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COMMISSION STAFF WORKING DOCUMENT

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) 435 final} - {SWD(2022) 436 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
This proposal has the aim of further ensuring the functioning of the internal market, taking as a base a high level of health, environmental and consumer protection. Hence, its legal basis is Article 114 of the Treaty on the Functioning of the European Union ('TFEU').
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of internal market, the Union competence is shared according to Article 4(2) TFEU.
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[1]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[2] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[3] sets out the areas for which the Unions has competence only to support the actions of the Member States.*
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[4]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
The proposal fulfils the procedure requirements of Protocol No. 2 given that there were wide consultations of all types of stakeholders at Union, national and regional level as well as public authorities, before proposing the act. Initial feedback was provided on the **inception impact assessment** published on the Commission's 'Have Your Say' website.[5] The feedback period ran from 4 May 2021 until 1 June 2021, and got 182 comments. As part of the impact assessment, an **open public consultation** (OPC) on the revision of the CLP Regulation ran for 14 weeks from 9 August 2021 to 15 November 2021.[6] The questionnaire was split

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN
[5] European Commission, Revision of EU legislation on hazard classification, labelling and packaging of chemicals, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals/feedback_en?p_id=24338728.

into two sections, one containing 11 questions for the general public, and one containing 37 questions for experts in the subject matter. Both sections allowed respondents to provide position papers.

The consultation was followed by a **targeted stakeholder survey** (TSS). The survey was open for 6 weeks (from 10 November to 22 December 2021). A stakeholder mapping exercise identified 548 stakeholders, to whom the survey was sent.

Furthermore, extensive discussions on specific issues of the revision of the CLP Regulation were held in 3 *ad hoc* meetings of the relevant expert group, the Competent Authorities for REACH and CLP (CARACAL), with wide Member State and stakeholder participation:

- CARACAL meeting on Poison Centres and Online Sales (27 October 2021),
- CARACAL meeting on Harmonised Classification and Labelling Prioritisation, Predicted No-Effect Concentration (PNEC), Derived No-Effect Level (DNEL), Derived Minimal Effect Level (DMEL) and Labelling (6 December 2021),
- CARACAL meeting on New Hazard Classes, More than One Constituent Substances (MOCS) and Self-Classification (14 December 2021).

Relevant discussions on specific topics covered by this proposal were also held previously in other CARACAL meetings.

In addition, **22 interviews** were conducted between December 2021 and February 2022 with public authorities, EU agencies, companies and business associations, non-governmental and other organisations. Their purpose was to complement the findings of the open public consultation, the targeted stakeholder consultation and the views provided by CARACAL members and observers.

Another open **public consultation on simplification and digitalisation of labels** on chemicals was open for 12 weeks, from 24 November 2021 to 17 February 2022.[7] The launch of that consultation was complemented by a **stakeholder workshop** on simplification and digitalisation of labelling requirements for chemicals, held on 26 November 2021. Additionally, two **online surveys**, on policy options for digitalisation and for information from professionals and industry users, were conducted.

The explanatory memorandum of the Commission proposal and the impact assessment accompanying the Commission proposal contain a section on the principle of subsidiarity. These sections that concern the principle of subsidiarity are also reproduced in the answer to question 2.2.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

Yes, those documents contain such a justification.

[6] European Commission, Revision of EU legislation on hazard classification, labelling and packaging of chemicals, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals/public-consultation_en.

[7] European Commission, simplification and digitalisation of labelling requirements, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Chemicals-simplification-and-digitalisation-of-labelling-requirements/public-consultation_en.

The explanatory memorandum mentions that "In the same way as when the CLP Regulation was adopted, the objectives of this proposed Regulation cannot be sufficiently achieved at Member States' level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level. To solve the same problems, one action at Union level will be less costly and more efficient than twenty-seven different actions.
Action at EU level is crucial to preserve free movement of chemicals in the EU's internal market. Individual actions at national level would impose significant administrative burdens on companies seeking access to the market of more than one EU Member State. Furthermore, chemical pollution and its negative impacts are transboundary by nature. Therefore, citizens in one Member State would be affected by the potential inaction in another Member State.".

More extensively but similarly chapter 3 of the impact assessment describes the necessity and added value of Union action.

It is necessary to act at Union level for the following reasons:

- Most problems (e.g., diseases and pollution through hazardous substances, insufficient compliance) result in costs for society and the general public (negative externalities) and their intensity may vary across the European regions, but they exist everywhere in the EU to a certain extent; to adopt a coherent approach tackling such problems, EU action is necessary;
- Most problems are transboundary in nature, or even have an international dimension and touch upon customs related matters, which cannot be sufficiently addressed by single Member States in isolation. To further improve the free movement of substances and mixtures and enable an even better functioning internal market, Member States cannot act alone, they need an overarching framework regulating such movement;
- Apart from different enforcement levels in the Member States, the problem drivers are the same, so that EU action addresses the problem drivers best;
- Certain Member States have already initiated national actions to address the issue of missing hazard classes before waiting for any EU action on the matter; this could lead to the undesirable effect of heavily fragmenting the internal market. Also, Member States' behaviour would not seem to be fully in line with the Treaty rules providing for the general principle that Member States shall not exercise their competence if the Union did already (I.e. to the extent that the Union has used its 'right of pre-emption'[8]). EU action would therefore make the overall system more coherent.

Regarding the added value of EU action, one action at Union level will be less costly and more efficient than twenty-seven different actions to solve the same problems (economies of scale exist), and therefore EU action brings added value. CLP replaced different national policies harmonising the rules at EU level, which has proven to be a success. EU action would aim at addressing the shortcomings of an already existing framework which will help achieving the objectives of CLP.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Most problems identified in the impact assessment are indeed transboundary in nature (e.g.

[8] Article 2(2) TFEU.

diseases and pollution through hazardous chemicals, sub-optimal hazard communication, sub-optimal notifications to poison centres, online sales from non-EU actors). Those problems and their impacts were quantified and, if impossible, a qualitative analysis was carried out.
(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[9] or significantly damage the interests of other Member States?
Yes, this would be the case, as a continued divergence of measures taken by Member States would disrupt the functioning of the internal market and would lead to different levels of protection of health and environment, even more considering that the CLP Regulation framework exists already.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
The Treaty establishes the obligation that Member States shall exercise their competence to the extent that the Union has not exercised its competence (Article 2(2) TFEU); by adopting the CLP Regulation in 2008 the Union has exercised its competence in the field. In this framework, the proposal does not make it possible for Member States to deviate from its provisions. On the other hand, the proposal gives some additional possibilities to Member States, including the possibility to submit dossiers for harmonised toxicity values and the option to nominate the European Chemicals Agency as appointed body responsible for receiving the information required to provide adequate emergency health response.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
Although the problem and its causes may (slightly) vary between the Member States, they exist everywhere in the EU to a certain extent.
(e) Is the problem widespread across the EU or limited to a few Member States?
There are different problems to be tackled (problems related to hazard identification, hazard communication and compliance), but they are spread overall the EU and certainly not limited to a few specific Member States.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
Yes, Member States are overstretched, since, in the absence of this initiative, the national actions that have been and would further be initiated by Member States to address some of the identified problems would not be able to achieve the objectives and would require a lot more resources, which are unavailable, than the resources needed in the framework of harmonised action.

[9] https://europa.eu/european-union/about-eu/eu-in-brief_en

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

There exist huge differences in available financial resources of public authorities how to tackle certain identified problems, but public authorities are of the uniform view that further action is needed and an agreement exists to a large extent about the direction of the proposed measures. Ultimately better hazard identification and communication will lead to better risk management of chemicals; hence this targeted revision is the right step in this direction.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

Yes, the objectives can be better achieved at Union level given that there is clear added value from EU level action, economies of scale exist and they are more effective, the internal market will be strengthened by further harmonising regulatory requirements and by further clarifying legal provisions without taking away any competences from Member States other than the ones already transferred to the Union.

(a) Are there clear benefits from EU level action?

Yes, there is added value from EU level action. Action at EU level is crucial in order to preserve free movement of chemicals in the single market. Different actions at national level would impose additional administrative burdens on large and SME operators. In addition, chemical pollution and societal costs are transboundary in nature, and diverging actions would lead to health and environmental impacts that could have been avoided.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

Yes, economies of scale exist and objectives are more efficiently met at EU level. This is the case, for example, for multilingual fold-out labels or for the potential nomination by Member States of ECHA as the appropriate body for emergency health response information. The functioning of the internal market will be improved, as a result of the clarification of various legal provisions, of the digital labelling possibilities, of improving submissions to poison centres, and of the increased level of compliance.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The area is already harmonised. This revision builds on this prior harmonisation.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

Since the area is already harmonised, Member States will neither gain nor lose any competence. The benefits of EU level action by means of the adoption of the CLP Regulation,

have already outweighed the loss of competence of the Member States in this area.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes, improving legal clarity is an aim of this targeted revision. This is especially addressed in relation to the provisions on online sales, notifications to poison centres, labelling of containers of refill chemicals, but also other provisions.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The explanatory memorandum mentions that the initiative does not go beyond what is necessary to achieve the objectives sought.

The supporting impact assessment[10] assesses the impacts of the proposed revision of the CLP Regulation. Both qualitative and quantitative assessment have been undertaken that show that the proposal is proportionate, i.e. that environmental and societal benefits are significantly higher than the costs incurred.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

This proposal is an appropriate way to achieve the intended objectives given that they can be better achieved at Union rather than at national level, while divergent national action would also risk impeding the functioning of the internal market and the effective protection of the environment and health. Moreover, the proposal does not go beyond what is necessary to achieve the set objectives, the chosen legal instrument revises and complements the already applicable one (a Regulation) and is therefore the most effective and simplest way forward, a common action entails significant cost savings, and specific circumstances in certain Member States were duly taken into account.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Yes, the initiative is limited to those aspects that the Member States cannot achieve as effectively on their own and where divergent national measures would risk distorting the functioning of the internal market and preventing the effective protection of the environment and human health. Therefore, the intended objectives can be better achieved at Union level.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives

[10] Impact Assessment Report; Executive Summary of the Impact Assessment Report

pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?
The targeted revision builds on the already applicable legal instrument, i.e. a Regulation, and proposes to amend that Regulation. This way forward is the most simple and effective way of achieving the said policy objectives.
(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)
The proposed Union action does not go beyond what is necessary to achieve the objectives. The legal instrument of a regulation ensures direct applicability, uniform application and uniform enforcement throughout the EU, which would not be possible in case of adoption of minimum standards by means of a directive. A less stringent policy instrument (e.g. also if it was decided to address the identified problems via guidance instead of by directly amending the legislation) would not be sufficient to achieve the said objectives.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative creates financial or administrative costs as well as costs for economic operators and citizens which can be better borne at EU level for 27 Member States than by each Member State alone (see also previous replies referring to savings due to economies of scale). However, those costs are commensurate with the objectives set and the benefits outweigh the costs (especially for society and the environment). The costs must also be compared to the costs of a decline in the level of protection of health and environment due to inaction.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
As already mentioned, the Commission consulted stakeholders and authorities widely and any issues raised that concern individual Member States or certain regions were duly taken into account. More specifically, some concerns expressed with regard to potential decreased demand for chemical products produced in specific regions, due to their potential harmonised classification in line with the new hazard classes, were not considered sufficient to challenge the proportionality of the latter measure and its necessity to address the objectives set by this initiative.