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PART 1/5

COMMISSION STAFF WORKING DOCUMENT

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) 436 final}

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Glossary

Term or acronym	Meaning or definition
CLP	Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures
CMR	Carcinogenicity, mutagenicity, reproductive toxicity
D	Driver
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
EU	European Union
GHS	(United Nations) Globally Harmonized System of Classification and Labelling of Chemicals
NGO	Non-governmental organisation
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
PBT and/ vPvB	Persistent, Bioaccumulative and Toxic and/ very Persistent and very Bioaccumulative
PMT and/ vPvM	Persistent, Mobile and Toxic and/ very Persistent, very Mobile
PO	Policy Option
SME	Small and medium-sized enterprise
SVHC	Substance of Very High Concern (under REACH)
SDG	Sustainable Development Goals (United Nations)
TFEU	Treaty on the Functioning of the European Union
VAT	Value-Added Tax

1 INTRODUCTION

1.1 Policy context

Chemicals are the building blocks of all materials and products we produce and use and are therefore important determinants of their overall safety and sustainability. All European citizens are exposed in their daily life to chemicals; many may also use chemicals at work.

The EU is the second largest producer of chemicals in the world with €499.1 billion sales turnover in 2020 (7.0% of EU manufacturing by turnover) and 14.4% of global sales[1]. Within the EU, two thirds of these sales are generated in four Member States: Germany (32.1%), France (13.5%), Italy (10.7%) and the Netherlands (8.9%). Around 50% of chemicals, in terms of sales, produced by the EU27 plus the UK, supply the other industrial manufacturing sectors (e.g., textiles, construction, agriculture, transport, health, hygiene, housing, food).

The European Green Deal[2] is the European Union's growth strategy to set the EU on a course to become a climate neutral, clean and circular economy by 2050. It has also set a goal to step up protection of human health and the environment from hazardous chemicals and to move towards a zero pollution ambition for a toxic-free environment, for which the Chemicals Strategy for Sustainability[3] adopted by the European Commission in 2020 was the first step, followed by the EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil'[4]. The Chemicals Strategy for Sustainability defines a 2030 vision and objectives where all chemicals will be produced and used safely and sustainably, so that their negative impacts on health and environment are avoided, while their benefits for the economy and society can be fully exploited. The EU's New Industrial Strategy for Europe supports those objectives through a set of measures for the twin transition to a green and digital economy, with a particular focus on strengthening the resilience of the single market, supporting the EU's strategic autonomy and business cases for the twin transition. That strategy also entails building capacity and supporting SMEs in their transition to sustainability.

Given the very cross-cutting nature of chemicals, which constitute the basic elements of virtually every material and product that we produce and use, the objectives of the Chemicals Strategy for Sustainability are closely linked to the other goals of the European Green Deal, in particular climate neutrality, circularity, biodiversity protection and the green and digital transition of the EU industry. Those objectives also contribute to the achievement of the United Nations Sustainable Development Goals (SDGs), of which 4 are directly relevant for chemicals: SDG #3 Good health and well-being, SDG #6 Clean water and sanitation, SDG #9 Industry, innovation and infrastructure, SDG #12 Ensure sustainable consumption and production patterns (see Annex 3 for more details).

The Chemicals Strategy for Sustainability announced the revision of the Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP), the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as well as a number of pieces of product sectorial legislation containing provisions on chemicals (e.g. cosmetics, toys, food contact materials, etc.). In particular, the Chemicals Strategy for Sustainability calls for the REACH and CLP Regulations to be reinforced as the EU's cornerstones

[1] CEFIC, Facts and Figures of the European Chemical Industry, 2022.
[2] COM(2019) 640.
[3] COM(2020) 667.
[4] COM(2021) 400.

for regulating chemicals, and to be complemented by coherent approaches to assess and manage chemicals in existing sectorial legislation, especially in relation to consumer products.

The targeted revision of CLP, as part of the Chemicals Strategy for Sustainability, was welcomed by the Council[5] and the European Parliament[6]. It echoed former calls from the European Parliament on tackling chemicals with endocrine disrupting properties. Industry positively responded to the Chemicals Strategy for Sustainability[7] while strongly calling for additional support and a collaborative approach to deliver on chemical sustainability in the EU. Non-governmental associations (NGOs) welcomed the targeted revision in the consultation on the Inception Impact Assessment (see Annex 2).

This impact assessment focuses on the revision of the CLP and is based on the shortcomings identified in recent evaluations[8,9] of the CLP and of its interfaces with other EU legislation regulating chemicals. It will assess how different measures can help achieving the goal of a toxic-free environment while fostering the internal market for chemicals and competitiveness of the EU industry[10]. Since CLP provides for a horizontal approach to identify and classify the hazards related to chemicals, its revision is a first necessary step for several elements of the revisions of REACH and other sectorial legislation.

1.2 Legal context (see Annex 5 for more details)

The objectives of CLP are to protect human health and the environment from hazardous chemicals and to facilitate the free movement of chemicals in the European market.

CLP in brief

CLP requires manufacturers, importers and downstream users to classify hazardous substances and mixtures. CLP contains rules on how to classify chemicals. A classification can be harmonised and applied across the EU to all duty holders. Such classification is adopted at EU level according to a regulatory procedure. Where such harmonised classification does not exist, duty holders have to assess and classify according to available data ('self-classification').

The hazard classification determines, amongst others, the appropriate labelling and packaging of the chemicals in the supply chain, in particular to protect workers, consumers and the environment (see Annex 5). Hazard communication also relies on notifications of substances which are self-classified by industry and included in the CLP classification and labelling inventory, a public database managed by ECHA. CLP also covers the notifications self-classifications of mixtures of chemicals to poison centres, to provide adequate emergency health response.

CLP focuses on the identification and classification of the intrinsic hazards of chemicals, i.e. the hazardous effects of chemicals on human health or the environment, and on communicating them to users of chemicals and decision makers (consumers, industry and authorities). Identifying the intrinsic hazardous properties of substances to derive a hazard classification is the first step in assessing chemical risks. The second step aims at quantifying at which dose the adverse effects

[5] Council Conclusions on Sustainable Chemicals Strategy of the Union, 2021.
[6] European Parliament, Resolution of 10 July 2020 on the Chemicals Strategy for Sustainability, 2020.
[7] CEFIC, Chemical Strategy for Sustainability, consulted 3/4/2022.
[8] SWD(2019) 199.
[9] SWD(2020) 251.
[10] Also in line with the EU Industrial Strategy COM(2021) 350 final and COM(2020) 102 final.

happen, whose outcome is a reference value, and is currently performed outside CLP. Risk management measures are adopted under REACH and relevant sectorial pieces of legislation (e.g. cosmetics, toys, waste, detergents etc., see Figure 1 below. More details are available on the interaction between legislation in Annex 5).

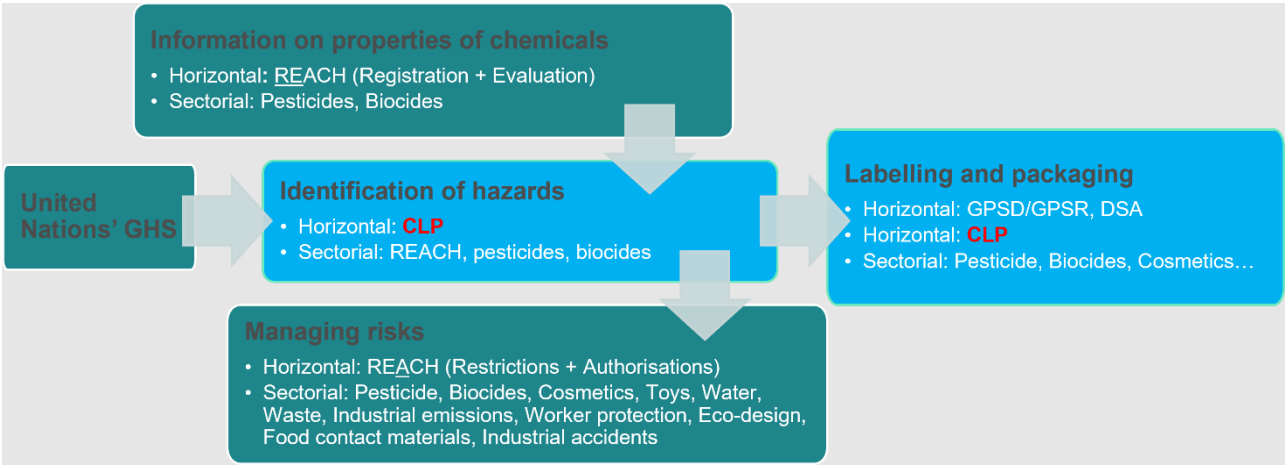

Figure 1: Mapping of the pieces of legislation according to the different steps of hazard and risk assessments

CLP follows the United Nations' Globally Harmonized System (GHS) of classification and labelling of chemicals setting up criteria for classification and communication of physicochemical, health, and environmental hazards. GHS is partly established on a "building blocks" approach, whereby each jurisdiction has the option to implement a GHS block into its own legislation[11]. So far, 83 countries worldwide implement the GHS[12]. CLP implements the GHS criteria into EU legislation, but complements them with certain elements from former EU legislation (Dangerous Substances Directive[13] and Dangerous Preparations Directive[14]).

CLP, together with other pieces of EU legislation, was evaluated in 2019[15]. An additional and more targeted Fitness Check was also published on endocrine disruptors[16]. Those evaluations, summarised in Annex 6, identified important issues and weaknesses holding CLP back from delivering its full potential. These evaluations pinpointed nine potential areas of intervention:

- Introducing criteria for five outstanding **new hazard classes** (Annex 8)
- Providing **harmonised reference values** in addition to harmonised classification (Annex 9)
- Improving **harmonised classification** (Annex 10)
- Improving and streamlining industry's **self-classifications** (Annex 11)
- Clarifying rules for **hazard (physical) labelling** (Annex 12)
- Introducing **digital labelling** (Annex 13)
- Reviewing the **exemption of a number of chemical products** from CLP (Annex 14)
- Addressing low compliance rate for **online sales of chemicals** (Annex 15)
- Closing **notification gaps for poison centres** (Annex 16)

[11] Global implementation map of GHS, September 2021.
[12] GHS Implementation, last updated 19 October 2021.
[13] Directive 67/548/EEC.
[14] Directive 1999/45/EC.
[15] SWD(2019) 199.
[16] SWD(2020) 251.

2 PROBLEM DEFINITION

2.1 The problem - Insufficient health and environment protection from hazardous substances in the internal market for chemicals

The chemicals Fitness Check concluded that the EU has the most advanced knowledge base on chemicals globally. The EU has been overall successful in creating an efficiently functioning internal market for chemicals and in reducing the risks to humans and the environment posed by certain hazardous chemicals. However, the weaknesses identified in CLP hinder the capacity of all market actors – in particular consumers, businesses and authorities - to base their decisions on robust and relevant knowledge on the intrinsic properties of chemicals. The problem manifests itself in three main areas, described in Table 1 and in the three following sections.

2.1.1 Hazardous chemicals are not comprehensively identified and classified

Hazardous chemicals cause harm to human health and the environment. While not all hazardous chemicals raise the same concerns, certain chemicals cause for example cancers or affect the immune, respiratory, endocrine, reproductive or cardiovascular system[17,18,19]. Human biomonitoring studies in the EU point to a high number of different hazardous chemicals present in human blood and body tissue[20,21], including more than 200 synthetic chemicals identified in umbilical cord blood. In addition, chemical pollution is one of the key drivers putting the environment at risk[22], impacting and amplifying planetary crises such as climate change, degradation of ecosystems or loss of biodiversity[23]. In the EU, reports from the European Environment Agency provide the extent of chemical contamination in water, soil and air compartments[24]. 84% of Europeans are worried about the impact of chemicals present in everyday products on their health, and 90% are worried about their impact on the environment[25].

[17] C&en, Linking pollution and infectious disease, 2019.
[18] Science Daily, Environmental toxins impair immune system over multiple generations, 2019.
[19] Substances such as PFOS and PFOA are associated with reduced antibody response to vaccination; EFSA, Scientific opinion on PFAS.
[20] European Commission, Study for the Strategy for the Non-Toxic Environment, p. 123.
[21] European Human Biomonitoring Data.
[22] L. Persson, B. M. Carney Almroth, C. D. Collins, S. Cornell, C. A. de Wit, M. L. Diamond, P. Fantke, M. Hassellöv, M. MacLeod, M. W. Ryberg, P. Søgaard Jørgensen, P. Villarrubia-Gómez, Z. Wang, and M. Zwicky Hauschild, Outside the Safe Operating Space of the Planetary Boundary for Novel Entities, 2022.
[23] Examples include negative effects on pollinators, insects, aquatic ecosystems and bird populations.
[24] European Environment agency, Chemical risk estimates, 2019. Adapted from Malaj et al, 2014. Organic chemicals jeopardize the health of freshwater ecosystems on the continental scale. Organic chemicals were likely to exert acute lethal and chronic long-term effects on 14 to 42% of over 4000 monitored sites.
[25] Eurostat, Eurobarometer, 2020.

Table 1: Problem tree			
A functional internal market for chemicals delivering a sub-optimal protection of human health or the environment			
Problems	Hazardous chemicals are not comprehensively identified and classified	D1. Missing provisions for identification of critical hazards	**Regulatory/administrative drivers**
		D2. Inefficient procedures for hazard assessment and classification	
	Sub-optimal communication on chemical hazards	D3. Complexity of some labelling provisions	
		D4. Some chemicals are not labelled according to CLP	
		D5. Current labelling rules do not sufficiently exploit new digital tools	
	High level of non-compliance (online sales and poison centres)	D6. Rules are inadequate to keep pace with new means of sale	
		D7. Unclear provisions on notifications to poison centres	

The chemicals Fitness Check found that the **EU's regulatory framework on chemicals does not allow a complete and consistent identification and classification of chemical hazards**. The main issues concern the identification of the most critical hazards, and the overall quality of the information on the substances that have been identified and classified.

2.1.1.1 Most critical hazards

Over the last 15 years, scientists have raised particular **concerns on the following hazards:**

- **Endocrine disrupting (ED) properties** have been the focus of increasing scientific research, and the accumulated knowledge identifies EDs as a concern to public and wildlife health[26,27]. The high and increasing incidence of many endocrine-related disorders in humans – such as asthma, birth defects, neurodevelopmental disorders, cancer, diabetes and obesity in children or adults – have important parallels in some wildlife populations. Some links have become apparent (e.g. polychlorinated biphenyls' exposure as a risk factor in breast and prostate cancers) while more research is necessary on the associations between EDs and other endocrine-related diseases[17,28].
- Substances with **persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) properties** do not easily break down in the environment and tend to accumulate in living organisms across the food web. Experience has shown that the accumulation of these substances in the environment is difficult to reverse, as cessation of emission does not readily result in lowering their concentration, and the effects of this accumulation are unpredictable in the long-term. Moreover, PBT/vPvB substances have the potential to contaminate remote pristine areas. They also pose particular challenges to the

[26] United Nations Environment Programme, State of the Science of Endocrine Disputing Chemicals - IPCP-2012.
[27] L.N. Vandenberg & J.L. Turgeon, Endocrine disrupting chemicals: Understanding what matters. In L. N. Vandenberg, & J. L. Turgeon (Eds.), *Endocrine-Disrupting Chemicals*, 2021.
[28] Kahn et al., Endocrine-disrupting chemicals: implications for human health, The Lancet. Diabetes & endocrinology, 8(8), 703–718, 2020.

reliability of quantitative risk assessment, as a safe concentration in the environment cannot be established with the available methodologies[29].

- Substances with **persistent, mobile and toxic and very persistent, very mobile (PMT/vPvM) properties** pose grave concerns because they can enter the water cycle, including drinking water, and spread over long distances, making the determination of their impacts very challenging[30]. Many PMT/vPvM substances are only partly removed by wastewater treatment processes and can even break through the most advanced purification processes at drinking water treatment facilities. Their incomplete removal coupled with ongoing emissions means that their concentrations in the environment increase over time.

CLP currently does not oblige manufacturers to identify those intrinsic properties. Substances with ED, PBT/vPvB properties are only identified through REACH on an ad-hoc basis and through the pesticide and biocide regulations. Substances with PMT/vPvM are only identified via REACH. The identification criteria in EU legislation are not harmonised (see driver 2.2.1 and Annex 8). Therefore, manufacturers only have to identify ED, PBT/vPvB and PMT/vPvM properties for REACH-registered substances, and not for other substances. Several Member States[31], the European Parliament and NGOs[32] have frequently called for addressing those hazards coherently at EU level, and some Member States are taking individual actions on one or more of these hazards. Different national criteria for the missing hazard classes would seriously impair the current well-functioning single market for chemicals.

Consequences

According to ECHA, only 67 substances have ED, PBT/vPvB and PMT/vPvM properties confirmed under REACH (see Table 2 and Annex 8) since 2008 and 1,113 are under assessment. This is in contrast with the minimum of 1,650 substances that, according to ECHA estimates, could have one of the three hazard properties.

Table 2: Number of substances identified, in the process of being identified or candidates for ED, PBT, PMT, vPvB, vPvM hazards (ECHA: registered substances under REACH, 2021. See Annexes 4 and 8).

	Already identified	Under assessment	Possible candidates
ED HH & ENV**	24	434	1,012
PBT and vPvB	34	324	396
PMT and vPvM	9	355	231

*ECHA's guestimates (subject to very high uncertainty) on how many substances could have the same hazard(s) among the remaining REACH registered substances ** ED category 1 only

Consumers and workers are widely exposed to those chemicals[33] in particular through consumer products (e.g., toys, food contact materials, cosmetics, furniture, textiles, etc.) or during

[29] Guidance on the Application of the CLP Criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. ECHA-17-G-21-EN. Version 5.0 – July 2017. European Chemicals Agency, 2017.

[30] Hale *et al.,* Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose an equivalent level of concern to persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances under REACH, *Environ Sci Eur* **32,** 155, 2020.

[31] Five Member States (Belgium, Denmark, France, The Netherlands and Sweden) launched a website in June 2020 having the aim of informing stakeholders about the current status of substances identified as EDs to increase the knowledge base on them. Those Member States call for action at EU level. France already adopted a decree on ED identification (Article L541-9-1 of the French Public Health Code).

[32] Chemical Watch, "NGO coalition urges EU Commission to publish EDC Strategy".

[33] In 2022, an analysis of the registration dossiers looked at uses mentioned in dossiers for substances identified as candidates for the new hazard classes. Paints, adhesives, washing and cleaning products and inks and toners are

professional uses. Release of those substances into the environment during their use phase or at end of life disposal can have long-term and large-scale environmental impacts on terrestrial and marine environment.

It is not possible to quantify fully the impact on human health and the environment of chemicals with the most critical hazards. However, exposure to certain EDs has been associated to IQ loss and intellectual deficiencies with a probability of causation of 70% to 100%, with moderate to high strength of human evidence. EDs are also suspected to cause male infertility, obesity, diabetes and other health issues with varying probabilities of causation and strength of human evidence[34]. Researchers estimated that exposure to EDs leads to substantial health-related societal costs between 46 and 288 billion Euro per year[35] (see also Annex 8). Persistent chemicals do not break down in the natural environment. The risk is that concentrations will build up in nature such that levels of exposures to humans and other biota are irreversible. Some 3.5 million sites around Europe are already contaminated by hazardous and persistent substances. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to loss of natural resources such as drinking water, land, soils and fish stocks from productive use[36].

2.1.1.2 Quality of information on classified substances

The chemicals Fitness Check also highlighted a particularly **high number of incorrect or obsolete classifications of substances as well as diverging classifications for the same substance** in the CLP classification and labelling inventory**.** In 2017, 59% of companies had multiple notified classifications for a single substance[37]. Companies also reported their difficulties to notify or update their notification on the substances they self-classify. The current process was overall assessed as bringing excessive costs and administrative burden, with companies - especially SMEs - needing specific trainings or to sub-contract tasks due to the complexity of the procedures and/or the lack of user-friendly IT tools[8]. More recently, ECHA concluded that the situation on diverging classifications had improved, as, in 2021, 78.4% of the 205,900 notified substances have only one self-classification[38] (see Figure 3).

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respectively the 3rd, 4th, 5th and 6th most frequently reported uses. VVA et al, 2022, Background document – Workshop on the extension of the generic approach to risk management under the REACH regulation (21 March 2022).

[34] Kahn, L. G., Philippat, C., Nakayama, S. F., Slama, R., & Trasande, L. (2020): Endocrine-disrupting chemicals: implications for human health. The Lancet. Diabetes & endocrinology, 8(8), 703–718. https://doi.org/10.1016/S2213-8587(20)30129-7

[35] I. Rijk, M. van Duursen, and M. van den Berg, Health cost that may be associated with Endocrine Disrupting Chemicals — An inventory, evaluation and way forward to assess the potential health impact of EDC-associated health effects in the EU, Institute for Risk Assessment Sciences, University of Utrecht, 2016.

[36] European Commission, Study for the Strategy for the Non-Toxic Environment, p. 123.

[37] Amec Foster Wheeler et al., A Study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers, 2017.

[38] ECHA's presentation at ad-hoc CARACAL of 14 December 2021.

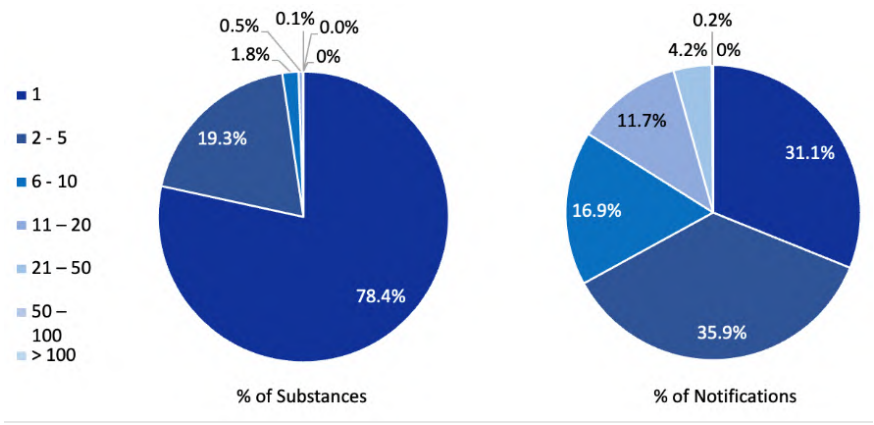


Figure 3: Diverging notified classifications per notified substances (left) or per notifications (right)

Consequences

Missing, incomplete and/or incorrect hazard identification and characterisation of chemicals leads to incomplete information for users of chemicals, which may increase their exposure to those chemicals. Furthermore, with hazard identification under CLP as the starting point for product specific risk assessments (e.g., for cosmetic products) and assessments under REACH, companies and authorities may not be able to set adequate risk management measures. This leads to an insufficient level of protection of consumers, workers and the environment, and causes the inefficient use of resources for authorities and companies who are forced to act with sub-optimal information or simply cannot take any action. Especially SMEs rely on hazard identification data for their chemicals classification. Moreover, incorrect data hampers competition between the businesses that identify correctly and those who do not.

2.1.2 Sub-optimal communication on chemical hazards

Labels are the primary means of communication to inform consumers and workers about the hazards of the chemicals they purchase, use or dispose. The specification of those labels is provided by CLP (see pictograms in Figure 4). A Eurobarometer survey in 2016[39] found that, while 70% of EU citizens find information on the hazards of chemicals on the label useful, only 45% of the respondents feel well **informed about the potential dangers of the chemicals** contained in consumer products. Respondents in particular felt that they had a relatively low level of understanding of certain pictograms, labels and precautionary statements on chemicals, especially due to limited readability of labels due to extended amount of information, the technical language and to the often too small font size. Consumer understanding of chemical labels is also very heterogeneous across Europe, with Northern Europeans reported feeling more informed compared with Southern Europeans. Understanding also varies between consumers and professional and industrial workers, as professional and industrial workers are generally trained to understand the information on the safety label. In the framework of this impact assessment, it is possible to broadly estimate an average level of 55% EU citizens considering not to be well informed about the potential dangers of the chemicals contained in consumer products (see Annex 12).

[39] Special Eurobarometer 456, 2017.

Secondly, complex and overloaded labels bring along also high compliance costs for industry, especially SMEs[40]. Ambiguous or difficult rules to apply in practice are not evenly implemented by companies or enforced between the Member States, hence hampering the level playing field (see also under 2.1.3. below). Feedback from the open public consultation showed that current labelling exemptions under CLP do not always provide practical solutions for an effective hazard communication via labelling and that simplification may be possible whilst providing the same or even better level of safety[41]. Most respondents considered that significant savings can be achieved by exempting certain very small products[42] (e.g. writing instruments) and certain chemicals sold in bulk to consumers (e.g. fuels), by extending the scope of fold-out labels and by introducing digital labelling[43].

Figure 4: Pictograms provided by CLP

Finally, for some categories of products, which are exempted from the scope of CLP – cosmetics, human and veterinary medicinal products, medical devices and food and feed stuff –, the **communication to consumers on the environmental hazards** of the substances present in those products is sub-optimal (see Annex 14). These products are exempted, based on the premise that the exempted sectorial legislations lay down more specific rules on classification and labelling. While for medicinal products and medical devices, warnings and use instructions to users may cover environmental hazards, these hazards are not addressed in the legislation concerning cosmetic products. Literature provides evidence that some of the exempted products (e.g., pharmaceuticals or rinse-off cosmetic products and sunscreens) and their ingredients (e.g., plastic microbeads, siloxanes, or UV filters) end up in the environment in significant quantities where they may cause damage to the aquatic environment [44,45,46]. An ongoing study[47] also identified hazardous substances reaching urban wastewater treatment plants and linked their release to pharmaceuticals and personal care products amongst other products. However, the supporting study did not directly identify CLP labelling as having an impact on consumer behaviour. Also, several relevant initiatives (e.g. the Proposal for Ecodesign for Sustainable Products Regulation, the revision of the Cosmetic Products Regulation, industry self-standards, see Annex 14) are currently under way and may significantly change the availability of information of environmental impacts, as well as the impact itself, of the

[40] SWD to the chemicals Fitness Check, p.62. The chemicals Fitness Check estimated that the average cost of redesigning and modifying labels to be compliant with CLP was €388 per substance and €475 per mixture.
[41] Summary in CARACAL CA/11/2021.
[42] Where the inner packaging of products contain up to 10ml of chemicals.
[43] Certain chemical industries, in particular the detergents industry, face a relatively high administrative burden to comply with labelling requirements and hence more innovative communication approaches to labelling could be explored; Annex 2 and 13.
[44] N.A. Vita, C.A. Brohem, A. D. P. M. Canavez, C. F. S. Oliveira, O. Kruger, M. Lorencini & C.M. Carvalho, Parameters for assessing the aquatic environmental impact of cosmetic products, *Toxicology letters*, *287*, 70-82, 2018.
[45] S. Bom, J. Jorge, H.M. Ribeiro & J. Marto, A step forward on sustainability in the cosmetics industry: A review, *Journal of Cleaner Production*, *225*, 270-290, 2019.
[46] C. Juliano and G.A. Magrini, Cosmetic Ingredients as Emerging Pollutants of Environmental and Health Concern. A Mini-Review, *Cosmetics*, 4, 11-29, 2017.
[47] Wood, Study supporting the Evaluation of Directive 91/271/EEC concerning urban waste water treatment, 2019.

exempted products. Therefore, this problem cannot be adequately addressed through this revision. Follow up discussions will continue with all relevant actors and more evidence would be needed.

Consequences

Sub-optimal communication on chemicals may hamper consumers' ability of making informed choices and can lead to the inappropriate use of chemicals, harming their health as well as the environment. Considering the increasing interest of consumers in the environmental impact of the products they buy[48], sub-optimal communication on environmental hazards limits their ability to lower their environmental footprint and, thereby, contribute to the EU Green Deal's goal of sustainable consumption.[49] Unnecessarily complex or ambiguous labelling provisions also lead to avoidable compliance costs by companies and an uneven level playing field due to different implementation by companies and enforcement by Member States (see also under 2.1.3. below).

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

Imported chemicals and online sales represent a particular challenge and the Chemicals Strategy for Sustainability identifies them as a priority area for action[50]. Almost 30% of the alerts on dangerous products on the market involve risks due to chemicals, with almost 90% of those products coming from outside the EU[51]. Many products that are sold online in the EU but manufactured outside the EU do not meet the EU product safety and chemical legislation requirements[52]. The volume of online sales is expected to grow, hence increasing the problem. A study on cross-border online sales observed a 14.4% increase in e-commerce revenues in 2019 compared to 2018[53]. Business models and intermediary services that did not yet exist in 2008 - e.g. social media, online marketplaces - nowadays connect online sellers and buyers worldwide[54].

[48] Megatrends, Supporting policy with scientific evidence, Consumers wish to be increasingly aware of the environmental performance of the products they buy; see megatrends in sustainable consumption.

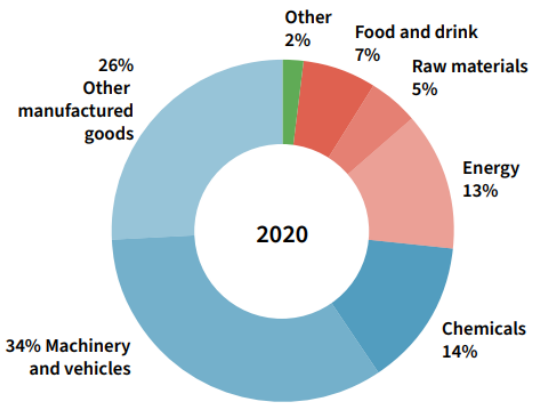
[49] The European Green Deal sets the ambition to empower consumers to make informed purchase choices and play an active role in the ecological transition.

[50] COM(2020) 667, p 17.

[51] RAPEX web reports.

[52] KEMI, Increased e-commerce – increased chemicals risks? A mapping of the challenges of e-commerce and proposed measures. Report of a government assignment, 2021.

[53] Cross-Border Commerce Europe (2020): Cross-Border Commerce Europe publishes the second edition of the "Top 500 cross-border retail Europe": an annual ranking of the best 500 European cross-border online shops. Other estimations show an increase of 1.1% between online sales from 2020 to 2021 and thus it can be expected that the number of non-compliant items sold will increase over time unless action is taken.



Source: Eurostat, https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Extra-EU_trade_in_goods#Evolution_of_extra-EU_trade based on Comext DS-06332.

Figure 5: Imported goods in the EU based on product amounts

Non-compliance **with the provisions of CLP on online advertisement very frequent, especially for chemicals sold online, both by EU and non-EU actors**. International research projects[49] found that the rate of non-compliance with CLP provisions was 75% of 2,752 inspected products in 29 EEA countries and 82.4% of 1,314 inspected products in 15 EU countries[54]. Based on estimations, non-compliances of non-EU sellers with CLP are higher than those of EU sellers in relative terms[55], and amount to yearly 7.3 million non-compliant products sold directly from non-EU actors to consumers (see Annex 15). A specific issue in terms of implementation relates to notifications that businesses have to submit to poison centres for emergency health response. Poison centres across the EU answer over half a million calls for support per year[56], therefore, it is essential that they have all the necessary information on e.g. the composition of mixtures in order to provide the appropriate advice to consumers or health carers. Although notifications significantly improved over the years for trade within Member States and imported chemicals, there are still two situations where implementation is sub-optimal as businesses fail to notify: in the case of intra-EU cross-border trade and/or re-branding/re-labelling. The estimation of mixtures currently not notified under those two scenarios is between 252,500 – 637,500 out of a total of 1.4 million mixtures notified in 2021 (see Annex 16).

Consequences

As a result of the issues described above, consumers and workers are often confronted with chemicals with no or incorrect labelling and packaging, in particular when buying online directly from non-EU sellers (and to a lesser extent when buying from intra-EU sellers). As online offers and advertisements often do not display hazardous information, consumers may not be able to make informed choices, or correctly use, store or dispose of mislabelled chemicals such as detergents or paints, leading to risks for their health and/or the environment. Furthermore, the lack of compliance with or enforcement of CLP rules for imports also leads to an uneven level playing field, including a competitive advantage of non-EU actors operating online compared to EU actors – such as importers, downstream users, distributors and manufacturers - who must comply with CLP (especially of SMEs who merely operate within Europe). Finally, the lack of the submission of correct emergency health response information to poison centres leads to insufficient health

[54] Non-compliant with Article 48(2) on advertisement of mixtures, ECHA, Final report on the Forum Pilot Project on CLP focusing on control of internet sales, 2018.
[55] For CLP the suggestion is 1.37 times higher.
[56] European Commission's webpage on https://ec.europa.eu/growth/sectors/chemicals/poison-centres_en.

responses or patients' overtreatment[57] (see Annex 16) as well as an uneven level playing field for businesses who correctly submit the correct emergency health response information. This affects their competitiveness compared to non-compliant companies[58].

2.2 The problem drivers

The problem and its manifestations are driven by several regulatory failures.

2.2.1 Missing provisions for the identification of critical hazards

CLP provides that, for hazards of highest concern, classification and labelling of substances should be harmonised throughout the EU. However, the hazards currently defined under CLP — the same defined under (UN) Globally Harmonized System (GHS) — are not exhaustive and horizontal **identification criteria and hazard classes are missing for some of the most critical hazards**, in particular EDs, PBT and vPvB, PMT and vPvM. While identification criteria do not yet exist in EU legislation for PMT/vPvM substances, some criteria and provisions to identify EDs and PBT/vPvB exist in some pieces of EU legislation (e.g. the Plant Protection Products Regulation[59] and the Biocidal products Regulation[60]) or as an international standard[61] (Annex 8 provides more details on the gaps and inconsistencies in the regulatory framework). However, a horizontal and systematic approach to identification is still missing across EU legislation[62] (see Annex 5). The lack of horizontal criteria for EDs was already identified as a priority area for action in the EU's 7th Environmental Action Plan as well as in the Fitness Check on endocrine disruptors, and the lack of progress has been regularly criticised, including by the European Parliament and the Council (see Annex 2).

2.2.2 Inefficient procedures for hazard characterisation and classification

The Chemicals Fitness Check and the study conducted for this impact assessment have evaluated the performance of the procedures to classify chemicals hazards, both via harmonised classification as well as industry's self-classification. It concluded that classification procedures are not fully efficient, and that there is room for improvement both in terms of speed of the processes as well as in terms of reduction of administrative burden for authorities and companies. Stakeholders also confirmed that improvements would be beneficial[8].

Almost all dossiers for **harmonised classification** are developed by Member States[63]. The situation reported in the chemicals Fitness Check reflects the amount of resources needed at Member State level – in terms of staff as well as expert capacity - for preparing a classification dossier, combined with reductions in resources and budgets allocated for this work. Considerable variation exists between Member States in their capacity and willingness to initiate harmonised classification

[57] According to the chemicals Fitness Check, hospitalisation costs amount from €960 to €15,600 for severe accidents.
[58] Currently 252,500 – 637,500 mixtures are not notified; assessments how much such legal ambiguities would affect competitiveness is not known.
[59] Regulation (EC) No 1107/2009.
[60] Regulation (EU) No 528/2012.
[61] such as the World Health Organisation (WHO) definition for EDs
[62] For example, there are 22,930 registered substances in 101,787 dossiers and 212,425 notified substances in the Classification and Labelling Inventory.
[63] Manufacturers, importers and downstream users are also entitled to submit harmonised classification and labelling dossiers in certain cases.

dossiers, with just about half of them carrying most of the burden[64]. It is also understood that the committee[65] assessing proposed harmonised classification currently operates at its maximum capacity, with some 60 opinions delivered per year (see Annex 10). Interviewed stakeholders respondents also noted the lack of a prioritisation of substances for classification and some competent authorities highlighted the lack of adequate resources in ECHA for classification processes.

The main weaknesses of the **self-classification** processes relate to its capacity to ensure convergent and updated information on the substances self-classified by industry and included in the CLP inventory maintained by ECHA. The divergence seems to be due to different elements intrinsic to the process. First, there is currently no legal requirement for notifiers to come to an agreement on self-classifications, only an obligation to 'make every effort'. The lack of transparency in the CLP inventory regarding the identity of notifiers also prevents communication between notifiers of the same substance, creating an additional barrier[66]. ECHA has recognised the issue of incorrect, diverging, or obsolete information in the inventory for some time[67] and has developed a process to encourage notifiers to communicate with one another in an effort to increase convergence. Although the process[68] has helped to improve the correctness of information in the inventory, there are hardly any incentives for agreeing on classifications after notifications are submitted to the inventory.

Finally, diverging **reference values** for a substance come from the absence of a harmonised methodology[69] or different toxicity data sets (see Annex 9). For the purpose of harmonising the safety assessment of chemicals, including methodologies and reference values, the Chemicals Strategy for Sustainability also envisages a 'One substance, one assessment' process (see also baseline in 5.1.).

2.2.3 Complexity of some labelling provisions

The chemicals Fitness Check shows that the complexity of the CLP labelling rules results in unsatisfactory implementation by companies, in particular SMEs, as well as high level of non-compliance on labelling.[70] The general labelling requirements can become even more complex when multiple pieces of legislation apply. In addition, there are some exemptions from the CLP labelling rules due to the practical constraints triggered by e.g. the size, shape or type of the packaging which can also induce complexity and have proven difficult to apply in practice. This complexity is also reflected in the relatively high level of non-compliance with CLP labelling requirements, which was found to range from 33.5% to 71%[71],[72] in particular for chemicals placed

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[64] ECHA, Transparent progress in addressing substances of concern. Integrated Regulatory Strategy annual report, 2021.

[65] The Risk Assessment Committee is composed of 45 experts from Member States and 5 co-opted ones appointing *intuitu personae*. They perform amongst other tasks the EU peer-review of proposed harmonised classification.

[66] CARACAL Document CA/77/2020 described ways to improve and re-design the CLP inventory to address some of the difficulties faced by the notifiers.

[67] ECHA, C&L inventory: convergence in self-classification ppt. CARACAL – 17 - 26th March 2015, 2015.

[68] ECHA, How to prepare a classification and labelling notification, October 2021

[69] Such as Derived No-Effect Levels (DNELs) or Predicted No–Effect Concentrations (PNECs). Diverging human and environmental reference values, have been identified in different REACH registration dossiers for a substance.

[70] Implementation complexity includes the specific labelling derogations applicable to certain products laid down in section 1.3. of Annex I of CLP.

[71] ECHA, REF-6 project report - Classification and labelling of mixtures, 2019.

[72] ECHA REF-8 project report on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online, 2021.

on the market for refill (e.g., detergents), or chemicals with very small packaging (e.g., pens), or sold in bulk to consumers (e.g., fuel at filling stations)[8].

2.2.4 Current labelling rules do not sufficiently exploit new digital tools

Since the entry into force of the CLP, digitalisation has led to the development of new labelling technologies which are not adequately captured by the current scope of the regulatory framework. The chemicals Fitness check already pointed out that the existing CLP provisions and requirements on labelling do not consider the opportunities offered by digitalisation, which could help reach consumers more effectively and reduce compliance costs for companies[73]. In particular, no mention is made in CLP of the possibility to use digital labelling solutions to improve hazard communication and other relevant pieces of information to users of chemicals (see Annex 13).

2.2.5 Rules are inadequate to keep pace with new sales channels

CLP has not sufficiently been adapted to some current societal and technological trends such as the increase in online sales (see 2.1.3). CLP does not apply to non-EU based economic actors, who can today more easily than in the past reach and sell directly to consumers in the EU. CLP does not consider situations in which consumers become *de facto* and *de jure* importers as they buy online directly from non-EU economic operators. In addition, the CLP is very ambiguous about online offers, online advertisements, the obligation to display labelling information in online offers and to mention certain hazard information (see Annex 15).

2.2.6 Unclear provisions on notifications to poison centres

CLP provides the obligation to downstream users and importers to submit relevant information for emergency health response – but not to distributors or any other suppliers placing mixtures on the market. This loophole leads to information loss for poison centres in two cases. Firstly, in the case of cross-border distribution within the EU: if a distributor purchases a product in one Member State and sells it in another, e.g., in the cases of intra-EU trade (no imports from outside the EU involved). Secondly, in the case of re-branding/re-labelling: if the original supplier or a downstream supplier places the mixture on the market in the same Member State but then re-brands or re-labels it[74]. Consulted stakeholders raised the issue of diverging interpretations of duty holders who are obliged to submit poison centres notifications. An ad-hoc meeting of the expert group of Competent Authorities for REACH and CLP also highlighted these differences[75].

2.3 How likely is the problem to persist?

Without any policy intervention (soft or hard law measures), the problems will subsist or worsen, especially in light of current trends in the production and consumption of chemicals and products (see also section 5.1.3).

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[73] SWD(2019) 199.

[74] E.g., the estimation of currently not notified mixtures falling under those two scenarios is between 101,000 - 255,000.

[75] The appointed bodies of four Member States agreed that there should be greater clarity on the inclusion of re-branders/re-labellers and (other) distributors. However, the appointed bodies of other three Member States stated that they already consider re-branders/re-labellers as downstream users whereas other Member States apply the proposed interpretation of ECHA that distributors should comply with and in certain cases notify by virtue of Art. 4(10) so that in practice the problem is solved. Ad-hoc Meeting of the CAs for the REACH and CLP Regulations (CARACAL) on Annex VIII. Available at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/9872d680-66c6-4f01-ba97-942980734fb0/details

2.3.1 Hazardous chemicals are not comprehensively identified and classified

Without policy intervention, the **identification of EDs, PBT/vPvB** will continue to be done differently across plant protection and biocidal products legislation, and REACH. It is also likely that Member States will address concerns from emerging hazards individually. PBT/vPvB, PMT/vPvM, and ED substances will continue to be identified under REACH on a case-by-case basis[76]. However, the pace of identification will remain largely dependent on the resources allocated for the process to identify substances of very high concern, and on the follow up processes to fill information gaps which can often take up to several years[77]. A systematic assessment of PBT/vPvB will be limited to substances above 10 tonnes/year under REACH representing only 50% of the registered substances[78] and only 5% of the substances notified in the CLP classification and labelling inventory. At the end of 2020, there were around 1,860 substances of potential concern needing further data generation, an increase of approximately 20% compared to 2019.

The number of chemicals identified as needing a (revision of their) **harmonised classification** increased over the last years[79]. The trend is expected to continue (see Annex 10) following more thorough checks by ECHA and the rolling out of other actions under the Chemicals Strategy for Sustainability, such as more knowledge being generated on registered substances.

Furthermore, other future actions identified in the European Green Deal and the Chemicals Strategy for Sustainability will trigger additional regulatory actions and risk management measures for critically hazardous chemicals in downstream regulations. Such measures would be based on harmonised classification. Moreover, the number of diverging self-classifications is also likely to persist and even increase due to the addition of new hazard classes.

2.3.2 Sub-optimal communication on chemical hazards

Problems related to complex and **impractical labelling requirements**, will remain very significant at EU level or get worse. Although appropriate guidance how to implement those provisions in the CLP already exists[80], it will not entirely solve the problem. For example, by 2040 it is expected that the market for **refill chemicals** will increase up to over 265,000 t/year and that between 6.62 and 66.2 million purchases of refill chemicals may happen without appropriate labelling in the absence of policy intervention. Also, labelling issues with chemicals placed on the market in **very small packaging** (e.g. writing instruments, lighters, essential oils) are expected to remain due to an estimated slight increase of the number of those products placed on the market by 2040[81]. The trend of consumers wanting to know the environmental impact of chemicals is also expected to continue, as part of the overall megatrends on consumers' willingness in making more **informed sustainable purchase choices**[82]. Moreover, digitalisation trends will continue and expand and the problem of CLP not keeping adequate pace with technological solutions will aggregate and CLP risks of missing out on remaining key instrument for consumers to make informed choices.

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[76] Via substances of very high concern (SVHC) identification.

[77] ECHA, *Transparent progress in addressing substances of concern. Integrated Regulatory Strategy annual report*, 2021, pp.17-19.

[78] See ECHA statistics on registration: 58c2d7bd-2173-4cb9-eb3b-a6bc14a6754b (europa.eu)

[79] This number has been multiplied by 7 between 2018 and 2021.

[80] ECHA guidance on labelling and packaging was first issued in 2011 and revised several times.

[81] Those products are broadly commercialized and purchased in EU: between about 734 to 898 billion units are placed on the EU market every year. See Annex 12.

[82] Supporting policy with scientific evidence, Megatrends, Consumers wish to be increasingly aware of the environmental performance of the products they buy; see megatrends in sustainable consumption.

2.3.3 High level of non-compliance

In future, safety of chemicals purchased online will be positively affected by new EU legislation related to product safety, market surveillance, digital services and customs (see baseline 5.1.). The Digital Services Act[83] and the General Product Safety Regulation[84] will significantly help solving implementation or compliance problems on online sales related issues. They will, however, not entirely solve issues of legal gaps or ambiguities specifically within CLP, especially when the proportion of online sales and imported products is increasing (see baseline in 5.1.) and the resources allocated by Member States for enforcement activities are not expected to increase substantially.

For poison centres, the problem will slightly increase given that distributors are expected to sell more across EU borders, and hence also re-branding. Due to legal ambiguities in CLP, some distributors will continue arguing that the currently applicable provisions do not oblige them to notify in certain cases where information to poison centres would be paramount.

3 WHY SHOULD THE EU ACT?

3.1 Legal basis

The EU has the right to act and maintains the same legal base in the revision as for the adoption of the original act, Article 114 of the Treaty on the Functioning of the European Union (TFEU). This revision entails further harmonisation of the internal market in the field of classification, labelling and packaging of chemicals and will take as a basis a high level of health, safety, environmental, and consumer protection. This revision takes into account other relevant provisions of the TFEU, i.e. Titles XIV on Public Health, XV on Consumer Protection and XX on Environment.

Following Article 4(2) TFEU, the EU has shared competence in the policy areas of internal market, environment, consumer protection and common safety concerns in public health matters. Therefore, the subsidiarity principle applies. The EU's compliance with the subsidiarity principle is ensured by explaining why Union action is necessary and Member States' actions are not enough to achieve the set objectives, and through following the procedure under Protocol No 2 of the TFEU by consulting national Parliaments widely.

3.2 Subsidiarity: Necessity of EU action

Measures at Union level to further improve classification, labelling and packaging of chemicals are necessary and relevant to improve the achievement of the main objectives in the CLP Regulation: ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and certain articles.

Action at Member States' level or at a more local level to achieve those objectives is not enough 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

[83] Proposal for a Regulation on a Single Market for Digital Services, COM(2020) 825 final.
[84] Proposal for a Regulation on general product safety, COM(2021) 346 final.

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 (see list above), so that EU action addresses the problem drivers best;
- Certain Member States have already initiated national actions to fix missing hazard classes before awaiting 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 providing for the general principle that Member States shall not exercise their competence if the Union did already (subsidiarity principle and TFEU on the approximation of laws[85]). EU action would hence make the overall system more coherent.

3.3 Subsidiarity: 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[8]. EU action would aim at addressing the shortcomings of an already existing framework which will help achieving the objectives of CLP.

4 OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1 General objectives

The general objective of this initiative 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. This initiative also aims at modernising and simplifying the classification and labelling of hazardous chemicals - where this is feasible, e.g., through the opportunities offered by digitalisation, and at eliminating unnecessary burdens (especially for SMEs) without undermining the objectives and benefits of the legislation.

4.2 Specific objectives

The initiative should achieve, at the end of the 20-year period considered to identify the impacts, three specific objectives detailed below linked to the three problems and their respective drivers:

4.2.1 Ensure that chemicals are classified adequately and in line with the severity of their hazards

The first specific objective is to ensure that all chemical hazards are adequately identified and characterised, through both harmonised classification and self-classification as well as through the harmonisation of reference values. This would also allow streamlining hazard assessments currently performed in other legislation[86]. In particular, this initiative would aim at:

[85] Article 2(2) TFEU.
[86] like the Biocidal Product Regulation and the Plant Protection Products Regulation.

- Ensuring comprehensive identification and classification of EDs, PBT/vPvB, PMT/vPvM substances and mixtures containing them;
- Increasing the number of substances with harmonised classification by 1/3[87];
- Improving self-classification and the CLP classification and labelling inventory to achieve agreed self-classification per substances, freeing the harmonised classification process for substances with critical hazards and reducing the need to solve divergence via a harmonised classification;
- Developing a scheme to harmonise and publish harmonised reference values for industrial chemicals, where divergence is identified. CLP would not only cover hazard identification but also hazard characterisation (see Figure 1: Mapping of the pieces of legislation according to the different steps of hazard and risk assessments).

4.2.2 Ensure comprehensive and comprehensible communication on chemical hazards

The second specific objective is to ensure that information on hazardous chemicals placed on the market is communicated to all market actors, in particular consumers, in a comprehensive and comprehensible manner. This also includes the related objective of increasing consumer understanding of CLP labels and, therefore, their awareness of the potential dangers of hazardous chemicals and of the safety precautions to be followed. The achievement of this objective would be measured by an increase of the percentage of EU citizens feeling well informed through CLP labelling on the dangers of hazardous chemicals.

4.2.3 Address main legal gaps and ambiguities of CLP rules

The third specific objective is to ensure that all businesses fully apply CLP rules, in particular where there is evidence on high non-compliance at the moment. This specifically concerns ensuring that CLP labelling is shown in online offers and online advertising – including B2C online (offers and) sales of chemicals – and ensuring that businesses submit the required emergency health response information to poison centres.

The achievement of these objectives would be measured by:

- The reduction of non-compliance rates on online advertising and offering of chemicals;
- The reduction of the relative non-compliance rate between non-EU and EU sellers;
- The reduction of the overall non-compliance rate for all online sales;
- An increased number of correct emergency health submissions to the poison centres.

5 WHAT ARE THE AVAILABLE POLICY OPTIONS?

Table 3 presents an overview of the intervention logic, highlighting the link between identified problems and drivers and suggested specific objectives and policy options.

[87] This would cover both new harmonised classifications and updated ones.

Table 3: Overview of the policy options and their link to identified problems and drivers			
Problems	**Drivers**	**Specific objectives**	**Policy options**
Hazardous chemicals are not comprehensively identified and classified	D1. Missing provisions for identification of critical hazards	1. Ensure chemicals are classified adequately and in line with the severity of their hazards	PO1a: New hazard classes
			PO1b: Consistent self-classification and improving transparency
	D2. Inefficient procedures for hazard assessment and classification		PO1c: More and prioritised harmonised classifications
			PO1d: Complementing hazard identification with hazard quantification
Sub-optimal communication on chemical hazards	D3. Complexity of some labelling provisions	2. Ensure comprehensive and comprehensible labelling on chemical hazards	PO2a: Update/prepare guidance
	D4. Some chemicals are not labelled according to CLP		PO2b: Improving and making more flexible existing labels
	D5. Current labelling rules do not sufficiently exploit new digital tools		PO2c: Digital labelling
High level of non-compliance (online sales and poison centres)	D6. Rules are inadequate to keep pace with new means of sale	3. Addressing main legal gaps and ambiguities	PO3a: Awareness campaigns
			PO3b: Provisions and clear responsibilities for online sales and imports
	D7. Unclear provisions on notifications to poison centres		PO3c: Clarifying provisions for notifications to poison centres

5.1 What is the baseline from which options are assessed?

The baseline includes a brief description of the wider socioeconomic context, the evolution of the macro-aggregates of the EU chemical industry and the assumptions on the continuation of the existing legal framework and scope. A 20-year period (2023-2042) is considered adequate for the projections under the baseline scenario and the impact assessment of the proposed options. Its length has been decided in consideration of the expected time-span for the realisation of impacts, especially for some adverse effects which only materialised in the (absence of) progeniture of parents exposed to hazardous chemicals.

5.1.1 Socioeconomic context

Although growth in 2022 is set to be better than previously forecast, the outlook for 2023 is significantly weaker for growth and higher for inflation compared to the European Commission's Summer interim Forecast. Amid elevated uncertainty, high energy price pressures, erosion of households' purchasing power, a weaker external environment and tighter financing conditions are expected to tip the EU, the euro area and most Member States into recession in the last quarter of the year. Still, the potent momentum from 2021 and strong growth in the first half of the year are set to lift real GDP growth in 2022 as a whole to 3.3% in the EU (3.2% in the euro area) - well above the 2.7% projected in the Summer Interim Forecast. As inflation erodes households' disposable incomes, the contraction of economic activity is set to continue in the first quarter of

2023. Growth is expected to return to Europe in spring, as inflation gradually relaxes. However, economic activity is set to be subdued, with GDP growth reaching 0.3% in 2023 as a whole in both the EU and the euro area. By 2024, economic growth is forecast to progressively regain traction, averaging 1.6% in the EU and 1.5% in the euro area. The OECD long-term projections forecast the GDP of the Euro Area (17 countries) to pass from USD_{2015} 13.97 billion (EUR_{2015} 12.59 billion) in 2020 to USD_{2015} 18.65 billion (EUR_{2015} 16.81 billion) in 2040 (33.5% growth)[88,89]. There are signs that this might be impacted by the Russian war in Ukraine and that this could lead to an inflation increase, but figures are still uncertain.

On the social dimension, the **EU27's population** is projected to increase from 447.7 million in 2020 and peak to 449.3 million in 2026, then gradually decrease to 446.8 million in 2040[88]. Both the size and the proportion of older people in the total population are expected to increase[89], with the share of the elderly (65 years and over) projected to grow from 21% in 2020 to 27% in 2040. Increasing demographic imbalances[90], such as the ageing population, pose challenges for public expenditure in relation to pensions, health care and long-term care costs.

At the same time, **the acceleration of technological change and hyperconnectivity** will also have a strong influence on all aspects of human life in the next decades. The fifth generation of mobile connectivity (5G), edge computing, next-generation batteries, precision sensors and quantum computing will enable innovation, in particular towards human augmentation[91]. This will empower consumers to be better informed when they purchase or use hazardous chemicals thanks to, for example, easier, faster, and more tailored information.

Finally, at the European but also global scale, **climate change[92] and environmental degradation[93]** are affecting human activities at multiple levels: degraded ecosystems are not longer able to provide the services on which human life depend, such as food, availability of clean water[94].

5.1.2 The chemical industry

In 2020, the EU chemical production dropped by 1.9% compared to 2019 levels, but it is expected to bounce back in 2021 (expected growth of 3%) and 2022 (2% growth). The long-term response of the industry to the economic impacts of the COVID-19 pandemic remains uncertain. The EU share of global sales continue to decrease (from 19.3% in 2010 to 14.4% in 2020, and projected to be 10.5% in 2030), but the global chemicals market is expected to keep growing markedly (from €3.5 trillion in 2020 to €6.2 trillion in 2030) resulting in an absolute growth of EU sales between 2020 and 2030 of around 30% (from €499.1 billion to €651 billion). The industry spent €9.4 billion in

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[88] Eurostat, Population on 1st January by age, sex and type of projection, 2021.
[89] Eurostat, Population Projections in the EU, 2020.
[90] Supporting policy with scientific evidence, Megatrends, Consumers wish to be increasingly aware of the environmental performance of the products they buy; see megatrends in sustainable consumption (one of the 14 'long-term global driving forces that are observable in the present and are likely to continue to have a significant influence for a few decades' — monitored by the European Commission for foresight exercises. The other 13 are: accelerating technological change and hyperconnectivity, aggravating resource scarcity, changing nature of work, changing security paradigm, climate change and environmental degradation, continuing urbanisation, diversification of education and learning, widening inequalities, expanding influence of East and South, growing consumption, increasing demographic imbalances, increasing influence of new governing systems, increasing significant migration, shifting health challenges.
[91] Gartner, Human Augmentation, 'Cognitive and physical improvements as an integral part of the human body'.
[92] IPCC, 2022: Summary for Policymakers [H.-O. Pörtner, D.C. Roberts, E.S. Poloczanska, K. Mintenbeck, M. Tignor, A. Alegría, M. Craig, S. Langsdorf, S. Löschke, V. Möller, A. Okem (eds.)]. In: Climate Change 2022: Impacts, Adaptation, and Vulnerability.
[93] EEA Report No 21/2019: Healthy environment, healthy lives.
[94] EEA Report No 1/2020: Is Europe living within the limits of our planet?

research and innovation (around 7.4% of added value). The sector included around 57,000 companies contributing roughly to €309 billion in Gross Added Value and employing over 1.6 million people. Chemicals are used in all aspects of modern life, and virtually all manufacturing sectors and many downstream sectors rely on chemical products, from agriculture to automotive and aerospace. The industry generates over 3.6 million indirect jobs. SMEs account for 96.7% of the number of enterprises in the chemical manufacturing sector and 16.1% of the total turnover[95].

5.1.3 Continuation of the existing legal framework and scope

As mentioned in section 2.3, the problems that have been identified are assumed to remain, if CLP were to remain as it currently stands. On-going actions considered under the baseline include updating existing guidance documents (e.g., on poison centres), improving IT platforms (e.g., IT tools by ECHA on self-classification), encouraging voluntary improvements of the current processes (e.g., to promote convergence of self-classifications) and enhancing market surveillance (e.g. through ECHA Forum on enforcement). In addition, the following assumptions were adopted to define the baseline (more details are provided in Annex 7):

Identification and classification of chemical hazards: Table 4 below summarises the estimated number of substances and mixtures with ED, PBT/vPvB, PMT/vPvM properties that would be identified by REACH or pesticide or biocide regulations via an ad hoc assessment performed by competent authorities under the baseline. Discussions have started to complement REACH information requirements in the area of endocrine disruption, broadening the amount of data available to authorities, onto which CLP-classification would be based. Under REACH, this would allow identifying more EDs as substances of very high concern (see section 5.1.4). The same happens for PMT and vPvM substances[96].

Table 4: Estimated number of substances and mixtures with ED, PBT/vPvB, PMT/vPvM properties that would be identified under the baseline

	2022	2032	2042
Number of substances*			
ED	13	210	290
PBT/vPvB	15	210	310
PMT/vPvM	7	70	110
Total	35	490	710
Number of mixtures**			
ED	100 – 300	2,300 – 5,100	3,200 – 7,300
PBT/vPvB	200 – 400	2,400 – 5,300	3,400 – 7,700
PMT/vPvM	100 – 200	700 – 1,700	1,200 – 2,700
Total	400 – 900	5,300 – 12,200	7,800 – 17,700

*Notes: *rounded to the nearest tens; **rounded to the nearest hundreds. As of March 2022, only 13 EDs, 15 PBT/vPvB and 7 PMT/vPvM SVHCs are still registered, and therefore on the market.*

Hazard classification: The systematic and comprehensive identification and classification of EDs, PBT/vPvB, PMT/vPvM imposed by the introduction of those hazard classes in CLP would increase the number of identified substances and mixtures having ED, PBT/vPvB or PMT/vPvM properties. The table below presents the estimate of the number of substances with harmonised classification that could be expected in 2032 and 2042 without the new hazard classes. Plant protection and biocide active substances would represent the largest share (see Annex 10):

[95] Eurostat, PRODCOM, 2021

[96] M. Neumann and I. Schliebner, Protecting the sources of our drinking water: The criteria for identifying persistent, mobile and toxic (PMT) substances and very persistent and very mobile (vPvM) substances under EU Regulation REACH (EC) No 1907/2006, Text 127/2019, Umweltbundesamt, 2019.

Table 5: Estimates of the number of harmonised classification and labelling substances in 2032 and 2042			
	2022	**2032**	**2042**
Linear forecast	4,385	4,450*	4,600*
Note: Value rounded to the nearest fifties			

On self-classifications, divergence currently affects around 22% of notified substances. Also, 69% of notifications diverge, but this figure is reduced to 23% once the agreement within group notifications – where one company notifies on behalf of others - is taken into account. The situation is believed to stay the same over the period under consideration. To be also noted that ECHA and the European Commission initiated a redesign of the CLP classification and labelling inventory in 2019 (see Annex 11), with the aim to improve how data are displayed, structured and overall improve its ease of use. The re-design is expected to be launched by 2023 but, although it is expected to increase transparency, it will not directly address the drivers of diverging classifications.

Types of chemicals with (most) labelling issues: Chemicals placed on the market for **self-refill** (mostly detergents and home care products) account for about 179,000 t/year and they are estimated to concern a range of 8.95 million to 89.5 million individual sales per year. By 2040 it is expected that this practice will increase up to over 265,000 t/year accounting for about 13.25 million to 132.5 million individual sales per year for self-refill chemicals. Chemicals placed on the market **in bulk** concern mostly fuel for transportation purposes purchased at fuel stations. Currently over 235,578 Kt per year of fuel are placed on the EU market. By 2040, this is expected to decrease to less than 100,000 Kt per year (due mostly to the development of electric cars). For chemicals placed on the market in **very small packaging** (e.g. writing instruments, lighters, essential oils), between about 734 to 898 billion units are placed on the EU market every year. By 2040, this number is expected to slightly increase, with an estimate from 367 up to 449 billion units.

Online sales: Online sales and their revenues are fast increasing year by year[97]. Based on estimations for 2021, instances of non-compliance related to chemicals sold online are high both for EU and non-EU sales, but relatively higher for non-EU sales[98]. Based on estimations, 16.6 million out of 111 million (EU sales), compared to 7.3 million out of 32.4 million (non-EU sales) of cleaning products or personal hygiene products were not CLP compliant in 2021[99]. Horizontal ongoing EU initiatives – i.e. the proposal for the Digital Services Act[100], draft General Product Safety Regulation[101], together with the Market Surveillance Regulation[102], and Consumer Rights Directive[103] - will partially address some of the problems. Therefore, the baseline is dynamic and non-compliance rates may decrease in the years to come, but the decrease is difficult to estimate.

Poison centres: the baseline is the currently applicable regulatory framework, i.e., obligations for duty holders[104] and clarifications of those obligations enshrined in ECHA guidance. Based on estimates, intra-EU distributors place between 220,000 – 560,000 products per year on another Member State's market and re-branders/re-labellers place between 32,500 and 77,500 products on their Member State's market, which amounts to a total between 252,500 – 637,500 cross-border or

[97] See Annex 13 and section 2.1.3.
[98] 1.37 times higher, see Annex 13.
[99] Annex 13.
[100] Proposal for a Regulation on a Single Market for Digital Services, COM(2020) 825 final.
[101] Proposal for a Regulation on general product safety, COM(2021) 346 final.
[102] Regulation 2019/1020, OJ L 169, p. 1.
[103] Directive 2011/83/EU, OJ L 304, p. 64.
[104] Obligations by downstream users and importers as per Article 45, by distributers and other supplier types as per Article 4(10)

re-branded/re-labelled distributed products. Based on estimates, 50% of those products are currently notified thanks to distributors adhering to other CLP provisions[105]. It can be assumed as well that not all distributors change their product portfolio each year, so that the number of non-notified mixtures is smaller than the 50% left.

5.1.4 Other policy developments

Several policy developments in interconnected areas and legislation will influence the evolution of the problem, making it in some cases more pronounced, while in others contributing to address it through complementary measures:

- The ongoing **revisions of REACH and product legislation** (e.g., cosmetics, toys, food contact materials): on the side of data available which classification processes could use, REACH is assessing a possible extension of data requirements for ED identification and for substances placed in lower volumes. This means more information on ED hazard will be available for adequate classification during the period considered in this impact assessment. On the side of risk management, REACH and product legislation are under revision to adapt their generic risk management which relies on harmonised classification as a starting basis. Some legislation based on pre-market authorisations may also depend on harmonised classification in the way plant protection products and biocides legislation do. Those revisions will very likely increase the reliance on harmonised classification for the most critical hazards, so that appropriate risk management measures can be adopted[106].
- The **'One substance, one assessment' process** launched by the Chemicals Strategy for Sustainability is providing a platform to improve harmonisation and ensure transparency of the safety assessments of chemicals, including through a new horizontal legal proposal on the transparency of chemical data and a common open data platform, including for reference values. More data will be available to foster accurate harmonised and self-classifications under CLP. Setting up CLP as the recipient for reference values would also harmonise this step across regulations (see section 4.2.1 and Annex 5). Even if multiple sectorial methodologies may still coexist, this would embody the part 'one substance, 'one *hazard* assessment' of this process.
- A number of policy initiatives coming from the European Green Deal will ensure that **consumers have access to updated information** on the impact of consumer products on human health and/or the environment. The Commission proposal for Ecodesign for Sustainable Products Regulation[107] introduces provisions to regulate consumer products on a number of sustainability dimensions. The proposal also improves the provision of **product information via digital tools,** in particular by a **Digital Product Passport** that will gather data on a product and its value chain. This Passport is particularly relevant for the introduction of digital labelling because it foresees the mandatory adoption of digital ways of communicating product information. However, chemical safety is excluded from the scope of this proposal. This means CLP should address the digitalisation of hazard communication for chemicals. This would improve the efficiency of such communication and adjust CLP to technological and societal changes.

[105] Article 4(10) of CLP. See Annex 16.
[106] Under CLP, the decision to classify a substance or a mixture is exclusively based on existing available information. The need to generate any additional data requirements is regulated by REACH. Any impacts arising from that situation will be assessed in the context of the revision of REACH.
[107] Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM(2022) 142 final.

- The on-going **revision of the General Product Safety Directive**[108] and the proposal for the **Digital Services Act**[109] are part of the baseline for this impact assessment, as well as with already applicable new pieces of legislation such as the Market Surveillance Regulation[110] or the Consumer Rights Directive on distance contracts[111]. These horizontal initiatives and regulations will help addressing ambiguities related to online sales, but not solve the problem outlined above entirely. Provisions on online marketplaces in draft General Product Safety Regulation will apply to CLP and will help consumers to make informed choices when they purchase chemicals online. However, the measures on mandatory economic actor in the EU responsible for compliance, already introduced by Market Surveillance Regulation and proposed by draft General Product Safety Regulation, do not cover CLP, hence will not solve the problem of chemicals being sold directly to consumers from outside EU via online sales. Therefore, it would be for CLP itself to address the problem of ensuring chemicals sold from outside the EU are safe.
- On **enforcement and compliance of chemicals and products legislation**, the revision of REACH is looking into ways to address shortcomings on a number of aspects related to both CLP and REACH, as enforcement authorities cover in most cases both these two regulations[112]. The REACH revision will look in particular at establishing an Audit Capacity to verify and strengthen the effectiveness of Member States' control systems on chemicals, the role and tasks of ECHA's Forum on enforcement, interlinks on customs-related issues and collaboration with customs authorities.

5.2 Description of the policy options

The policy options have been constructed by selecting from a comprehensive list of potential policy measures based on the evaluations of the existing legislation and on the input received from stakeholders (see Annexes 8 to 16 for more details). These measures were screened[113] to identify those that should be retained for further analysis. The screening process resulted in a **list of 22 measures retained for the impact assessment** (see Table 6). Each measure is mainly relevant for a single problem area/objective. Measures which are of a legislative nature bear a "*".

[108] Proposal for a Regulation on general product safety, COM(2021) 346 final.
[109] Proposal for a Regulation on a Single Market for Digital Services, COM(2020) 825 final.
[110] Regulation 2019/1020, OJ L 169, p. 1.
[111] Directive 2011/83/EU, OJ L 304, p. 64.
[112] https://echa.europa.eu/about-us/who-we-are/enforcement-forum
[113] Screening (see Annex 7) was developed in accordance with Tool #17 of the Better Regulation Toolbox. The longlist of measures were assessed against eight criteria provided there.

Table 6: Retained policy measures (brought forward for the impact assessment)		
Measures	**Description**	**Addressees**
Classification of chemical hazards (Policy Option 1)		
#1 New hazard classes*	Add new hazard classes in CLP for the most critical hazard properties: ED, PBT, vPvB, PMT, vPvM.	Companies to identify, classify and label their ED, PBT, vPvB, PMT, vPvM substances. Companies to update their notification if their substance is identified as ED, PBT, vPvB, PMT, vPvM. Member States or companies to submit harmonised classification and labelling dossiers for the new hazard classes if they justify that there is an interest for the EU.
#2 Prioritise new hazard classes*	Prioritise the new hazard classes (ED, PBT, vPvB, PMT, vPvM) for harmonised classification, considering the new hazard classes are of highest concern (same concern as for substances that are carcinogenic, mutagenic or toxic to reproduction).	Member States competent authorities and/or companies to submit harmonised classification and labelling dossiers for the new hazard classes. ECHA's Risk Assessment Committee to assess the dossier and adopt an opinion to be forwarded to the Commission. Commission to decide after consultation of expert group.
#3 Justified divergences*	Request and make available in ECHA's classification inventory the reasons for diverging notified self-classifications.	Companies to update their notification where necessary. ECHA to modify the CLP classification and labelling inventory to allow for publication of the justification for diverging classifications for a substance and for reviewing notifications.
#4 Transparent notifiers*	Request publication of names of legal persons notifying their self-classifications to ECHA.	ECHA to make notifiers' names public and review confidentiality requests. Companies to make confidentiality requests in justified cases
#5 Swift notification updates*	Require notification of updated self-classifications within a certain deadline after new pieces of evidence is available.	Companies to monitor the availability of new data, update their classifications and notify them to ECHA at the latest 6 months after new data inducing the change become available. Companies re-labelling and modifying safety information provided to users if needed. ECHA to monitor the level of divergence between notified self-classifications.
#6 Regular notification updates *	Require update of all notifications every 2 years.	Companies to update their notification systematically every two years and re-classify/re-label/update their safety information[114] provided to users if need be. ECHA to monitor the level of divergence between notified self-classifications

[114] Safety Data Sheet in line with REACH Annex 2.

#7 Early prioritisation for harmonised classification dossiers	Develop prioritisation criteria[115] and submit harmonised classification and labelling dossiers according to a list drawn from those criteria.	ECHA to use the new hazard classes as additional criteria when screening registered substances. Commission, ECHA and Member States to develop prioritisation criteria (including for new hazard classes) and apply them to substances identified for harmonised classification. Member States to submit harmonised classification and labelling dossiers according to the prioritisation list agreed at the Risk Management and Evaluation platform (RIME+)[116]
#8 EU agreement on prioritised harmonised classification dossiers	Member States to agree on the list of future harmonised classification and labelling dossiers, according to prioritisation criteria.	Commission, ECHA and Member States to develop prioritisation criteria (including for new hazard classes). Member States' competent authorities to review intentions of harmonised classification and labelling dossiers and agree on those meeting the prioritisation criteria.
#9 Commission's mandate for harmonised classification and labelling*	Allow the Commission to initiate and fund more harmonised classification and labelling dossiers, including by a mandate to ECHA.	Commission to identify substances where a harmonised classification and labelling dossier is outstanding. Commission to fund and mandate ECHA and/or to contract out to Member States' agencies and/or consultancies for the development of a harmonised classification and labelling dossier. Commission to submit the harmonised classification and labelling dossier to ECHA.
#10 Harmonised reference values *	CLP to not only provide for hazard identification but also for the setting of toxicity values.	Member States' competent authorities to submit dossiers for harmonised toxicity values. ECHA's Committee for Risk Assessment to assess the dossiers. Commission to decide after consultation of the Committee.

Communication of chemical hazards (Policy Option 2)		
#11 Guidance on labelling	ECHA to update guidance to clarify the applicability of the CLP Regulation and the corresponding rules for chemicals supplied in very small packaging (e.g. pens), to consumers in bulk (e.g. fuels) and via refill of containers (e.g. detergents).	Companies to follow new or revised guidance on labelling.

[115] Criteria laid down in CLP Art. 36 of CLP set a first level of prioritisation based on the type of hazards. There is a need for additional criteria as a high number of substances meet those criteria and a harmonised classification cannot be set for all of them over the considered period.
[116] RiME+ is an informal forum where ECHA and competent authorities from Member States (Risk Management and Evaluation) platform - RiME+ (Risk Management and Evaluation) platform - ECHA (europa.eu)

#12 Improving readability*	The Commission to introduce general provisions for a minimum font size and other provisions to improve the readability of the label.	Companies to relabel accordingly, to apply the mandatory font size if that font size is not yet applied.
#13 Voluntary digital labelling*	Allow some supplemental information to go digital only where their physical availability on the label is not instrumental for the protection of health and the environment. In addition, this measure would create a framework for further digital labelling of this information. Yet, information that is obligatory under GHS would remain on the physical label.	Companies to consider the harmonised requirements in case they wish to digitalise CLP label (on top or instead of the physical CLP label).
#14 Facilitating refill sales through proper labelling and other related requirements*	Provide legal clarity to retailers on the applicable rules for labelling of containers of refill chemicals. To avoid an unacceptable risk for health and the environment (e.g. risks of serious incident during the refill process or later use at home), refill practice would also be limited to less harmful chemicals.	Retailers to comply with the labelling and packaging rules when selling refill products. Refill sales to be limited to less hazardous chemicals.
#15 Facilitating the use of fold-out labels*	Amend labelling provisions to allow for a broader use of fold-out labels or tie-on tags to increase the effectiveness of hazard communication whilst facilitating the free movement of chemicals in the internal market.	Companies allowed using multilingual fold-out labels in more cases.
#16 Labelling exemptions for chemicals sold in bulk to consumers and in very small packaging*	Amend labelling provisions to include a labelling derogation for chemicals sold in bulk to consumers at filling station (labelling on the pump will suffice) and for small packaging (e.g. pens).	Companies to benefit from these exemptions and Member States' competent authorities to take into account the conditions for the application of derogations.

Closing legal gaps and ambiguities (Option 3)		
#17 Rules for online offerings and advertisings*	Amend CLP provisions to make them explicitly apply to online offerings and online advertising and to clarify that labels need to be provided also for online sales.	Online platforms and online traders to comply with online offering and advertising rules in CLP and in line with horizontal EU legislation, which is in place already or currently at draft stage.
#18 Responsible economic	Introduce a responsible economic actor by default for imports of	Non-EU based actors will be able to place chemicals on the market only when a

actor *	non-EU goods.	responsible economic actor in the EU has ensured that these chemicals meet the requirements of CLP. The responsible economic actor would be a supplier, acting in course of a commercial activity (therefore, excluding consumers).
#19 Full notifications to poison centres*	Request suppliers of chemicals to always notify their mixtures to poison centres.	All distributors to notify to poison centres.
#20 Notifications to poison centres by re-branders and re-labellers*	Define the role of re-branders and re-labellers under CLP and oblige them to notify to poison centres.	Re-branders/re-labellers would have to notify to poison centres (whilst cross-border distributors would not have to notify).
#21 Targeted notifications to poison centres*	Suppliers notify their mixtures to poison centres in case of information loss, i.e. cross-border distribution or re-branding/re-labelling.	Distributors (including re-branders/re-labellers) to notify under certain circumstances.
#22 Awareness campaigns on online sales	Periodically run awareness campaigns on the display of labelling elements online.	ECHA or other entities to run such campaigns.

The above individual policy measures retained have been packaged into 3 policy options and (alternative) sub-options which address the three problems and related drivers.

Policy option 1 - Classification of chemical hazards

Policy option 1 (PO1) includes 10 measures, grouped into 4 sub-options, aimed at ensuring comprehensive identification and classification of chemical hazards (see Table 7).

Table 7: PO1 Classification for chemical hazards

Policy options	Drivers addressed by the options
PO1a: New hazard classes (measure #1 New hazard classes) PO1a would introduce new hazard classes in CLP for substances with the most critical hazards: EDs, PBT/vPvBs, PMT/vPvMs.	**D1. Missing provisions for identification of critical hazards** PO1a would allow for a systematic identification of the most critical hazards (across legislation).
PO1b: Consistent self-classification and improving transparency (measures #3 Justified divergences, #4 Transparent notifiers, and #5 Swift notification updates <u>or</u> #6 Automatic updates) PO1b aims at improving companies' self-classification of substances and at introducing stronger incentives and provisions for companies to appropriately classify. Measures #5 and #6 are two different alternatives to ensure timely updates of notifications.	**D2. Inefficient procedures for hazard classification and characterisation** PO1b would improve self-classification processes, focusing on transparency and convergence of self-classifications.
PO1c: More and prioritised harmonised classifications (measures #2 Prioritise new hazard classes, #7 Early prioritisation of harmonised classification <u>or</u> #8 EU agreement on prioritised harmonised classification, #9 Commission mandate for harmonised classification) PO1c aims at boosting the efficiency and effectiveness of harmonised classification processes, including for the most critical hazards. Measures #7 and #8 are alternative options to prioritise future harmonised classifications.	**D2. Inefficient procedures for hazard assessments and classification** PO1c would improve harmonised classification processes by making them faster and more targeted to the most critical hazards.
PO1d: Complementing hazard identification with hazard characterisation (measure #10 Harmonised reference values) PO1d could be complementary to PO1a and PO1b. As part of the vision and process on "One substance, one assessment", CLP would allow for the harmonisation of reference values in order to be able to quantify the toxicity of hazardous substances, to complement the identification of their hazards.	**D2. Inefficient procedures for hazard assessments and classification** PO1d aims to help ensuring that methodologies are made more coherent and to the extent possible, harmonised, in particular to ensure convergence of hazard assessments.

Policy option 2 - Communication of chemical hazards

Policy option 2 includes 6 measures (#11 to #16), grouped into 3 sub-options, aiming at ensuring fully functional communication of chemical hazards (see Table 8).

Table 8: PO2 Communication of chemical hazards

Policy measures	Drivers
PO2a: Update/prepare guidance (measure #11 Guidance on labelling) PO2a would lead to updating and/or developing on refill chemicals, chemicals sold in bulk to consumers, chemicals in very small packaging and on digital labelling.	**D3: Complexity of some labelling provisions** PO2 would aim at supporting companies in addressing the complexity of labelling provisions through clarifying guidance.
PO2b: Improving and making more flexible existing labels (measures #12 Minimum font size Improving readability, #14 Facilitating refill sales through proper labelling and other related requirements, #15 Facilitating the use of fold-out labels, #16 Labelling exemptions for chemicals sold in bulk to consumers and in very small packaging) PO2b aims at simplifying and complementing current labelling requirements through provisions that would improve readability of the labels and clarify the scope of the labelling requirements.	**D3: Complexity of some labelling provisions** Similar to PO2a, PO2a aims at addressing the complexity of the labelling rule, but by clarifying their provisions as well as their scope and facilitating new forms of trade without lowering the level of safety.
PO2c: Digital labelling (measure #13 Voluntary digital labelling) Some supplemental information would go digital only where their physical availability is not instrumental for the protection of health and the environment. In addition, PO2c would create a framework for further digital labelling of this information. Yet, information that is obligatory under GHS would remain on the physical label.	**D5. Current labelling rules do not sufficiently exploit new digital tools** PO2c aims at exploiting the potential of digital labelling while remaining flexible (see discarded measures on mandatory digital labelling).

Policy option 3 - Closing legal gaps and ambiguities of CLP provisions

Policy option 3 includes 7 measures (#17 to #22), grouped into three sub-options, aimed at addressing the legal gaps and ambiguities concerning online sales and poison centre notifications, and therefore improving compliance (see Table 9).

Table 9: PO3 Addressing the main legal gaps and ambiguities

PO3a: Awareness campaigns (#22 Awareness campaigns) PO3a aims at raising consumer awareness on the chemical risks of buying online.	**D6: Rules are inadequate to keep pace with new means of sale** PO3a aims at increasing the awareness of consumers on the risks of buying online sale chemicals which lack hazard information.
PO3b: Provisions and clear responsibilities for online sales and imports (measures #17 Rules for online offerings and advertisings, #18 Responsible economic actor)	**D6: Rules are inadequate to keep pace with new means of sale** PO3b would ensure that CLP rules clearly apply to online sales and imports of chemicals.

PO3b would ensure legal clarity by addressing shortcomings in CLP provisions on online sales.	
PO3c: Clarifying provisions for notifications to poison centres (measures #19 Full notifications to poison centres or #20 Notifications to poison centres by re-branders and re-labellers or #21 Targeted notifications to poison centres) PO3c would ensure legal clarity by addressing shortcomings in CLP provisions on notifications to poison centres. The three measures are alternative ways to provide legal clarity.	**D7. Unclear provisions on notifications to poison centres** PO3c would ensure that poison centres receive updated information also in case of intra-EU distribution and re-branding/re-labelling, so that appropriate health response can be taken for people exposed to hazardous chemicals.

5.3 Options discarded at an early stage

Annex 7 provides the full list of measures that have been considered but discarded and the rationale behind their screening out from further assessment. The justification for the most relevant discarded measures is summarised below:

Await new hazard classes at the international level (UN GHS): several industrial stakeholders were of the view that new hazard classes should be first introduced in GHS, and only after in CLP, in order to ensure a level playing field and global harmonisation of rules. However, the lack of new hazard classes was long identified by scientists and stakeholders as an area where urgent action is needed, and it is one of the high priorities identified in the Chemicals Strategy for Sustainability. The option was discarded on three main grounds: i) GHS is based on a 'building block' system, leaving margins of flexibility to what their parties can require internally; ii) discussions and agreements at UN level are very lengthy processes, and former Commission's and/or EU Member States' suggestions of new hazard classes were not successful. EU legislation and standards on chemicals have traditionally been the driver for higher international standards, including for GHS and the EU criteria for the new hazard classes would be again the starting basis for a global discussion; iii) introducing new classes in CLP before GHS could lead to non-tariff barriers to trade, but, on the basis of modelling from past studies, the impact on international trade was estimated not be significant and that other variables – such as energy prices – are much more relevant. Moreover, from a competitiveness angle, acting at EU level first will strengthen the EU's role as a global front-runner in health and environmental standards, driving the EU industry's leadership in producing and using sustainable chemicals, levelling the playing field, and thereby giving the EU industry a competitive advantage allowing it to increase its global market share for chemicals and safer alternatives.

Digital labelling as full alternative to physical label/mandatory digital labelling: these options were dismissed because of the expected significant costs that they would entail for businesses – SMEs in particular – and for the difficulties of access for groups of EU citizens due to lack of access to digital tools, lack of digital skills and/or lack of internet connection. Those options were also not widely supported by stakeholders, particularly national authorities, as they would deviate from commitments of the EU under GHS.

6 WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

The impacts were assessed for each policy option proposed, and detailed explanation, including on the methodology, is provided in Annexes 8 to 16. In chapters 6 and 7 below and in Annex 3, the impacts have been combined by policy option.

All of the below cost calculations are annual or annualised estimates for a 20-year period, starting in 2023 and taking into account where necessary a discount rate of 3%, unless stated otherwise. When possible, lower-bound and upper-bound costs are provided to picture the uncertainties associated with the estimates provided. Amongst measures under PO1, most of the impacts will trigger costs for SMEs which are expected to be proportionally higher than those of large companies. However, for Classification and Labelling Inventory related measures, SMEs are expected to grasp the benefits of the measure to a greater extent than the large companies.

6.1 Classification of chemical hazards (Policy Option 1)

6.1.1 Economic impacts

6.1.1.1 Administrative costs on businesses and conduct of business and possible benefits on society

Table 10: Summary of cost and benefits of policy option 1a	
Costs - businesses	
Total one-off costs over a 20-year period	x11 (9%-25%)[117]: €587M - €1,253M
PV of one-off costs (20 years; 3%) of which:	x11 (9%-25%): €39M - €84M
- Direct adjustment costs	x11 (9%-25%): €26M - €73M
- Direct administrative costs	x11 (9%-25%): €13M - €11M
- Direct regulatory fees and charges	-
- Indirect costs	x11 (9%-25%): €0.3M - €0.2M
Average cost (PV: 20y; 3%) per person employed (SMEs)	x11 (9%-25%): €4-€9
Average cost (PV: 20y; 3%) per person employed (large enterprises)	x11 (9%-25%): €20-€43
Benefits - Society	
Number of statistical cases to be avoided per substance	x11 (9%-25%): 0.62 – 4.97
Benefits per kg PBT/vPvB or PMT/vPvM to offset PO1 costs	Minimum €0.2 – 0.7

PO1a (New hazard classes) may allow the identification of around 2,320 substances and around 25,520 chemical products containing those substances which would need to be relabelled and/or voluntarily reformulated (see Annex 8). The annual costs for industry would be €39.4 million - €84.2 million[118] over a 20y period. The average administrative burden per person employed per year for a large enterprise is €20.1 while for SMEs is €4 (see Annex 8, especially Table 60 page 172).

[117] 11 mixtures per substance, 9%-25% of substances substituted and 9%-25% of mixtures reformulated.
[118] Based on 11 mixtures per substance and a reformulation rate of, respectively, 9% and 25%.

Without the new hazard criteria being prioritised, there is a risk of an uneven level playing field because of diverging self-classifications amongst manufacturers of the same substances. The changes may temporarily affect EU exports of chemicals classified according to the new hazard classes. The discrepancy with other main global players is expected to last some years, for the development of equivalent UN GHS criteria and their following uptake in the national legislation. This would lead to non-tariff barriers to trade, but, on the basis of modelling from past studies, the impact on international trade was estimated to not be significant and that other variables – such as energy prices – are much more relevant.

The European Chemical Industry Council (Cefic) commissioned a study[119] to document the economic impact of various actions announced in the Chemicals Strategy for Sustainability. The authors concluded that CLP could be responsible for the reduction of 1% of the total potentially affected portfolio, equivalent to around €5.8 billion.[120] However, this figure should be considered as an illustration of the size of the sectors involved rather than an indicator of economic losses,[121] and it is therefore not comparable with the estimates provided in this impact assessment.

Estimating the magnitude of the benefits of the introduction of new hazard classes in CLP and their complete monetary valuation is confounded by a number of problems, including the possibility of estimating the attributable fraction of disease incidence, prevalence and mortality to certain chemical products. Due to the limitation in the availability of data and the large uncertainties surrounding the monetary evaluation of the health and environmental benefits of the policy action, a break-even approach was adopted to weigh up the likely relative advantages and drawbacks: for illustrative purposes, a 'statistical health outcome case' was constructed by aggregating the values of four possible outcomes of EDs' exposure. The value of the statistical case was then compared with the total costs, obtaining the number of statistical cases to be avoided per substance identified. The same approach was used for obtaining the required level of benefits per kg of PBT/vPvB or PMT/vPvM substances withdrawn from the market to offset the total costs of the policy action. The socioeconomic burden associated to EDs' exposure was estimated by different authors as ranging between tens to hundreds of billions of euros per year. Estimates carried out in the context of this study for a subset of four health outcomes — among the over 80 health endpoints which have been associated in the literature to EDs' exposure — put the socioeconomic burden in over €300 million per year. How much of the overall burden can be avoided through the CLP revision is unknown, but considering that the introduction of identification and classification criteria for the new hazard classes is a prerequisite for the delivery of benefits — directly and indirectly through other legislative mechanisms — these estimates suggest that, if all attributable impacts were considered, the benefits are very likely to exceed significantly the costs of the policy option.

PO1b (Consistent self-classification and improving transparency) covers various measures aiming at improving the inventory of notified self-classification. The direct costs of those measures are specific (see Annex 11) but the indirect costs such as relabelling, updating the registry and/or documentation are considered equivalent to other measures. The additional administrative costs would equate to between €3.99 million and €10.1 million with measure #6 included, of which, between €1.50 million and €3.84 million would apply to SMEs. These costs would be reduced to

[119] Ricardo (2021) Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability – Phase 1 Report (ED 14790 – Issue number 1, 18/11/2021)

[120] Information provided by Cefic in response to a request by the European Commission.

[121] A better measure would be the 'value added foregone', since it provides an estimate of the Industry's profits that would have been earned during the loss period would there be no intervention. This estimate can be calculated by subtracting the cost of all inputs except capital and labour from the production value. But even this measure is difficult to take as a proxy of the costs in a cost-benefit analysis or cost-effectiveness analysis, since it is not comparable to compliance costs. Whether the 'value added foregone' is a cost depends on whether the production factors (capital and labour) can be productively re-employed or not.

between €1.96 million and €8.07 million when considering measure #5 as an alternative to measure #6. Only €1.99 million of those costs are one-off ones. Savings from a quicker navigation in the CLP classification and labelling inventory could equate to around €8.7 million (including €2.2 million for SMEs), based on a general improvement. The overall impact of PO1b with measure #5 would be between savings up to €4.97 million and costs of €0.93 million. No quantification of adjustment costs was possible as granular-enough data were missing.

PO1c (More and prioritised harmonised classification) leads to both administrative and adjustment costs (but no specific ones). No robust quantification of adjustment and administrative costs was possible in the absence of sufficiently granular data. These measures may have more impacts on SMEs in relative terms which benefit less from economies of scale and have less capacity to absorb costs.

PO1d (Complementing hazard identification with hazard quantification) would bear no direct administrative costs for industry. However, there may be voluntary updates by REACH registrants, but those adjustment costs are considered outside the scope of this impact assessment.

Table 11: Summary of the economic costs to European businesses (annualised and annual recurrent costs, central estimates, € million, period: 20y)

Policy option	Administrative costs	Adjustment costs
PO1a	13.04 (one-off costs)	26.40 (one-off costs)
PO1b	9.43 (of which, 5.14 are recurrent costs and 4.29 one-off ones)	Existing but not possible to quantify
PO1c	Existing but not possible to quantify	Existing but not possible to quantify
PO1d	(1.00 for authorities)	-

6.1.1.2 Public authorities: Change in costs to the Commission, ECHA and Member States Competent Authorities

PO1a will not entail significant additional costs for ECHA, Member States Competent Authorities and the Commission. Tasks like identification of PBT substances would be moved from REACH, plant protection product and biocide regulations to CLP, mostly leading to reshuffling in resources[122].

Under **PO1b**, as explained in the baseline, ECHA is already reshaping the IT system for improving the CLP classification and labelling inventory, and that could also include an IT screening tool. Manual follow-ups to the IT screening will be needed but it is understood that such resources could be found via internal reallocation and no additional staff for this task would be required. Measure #6 (Regular notification updates) and #3 (Update to justify divergences) would however need additional resources. Lower additional costs are forecasted for measures #4 (Transparent notifiers) and none for #5 (Swift notification updates).

When considering an early prioritisation step informally at EU level (#8 EU agreement on prioritised harmonised classification dossiers), costs of **PO1c** would range from €0.6 million to €1.1 million to the EU budget. The difference in costs lies in the organisation required to develop

[122] e.g. ECHA's PBT expert group or resources in the Member States Committee assigned for PBT identification.

harmonised classification dossiers. The most expensive option — where ECHA is mandated by the Commission to develop CLH dossiers — is factored in. But as each dossier is different, the most cost efficient and qualitative process depends on the substance or group of substances at stake. When it comes to prioritisation, many Member States authorities voiced concerns about the effectiveness of a formal EU decision on intentions for new dossiers. Therefore, the additional costs of this option for competent authorities, ECHA and the Commission are not quantified.

The administrative burden related to **PO1d** (Harmonised reference values) is estimated for Member States at €0.6 million. Costs to ECHA amount to €0.6 million.

6.1.2 Impact on the environment and on human health

There is no comprehensive evidence available to quantify the impacts on human health and the environment of the policy packages of **PO1**. The benefits of all policy packages can however be qualified.

PO1a would allow to identify more than twice the number of substances than currently under REACH or pesticide and biocide regulations. Voluntary substitution of chemicals with the most critical hazard properties (up to 25% of impacted mixtures) would also significantly reduce the exposure of consumers, workers and the environment (see Annex 8). The reduction of the exposure to the self-classified hazardous substances would start earlier, but possibly for a lower number of chemicals than the ones which would fall under harmonised classification, where all manufacturers would apply the same classification. The consequent reduction of the costs of exposure to EDs for the EU public health services cannot be fully monetised. However, proper identification, classification and labelling of EDs, PBTs, vPvBs, PMTs, vPvMs would alleviate part of the ED-related costs of €46 billion per year. Avoiding between 853 and 1,919 ED-related human outcomes between 2023 and 2043 would offset PO1 costs for ED substances. This equates to 0.62 to 4.97 cases/outcomes to be avoided per possible candidate substance (see Annex 8).

A reduction of the emissions of ED, PBT, PMT substances into the environment would decrease the costs of depolluting urban wastewater from micro-pollutants, which currently equal €1.2 billion per year. If the benefits of withdrawing PBT/vPvB and PMT/vPvM substances are €0.7 or above, then PO1a would be justified from an environmental point of view.

PO1b and **PO1c** would enhance the accuracy of hazard information communicated to consumers, professional users and industrial workers, which will lead to their increased protection from hazardous substances and mixtures and ensure they dispose of the chemicals in a safe way. This is expected to have a positive impact on the appropriateness of risk management and waste disposal measures in the workplace, thus leading to improved environmental protection. This would be expected to positively reduce pollution affecting aquatic species, surface and ground water and land contamination. However, this impact would be milder than the one generated by PO1a.

PO1d is not expected to trigger significant direct benefits, as it would be up to sectorial downstream legislation to provide for the uptake of harmonised reference values. However, as an illustrative comparison, the harmonised value for N,N-dimethylformamide solvent determined under REACH was 60% lower than an existing sectorial value. Implementing this harmonised value would contribute to lower the exposure of workers to that solvent, which is classified as toxic to reproduction.

6.1.3 Social impact

Under **PO1a** and **PO1c**, some substances classified according to the new hazard classes (either through self- or harmonised classification) may be voluntarily phased-out by industry from some mixtures, in particular those with consumer uses, and replaced by less hazardous alternatives when possible. The availability of alternatives varies from substance to substance and there is very high uncertainty on the substances that may be classified for the new hazard classes. It is therefore not possible to determine the proportion of substances and mixtures that may be withdrawn from the market because of a lack of alternatives[123].

For **PO1b**, companies with very large substance portfolios may have to increase their number of regulatory staff to accommodate the additional regulatory burden (adjustments to diverging classifications, updates of incorrect classifications). Whilst the estimated costs may not cause discontinuation of business, levels of employment may increase and the impact is expected to be weakly positive. As an example, measure #6 would entail about 20,000 working days over 2023-2040.

No social impact was identified for **PO1d**.

6.1.4 Stakeholders view on PO1

The introduction of new hazard classes was not disputed and generally strongly supported, even if industry clearly indicated their preference to propose them at UN level directly (see discarded options below). It also addresses strong calls from the co-legislators[5,6]. The need to improve self-classification by improving the CLP inventory was shared by the stakeholders in general, though there were diverging views regarding the way to realise those improvements. However, stakeholders rated the measures assessed amongst the most appropriate ones in 2017. Public authorities were not very supportive of measure #6 Automatic updates, doubting that benefits would balance the costs of revamping the inventory. There was mixed feedback from industry side. Measure #3 Justified divergences was agreed on content but views diverged when it comes to its practical feasibility. Regarding measure #4 Transparent notifiers, there were also split views, with reservations regarding confidentiality needs, especially for substances used for research.

The majority of stakeholders welcomed the measures proposed to improve the number of harmonised classification and labelling dossiers (measures #7, #8 and #9). However, all categories of stakeholders pointed that those measures should not add complexity to an already complex system, nor restrain the Member States' right of initiative. Several stakeholders also considered that more resources, specifically at ECHA's level, should be tapped into the classification processes. A minority of stakeholders raised the issue of possible complication when the Commission would disagree with an opinion diverging from the harmonised classification and labelling dossier they would have initiated. Most of stakeholders also believed that CLP is not the right tool for the

[123] Based on the survey of 100 large chemical manufacturers, Ricardo (2021) estimates that businesses may be able to substitute and reformulated one third of the portfolio, in terms of turnover, likely affected by the changes to the CLP Regulation and the extension of the generic approach to risk management. According to Ricardo, for around 10% of the likely affected portfolio it may be possible to apply and obtain derogations, and for 30% of the portfolio, businesses would have to face increased regulatory burden. The remaining 40% is the net reduction of the likely affected portfolio in terms of turnover. Such portfolio reduction may have repercussion in terms of competitiveness and employment levels. However, it is not possible to attribute how much of the reduction would depend on changes to CLP and how much to the extension of the GRA. Moreover, Ricardo (2021) considers more hazard classes than those proposed in PO1a. Finally, it is not possible to triangulate this information. In any case, the figures on 'affected turnover' or 'affected portfolio' provided in Ricardo (2021) should be considered as illustrations of the size of the sectors involved rather than indicators of economic losses (see discussion above).

harmonisation of human and environmental reference values (measure #10). Stakeholders do see with favour, however, the creation of a new framework for harmonised human and environmental reference values.

6.2 Communication of chemical hazards (Policy Option 2)

6.2.1 Economic impact

The business impacts of **PO2a (New or revised guidance)** – drawing from the experience gathered through the six updates already done by ECHA on the CLP guidance - would be low, both in terms of costs as well as expected benefits. In particular, benefits for business are expected to be very limited where legal provisions are unclear or can be interpreted differently.

PO2b (Improving labelling and packaging and making labelling more flexible) is overall expected to reinforce label readability, ensure that packaging is appropriate and provide legal clarity and certainty for economic operators and competent authorities compared to the baseline under which the high non-compliance rate would stay. It would bring limited additional administrative costs for businesses, and to a larger extent to those, mostly SMEs, selling refill chemicals and that are not yet complying with the current rules, for an annualised one-off cost between €23,320 and €40,670[124]. It would also provide recurring savings to industry between €20-59 million per year, because of increased legal certainty and labelling flexibility which would help to reduce compliance costs.

Allowing **digital labelling** through a voluntary scheme, under **PO2c**, would lead to overall positive economic impacts, as it would provide a harmonised and predictable framework, and, therefore, administrative burdens for industry would decrease. Digital labels would also allow business to target consumer groups better, thus offering business opportunities.

Table 12: Summary of PO2 economic costs to European businesses (one-off annualised and annual recurrent costs, central estimates € million, period: 20y)

Policy option	Administrative costs	Adjustment costs
PO2a	Existing but not possible to quantify	-
PO2b	1.72 (of which 1.66 are recurrent costs and 0.06 are one-off ones)	-
PO2c	-	Existing but not possible to quantify

6.2.2 Environment and health impacts

The environmental and health impacts of **PO2a** – drawing from the experience gathered through the six updates already done by ECHA on the CLP guidance – are expected to be low.

The impact of the clarification of labelling provisions for refills under **PO2b** (Improving labelling and making it more flexible) would be positive on public health effects, as consumers would have complete information and could take informed choices for their health and the environment. It is understood that their capacity to understand the labelling of chemicals can only improve with the

[124] This does not take into account the cost of improving the readability.

changes brought under policy option 2. However data available in the supporting study do not allow for a more granular qualification, especially regarding a detailed analysis of consumer behaviour. Refill practices have large environmental benefits for the reuse of packaging and related reduction of resources needed to produce new packaging as well as the consequent reduction in packaging waste. Simplifying labelling and making it more flexible is expected to also have a small positive impact in terms of (reduced) packaging waste. In addition, prohibiting the refill sales of chemicals displaying hazardous properties (such as corrosivity) will limit exposure of consumers and reduce the likelihood of damage to the environment. Improved readability criteria are expected to increase the effectiveness of hazard communication for both human health and environment.

For **PO2c**, additional digital labelling would lead to positive social impacts in terms of increased understanding of chemical labels and effectiveness of hazard communication for both human health and environment. Through more comprehensive communication, it could in particular reduce adverse effects on consumer health stemming from inadequate use of products. As the physical label as it is today will remain mandatory to a large extent, there will be no negative impact for population groups without or with limited access to digital tools or the internet. At the same time, digital labels could have significant positive impacts for vulnerable groups like those with visual or other impairments (e.g. through the aid of read-out-loud digital labels). Digital labels would also allow to integrate additional language versions for those users that are not sufficiently fluent with the official languages of the Member State where they live. Data available in the supporting study or other impact assessment on digitalisation[125] do not unfortunately allow for a more granular qualification.

6.2.3 Stakeholders views on PO2

With regard the PO2, respondents to the open public consultation generally welcomed a broader use of multilingual fold-out labels and introduction of tailored labelling rules where there is insufficient space on the packaging (such as derogations). Most respondents to the open and targeted consultations emphasised the importance of proper arrangement of content on labels – effectively using small packaging space by prioritising visual information, reducing the volume of information on the label, etc. Furthermore, most emphasised the importance of proper CLP labelling for refill chemicals, in particular to ensure that customers get all relevant safety information. Similar concerns were raised in the discussions with the Competent Authorities for REACH and CLP (CARACAL) expert group.

Most stakeholders highlighted the importance and opportunities of digital labelling as innovative means for hazard communication. However, some respondents – including competent authorities - expressed concern on digital labels becoming the only means for hazard communication, as citizens without access to digital technologies or skills would be put in a disadvantaged position. Allowing digital labelling of a very specific set of information is an overall preferred measure by stakeholders, as this would also allow for the necessary simplification, while avoiding digital divides (see more details in Annex 8).

6.3 Addressing main legal gaps and ambiguities (Policy Option 3)

6.3.1 Economic impacts

The costs of **PO3a (awareness campaigns)** are associated with the operation of a consumer awareness campaign on online sales. This could be included within existing campaigns (such as the European Interactive Digital Advertising Alliance) or could be standalone. As the intended target of

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such a campaign would be online consumers, operation of a digital campaign would be the method of choice, making it relatively inexpensive to operate. Assuming €150,000 in staff costs (3 full-time equivalents) and €150,000 for equipment and operational costs would imply costs of around €300,000 per year to the EU budget.

PO3b (Provisions and clear responsibilities for online sales and imports) would not require a change to the physical label or the packaging to which it is attached. Information would need to be included in future online adverts/offerings. The costs of such actions would already be borne by online traders and platforms in order to comply with the General Product Safety Regulation, once adopted. Sellers based outside the EU would have to sell via a new or already established EU based responsible economic actor and are likely to have to pay a commission to that responsible actor. These same costs (to outside sellers) would bring benefits for the newly established responsible economic actors in the EU. Based on estimations, approximately 32.4 million products subject to CLP requirements reach EU consumers from outside the EU (see Annex 15). At a value of €20 for each product (consistent with the €22 VAT free cut-off that applied until July 2021) and a commission of 2%, this equates to an EU benefit of around €12.96 million per year for chemicals subject to CLP. A commission of 5% would equate to benefits to the EU of around €32.4 million per year. Moreover, sellers from outside the EU would have to bear the compliance cost of adhering to the CLP rules and this would level the playing field between sellers from in and outside the EU, with sellers from inside the EU benefitting from the resulting fairness in competition. In particular SMEs relying on online platforms to trade their products would benefit from this adjustment. It was impossible to assess quantitatively how much it costs to comply with CLP rules, or how much the EU-based sellers would gain from enhanced competitiveness. Costs for enforcement authorities would already be partially alleviated by the draft General Product Safety Regulation even if they would have to check on the responsible actors.

Also national enforcement authorities would have costs to check if responsible actors are appointed and goods are indeed sold via the responsible actor. These costs will be much lower if rules for online offerings and savings include a reference to or information on the responsible actor (combination of #17 and #18, full PO3b).

PO3c (Clarifying provisions for notifications to poison centres) covers three mutually exclusive measures that would have moderately to high negative impacts on the administrative burden on businesses (one-off and annualised costs), and neutral to moderate negative impacts on public authorities. Under PO3c, all policy measures are likely to have a positive market impact in levelling the playing field across the EU and in improving human health protection. The kind of impacts are the same, albeit with different magnitudes. Asking all distributors to notify the classification of their mixtures to poison centres raises annualised one-off costs between €1.5 million and €11.4 million. This can be reduced to €0.05 million and €0.4 million if notifications are required only in case of information loss. The last option targeting re-branders and re-labellers would cost between €0.4 million and €3.5 million. The latter would however make the current system more complex by setting up new actors or roles. As part of the portfolio is reformulated every year, recurrent costs would amount to 25% of the one-off costs just described (see also Annex 16). The overall cost can be expected to be less than that of large enterprises, given that SMEs do not distribute cross-border. Also, companies do not have to pay submission fees to poison centres except for three Member States[126].

Costs for enforcement authorities under PO3c will increase in order to carry out compliance checks with the new provisions. Costs for national authorities would be alleviated by ECHA providing a

[126] Belgium, Greece, Italy; ECHA overview table of Annex VIII implementation by Member States.

centralised dispatch mechanism and searchable database to which Member States can have access for free (they would just have to adapt their national IT systems to receive the data). Nevertheless, national authorities could have an increase in costs for poison centres receiving more data and running their systems. Such adaptation of national IT systems is proportionate with the number of notifications.

Table 13: Summary of PO2 economic costs to European businesses (one-off annualised and annual recurrent costs, central estimates € million, period: 20y)

Policy option	Administrative costs	Adjustment costs
PO3a	-	-
PO3b	-	Existing savings but not possible to quantify
PO3c	0.4 (recurring cots)	Existing but not possible to quantify

6.3.2 Social and environmental impacts

Social (human health) and environmental impacts of **PO3a** and **PO3b** are all positive, although the magnitude of the positive impact varies. Those benefits are associated with a reduction of non-compliant products circulating in the EU, either because they were sold intra-EU or imported. The consequence of more compliant products sold online translates into consumers being better informed about the products they use and better management of their hazards, ultimately limiting the risk of accidental exposure of consumers and the environment (less spillage, less emissions, less pollution, safer disposal) to wrongly classified and labelled chemicals[127]. The estimated number of non-compliant items in the EU would be reduced to between 2.4 million and 4 million products per year depending on the measures, and even more considering synergies between those measures (see Annex 15).

Regarding the social impacts of **PO3c**, savings up to €1.12 million are identified as a reduced number of consumers would be harmed by non-compliant chemicals (see Annex 16). From a qualitative point of view, clarifying the scope of obligations under Article 45 of CLP (regarding notification to poison centres) will lead to better and more timely medical advice being given, thus reducing the number and severity of cases of ill health, and instances where overtreatment is given. It has been estimated that on average poison centres receive and treat 600,000 calls per year (almost 1,700 calls per day, mostly related to exposure of children to chemicals) and the number of fatalities related to chemical exposure in the EU is more than 400 per year[128]. No negative or positive environmental impacts are expected from PO3c since Article 45 does not target environmental hazards.

6.3.3 Stakeholders view on PO3

All stakeholders – industry (including SMEs), national authorities, NGOs - unanimously agreed that action is needed to adapt CLP to online sales, to ensure safe purchase and use both for goods originating from in and outside the EU. They stressed that this would further improve consumer and

[127] It was impossible to carry out a quantitative estimation of the benefits of fewer non-compliant chemicals circulating.
[128] Study on the harmonisation of the information to be submitted to Poison Centres, according to Article 45 (4) of the Regulation (EC) No. 1272/2008 (CLP Regulation), DocsRoom - European Commission (europa.eu)

environmental safety and ensure competitiveness between online and traditional sales. 93% of all respondents to the open public consultation shared the need to apply the same rules regardless of the sales' channel, 99% of all respondents agreed that the display of the hazard information is essential when purchasing online and 90% agreed that there is need to have a responsible actor in the EU for chemicals bought online from outside the EU directly reaching the consumer.

Stakeholders also broadly supported measures to solve issues of non-compliance or legal voids in order to improve information provision on hazardous mixtures to poison centres. Industrial stakeholders, whether during the open public consultation or via targeted stakeholders surveys, raised the issue of diverging interpretations by various duty holders, which cause a non-harmonised approach and an uneven level playing field. National authorities similarly commented at a dedicated expert group meeting that the current approach is not uniform.

7 HOW DO THE OPTIONS COMPARE?

7.1 Classification of chemical hazards (Policy Option 1)

The different options are complementary.

PO1a is expected to help achieve a comprehensive identification of hazardous substances, with the extension of CLP to new hazard classes (see Table 14). This will allow increased harmonisation of classification of hazardous chemicals and hence contribute to the objective of a fully harmonised internal market for chemicals. It may temporarily affect EU exports of chemicals as the process to develop equivalent criteria at the international level (UN GHS) and their following uptake in national law will take some years. On the other hand, if and when these criteria will be integrated in the UN GHS, and implemented nationally or regionally, it will allow for a wide harmonisation and related benefits. **PO1b** focuses on available and transparent up-to-date notification and information from notifiers. This would reinforce the level playing field in a dynamic way. Companies such as downstream users often rely on information provided in the CLP classification and labelling inventory on the substances they use to produce their mixture, in order to classify their mixture. **PO1c** completes PO1b by fostering and extending the scope of harmonised classification. It brings additional costs, counterbalanced by additional added values (e.g., more harmonised classification). **PO1d** extends the scope of CLP to hazard assessment. While harmonised human and environmental reference values are useful, CLP cannot provide for their use in other chemical legislation, bringing additional costs and little added value.

The best set of measures comes for the combination of PO1a, PO1b and PO1c. There is no significant added value and almost no support for option PO1d.

7.2 Communication of chemical hazards (Policy Option 2)

The different options are complementary.

PO2a is expected to deliver some benefits in terms of clarifications, especially for topics lacking specific guidance. Guidance is assessed as ineffective in case the legal text lacks clarity (such as on the labelling of online offers or on broader use of fold-out labels). Although ECHA guidance on CLP has been updated several times, some issues are still creating difficulties in terms of implementation and enforcement. Guidance in itself will, therefore, not suffice to address the problem. **PO2b** proposes to strengthen the minimum requirements for hazard communication introducing obligatory formatting rules such as minimum font size or establishing labelling obligations. Those requirements partially would result in increased costs for economic operators and in increased benefits for human health and the environment. Overall, this option results in

positive benefits with medium efficiency. **PO2c** considers measures to simplify the burden of economic operators in terms of hazard communication without compromising current levels of safety. Most of the economic benefits are related to a broader use of multilingual fold-out labels. Overall, this option has a highly positive costs and benefits ratio with a high efficiency. From the comparison of the options, PO2c displays an effective economic, social and environmental impacts and benefit/cost ratio.

7.3 Addressing main legal gaps and ambiguities (Policy Option 3)

Amongst **PO3c** including the mutually exclusive measures #19 (Full notifications to poison centres), #20 (Notifications to poison centres by re-branders and re-labellers) and #21 (Targeted notifications to poison centres), #21 would cater for preventing both cases of information loss without obliging each distributor to notify by default. First the distributor would have to check if a notification is required and only then it would have to notify. To carry out such checks, a good supply chain communication with the upstream supplier(s) is paramount for both (i) alleviating the downstream supplier's burden of notification and (ii) providing poison centres the utmost detailed information (as a last resort, they may end-up with a minimal information set). #19 has more economic impacts on business and administration than #21 and results in the same strongly positive social impact. #20 would have a weakly negative impact on businesses and administration and be better than #21 from an economic impact point of view, but worse from a social impact perspective since it does not cater a solution for cross-border distribution. More, #20 would bring incoherence to the CLP/REACH framework, since it would result in having a definition of re-branders/re-labellers in CLP which is not provided for in REACH, leading to inconsistencies between the two frameworks that should be avoided[129].

Between the alternative options **PO3b and PO3a**, PO3b is more effective and holistic to address problems related to online sales. Clarifying the rules for online offerings and advertisings is more effective than awareness campaigns to make consumers aware about chemical hazards when buying online since it will help ensuring that online traders and platforms abide by their obligations of providing chemical safety information when offering or advertising. Consumers might not remember the content of the awareness campaigns when buying online. Ensuring that there is a responsible economic operator is the only viable measure for ensuring the compliance of chemicals sold from outside EU via online sales with CLP requirements and making that economic actor liable in the EU in cases where imported products directly reach the consumer.

In addressing legal gaps and ambiguities on online sales related matters, PO3b including measures #17 and #18 is the strongest option given that they are more effective and efficient than PO3a.

In addressing legal ambiguities for poison centres, PO3c and measure #21 is the best option.

[129] See recital 12 of CLP advocating for a consistent use of the terms and definitions under REACH and CLP. Based on REACH Guidance for downstream users, re-branders, which are actors who affix their own brand to a product that somebody else has manufacturer, are distributors.

Table 14: Comparison of measures to improve the hazard classification of chemicals (annualised one-costs and annual recurrent ones, € million)								
Options	**Effectiveness**	**Key impacts**			**Benefit/cost ratio**	**Efficiency**	**Coherence**	**Consistency with climate objectives**
		Economic	Social	Environmental				
PO1a New hazard classes	High, more than twice more substances identified compared to the current situation.	Negative: costs for industry between €39.4 and €84.2 million. Possible temporary impact on chemical trade Positive: EU chemical industry at the global forefront for sustainable chemistry	Highly positive, considering the number of identified substances and voluntary substituted mixtures	Highly positive, considering the number of identified substances and voluntary substituted mixtures	High	Medium (without prioritisation of the new hazard classes, see PO1c)	Strong (high level of protection of human health and of the environment)	No inconsistencies. Relabelling (recalling chemicals in the supply chain to label them and shipping them again) may generate some CO2 emissions. Chemicals which are voluntarily substituted may be destroyed, generating some CO2 emissions. A mandatory biennial update may generate some CO2 emissions without added value (see effectiveness) Identification of hazardous substances may slightly contribute to an environment more resilient to climate changes
PO1b Consistent self-classification and improving transparency	Medium (large companies) to very high (SMEs)	Slightly negative to positive: Between a cost €0.93 million and savings up to €4.97 million, mainly for SMEs Improve the level playing field in the internal market for chemicals. SMEs will benefit from this more than larger companies	Slightly positive (as the number of agreed and possibly more accurate self-classifications will increase)	Slightly positive (as the number of agreed and possibly more accurate self-classifications will increase)	High	Medium	Strong (improved internal market),	
PO1c More and prioritised harmonised classification	Low (in case of late prioritisation) to high (in case of early prioritisation)	Negative: costs between €0.75 and 4.71 million euros Fostering the level playing field as harmonised classification applies to all companies of the same substance, whether SMEs or larger companies	Slightly positive to very positive depending on the number of substances with accurate harmonised classification	Slightly positive to very positive depending on the number of substances with accurate harmonised classification	High	High (as building up on increased benefits from self-classification and the new hazard classes)	Strong (harmonisation at EU level)	
PO1d Complementing hazard identification with hazard quantification	Medium	Neutral, up to slightly positive if industry uses the harmonised reference values	Slightly positive	Slightly positive	Weakly positive	Weak	Weak	

Table 15: Comparison of policy options for hazard communication.								
Options	**Effectiveness**	**Key impacts**			**Benefit/cost ratio**	**Efficiency**	**Coherence**	**Consistency with climate objectives**
		Economic	Social	Environmental				
PO2a Update/prepare guidance	Limited extension of clarifications	Neutral to weakly positive as (existing) guidance is not always implemented	Minimal positive	Minimal positive	Very limited benefits with very limited costs	Low	Neutral	Neutral as minimal changes are foreseen
PO2b Improving and making more flexible existing rules	High – in tackling absence of labels and increased readability and burden reduction and cost savings	Highly positive: the limited negative impacts are offset by savings (up to €59 million) from labelling simplification. The savings may be higher for larger companies than SMEs.	Highly positive (increased safety information available to users and simplification provided without significantly lowering safety)	Slightly positive (e.g. through increased awareness of impacts of dispersion of harmful substances in the natural environment)	Highly positive	High	Highly positive	In the long term, it would reduce CO2 emissions thanks to legislative streamlining. Refilling would bring benefits in terms of packaging waste reduction, hence energy saved.
PO2c Digital labelling	Weakly positive	Weakly positive, as the application would be voluntary (application where companies' benefits outweigh their costs). The volunteer companies would be digital/future proofed front-runners	Highly positive (digital information complements the information on labels)	Weakly positive	Highly positive (companies would implement this on a voluntary basis, meaning in cases where their benefits outweigh their costs)	Neutral	Highly positive	Neutral

Table 16: Comparison of policy options to address the non-compliance of online sales of chemicals and insufficient information to poison centres								
Options	**Effectiveness**	**Key impacts**			**Benefit/cost ratio**	**Efficiency**	**Coherence**	**Consistency with climate objectives**
		Economic	Social	Environmental				
PO3a Awareness campaigns	Very low	Very small to moderately negative	Weakly positive.	Weakly positive	Limited benefits/small costs	Rather low	Coherent with Digital Agenda	Neutral
PO3b Provisions and clear responsibilities for online sales and imports	High for PO3b.	Positive – limited costs for EU industry and online actors while providing a level playing field between EU and 3rd country actors.	Positive – increased level of information and enforceability, reinforcing the protection of citizens	Positive – increased level of information and enforceability, reinforcing the protection of the enviroment	High as there are no costs but some benefits	high	Coherent with Digital Agenda and with the competitiveness of EU online and brick and mortar actors.	Neutral
PO3c Clarifying provisions for notifications to poison centres	Highly effective but very burdensome	Very negative for industry, negative for national authorities;	Positive	N/A	High costs/high benefits	Moderate	N/A	Neutral
	Solves only part of the problem	Moderately negative for industry and authorities	Positive		Moderate costs/moderate benefits	Moderate		
	High	Negative for industry, neutral to moderately negative for authorities	Moderately positive		Moderate costs/high benefits	High		

8 PREFERRED OPTION

8.1 Description of combined preferred option

Table 17 below lists the options and list of measures retained in the preferred policy package.

Table 17: Preferred policy options and related measures	
Classification of chemical hazards	
PO1a, PO1b and PO1c	• Add new hazard classes in CLP for substances with ED, PBT, vPvB, PMT, vPvM properties and prioritise them for harmonised classification • Request and make available in ECHA's classification and labelling inventory the reasons for diverging notified self-classifications and make the names of notifiers public • Require updates of notifications of self-classifications within a certain deadline • Reinforce prioritisation for harmonise classification at an early stage • Allow the Commission to initiate and fund more harmonised classification and labelling dossiers, including by mandate to ECHA
Communication of chemical hazards	
PO2b and PO2c	• Explicitly address the concept of refill and labelling obligation of chemicals in the CLP and limit this practice to mild hazards only • Increase readability of CLP labels for chemicals introducing specific formatting requirements for CLP labels as currently already outlined in guidance • Allow some supplemental information to go digital only where their physical availability on the label is not instrumental for the protection of health and the environment. In addition, this measure would create a framework for further digital labelling of this information. Yet, information that is obligatory under GHS would remain on the physical label. • Allow broader use of fold-out labels for chemicals traded in several EU countries • Provide derogation from labelling requirements for chemicals sold to consumers in bulk (e.g. fuel) and in very small packaging (e.g. writing instruments)
Addressing main legal gaps and ambiguities	
PO3b and PO3c	• Clarify rules for online offerings and advertisings • Introduce a responsible economic actor by default • Targeted notifications to poison centres

The preferred policy package will generate **significant and positive health and environmental impacts** (especially from PO1a and PO2b) and incur **limited negative economic impacts** (considering all retained policy options). Overall costs will be largely outweighed by the benefits, whilst the problems identified by the previous policy evaluations would be comprehensively addressed. The package would strongly contribute to achieving the EU's ambition embedded in the European Green Deal and the Chemicals Strategy for Sustainability in terms of moving toward a toxic free-environment, as well as to supporting the green and digital transition of industry, as defined in the Industrial Strategy. Also, an overall improvement of certain legal provisions and the closure of identified legal gaps would lead to better implementation, simplification and compliance (expected through PO3b and PO3c but also by simplification/clarification of labelling provisions under PO2b and c) bringing about environment/health benefits as well as **fostering the level playing field** for EU companies and thereby **enhancing competitiveness (including for SMEs)**. The impact assessment concludes that policy options 1d, 2a and 3a and some measures within PO3c (measures #19 and 20) will not materialise in benefits and increased effectiveness. Those options are dropped, even if they do not contain significant costs.

Health and environmental benefits would stem in particular from ensuring that adequate provisions exist for identifying and classifying for the most critical hazards, so that other actors can take adequate risk management measures, and so that processes can deliver outcomes faster (e.g. through the mandate to the Commission to initiate harmonised classifications dossiers). Other relevant expected benefits for health and the environment would stem from the expected improvement in the consumers' understanding of the health and environmental hazards of chemicals (and ultimately of their ability to make informed choices), thanks to improved labelling. This includes a voluntary and harmonised scheme to facilitate and promote digital labelling - as well as addressing legal gaps and ambiguities in the CLP rules for online sales and imports. Further benefits on health would be guaranteed by ensuring that comprehensive information on chemical hazards effectively reaches poison centres.

Economic impacts are estimated to be **significant for industry** and authorities, in particular for PO1. Inevitably, the new hazard classes will come along with additional costs for the industry compared with status quo (direct costs, which will be borne progressively as substances to be classified for the new hazard classes are identified, mainly thanks to REACH, BPR and PPPR, and indirect costs such as voluntary substitution). The European chemicals industry is ready to bear those costs[130], as long as the EU policy maker ensures **investment predictability** on *which* chemicals will undergo regulatory measures and *when*. The identification will be coordinated and communicated at EU level, in order to provide investment predictability in the single market. Targeted initiatives by the Commission will ensure such predictability[131]. Concerning costs for authorities, PO1 will imply certain costs which would amount to between €39.4 and 84.2 million (central estimates) also for them to adapt to changes involving classification criteria for new hazard classes (minor costs), improvements of the classification and labelling inventory (moderate costs) and the prioritisation schemes (moderate costs).

[130] CEFIC, Chemicals Strategy for Sustainability - cefic.org.

[131] E.g., see the planned transition pathway for chemicals that CEFIC fully supports; CEFIC, Chemicals Transition Pathway.

Efficiency gains – for authorities as well as for companies - would be generated by an overall improvement of the classification processes, but also by the simplification and clarification of the labelling requirements. This will warranty a fully harmonised internal market for chemicals. Labelling requirements will become easier to apply translating into less compliance costs for industry abiding by the rules as well as into easier enforceability by authorities of non-compliant competitors. The preferred package under PO1 would also significantly promote **synergies and coherence of EU legislation on chemicals**, in line also with the overall process of 'One substance, one assessment' initiated with the Chemicals Strategy for Sustainability across EU legislation and aimed at harmonising safety assessments on chemicals. In particular, harmonised identification and classification for the most critical hazards, but also ensuring stronger convergence of self-classifications by industry as well as greater transparency, are essential to achieve this goal.

Furthermore, actions on digital labelling under PO2 and online sales under PO3 will encourage the use of **digital tools** for improving consumer awareness on chemicals hazards, while at the same time managing the challenges posed by increased digitalisation and globalisation and new trends in sales of consumer products.

The overall impact of the preferred option is summarised in Annex 3.

8.2 Potential for burden reduction and simplification

Measures included in PO1b and PO2c, in particular, are expected to bring high benefits in terms of **burden reduction and cost savings for industry**, as well as **stronger basis for Member States' Enforcement Authorities.** They are indeed expected to simplify the burden of economic operators in terms of hazard classification (without lowering on safety), in particular through a simplified and easy to search inventory (savings estimated slightly less than €9 million). On the side of hazard communication, a broader use of multilingual fold-out labels (savings estimated to about €48.5 million considering the detergent industry only) and introducing exemptions to labelling requirements for some chemicals (savings amounting to more than €10 million) will also add up. This preferred option will therefore also contribute to the 'one in, one out' commitment of the European Commission. As experience and confidence is gained, increasing the amount of information available digitally may further increase the simplification potential for industry, provided that this possibility exists without violating EU commitments under GHS.

Measures related to self-classification under PO1b, i.e. to improve the Classification and Labelling Inventory will bring about simplification. Strengthened rules to come to an agreed entry will level the playing field also for the vast majority of substances that do not have a harmonised classification. This is particularly important for SMEs who notify substances that are not subject to REACH registrations because they are manufacturing or importing them below one ton. Hence, the data provided in the inventory regarding those notifications is the only benchmark for SMEs dealing with the same substance. Indeed, if notifiers know each other's name, they will spend less time navigating the inventory. Also, providing a maximum of 6 months to update a notification after a change of classification has been decided, will trigger a burden reduction and simplification as companies are given more time to re-notify. Measures under PO1a do not directly imply a burden reduction for companies, but they might if one would take into account the costs of non-Europe. A coherent, EU-wide framework will prevent national initiatives putting at risk the internal market for chemicals, which we have already seen from some Member

States, and which would no doubt proliferate if the Commission would remain inert[132]. Also, pushing the EU model on new hazard classes forward at GHS 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 giving it a competitive advantage allowing it to increase its global market share for chemicals. In the long run, this should be a burden reduction.

Measures under PO3b on online sales will not directly reduce the burden for EU industry, but they will protect it from non-EU free-riders undermining competitiveness. Whilst EU industry will not have any additional burden, non-EU actors will have to appoint a responsible economic actor in the EU if they want to continue placing their chemicals on the market. In other words, the burden will be levelled.

8.3 Application of the 'one in, one out' (OIOO) approach

The recurrent and one-off costs and savings for businesses, citizens and public authorities are presented below:

Table 18: Administrative costs for businesses, citizens, and public authorities for the preferred policy option

	New Recurrent costs (m€)	*Savings in recurrent costs (m€)*	*New-one off costs (Total in m€)*	*One-off savings (Total in m€)*
Within the scope of 'one-in-one-out'				
Business	23.2	57.4	258.7	13.5
Citizens	8.6	0.0	0.0	0.0
Total	31.8	57.4	258.7	13.5
Outside of the scope of 'one-in-one-out'				
Public authorities	1.0	0.3	13.5	0.00

The preferred option would create *net savings* in recurrent administrative costs on businesses and citizens of 25.6 million EURO per annum. The preferred option would however impose *net* (total) one-off administrative costs on businesses and citizens of 245.2 million EURO. Public authorities will be expected to have slightly increased recurrent administrative costs of 0.7 million EURO and additional one-off administrative costs of 13.5 million EURO.

9 HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The Chemicals Strategy for Sustainability recognises the need to improve knowledge on chemicals and commits to develop by 2024 a 'framework of indicators to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals

[132] Five Member States (Belgium, Denmark, France, The Netherlands and Sweden) launched a website in June 2020 having the aim of informing stakeholders about the current status of substances identified as EDs to increase the knowledge base on them (https://edlists.org/about-this-site). Those Member States call for action at EU level (https://www.wemos.nl/wp-content/uploads/2016/06/Measures_against_endocrine_disrupting_chemicals_June2016.pdf). France already adopted a decree on ED identification (Article L541-9-1 of the French Public Health Code).

legislation'. The development of this framework is currently ongoing, with the close involvement of the expertise of all relevant services, in particular the European Environment Agency (EEA) and ECHA. This framework of indicators under development is flexible in the medium to long term and will be able to align with ongoing revisions of the chemicals legislation, in order to ensure that specific objectives of those can be duly monitored. A number of areas and potential indicators have been identified for further technical work amongst which the following are relevant for the CLP revision, in addition to the existing ones on consumption and production of hazardous chemicals:

- Production and consumption of chemicals, including in terms of turnover, consumer expenditure etc., with a focus on SMEs, online sales, and non-EU sales;
- Safe and sustainable by design chemicals including key performance indicators on the industrial transition to safe and sustainable chemicals;
- Consumption footprint, chemicals in products and in the Circular Economy;
- Environmental and human (bio)monitoring;
- Enforcement of REACH and CLP.[133]

This framework will be fully aligned – as well as complementing - the Monitoring and Outlook Framework for the EU Zero Pollution Action Plan and the monitoring framework of the Environmental Action Programme to 2030 (8th EAP).

In terms of some specific objectives of the CLP revision, a number of additional streams will also be extremely relevant and would feed into a future evaluation of the revised CLP:

- **Identification and classification of hazards**: It is foreseen to periodically (once a year) assess via the Integrated Regulatory Strategy performed by ECHA the number of substances for which harmonised classification is needed for the most critical hazard classes and take stock of the number of substances for which the classification was harmonised. The Classification and Labelling Inventory will be analysed periodically to identify the level of harmonisation of self-classification, the number of updated notifications as well the number of substances newly classified for the new hazard classes. Compliance check of registration dossiers performed under REACH could also be used to assess the adequacy of the classification of registered substances for the new hazard classes.

- **EU barometer surveys**: Eurobarometer surveys provide very useful information on how citizens/consumers feel well informed about the dangers and safety of chemicals and on their level of understanding of labelling. As the last Eurobarometer survey found that about 55% of the interviewers felt not well informed, it is proposed that after 5 years from the entry into force of the new measures a new survey includes questions to assess progress on the level of knowledge and understating on the safety of chemicals.

- **EU enforcement projects**: the level of compliance with CLP rules is regulatory monitored by ECHA's Forum for Exchange of Information on Enforcement (the Forum), a body of the Agency that constitutes a network of authorities

[133] Although purely enforcement related matters of CLP will not be dealt with in this impact assessment as outlined under 5.1.4.

responsible for the enforcement of REACH, CLP, the 'Prior Informed Consent Regulation'[134], the 'Persistent Organic Pollutants Regulation'[135] and the 'Biocidal Product Regulation'. The Forum has been driving in the past years a number of EU wide enforcement studies (led by ECHA's secretariat), which have been instrumental to identify the level of non-compliance of CLP across EU Member States. Those studies were also widely used for the evidence collected for this impact assessment, in particular to identify the communication gaps on labelling and the implementation gaps for online sales and imported articles. As the Chemicals Strategy for Sustainability also prioritises those areas for further action by Member States and the Forum, it is proposed to monitor progress on those through targeted Forum activities. Those data will also feed into the overall enforcement and compliance indicators as part of the future framework of indicators on chemicals (currently under development).

[134] Regulation (EU) No 649/2012.
[135] Regulation (EU) 2019/1021.