burdens on large operators and SMEs, obstructing free movement. Furthermore, chemical pollution is transboundary in nature and societal costs negatively impact the EU wellbeing and economy. Inaction in one Member State leads to costs in others.

B. Solutions

What are the various options to achieve the objectives? Is there a preferred option?

Based on evaluations of existing legislation and stakeholder input, a comprehensive list of potential measures was created. Following initial screening, 22 measures were retained for in-depth assessment. In the end, 17 preferred measures were bundled into 3 independent policy options, corresponding to each of the 3 identified problem areas:

1. Adequate classification of critically hazardous chemicals will be ensured by:

- introducing ED, PBT, vPvB, PMT and vPvM as new hazard classes in the CLP Regulation and prioritising them for harmonised classification;
- publishing the reasons for diverging notified self-classifications in ECHA's classification and labelling inventory, along with the names of the notifiers;
- requiring updates of notifications of self-classifications within a certain deadline;
- reinforcing prioritisation for harmonised classification at an early stage; and
- allowing the Commission to initiate and fund more harmonised classification and labelling dossiers, including by mandate to ECHA.

2. Improvement of hazard communication will be ensured by:

- explicitly addressing the concept of refill sales with some derogations from labelling obligations and limiting this practice to mild hazards only;
- increasing readability of CLP labels by regulating label formatting;
- allowing some supplemental information that is not obligatory under UN GHS to go digital where their physical availability on the label is not instrumental for the protection of human health and the environment and creating a framework for further digital labelling of this information;
- allowing broader use of fold-out labels for chemicals traded in several EU countries; and
- providing derogation to labelling requirements for chemicals sold to consumers in bulk (e.g., fuel) and very small packaging (e.g., writing instruments).

3. Addressing main legal gaps and ambiguities will be insured by:

- clarifying rules for online offerings and advertising;
- reinforcing the obligation on a responsible economic actor for online sales to comply with the requirements of CLP; and
- introducing targeted obligations for notification to poison centres in case of information loss, e.g., when chemicals move between Member States or are re-labelled.

The above options were preferred over the following discarded ones:

Firstly, regarding hazard classification, the policy option to introduce harmonised human and environmental reference values for toxicity. While such values are useful, CLP cannot provide for their use in other chemical legislation, which would result in additional costs, little added value. Moreover, there was little support for such measure during public consultation. By contrast, the preferred options complement each other, tackle different drivers of the problem at hand and counterbalance the additional costs by additional added value.

Secondly, the policy option calling for an update piece of guidance to clarify the CLP obligations concerning chemicals sold in very small packaging, in bulk and via refill containers does not sufficiently address the problem. As the legal text itself lacks clarity, guidance does not have same legal value as a clarified legal text.

Thirdly, the policy option to run periodic awareness campaigns on the display of labelling elements online. This option is less effective, as consumers might not remember the content of awareness campaigns when buying online, than setting rules on online offerings and reinforcing rules on online advertisings and reinforcing the need of a responsible economic actor in the supply chain. As for the poison centre-notifications, the mutually exclusive measures of full notifications to poison centres by all actors in the supply chain and notifications to poison centres by re-branders and re-labellers were discarded in favour of targeted notification obligations. The latter has the best cost to operators - social benefit ratio, since it prevents multiple cases of information loss without obliging all distributors to notify by default.

What are different stakeholders' views? Who supports which option?

The introduction in the CLP Regulation of new hazard classes is generally strongly supported. The EU industry indicated a strong preference, however, for the EU to propose the new hazard classes first at UN level before introducing them in EU legislation. Stakeholders also generally welcome the strengthening of the system for harmonised classification, albeit warning of the resource implications.

Stakeholders generally welcome the new possibilities offered by increased use of foldout labels and the regulation of refill sales, replying that it would ease the burden for SMEs. Certain concerns are expressed about the digital divide, but it is generally accepted that a limited set of information could be provided by digital means only. Strengthening the rules for online sales received strong and unanimous support from all categories of stakeholders. The extension to certain economic operators of the obligation to notify poison centres of chemicals is also generally welcomed.

C. Impacts of the preferred option

What are the benefits of the preferred option?
The benefits of the preferred option stem mainly from improvement of the protection of health and the environment. Savings to public health systems and depollution schemes could amount to more than EUR 300 million per year. Adequate and homogenous hazard classification allows chemicals suppliers, users and public authorities to take adequate measures to manage chemicals risks while preserving the integrity of the single market and levelling the playing field between economic operators. Improved communication on chemical hazards will allow consumers to make informed choices and avoid unnecessary risks to health or the environment. Finally, simplified labelling rules will save costs for businesses. Closing legal gaps related to online sales and poison centres will ensure better compliance ultimately leading to better implementation and easier enforcement.
What are the costs of the preferred option?
The initiative will entail significant costs for industry actors placing chemicals on the EU market, both administrative annual costs for compliance with the new rules (EUR 28.47 million) and adjustment costs for voluntary substitution down the supply chain for substances which will be covered by the new hazard classes (EUR 26.40 million).
What are the impacts on SMEs and competitiveness?
Costs for SMEs will be higher in relative terms, as they benefit less from economies of scale and have less capacity to absorb fixed costs. New responsibilities for economic actors involved in distance sales, including online sales, from out- or inside the EU will ensure fair and equal competition among all businesses selling chemicals, especially for SMEs who sell mainly within the EU and rely on online platforms to trade their products. The introduction of new hazard classes, while increasing costs on the short term, will translate into the EU industry being the global front-runner in health and environmental standards, driving the EU industry's leadership in producing and using sustainable chemicals, and thereby allowing it to increase its competitiveness and global market share. The measures to ensure homogeneity of classification of identical substances manufactured by different companies will level the playing field and contribute to fair competition, in particular for SMEs. SMEs will be able to rely more on existing self-classifications in the classification and labelling inventory instead of classifying themselves, which is costlier for SMEs than it is for large enterprises.
Will there be significant impacts on national budgets and administrations?
No.

Will there be other significant impacts?
No.
Proportionality?
The initiative does not go beyond what is necessary to achieve its objectives.
D. Follow up
When will the policy be reviewed?
The impacts of the initiative will be documented by the indicator framework for the effectiveness of chemicals legislation announced for 2024 by the Chemicals Strategy for Sustainability. The revised CLP Regulation may be (partially) reviewed once evidence will be available under this framework.