BRIEFING

Initial Appraisal of a European Commission Impact Assessment



Classification, labelling and packaging of substances and mixtures

Impact assessment (SWD(2022) 435 and SWD(2022) 436 (summary)) and SWD(2022)434 (subsidiarity grid) accompanying a Commission 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.

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's impact assessment (IA) accompanying the above-mentioned proposal, submitted on 19 December 2022 and referred to the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI). The proposal would revise the existing Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) to ensure that all hazardous chemicals are classified adequately and uniformly in the EU. It also seeks to make labels more accessible and comprehensible for users of chemicals, and to ensure that the CLP rules are applied by all relevant players in the supply chain. By modernising and simplifying the CLP, the initiative aims to reduce unnecessary burdens for businesses (especially for SMEs). This initiative, included in the Commission 2022 work programme, is set in the context of the European Green Deal, the chemicals strategy for sustainability and the EU's zero pollution action plan for 2050.1

Problem definition

The EU has two core pieces of legislation that regulate chemicals. The REACH Regulation (Regulation (EC) No 1907/2006) concerns the registration, evaluation, authorisation and restriction of chemicals, and the CLP Regulation is about the classification, labelling and packaging of substances and mixtures. The CLP - which follows the United Nations' Globally Harmonised System (GHS) of classification and labelling of chemicals - aims to protect health and the environment from hazardous chemicals and to enhance the free movement of chemicals in the EU internal market. The CLP obliges manufacturers, importers and downstream users to classify hazardous substances and mixtures. The classification can be harmonised – that is, set by the EU and applied across its territory– or, in the absence of harmonised classification, the duty holders do the classification themselves (self-classification). The focus of the CLP is to identify and classify the intrinsic hazards of chemicals, and to communicate their hazardous effects on human health or the environment to users of chemicals and decision makers. Following the 'evaluation first' principle, the CLP was evaluated in 2019 (<u>fitness check on the EU chemicals legislation</u>). In addition, a more targeted <u>fitness check</u> (report 2020) was conducted on endocrine disruptors (EDs). The evaluation found that the EU chemicals legislation meets its objectives and has managed to reduce the risks to humans and the environment posed by certain hazardous chemicals. However, it also identified weaknesses in the CLP, which hinder the CLP from delivering its full potential, and consumers, businesses and authorities from making well-informed decisions based on relevant knowledge about the properties of chemicals. The evaluation pointed out areas that could be improved further, such as implementation and enforcement, harmonised classification and hazard labelling requirements (IA, pp. 6, 147-149).

The IA defines three problems (pp. 7-15):



EPRS | European Parliamentary Research Service

P1) Hazardous chemicals are not comprehensively identified and classified

According to the fitness check on chemicals, the EU regulatory framework does not allow a complete and consistent identification and classification of chemical hazards. The IA specifically points out the most critical hazards, which have properties of being: endocrine disrupting (ED); persistent, bio-accumulative and toxic (PBT); very persistent, very bio-accumulative (vPvB); persistent, mobile and toxic (PMT) and very persistent, very mobile (vPvM). The IA notes that the CLP does not require manufacturers to identify any of these properties, while some of them are identified through other legislation (e.g. REACH). The IA stresses that workers and consumers are widely exposed to chemicals, and according to a study, exposure to EDs entails annual health-related costs amounting to €46-288 billion per year. The IA also refers to environmental impacts and states that 3.5 million sites in Europe have been contaminated with hazardous and persistent substances. The IA draws attention to the excessive costs and the administrative burden that the classification process entails, and to a high number of incorrect or obsolete classifications of substances, which results in the provision of incomplete information to users and in inadequate protection of consumers, workers and environment.

P2) Sub-optimal communication on chemical hazards

The IA considers that certain issues, such as limited readability or the use of technical language, hinder users' understanding of the labelling of chemicals. According to a 2016 <u>Eurobarometer survey</u>, around 55% of EU citizens feel that they are not well informed of possible risks related to the chemicals in consumer products. Moreover, complex labels create high compliance costs for companies, SMEs in particular. The fitness check estimated that the average cost of modifying labels to comply with the current CLP is €388 per substance and €475 per mixture. The IA also mentions that some products are exempted in the CLP, and that consequently the hazards posed by the chemicals in those products are communicated to users in a sub-optimal way, which may lead to harmful effects on health and the environment due to the inappropriate use of such chemicals.

P3) High level of non-compliance (online sales and poison centres)

The IA mentions that several products that are manufactured outside the EU and sold online, do not fulfil the EU product safety and chemical legislation requirements. Online advertisements often do not comply with the CLP requirements (the rate of non-compliance was 75 % for 2 752 inspected products in 29 EEA countries in 2017). The IA also finds that businesses do not always submit notifications to poison centres for emergency health response, especially in the context of intra-EU cross-border trade and in the case of re-branding/relabelling.

The IA identifies the corresponding **problem drivers** (pp. 15-17) as follows: D1) Missing provisions for the identification of critical hazards (P1); D2) Inefficient procedures for hazard characterisation and classification (P1); D3) Complexity of some labelling provisions (P2); D4) Current labelling rules do not sufficiently exploit new digital tools (P2); D5) Rules are inadequate to keep pace with new sales channels (P3); D6) Unclear provisions on notifications to poison centres (P3).

The IA explains that without EU action the problems would persist. The trend of an increasing number of chemicals requiring harmonised classification would continue, and the IA points out that future measures under the European Green Deal and the chemicals strategy for sustainability relating to hazardous chemicals would be based on harmonised classification. Regarding labelling issues, the IA also refers to digitalisation trends and the need for the CLP to take into account technological solutions to address consumers' needs to have information on products. The IA expects that even though other pieces of EU legislation (e.g. the <u>Digital Services Act</u>, the <u>General Product Safety Regulation</u>) would have a positive impact on the safety of online sales of chemicals, it would not entirely address all the legal gaps in the CLP due to the expected increase of online sales and imported products (pp. 17-19). Overall, the IA presents a well-evidenced problem definition, including the description of the scale of the problems, and convincingly explains the need for the revision of the CLP.

Subsidiarity / proportionality

The legal basis is Article 114 of the Treaty on the Functioning of the European Union (TFEU). The IA sufficiently explains the necessity of EU action and its added value. It considers that EU level action would address the problems more effectively and efficiently in the already existing EU framework, given also that most of the problems are transboundary and that national measures would create fragmentation in the market. The IA provides a <u>subsidiarity grid</u>, which typically accompanies significant or politically sensitive proposals as per the <u>Better Regulation Guidelines</u> (BRG). The proportionality aspect is embedded in the initiative, as it also seeks to reduce unnecessary burden for companies (in particular for SMEs); however it is not specifically discussed in the comparison of options. Under the <u>subsidiarity check</u>, none of the national parliaments submitted a reasoned opinion by the deadline of 31 March 2023.

Objectives of the initiative

According to the IA, the general objective is to 'ensure a well-functioning single market for chemicals and a high level of protection of human health and of the environment from hazardous chemicals'. In addition, the initiative seeks to modernise and simplify the classification and labelling of hazardous chemicals, and to eliminate unnecessary burdens (in particular for SMEs) without undermining the objectives and benefits of the legislation (p. 20). The IA defines three specific objectives (SO), linked to the time period of 20 years (2023-2042) during which impacts would be considered: SO1) Ensure that chemicals are classified adequately and in line with the severity of their hazards; SO2) Ensure comprehensive and comprehensible communication on chemical hazards; and SO3) Address the main legal gaps and ambiguities of CLP rules. The objective of avoiding unnecessary burdens does not appear in the formulation of the specific objectives; the IA could have clarified which SOs would address it. According to the SMART criteria of the BRG, the objectives should be specific, measurable, achievable, relevant and time-bound. Contrary to the BRG, the IA does not provide operational objectives that set out the deliverables of the preferred option, which may weaken the measurability of success of the initiative. However, the IA indicates how the achievement of these objectives would be measured. Therefore, the objectives appear to meet the SMART criteria.

Range of options considered

The IA presents three policy option packages, linked to the respective three problems and the problem drivers, against the baseline. Under these packages, it is the sub-options that are the de facto policy options, although there are in fact only a few alternative choices. All the sub-options under the Option 1 package are complementary, although within sub-options 1b and 1c, there are alternative measures. All the sub-options under the Option 2 package are complementary. Under the Option 3 package, sub-options 3a and 3b are mutually exclusive, and sub-option 3c includes alternative measures. Overall, the IA does not present self-standing policy options addressing all the problem drivers. The preferred options are shown in grey.

Baseline: No policy change.

Problem 1: Classification of chemical hazards ('Policy Option 1' package)

<u>Sub-option 1a (New hazard classes)</u> would introduce new hazard classes in the CLP for substances with the most critical hazards (EDs, PBT/vPvBs, PMT/vPvMs).

<u>Sub-option 1b (Consistent self-classification and improving transparency)</u> aims to improve companies' self-classification of substances and to introduce stronger incentives and provisions for companies to appropriately classify. This sub-options offers alternatives to ensure timely updates of notifications (swift updates or automatic updates).

<u>Sub-option 1c (More and prioritised harmonised classifications)</u> would improve the efficiency and effectiveness of harmonised classification processes, including for the most critical hazards. It

provides alternatives to prioritise future harmonised classifications (early prioritisation of harmonised classification or EU agreement on prioritised harmonised classification).

<u>Sub-option 1d (Complementing hazard identification with hazard characterisation)</u> suggests that the CLP would allow for the harmonisation of reference values as part of the 'one substance, one assessment' process, to make it possible to quantify the toxicity of hazardous substances.

Problem 2: Communication of chemical hazards ('Policy Option 2' package)

<u>Sub-option 2a (Update/prepare guidance</u>) would support companies in addressing the complexity of labelling provisions through clarifying guidance (e.g. refill chemicals, small packaging, digital labelling).

Sub-option 2b (Improving and making more flexible existing labels) would simplify and complement current labelling requirements through provisions that would improve the readability of the labels and clarify the scope of the labelling requirements.

<u>Sub-option 2c (Digital labelling)</u> would exploit the potential of digital labelling, while keeping flexibility. According to this sub-option, some supplementary information could be in digital form only, whenever its physical availability would not be necessary for the protection of health and the environment. However, information that is required under the GHS would remain on the physical label.

Problem 3: Closing legal gaps and ambiguities of CLP provisions ('Policy Option 3' package)

<u>Sub-option 3a (Awareness campaigns)</u> would increase the awareness of consumers on the risks of buying online chemicals that lack information related to the hazards they pose.

<u>Sub-option 3b (Provisions and clear responsibilities for online sales and imports)</u> would ensure that the CLP rules clearly apply to online sales and import of chemicals. This option would provide legal clarity by addressing the shortcomings of the CLP provisions on online sales.

<u>Sub-option 3c (Clarifying provisions for notifications to poison centres)</u> would ensure legal clarity by addressing the shortcomings of the CLP provisions on notifications to poison centres. The sub-option offers different notification alternatives (a) full notifications; b) targeted notifications; or c) notifications by re-branders and re-labellers). This option would ensure that poison centres receive updated information and that an appropriate health response can be provided for people exposed to hazardous chemicals.

The IA provides information on the **discarded measures** in Annex 7 (pp. 150-186). Examples include: a) awaiting new hazard classes at the international level (UN GHS) before introducing them in the CLP (favoured by the industry); and b) digital labelling as a full alternative to physical labelling, or mandatory digital labelling. The first one was discarded because the UN level process is lengthy, among others, and the second one because the expected costs for businesses (especially for SMEs) would be high and because vulnerable people may lack digital access.

Assessment of impacts

The IA analyses qualitatively and partially quantitatively the main **economic, environmental and social impacts** of the policy options (IA, pp. 35-44; Annexes 7-16, pp. 150-625). Under the **economic assessment**, the IA considers costs for businesses and public authorities for a 20-year period (2023- 2042), a timespan considered sufficient to assess impacts). For example, under the PO1 suboptions, the IA estimates that sub-option 1a would entail one-off administrative costs of €13.04 million and one-off adjustment costs of €26.40 million for businesses. Under sub-option 1b, administrative costs are estimated at €9.43 million (recurrent costs of €5.14 million, one-off costs of €4.29 million); adjustment costs are not estimated due to quantification issues. The IA states that quantified estimates were not possible for sub-option 1c, and for 1d there were no direct costs for businesses. Under the PO2 sub-options, the IA expects that there would be administrative costs for businesses for sub-option 2a (not quantified) and adjustment costs for sub-option 2c (not

quantified). Sub-option 2b would entail additional administrative costs of €1.72 million, but also savings to businesses ranging from €20 million to 59 million per year due to legal certainty and labelling flexibility. The voluntary **digital** labelling scheme under sub-option 2c is expected to generate positive economic impacts (not quantified). Relating to the PO3 sub-options, the IA estimates that a digital awareness campaign under sub-option 3a would cost around €300 000 per year (EU budget). The IA points out that the costs under 3b are already being borne by EU online traders due to their obligation to comply with the General Product Safety Regulation. On the other hand, sellers outside the EU would also incur compliance costs due to the CLP rules and possible commission charges to EU-based players through whom they are obliged to sell. The estimated annualised one-off costs for alternative measures under PO3c would be €1.5-€11.4 million (alternative a), €0.05 million-€0.4 million (b) and €0.4-€3.5 million (c).

In the assessment of **environmental and social impacts**, the IA considers, for example, that under sub-option 1a, better identification, classification and labelling (EDs, PBTGs, vPvBs, PMTs, vPvMs) would reduce the ED-related costs of €46 billion per year. The IA also mentions that the sub-options 1a, b and c would improve hazard information to consumers. The sub-option 2b, that would clarify labelling provisions for refills, is expected to bring positive public health impacts through improved information for consumers. Moreover, the IA considers that the voluntary digital labelling measure under sub-option 2c could benefit vulnerable people (e.g. digital labels for the visually impaired/read-out-loud digital labels). According to the IA, sub-options 3a and 3b would improve consumer awareness and the environment would face fewer risks of exposure to harmful chemicals. Measures in sub-option 3c would reduce the number of consumers who have been harmed by noncompliant chemicals; the IA estimates that this would bring savings of up to €1.12 million.

The IA briefly considers **territorial impacts** in classification measures and finds that in specific regions, a classification of certain products as ED may result in a significant decrease (not quantified) in the demand of those products, which would have socio-economic impacts (p. 226).

The IA compares the options against the Better Regulation criteria of **effectiveness**, **efficiency** and coherence; proportionality is not specifically discussed (pp. 44-52). When considering the effectiveness of PO1 sub-options, 1a is considered highly effective, 1b effective (medium) for large companies and very effective for SMEs, 1c either slightly ('low') (late prioritisation) or highly effective (early prioritisation), depending on which alternative measure would be chosen, and 1d is found effective (medium). In the PO2 sub-options, the effectiveness of 2a is limited, that of 2b is high and 2c is 'weakly positive'. In the PO3 sub-options, the effectiveness of 3a is very low and 3b is high. The alternative measures of sub-option 3c are found highly effective; except the second one that would solve the problem only partially. When assessing efficiency, the IA finds the PO1 sub-options as being highly efficient, except 1d which is 'weakly positive'. PO2 sub-options are either low (2a), high (2b) or neutral (2c). In the case of PO3, sub-option 3a is 'rather' low, 3b high and 3c moderate (alternative measures 1-2) or high (alternative measure 3). In the coherence assessment, it would have been useful if the IA had clarified what the coherence reference is, as it uses different or unclear references. Examples include: coherence is estimated to be strong in sub-option 1a, given that there is a 'high level of protection of human health and of the environment'; in sub-option 1b it is strong, given the 'improved internal market'; in sub-option 1c it is strong, given that there is 'harmonisation at EU level'; and in sub-option 1d it is weak (without an explanation). Furthermore, in sub-option 3c, the IA states that the coherence criterion is non-applicable, even though it finds one of the alternative measures (notifications by re-branders and re-labellers) to be inconsistent with REACH. The IA compares the options in relation to the climate objectives and finds that the PO1 sub-options may generate 'some' CO2 emissions due to labelling requirements. In the same context, it considers the sub-options under PO2-3 to be neutral, though sub-option 2b is expected to reduce CO2 emissions and packaging waste in the long run. Overall, further clarification would have benefited the comparison of options. The IA does not score the options, but describes them qualitatively and without using comparable expressions, e.g. it is not clear how 'low' or 'weakly positive', 'slightly positive', 'moderate' or 'weak' correlate with each other.

The preferred option package consists of sub-options 1a-c, 2b-c and 3b-c. The IA considers that it would generate 'significant' positive health and environmental impacts, while keeping negative economic impacts limited. The IA explains and provides calculations of the expected benefits (IA, pp. 49-52; Annex 8, pp. 233-241). The summary of costs and benefits of the preferred option package is described in Annex 3 (IA, pp. 84-86).

SMEs / Competitiveness

The fitness check drew attention to the complexity of procedures, the costs and the administrative burden associated with the classification and labelling requirements for companies, SMEs in particular. The SME dimension is embedded in the initiative, as one of its general objectives is to eliminate unnecessary burdens, in particular for SMEs, who are users and importers of mixtures in the market. The IA refers to an SME test and to the BRG (also Tool 23), and assesses the costs of the policy options per company size, including SMEs (pp. 226-227, 298, 301-313, 323, 336, 343, 357, 619). The IA does not specifically explain the SME test, e.g. in a separate annex; however, it would appear that the test elements have been addressed. According to the IA, the classification and labelling measures, including the Labelling Inventory, and measures on legal certainty would bring about substantial benefits for businesses (pp. 10, 12, 16, 20, 42). The IA considers that the initiative would help to level the playing field and increase the **competitiveness** of EU companies thanks to improved provisions and closed legal gaps. For instance, the measures on online sales would contribute to fair terms for all, as sellers from outside the EU would themselves have to face costs (not quantified) to comply with the CLP rules. At the same time, the IA notes that the classification of chemical hazards may temporarily affect EU export of chemicals, because it takes time to introduce the corresponding criteria at the international level (UN GHS) (pp. 14, 36, 42, 44).

Simplification and other regulatory implications

According to the IA, the initiative would contribute to burden reduction and cost savings for the industry. It specifically mentions the measures laid out in sub-options 1b and 2c, which would improve hazard classification and the Labelling Inventory. One example of cost savings − worth €48.5 million − that would benefit the detergent industry, would accrue from a broader use of multilingual fold-out labels. The IA also considers the 'one-in, one-out' (OIOO) approach, as required in the BRG (see also Tool 59). It estimates that the preferred option would bring net savings of €25.6 million per year for businesses and citizens in the recurring administrative costs, while the net one-off administrative costs would be €245.2 million. According to the IA, this initiative would be in line with the European Green Deal, the chemicals strategy for sustainability, the EU's zero pollution action plan for 2050 and the EU new industrial strategy. It would contribute to the UN Sustainable Development Goals (SDG 3: Good Health and Well-Being; SDG 6: Clean Water and Sanitation; SDG 9: Industry, Innovation and Infrastructure; SDG 12: Sustainable Consumption and Production Patterns). The IA explains how this initiative relates to existing or proposed legislation, such as the Market Surveillance Regulation and the proposed eco-design requirements for sustainable products, as well the upcoming revision of REACH(pp. 26-27; Annex 5, pp. 142-146).

Monitoring and evaluation

Regarding the monitoring and evaluation of the effectiveness of this initiative, the IA explains that the Commission is developing a framework of indicators on chemicals by 2024 (chemical pollution, chemicals legislation) with the involvement of the European Environment Agency (EEA) and the European Chemicals Agency (ECHA). The IA does not specifically mention the timeframe for the evaluation of this initiative.

Stakeholder consultation

The IA provides a summary of the extensive stakeholder consultation activities in a dedicated Annex 2 (pp. 63-82), as required in the BRG. The feedback period for the **call for evidence for an impact assessment** ran between 4 May 2021 and 1 June 2021, gathering 182 replies. An **open public**

consultation on the revision of the CLP was carried out between 9 August 2021 and 15 November 2021: it met the BRG requirement of 12 weeks and received 625 responses. Stakeholders were asked for feedback on the intervention areas (the problem drivers). They were divided with regard to the problem area of CLP scope exemptions. Citizens, public authorities and civil societies were of the view that the provision of information on the environmental hazards concerning a number of products (e.g. medical devices, cosmetics) had to be solved, while businesses considered that there was an issue only regarding human medicines. The Commission conducted another open public consultation on simplification and digitalisation of labels on chemicals between 24 November 2021 and 17 February 2022 (in line with the 12-week requirement under the BRG), which yielded 205 replies. A stakeholder workshop and two online surveys on the same topic were also conducted. Other consultation activities held included targeted stakeholder consultations, including surveys; three expert group meetings of competent authorities; and interviews with a wide range of stakeholders. The stakeholder groups that participated in the consultations were composed of companies (differentiated by size) and business associations, public authorities, citizens, civil societies (e.g. research institutions, consumer organisations). The IA explains the stakeholder groups' views on the sub-options. It appears that while stakeholders widely support most of the proposed measures, they are much less supportive of sub-option 1c, as they do not consider the CLP to be the right tool to address human and environmental reference values. On some measures, stakeholders were of divergent views. Industry would have preferred that new hazard classes would be introduced in the GHS first and only after that in the CLP, for competitiveness reasons. Public authorities had doubts on the cost-benefit aspects of the alternative regarding automatic updates under sub-option 1b, and under 1b the measure of transparent notifiers raised concerns due to confidentiality needs in the research field. In relation to sub-option 2c on digital labelling, some stakeholders (e.g. competent authorities) stressed that not all people have access to digital technologies (IA, pp. 39-44). It would have been useful if the summary had included more detailed information on the consultation of SMEs; information on SMEs is guite fragmented in the IA and its extensive annexes.

Supporting data and analytical methods used

The IA provides qualitative and quantitative data in the analysis. It draws on several data sources, including two external supporting studies (referenced, no hyperlinks provided; these do not appear to have been published), two fitness check reports (2019, 2020), a stakeholder consultation, independent research and reports in this policy field. The IA explains the analytical methods used in Annex 4 (e.g. the EU standard cost model for estimating administrative costs to industry and public authorities) (pp. 88-141). The IA recognises limitations in the analysis, such as quantification of costs and benefits, and impacts on environment and health (pp. 36, 38, 42-43, 60-62).

Follow-up to the opinion of the Commission Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) gave a positive <u>opinion</u> with reservations on the draft IA report on 13 May 2022. The RSB still found significant shortcomings as regards, for example, the presentation of the costs and benefits, which was not sufficiently clear or coherent. The RSB also asked for transparency in the methodology for estimating costs and benefits, and for a further justification of the preferred option, including the proportionality aspect. In addition, the RSB considered that the distributional impacts across all affected groups should be presented, including SMEs. The report should clarify the expected impact of labelling on consumer behaviour and assess the impact on the competitiveness of EU businesses in more detail. It also asked that a dedicated section of the administrative costs and savings in the scope of the 'one in, one out' approach be clarified further. The report should explain the reasons why the quantification of the expected significant health and environment benefits is not possible. It should also provide a robust qualitative analysis of the expected benefits, to justify the conclusion that the benefits outweigh the costs for this initiative. The report should clearly describe how the CLP relates to other chemical legislation, notably REACH, and analyse the remaining regulatory gaps compared to related

measures, such as the General Product Safety Regulation, the Market Surveillance Regulation and the Digital Services Act. As required in the BRG, the IA explains in Annex 1 how it has taken into account the points raised by the RSB (pp. 56-60). It appears that the RSB's comments have been addressed. However, it is not possible to fully ascertain this, because the previous version of the IA is not publicly available.

Coherence between the Commission's legislative proposals and the IA

The legislative proposal appears to follow the preferred option package.

The IA provides a convincing justification on the need to revise the CLP. It presents a well-evidenced problem definition and describes the scale of the problems. The IA does not provide self-standing policy options addressing all the drivers. Instead, it provides three policy option packages, under which the sub-options are the policy options; however, there are in fact only a few alternative choices. The IA explains the policy options and their impacts in detail in extensive annexes. The comparison of the options would have benefited from further clarification, as the IA does not score the options but instead it describes them qualitatively and does not use comparable expressions. The preferred option package is sufficiently justified and the reasons for discarding measures have been explained. The IA openly explains the limitations in the analysis, in particular in relation to quantification. The IA provides a description of the broad stakeholder consultations. It appears from the annexes that an SME test was conducted; however it would have been more reader-friendly if this had been explained in the main text or at least in a separate annex, as the information related to different elements of the SME test is presented in a rather fragmented way throughout the IA. The IA could have clarified for the sake of transparency, whether the supporting studies are publicly available.

ENDNOTES

Karamfilova E., <u>Revision of the EU Regulation on classification, labelling and packaging of substances and mixtures</u>, EPRS, European Parliament, 2023.

This briefing, prepared for the Committee on environment, public health and food safety (ENVI), analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the European Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal.

DISCLAIMER AND COPYRIGHT

This document is prepared for, and addressed to, the Members and staff of the European Parliament as background material to assist them in their parliamentary work. The content of the document is the sole responsibility of its author(s) and any opinions expressed herein should not be taken to represent an official position of the Parliament.

Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the European Parliament is given prior notice and sent a copy.

© European Union, 2023.

eprs@ep.europa.eu (contact)

www.eprs.ep.parl.union.eu (intranet)

www.europarl.europa.eu/thinktank (internet)

http://epthinktank.eu (blog)