EUROPEAN COMMISSION

Brussels, 13.5.2022
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REGULATORY SCRUTINY BOARD OPINION

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}
{SWD(2022) 434 final} {SWD(2022) 435 final} {SWD(2022) 436 final}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / Revision of EU legislation on hazard classification, labelling and packaging of chemicals

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The regulation on classification, labelling and packaging of substances and mixtures (the CLP Regulation) lays down obligations to classify chemicals according to their hazards and provides for rules on the labelling and packaging of these chemicals. The classification and labelling information needs to be notified in the CLP classification and labelling inventory (CLI) which is a public database. In addition, certain information needs to be notified to poison centres to ensure they are able to provide an adequate emergency health response.

The CLP Regulation is one of the cornerstones of European chemical legislation, together with the Regulation on registration, evaluation, authorisation and restriction of chemicals (REACH). CLP hazard classification is also used in sectorial product legislation such as for cosmetics and detergents, and biocides and plant protection products. Duty-holders have to self-classify their products and in particular cases a harmonised classification involving action from Member States and the European Chemicals Agency (ECHA) is needed.

The revision stems from the Chemicals Strategy for Sustainability, the fitness check of the most relevant chemicals legislation (excluding REACH) and the fitness check on endocrine disruptors.

This opinion concerns a draft impact assessment which may differ from the final version.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting and commitments to make changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the lead DG to rectify the following aspects:

(1) The presentation of the costs and benefits is neither sufficiently clear, nor coherent. The methodology of estimating costs and benefits and their corresponding calculations are not transparent.

(2) The report does not sufficiently justify the proportionality of the preferred option. The qualitative analysis of non-quantified benefits is not sufficiently developed.

(C) What to improve

(1) The analysis of the costs and benefits should be presented in a clear and transparent manner. The totals, bringing together all quantified costs and benefits, should be set out in the report in present values and annualised. The figures in the annexes and the main report should be clearly referenced and coherent with each other. The report should be clearer on the methodology of the cost benefit analysis including explaining why the 20-year appraisal period was chosen.

(2) The report should transparently present the distributional impacts across all affected groups. In particular, this should cover the overall impact on businesses including a separate analysis of the impacts on SMEs. The report should clarify the expected impact of labelling on consumer behaviour. It should also provide more detail on the impact on the competitiveness of EU businesses. A dedicated section of the administrative costs and savings in scope of the 'one in, one out' approach should be further clarified. It should differentiate between one-off and recurrent costs and cost savings and the figures should be recalculated to eliminate the mistakes.

(3) The report should explain why it is not possible to quantify the expected significant health and environment benefits. Even if causality cannot be demonstrated, the report should provide qualitative evidence that the exposure of users and of the environment to the identified hazardous substances will decrease as a result of this initiative. The report should provide a robust qualitative analysis of the expected benefits, including an indication of the order of magnitude of these benefits, to justify the conclusion that the benefits outweigh the costs for this initiative.

(4) The report should make greater use of the cost-benefit analysis, both quantitative and qualitative, and strengthen the justification of the preferred option.

(5) The report should clearly describe the links and overlaps of the CLP Regulation with other chemical legislation, notably REACH, articulate its purpose and pinpoint the remaining regulatory gaps compared to related measures, such as the General Product Safety Regulation, the Market Surveillance Regulation and the Digital Services Act.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion **The lead DG must revise the report in accordance with the Board's findings before launching the interservice consultation.** **If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.**	
Full title	Revision of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45 EC, and amending Regulation (EC) No 1907/2006 (CLP Regulation)
Reference number	PLAN/2021/10629
Submitted to RSB on	13 April 2022
Date of RSB meeting	11 May 2022

SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Labelling Reduction Costs	€0.91 million	Annual savings for businesses (fuels and very chemicals in small packaging).
Labelling Reduction Costs	€48.50 million	Annual savings for businesses (fold-out labels).
Reduced ED sickness and negative impacts on the envrionment		Part of €46,000 million (ED costs for reproductive fertility treatment) would be saved. Part of €1,185 million[1] (cost for the management of waste generated by micropollutant treatments of urban wastewaters) would be saved.
Indirect benefits		
Easier navigation in the Classification and Labelling Inventory	€8.94 million	Annual savings for businesses (cost saving of navigating the CLI).
Reduced compliance checks by market surveillance authorities	€1.45 million	Reduced enforcement costs.
Administrative cost savings related to the 'one in, one out' approach*		
Total (direct/indirect)	€58.64 million	

*(1) Estimates are gross values relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in adjustment costs, administrative costs, regulatory charges, enforcement costs, etc.;); (4) Cost savings related to the 'one in, one out' approach are detailed in Tool #58 and #59 of the 'better regulation' toolbox. * if relevant*

[1] Commission, 2022, Staff Working Document on the Revision of the Urban Waste Water Directive. The savings would only come from less contaminated waste or less waste generated as the specific treatment to remove mobile micropollutants would anyhow be needed.

II. Overview of costs (in €) – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Classification of chemical hazards PO1a, PO1b (with measure #5) and PO1c (with measure #8)	Direct adjustment costs	-	-	-	-		
	Indirect adjustment costs	-	-	26.40 million			
	Direct administrative costs	-	-	12.89 million	3.85 million	1.81 million	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	4.45 million	1.29 million		
Hazard labelling	Direct adjustment costs	-	-	-	-	-	-
	Direct administrative costs	-	-	0.06 million	1.63 million	-	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	8.61 million	-	0.03 million	-	0.1 million
Poison centres Online Sale	Direct adjustment costs	-	-	-	-	-	-
	Direct administrative costs	-	-	2.16 million	31.53 million	-	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-

	Indirect costs	-	-	-	-	-	-
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	-	-	-	-		
	Indirect adjustment costs	-	-	26.40 million	-		
	Administrative costs (for offsetting)	-	-	19.57 million	38.33 million		

(1) Estimates (gross values) to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (adjustment costs, administrative costs, regulatory charges, enforcement costs, indirect costs;). (4) Administrative costs for offsetting as explained in Tool #58 and #59 of the 'better regulation' toolbox. The total adjustment costs should equal the sum of the adjustment costs presented in the upper part of the table (whenever they are quantifiable and/or can be monetised). Measures taken with a view to compensate adjustment costs to the greatest extent possible are presented in the section of the impact assessment report presenting the preferred option.