125808/EU XXVII. GP
Eingelangt am 20/12/22

Council of the European Union

Brussels, 20 December 2022
(OR. en)

16258/22
ADD 4

Interinstitutional File:
2022/0432(COD)

ENT 177
MI 975
CHIMIE 107
COMPET 1069
ENV 1334
SAN 672
IND 576
CODEC 2076

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	19 December 2022
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2022) 435 final - Part 2/5
Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Part 2/5 Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Delegations will find attached document SWD(2022) 435 final - Part 2/5.

Encl.: SWD(2022) 435 final - Part 2/5

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EUROPEAN
COMMISSION

Brussels, 19.12.2022
SWD(2022) 435 final

PART 2/5

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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Annex 1 – Procedural information

LEAD DG, DECIDE PLANNING/CWP REFERENCES

The preparation of this Impact Assessment Report was led by DG Environment (ENV) and DG Internal Market, Industry, Entrepreneurship and SMEs (GROW).

The agenda planning reference is PLAN/2021/10629.

The initiative, to which this impact assessment relates, is referenced in the 2022 Commission Work Programme[1], under the policy objective 1. Zero pollution package.

ORGANISATION AND TIMING

The revision of the CLP Regulation (Regulation (EC) No 1272/2008 on the classification, labelling, and packaging of substances and mixtures) is a core deliverable under the European Green Deal and the Chemicals Strategy for Sustainability.

The Inception Impact Assessment was published on the "Have your say" website on 4 May 2021 with a feedback period until 1 June 2021[2]. 182 comments were received and taken into account to develop the impact assessment.

The Inter Service Steering Group (ISSG) for the Impact Assessment was set up by DG ENV and DG GROW, who are co-responsible for CLP. It included the following DGs and services: BUDG (Budget), CLIMA (Climate Action), COMP (Competition), CONNECT (Communications Networks, Content and Technology), ECFIN (Economic and Financial Affairs), EEAS (European External Action Service), EMPL (Employment, Social Affairs and Inclusion), ENER (Energy), Eurostat, FPI (Foreign Policy Instruments), INTPA (International Partnerships), JRC (Joint Research Centre), JUST (Justice and Consumers), MARE (Maritime Affairs and Fisheries), MOVE (Mobility and Transport), NEAR (European Neighbourhood and Enlargement Negotiations), OLAF (European Anti-Fraud Office), REGIO (Regional and Urban Policy), RTD (Research and Innovation), SANTE (Health and Food Safety), SG (Secretariat-General), TAXUD (Taxation and Customs Union), TRADE, as well as ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority). A total of 7 meetings of the ISSG were organised between spring 2021 and spring 2022: more specifically, meetings were held on 31/05/21, 15/10/21, 18/01/22, 17/02/22, 14/03/22, 28/03/2022 and 06/04/2022.

The ISSG meetings discussed the main milestones in the process, in particular the following: the Inception Impact Assessment, evidence gathering, coherence with other ongoing draft legislative initiatives, the consultation strategy and main stakeholder consultation activities.

An open public consultation, intended to gather opinions on the revision, was open for a duration of 14 weeks from 9 August 2021 to 15 November 2021. Moreover, a targeted stakeholder survey was open for a duration of 6 weeks, from 10 November to 22 December

[1] COM(2021) 645

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

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2021. The latter was intended to gather opinions on the CLP revision from Member State authorities/competent bodies, representatives of EU industry associations/EU- and national-level worker representative groups/trade unions, NGOs/environmental charities and consumer associations, academics/experts, as well as SMEs and retail.

In addition, the progress and updates of the impact assessment activities were presented at the following open session meetings of the Competent Authorities for REACH and CLP (CARACAL)[3] expert group: CARACAL-40 (29-30 June 2021) and CARACAL-42 (17-18 November 2021). These meetings were attended by Member State Competent Authorities and accredited stakeholder organisations, and in their framework discussions were held and feedback was given.

Furthermore, extensive discussions on specific issues of CLP revision were held in 4 *ad hoc* meetings of CARACAL on CLP revision, with wide Member State and stakeholder participation: CARACAL on Persistent, Mobile and Toxic, very Persistent and very Mobile, Persistent, Bioaccumulative and Toxic, very Persistent and very Bioaccumulative (PMT, vPvM and PBT, vPvB) substances (30 September 2021), CARACAL on Annex VIII (Poison Centres) and Online Sales (27 October 2021), CARACAL on harmonised classification and labelling (CLH) prioritisation, Predicted No-Effect Concentration (PNEC), Derived No-Effect Level (DNEL), Derived Minimal Effect Level (DMEL) and Labelling (6 December 2021) and CARACAL on New Hazard Classes, More than One Constituent Substances (MOCS) and Self-classification, (14 December 2021). Relevant discussions on specific topics covered by this Staff Working Document were also held previously in CARACAL meetings (e.g. self-classification, labelling, poison centres) or in meetings of specific groups as e.g. the Competent Authorities Sub-Group on Endocrine Disruptors and the ECHA PBT Expert Group where stakeholder representatives were also present. Finally, a stakeholder workshop on the simplification and digitalisation of labelling requirements for chemicals was held on 26 November 2021.

CONSULTATION OF THE RSB

An informal upstream meeting with the RSB took place on 6 October 2021. The feedback after this this meeting is provided below. It will be deleted and replaced with the opinion that will be delivered after the meeting with the Board on 11 May 2022.

Context

- The IA needs to differentiate between the political context emerging from the Chemicals Strategy and the available evidence of the problems, which the initiative aims to tackle. The impact assessment should be based on robust evidence.

- The interrelationship of the different pieces of upstream and downstream legislation and their respective roles should be well described in the IA report.

- The report should be very clear on the correlation and links of this proposal with REACH and other legislation and initiatives, including on digital services. The

[3] REACH Competent authorities, available at: https://ec.europa.eu/environment/chemicals/reach/competent_authorities_en.htm

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correlation of this proposal with the initiative on digital labelling and simplification (for CLP, fertilisers and detergents) should be spelled out.

Problem definition

The report should provide robust evidence showing that consumers demand more comprehensive chemical information and, as there is incomplete information, this impacts their consumer behaviour (as stated in the intervention logic).

Policy options

The baseline should not be presented as a policy option and should be seen as dynamic evolution of the current situation. It could, for example, already include possible non-regulatory measures, currently conceived as option 2. The baseline should cover all existing and proposed legislation at the time of finalising the impact assessment.

Options should bring out clearly what choices have to be made and what alternatives are available.

The currently presented option 3 may need to be unbundled. Options can be designed per problem area and integrated in packages which can contain regulatory and non-regulatory measures. Options should address all problems identified.

The simplification and burden reduction potential should be thoroughly assessed, given the REFIT nature of the initiative.

Analysis and impacts

The impact analysis should assess unavoidable impacts (costs and benefits) on downstream legislation following the proposed changes in the CLP. If discretion is possible in the revision of downstream legislation, this should be clearly indicated.

The report should assess how the changes in the CLP legislation will impact industry and sales and if this will lead to less or more use of hazardous substances. How will the success look like? (a decrease in demand for products with high health and environmental hazard?)

The impact of changing a label on consumer behaviour should be assessed.

The impact on international competitiveness should be assessed, in particular when EU rules deviate from internationally agreed standards. When international standards are followed, this should be justified.

Specific attention should be drawn on impacts for SMEs and possible ways to mitigate these impacts.

The administrative burden should be analysed quantitatively with a view to the one-in-one-out approach.

All suggestions above from the RSB were taken into account when developing this Staff Working Document.

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Table 1 below provides an overview of the RSB suggestions at the Upstream meeting and how they have been addressed.

Table 1: Overview of the RSB suggestions and follow-up

RSB suggestions on draft IA	**Follow-up of RSB suggestions in the IA**
Distinguish with CSS and provide robust evidence	Envisaged measures were impact assessed and preferred option determined on that basis
Description of interrelationship with upstream and downstream legislation	See Annex 5
Correlation with other legislative initiatives (REACH, digital services, digital labelling…)	See point 5.1.4., further detailed in Annex 5 and in Annex 8 (REACH), Annex 13 (digital labelling) and Annex 15 (on-line sales)
Consumer demand more information and this impacts their behaviour	There are no measures proposed which are expected to increase the level of consumer information compared to the current legal text; However desk research performed on the scope of CLP did not identify a possible impact from CLP on consumer behaviour. Therefore this problem will not be addressed by this assessment.
Baseline should not include policy option	We have taken care of describing a dynamic baseline (Section 5 and Annex 7)
Options to be clear on choices made and available alternatives	Where alternatives were available and not pursued, these have been clearly motivated
Option 3 should be unbundled - options can be designed per area and integrated in packages	Policy options were unbundled and packed again – See intervention logic
Options should address all problems identified	See new version of the intervention logic
Simplification and burden reduction potential (REFIT initiative)	See section 8.2
Unavoidable impacts (cost/benefits) on downstream legislation + indication if discretion is possible in revision of downstream legislation	See chapter 6 and 7 and Annex 8 and 10
Impact on industry and sales – less or more use of hazardous substances	Impacts on industry have been assessed in all annexes– the impact on use of hazardous substances has been assessed in Annex 8 and 10. Direct administrative costs, adjustment costs and impact on trade are reported in sections 6 and 7.
Impact of changing a label on consumer behaviour	This is covered by the study on digital labelling, which is reported in Annex 13, as well as Annexes 2 and 4.
International competitiveness impact to be assessed (when international standards are	See Chapter 6.1.1 and Annex 8

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deviated from)	
In case international standards are followed this should be justified	This is the case for ED criteria which have be designed using WHO standards. This is also the case for the starting point on digital labelling. Elements required by the GHS on a physical label would not be moved to a digital one.
Impacts on SMEs and ways to mitigate them	The impacts on SMEs have been assessed – mitigating measures in case of increased burden will consist essentially in additional support, which could be implemented in the framework of EU SME tools developed within DG GROW and support by ECHA
Quantitative analysis of administrative burden (one-in-one-out-approach)	Impact on administrative burden for industry and authorities has been assessed.

Following the RSB opinion on 11 May 2022, DG ENV and GROW updated this SWD in the following areas:

Table 2: Overview of the RSB comments and follow-up

RSB suggestions on the SWD	**Follow-up of RSB suggestions in the revised SWD**
(1) The analysis of the costs and benefits should be presented in a clear and transparent manner. The totals, bringing together all quantified costs and benefits, should be set out in the report in present values and annualised. The figures in the annexes and the main report should be clearly referenced and coherent with each other. The report should be clearer on the methodology of the cost benefit analysis including explaining why the 20-year appraisal period was chosen.	The revised SWD now contains more information about how the costs and benefits break down (see e.g. Table 10 in section 6.1.1.1). Each section under section 6 holds a table with a grand total per policy option. Annexes now report clearer quantifications of both costs and benefits, where impacts can be quantified (see, e.g., section on economic impacts of policy measure 1a, p. 175 Annex 8). When it comes to benefits, we now provide various calculations to frame the possible positive impacts on human health and on the environment (see pages 175 to 199 Annex 8 and more specifically tables 69 and 70). This order of scale is reported in the body of this SWD. The justification of the 20-year appraisal period is better developed (see section 5.1). A new heading in annex 4 (p. 90) summarises the general principles applied for the cost (and savings) analysis. Specific details for each measure or group thereof are provided in the respective annexes (see e.g.,
(2) The report should transparently present	We updated tables 14 to 16. We now provide

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the distributional impacts across all affected groups. In particular, this should cover the overall impact on businesses including a separate analysis of the impacts on SMEs. The report should clarify the expected impact of labelling on consumer behaviour. It should also provide more detail on the impact on the competitiveness of EU businesses. A dedicated section of the administrative costs and savings in scope of the 'one in, one out' approach should be further clarified. It should differentiate between one-off and recurrent costs and cost savings and the figures should be recalculated to eliminate the mistakes.	the same level of information, including on SMEs, consumers and competitiveness, where possible. Since the study could not be extended to fully cover consumer behaviour, we can only report guestestimate on the impact on the consumer behaviour. This is clarified in section 6.2.2. The section on OIOO has been revised, developed and checked. The period of analysis is clarified and justified. Annex 3 reports the analysis developed for the OIOO calculator for both 10 years and 20 years.
(3) The report should explain why it is not possible to quantify the expected significant health and environment benefits. Even if causality cannot be demonstrated, the report should provide qualitative evidence that the exposure of users and of the environment to the identified hazardous substances will decrease as a result of this initiative. The report should provide a robust qualitative analysis of the expected benefits, including an indication of the order of magnitude of these benefits, to justify the conclusion that the benefits outweigh the costs for this initiative.	See changes implemented for comment (1) above. When it comes to benefits, we now provide various calculations to frame the possible positive impacts on human health and on the environment (see pages 175 to 187 Annex 8 and more specifically tables 69 and 70). This order of scale is reported in the body of this SWD.
(4) The report should make greater use of the cost-benefit analysis, both quantitative and qualitative, and strengthen the justification of the preferred option.	See changes introduced to address comment (1) as well.
(5) The report should clearly describe the links and overlaps of the CLP Regulation with other chemical legislation, notably REACH, articulate its purpose and pinpoint the remaining regulatory gaps compared to related measures, such as the General Product Safety Regulation, the Market Surveillance Regulation and the Digital Services Act.	Improved link and references between sections 7 and 8. Figure 1 deleted and Figure 2 updated in Section 1 of the SWD. Section 5.1.4 describes in more details the on-going changes and how they cover or not CLP-related issues. Clarification is brought in Annex 5.
Some more technical comments have been sent directly to the author DGs.	The report was improved according to the comments received.

EVIDENCE, SOURCES AND QUALITY

Two studies were contracted to update, confirm and gather more information on the findings of the two Fitness Checks published in 2019 and 2020. For more information, see annex 6.

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CLP revision study

The Commission was assisted by an external contractor through a service contract on specific aspects of the CLP revision,[4] both for the data collection and the analysis phase of the different policy options in the impact assessment.

The tasks of the contractor were the following:

Provide support in defining the problems (including the scale of the problems and scope of those affected, the subsidiarity and the EU dimension) that the revision of CLP intends to solve, and the intervention logic of the impact assessment.
Refine the baseline and further develop the policy options.
Compile information from previous and ongoing studies.
Process and analyse the outcome of the open public consultation.
Conduct targeted consultations with representatives from Small and Medium sized Enterprises, retailers/importers and other sectors of the chemical industry.
Analyse the impact of the refined options taking into account solutions identified from the consultation strategies.
Draft a synopsis report of all consultation activities.

The contractor participated in the ISSG meetings that were held after the signature of the contract as well as in the CARACAL meetings. In addition, the contractor worked in close cooperation with the Commission throughout the different phases, particularly in the latter stages of assembling a coherent evidence base and in assessing and adjusting policy options.

On this basis, evidence was compiled by the contractor for the seven potential intervention areas: new hazard classes (hazard identification); toxicity reference values and harmonised classification and labelling; self-classification; labelling; CLP scope exemptions; online sales of chemicals; poison centres.

For two of these areas – new hazard classes (hazard identification) and CLP scope exemptions – extensive supporting studies were carried out. These supporting studies used the following methods: rapid literature review methodology (also known as rapid evidence assessment) for data collection and interpretation, legislative document analysis (for the CLP scope exemptions) and data analysis (for the new hazard classes).

Evidence was also collected from the various consultation activities, by means of the following methods: questionnaire survey, for the general public and experts, including the main stakeholders; semi-structured interviews with civil society associations, public authorities, academia, and business entities and associations; as well as observation and document analysis for collecting the opinions of CARACAL and its sub-group members and observers.

Annex 4 provides detailed descriptions of the methodology used for the collection and analysis of the evidence. Moreover, detailed information regarding the evidence compiled by

[4] Service contract "Technical and Scientific Support to the Commission's Impact Assessment for the revision of the Regulation on Classification, Labelling and Packaging of substances and mixtures", under the framework contract No. ENV.B.2/FRA/2020/0010 (group led by RPA Europe S.R.L.), "Scientific and technical assistance for the implementation of chemicals legislations on REACH, CLP, PIC and POPs".

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the external contractor, is given in the respective Annexes that address the respective intervention areas.

Digital labelling study

Regarding digital labelling, the Commission launched a different contract than the service contract mentioned above on the "simplification of labelling and the use of IT tools to communicate hazard and safety information on chemicals as well as use instructions to consumers"[5].

This led to the initiative on "simplification and digitalisation of labelling requirements" with an inception impact assessment commenting period lasting from 14 July to 20 September 2021 and the open public consultation from 24 November 2021 to 17 February 2022[6].

CLP relevant parts of this initiative are part of this impact assessment.

In addition to the evidence gathering above mentioned for the CLP revision study (stakeholders surveys etc.), the study on simplification and digitalisation of labelling requirements included a behavioural experiment (see Annex 4 – Analytical Methods, Part VI).

Annex 4 provides detailed descriptions of the methodology used for the collection and analysis of the evidence. Moreover, detailed information regarding the evidence compiled by the external contractor is given in the respective Annexes that address the respective intervention areas.

[5] https://ted.europa.eu/udl?uri=TED:NOTICE:363150-2019:PDF:EN:HTML
[6] Chemicals – simplification and digitalisation of labelling requirements (europa.eu)

Annex 2 – Stakeholder consultation (Synopsis report)

The synopsis report summarises the results of all consultation activities (open public consultation, targeted stakeholder consultation, interviews and workshops) conducted as part of 'Technical and Scientific Support to the Commission's Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP)' on the one hand and of 'Impact Assessment Study on the Simplification of the Labelling Requirements for Chemicals and the Use of e-Labelling' on the other hand. The aim is twofold:

To inform policymaking on the outcome of all consultation activities;
To inform stakeholders on how their input was taken into account.

As this impact assessment also relies on another initiative on digital labelling of chemicals, including detergents, a separate consultation with its own strategy has been conducted and is included in this annex.

OUTLINE OF THE CONSULTATION STRATEGY

The aim of the consultation activities was to gather stakeholder opinions on the revision of the CLP, and to ensure that stakeholders' views, practical experience and data were considered in the policy development process, ensuring higher quality and balanced analysis of arguments from different sources, and greater transparency for the policy development process. Information was sought in relation to seven intervention areas. The consultation activities covered the following intervention areas:

Hazard identification.
Toxicity reference values and harmonised classification and labelling.
Self-classification.
Labelling.
Digital labelling.
CLP scope exemptions.
Online sales of chemicals.
Poison centres.

For each area, the study team collected opinions about the nature of problems in an area, possible measures to tackle the problem, impacts of measures to various target audiences, benefits and costs of the measures.

The information collected on the respondents' profile included stakeholder type, geographical location, organisation size, level of knowledge of the Regulation.

In the case of the open public consultations (OPC), different questions were provided for experts and non-experts, to ensure that the questions were appropriately targeted to the different audiences. In the case of the targeted stakeholder surveys (TSS), question logic was applied to ensure that questions displayed were relevant to the given stakeholder group. The interview templates were developed to complement, validate and enrich data collected through quantitative surveys. Finally, the behavioural experiment investigated consumers'

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understanding of chemical and detergents labels, the importance of different label elements as well as their interpretation with respect to safe use. Furthermore, the experiment tested potentials ways to simplify labels and whether the introduction of digital tools could support consumers.

Table 2 below summarises the consultation tools and strategies applied by stakeholder group.

Table 2: Consultation tools and strategies applied for by stakeholder groups

Stakeholder group	Consultation tools and strategies applied
General public/consumers	OPC, behavioural experiment, online survey
Representatives of the Commission and EU agencies (e.g., European Medicines Agency, European Food Safety Authority, etc.), relevant EU committees (e.g., CARACAL and its CASG sub-committee), experts (e.g., academic institutions, CARACAL observers, etc.)	Targeted consultation, in-depth interviews and ad-hoc consultation, online surveys
Relevant Member State Authorities	OPC, targeted consultation, follow-up interviews, online surveys
Representatives of EU industry associations/CLP consortia	OPC, targeted consultation, interviews, online surveys
EU and national-level worker representative groups/trade unions	OPC, targeted consultation, interviews, online surveys
Interested NGOs/environmental charities and consumer associations, academics/experts	OPC, targeted consultation, interviews, online surveys

Consultation activities

The planning of the consultation activities was informed by the general principles and minimum standards for consultation of interested parties by the Commission.[7]

The **OPC on CLP** was open for 14 weeks from 9 August 2021 to 15 November 2021. The OPC questionnaire was prepared by the Commission and distributed using the EU Have Your Say portal. The aim of the OPC was to gather opinions on the revision of the CLP Regulation from a broad range of stakeholders. The OPC was open to anyone interested in CLP e.g.; EU (and non-EU) citizens, researchers, businesses (including small and medium-sized enterprises (SMEs)), industry, industrial/business associations and trade bodies, governmental and non-governmental organisations (international, European, national and local), as well as social partners and actors. Respondents were able to provide a response to the questionnaire on behalf of organisations/institutions (i.e. as one of the organisations stated above), or as individuals. Respondents registered with the EU Survey portal were able to submit additional position papers to supplement their answers. Several additional papers were submitted via email without providing a questionnaire response. The questionnaire was split into two

[7] EC (2002): Communication from the Commission. Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission. Brussels, 11.12.2002 COM(2002) 704 final.

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

The OPC on simplification and digitalization of labels on chemicals was open for 12 weeks. It aimed to gather experiences and opinions on a possible introduction of digital labelling of many daily used products such as glues, laundry and dishwashing detergents and fertilising products, under CLP, the Detergents Regulation and the Fertilising Products Regulation. The findings presented in this synopsis report and integrated in the report represents an analysis of the responses collected on 17 February, with 205 respondents. For the purpose of this synopsis report, only the answers to the questions related to CLP have been taken into account. The full analysis integrating findings to the questions related to detergents products will be presented in the next report. These answers have been divided by stakeholder categories: 141 from the private sector (companies, business associations, trade unions), 11 from public authorities, and 53 from consumers' representatives (48 citizens, 4 consumer association and 1 NGO). Similarly as the interview analysis, the imbalance of representation among stakeholders groups and their different interests has been taken into account when processing the answers.

The **TSS** on CLP was open for six weeks from 10 November to 22 December 2021. It was uploaded in a questionnaire format and was distributed using Alchemer®. The aim of the TSS was to gather opinions on the revision of the CLP from an expert audience, e.g., MSCAs involved in the implementation and enforcement of the Regulation, duty-holders and their representing associations, NGOs and academics active on chemical risk management and the regulatory framework. A stakeholder mapping exercise was performed to identify key target groups. The list included those stakeholders that provided feedback to the inception impact assessment report, as well as key stakeholders in relevant sectors that have previously participated in similar consultations (e.g., Consultation on the regulatory fitness of chemicals legislation (excluding REACH)). Additional stakeholder sources included National CLP Helpdesks, poison centres and competent authorities. The mapping exercise identified a total of 548 stakeholders, of which 80% were companies and business associations, ten percent were public authorities, and the remaining ten percent were stakeholders from the civil society. Particular effort was put to identify companies and business associations, given the broad range of sectors impacted by the Regulation. The questionnaire was split into two sections depending on the stakeholder type: one section containing questions for companies/business associations and civil society (all other stakeholders), and one containing questions for public authorities. The section for companies/business associations and civil society (all other stakeholders) contained 61 questions (36 closed and 25 open text questions) and the section for public authorities contained 58 questions (33 closed questions and 25 open questions); both sections allowed respondents to provide position papers.

Two **online surveys**, one on policy options for digitalization and for information from professionals and industry users, were conducted. The consultation on policy options aimed at gathering the opinion of the various stakeholders (consumers, professional and non-professional product users, industry, civil society organisations, national authorities and any other interested stakeholders) on the latest version of policy options analysed in this study. This survey allowed stakeholders to provide a punctual opinion on the measures taken into consideration for this analysis. The answers have been divided by stakeholder category: 12 Member State authorities, 1 consumer organisation, 43 industry representatives (industry associations, businesses). The online survey for professionals and industry users collected

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information from the stakeholders representing professionals and the industry on the importance of having certain pieces of information1 on the packaging of the specific chemical products[8] as well as the easiness to understand the information concerning these elements in these products.

Between September and December 2021, the Commission organised **CARACAL and CASG ad-hoc consultations** on the different intervention areas, discussing problems and possible ways forward. One-day long events were organised on:

CASG ad-hoc consultation on endocrine disruptors (13/09/2021).
CARACAL ad-hoc consultation on PMT/vPvM and PBT/vPvB (30/09/2021).
CARACAL ad-hoc consultation on Annex VIII CLP (Poison centres) and online sales (27/10/2021).
CARACAL ad-hoc consultation on CLH prioritisation, PNEC, DNEL, DMEL, labelling, including digital labelling (06/12/2021).
CARACAL on new hazard classes, MOCS, self-classification (14/12/2021).

It should be noted that some of the issues have been discussed by CARACAL for a number of years (e.g., criteria on endocrine disruptors). The study team observed the discussions during each meeting and reviewed all written feedback provided by CARACAL and CASG members to get a more comprehensive understanding of the problems, their drivers as well as possible measures to tackle the problems and their impacts. The study team followed up with some of the CARACAL members through semi-structured interviews.

Twenty-two **interviews** were conducted between December 2021 and February 2022. The aim was to complement the findings of the TSS and OPC and the views provided by CARACAL members and observers. Interviews were targeted to representatives from a sufficiently diverse group of stakeholders, while also eliciting participation from those stakeholder categories underrepresented in OPC and TSS responses.

METHODOLOGIES AND TOOLS TO PROCESS DATA

The OPC and TSS surveys were designed and launched via **online survey tools** (EUSurvey for the OPC and Alchemer for the TSS). These online survey tools enable surveys to be distributed and read widely online (including via smartphones), offer a variety of question types and ensures flexible access by allowing participants to save their contribution as a draft and continue at a later date. The accessibility mode was also activated on EUSurvey to enable the format to be adapted for the visually impaired. Results were downloaded in Excel spreadsheets, and then added to an analytical master spreadsheet to create statistical summaries (via tables and graphs) of the responses received. The statistical summaries were anonymised and aggregated per stakeholder group and Member State.

All data were checked for **campaigns** prior to analysis to prevent the overall results being skewed to a particular interest group. The study team used the qualitative data analysis software NVivo® to calculate the level of similarity between the responses (by assessing the Jaccard correlation of word similarity to produce coefficients between responses) and to ensure a systematic approach to identifying campaigns. Where text was identified as having a high level of correlation (between 0.5 to 1), responses were grouped for manual review and

[8] Laundry detergents; Cleaning detergents; Glues; Paints; Sealants or fillers.

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an analysis of the campaigns identified was provided separately for both the OPC and the TSS. The total number of identified answers had to be equal or above five percent (≥ 5%) of the total number of responses to be considered as a campaign.

All position papers received in the OPC and the TSS were read manually; themes identified were coded in Excel and a summary of position paper responses was provided (in an anonymised format) for both the OPC and TSS separately. To ensure an efficient approach, where identical papers had already been provided by respondents under the OPC, or where themes had already been covered, these were not taken forward for analysis in the TSS.

Interviews were carried out employing virtual platforms (Ms Teams and Webex). To develop a sufficiently diverse expert sample, the study team combined convenience and purposive sampling. Experts were identified by analysing the answers to the consultation surveys and by area of expertise —through the analysis of initiatives and projects, publications and membership to expert groups. The semi-structured interview approach was applied to achieve the maximum level of detail on each topic and get comparable results from different interviews. For interpretation of the interviews, thematic analysis was applied. Questions were provided to all participants in advance. All interviews were recorded, and transcripts automatically generated by MS Teams® were cleaned and analysed thematically. The main limitation is the limited number of interviews carried out on each intervention area, as these are complex and cover a wide range of topics. As mitigation measure, interviewees were asked to comment on several areas and to submit their views in writing where appropriate.

RESULTS OF CONSULTATION ACTIVITIES FOR THE CLP REVISION (EXCLUDING DIGITAL LABELLING)

Number of respondents and respondent profiles

Open Public Consultation for the CLP

All responses were clustered according to the following broad stakeholder categories to facilitate visualisation:

Companies – companies and business associations;
Citizens – EU and non-EU;
Public authorities; and
Civil society (all other stakeholders) consisting of academic/research institutions; consumer organisations; environmental organisations; Non-Governmental Organisations (NGOs); trade unions; and other.

Under the stakeholder group 'Civil society (all other stakeholders)', respondents were grouped together due to the comparatively low response rates, to ensure meaningful conclusions could be drawn from the data. A total of **625 responses to the OPC** were received, most from companies and business associations (45%), and EU and non-EU citizens (39%) (Figure 1).

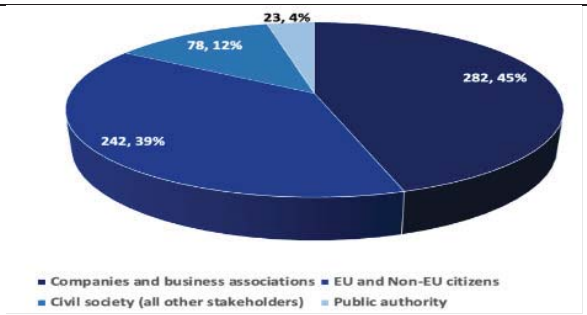

Figure 1: Number of responses to the OPC by stakeholder categories – Total: 625

Figure 2 provides a breakdown of the 383 responses from businesses by company size. SMEs provided almost 69% of responses.

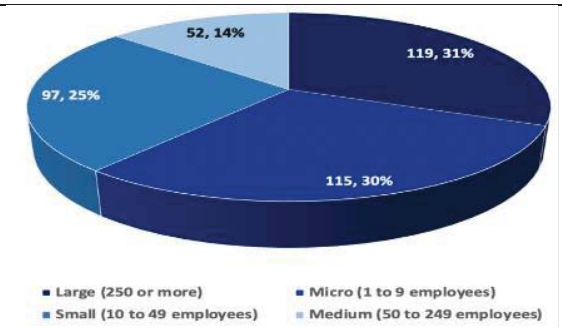

Figure 2: Number of OPC responses from businesses by company size – Total business responses: 383

Figure 3 shows the total number of OPC responses by country. Most responses were received from France (28%) and Germany (20%). No campaigns were identified in these Member States.

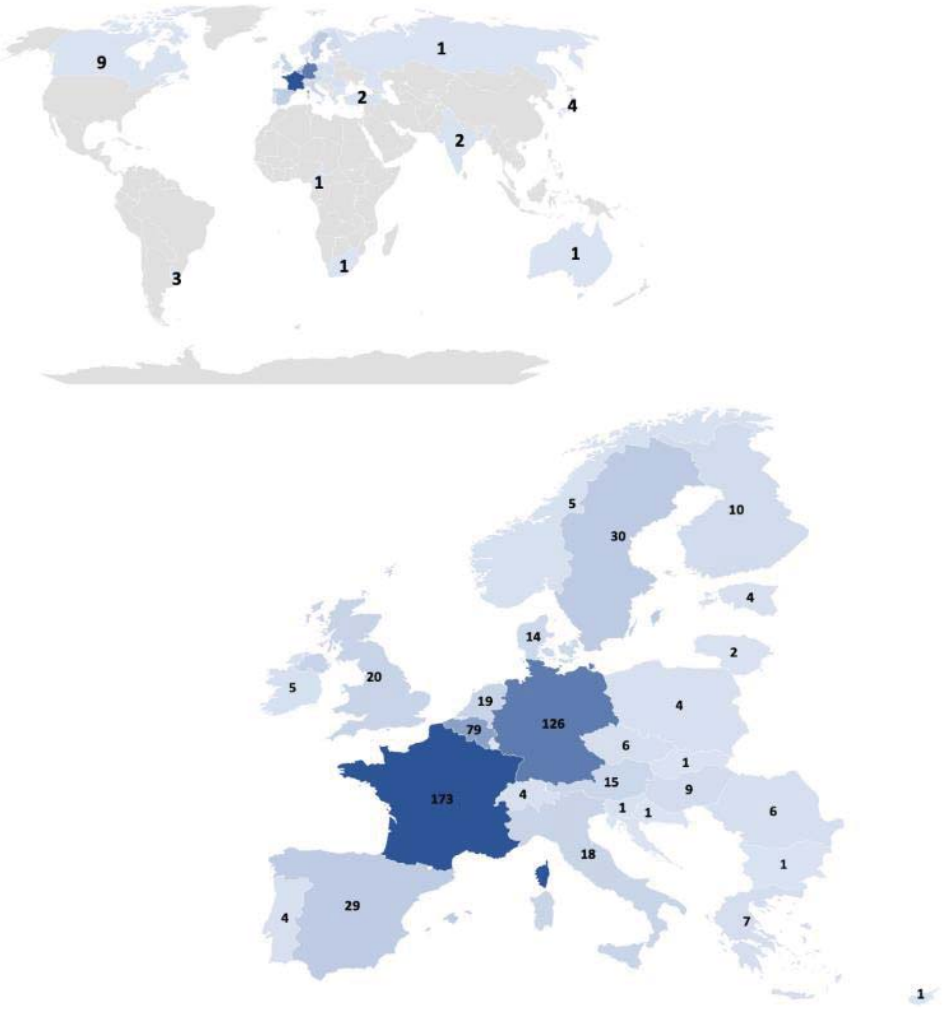

Figure 3: Number of OPC responses per country (worldwide and Europe) – Total: 625

Position papers

The OPC participants uploaded **144 position papers**. Of these, four were duplicates and were therefore removed from the analysis. Subsequently, there were 140 valid position papers which the study team reviewed manually and checked for key themes. Figure 4 shows the number of position papers submitted by different stakeholders.

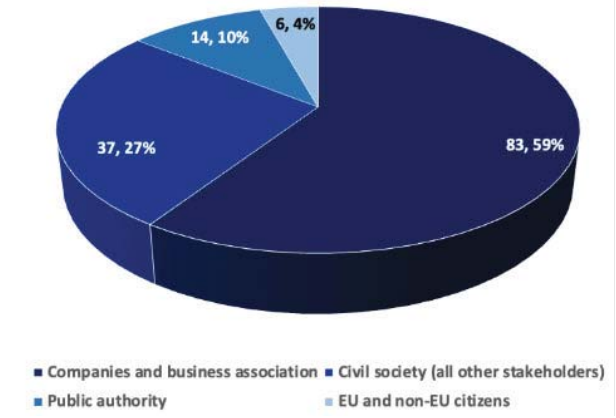

Figure 4: Position papers received per stakeholder group – Total: 140 valid position papers

Campaigns

The analysis of the OPC results revealed only **one campaign**. In total **47 responses** were identified as having high levels of similarity across their responses and were referred to as 'Campaign 1'. Campaign 1 primarily consisted of business associations (49%) and companies (47%). Additional members of this campaign were from academic/research institutions (2%), and 'other' (2%). There were no consistencies across their countries of origin, and businesses' responses part of Campaign 1 were provided by companies of different size: micro (21%), small (26%), medium (9%), and large (45%). While no information on the industry sector was collected through the questionnaire, from the screening of the organisation names, it was possible to broadly define the campaign as originating from a **business association relating to chemical products**, comprising from large chemical manufacturers to smaller formulators of household chemical products. This cluster was identified as a complex campaign, as the positions held in each area of interest often differed according to sectors.

Targeted Stakeholder Survey

The TSS received a total of 167 responses. Figure 5 (overleaf) shows the number of responses to the TSS per stakeholder group and the breakdown of business responses (82) by company size. Almost 60% (64 out of 108) of the businesses and industry associations indicated that their primary business sector is the manufacturing of chemicals and chemical products. Over 18% (32 out of 108) were active in downstream sectors (e.g. manufacture of textiles and other manufacturing), over 6% (7 out of 108) in upstream sectors (e.g. manufacture of coke and refined petroleum products and manufacture of basic chemicals), and five contributions (4.6%) came from businesses/associations which final products are exempted by CLP (manufacturing of food products and manufacturing of basic pharmaceutical products and pharmaceutical preparations). Three responses (2.8%) were provided by entities in retail trade and two (1.8%) from entities in other professional, scientific and technical activities. When asked about their activities in relation to chemical products (to understand the type of duty-holders), 43% (58 out of 136) indicated to be active in the manufacture of chemical substances, 74% (101 out of 136) in the manufacture of mixtures, 63% (86 out of 136) in the import of chemical substances and mixtures, 54% (74 out of 136) in the distribution of substances and mixtures, 51% (70 out of 136) in the use of chemical products.

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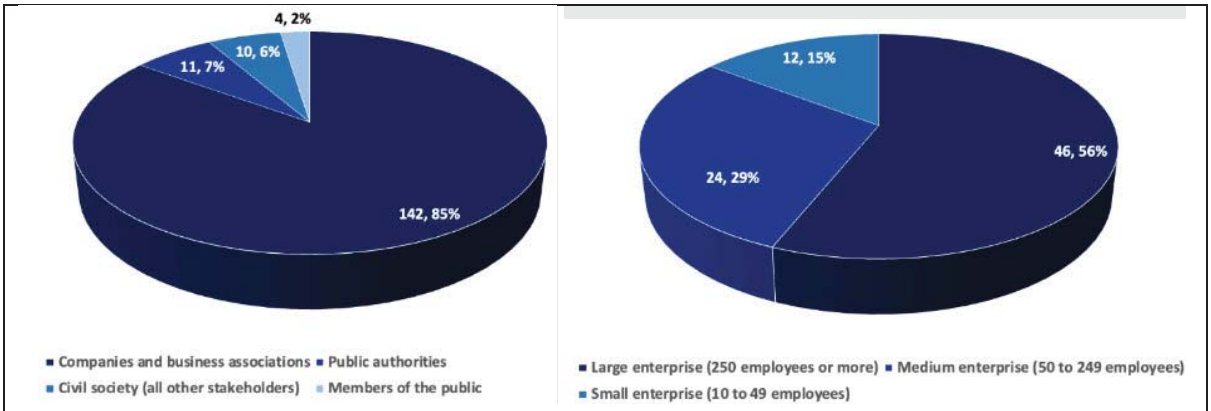

Figure 5: Number of TSS responses by stakeholder category – Total: 167 and number of TSS business responses by company size – Total business responses: 82

Two responses were provided by national helpdesks, one from a poison centre, five from competent authorities for the implementation of CLP, two from authorities competent for the enforcement of CLP and one from a competent authority on workers' health and safety. Figure 6 shows the number of responses received in response to the TSS by Member State. Eighteen responses were received by organisations operating EU-wide and 10 responses from organisations outside the EU. The results show a large number of responses from Germany (33% of the total), which include a campaign of German industry associations (additional details are provided in the subsection 'campaigns').

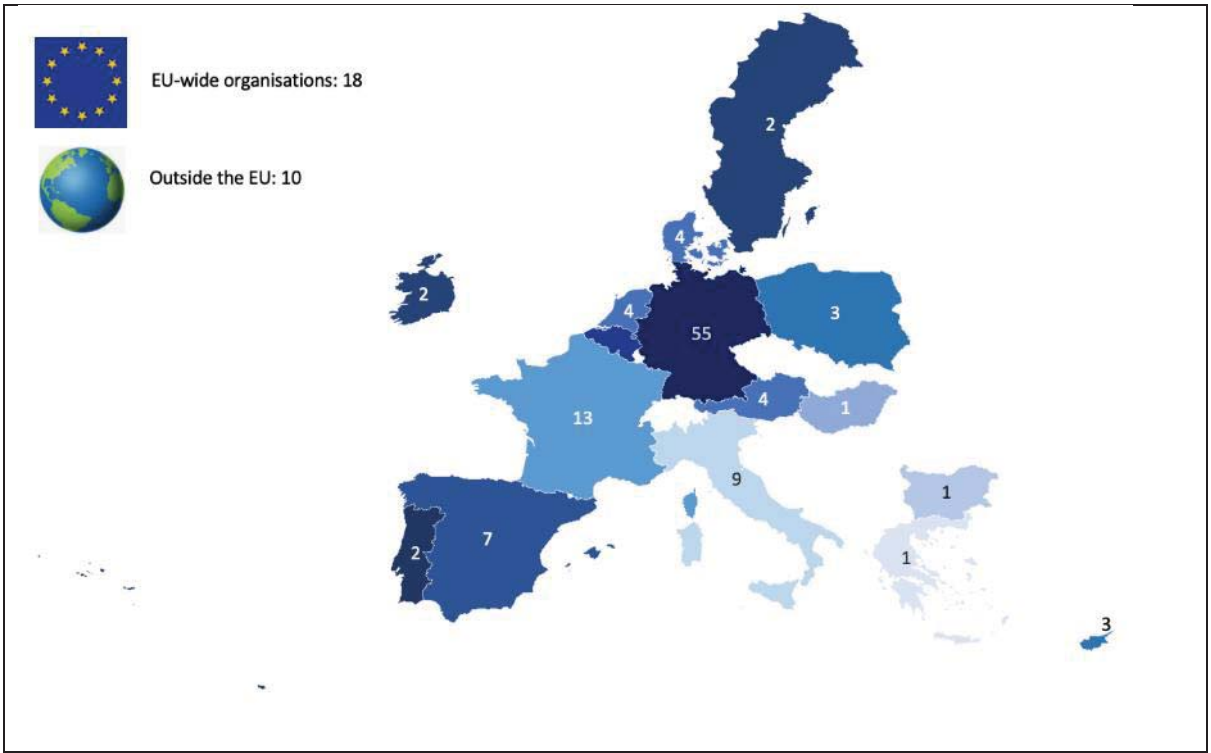

Figure 6: Number of TSS responses by country – Total: 167

Position papers

A total of 39 documents were uploaded in response to the TSS. Each document was reviewed for key information. Around 30 documents were already provided during the OPC and were therefore excluded from the analysis. The remaining 9 documents were submitted by 8 business associations and one NGO.

Campaigns

Overall, **4 main campaigns** (48 replies in total) originating from industry associations were identified based on similarities of replies to the open text questions (using NVivo and applying a Jaccard coefficient larger than 0.5). Three of the campaigns (A, B and C) met the criteria of more than 5% of the total number of replies. However, one further campaign was identified (D) with six replies and was included for transparency. **Campaign A** consisted of 19 replies, and originated from European chemicals associations. **Campaign B** consisted of 15 replies, and originated from German industry associations. **Campaign C** consisted of 8 replies originating from European and German paint associations and companies. **Campaign D** consisted of 6 replies originating from cosmetics associations and industries.

Interviews

The study team carried out 22 semi-structured interviews with experts who represented: public authorities (5), EU agencies (2), business entities and associations (10), civil societies (3), academic researchers (1), professional organisations (1). Nine conversations were group interviews, while 13 – individual interviews.

CONSULTATION ACTIVITIES ON DIGITAL LABELLING OF CHEMICALS

Interviews

Firstly, the study team conducted 10 scoping interviews with EU and international experts on labelling requirements and the use of digital tools to communicate hazard and safety information and instructions to users. Scoping interviews help to familiarise further with the topic and understand its main challenges. The objectives of the scoping interviews were to:

- Ensure that the study team is aware of all relevant background documentation and latest regulatory developments in the field;
- Collect contact details of relevant stakeholders to be contacted during the data collections exercises (i.e., identifying potential future interviewees);

Raise awareness among stakeholders of the study and its benefits and enlist their future cooperation.

In a second phase, interviews were conducted with various types of stakeholders involved in labelling requirements of chemicals and the use of digital tools to communicate hazard and safety information and instructions to users.

The objectives of the interviews were to collect stakeholders' feedback on different topics related to the labelling of chemical products and e-labelling, including:

- Perceived current understanding of chemical labels by different categories of users;
- The usefulness and relevance of information provided currently on chemical labels;
- The assessment of labelling requirements and needs of users;

The analysis of existing IT solutions available for e-labelling;
Identification of information that should remain on the physical label and suggestions of information to put on an e-label for chemical products.

In total 41 interviews have been conducted with the following categories of stakeholders:

5 European and national authorities;
11 NGOs, including 8 consumer associations;
25 Business representatives (from business associations and companies).

While all categories of stakeholders targeted for this stakeholder consultation have been reached, it must be noted that, among the respondents, a majority of them are representing the interests of the industry. This imbalance and the interests represented by this category of stakeholders have been taken into account in the analysis of the findings of the interviews.

Behavioural experiment

The aim of the behavioural experiment was to investigate consumers' understanding of chemical and detergents labels, the importance of different label elements as well as their interpretation with respect to safe use. Furthermore, the experiment tested potentials ways to simplify labels and whether the introduction of digital tools could support consumers.

Therefore, a state-of-the-art online experiment was designed that included six treatments, i.e. two different products (laundry detergent and glue) as well as three different labelling options (Status Quo Label in accordance with current regulation, Simplified Label with QR-Code and No Label Baseline). Participants were incentivised for taking part in the study as well as for their decisions in the different tasks. Furthermore, the treatment assignment was fully randomised.

Although representative products and labels were used in the experimental design and participants were tracked when consulting the labels presented on screen, it must be noted that the experiment can only mimic reality, i.e. a situation of consulting a label in everyday life. Main data collection was conducted in four Member States, i.e. DE, EL, FR and RO, and a total of 4,003 consumers took a part in the study.

Participants were recruited from an actively managed online panel and quotas to reach representativeness of the country-specific samples were used.

Open Public Consultation - Simplification and digitalisation of labels on chemicals

The findings presented in this Annex represents an analysis of the responses collected on 17 February, with 205 respondents. Only the answers to the questions related to the CLP-regulation have been taken into account.

These answers have been divided by stakeholder categories: 141 from the private sector (companies, business associations, trade unions), 11 from public authorities, and 53 from consumers' representatives (48 citizens, 4 consumer association and 1 NGO). Similarly as the interview analysis, the imbalance of representation among stakeholders groups and their different interests has been taken into account when processing the answers.

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Online survey on policy option

This consultation, run by VVA, aimed at gathering the opinion of the various stakeholders (consumers, professional and non-professional product users, industry, civil society organisations, national authorities and any other interested stakeholders) on the latest version of policy options analysed in this study. This survey allowed stakeholders to provide a punctual opinion on the measures taken into consideration for this analysis.

The answers have been divided by stakeholder category: 12 Member State authorities, 1 consumer organisation, 43 industry representatives (industry associations, businesses).

Online survey for professionals and industry users

The aim of the survey was to collect information from the stakeholders representing professionals and the industry on the importance of having certain pieces of information[9] on the packaging of the specific chemical products[10] as well as the easiness to understand the information concerning these elements in these products.

STAKEHOLDERS' VIEWS

Area 1: Hazard identification

The **OPC** results show that **opinions about the introduction of new hazard classes substantially varied between different stakeholder groups**:

Civil societies, public authorities and citizens were in favour of 'a sub-categorisation for chemicals with a high level of certainty on their endocrine-disrupting properties', while 63% of companies and business associations were not in favour.

Most respondents (69% overall) did not believe that a category for suspected PBT (and one for suspected vPvB) would be needed. However, citizens were polarised in their responses (44% yes, 56% no). Stakeholders' views also varied regarding whether categories for suspected PMT and vPvM would be needed: companies and business associations were mostly not in favour (75%), while most respondents of the other stakeholder groups were in favour (civil society, 79%; citizens, 62%; and public authorities, 53%).

Of all respondents, 36% considered developing a hazard class or criteria for immunotoxicity 'very relevant', whilst 21% are 'neutral' and 16% consider it 'somewhat relevant'. Thirty-six percent (36%) of all respondents consider the development of a separate specific hazard class or criteria for neurotoxicity 'very relevant'. Companies and business associations were most likely to consider the issue 'very irrelevant' (25%), while public authorities responded neutrally or 'somewhat relevant'.

[9] Name of the product; Address and telephone number of the supplier; Instructions for use; Dosage recommendations; Marketing information; Quantity; List of ingredients contained in the product, such as allergens, preservatives or enzymes; Weblink to receive full ingredients list; Information relevant in case of intoxication e.g. poison centre telephone number; UFI-code etc.; Hazard pictogram; Signal word, i.e., "Warning" or "Danger"; Statements on the products hazards for human health environment and physical hazards; Statements on the precautions to be taken on the use, storage and disposal of the product; Statements on how to prevent and minimise adverse effects when accidentally exposed.

[10] Laundry detergents; Cleaning detergents; Glues; Paints; Sealants or fillers.

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TSS responses analysis confirmed that business entities and associations were, mostly, not in favour of introducing new hazard classes. The key argumentations were that it will cause information overload in hazard communication, distort the level playing field in international trade and lead to an increase in costs for various activities, including hazard assessment, classification and reclassification of substances, labelling and relabelling of substances and mixtures, update and distribution of revised safety data sheets (SDS), packaging, reformulation of mixtures, update of IT systems and training the staff. They also pointed to overlaps in hazard classes and other problems in hazard class definitions, which are still premature from a scientific point of view. In this regard, the common arguments against new hazard classes, many of them advocated by business entities, were as follows:

- Endocrine disrupting properties of chemicals refer to a mode of action, not a hazard. Also, properties such as persistency, mobility and similar are not necessarily related to hazards, i.e. they do not automatically mean that a chemical is hazardous.
- The existing hazard classification in the CLP Regulation already covers the hazards of endocrine-disrupting substances.

Consultees provided **counterarguments**, for instance, for treating endocrine disrupting properties as a mode of action. They stated that EDs affect various organisms in very different ways; therefore, one cannot speak of a single mode of action. Similarly, some counterarguments were available in the written responses of **CARACAL members** on PBT/vPvB/PMT/vPvM properties. For instance, some CARACAL members highlighted those substances with a combination of specific properties, e.g., very persistent and very mobile or persistent, mobile and toxic pose a threat to drinking water sources. Such combinations of properties increase the chances of chemicals passing natural and artificial barriers in wastewater treatment facilities.

Supporters of the introduction of new hazard classes highlighted reduced exposure to hazardous chemicals, safer workplaces, substitution and better control of hazardous chemicals as the key reasons for having new hazard classes in CLP. On the other side, opponents pointed to the issues in international trade, the potential for regrettable substitutions as well as the increased costs and burdens for businesses as the main arguments for not including new hazard classes.

Area 2: Toxicity reference values and harmonised classification and labelling

Stakeholders' views on harmonising toxicity reference values in the CLP Regulation ranged from neutral to negative in the different consultation activities. With regards to the importance of harmonising toxicity reference values (i.e., DNEL, DMEL, PNEC) under CLP, responses to the **OPC** among the stakeholder types remained broadly neutral, with some variation between companies and business associations who were more likely to respond 'not important', and public authorities and citizens who were more likely to respond 'important'. Sixty per cent of the TSS respondents did not consider the inclusion of toxicity reference values in harmonised classifications particularly important. Many stressed that **the issue of hazard quantification, and therefore the establishment of harmonised toxicity reference values, is out of the scope of the CLP Regulation**.

Most respondents of the OPC and TSS supported the prioritisation system in the harmonised classification and labelling (CLH). Sixty-eight percent (68%) of the OPC respondents and 54% of TSS respondents agreed that the CLH system should allow for the prioritisation of substances raising high level of concern.

However, opinions about providing the Commission with the right to initiate CLH varied. Forty-six per cent of the OPC respondents strongly agree with such an option, while 20% - strongly disagree. Civil society, public authorities and citizens were more likely to strongly agree with this statement than companies and business associations.

Strong support (89% of TSS respondents - 'very important'/'fairly important', except civil societies) was expressed **for the provision of the right to propose modifications to existing CLH to manufacturers, importers and downstream users** subject to specific conditions, including priority assessment by the Commission.

Regarding the CLH process, two opposite opinions dominated: some respondents consider the CLH process as inefficient (e.g., in terms of time, organisation of procedures, etc.); others believe that the process is organised properly and does not require improvements. Some interviewees noted the lack of scientific quality and fair prioritisation of substances for CLH. Importantly, some **CARACAL members** highlighted that ECHA and RAC work at maximum capacity.

Area 3: Self-classification

Consultees believe that **ECHA should be able to remove incomplete, incorrect or obsolete notifications** from the Classification and Labelling Inventory (CLI) after having informed the notifier.

Around 70% of TSS respondents stressed that it is important to **improve ECHA's digital tools** for classification and labelling notification. Seventy-two percent (72%) of respondents to the OPC believed that the **obligation to agree on a CLI entry** should be strengthened.

While many respondents acknowledged that the Inventory contains obsolete information and errors and diverging self-classifications of the same substance, they do not see these as major problems. Some do think that the quality of the information is not good and the CLI cannot be trusted, but these issues do not have any major impact on stakeholders.

Area 4: Labelling

Mixed views were received from respondents concerning **how clear and easy to understand chemical labels are in general**. The only respondent stakeholder group to indicate that labels are generally 'clear/understandable' were public authorities, with the remaining stakeholder groups indicating somewhere between 'unclear and hard to understand' and 'clear/understandable', suggesting room for improvement.

When given the option to provide less but clearer information on labels or 'as much information as possible' (making the label more difficult to read in some cases), most respondents (80%) indicated that they would prefer **less but clearer information on labels**. This was true across all the stakeholder groups, although responses from civil society were more evenly split (52% would prefer less information, 48% would prefer as much information as possible).

A varying level of support for digital labels was expressed by OPC and TSS respondents. Ninety-two percent (92%) of business entities and associations who responded to the TSS welcomed digital labelling as a complementary hazard communication measure. Thirty-eight percent (38%) of the OPC respondents chose digital labels as the best options for

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receiving information on hazards and safety instructions when buying re-fill detergents. It was highlighted that care must however be taken as not all product users may have access to digital information.

With regard to **the labelling of chemical products provided in small packages**, companies and business associations felt that this is beneficial only when the presence of a hazardous substance has a realistic chance to cause actual harm to the user.

Furthermore, **business entities and associations who responded to the TSS strongly supported other labelling measures**, such as derogation from labelling requirements for substances and mixtures supplied in bulk (71% rated as 'very important'/'fairly important'), derogation from labelling requirements for substances and mixtures contained in very small packaging (90% rated as 'very important'/'fairly important'), and the use of fold-out labels to provide information in the EU languages (76% rated as 'very important'/'fairly important').

In the **OPC**, all stakeholder groups agreed that there would be **significant cost savings** from the following four policy options: exempting small products (pens, lighters) from certain labelling requirements, allowing a wide use of multilanguage labels/fold-out labels, providing certain obligatory labelling information digitally instead of on the label, and providing additional information digitally. Public authorities were the most likely to suggest that obligatory provision of information via digital labelling instead of the traditional label could have significant negative health, safety and environmental impacts. Business entities and associations were more likely to see **some cost savings** as a result of labelling derogations for smalls products and bulk chemicals, application of digital labelling and fold-out labels, as well as using symbols instead of multilingual texts on the label.

Interviewees consider that the lack of information through labels for **re-fill chemicals** as a significant gap. **The insufficient granularity of opinions was observed with regards to chemicals sold in bulk**, which were mainly treated as fuels. In the open text responses to the TSS, businesses expressed different opinions regarding bulk chemicals. Some respondents draw attention to the fact that hazards of chemicals sold in bulk (fuels in particular) are not communicated, while others emphasised that fuels are sold to trained users who are well-aware of the product and buy it repeatedly. Similar concerns were voiced by **CARACAL members**.

Area 5: digital labelling

Views on consumers' understanding of chemical labels: A majority of stakeholders from both the business sectors (22 out of 24) and consumer associations (6 out of 10) believes that, the chemical labels as they are now, are not well understood by consumers, for a variety of reasons. First of all, the main arguments highlighted that would explain a poor understanding of chemical labelling by consumers rely on the fact that consumers do not spend enough time reading the label (only a few seconds, except in case of accidents), and interpret them quickly and intuitively. Moreover, the overloaded character of labels and the long texts in small prints (as highlighted by all categories of stakeholders) reduce the readability and understanding of labels. Stakeholders from all categories have also underlined the use of technical terminology (e.g. chemical names) as an obstacle for consumers' understanding. While stakeholders from the business sector also argued that GHS pictograms are not well understood by consumers, stakeholders representing national authorities and consumers associations underlined the fact that consumers know pictograms and that they are better understood than texts.

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Views on usefulness of information provided on chemical products labels in general: During interviews, stakeholders have been asked to discuss, among the information currently provided on labels, which information they found particularly important to be provided for consumers', and which information they deemed non-essential. Stakeholders from all categories agreed that hazard information (notably the hazard statements) was one of the most useful information to be conveyed to consumers. However, they also noted that in some cases there could be an overlap or a redundancy of information given between the hazard statements and the precautionary statements, and that this redundancy could be addressed to simplify and optimise space on the label.

Communicating information on the safe and appropriate use of products to consumers – notably through precautionary statements – was agreed by all stakeholders to be the most important type of information to be communicated on chemical labels, including information related to the safe use (e.g. purpose of product, how to use the product, and with which equipment), information on safe storage of the products (e.g. keep away from children), and information in case of emergency situations.

There was a consensus among stakeholders that pictograms on chemical labels are favoured over texts. On the other hand, a couple of stakeholders from the industry and national authorities raised doubts about consumers' understanding of GHS pictograms. Nonetheless, several consumer associations pointed out that their usefulness also lies in the fact that they are important for catching the consumers' attention and prompt them to read the hazard statement.

The presence of the recently added UFI code was also deemed useful to be communicated on chemical labels.

Perspectives on multilingual labels: Business representatives explained that multilingual labels are used to achieve economies of scale, and one business association also mentioned e-commerce which must accommodate the needs of consumers coming from a wide range of countries. According to businesses and business associations multilingual labels allow the industry to produce one label for several countries, which is particularly useful when businesses have to distribute a product in countries with a low population and different languages. They also mention that scale through multilingual packs saves money and materials, allows a bigger flexibility in planning, and reduces scrapping. The business sector further explained that if companies had to produce quantities of products separately for all markets, the exercise would be so complex that companies might abandon smaller markets, thus depriving consumers from future innovations. The business sector explained that the simplification of labels, in other words the optimisation of labels with less information provided on pack was essential in their opinion.

On the other hand, national authorities explained that featuring multiple languages makes labels hard to read at the expense of communicating important safety and hazard information. In their view reducing languages on the label would allow more room for presenting essential information in a clear and legible manner. Consumer associations had similar views in this regard, highlighting also that the purpose of multi-lingual labels would be to meet consumers' needs in the specific countries, and proposing to add additional languages only if there is adequate space left on the label after essential information for safety and hazard was included in a readable manner in the official language(s) required.

Feedback on the potential use of IT tools for chemical labelling: The perceived readiness of consumers to use digital tools to access information on chemicals was very heterogeneous among stakeholders. The majority of stakeholders from the industry argued that consumers seem ready now to use IT tools to access information on a digital environment. To this regard, they pointed out the high awareness of QR codes (especially since the COVID-19 crisis and the increase in their use in day-to-day activities to limit physical contact).

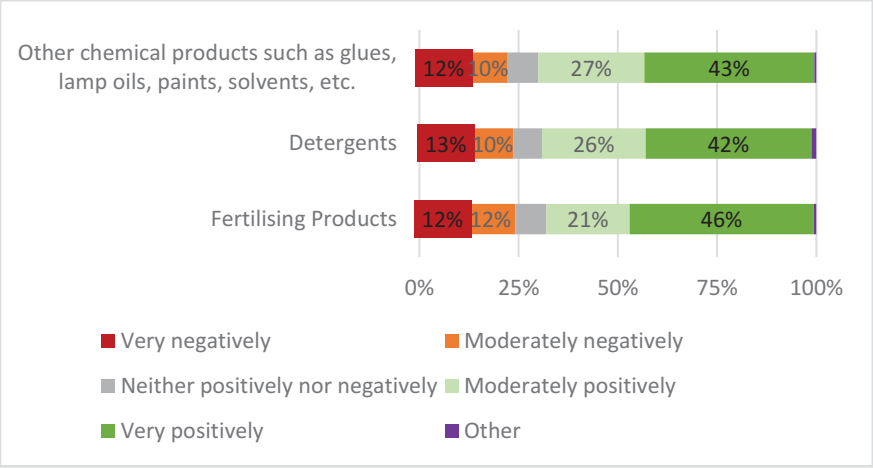
On the other hand, several stakeholders from all categories have argued that consumers were not ready to shift their habits and use IT tools in their day-to-day lives when it comes to buying and using chemical products. First of all, they have pointed out that consumers' readiness can vary widely depending on age groups (young people being more ready than older consumers), on country, education, and training. Moreover, several other issues have been highlighted, such as the lack of internet coverage in some geographical areas, the fact that not every consumer owns a smartphone or has an easy access to internet at home, as well as the need to educate consumers at national level about the possibilities to access information digitally and benefit from the presence of e-labels.

Overall, the behavioural experiment shows that the Status Quo and Simplified Label with QR-code perform better than the No Label Baseline w.r.t. labelling understanding. Furthermore, the Status Quo and Simplified Label perform equally well. Although, it must be noted that average understanding of labels is generally not good. Subjective risk interpretation of the Status Quo and Simplified Label is in line with the actual dangers of products. Furthermore, subjective ratings of understandability and ease to find of label elements are not different between the Status Quo and Simplified Label.

The majority of the respondents[11] indicated that, in the context of the below chemical products, removing some of the information from the on-pack label to the digital labels would have a moderately positive or a very positive effect overall:

[11] 125 out of 180 respondents who have answered to a part on the other chemical products such as glues, lamp oils, paints, solvents, etc., 112 out of 165 respondents who have answered to a part on the detergents, and 103 out of 153 respondents who have answered to a part on the fertilising products.

Table 3: Analysis of replies on effect of removing some of the information from the on-pack label to the digital labels

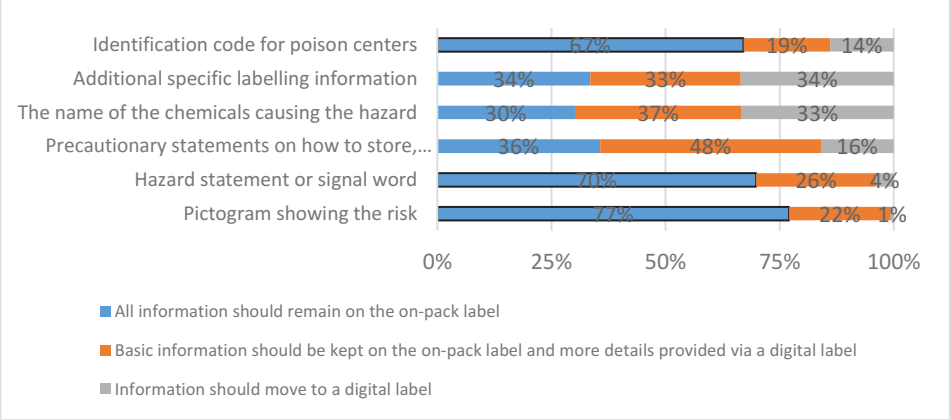


Respondents: N = 153 for Fertilising Product, N= 165 for Detergents, and N = 180 for other chemicals.

The majority of the respondents, including consumer representatives[12] indicated that information should remain **on the on-pack label (for a chemical product such as a glue, lamp oil, paint, solvent, etc.)** concerning the: identification code for poison centers[13]; hazard statement or signal word[14]; and pictogram showing the risk[15].

In regards to the other sources of information, the respondents (including consumer representatives) had different views on what kind of information could move to a digital label. The full overview of the responses to this question is provided in the table below:

Table 4: Replies of the information to be moved to a digital label



Area 6: CLP scope exemptions

A large group of the **OPC respondents** (43%-49%), consisting mostly of citizens, public authorities and civil societies felt that the **provision of information on the environmental**

[12] 39 out of 50 answers for "pictogram showing the risk"; 35 out of 49 answers for hazard statement or signal word"; and 31 out of 50 answers for identification code for poison centres".
[13] 106 out of 158 total responses.
[14] 109 out of 156 total responses.
[15] 121 out of 157 total responses.

hazards of veterinary medicines, medical devices, cosmetics, and food or feed, was 'an issue which should be immediately solved'. Differently from other respondents, business entities and associations felt that there is an issue to be immediately solved only for human medicines (53% of business respondents), while for other exempted products there is no issue at all.

Opinions on the regulatory gaps in addressing the environmental hazards borne by the products exempted from the CLP Regulation gathered through the TSS vary. Business entities and associations (60%-66%) are of the view that the environmental hazards of the exempted products are properly covered by sectorial legislation. Public authorities believed that the environmental hazards are insufficiently addressed by the sectorial legislation regulating human and medicinal products, as well as medical devices, but they considered that the sectorial legislation adequately addresses the environmental hazards of cosmetics, food and feed products. It should be noted that a very low number of public authorities and NGOs participated in the TSS to confidently judge the predominant view within these groups.

Many interviewees commented that the measures to address the potential environmental hazards of the exempted products are in place, although they are risk-based rather than hazard-based.

Area 7: Online sales of chemicals

The findings of consultation activities show that **all stakeholders agree that online sales of chemicals pose challenges and problems**. In the **OPC**, the overwhelming majority of respondents (93%, with agreement across all stakeholder groups) believed that there is a great need to apply the same CLP obligations (e.g., labelling, classification and notifications to poison centres) to chemical products sold online. In the **TSS**, all groups of stakeholders 'agreed' (average answer in all groups – 4 'agree') that the current gaps in the CLP Regulation considering online sales hinders its ability to protect human health and the environment and its ability to ensure the free movement of chemicals.

Interviewees indicated that non-compliance of online sales of chemicals with classification and labelling as well as CLP Article 48 requirements is a problem, pointing in particular to non-EU traders and small business entities engaged in e-commerce.

Area 8: Poison centres

Most responses were not descriptions of the problem as perceived by the respondents, but rather reactions to potential actions or measures that the respondents foresaw (e.g., the lack of information in poison centres was equated with actions on increasing the clarity of Article 45 of the CLP Regulation).

The analysis of **open-text responses and position papers in the OPC** allows us to conclude that the problem of ambiguous obligations in Article 45 was recognised by the stakeholders, as most of them welcomed the clarification of obligations. However, most **OPC respondents (67%) think that it is 'not useful' to submit poison centres notifications on substances**.

Some TSS respondents believed that the problem is in the **diverging interpretation of Article 45** by the Member States leading to specific national requirements. In case of introducing notification obligation for distributors in Article 45 and notification obligation for

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substances, business entities and associations felt that their **costs of updating IT systems and training the staff might increase**.

Annex 3 – Who is affected and how?

1 PRACTICAL IMPLICATIONS OF THE INITIATIVE

Classification of chemical hazards

First on new hazard classes, industry will be required to review the data available for the substances and mixtures they placed on the market. They should identify, classify, notify and label their ED, PBT, vPvB, PMT, vPvM substances and mixtures. Some companies would phase out the identified substances in their portfolio and/or as ingredients of their chemical products. The exposure of users and of the environment to the identified hazardous substances will decrease, thanks to adequate hazard information communicated to the users of chemicals and by voluntary reformulation from some companies.

Second, the changes introduced to improve self-classifications will request companies to swiftly update their self-classification once new data is identified. They should also justify their self-classification when diverging from existing ones. They should also submit confidentiality requests to ECHA when publishing their names would disclose business confidential information. They would then update their notification to ECHA's Inventory, where appropriate. An inventory where information is easier to access will save time and foster accurate (mixtures) self-classification. ECHA would need to check the confidentiality requests as well as whether updates have been performed within the required timeline.

Third, more harmonised classifications will focus on substances with carcinogenic, mutagenic, toxic to reproduction, endocrine disrupting, PBT, vPvB, PMT and/or vPvM properties. Companies should update their classifications, notifications and relabel their substances and mixtures, where appropriate. Some companies may phase out the identified substances in their portfolio and/or as ingredients of their chemical products. When it comes to carcinogenic, mutagenic, reprotoxic substances, current risk mitigation measures laid down in REACH or sectorial regulations would apply. The exposure of users and of the environment to the identified hazardous substances will decrease, thanks to adequate hazard information communicated to the users of chemicals and by voluntary or compulsory reformulation from some companies. ECHA, Member States, maybe with the help of consultant, would develop more dossiers for ECHA to assess. It is not clear how ECHA would deliver on this increased stream of dossiers.

Communication of chemical hazards

Companies would have to update their label and relabel their products where necessary. With the use of fold-out labels, companies could access the market of multiple Member States. Companies placing on the market fuels in bulk or chemicals in very small packaging will gain certainty on alternatives to physical labels for hazard communication. Retailers will need to adapt their refill stations and chemical portfolio for refill sales. Duty-holders may take the opportunity to digitalise part of their labelling.

Closing gaps and ambiguities

Companies placing chemicals on the EU market without an economic actor established in the EU will need to authorise a representative or contract a fulfilment service provider.

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Distributors (including re-branders and relabellers) would notify their self-classification of mixtures to poison centres.

2 SUMMARY OF COSTS AND BENEFITS

The tables below present the overview of the costs and benefits identified for the preferred option. These figures are estimates, based on the sometimes limited data available. In sub-sections I and II, figures are drawn up against a period of 20y as some benefits may only arise in more than one generation.

The One-In-One-Out analysis is presented in tables III and IV. The figures for one-off costs are not annualised.

I. Overview of Benefits (total for all provisions) – Preferred Option – 20y basis		
Description	***Amount***	***Comments***
Direct benefits		
Labelling Reduction Costs	€9.91 million	Annual or annualised savings for businesses (fuels and chemicals in very small packaging, including pens).
Labelling Reduction Costs	€39.50 million	Annual savings for businesses (fold-out labels).
Reduced ED sickness and negative impacts on the environment		It is not possible to precisely quantify the benefits. However indicative calculations are provided in Annex 8, pages 186 to 199. Potential savings are in the same order of magnitude as the costs. They could be higher than the costs.
Indirect benefits		
Easier navigation in the Classification and Labelling Inventory	€8.94 million	Annual savings for businesses (cost saving of navigating the CLI).
Reduced compliance checks by market surveillance authorities	€0.29 million	Reduced enforcement costs.

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

II. Overview of costs (in €) – Preferred option – annualised according to 20y basis							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Classification of chemical hazards PO1a, PO1b (with measure #5) and PO1c (with measure #8)	Direct adjustment costs	-	-	26.40 million	-	-	-
	Indirect adjustment costs	-	-	-	-	-	-
	Direct administrative costs	-	-	12.89 million	3.85 million	0.91million	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	7.76 million	1.29 million	-	-
Hazard labelling	Direct adjustment costs	-	-	None quantified	-	-	-
	Direct administrative costs	-	-	0.06 million	1.64 million	-	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	0.1 million
	Indirect costs	-	8.61 million	-	0.03 million	-	-
Poison centres Online Sale	Direct adjustment costs	-	-	-	-	-	-
	Direct administrative costs	-	-	-	0.4 million	-	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	-	-	-	-

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

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III. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Administrative cost savings related to the 'one in, one out' approach*		
Costs associated with changes to labelling and packaging.	57.4 million EURO per annum	Savings in recurrent administrative costs on businesses
Costs associated with changes to labelling and packaging.	13.5 million EURO (one-off)	One-off administrative cost savings for business related to labelling

IV. Overview of costs – Preferred option (million EURO)						
	Citizens/Consumers		**Businesses**		**Administrations**	
	One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Costs related to the 'one in, one out' approach						
Administrative costs	0.0	8.6	258.7	23.2		

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.

3 RELEVANT SUSTAINABLE DEVELOPMENT GOALS

V. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG #3 Good health and well-being	Reduction of exposure of humans and the environment to hazardous substances as meeting one of the existing hazard classes (improvement of self and harmonised classifications) or new ones for EDs and PMT, vPvM, PBT and vPvB substances. Around 2,250 substances may be identified by 2030. Furthermore, between 2,200 and 14,000 mixtures may be voluntarily reformulated to remove substances newly identified as hazardous over the same period.	Specific Target 3.9 'By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination'
SDG #6 Clean water and sanitation	Identification of PMT and vPvM substances, which are difficult to remove from waste waters will help to reducing the pollution of water bodies. By 2030, 35 substances may be identified as PMT or vPvM substances. Up to 220 mixtures may be voluntarily reformulated to remove the newly hazardous substances	Specific Target 6.3 'By 2030, improve water quality by reducing pollution, eliminating dumping and minimising release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally'
SDG #9 Industry, innovation and infrastructure	Setting criteria to identify hazardous substances and improving both the self and harmonised classification processes will allow the European chemical industry to transition to more sustainable and future-proofed chemicals. Voluntary substitutions of substances classified as hazardous as such or in mixtures will also foster innovation in the chemical industry. Measures to improve classification processes are expected to contribute to SDG #3, #6 and 12, albeit indirectly.	Specific Target 9.4 'By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities'
SDG #12 Ensure sustainable consumption and production patterns	Information on chemical hazards will be improved so consumers and users of chemical can not only protect themselves better but also make informed choices. Self-refill chemicals will be better regulated to allow only refill of mildly hazardous substances. When it comes to online sales of chemicals, customers will have access to more comprehensive information on chemical hazards. Voluntary substitution of hazardous substances in mixtures will also help producing more sustainable chemical products.	Specific Target 12.4 'By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimise their adverse impacts on human health and the environment'

Annex 4 – Analytical Methods

This Annex reports the following methodologies used in this SWD.

- Methodology developed by ECHA to screen registered substances meeting specific hazard criteria;
- Methodology used for the behavioural study;
- Methodology to derive quantified administrative costs and savings.

OVERVIEW

The research carried out by the project teams follows the Better Regulation Policy Guidelines for the impact assessment and uses various methods to collect and analyse evidence necessary for the impact assessment of the CLP Regulation. Figure 7 summarises how project research tasks supporting the development of the impact assessment report in line with Better Regulation requirements.

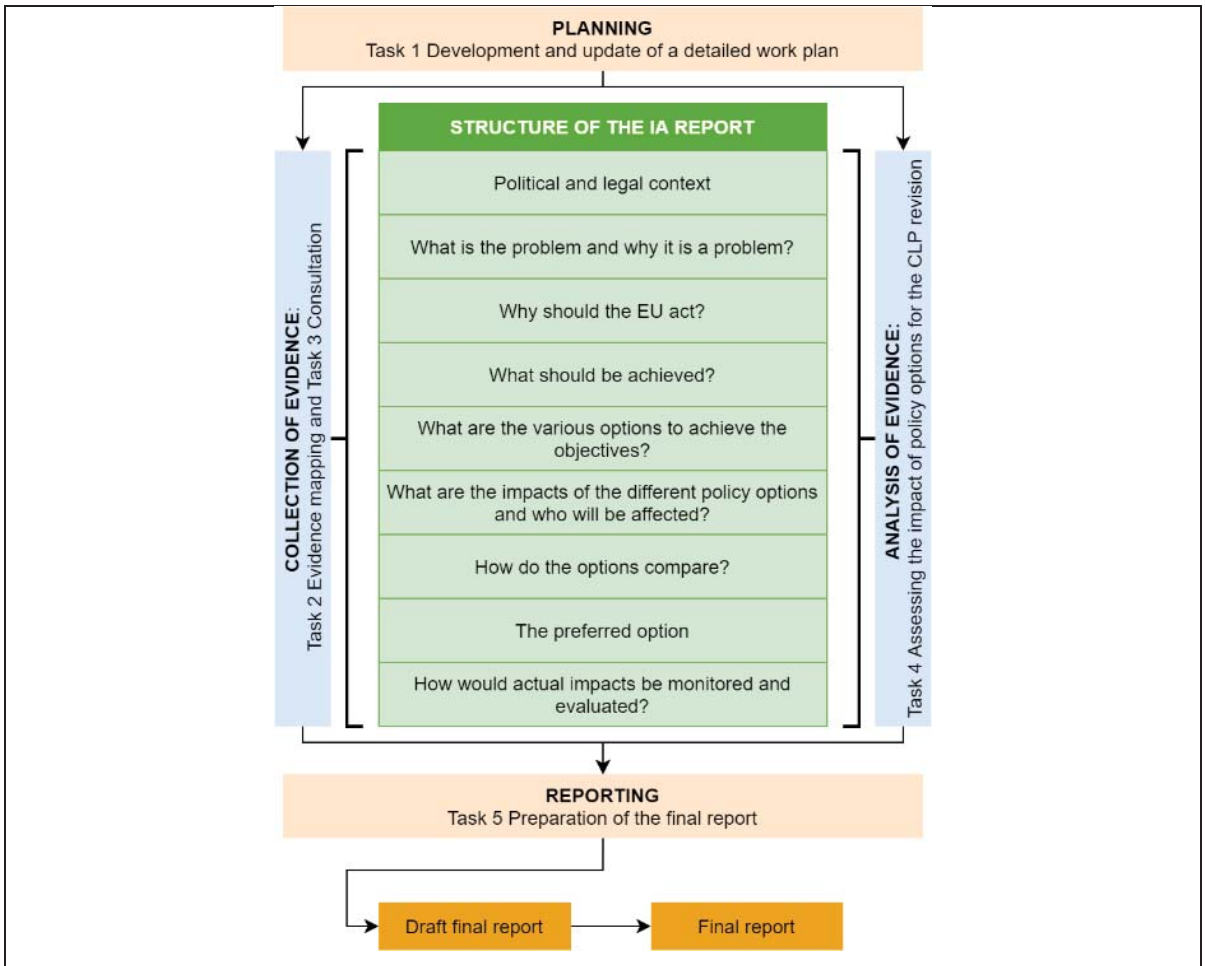

Figure 7: Overview of the tasks supporting the impact assessment study

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Project tasks 1 and 5 support the implementation of the project, while the research programme of the study is implemented in tasks 2, 3 and 4. Analytical methods used for completing the latter tasks will be overviewed in the following sections.

EVIDENCE COLLECTION METHODS

Evidence gathering (Task 2) aimed to collect, analyse and evaluate the available evidence that is relevant for the impact assessment of the CLP Regulation, in particular, for developing problem definitions, policy options, assessment of the impact of these as well as developing questions for open public consultation. Evidence collection covered the seven problem areas defined in the Terms of Reference for this study:

1 new hazard classes (hazard identification);
2 toxicity reference values and harmonised classification and labelling;
3 self-classification;
4 labelling;
5 CLP scope exemption;
6 online sales of chemicals;
7 poison centres.

A **rapid literature review methodology** (also known as rapid evidence assessment – REA) was used for data collection and interpretation. Rapid reviews are widely used for the analysis of the broad spectrum of topics or issues, which is the case of this study. They are based on the main principles of systematic literature reviews, which contributes to their robustness; however, rapid reviews do not develop sophisticated methodologies for evidence weighting and inclusion as well as for quantitative analysis designs for the presentation of findings. The absence of extensive and complex research methodologies substantially reduce time needed to conduct a literature review. Rapid reviews give comprehensive qualitative narrative overviews of the selected domain. Collection and evaluation of robustness of evidence followed Better Regulation Tool #4.

For two problem areas – new hazard classes (hazard identification) and CLP scope exemptions, extensive supporting studies were carried out. In addition to rapid literature review these studies used other method – **legislative document analysis** (CLP scope exemptions) and **data analysis** (new hazard classes).

CONSULTATION METHODS

Consultation activities (Task 3) ensured that stakeholders' views, practical experience and data were taken into account in the policy development process, ensuring higher quality analysis and support for implementation. All information gathered in Task 3 was fed into the wider impact assessment regarding the analysis of policy options and any associated impacts.

Several methods were used in consultation for **data collection** – questionnaire surveys, semi-structured interviews and document analysis.

General public and experts, including the main stakeholders, such as citizens, public authorities, business entities and associations, civil societies, academic researchers were reached by launching two questionnaire surveys – open public consultation and targeted stakeholder consultation. Following Better Regulation Tool #52, **open public consultation survey** aimed to enable the public and stakeholders to freely contribute to the impact

assessment study with their opinions, while **targeted consultation survey** addressed main stakeholders of the study. Two data analysis methods were applied to interpret the results of both surveys: descriptive statistics and thematic analysis. **Descriptive statistics** was used to analyse closed quantitative responses to the surveys, while **thematic analysis** was applied to interpret answers to open questions and the content of the position papers. Thematic analysis is a data interpretation method that allows systematic approach to categorising qualitative unstructured input by stakeholders into the hierarchy of topical categories. Thematic analysis was supported by *Nvivo* software package. **Thematic category maps** were developed for data visualisation by using open-source software *Free Mind*.

To complement and cross-check with the findings of quantitative surveys and evidence collection in Task 2 **semi-structured interviews** were carried out with civil societies, public authorities, academia, and business entities and associations. For making the study more inclusive to opinions of the stakeholders the study team conducted both **individual and group interviews**. The study team used **thematic analysis** for data interpretation supported with thematic category maps for visualisation of the findings.

Furthermore, the study team applied **observation** and **document analysis** for collecting the opinions of CARACAL and its CASG sub-group members and observers. Observation of the CARACAL meeting was carried out by non-intrusive observation of CARACAL discussions and making notes that were later used for the study purposes. Document analysis was used for processing the written feedback submitted after each meeting by the CARACAL members and observers.

IMPACT ASSESSMENT METHODS

Impact assessment provided the core output of the study with the assessment of the economic, social and environmental impacts of each of the policy options identified. It brought together data gathered through evidence collection and consultation activities. Impact assessment (Task 4) followed the methodology specified in the Better Regulation Guidelines and consisted of **six sub-tasks**.

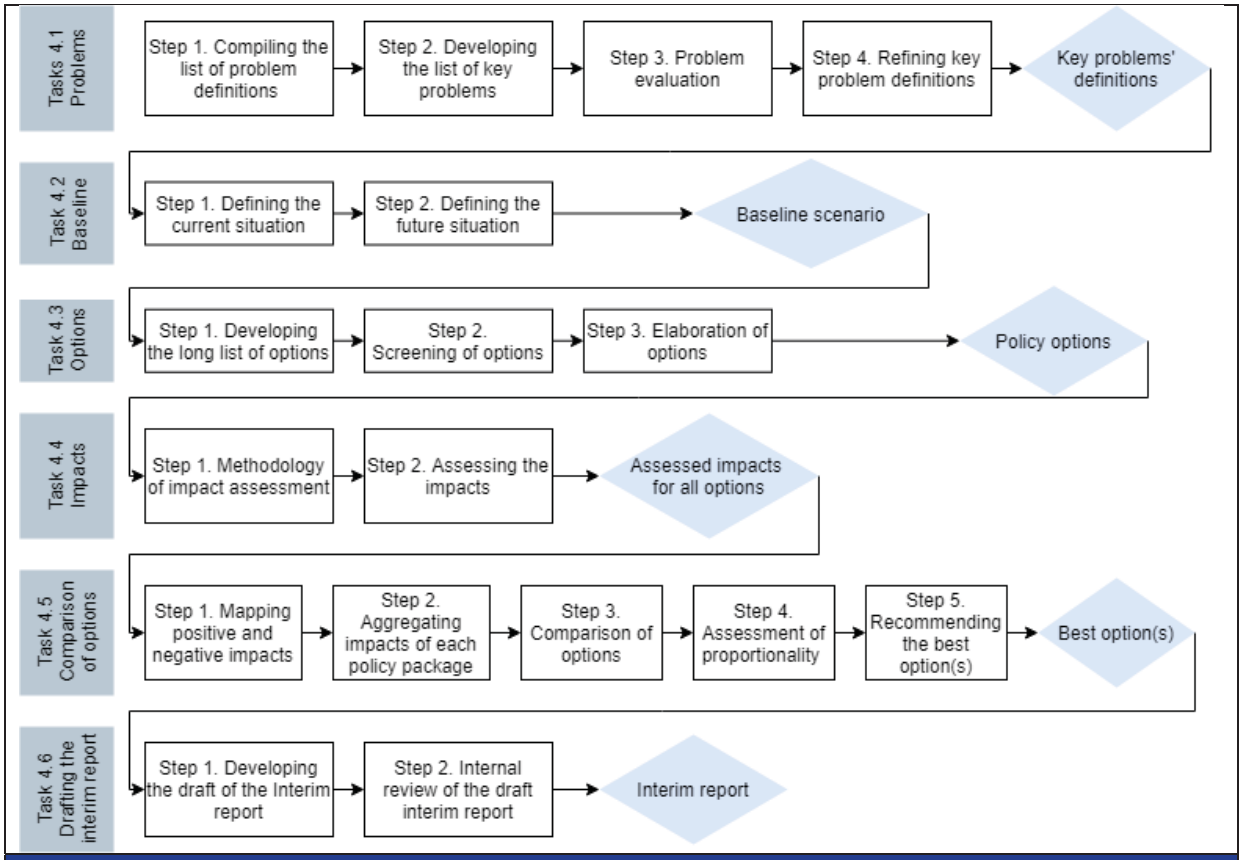

Figure 8: Task 4 workflow

Problem analysis aimed to identify and analyse the key problems to be addressed in the report supporting the impact assessment of the CLP Regulation. It was carried out following the methodology suggested in Better Regulation Guidelines, Tool #13 "How to analyse problems".

Following Better Regulation Tool #16, **baseline**, i.e. "no policy change" scenario, was developed. It provided a reference point for assessing changes and impacts, as it establishes a basis for comparing the situation before and after an intervention.

A set of policy measures was developed to solve the problems in each of the seven areas that were investigated in the study. Following the recommendations of Tool #16, policy measures were grouped into several **policy option packages**. The long-list of policy options was screened and some of the measures contained in policy option packages were discarded.

Impacts of all retained policy options were assessed. The main **direct impacts** were quantified and monetised (both the baseline and the policy options under consideration). Furthermore, **indirect impacts** were quantified, where possible, and if not then they were assessed qualitatively with a clear indication of their nature and likely magnitude. **Costs and benefits** were disaggregated, as far as possible, according to each identifiable action under the different options and identified according to the standard typology of costs (e.g., administrative, enforcement) and benefits (Tool #58 and #59). The assessment was undertaken in line with the Better Regulation Guidelines and, in particular, Chapter 8 ("Methodologies for analysing impacts in impact assessments, evaluations and fitness checks").

The **options were compared** both to the baseline scenario and to each other and provide the Commission with a recommended option or combination of options. This sub-task brought together both quantitative and qualitative findings to present a coherent set of conclusions and recommendations. Policy options were compared based on their effectiveness (i.e., the potential to deliver on the objectives), efficiency and coherence, against the objectives of the CLP and specific options defined in the earlier tasks.

SCREENING REGISTERED SUBSTANCES

Databases considered

The focus was on the REACH registered substances, including biocidal and pesticidal active substances. Cosmetics have only been included if they are present in one of these inventories. Regarding biocides and pesticides only active substances that can currently be used in the market were kept, e.g. biocide active substances that have been assessed and not approved for any product type were excluded.

With regard to the REACH registered substances ECHA used the recently published chemical universe (https://echa.europa.eu/universe-of-registered-substances). Substances present in more than one inventory (duplicates) were identified based on the presence of at least one common identifier (EC number, CAS number or substance names). The combined substance inventory contains 23751 unique substances, out of which 23043 are only registered under REACH, 379 are only active pesticides, 98 are only active biocides and 231 are in more than one inventory (most of which are registered under REACH). There are 2264 substances registered according to Annex X of REACH (this number is used for the projections of basket 3). 12239 substances have at least one active registration according to Article 10 and an additional 509 substances are active pesticides and/or biocides. The remainder of the 23751 substances are intermediates registered under REACH, NONs (claimed or unclaimed) that have not been updated under REACH or only have registrations that are currently ceased. The inventory of substances is provided as a separate dataset (substance_inventory.xlsx, see annex). It does not include substances that are only notified to the CLP inventory but have not been registered.

Identification of registered substances

For each endpoint[16], substances have been divided into 3 baskets:

Basket 1 - Substances with confirmed hazard(s): For endpoints included in CLP these are based on either their harmonised classification (inclusion in Annex VI to CLP) or the reported self-classification in the registration dossier[17]. For other endpoints these are based on identification as SVHCs (inclusion in the Candidate List), identification under BPR or agreed in the ED/PBT Expert Groups. Hazard(s) are based on available information; lists as well as numbers of substances are provided.

[16] ED, PBT, vPvB, PMT and vPvM

[17] Certain entries on Annex VI to CLP are conditional (e.g. the classification only applies if certain impurities are present). These have been removed from the analysis. In addition, self-classification can be impacted by the presence of impurities. In this analysis, no attempt has been made to identify and remove substances if the self-classification is based on impurities.

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Basket 2 - Substances where the hazard(s) are under consideration: These are substances with on-going data generation or assessments; lists as well as numbers of substances are provided; it includes also an estimate on how many would likely turn out positive (based on past experience).

Basket 3 - Guestimate on how many substances could have the same hazard(s) among the remaining REACH registered substances: Numbers provided were extrapolated to all REACH registered substances using the frequencies of the hazards in Basket 1 and 2. The numbers provided are associated with a very high uncertainty. It is not possible to provide lists of substances as these are extrapolations and no substance specific data have been considered.

Each substance in the analysis has been assigned to either Basket 1 or 2 (see above) for a given hazard property. Substances have been assigned to **Basket 1** on the basis of the criteria set out above.

Basket 2 has been compiled using a number of input lists for each hazard property: e.g. CORAP[18] substances, substances under ongoing assessment by ED or PBT Expert Groups, etc. It is expected that only a proportion of the substances in basket 2 will have the hazard confirmed and consequently move to Basket 1 in the future. Different weighting factors have been assigned to the input lists, based on the likelihood that the hazard will be confirmed as follows:

Low likelihood that the hazard will be confirmed - weighting factors between 0-0.3;

Medium likelihood that the hazard will be confirmed - weighting factors between 0.4-0.6;

High likelihood that the hazard will be confirmed weighting factors between 0.7-1.

If a substance appears in more than one input list, it is counted only once considering the highest weighting factor/highest probability that the hazard will be confirmed. In basket 2, the total number of substances expected to have the hazard confirmed, and consequently move to basket 1 in the future, is calculated by adding up all the weighting factors for the substances in each endpoint basket[19]. It should be recognised that uncertainties apply to the use of these weighting factors but in most cases the number of substances in question is relatively limited. Therefore, the size of the weighting factor will not have a significant bearing on the overall number of substances predicted to fall in Basket 1.

Basket 3 represents an estimation based on the assumption that the same proportion of hazardous substances exists regardless of the 'Annex' registered i.e. regardless of their tonnage. The starting point for the estimations is

- the number of substances with the hazard confirmed (Basket 1) and
- the number of Basket 2 substances which are estimated to be confirmed with the respective hazard (see above).

[18] Community Rolling-out Action Plan

[19] For example, if 5 substances were in basket 2 for a particular endpoint, each with a weighting of 0.2, 1 substance (5 x 0.2) would be expected to be confirmed as having the hazard property in question.

For Annex X substances it is considered that the hazards are already known (Basket 1) or under investigation (Basket 2) - in other words "dealt with". As the proportion of Annex X substances registered at annex X of REACH is about 9% of the substances in scope of this exercise[20], the figure for annex X was simply multiplied by a factor of 11 to derive the projections for basket 3.

It is however noted that the estimations for basket 3 have a high degree of uncertainty and should be used only as very basic indicative numbers. Moreover, these estimations do not consider whether there is sufficient information available for those substances to enable deciding on the hazardous properties (e.g. substances registered with Annex VII and VIII have in general a very limited data set).

BEHAVIOURAL EXPERIMENT FOR DIGITAL LABELLING

The aim of the behavioural experiment was to investigate **consumers' needs with respect to the labelling of chemical substances**. Therefore, a state-of-the-art behavioural experiment was designed and conducted to collect data on consumers' cognition and preferences.

Research Questions

Overall, the experiment answers **five research questions**:

What is the level of understanding of chemical and detergents labels?

What is the **importance of different elements** contained in labels? Which information is considered essential?

How do consumers interpret labels with respect to hazards and safe use?

Does label **simplification and the introduction of digital tools** positively or negatively affect consumers' understanding and perceptions?

Do consumers prefer information to remain on the physical label or to be communicated via digital tools?

In the subsequent section the methodological approach is presented on how the behavioural experiment design informs the research questions. Hereafter the results from the main data collection are summarized.

Methodology

In the following, the experiment design including products, treatments, main variables as well as further methodological considerations are presented. The **general structure of the experiment** is summarised in Table 5.

[20] There are 2264 Annex X substances

Table 5: General Structure of the Behavioural Experiment			
Online behavioural experiment + supporting consumer survey Duration 15 Minutes			
Target audience: Consumers; Nationally representative for age and gender (hard quotas) and education and income (soft quotas)	Incentives: Flat-fee payment and additional incentives for questions on objective understanding	Pilot: To test experiment before launch of main fieldwork with n=101 in DE	Sample size main data collection: N=4,003 with n□1,000 collected in each of DE, FR, EL, RO
Test method: Randomised controlled trials using various types of treatments for robust and generalisable results.			

In order to answer the research questions a **randomised controlled trial-design** was implemented that systematically varied types of labelling-treatments (see section 1.1.3). In addition, a supporting consumer survey was designed in order to collect further insights on non-behavioural variables. Furthermore, the experiment was **incentivised** (see section 1.1.5).

In preparation of main data collection, a **pilot** was implemented in July 2021. It included n=101 observations from Germany and aimed at investigating the correct functioning of the experimental set-up and programming. Therefore, timing to complete the study as well as randomisation of treatment assignment was thoroughly checked. Furthermore, in the pilot study it was assured that "don't know"- or "other"-frequencies for questions were not a problem and that participants were able to understand tasks (open question at the end of the pilot). After minor revisions of the experimental design and questionnaire, the main data collection script was programmed and the study was fully translated.

Main data collection was performed in September and October 2021 in four Member States, i.e. Germany, France, Greece and Romania with a total of 4,003 participants. The target audience was consumers in general, recruiting for representative general population samples per country. The complete experiment script has been provided to the EC after sign-off in September 2021.

Overview of Modules

The experiment consisted of **five subsequent modules** that are displayed in . Each participant went through the same sequence of modules and completed several tasks on label understanding, interpretation as well as preferences regarding labelling elements and their communication channels.

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Table 6: Overview of Modules in Behavioural Experiment	
Module 1	**Screening and introduction** • Achieve representative sample • Explanations on study objectives
Module 2	**Label understanding and interpretation** Objective understanding of labels Perception of labels Behaviour given label information
Module 3	**Rating of information contained in labels** Importance of label elements Understandability of labels Ease to find information on labels
Module 4	**Comparative Choice** 1) Ability to select less harmful product
Module 5	**Label preferences, socio-demographic aspects and attitudes** 2) Preference for analogue versus digital labelling 3) Experience with chemicals, chemical worker, training 4) Digital readiness 5) Behavioural variables, i.e. trust and risk aversion

Products

At the heart of the experiment stand **two products** containing chemical substances that fall either exclusively under the CLP Regulation or under both the CLP and the Detergents Regulations[21]. The two products were carefully selected so that they cover products consumers are familiar with and frequently handle in their personal life. A further requirement for product selection was that products differ in their degree of potential harmfulness, i.e. with respect to their physical, health-related as well as environmental hazards. Following desk research on representative product types available on consumer markets, the choice fell on a **laundry detergent** and a **glue**.

In order to design the experiment as realistic as possible, further desk research was performed and **representative products** were identified. These representative products were replicated for the purpose of the experiment and can be purchased in supermarkets, drugstores or DIY-stores. Hence, the experimental products are replica of actual laundry detergents and glues consumers handle in their everyday life. Furthermore, desk research was performed to identify substances usually contained in the products, to ensure that the ingredients were realistic. The same applies to the labelling information on hazards as well as precautions on the selected products. To avoid behavioural bias from brand familiarity and personal product preferences, the products were given a fictive name. Similarly, the manufacturer's name and company information were fictive and framed in a neutral way.

[21] Given that detergents' labelling falls by default under these two pieces of EU chemicals legislation.

Treatments

Following product selection, different types of labels were designed for the laundry detergent and glue. Overall, the experiment tested **three different types of labels** which are presented in the following.

Status Quo Label

The first label was the **Status Quo Label** which comprises labelling requirements from current legislation. It contained all informational elements necessary, i.e. dosage information, ingredients, UFI-code, GHS-pictogram, signal words as well as hazard and precautionary statements. Figure 9 displays the Status Quo Label for the laundry detergent and Figure 10 displays the variant for the glue.

Figure 9: Status Quo Label – Laundry Detergent

Figure 10: Status Quo Label – Glue

Simplified Label with QR Code

Following the main research questions, an objective of the experiment was to test whether labels of chemical products can be simplified and whether digital tools could support consumers' understanding. Hence, the second treatment included the **Simplified Label with a QR Code**.

In the case of the **laundry detergent,** the simplification consisted of reducing the dosage table, i.e. instead of the full dosage table including separate rows for different degrees of water hardness, the Simplified Label only contained one row for medium water hardness. Furthermore, the list of ingredients was removed from the package label. The reduced / removed information was made available via a website which could be accessed via a QR Code added to the packaging. Hence, the full dosage table for different degrees of water hardness and the list of ingredients was available on the website. Furthermore, the label was amended by further pictograms that were taken from A.I.S.E. (International Association for

Soaps, Detergents and Maintenance Products).[22] The GHS-pictogram, signal word and hazard and precautionary statements remained on the label in accordance with current legislation. Figure 11 displays the label for the laundry detergent as well as the website to be opened when scanning the QR code.[23]

Figure 11: Simplified Label with QR Code – Laundry Detergent

In a similar way, the simplified label of the **glue** was designed. Information on the ingredients was removed from the package and moved to a website to be accessed via a QR code. Additionally, A.I.S.E. icons were added to the packaging while information on hazards and precautions, pictograms and signal word remained in accordance with current regulation (status quo). Figure 12 displays the Simplified Label for the glue as well as the website on ingredients.

[22] A.I.S.E. (2021). Safe Use Icons. Retrieved from: https://www.aise.eu/library/artwork/safe-use-icons.aspx (30.06.2021)

[23] Please note that scanning the QR-code was mimicked in the experimental design by a pop-up to be opened in the browser. More information on this aspect may be found in section 0.

Figure 12: Simplified Label with QR Code – Glue

No Label Baseline

Lastly, one of the tested treatments displayed only the front packaging of the two products. Hence, it is referred to as the **No Label Baseline**. It was introduced as a methodological control in order to robustly test whether labelling information in the other two treatments indeed informs consumers' understanding. Participants in the No Label Baseline answered the same set of questions as in the other treatments but without consulting the labels, i.e. responses were based on the **experience consumers have with the products**. Figure 13 and Figure 14 display the image for the laundry detergent and glue.

Figure 13: No Label Baseline – Laundry Detergent

Figure 14: No Label Baseline – Glue

Randomisation, Variables and Tasks

At the beginning of the experiment participants were **randomly assigned** to one of the two products, i.e. either laundry detergent or glue, and to one of the three treatments, i.e. either Status Quo Label, Simplified Label or No Label Baseline. They remained within their treatment for the whole course of the experiment and underwent several tasks and questions.

The **main variables** elicited in the experiment were:

Objective understanding of labels;

Ability to identify a less harmful product given label information;
Perception of labels;
Anticipated behaviour given label information;

Rating of importance of label elements as well as understandability and ease to find information.

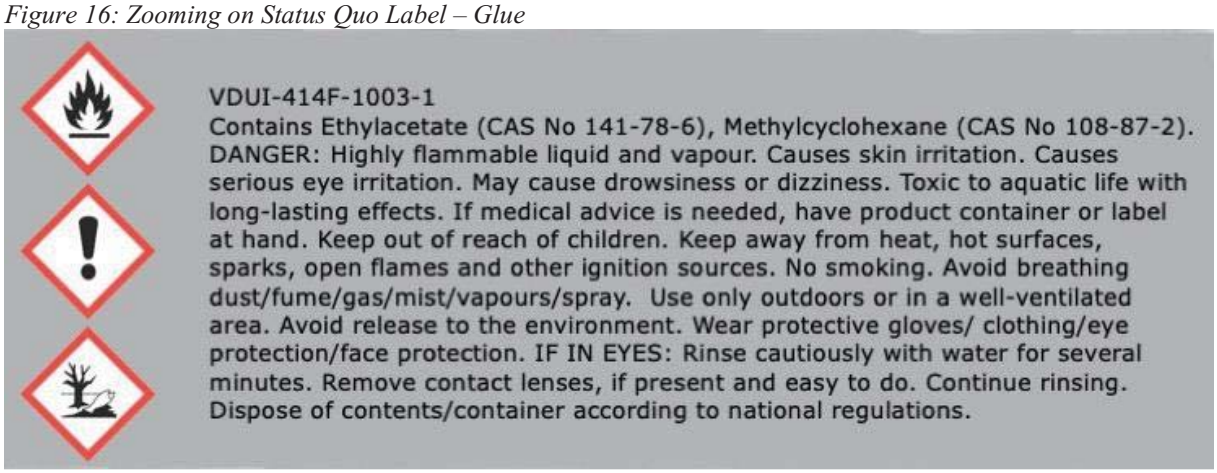
The exact framing of questions and tasks was provided with the scripting document. For all label-related questions participants saw the image of the product on the left side of the screen. The question text was displayed on the right side of the screen. Furthermore, in some of the treatments, participants were able to enlarge labelling information which is described in the subsequent paragraph.

Behavioural Variables when Consulting Labels

In testing consumers' understanding and appreciation of labels, an important aspect is **whether** they **indeed consult the label**. In reality, consumers have a physical packaging in front of them and whenever they need information contained in the label, they take the packaging and read the relevant labelling section. Ideally, the experiment would allow tracking whether the participant actually looked at the label at display – which for example could be done by implementing eye-tracking during the tasks. As eye-tracking was not in scope of the underlying study, the experiment design included a technical featured that mimicked "zooming" on (looking at) the label. This **zooming-function** allowed participants to hover with their mouse cursor over the label image in order to open a pop-up of the enlarged label. While the whole packaging was by default displayed in small size, i.e. relevant information on hazards and precautions was in very small font, the zoomed-label was of readable size. Figure 15 and Figure 16 display zooming (pop-up) for the Status Quo Label for the laundry detergent as well as the glue.

Figure 15: Zooming on Status Quo Label – Laundry Detergent

Figure 16: Zooming on Status Quo Label – Glue



The experiment set-up allowed recording individual zooming of participants at all points of the survey, i.e. for each question referring to the label elements. Nevertheless, it must be noted that this experimental feature can only serve as an indication of whether participants indeed read the label thoroughly. Furthermore, in reality consumers might have different motives to consult the label, e.g., to minimise adverse effects when an accident occurs. This cannot be mimicked in the underlying design.

As introduced above, one treatment was a simplified label that also introduced a digital element, i.e. a QR code to a website containing further information (see section 0). In reality consumers would open a QR code by using their smartphone. As this actual scanning of a QR code was not feasible in the experimental environment, the experiment introduced an **open-website-function**. By hovering over a link displayed at the bottom of the screen a pop-up of the website opened on screen. Again, the opening behaviour was tracked for all relevant questions.

The last behavioural variable that was elicited over the course of the experiment was the **time spent on answering** each question. This variable could serve as a control for reading time, i.e. the longer participants spent on screen, the higher the probability of reading and consulting the labelling information.

Comparative Choice Task

As indicated above, the aim of the experiment was also to measure consumers' **ability to identify a potentially less harmful product** by reading and understanding labelling information. Therefore, the experiment included a comparative choice task where participants were presented with two variants of the product, i.e. the product "original" and its "twin". The product twins were constructed in parallel to their original versions and differed only with respect to the potential hazards for human health and the environment.[24] For the laundry detergent the product original was less harmful than its twin, while for the glue the original was more harmful than the twin.

Within the task, participants saw both the original and the twin next to each other on screen and had to **select the potentially less harmful variant**. The alignment to either right or left was fully randomised. Furthermore, participants repeated the task for both the laundry detergent as well as the glue (order was randomised as well).

Each participant remained within the treatment they were assigned to at the beginning of the study, i.e. when assigned to the Status Quo Label, the participant also answered the comparative choice task on the Status Quo Label. Additionally, the comparative choice task included the zooming-feature for the Status Quo and Simplified Label as described above. In order to enlarge labelling details, participants were able to hover over both of the label images of the original and twin and a pop-up opened. Figure 17–Figure 22 display the original and twin product for the laundry detergent and glue in the Status Quo Label, Simplified Label and No Label Baseline treatment.

[24] Furthermore, the fictious brand and company information differed.

Figure 17: Comparative Choice Task for Status Quo Label – Laundry Detergent

Figure 18: Comparative Choice Task for Status Quo Label – Glue

Figure 19: Comparative Choice Task for Simplified Label – Laundry Detergent

Figure 20: Comparative Choice Task for Simplified Label – Glue

Figure 21: Comparative Choice Task for No Label Baseline – Laundry Detergent

Figure 22: Comparative Choice Task for Simplified Label – Glue

Since for the No Label Baseline the package images only contained the front of the packaging without any information on product hazards, participants that were assigned to the treatment not only were allowed to choose between either of the two products at display but also were able to choose "don't know / I would need more information to make that choice". This measure was introduced after the pilot analysis.

Further Variables

Following the experimental tasks where labels were at display, the last part of the experiment consisted of a **consumer survey**. The purpose of the survey was two-fold. On the one hand, **preferences for receiving labelling information** (on-pack versus digital) were elicited. On the other hand**, participants' characteristics** were collected. These include personal or professional experience with chemical products, digital readiness as well as trust and risk attitudes.

Incentives

As it is common practice in behavioural science, participants were incentivised in the experiment in two ways. Firstly, they received a **flat fee** for their overall time spent on the tasks. By that it was ensured that they reciprocate by paying attention and providing answers to their best knowledge and ability.

Secondly, the questions on objective understanding of labelling information were incentivised by paying an **additional amount per correct answer**. This methodological measure was applied to ensure that participants paid specific attention to the task itself and were motivated to solve the questions correctly. Nevertheless, it must be noted that this procedure only mimics the incentives of consulting a chemical label in the real world. If an accident occurs, consumers are inherently motivated to reduce the negative health impacts and pay attention to the label. This scenario and the inherent motives cannot be replicated by the experimental set-up.

Overview on the Data Set

The experiment was conducted with 4,003 participants in September and October 2021. Data collection took place in four Member States, i.e. Germany (1,000), France (1,001), Romania (1,000) and Greece (1,002) and the median time to complete the experiment was 17 minutes.

Sample description

Participants were recruited from an actively-managed online-panel and hard quotas on age and gender were applied in order to reach representativeness. Furthermore, soft quotas on education and income were applied. Table 7 gives an overview on the sample characteristics per country.

Table 7: Sample Description

	DE (N=1,000)	FR (N=1,001)	RO (N=1,000)	EL[25] (N=1,002)
Age mean (s.d.)	50.26 (16.53)	49.53 (16.94)	47.98 (16.11)	46.05 (14.89)
Gender (male / female / other-diverse)	49.3% / 50.7% / 0%	48.2% / 51.8% / 0.1%	48.4% / 51.6% / 0%	49.0% / 50.6% / 0.4%
Education[26] (low / Medium / high)	19% / 53% / 28%	9% / 55% / 36%	20% / 57% / 22%	8% / 46% / 46%
Income[27] (low / medium / high)	34.0% / 31.6% / 34.0%	34.0% / 35.5% / 30.6%	43.1% / 50.6% / 6.2%	31.0% / 40.6% / 28.4%

[25] Given that quotas on age in Greece were difficult to reach, in the analysis individual weights for Greek participants were used in order to draw upon representative results. The reason was that especially elderly participants are challenging to recruit for online studies given limited access to devices.

[26] As can be seen from the sample description consumers with lower educational level are slightly underrepresented in the sample. Especially in Greece the share of participants holding a university degree is comparatively large.

[27] Please not that income categories were defined within each country, i.e. using different tertile cut-off values for each country, because income distribution in absolute monetary terms differs per country.

Treatment assignment

As described in the methodological section, participants were randomly assigned to one of two products, i.e. either laundry detergent or glue, and to one of three labelling treatments, i.e. either Status Quo Label, Simplified Label (QR) or No Label Baseline. Table 8 displays the number of observations per product-treatment-combination.

Table 8: Treatment Assignment

	Laundry Detergent	Glue
Status Quo Label	16.7%	16.7%
Simplified Label (QR)	16.7%	16.7%
No Label Baseline	16.6%	16.6%

Furthermore, in the comparative choice task participants were randomly assigned to the order of products to be displayed, i.e. either laundry detergent first, then glue or glue first, then laundry detergent. Within the task the alignment of product variants was additionally randomised, i.e. original left and twin right or twin left and original right. Again, data reveals that for both order and variant alignment randomisation worked well (50% of the sample in each display condition).

RQ 1: What is the level of understanding of chemical and detergents labels?

To answer the first research question on consumers' understanding, the experiment included several questions which are presented in the following. All results are based on a **comparison** of the **Status Quo Label and** the **No Label Baseline** in order to confirm whether current legislation indeed enhances consumers' understanding.[28]

Objective Understanding of Product Hazards

Based on the desk research performed to design the two products, **different hazards apply** to the laundry detergent and glue. These include, for example: "Causes serious eye irritation" (H319) or "Toxic to aquatic life with long lasting effects" (H411).[29] The question was presented as a set of correct as well as incorrect hazard statements and participants were asked to identify the correct ones (additional payment for correct answer).

Figure 23 displays the percentage of participants that correctly answered the question on product hazards by product.[30] For the **Status Quo Label** of the laundry detergent **54%** of the participants answered the question on hazards **correctly** while **only 8%** in the **No Label**

[28] Results on the performance of the Simplified Label with QR code may be found further below, i.e. section on the fourth research question.

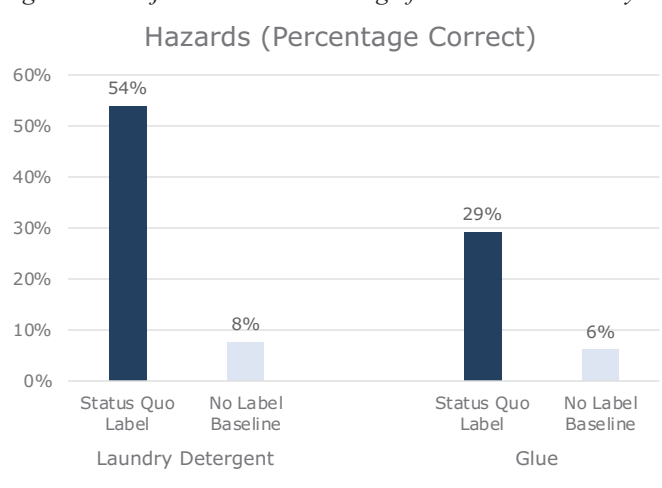
[29] Please note that the hazards differed by product. As described in the methodological section the laundry detergent was designed to be less harmful, while the glue included more hazards. The actual statements are representative for products to be found in supermarkets, drugstores and DIY-stores. A complete list may be found on the label-images provided in the methodological section.

[30] For better readability, in the following results are rounded to the nearest whole number. Hence, it might be possible that shares do not add up to 100%.

Baseline were successful. The difference between the two conditions is highly significant ($p<0.001$)[31].

The same pattern can be observed for the glue – although objective understanding was lower than for the laundry detergent. In the **Status Quo Label** treatment **29%** of the participants answered the question **correctly** while the percentage in the **No Label Baseline** was **only 6%**. Again, the difference between the two labelling treatments is highly significant. An explanation for the worse performance of the glue compared to the laundry detergent might be that the product itself was constructed in a way to be more harmful, i.e. more hazard statements apply to the product.

Figure 23: Objective Understanding of Product Hazards by Treatment



Notes: The question was: "Please select all statements that are true about the product displayed on the left:" (Status Quo Label) and "Thinking about a [laundry detergent / glue], please select all statements that are usually true about such a product:" (No Label Baseline).
Number of observations: N=1,333 (LD), N=1,335 (G)
Source: ConPolicy analysis of the experiment and survey data.

Furthermore, data reveals that **73%** of the participants in the Status Quo treatment of the **laundry detergent zoomed in on the label**, i.e. took a closer look at it. Of those who zoomed, 70% were able to answer the question on hazards correctly, while only 12% of those who did not zoom were successful. The difference is again highly significant ($p<0.001$). The same may be observed for the **glue** where **78%** of the participants in the Status Quo treatment **zoomed in on the label**. Of those who zoomed, 36% answered the question on hazards correctly, while the share among those who did not zoom was only 4% ($p<0.001$).

The time spent to answer the question in the Status Quo treatment was on average 62 seconds for the laundry detergent and 78 seconds for the glue. For both products a positive, significant relationship between time spent to answer and performance in the question can be found (0.49 for laundry detergent and 0.48 for glue, both $p<0.001$). I.e. the more time participants spent on the questions, the higher are the chances that they answer the question on product hazards correctly.

[31] If not otherwise specified, the statistical tests were Chi-2-test analysing the relationships between answer behaviour and categorial variables, i.e. treatments.

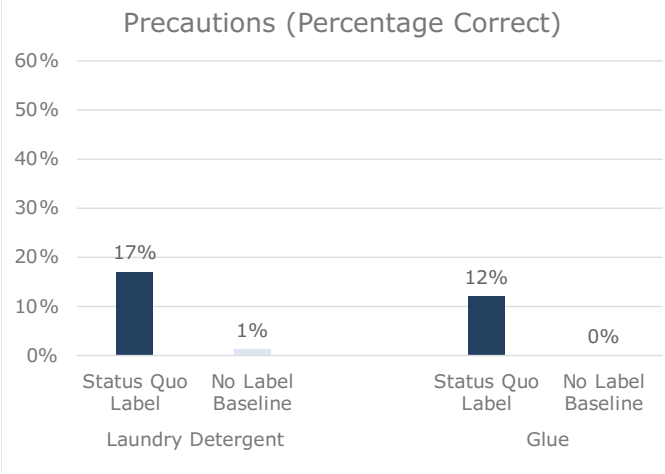
In summary, the results show that **providing labelling information and reading** it **helps consumers to understand hazard information**. Certainly not all consumers who were provided with a label under current legislation (Status Quo Label) performed equally well but compared to a situation where information is not available, they performed significantly better. When consumers solely answered based on their personal experience of chemical products (No Label Baseline) understanding was overall poor. Furthermore, **participants were motivated to consult labelling information** in the experiment and **when they did,** they also **performed significantly better** than when they did not actively read the label.

Objective Understanding of Precautionary Measures

Similarly, **different precautionary statements apply** to the two products. These included for example: "Keep out of reach of children" (P102) or "IF IN EYES: Rinse cautiously with water for several minutes" (P305+P351).[32] Again, the question was presented as a set of correct as well as incorrect precautionary statements and participants were asked to identify the correct ones (additional payment for correct answer).

Figure 24 displays the percentage of participants that correctly answered the question on product precautions by product. It can be seen that the Status Quo Label again performs better than the No Label Baseline. For both products the difference is highly significant ($p<0.001$). For the **laundry detergent 17%** in the **Status Quo Label** treatment and **1%** in the **No Label Baseline** answered correctly. For the **glue 12%** in the **Status Quo Label** treatment and **0%** in the **No Label Baseline** answered correctly.

Figure 24: Objective Understanding of Precautions by Treatment



Notes: The question was: "From your reading of the label, when using this product would you: (Select all that apply)" (Status Quo Label) and "When using a [laundry detergent / glue] would you: (Select all that apply)" (No Label Baseline).
Number of observations: N=1,333 (LD), N=1,335 (G)
Source: ConPolicy analysis of the experiment and survey data.

When looking at **zooming behaviour, 63%** of the participants in the **Status Quo Label** of the **laundry detergent** took a closer look at the label. Of those who zoomed on the label 26% answered the question correctly while those who did not zoom only answered the question on

[32] Again, these precautionary statements are only examples, and the complete list of applicable precautions may be found in the methodological section of the report.

precautions correctly in 1% of the cases (difference highly significant, $p<0.001$). The same pattern may be observed for the Status Quo Label of the **glue** where **66%** of the participants took a closer look at the label. Of those who zoomed 18% answered the question correctly, while those who did not zoom only answered the question correctly in 2% of the cases (difference highly significant, $p<0.001$).

Overall, participants in the Status Quo treatment spent 53 seconds to answer the question on the laundry detergent and 68 seconds for the glue. Again, a positive significant correlation between time spent and performance can be detected (0.40 for laundry detergent and 0.39 for glue, both $p<0.001$). I.e. the more time participants spent on the question, the higher are the chances that they answer the question on product precautions correctly.

In summary, objective understanding of the precautions applicable to chemical products follows the same pattern as for hazards. **Receiving labelling information** as defined by current regulation (Status Quo Label) **resulted in significantly better performance than answering on experience** (No Label Baseline). Overall, the understanding of precautions was poor and on average worse than for hazards. This might be due to the amount of precautions to be taken for safe use (especially for the glue, for which, as a more harmful product, legislation requests a long list of precautionary statements). Similarly, the results show that the majority of **participants** were **motivated to consult labelling information** in the experiment**,** and **if they did**, they also had a **better objective understanding**.

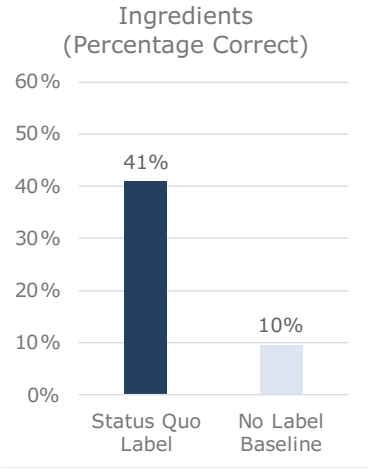
Objective Understanding of Ingredients

Lastly, a question on the **ingredients** was presented. It was only asked of participants that were assigned to the laundry detergent. Again, the question was presented as a set of correct, e.g. "enzymes" or "perfumes", and incorrect answer items and participants were asked to select the correct ones (additional payment for correct answer).[33]

[33] The list of ingredients may be found on the label-images contained in the methodological section of the report.

Figure 25 displays the percentage of participants that correctly answered the question on product ingredients for the laundry detergent. It can be seen that **41%** in the **Status Quo Label** treatment answered the question on ingredients correctly, while the share was **only 10%** in the **No Label Baseline**. The difference between groups is statistically highly significant ($p<0.001$).

Figure 25: Objective Understanding of Product Ingredients by Treatment



Notes: The question was: "From your reading of the label, which ingredients are contained in this product? (Select all that apply)" (Status Quo Label) and "From you experience with laundry detergents which ingredients are usually contained in such a product? (Select all that apply)" (No Label Baseline).
Number of observations: N=1,333
Source: ConPolicy analysis of the experiment and survey data.

Again, zooming behaviour is indicative for performance. Overall, **74%** of the participants **zoomed** in on the label. Among those who took a closer look the share of participants answering correctly was 54%, while the share was only 3% among those who did not zoom ($p<0.001$).

In addition, data reveals that in the Status Quo treatment participants spent on average 43 seconds to answer the question. The correlation between time spent and performance is positive and significant (0.53, $p<0.001$), i.e. the more time participants took to answer the question, the higher the chance of answering the question on product ingredients correctly.

In summary, the results confirm previous findings and show that **labelling information enhanced consumers understanding** of ingredients as well. Again, **participants** in the experiment **were overall willing to consult the label** and **if they did**, they **performed significantly better**.

Ability to Identify a Less Harmful Product

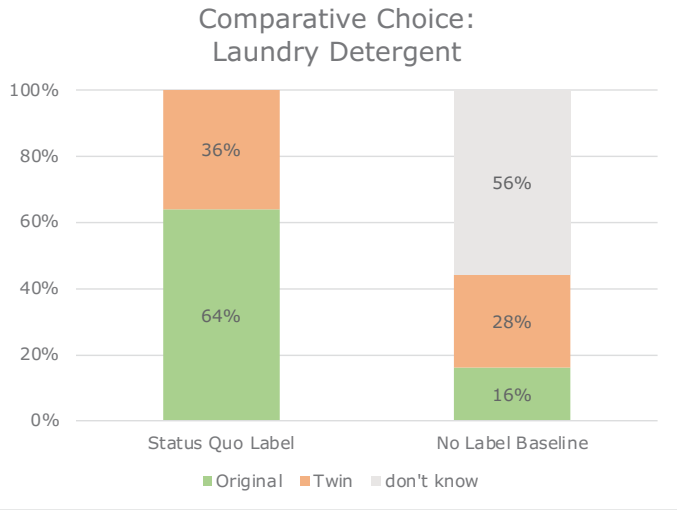
Further evidence on consumers' understanding of labelling information can be taken from the **comparative choice task**. Participants were asked to **identify the less harmful product** among two products which differed with respect to their properties.

For the **laundry detergent,** the product original was less harmful than its twin, i.e. less hazards and precautions applied. Furthermore, the GHS pictogram and signal word differed. Further information on the product labels presented in the task may be found in the methodological section of the report.

Figure 26 displays the percentage of participants correctly identifying the original product to be less harmful than its twin. As can be seen **64%** in the **Status Quo** treatment answered the question **correctly**. In the No Label Baseline performance was significantly worse because participants were asked to answer the question based on their experience without any further information. Since the **No Label Baseline** only included the front packaging without any

information on hazards (pictogram, statements), the majority of participants (**56%**) selected that they don't know the answer or would **need more information** to make the choice. 16% chose the correct product and 28% chose the wrong product. Again, the difference between the treatments is statistically highly significant (p<0.001).

Figure 26: Comparative Choice Task Laundry Detergent by Treatment



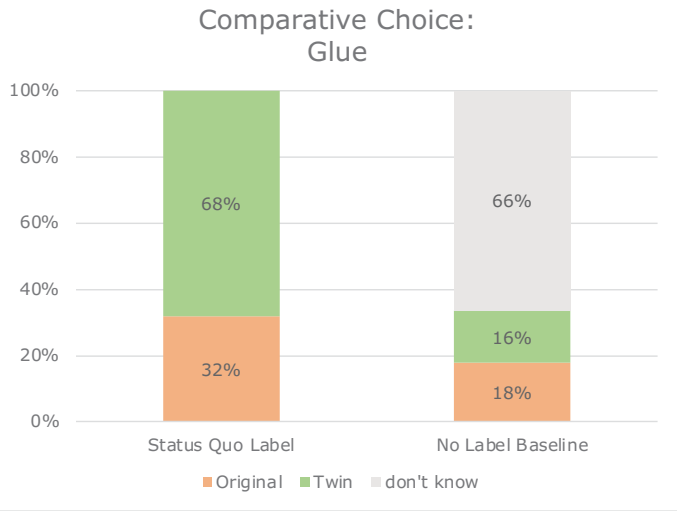
Notes: The question was: "Please take a look at the two laundry detergents. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.
Number of observations: N=1,340 (Status Quo Label), N=1,328 (No Label Baseline)
Source: ConPolicy analysis of the experiment and survey data.

72% of the participants **zoomed on both labels** at display, **20% on one** of the two and **9% did not zoom**. Of those who zoomed on both 67% of the participants answered the question correctly, of those who zoomed on one 56% answered correctly and of those who did not zoom 58% answered correctly (difference is significant, p=0.002).

For the **glue,** the product original was more harmful than its twin, i.e. more hazards and precautions applied to it. Furthermore, the number of GHS-pictograms differed. Further information on the product labels presented in the task may be found in the methodological section of the report.

Figure 27 displays the percentage of participants correctly identifying the twin product to be less harmful than the original. Again, the same pattern may be observed. In the **Status Quo Label** treatment, the majority of **68%** selected the **correct** product. In the **No Label Baseline** the majority of **66%** indicated that they did not know the answer and **needed more information** for making their choice. The share of choosing the correct product was 16% and the share of choosing the incorrect product was 18%. Again, the difference between the two treatments is statistically highly significant ($p<0.001$).

Figure 27: Comparative Choice Task Glue by Treatment



Notes: The question was: "Please take a look at the two glues. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.
Number of observations: N=1,340 (Status Quo Label), N=1,328 (No Label Baseline)
Source: ConPolicy analysis of the experiment and survey data.

Regarding zooming behaviour, it can be found that **68%** of the participants in the Status Quo Label treatment **took a closer look at both products** at display, **25%** looked at **one** of the two and **7%** looked at **none**. Of those who zoomed on both products 71% were able to correctly identify the less harmful product, among those who looked at one product the share of correct answers was 64% and of those who did not zoom the share was 61% (p=0.03).

In conclusion, results are confirmative of the findings from the previous sections. **When labelling information was available** (Status Quo Label), the **majority of consumers were able to identify a less harmful product**. In contrast, when labelling information was not available, i.e. CLP information was not provided (No Label Baseline), consumers were not able to correctly identify the less harmful product but rather indicated that they would need more information to make their choice. Again, it can be observed that experiment-**participants were willing to consult the label** for further information and when they did, they at least slightly performed better than without zooming in on information. Nevertheless, it must be noted that even without zooming on further information such as a readable list of hazards and precautionary statements, the packaging was already indicative of the degree of harmfulness, i.e. the GHS-pictograms on the packaging for example already showed which product is more harmful.

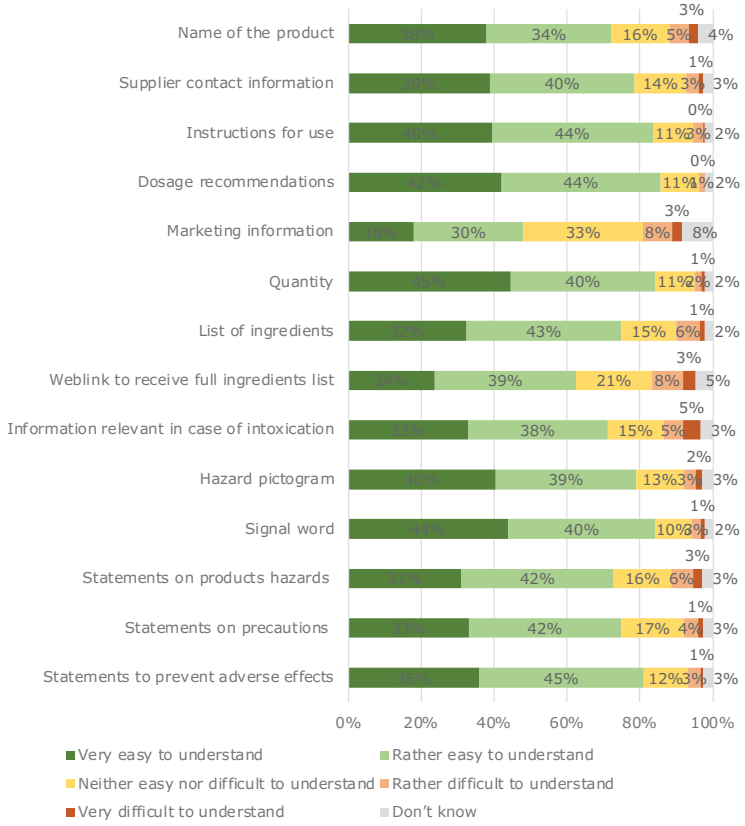
Lastly, it must be noted that results only provide information on consumers' objective understanding and not whether labelling information also causes consumers to purchase the less harmful product. Furthermore, results also cannot demonstrate whether better objective understanding also causes consumers to behave more appropriately in case of an accident, i.e. whether they would follow instructions to minimise adverse effects. Therefore, the follow-up questionnaire of the experiment can shed further light on consumers' behaviour (see section on the third research question).

Rating of Understandability of Relevant Label Elements

Next to the objective questions on label understanding, the experiment contained a subjective understanding question. Participants were asked to indicate the **perceived understandability of different label elements** such as the hazard and precautionary statements, GHS-pictograms, ingredient lists or dosage instructions. The question was elicited on a 5-point-Likert-scale from "very easy to understand" to "very difficult to understand".

Figure 28 displays the subjective understandability of the Status Quo Label for the laundry detergent. All **aspects related to the CLP Regulation** performed well and were perceived as at least rather **understandable** by the vast majority of participants (above 70%). The only aspect that stands out to be different is marketing information. Here only 48% of the participants rated information as understandable.

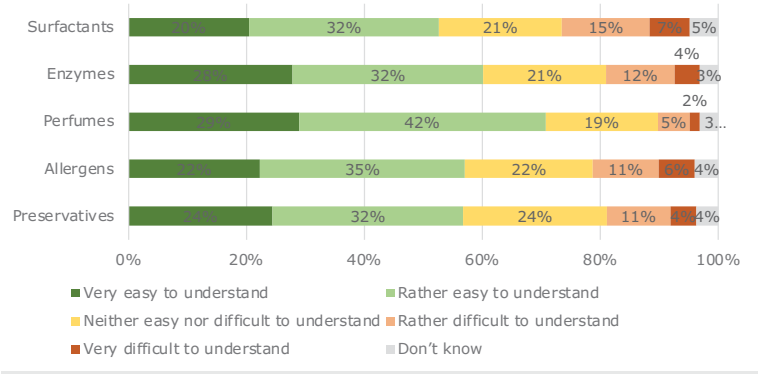
Figure 28: Rating of Understandability of Label Elements (Status Quo Label, Laundry Detergent)



Notes: The question was: "Still looking at this label, how easy to understand do you find each piece of information?".
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

Figure 29 displays the subjective understandability of ingredients information of the Status Quo Label for the laundry detergent. Compared to the previous results on CLP-related labelling elements the rating was lower. Nevertheless, the **majority** of the participants indicated that **specific ingredient information** was **(rather) easy to understand**.

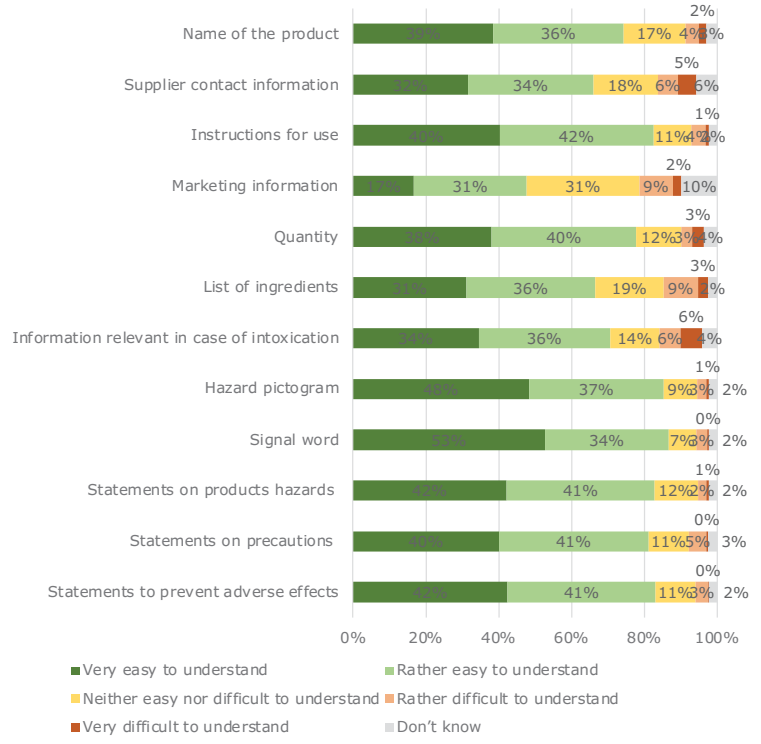
Figure 29: Rating of Understandability of Label Elements on Ingredients (Status Quo Label, Laundry Detergent)



Notes: The question was: "Still looking at this label, how easy to understand do you find the specific information on the ingredients contained in the product?".
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

Lastly, Figure 30 displays the subjective understandability of the Status Quo Label for the glue. Again, the ratings of **CLP-related information** are good with a **majority** of over 70% indicating that information was very or rather **easy to understand**. The only aspect that stands out is marketing information which received a lower understandability rating (48%).

Figure 30: Rating of Understandability of Label Elements (Status Quo Label, Glue)



Notes: The question was: "Still looking at this label, how easy to understand do you find each piece of information?".
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

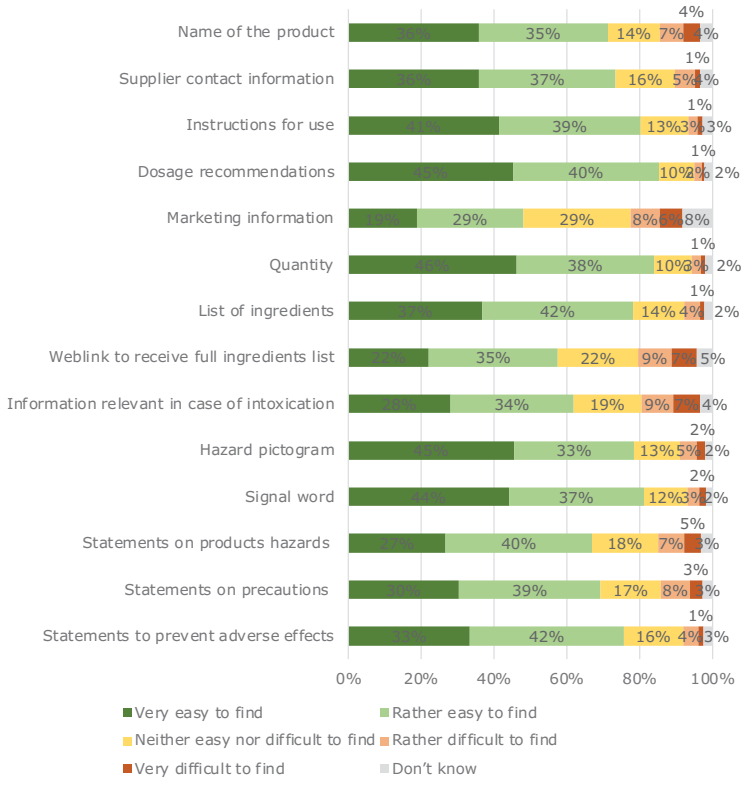
In conclusion, the data shows that overall **consumers perceived relevant labelling elements as (rather) understandable**. Nevertheless, it must be emphasised that this result is based on an individual and subjective self-assessment. When looking at the objective understanding of safe use information contained on labels performance was rather poor.

Rating of Ease to Find Relevant Label Elements

In order to understand label information, it is also important that consumers are able to find all the information contained on a label in an easy way. Hence, the experiment included a question on the subjective **ease to find relevant label elements**. The question was elicited on a 5-point-Likert-scale from "very easy to find" to "very difficult to find".

Figure 31 displays the rating of the **ease to find label elements** for the Status Quo Label of the laundry detergent. **Over 60%** of the participants indicated that **CLP-related information** was very or rather **easy to find**. Additionally, dosage recommendations provided as a table on the label were perceived as very or rather easy to find by 85% of the participants. On the other hand, marketing information was perceived as easy to find by only 48% of the participants.

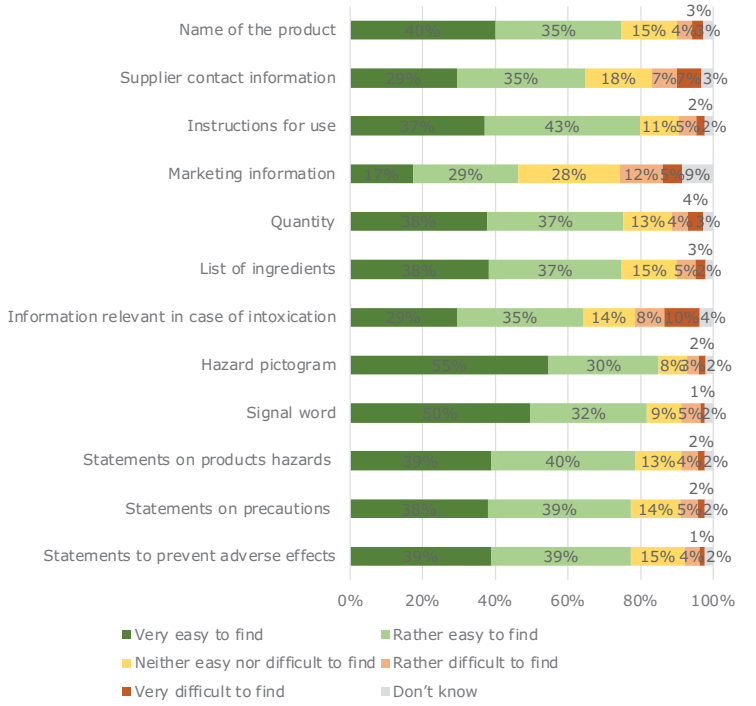
Figure 31: Rating of Ease to Find Label Elements (Status Quo Label, Laundry Detergent)



Notes: The question was: "Still looking at this label, how easy is it to find each piece of information?".
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

Figure 32 displays the rating of the ease to find label elements for the Status Quo Label of the glue. Again, all **CLP-related elements** were very or rather **easy to find** (above 60%) while marketing information stands out with a lower rating (36%).

Figure 32: Rating of Ease to Find Label Elements (Status Quo Label, Glue)



Notes: The question was: "Still looking at this label, how easy is it to find each piece of information?".
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

In conclusion, results on the ease to find label elements on the packaging given current regulations are positive. The **majority of the participants** indicated that the **relevant elements** are (rather) **easy to find**.

Conclusion

Taken the results from the previous section together, it can be shown that **labelling information under current regulation** (Status Quo Label) **performs systematically better than when consumers are not provided with CLP- and Detergent-relevant information**. Overall, objective understanding is rather poor and performance of consumers is dependent on the amount of information that needs to be processed, i.e. is displayed on the label. For a more harmful product, legislation requires more text to be displayed on the label, which might be especially problematic on small packaging. Nevertheless, participants in the experiment were motivated to consult the label and were partially able to find relevant information.

As flagged in the methodology section, the experiment was only able to mimic consumers' decision context, i.e. they found themselves in an artificial environment and were paid monetary incentives for their performance in the tasks. Nevertheless, when it comes to the actual health of consumers and their relatives, one would expect that they are even more motivated to read and understand the specifics of chemical substances. In that manner, the results support that current legislation is helpful for consumers' understanding.

One other aspect that makes the experimental set-up different is the time spent on the label, or at least, the time spent on answering questions on objective understanding. Data reveals that participants take rather sufficient time to answer questions and there also exists a positive

correlation between time spent on the question and performance. On the one hand, this is a positive result as it confirms that consulting a label supports consumers' understanding. On the other hand, spending that much time on a label of a chemical substance or detergent is rather uncommon (e.g. in shopping situations labels are not consulted this thoroughly and in the case of an accident induced stress could also lower consultation times).

Lastly, results show that consumers subjectively rate the Status Quo Label in a positive way. Overall, **CLP- and Detergent-relevant information items are rated** as both **easy to understand as well as easy to find**. This stands **in contrast to the rather poor objective understanding** and might be **because subjective understanding is self-reported**, i.e. consumers overestimate their understanding. One aspect that systematically stands out in the results was marketing information provided on the packaging. It was rated as more difficult to understand and to find on the packaging. Certainly marketing information is not regulated by CLP, however, in practice it takes a comparatively large space on the packaging of products and competes with information relevant for safe use.

RQ 2: What is the importance of different elements contained in labels? Which information is considered essential?

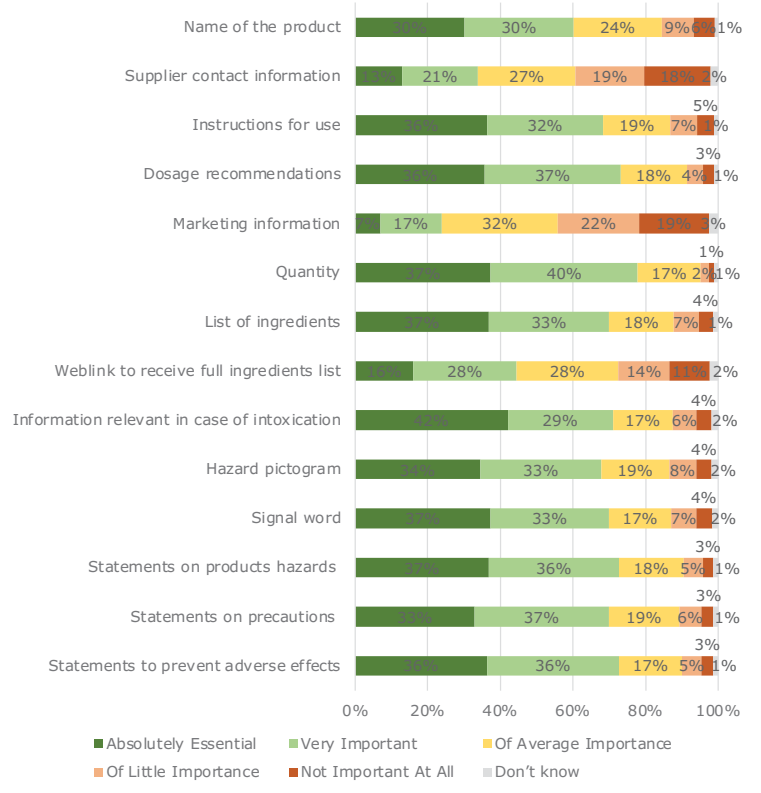
In order to answer the second research question on consumers' perceived importance of label elements, the experiment contained two questions which are presented in the following sections. The first question was asked at the beginning of the experiment before the participants saw the label images on screen, i.e. it was solely based on consumers' experience with chemical labels. By that the **general label appreciation** was elicited. The second question was asked at a later stage of the experiment when the participants were already familiar with the labelling content, i.e. they had already answered questions on objective understanding and label interpretation. By that the **label appreciation under current regulation** was elicited.

Rating of Importance of Label Elements Without Seeing a Label

As indicated above, the **importance of different label elements** was elicited **without label display** at the beginning of the experiment. Hence, the overall rating for the whole sample is displayed regardless of treatment assignment. The question was elicited on a 5-point-Likert-scale from "Absolutely essential" to "Not important at all".

Figure 33 displays the rating of the importance of label elements for the laundry detergent. **CLP- and Detergent relevant information** such as the hazard pictogram, signal word, statements on hazards and precautions and dosage instructions were rated as either **absolutely essential or very important by more than 70%** of the participants. The weblink to receive the full ingredient list received a share of 44% and supplier contact information of 34%. The lowest rating was assigned to marketing information with only 24% who indicated the information to be absolutely essential or very important.

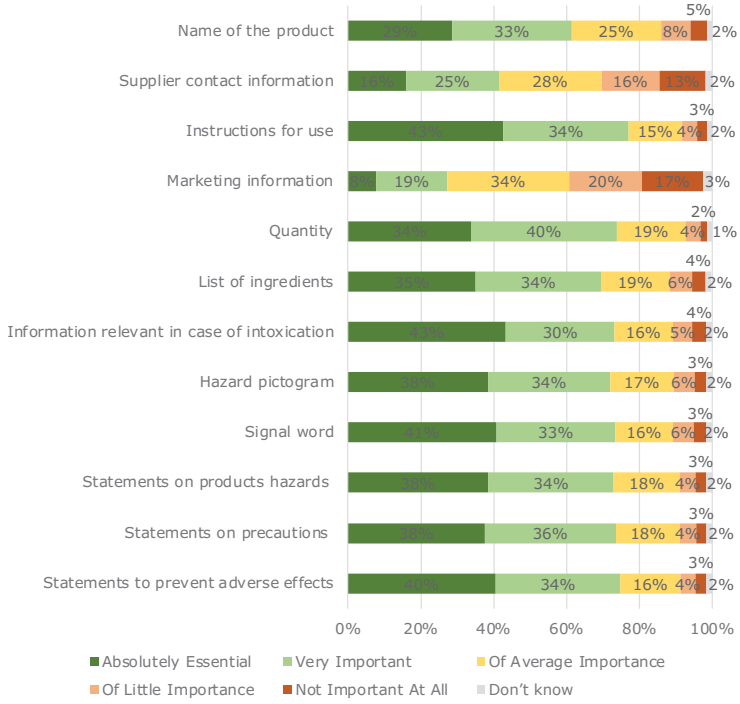
Figure 33: Rating of Importance of Label Elements Without Label (Status Quo Label, Laundry Detergent)



Notes: The question was: "Please think about your last purchase or use of a laundry detergent: In general, on the packaging of a laundry detergent how important do you rate having the following pieces of information?"
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

displays the rating of the importance of label elements for the glue. Again, the same patterns may be observed. **CLP-relevant information received high ratings** of **above 70%** (absolutely essential or very important). Supplier contact information received a lower rating of 31% and the lowest importance was again attached to marketing information were 17% of the participants rated the information to be absolutely essential or very important.

Figure 34: Rating of Importance of Label Elements Without Label (Status Quo Label, Glue)



Notes: The question was: "Please think about your last purchase or use of a glue: In general, on the packaging of a glue how important do you rate having the following pieces of information?"
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

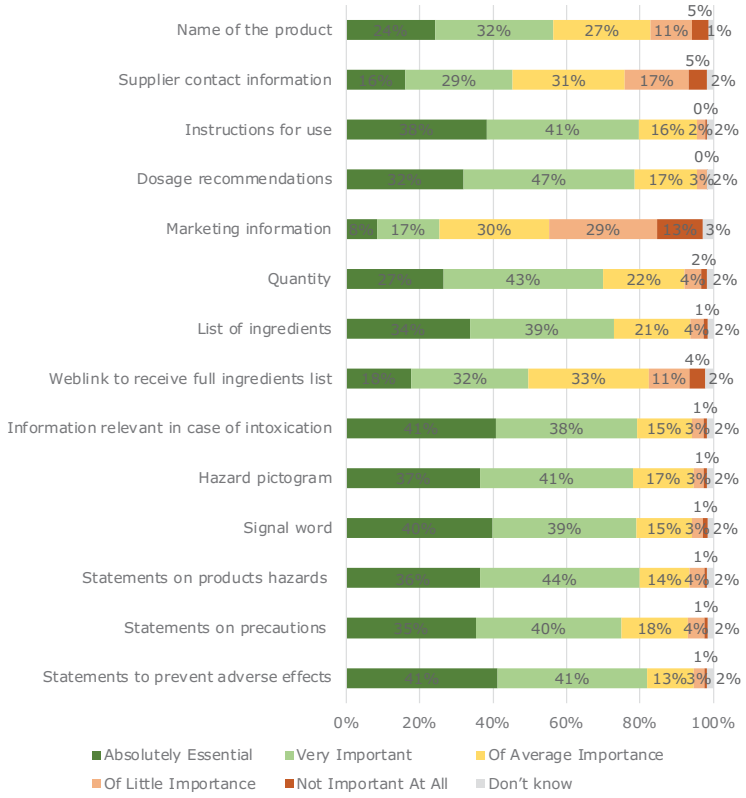
Overall, the **appreciation of different CLP- and Detergent-relevant label elements was high**. Even without seeing a label at display, consumers indicated that information on hazards and precautions are highly important.

Rating of Importance of Label Elements When Seeing a Label

Participants assigned to the **Status Quo Label** treatment were asked the rating question a second time, i.e. after they completed several experimental tasks and were familiar with the labels. Again, the question was elicited on a 5-point-Likert-scale from "Absolutely essential" to "Not important at all".

Figure 35 displays the rating of the **importance of label elements** for the Status Quo Label of the laundry detergent. The patterns are in accordance with the previous results. It can be found that **CLP- and Detergent relevant elements received ratings well above 70%**. The weblink to receive the full ingredients list was rated absolutely essential or very important by 50% of the participants and supplier contact information by 45%. The lowest rating again may be found for marketing information. Only 25% of the participants rated this type of information as absolutely essential or very important.

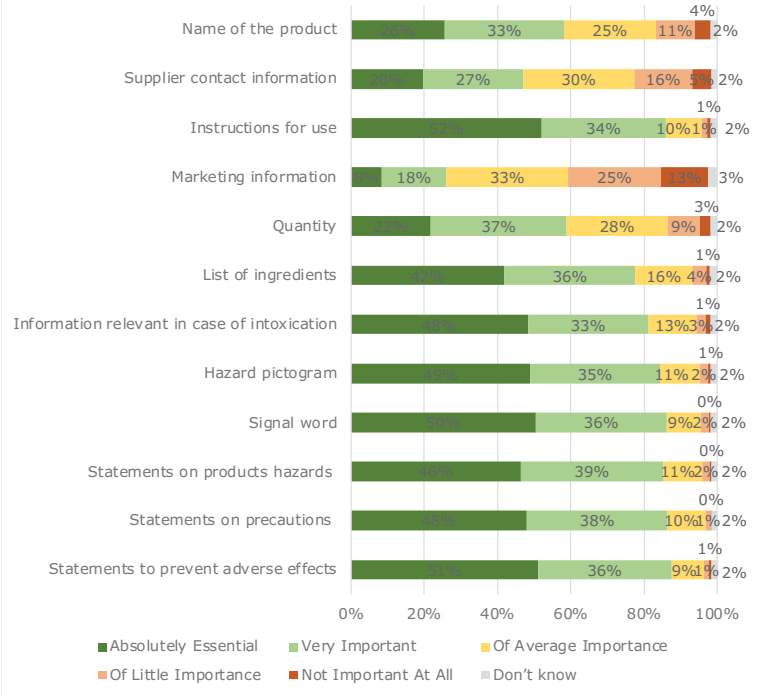
Figure 35: Rating of Importance of Label Elements With Label (Status Quo Label, Laundry Detergent)



Notes: The question was: "Looking at this label, how important do you rate having the following pieces of information?".
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

Figure 36 displays the rating of the importance of label elements for the Status Quo Label of the glue. Again, the results are in accordance with the previous results. While **CLP-relevant information** such as hazard and precautionary statements or the pictogram received **shares of above 80%** (absolutely essential or very important), marketing information was rated less relevant. Only 26% of the participants indicated that it is absolutely essential or very important.

Figure 36: Rating of Importance of Label Elements With Label (Status Quo Label, Glue)



Notes: The question was: "Looking at this label, how important do you rate having the following pieces of information?"
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

Hence, the results are confirmative and show that **CLP- and Detergent-relevant label elements** are perceived as **very important** by consumers.

Conclusion

Taken the results together it can be shown that **label elements** that support consumers with the **safe use of chemical substances**, i.e. hazard and precautionary information, are **essential**. Furthermore, aspects relevant under Detergent regulation, e.g. dosage instructions, are perceived as essential. Marketing information, on the other hand, systematically stands out as less important. The later aspect should also be discussed in the light of results from the first research question, where consumers indicated that marketing information is less understandable and easy to find on packaging. In general, this result appears not to be problematic as marketing information is not necessary for consumers' understanding of safe use and therefore, there exists no objective need for improvement. Nevertheless, in practice marketing information takes a lot of space on the packaging of chemical products and therefore, competes with the space available for CLP-relevant information which is rated as more important by consumers.

RQ 3: How do consumers interpret labels with respect to hazards and safe use instructions?

The third research question regards the interpretation of labels given provided information. Therefore, several questions were included in the experiment. The first set of questions focussed on the products' **risk perception** while the second investigated **behaviour induced by the labels**.

Risk Perception Induced by Label

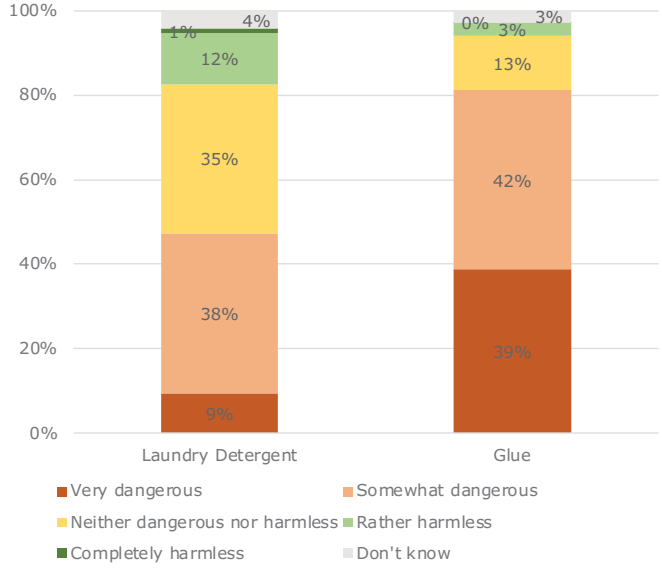
The experiment design included two different **products** that **differed in their degree of potential harmfulness**. Among other aspects, the labels at display differed in the amount of GHS-pictograms presented (one versus three), the signal word ("warning" versus "danger") as well as the amount and severity of the included hazard and precautionary statements. More information on the product specifics may be found in the methodology section.

Risk perception was investigated by three different questions, i.e. on the **general risk perception of use, risk following wrong application** as well as **risks attached to different hazards**. It must be noted that the purpose of the questions was not to interpret the average rating of each of the products, i.e. it is not relevant whether a laundry detergent or glue is perceived as "dangerous" or "harmless". The questions aimed at investigating whether displayed information causes participants to rate the glue as *more harmful* than the laundry detergent. Hence, the analysis aims at comparing the ratings by product type.

Risk Perception of Use

The question on **general risk perception of use** was elicited on a 5-point-Likert-scale ranging from "very dangerous" to "completely harmless". Figure 37 shows the results by product type. It can be seen that the glue indeed was rated as more dangerous than the laundry detergent. For the **glue 39%** of the participants indicated the product to be very **dangerous** while the share for the **laundry detergent** is **only 9%**. The difference in danger ratings between the two products is highly statistically significant ($p<0.001$).

Figure 37: Risk Perception of Use by Product (Status Quo Label)

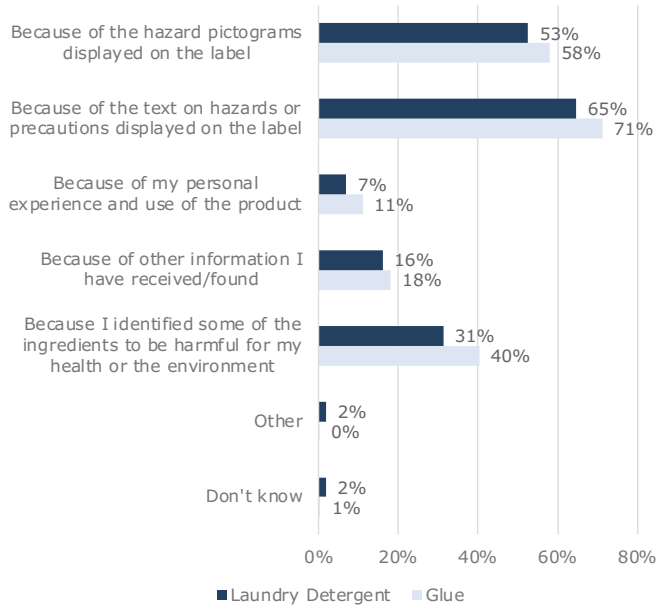


Notes: The question was: "In general, how dangerous do you rate using this product?"
Number of observations: N=670 (LD), N=670 (G)
Source: ConPolicy analysis of the experiment and survey data.

Subsequently, participants rating product use as very or somewhat dangerous were asked to indicate their **reasons for** their **danger perception**. Figure 38 displays the replies by product. It can be seen that for both products the **hazard and precautionary statements** on the label were the **most relevant** reason for rating the product as dangerous (69% for both product types). Similarly, the **hazard pictograms** were rated as **relevant information** for indicating

the products to be dangerous (56% for both product types). The ingredients contained in the product were a reason for 37% of the participants, while only 17% and 10% named other information and personal experience.

Figure 38: Reasons for Risk Perception by Product (Status Quo Label)



Notes: The question was: "You indicated that you rate using this product as somewhat or very dangerous. Why?" (multiple answers)
Number of observations: N=313 (LD), N=543 (G)
Source: ConPolicy analysis of the experiment and survey data.

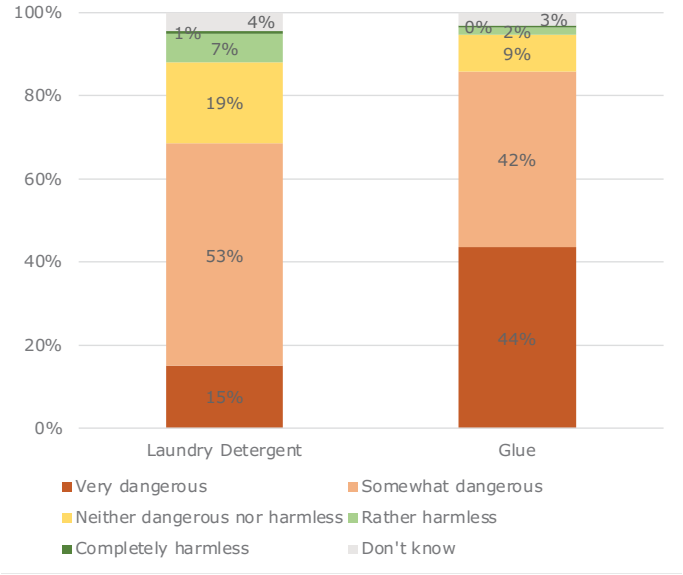
Hence, the results show that **under current regulation** (Status Quo Label) consumers were indeed **able to interpret** the provided information **correctly** and attached more risk to an objectively riskier product. The result confirms findings from the comparative choice task (see section on the first research question). Furthermore, consumers indicated that CLP-relevant information contained on the labels causes this perception.

Risk Perception of Wrong Application

The question on general risk perception of wrong application was elicited on a 5-point-Likert-scale ranging from "very dangerous" to "completely harmless".

Figure 39 shows the results by product type. Again, consumers rated the wrong application of the products differently. For the **glue 44%** indicated wrong use as **very dangerous** while the share for the **laundry detergent** was **only 15%**. The difference between product variants is statistically highly significant ($p<0.001$).

Figure 39: Risk Perception of Wrong Application by Product (Status Quo Label)



Notes: The question was: "In general, how dangerous do you rate the wrong application of this product, e.g. when an accident occurs?"
Number of observations: N=670 (LD), N=670 (G)
Source: ConPolicy analysis of the experiment and survey data.

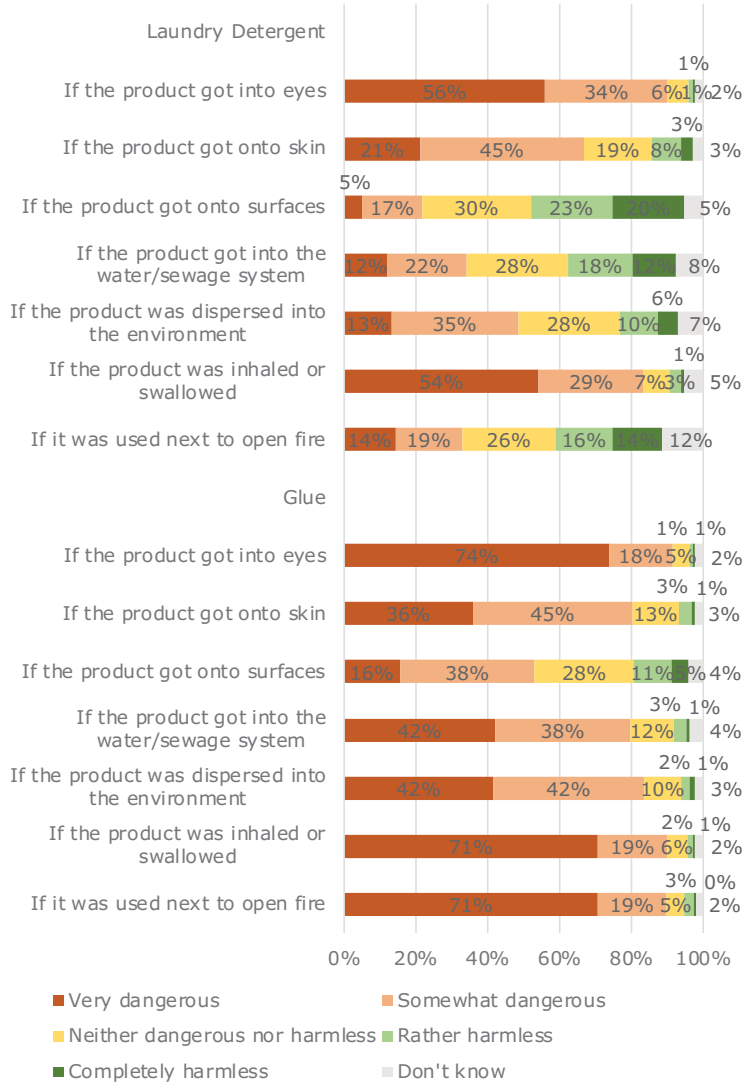
Hence, it can be concluded that labelling information induces the **correct perception** of **application dangers** as well.

Risk Perception of Different Hazards

Lastly, a question on the **risk perception of different specific hazards** was elicited. It focused on risks attached to the product getting into eyes or being inhaled or swallowed. Again, a 5-point-Likert scale ranging from "very dangerous" to "completely harmless" was used.

Figure 40 displays the results by hazard category and product. For all categories the glue was on average rated as more dangerous ($p<0.001$). Furthermore, the rating of product getting into eyes was comparatively large for both product types. This is **in accordance with the actual information displayed on the labels**, i.e. a specific hazard statement is included on the packaging. Dispersing the product into the water systems or the environments was rated more threatening for the glue. Again, this is in accordance with the information contained on the specific labels, i.e. specific hazard statement as well as a GHS pictogram included on the packaging. The same applies to the products being used next to fire, where the glue received a higher rating than the laundry detergent. Similarly, a reason for this difference might be the actual hazard statements and GHS pictogram included on the packaging (the glue was constructed to be flammable while the laundry detergent was not).

Figure 40: Risk Perception of Different Hazards by Product (Status Quo Label)



Notes: The question was: "From your reading of the label, please rate how dangerous each of the following would be:"
Number of observations: N=670 (LD), N=670 (G)
Source: ConPolicy analysis of the experiment and survey data.

Additionally, it may be concluded that consumers not only **correctly interpret** the general risk of products, but also **specific risks** that may differ by product.

Behaviour Induced by Label Information

The second set of questions focussed on the behaviours induced by label information. It included questions on the **motivation to read and follow instructions**, **behaviour in case of an accident** as well as on **dosage behaviour**.

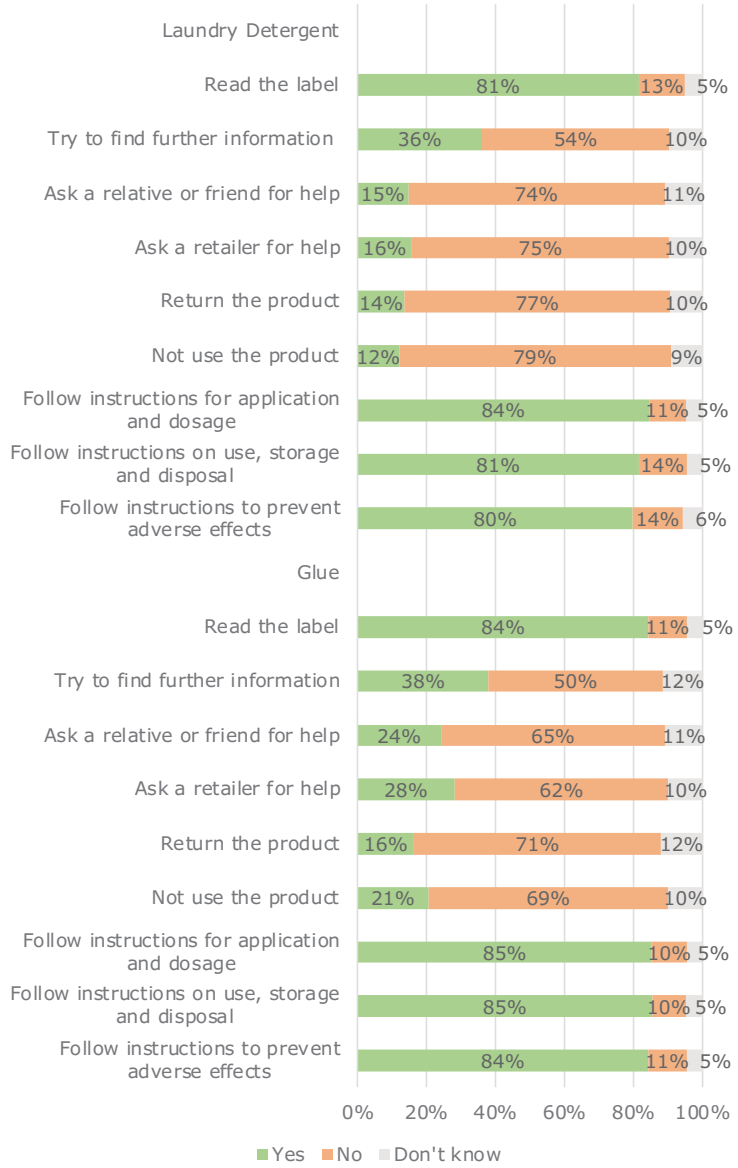
It must be noted that objectively there are no wrong answers for these questions. Nevertheless, from a policy perspective reading the information on package is relevant to avoid adverse effects or dose the product correctly, whereas the need to ask other people for help or consulting external sources would be less desirable. Similarly, bringing the packaging to a doctor or applying first aid measures in the case of an accident could be interpreted as

positive, while the need to additionally consult a search engine would indicate that information on the packaging is not sufficient.

Motivation to Read and Follow Instructions

Results regarding consumers' motivation to read and follow instructions may be found in Figure 41. The results show that over **80%** of the participants (regardless of product) would indeed **read the label** and **follow the relevant instructions** on dosage, use and precautions. Trying to find **further information** only applies to **37%** of the participants and asking for **further help** either from relatives or friends or the retailer is **only** applicable to **19% and 22%** respectively.

Figure 41: Motivation to Read and Follow Instructions by Product (Status Quo Label)



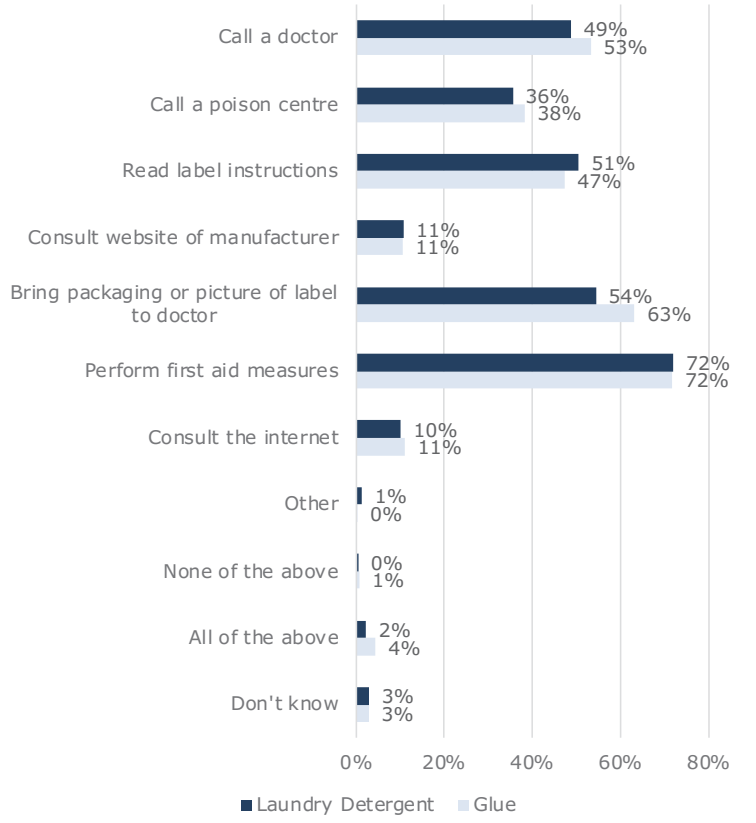
Notes: The question was: "Does this label motivate you to:"
Number of observations: N=670 (LD), N=670 (G)
Source: ConPolicy analysis of the experiment and survey data.

In conclusion, results show that consumers are **motivated to apply appropriate steps** related to labelling information. Especially **reading the label** and **following instructions** appears to be relevant whereas there is no indication that provided information was insufficient and consumers would need further information or help.

Behaviour in Case of an Accident

Results regarding consumers' behaviour in case of an accident are displayed in Figure 42. The results show that consumers indeed would be **willing to take appropriate actions**. The majority indicated performing first aid measure, bringing the packaging to the doctor and calling a doctor. In contrast, **only 11%** indicated that they would **need to consult further sources**, i.e. via a search engine or the website of the manufacturer.

Figure 42: Behaviour in Case of an Accident by Product (Status Quo Label)



Notes: The question was: "Imagine an accident occurs while using this product. This could be that you or a member of your household swallows the product or the product splashes into someone's eyes. What would you do? (Select all that apply)"
Number of observations: N=670 (LD), N=670 (G)
Source: ConPolicy analysis of the experiment and survey data.

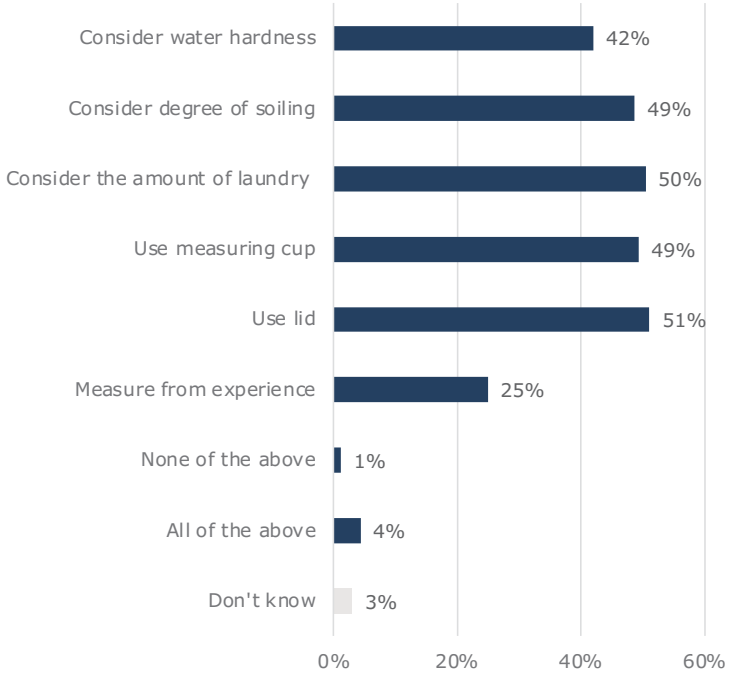
The results confirm previous findings and show that consumers would **take the appropriate measures** in case of an accidents. Furthermore, they **did not** indicate a **need** for **further information** by consulting additional resources.

Dosage Behaviour

As highlighted before, there is no "good" or "bad" behaviour when it comes to dosing the product. Nevertheless, dosage information following legislation considers several relevant aspects such as the water hardness and degree of soiling that determine the optimal amount of a product. Furthermore, tools such as a measuring cup or the product lid are helpful in order to avoid over-dosing. On the other hand, measuring from experience would only be appropriate if a consumer uses a product that he/she used before (and already considered relevant dosage information).

Figure 43 displays the results on dosage behaviour for the laundry detergent.[34] Results show that indeed **relevant measures** were claimed to be **taken by at least 40%**, whereas only **25%** of the participants would **rely on their personal experience** of using such a product. Lastly, **only 1%** of the participants indicated to take **none of the presented actions**.

Figure 43: Dosage Behaviour for Laundry Detergent (Status Quo Label)



Notes: The question was: "Imagine you would like to use this product. Which aspects do you consider and which tools would you use when dosing the product? (Select all that apply)"
Number of observations: N=670
Source: ConPolicy analysis of the experiment and survey data.

Again, results demonstrate that consumers would **follow relevant instructions** included in the **dosage table** of a product. Therefore, both water hardness as well as degree of soiling would be considered. Similarly, consumers indicated that they would measure the product by using a tool instead of basing their decision on experience alone.

[34] Dosage behaviour was not elicited if a participant was assigned to the glue treatments.

Conclusion

Taken the results on the third research question together **consumers are (subjectively) able to interpret chemical labels under the current legislation/regulations**. They draw appropriate conclusions from the given information at display, i.e. the questions on risk ratings uniformly show that consumers attach more risk to an objectively riskier product. Furthermore, they are able to interpret specific label elements on hazards and process them correctly. In addition, the results show that CLP-relevant label elements are the ones consumers base their perception on, i.e. the GHS pictogram as well as hazard and precautionary statements. In the light of the second research question on the importance of labelling elements, results are confirmative. Hence, consumers not only rate CLP elements as important but also base their risk perception on them.

Next to the interpretation of labels it is also important that labelling induces appropriate behaviour. Hence, labelling should be constructed so that consumers take the correct measures in case of an accident and it should be assured that no further information is lacking. The results show that indeed **consumers would take appropriate measures** and **do not** indicate a **need** for **further information or help**. Additionally, consumers are motivated to read instructions and consider dosage aspects as instructed. It must be noted that results are not based on actual behaviour but rather self-reported. Nevertheless, it is in the best interest of consumers to follow instructions in order to promote safe use and prevent adverse effects that may arise from chemical substances.

RQ 4: Does label simplification and the introduction of digital tools positively or negatively affect consumers' understanding and perceptions?

The fourth research question aimed at investigating whether labels could be simplified. As described in the methodology section based on desk research a third treatment was introduced that was a simplification of the Status Quo Label. While most CLP-related information was maintained, certain aspects were reduced and moved to a website that could be accessed via a QR code. In the following, we refer to the third label as **Simplified Label with QR Code** and investigate how it performs compared to the No Label Baseline as well as the Status Quo Label. Therefore, several questions on understanding as well as consumer perceptions are presented.

Objective Understanding

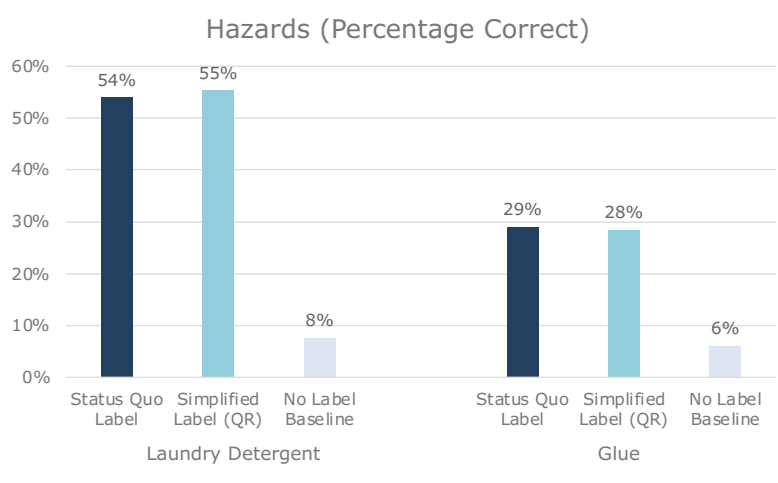
The first set of questions that aimed at investigating the performance of the different labelling treatments regarded the objective understanding of label information. Therefore, participants were asked to reply to three **objective questions** on **hazards**, **precautions** as well as **ingredients** that applied to the products.

Figure 44 displays the results for product hazards. **55%** of the participants in the **Simplified Label** treatment of the **laundry detergent** were able to **correctly** answer the question on hazards. The share of correct answers in the Status Quo treatment was 54% and in the No Label Baseline 8%. When comparing performance by treatment the difference between the Simplified Label and No Label Baseline is highly statistically significant ($p<0.001$). Performance between the Simplified and Status Quo Label on the other hand is not ($p=0.61$).

The same pattern may be observed for the **glue**. In the **Simplified Label** treatment **28%** of the participants answered the question **correctly**, in the Status Quo Label treatment the share

was 29% and for the No Label Baseline it was only 6%. Again, the difference between the Simplified and Status Quo Label is not significant (p=0.79) while it is highly significant for the Simplified Label and the No Label Baseline (p<0.001).

Figure 44: Objective Understanding of Product Hazards by Treatment



Notes: The question was: "Please select all statements that are true about the product displayed on the left:" (Status Quo Label & Simplified Label (QR)) and "Thinking about a [laundry detergent / glue], please select all statements that are usually true about such a product:" (No Label Baseline).
Number of observations: N=2,001 (LD), N=2,002 (G)
Source: ConPolicy analysis of the experiment and survey data.

Furthermore, data reveals that **75%** of the participants assigned to the **Simplified Label** of the **laundry detergent zoomed** in on the label. Of those who took a closer look 70% answered the question on hazards correctly, while the share of correct answers among those who did not zoom was only 11%. The difference between the groups is statistically highly significant (p<0.001). The same pattern emerges for the **glue**. Overall, **80%** of the participants in the **Simplified Label** treatment **zoomed** in on the label. Among those who zoomed the share of correct answers was 34%, while it was only 5% among those who did not take a closer look at the label. Again, the difference is highly statistically significant (p<0.001).

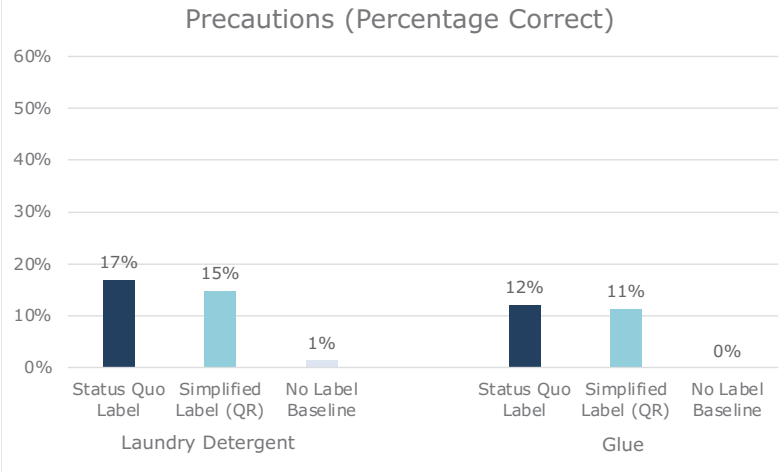
Overall, participants in the Simplified Label treatment of the laundry detergent spent on average 78 seconds to answer the question on hazards. For those assigned to the glue the average was 89 seconds. Furthermore, the data reveals that there exists a positive and significant correlation between time spent on the question and performance (0.43 for the laundry detergent and 0.41 for the glue, both p<0.001).

Figure 45 displays the results for precautionary statements that apply to the products. As can be seen on the left (**laundry detergent**), the share of participants who **correctly** answer the question in the **Simplified Label** treatment was **15%**. For the Status Quo Label it was 17% and for the No Label Baseline 1%. The difference between the Simplified Label and the No Label Baseline is highly statistically significant (p<0.001), while it is not when comparing the Simplified and the Status Quo Label (p=0.31).

The same picture emerges when considering the **glue** (right side of the figure below). **11%** in the **Simplified Label** treatment answered the question **correctly**. The share for the Status Quo Label was 12% and for the No Label Baseline it was 0%. The difference between the

Simplified Label and the No Label Baseline is again highly statistically significant (p<0.001), while it is not when comparing the Simplified and Status Quo Label (p=0.61).

Figure 45: Objective Understanding of Precautions by Treatment



Notes: The question was: "From your reading of the label, when using this product would you: (Select all that apply)" (Status Quo Label & Simplified Label (QR)) and "When using a [laundry detergent / glue] would you: (Select all that apply)" (No Label Baseline).
Number of observations: N=2,001 (LD), N=2,002 (G)
Source: ConPolicy analysis of the experiment and survey data.

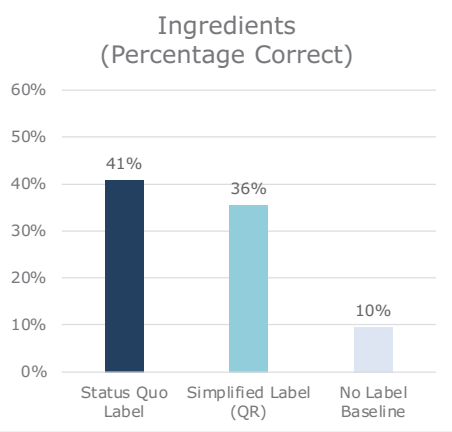
With respect to taking a closer look at the Simplified Label (zooming) the following results emerge: In the **Simplified Label** treatment of the **laundry detergent 64%** of the participants **zoomed** in on the label. Of those who zoomed 22% answered the question on precautionary statements correctly, while the share of those who did not take a closer look was only 2% (difference statistically significant, p<0.001). Similarly, **68%** in the Simplified Label treatment of the **glue zoomed** in on the label. Among those participants who took a closer look 16% answered the question correctly and among those who did not zoom the share was 1% (difference statistically significant, p<0.001).

Furthermore, the time spent to answer the question was on average 53 seconds for the laundry detergent and 69 seconds for the glue. The more time participants spent to answer the question, the higher were chances of answering the question correctly (correlation 0.37 for laundry detergent and 0.31 for glue, both p<0.001).

Lastly,

Figure 46 displays the results for ingredients contained in the laundry detergent. Participants in the **Simplified Label** treatment answered the question **correctly** in **36%** of the cases. The share of correct answers in the Status Quo Label treatment was 41% and in the No Label Baseline it was 10%. Performance in the Simplified Label treatment was significantly better than in the No Label Baseline ($p<0.001$). Similarly, performance in the Status Quo Label treatment was weakly, significantly better than in the Simplified Label treatment ($p=0.05$). Nevertheless, the effect size of the performance is negligible (Cohen's $d = 0.11$).

Figure 46: Objective Understanding of Product Ingredients by Treatment



Notes: The question was: "From your reading of the label, which ingredients are contained in this product? (Select all that apply)" (Status Quo Label & Simplified Label (QR)) and "From you experience with laundry detergents which ingredients are usually contained in such a product? (Select all that apply)" (No Label Baseline).
Number of observations: N=2,001
Source: ConPolicy analysis of the experiment and survey data.

Information regarding the ingredients was not included on the actual packaging of the Simplified Label but only could have been accessed via the QR code and the corresponding website (pop-up to be shown on screen). Overall, **63%** of the participants **accessed the website** with the ingredients list. Among those who accessed the website the share of answering the question on ingredients correctly was 54% while it was only 4% for those who did not access the website ($p<0.001$). Hence, consulting information enhances objective understanding by consumers.

Furthermore, participants on average took 48 seconds to answer the question. Again, there exists a positive and significant relationship between time spent to answer the question and performance (0.38, $p<0.001$).

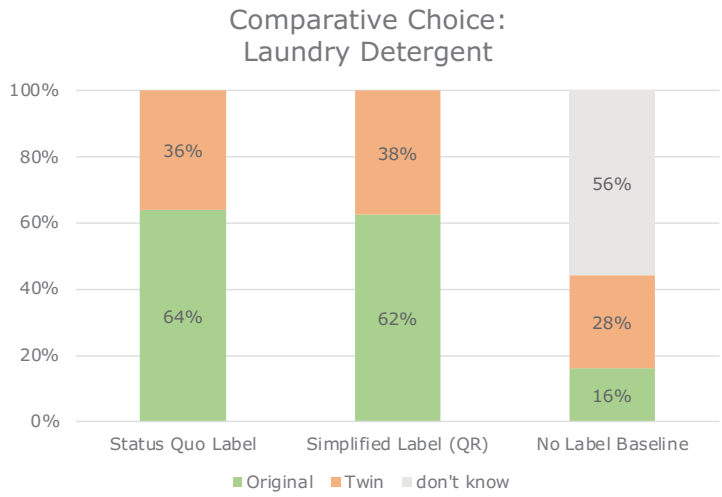
In conclusion, the data shows that the **Simplified Label** with a QR Code **performs significantly better than** the **No Label Baseline**, i.e. receiving relevant information induced consumers to better understand safe use information compared to simply answering on experience with chemical products. Furthermore, the **Status Quo Label** and the **Simplified Label perform equally** with respect to hazards and precautions. Objective understanding of the ingredients contained in the product was – at least weakly significantly – worse in the Simplified Label treatment compared to the Status Quo Label, but the effect size was negligible. An explanation for this could be that ingredient information in the Simplified Label treatment was moved to a separate website to be accessed via a QR-code (pop-up on screen). **Accessing** this **website might be causing additional effort** on the side of the consumer and hence, not taking this further step on average negatively affects objective understanding. Lastly, the data on actively consulting the label, i.e. zooming, confirms previous results. The **majority of participants were willing to take a closer look** at the label in the experiment and **if they consulted** the label their **understanding was** also **better** than when they did not consult the label.

Ability to Identify a Potentially Hazardous Product

In addition to the questions on objective understanding, the **comparative choice task** carried out in the experiment may be taken as further evidence on consumers' understanding of labelling information. Participants were asked to **identify the potentially less harmful product** among two.

As described previously for the **laundry detergent,** the original product was less harmful than its twin. Figure 47 displays the results by treatment. It can be observed that the majority of the participants (**62%**) in the **Simplified Label** treatment were able to **correctly** identify the less harmful product. The share among participants in the Status Quo Label was 64% and in the No Label Baseline it was 16%. When comparing the treatments with respect to correct answers, it can be found that the distribution of the Simplified Label and the No Label Baseline is highly statistically different ($p<0.001$). The difference between the Simplified Label and Status Quo Label, on the other hand, is not statistically significant ($p=0.46$).

Figure 47: Comparative Choice Task Laundry Detergent by Treatment



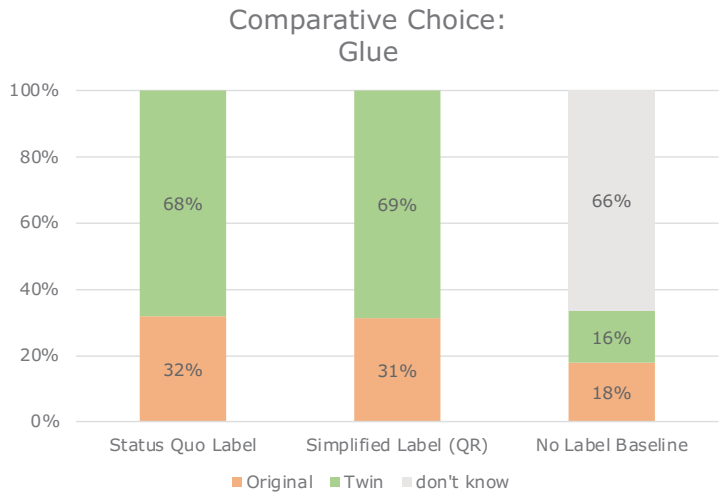
Notes: The question was: "Please take a look at the two laundry detergents. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

Furthermore, the data from the comparative choice task shows that **72%** of the participants **zoomed** in **on both labels** displayed on screen. **21% consulted one** of the two labels and **8% did not zoom**. Among those who zoomed in on both labels 66% were able to correctly identify the less harmful product. The share among those who only consulted one of the two labels was 55% and among those who zoomed in on none it was 47% (difference highly statistically significant, $p<0.001$).

The comparative choice task for the **glue** was designed such that the original product was more harmful than its twin. Hence, correctly interpreting labelling information would lead participants to choose the twin product. Figure 48 displays the results by treatment. Again, the majority of participants (**69%**) in the **Simplified Label** treatment were able to make the **correct** choice. The share for the Status Quo Label is 68% and for the No Label Baseline it is 16%. When comparing the distribution of correct answers by treatment it can be found that the Simplified Label treatment and the No Label Baseline are highly statistically different

(p<0.001). The difference between the Simplified Label and the Status Quo Label, on the other hand, is not significant (p=0.77).

Figure 48: Comparative Choice Task Glue by Treatment



Notes: The question was: "Please take a look at the two glues. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

With respect to zooming behaviour the data shows that **71%** of the participants in the **Simplified Label** treatment **consulted both labels**, **25%** consulted **one** of the two and **5%** consulted **none**. Among those who consulted both labels, 70% answered the question correctly, among those who zoomed on one of the two labels the share was 65% and among those who did not zoom the share was 65% (differences not statistically significant, p=0.24).

In conclusion, the results from the comparative choice task confirm the findings from the previous question on objective understanding. The **Simplified Label performs significantly better than** the **No Label Baseline**, i.e. having label information allows consumers to make the correct choice. Similarly, the **Simplified Label and** the **Status Quo Label perform equally well**. Lastly, **consumers were willing to consult** the label to gather relevant information and zooming in on the label partially helped consumers to make a better choice.

Rating of understandability and ease to find

As presented in the section on the first research question, consumers rated the Status Quo Label on average as rather or very easy to understand. Similarly, the individual label elements such as GHS-pictograms, hazard and precautionary statements were on average rated as rather or very easy to find on the packaging. In the following the rating of understandability and ease to find of the Simplified Label with QR-code is presented. Furthermore, the difference between the two labelling variants is statistically analysed.

The question on **understandability** was rated on a scale from "very easy to understand" (1) to "very difficult to understand" (5). The average rating over both products and all information elements was 2.00 for the **Simplified Label** which corresponds with **"rather easy to understand"**. The average rating of the Status Quo Label was slightly better with 1.94 which also corresponds with "rather easy to understand". Although the difference

between the Simplified and Status Quo Label is weakly statistically significant (p=0.04) the absolute difference is rather negligible.

The question on **ease to find** the relevant label elements was rated on a scale for "very easy to find" (1) to "very difficult to find" (5). The average rating over both products and information elements was 2.06 for the **Simplified Label** which corresponds with **"rather easy to find"**. The average of the Status Quo Label was slightly better with 2.00 which also corresponds with "rather easy to find". Although the difference between the two label variants is weakly statistically significant (p=0.05), it again appears not very large.

As noted above, the Simplified Label was constructed such that the dosage table on-pack was reduced and the full table was available on a separate website to be accessed via the QR code. Furthermore, the list of ingredients was removed from the package label and moved to the QR code website. Hence, the analysis investigates the ease to find for those two label elements in more detail and compares the ratings between the Status Quo and Simplified Label. The average rating of the ease to find the dosage table was 1.70 for the Status Quo Label and 2.10 for the Simplified Label, i.e. "rather easy to find". Although the difference is statistically significant ($p<0.001$), the effect size is low (Cohen' $d = 0.43$). Similarly, the ease to find-rating of the list of ingredients was on average 1.90 for the Status Quo Label and 2.19 for the Simplified Label. The difference is statistically significant ($p<0.001$), but again, the effect size is only small (Cohen's $d = 0.32$).

Hence, both the results from subjective understanding and ease to find relevant label elements show that the **Simplified and the Status Quo Label are rated equally well** by consumers. Nevertheless, it must me noted that the rating questions are subjective and self-reported and hence, the appreciation of the labels could be over-rated by participants. Especially, because the overall performance in the questions on objective understanding is poor. But both subjective ratings and objective performance point in the same direction, i.e. the Status Quo Label and the Simplified Label perform equally.

Conclusion

In conclusion, the results on the fourth research question show that the **Simplified Label with QR code performs significantly better than** the **No Label Baseline**. Hence, providing this type of labelling information can inform consumers with respect to relevant measures on safe use. Additionally, the **Simplified Label performs equally well as** the **Status Quo Label**, with the **exception of ingredients information** where the Status Quo Label performs slightly better.

An explanation for the later finding may be that the **effort of receiving ingredients information** is **larger for the Simplified Label**, i.e. information is moved to a separate website to be accessed via the QR-code. It must be noted that the experiment was only able to mimic access behaviour, i.e. opening the QR code in the experiment was comparatively easy and consumers could access the website as a pop-up directly on screen. In reality consumers would need to take their smartphone and scan the QR code in order to receive relevant information which might require more effort. Furthermore, accessing the QR code is only possible for consumers that own a smartphone and have access to mobile data.

Lastly, **both labels** are also **subjectively rated very positive**, i.e. with respect to subjective understanding and ease to find relevant labelling elements. The Status Quo Label under

current regulation is rated slightly better than the Simplified Label. Nevertheless, the difference is not great and hence, both labels should be interpreted as equally good.

RQ 5: Do consumers prefer information to remain on the physical label or to be communicated via digital tools?

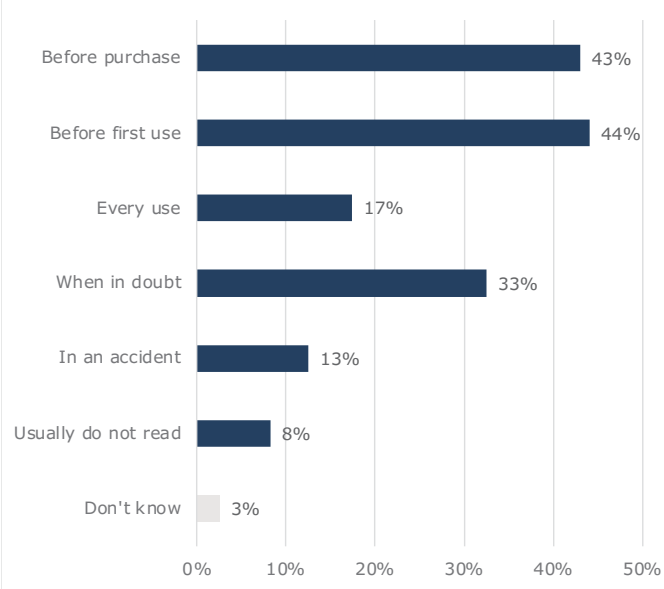
The fifth research question focusses on consumers' preferences regarding the ways to communicate CLP- and Detergents-relevant information. As the previous section demonstrated, both the Status Quo Label under current regulation and the Simplified Label with a QR code performed equally well with respect to objective understanding of hazards and precautions. Although the understanding of ingredients and ratings of subjective understandability and ease to find were slightly lower for the Simplified Label, the results are not conclusive regarding whether analogue or digital labelling is preferred by consumers.

Hence, the final set of questions asked participants to indicate their **willingness to consult labelling information via different means**. Furthermore, participants were asked to **choose between physical and digital communication** for CLP- and Detergents-relevant labelling aspects.

Reading Behaviour

As a first step, participants were asked about their reading behaviour of chemical labels, i.e. the point in time when they would usually read safety information. Figure 49 displays the results. The most frequent answers with **44% and 43%** respectively indicated reading the **label before first use or before purchase**. 33% said to read it when in doubt and 17% every use. 13% indicated to read it in case of an accident and only 8% said not to read the label.

Figure 49: Reading Behaviour of Labels



Notes: The question was: "When do you usually read the safety information on a label of a chemical product such as a laundry detergent or glue? (Select all that apply)"
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

Hence, the point in time when consumers usually consult labelling information is either **at purchase** (before buying the product) **or before using the product** at home. Hence, the

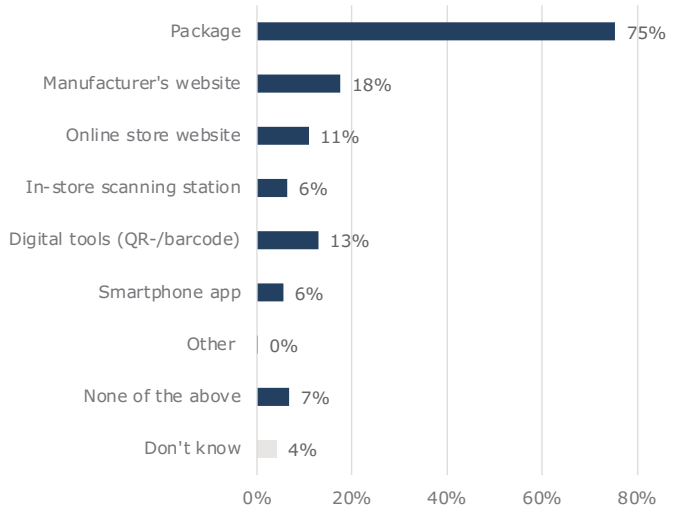
means of communicating relevant information on safe use, ingredients and dosage should be tailored to these situations. The share of consulting the label in case of an accident was comparatively low which might be because not too many consumers "usually" experience accidents with chemical products. When looking at the results from the third research question, it can be seen that consulting the label in case of an accident is indeed a relevant measure to prevent adverse effects.

Information Channels

The second question focusses on the **general willingness to consult** chemical labels **by different analogue and digital means**. Therefore, participants were asked to indicate whether they would actively consult label instructions and safe use information via the package label, different types of websites as well as digital tools such as QR-codes or smartphone apps.

Figure 50 displays the results by information channel. The **vast majority** of participants **(75%)** indicated that they would **consult** labelling information **via the physical packaging.** All other means were less popular. 18% chose the manufacturer's website, 13% digital tools such as QR- or barcodes, 11% an online store website and 6% an in-store scanning station or smartphone app. The percentage of consumers who are willing to **consult at least one digital tool** is **35%**.[35]

Figure 50: Willingness to Consult Labelling Information via different Information Channels



Notes: The question was: "When purchasing or using a chemical product such as a laundry detergent or glue, would you actively consult use instructions, information on hazards or precautions via any of the following means: (Select all that apply)"
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

In conclusion, the results are a first indication that physical labelling is the preferred option. The vast **majority** indicated to be willing to consult information **via** the **packaging** of the

[35] The binary variable groups those consumers who selected either the manufacturer's website, online store website, in-store scanning station, digital tools (QR- / barcode), smartphone app or a combination of the digital tools versus those who did not select any digital tool.

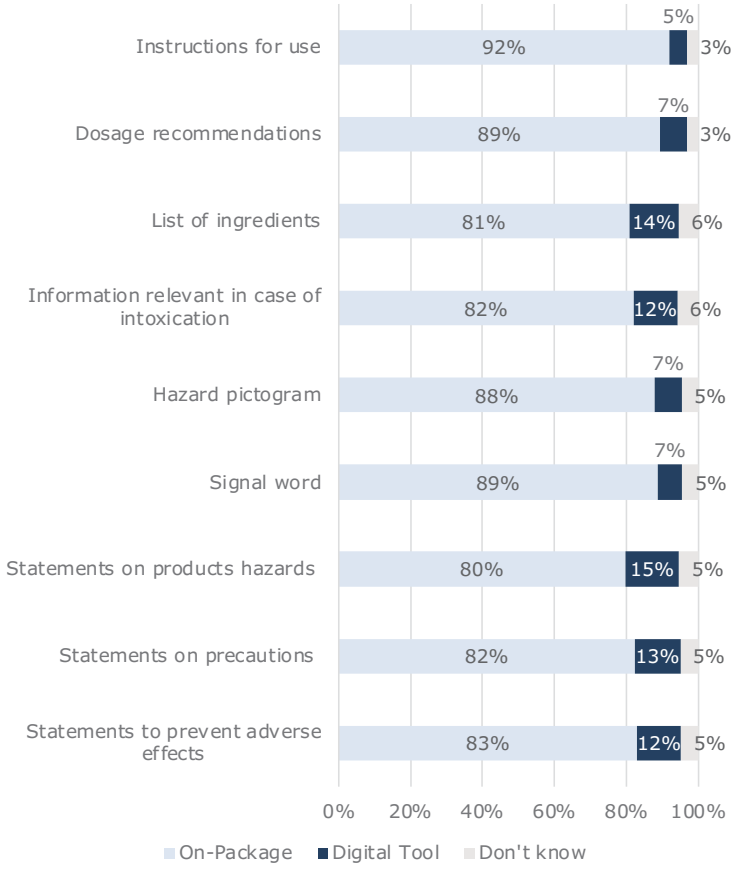
product. Nevertheless, it must also be noted that **approx. one third** of the consumers are **at least willing to consider digital means**.

Preference for Communicating Label Elements (analogue versus digital)

Following the previous results on the general willingness to consult labelling information via different means, the subsequent question asked participants to indicate their **preference between physical and digital labelling** for different CLP-related information elements such as hazard pictograms, ingredients, and instructions for safe use.

Figure 51 shows that for all types of labelling elements the **majority of over 80% prefers physical labelling over digital tools**.

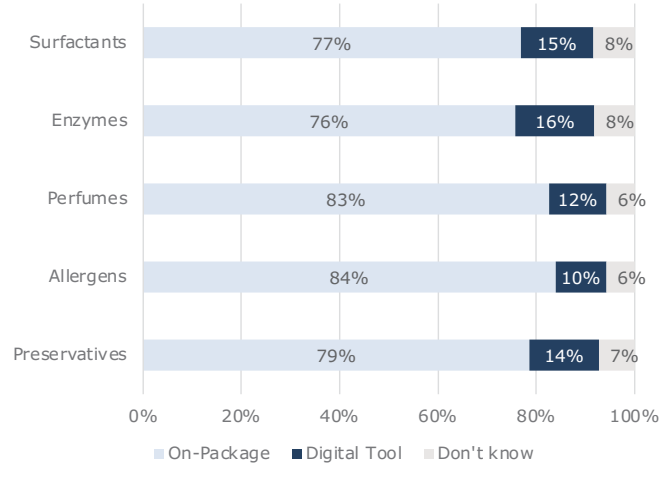
Figure 51: Preference for Communicating Label Elements (analogue versus digital)



Notes: The question was: "Thinking of a product label for a chemical product such as a laundry detergent or glue, how would you like to receive the following product information: You can either choose to have it on the package label or to access it through / by using a digital tool such as websites, QR-codes or apps. Please select one answer per row"
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

Furthermore, the question was repeated for ingredients contained in detergent products. Participants again were asked to choose among physical or digital labelling for a list of specific laundry detergent ingredients. Again, the results confirm previous findings (see Figure 52). For all different types of specific ingredients potentially contained in detergents, **approx. 80% preferred the physical label over digital means**.

Figure 52: Preference for Communicating Ingredient Information (analogue versus digital)



Notes: The question was: "Thinking of a product label for a laundry detergent in specific, how would you like to receive the information on certain / some of the ingredients contained in the product:"
Number of observations: N=4,003
Source: ConPolicy analysis of the experiment and survey data.

The findings show that the preferences of consumers are clear. When having the choice between either analogue or digital means, the **analogue communication was strictly preferred**. This holds true for all CLP- and Detergent-relevant labelling elements.

Furthermore, the preference for analogue versus digital labelling was analysed with respect to two socio-demographic aspects, i.e. age and digital readiness. The preference in favour of digital labelling is negatively correlated with age (–0.28, $p<0.001$). Nevertheless, the correlation is rather low. Furthermore, the preference for digital labelling is positively correlated with digital readiness (0.25, $p<0.001$), hence, again rather low.

Conclusion

The results on the fifth research question on the preference between physical and digital labelling can be summarised as follows: Firstly, the survey data shows that consumers usually **read labelling information either before first use or before purchase**. Therefore, all means of communication **should be accessible** in both situations, i.e. not only when consumers are at home but also when they are in the shop deciding upon a product. When considering digital tools, it is therefore relevant that consumers either have a personal device to access information or the retailer provides an accessible way to gather information.

Overall, **approximately a third of consumers is open to consult labelling information via digital tools** such as websites, scanning stations or their phone. It must be noted that especially in-store scanning stations as well as specific smartphone apps for labelling information are currently rather uncommon. Hence, consumers do not have experience with using such tools, but their general openness shows that at least some would consider them.

Nevertheless, the results demonstrate that when consumers would need to decide between either physical labelling on the packaging or digital tools, their preferences are clear. The **majority prefers physical over digital labelling** when it comes to relevant CLP- and Detergents-information. A potential explanation could be consumers' age and their digital readiness. Nevertheless, the analysis only indicates the effects to be small.

Assumptions for the estimation of economic impacts

The EU Standard Cost Model has served as the basis for estimating administrative costs to industry and public authorities. It estimates the costs of reporting as:

$$\text{Administrative cost} = \Sigma\ P \times Q$$

$$P\ (\text{Price}) = \text{Tariff} \times \text{Time}$$

$$Q\ (\text{Quantity}) = \text{Number of businesses} \times \text{Frequency}$$

In relation to the reporting required under the policy options considered here, the costs elements are:

- Tariff = hour salary for staff;
- Time = hours to perform the activity;
- Frequency = annual expectation for activity;
- Number of businesses = number of duty-holders that have to classify, label, use suitable packaging and/or notify to poison centres.

The tariff used in all subsequent calculations is 40 EUR/hour, as reported in the Fitness Check (EC, 2019e) as the hourly rate for a professional. The administrative costs have been calculated according to the costs accrued by the companies individually where possible. If the total number of companies affected is not known, the total cost across all companies is shown. The activities can comprise of one-off and recurrent costs. The one-off costs relate to the initial adjustment to a new requirement, such as the (re-)classification of substances to consider the new hazard classes. The recurrent costs encompass the repeated requirements to update, e.g. CLI notifications. When it comes to costs for administration, including ECHA, a full-time equivalent was used. The cost of such an FTE, including 19% of over-head costs is equal to €170,000 per year.

Where possible and accurate to do so the impacts have been assessed quantitatively, otherwise a qualitative approach has been taken. The impacts have been categorised according to their direction (Positive (+)/Neutral (o)/Negative (-)), their causation (Direct/Indirect) and their frequency (One off/Recurrent).

Where appropriate, separate consideration has been given to SMEs compared to larger companies. In this respect, efforts were made to ensure SME views are represented, for example, through discussions with relevant European associations (SMEunited, CIHEF) and separate analysis of cost information provided by SMEs where relevant.

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Annex 5 – The CLP Regulation and other Pieces of Chemical Legislation

THE CLP REGULATION

Introduction

The CLP is a legal instrument that provides for obligations on duty-holders to classify, label and package substances and mixtures, and in some cases pertains to articles. However, not all duty-holders have the same obligations. Downstream users e.g. can use the labelling information from their supplier provided they do not change the composition of the substance or mixture that had been supplied to them. Notification to Poison Centres is required only from importers and downstream users of mixtures.

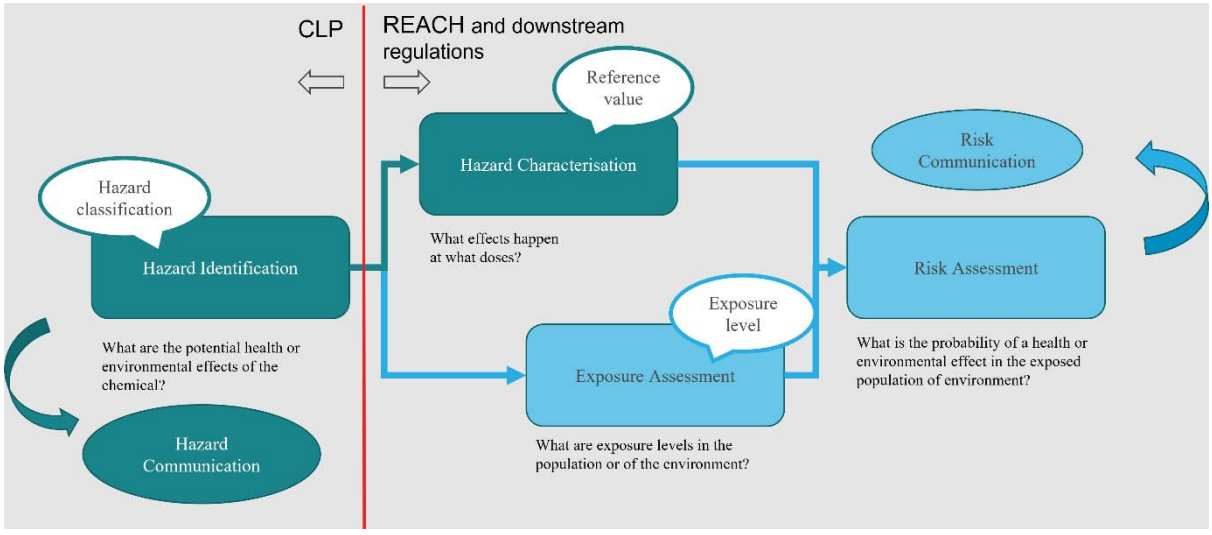

Figure 53: Breaking down the risk-assessement and hazard communication related parts.

Hazard identification, evaluation and classification

The first step to determine whether a substance or a mixture is hazardous is to identify and evaluate, based on available data, whether they correspond to the classification criteria as provided for in Annex I of CLP. In that Annex, each of the hazard classes (e.g. carcinogenicity, chronic aquatic toxicity) is described with the criteria to be fulfilled and the type of evidence to be provided, as well as, the category/ies within each hazard class – the latter reflects the 'severity' of a hazard (e.g. carcinogenic 1A is more severe than carcinogenic 2). Sometimes, such evaluation needs to weigh different pieces of evidence against each other ('weight of evidence' approach) and is based on expert judgment. Once the evaluation is performed and it is concluded that a substance or mixture fulfils the criteria of one or more hazard classes/categories, the duty-holder has to 'classify' its substance or mixture. It may happen that such classification is warranted only for a particular endpoint (e.g. the inhalation route only). Classification of substances may be based on 'self-classification' or on 'harmonised classification'. The latter is possible and required only when

a classification has been harmonised, which in practice means that an entry exists in Table 3 of Part 3 of VI to CLP. That table is regularly updated via the 'Adaptations to Technical and Scientific progress' which are in the form of 'Commission Delegated Regulations'. Those Regulations group many entries on which ECHA has delivered an Opinion and which it transmits to the Commission for decision-making, in accordance with the procedure in Article 37 of CLP.

Hazard communication

Labelling

Once a substance or mixture has been classified, such classification information needs to be communicated so that each actor in the supply chain is aware of the potential hazards of the substance or mixture. That communication is usually performed via the label, which displays hazard pictograms as well as hazard statements and precautionary statements. More detailed information is provided in the Safety Data Sheets, developed according to the REACH provisions (in particular Article 31 and Annex II to REACH). In case of harmonised classification, most of the labelling elements pertaining to the hazards will also be harmonised and hence duty holders have no choice but applying the labelling information corresponding to each respective substance included in Table 3 of Part 3 of Annex VI. In case no harmonised classification exists – which is the case for mixtures and most of the substances - it will be up to the duty holder to check the labelling information triggered by its classification decision.

Notification to the classification and labelling inventory

CLP also provides for the obligation for manufacturers, importers and downstream users to notify certain information to ECHA, which will feed into the CLI (database). The inventory was set up with the view to ensure a harmonised level of protection for the general public (in particular persons who come into contact with certain substances) and to ensure proper functioning of legislation relying on classification and labelling. Notifiers need to update their notifications in case of changed classifications and they are required to make every effort to come to an 'agreed entry', meaning a classification of a substance on which all notifiers agree - which does not prevent that in certain cases divergent classifications may be justified because e.g. the presence of an impurity.

Notifications to poison centres

Another aim CLP pursues is to ensure that information on mixtures is available in case of poisoning accidents. Poison centres will collect the information that is notified to them, which will enable them to give the most appropriate advice to carers in emergency situations. Importers and downstream users need to communicate the composition of their mixture which will feed into the poison centre's databases (which is either a national database or the EU database managed by ECHA).

Packaging

CLP contains a number of packaging provisions, to ensure that the packaging of hazardous substances and mixtures is sufficiently resistant under normal conditions of use. A few generic provisions are included in the main text of CLP, which refers to more specific provisions which apply depending on the type of hazards or product (e.g. packaging of

substances and mixtures containing 3% or more of methanol will require a child resistant fastening).

The United Nations' Globally Harmonised System (UN-GHS)

The CLP is based on the UN-GHS classification and labelling system and is implementing it. The aim is to have globally harmonised classification and labelling rules, in order to allow for classification and labelling of the same substances and mixtures in the same way at global (UN) level. It needs to be noted that the UN-GHS is a system that operates through the so called 'building block approach', meaning that Members may implement some parts of the UN-GHS rules or follow a stepwise approach. It also needs to be noted that the UN-GHS harmonises rules and criteria but there are no 'UN wide classified substances' as the actual harmonised classification process is performed by each member individually and endeavours to come to a 'global list' have not been very successful so far.

MAPPING LINKAGE FROM CLP TO OTHER PIECES OF CHEMICALS LEGISLATION

Data generation

Chemical risk assessment involves the analysis of the inherent hazardous properties of a substance or a mixture and the extent of exposure to that substance or mixture. The human health and environmental risks related to exposure to hazardous chemicals are addressed via the hazard and risk assessment procedures and requirements set out in the different key pieces of the EU chemicals legislation such as the CLP, the Plant Protection Products and Biocidal Products Regulations, etc. To be noted that, while additional information requirements in REACH could lead to additional animal testing, there is no data requirement under CLP with regards animal testing. The decision to classify a substance or a mixture is exclusively based on existing available information.

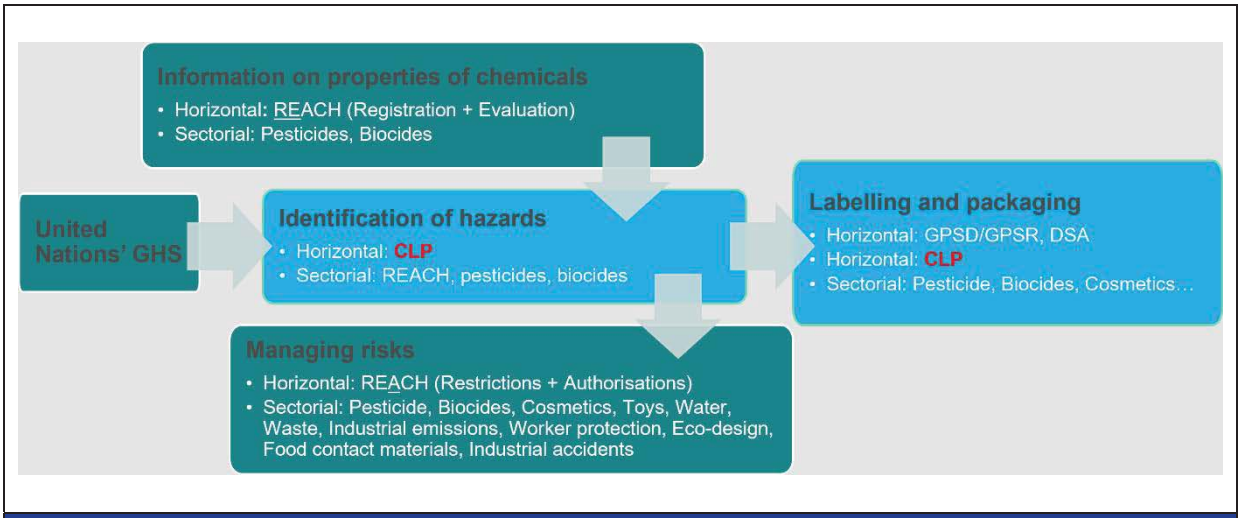

Figure 53: Interaction between CLP and other pieces of legislation (from figure 1 in the SWD)

Regulations using hazard identification from CLP

The main steps of a chemical risk assessment involve:

hazard identification (based on toxicity tests and other relevant information);

dose (concentration) – response (effect) assessment;
exposure assessment – exposure scenarios (based on models and measurements of the occurrence of the chemical);
risk characterisation; and
risk estimation.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

Regulations using hazard identification from CLP

There are two basic approaches to risk management often used in combination, in the EU chemicals acquis: one based on specific risk assessment (SRA) and the other one based on generic risk considerations (GRC).

The main difference between these two approaches is the point in time when the exposure assessment is considered and the specificity of the exposure assessment. For risk management based on GRC, the potential exposures and risks are considered generically, prior to the adoption of legislation. The GRC-based approach is built into the legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of the chemical, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. For example, under the Cosmetic Products Regulation any substance classified as carcinogenic, mutagenic or toxic for reproduction (CMR) categories 1A/B and 2, shall be banned from use in cosmetics (subject to strict derogations), given the fact that direct exposure of humans is taking place through the application of a cosmetic product on the external parts of the human body (or teeth or mucous membranes of the oral cavity). Similar approaches have been taken for active ingredients in plant protection products and biocides, for substances in toys, etc.

The decision to link particular hazard properties (e.g. CMR, persistent bioaccumulative and toxic substances (PBT), endocrine disruptors (EDs)) to automatic risk management measures without the intervening step of a specific risk assessment is done on the basis of generic risk consideration without prejudice to performing also a full risk assessment for the other properties of the substances which are not linked to the related hazard properties. In the legislation evaluated in this Fitness Check, the generic risk consideration approach is typically applied for the following use applications and the following substances:

Use applications:

when there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management (e.g. labelling obligations under CLP, labelling requirements and use instructions under the Plant Protection Products and the Biocidal Products Regulations).
for use in widely dispersive or open applications which result in a significant exposure of humans or the environment (e.g. plant protection products).

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for use in applications where the exposure is considered to be more difficult to control and monitor (e.g. plant protection products).

for use in applications resulting in exposure of vulnerable groups (e.g. children).

for use to prioritise the risk assessment of certain chemicals and under certain conditions (e.g. food contact materials).

Substances:

for substances with hazard properties that result in severe adverse effects on human health or the environment should exposures occur (e.g. CMR, PBT, EDs, chemicals with Single Target Organ Toxicity (STOT) properties); and

for substances where it is difficult/impossible to identify a safe threshold and, therefore, where most specific risk assessments are likely to identify risks that lead to a need for risk management measures (e.g. PBT, vPvB, respiratory sensitisers).

The Commission Staff Working document on the Fitness Check of the most relevant chemicals legislation (excluding REACH)[36] contains an Annex (Annex 4) that provides a summary of legislation of hazard/risk assessment chemicals legislation that distinguished between legislation that relies or not on the hazard assessment according to CLP.

[36] COMMISSION STAFF WORKING DOCUMENT FITNESS CHECK of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries Accompanying the document REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses, p 164-178, https://ec.europa.eu/info/sites/default/files/swd_2019_0199_en.pdf .

Annex 6 – Summary of the findings of the Fitness Check on Chemical Regulations (except REACH)

This annex sums up the findings of the Fitness Check performed on the most relevant pieces of chemical legislation (excluding REACH). Only CLP-relevant findings are reported below.

The development of EU legislation on chemicals started with the adoption of the Dangerous Substances Directive in 1967, followed by the Dangerous Preparations Directive in 1988, which were the forerunners of the CLP harmonizing the criteria for classification, labelling and packaging of substances and mixtures. The CLP identifies hazardous chemicals and provides criteria how to classify those chemicals (either via self-classification or harmonised classification). Based on the classification, the CLP provides rules on their labelling and packaging.

The Commission decided to undertake this Fitness Check to see what elements of the European chemicals acquis work well and what needs to be improved, both in terms of meeting the policy objectives and in terms of reducing regulatory burden. An assessment of the CLP framework is part of that Fitness Check.

Overall, the Fitness Check concludes that EU Chemicals legislation, including CLP, meets its objectives in terms of hazard assessment and management.

The linkages between the different pieces of EU chemicals legislation are generally well-established and functioning reasonably well. The EU legal framework on chemicals is generally designed to make science- and evidence-based decisions. The approach allows it to deliver in an effective, efficient and coherent way. The added value of policy action at the EU level is high and remains relevant. Significant benefits in terms of avoided health and environmental impacts (e.g. healthcare costs, productivity losses, suffering and premature deaths, remediation costs, and degradation of environmental/eco-system services) could be registered. Also quality and the availability of data needed to perform robust risk assessments and to make sound risk management decisions has improved considerably in recent years.

Remaining challenges, gaps and weaknesses identified by the Fitness Check – and relevant for CLP – are the following:

Implementation and enforcement

The correct functioning of the EU chemicals legislation relies heavily on the availability of the resources of public authorities in charge of its implementation and enforcement but variations between the capacity, available resources and expertise of Member States' competent authorities present significant challenges for implementation and enforcement and the systems' overall effectiveness and efficiency.

Resource constraints at national level affect the capacity to carry out different enforcement activities, such as inspections and other controls including market surveillance activities or reporting. There is also a considerable lack of information on the level of compliance with the existing EU chemicals legislation, particularly with respect to consumer products.

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Duplication, burdens and pace of procedures

Scientific advice and risk assessment are provided to the Commission by different agencies and scientific committees depending on their areas of intervention and their competencies. Ensuring good and effective cooperation among the EU agencies and the rules of procedure governing the functioning of the existing committees is a must and could be improved. The substance-by-substance approach could be improved as well, especially in view of assessing chemicals with similar hazard, risk or function as a group a more holistic approach should be considered.

Communication of hazard and safety information:

A survey found that 45% of correspondents feel well informed about the potential dangers of chemicals contained in products. The relatively low level of understanding of certain labels and statements is partly due to the overload of information or to the overlaps in legal requirements. This makes it difficult for downstream users and consumers to focus on the essential hazard information. At the same time, the lack of some information on consumer goods (labelling requirements on environmental hazards for cosmetic products) impacts the consumers' ability to make informed choices. The communication of hazard and safety information to consumers can thus be improved and simplified, including by using digital technologies such as Q-R codes. Also ECHA's classification and labelling inventory (C&L) could be improved so as to reduce the number of different entries for the same substance.

Consistency of risk management measures

A potential important gap is the lack of an overarching approach to the protection of vulnerable groups. Reference to vulnerable groups is not systematic across the legislation and risks to these groups are not always addressed in a consistent manner across product, risk, or sector specific legislation.

Due to different risk management decisions of various legislations, inconsistencies exist for substances that are endocrine disruptors, persistent, bio-accumulative, toxic, very persistent and very bio-accumulative and fulfil the classification criteria for specific target organ toxicity. The potential added value of introducing new hazard classes in the CLP Regulation (e.g. terrestrial toxicity, neurotoxicity, immunotoxicity, endocrine disruption, persistent bioaccumulative and toxic, very persistent very bioaccumulative) could be explored.

Risk assessment, knowledge gaps and challenges in keeping up with science

The proper functioning of the EU chemicals legislation and its capacity to respond to future challenges depends on the ability of the EU and Member States to make their decisions based on robust and relevant up-to-date data. Important knowledge gaps remain regarding exposure to hazardous chemicals, their use and their impacts on humans and the environment, including on biodiversity and ecosystems' resilience.

Moreover, there are still barriers to the use and acceptance of alternative (non-animal) test methods for regulatory purposes, partially linked to gaps in the available test guidelines.

Lack of knowledge about substances in articles is increasingly concerning as the EU is in the process of shifting towards a more circular economy, therefore, a life-cycle assessment is needed and information on recyclability.

Global competitiveness, innovation and sustainability

Globalisation, a strong growth in the production of chemicals in other parts of the world and rapid technological change are the main challenges for the EU chemicals industry. Significant efforts will be needed by all interested parties at all levels and most importantly by industry itself to maintain and reinforce Europe's industrial leadership (main assets of the EU chemicals industry are a high level of technological development, a skilled and talented workforce and a world-class science base).

The internal market is another asset that the EU and Member States authorities as well as the EU industry can build upon such as digitalisation, IT tools and other smart technologies. Smart technologies offer better communication of chemical hazard and safety information to consumers and digitalisation means potential burden reduction for SMEs.

Additional support to the development of smart, innovative, and sustainable chemicals and to encourage ‘green chemistry’ will be critical to ensure sustainability as well as the competitiveness of the EU chemicals industry for the future.

Annex 7 – Baseline, discarded measures and assessment of policy measures

1 BASELINE

The baseline has been defined to allow for the assessment of the environmental, economic and social impacts of the policy options considered. It includes a brief description of the wider socioeconomic context, the evolution of the macroaggregates of the EU chemical industry and the assumptions on the continuation of the existing legal framework and scope. The latter is described in more detail by the seven intervention areas.

Box 1 – Choice of the appraisal period

The 2023-2042 period (20 years) 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: the policy options considered are expected to entail one-off and recurring costs for businesses and Member State competent authorities. It is important to stress that even the one-off costs are expected to be borne gradually over a number of years rather than all in year one: for example, the costs of classifying and labelling chemical substances and mixtures as endocrine disruptors depend on a number of factors:

The introduction of information requirements on endocrine disruption in REACH;

The generation of data by REACH registrants through the required testing: some of the tests require two to three years to generate results;

The quality of the data generated and the follow-up activities by ECHA and Member State competent authorities to fill data gaps and improve the overall information quality.

Also the benefits and cost savings of the policy options considered are expected to be obtained over a number of years: while some of the cost savings may be generated relatively shortly after the implementation of the measures (e.g. benefits accruing from the improvements to the CLI, changes in the labelling requirements), human health and environmental benefits of the introduction of new hazard classes to CLP may be obtained only in the long term. To account for the long latency of some of the relevant health outcomes, a sensitivity analysis was performed, considering a longer discounting period (40 years).

Finally, the 20-year period is also consistent with the period considered by Ricardo (2021).

Context

1.1.1 Socioeconomic context

The short-term economic outlook for the EU is positive, as the economy is rebounding from the crisis onset by the COVID-19 pandemic faster than expected. Households' spending is recovering but supply's growth is hindered by labour shortages, challenges in global logistics,

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shortages in the production of key raw materials and microprocessors, and surging energy prices[37]. 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).[38]

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[39]. Both the size and the proportion of older persons in the total population are expected to increase[40], with the share of elderly persons (65 years and over) projected to grow from 21% in 2020 to 27% in 2040[41]. **Increasing demographic imbalances**[42], such as the ageing population, pose challenges for public expenditure in relation to pensions, health care and long-term care costs.

Accelerating technological change and hyperconnectivity is also expected to 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 are expected to enable innovation, in particular towards human augmentation[43] (EY, 2020). This includes empowering consumers through enhanced decision-making thanks to, for example, easier, faster and more tailored information. New disruptive technologies challenge existing regulations but may also enable new regulatory approaches.

Climate change and environmental degradation is affecting human activities at multiple levels: ecosystems' degradation is decreasing their ability to provide the services on which human life depend on, such as food, availability of clean water, absorption and retention of carbon dioxide, clean air and shelter. Climate change is likely to amplify other long-term driving forces, such as **significant migration** and **social inequalities**.

The expanding influence of countries in the East and South of the world, fuelled by their young populations and growing living standards, is driving the global economy to increased protectionism, which may result in trade and investment flows becoming more regional. The

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[37] Autumn 2021 Economic Forecast: From recovery to expansion, amid headwind, available at: https://ec.europa.eu/info/business-economy-euro/economic-performance-and-forecasts/economic-forecasts/autumn-2021-economic-forecast-recovery-expansion-amid-headwinds_en

[38] GDPVD, Gross Domestic Product, volume in USD, at constant 2015 purchasing power parities. Source: https://www.oecd-ilibrary.org/economics/data/oecd-economic-outlook-statistics-and-projections/long-term-baseline-projections-no-109-edition-2021_cbdb49e6-en
2015 Exchange rate 1 USD – 0.9015 EUR. Source: https://www.exchangerates.org.uk/USD-EUR-spot-exchange-rates-history-2015.html

[39] https://ec.europa.eu/eurostat/databrowser/view/proj_19np/default/table?lang=en

[40] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=People_in_the_EU_-_population_projections&oldid=497115

[41] https://ec.europa.eu/eurostat/databrowser/view/proj_19np/default/table?lang=en

[42] One of the 14 global megatrends — '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 and regularly used in 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. *Source: https://knowledge4policy.ec.europa.eu/foresight/tool/megatrends-hub_en*

[43] Gartner, Human Augmentation, 'Cognitive and physical improvements as an integral part of the human body'.

pandemic has also exposed the fragility of the global supply chains, which is encouraging companies — but also governments — to explore more resilient systems.

1.1.2 The chemical industry

The EU27 chemical manufacturing industry accounts for approximately 7% of the total EU industrial production (EC, 2019e). In 2020, 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.[44] Chemical sales accounted for €499 billion, contracting by 8.1% (€44 billion). 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 R&I (around 7.4% of added value).[45]

Table 9 provides an overview of the main economic aggregates (turnover, value added at factor cost, number of enterprises and number of persons employed) of the chemical sector (manufacturers, formulators and distributors):[46] 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.[47]

Table 9: Forecast of main aggregates for C20 Manufacture of chemicals and chemical products; G46.12 Agents involved in the sale of fuels, ores, metals and industrial chemicals; G46.75 Wholesale of chemical products

	2018	2020	2032	2042
C20 Manufacture of chemicals and chemical products				
Enterprises - number	27,986	28,168	31,469	34,221
Turnover or gross premiums written - million euro	600,000	588,578	735,051	857,111
Value added at factor cost - million euro	130,000*	146,077	221,768	284,843
Persons employed - number	1,200,000	1,147,873	1,288,314	1,405,349
G46.12 Agents involved in the sale of fuels, ores, metals and industrial chemicals & G46.75 Wholesale of chemical products				
Enterprises - number	43,413	41,337	30,591	21,636
Turnover or gross premiums written - million euro	198,268	200,906	205,727	209,744
Value added at factor cost - million euro	20,381	22,763	31,003	37,869
Persons employed - number	248,356	247,995	265,618	280,303

Source: Eurostat Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) – 2018 data
*Notes: *2017 data; cells in light blue are linear forecasts based on Eurostat 2011-2018 values*

[44] CEFIC, Facts and Figures of the European Chemical Industry, 2022.
[45] See CEFIC above.
[46] It should be noted that many other companies categorised by Eurostat with other NACE codes may have CLP duties. In other words, there may be companies which primary business activity is e.g. the 'manufacture of rubber and plastic products' and therefore included in NACE code C22, that may have to classify substances and label and package chemical products according to CLP requirements.
[47] SWD(2019) 199.

SMEs account for 96.7% of the number of enterprises in the chemical manufacturing sector and 16.1% of the total turnover (Eurostat data).

Baseline by policy area

The baseline, or 'no-policy-change' scenario assumes the realistic implementation and enforcement of the existing legislation. The following subsections describe the key assumptions on the policies and measures contained in the baseline. These are presented by the seven intervention areas identified for the revision of the CLP Regulation:

Area 1: Hazard identification;
Area 2: Toxicity reference values and harmonised classification and labelling;
Area 3: Classification and Labelling Inventory and self-classification;
Area 4: Labelling;
Area 5: CLP scope exemptions;
Area 6: Online sales;
Area 7: Poison centre notifications.

1.1.3 Area 1: Hazard identification

As explained in Section 2, CLP is the horizontal reference point for the identification and classification of the physical, health and environmental hazards of chemical substances and mixtures for most EU chemicals and chemicals-related legislation. However, the hazards defined under CLP — and the UN GHS — are not exhaustive, resulting in lack of communication on the hazards not covered by CLP.

As CLP does not contain hazard identification criteria for substances with ED, PBT/vPvB and PMT/vPvM properties, under the baseline these substances will keep being identified through REACH (ED, PBT/vPvB and PMT/vPvM substances), BPR and PPPR (ED, PBT/vPvB substances). The BPR and the PPPR have established identification criteria for EDs. While REACH does not contain identification criteria for EDs, these can be identified as SVHCs on a case-by-case basis following the IPCS/WHO definition and the assessment of the "equivalent level of concern" carried out by the REACH Member State Committee. REACH requires registrants to carry out a PBT assessment for substances placed on the market in quantities of 10 tonnes or more per year. Any substance under the scope of REACH can be identified according to the criteria listed in Annex XIII of REACH as PBT or vPvB and, as for EDs, may be identified as SVHCs (article 57 of REACH). The BPR refers to REACH Annex XIII criteria, and the PPPR contains PBT/vPvB identification criteria. Neither REACH nor any other legislative framework have identification criteria for substances with PMT/vPvM properties, but they can be identified as SVHCs under REACH.

ECHA's integrated regulatory strategy brings together the various regulatory processes of REACH and CLP. It is based on the efficient selection of substances and groups of substances that raise potential concern, so that information needed to assess their safety is generated and any remaining concerns addressed through the most suitable regulatory risk management measures. ECHA and MSCAs carry out the following substance-specific activities: data generation and assessment (dossier evaluation, substance evaluation, informal hazard assessment of PBT/vPvB/ED properties); assessment of regulatory needs (ARN); and

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regulatory risk management (harmonised classification and labelling, SVHC identification, restriction).[48]

Under the baseline, it is assumed that these activities will keep contributing to the identification of ED, PBT/vPvB and PMT/vPvM substances. The assessment of regulatory needs may be based on sufficient available information or on data generated on missing hazard information following compliance checks, testing proposals and substance evaluation. In addition, the ED and PBT expert groups assuport the identification of ED and PBT/vPvB substances.

ECHA and MSCAs select substances that are to be evaluated to clarify whether their use poses a risk to human health or the environment. The selection is carried out on the basis of risk-based criteria. The substances selected for substance evaluation (Chapter 2 of the REACH Regulation) are included in the community rolling action plan (CoRAP) following the opinion of the Member State Committee. The evaluation of each substance is carried out by a designated Member State by assessing all registration dossiers from all registrants specific to the same substance or group of substances, considering other sources of information and by requesting and assessing new data from the registrants, typically going beyond the standard REACH information requirements. Following the assessment of all information, if the evaluating Member State considers that the use of the substance poses a risk, it may proceed by proposing: harmonised classification and labelling for certain hazards, identification of the substance as SVHC, an EU-wide restriction, EU-wide occupational exposure limits, national measures or voluntary industry actions.

As of February 2022, the CoRAP includes 392 unique substances/entries (Figure 53).[49] Between 2012 and 2023, Member States evaluated, are evaluating or plan to evaluate 90 substances for their suspected ED properties and 151 substances for their suspected PBT/vPvB properties. Additionally, 23 substances are undergoing an ED assessment under the BPR.[50] No data could be found on the number of substances undergoing an ED or PBT/vPvB assessment under the PPPR.[51] So far, no substances have been included in the CoRAP to investigate suspected PMT/vPvM properties.

[48] Planned, ongoing or completed activities are listed in the Public Activities Coordination Tool (PACT).
[49] Note that ECHA webpages may indicate a slightly lower number of substances/entries than those listed in the downloadable list, also because group entries are split in different rows. Source: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
[50] https://echa.europa.eu/ed-assessment
[51] It should be noted that the review under BPR and PPPR is systematic, but limited to ED category 1.

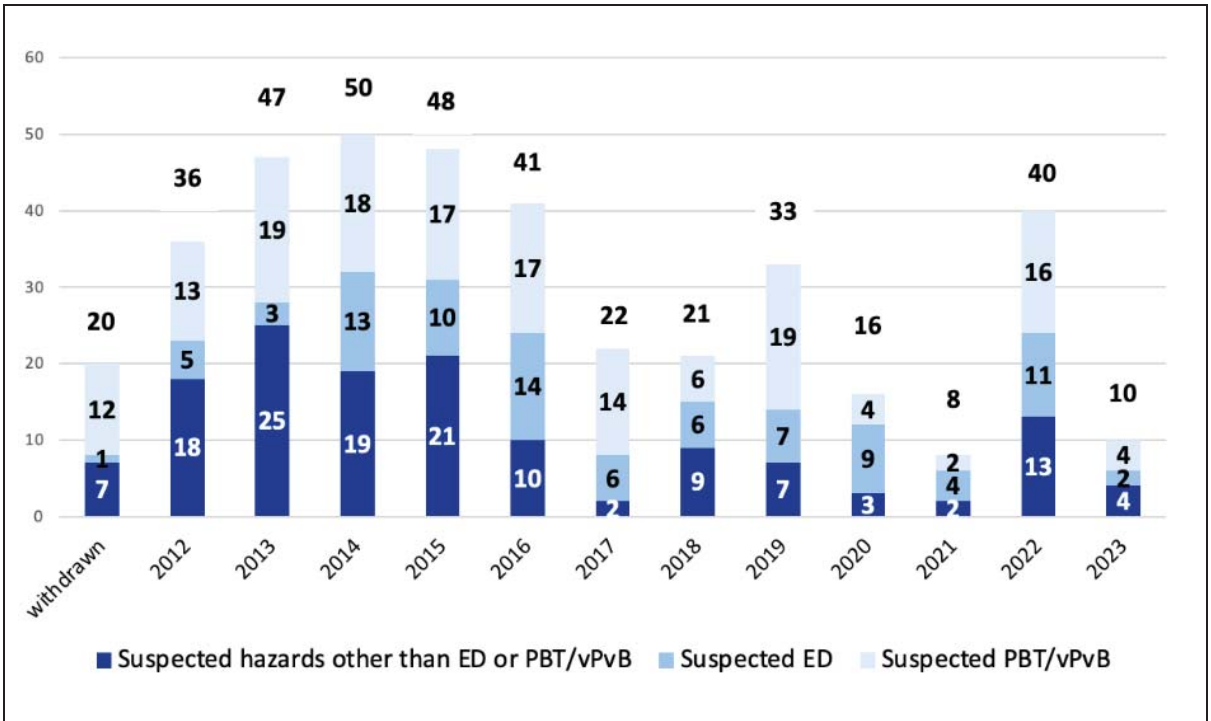

Figure 53: Number of substances with suspected ED or PBT/vPvB properties or other hazards per planned evaluation year - Note: substances can be evaluated for multiple suspected hazards - Source: CoRAP

Following data generation (or the evaluation of the available information considered sufficient for the purpose), the regulatory needs of substances and groups of substances are assessed.[52] The outcome can be that either there is no need for action or that regulatory risk management at EU level is required. The follow-up regulatory actions are: harmonised classification and labelling, SVHC identification, restriction, or action through other EU legislation. The assessment can also result in a request for additional data (e.g. through substance evaluation).

As of February 2022, the candidate list of substances of very high concern for authorisation includes 444 entries, of which 113 were included because of their ED properties, 114 because of their PBT/vPvB properties and 21 because of their PMT/vPvM properties. It is assumed that Member States or ECHA would keep proposing substances to be identified as SVHCs at the same rhythm. It should be noted that the group approach may result in higher numbers of substances being identified as EDs or with PBT/vPvB or PMT/vPvM properties. Substances and groups of substances can also be identified for restriction rather than authorisation. The effect of the inclusion of groups of substances could be large: for example, the announced intention to submit a restriction proposal for PFAS would affect more than 6,000 substances,[53] although only around 2,000 are currently registered.[54] Finally, biocidal and

[52] As of February 2022, the ARN registry (https://echa.europa.eu/assessment-regulatory-needs) lists 754 entries between substances and groups of substances, for a total of 2,116 substances. In the downloadable spreadsheet, group entries are split in different rows. However, not all groups are split (e.g. PFAS has one single row) and therefore the total number of unique substances is larger. The need for regulatory action, if any, can be identified for the whole group, a subgroup or a single substance.

[53] Dutch Ministry of Health, Welfare and Sport, Official start to ban PFAS in Europe, available at: https://www.rivm.nl/en/pfas/official-start-to-ban-pfas-in-europe

[54] ECHA Page on Perfluoroalkyl chemicals (PFAS), available at: https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas

plant protection active substances that exhibit ED or PBT/vPvB properties should not be approved, in principle,[55] for their use in biocidal and plant protection products, in accordance with the BPR and PPPR.[56]

By forecasting numbers of substances through linear regression using the known values for the period 2008-2022, in 2032 the candidate list would include 799 substances, of which 206 for ED properties, 214 for PBT/vPvB properties and 67 for PMT/vPvM properties. In 2042, the candidate list would include 1,126 substances, of which 293 for ED properties, 306 for PBT/vPvB properties and 110 for PMT/vPvM properties (Figure 54).

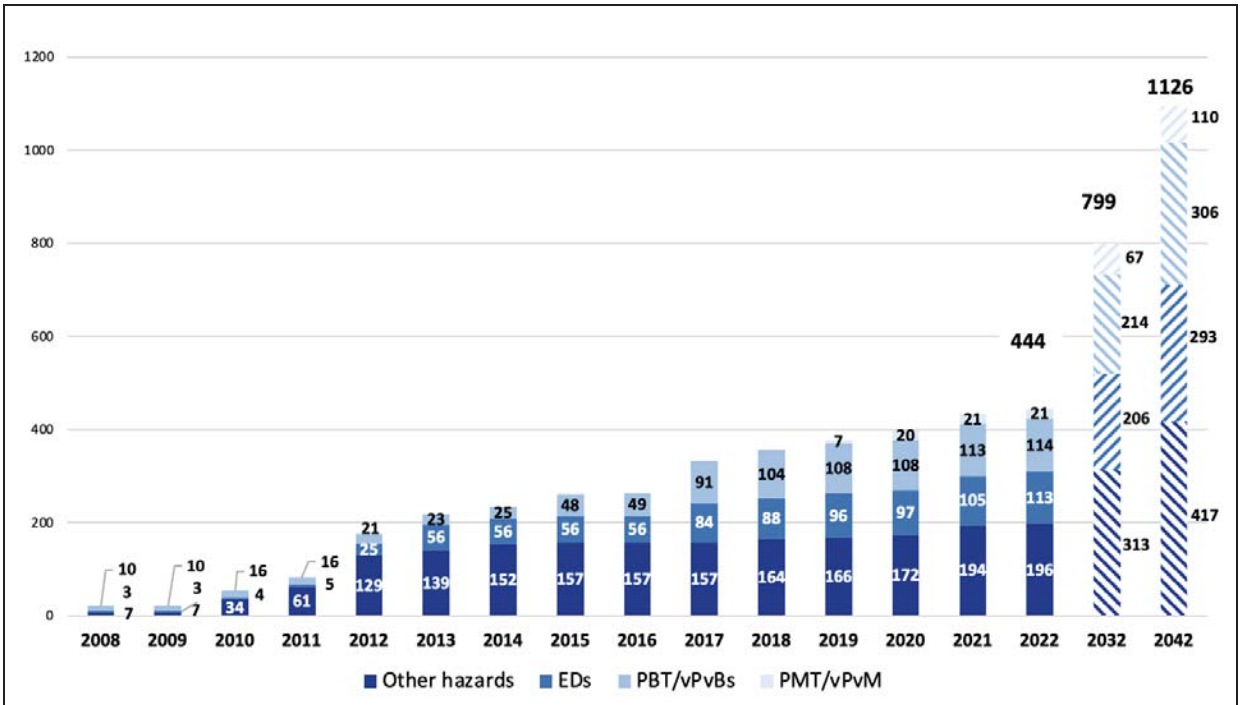

Figure 54: Number of substances included in the candidate list of SVHCs for ED, PBT/vPvB or PMT/vPvM properties or other hazards per year - Source: ECHA Candidate list (projections of the authors)

As most of the substances may be used in more than one mixture, it is necessary to estimate the number of mixtures that would be impacted by the identification of a substance with one or more of the considered properties. Estimating this is difficult for several reasons:

There is no central repository that compiles information on the number of mixtures for the entire EU;

Some of the possible information sources are not publicly available, such as the information provided to Poison centres for medical emergency[57] or the German Federal Institute for Risk Assessment (BfR).[58]

[55] Derogations are foreseen.
[56] The reasons for non-approval of active substances are not easily retrieved from ECHA and EFSA databases, if not by checking the opinions one-by-one.
[57] https://poisoncentres.echa.europa.eu
[58] See e.g. https://www.bfr.bund.de/en/notification_of_products-10144.html, accessed November 2021.

Ricardo (2021) estimated that 16,969 substances (including UVCBs) and 190,702 mixtures would be impacted by the extension of the generic approach to risk management to the following hazard classes: ED, PBT/vPvB, PMT/vPvM, respiratory sensitisation Cat. 1, 1A and 1B, STOT RE/SE Cat. 1 and 2, immunotoxicity, neurotoxicity, CMR Cat. 2, Skin Sensitisation Cat. 1, 1A and 1B, aquatic chronic 1 and 2 (Ricardo, 2021, p.50). These estimates imply an average number of mixtures per substance of around 11.

An alternative estimate was derived by analysing the SPIN (Substances of Preparations in Nordic Countries) and extrapolating the result to the EU.[59] The average of five mixtures per substance was multiplied by a factor of five for projection to the entire EU, resulting in an average of 25 mixtures placed on the EU market per single substance. This is consistent with the estimates in the 2017 Fitness Check, which used figures of 99,000 substances and 2.5 million mixtures subject to reclassification, labelling and safety data sheets preparation to produce an average of about 25 mixtures per substance.

Applying these two estimates (11 and 25 mixtures per substance) to the numbers of SVHCs in 2022 and the estimated number of SVHCs in 2032 and 2042 produces the estimates for the total numbers of mixtures in the table below.

Table 11: Estimated number of mixtures containing SVHCs with ED, PBT/vPvB, PMT/vPvM properties

	2022	2032	2042
Number of mixtures based on 11 mixtures per substance			
ED	100	2,300	3,200
PBT/vPvB	200	2,400	3,400
PMT/vPvM	100	700	1,200
Total	400	5,300	7,800
Number of mixtures based on 25 mixtures per substance			
ED	300	5,100	7,300
PBT/vPvB	400	5,300	7,700
PMT/vPvM	200	1,700	2,700
Total	900	12,200	17,700

More accurately, the totals provided in the table relate to the number of classifications for mixtures rather than the number of mixtures. This is because some mixtures may meet the classification criteria for more than one of the hazards.

The table below the estimates of the numbers of substances and mixtures with ED, PBT/vPvB, PMT/vPvM properties that would be identified and classified under the baseline.

Table 12: Estimated number of substances and mixtures with ED, PBT/vPvB, PMT/vPvM properties that would be identified and classified 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

[59] The methodology and the results are detailed in Annex 1.

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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*			

1.1.4 Toxicity reference values and harmonised classification and labelling

Already some initiatives or measures may be envisaged as developing harmonised toxicity reference values. For example, the restriction of the aprotic solvent N,N-dimethylformamide[60] involved the derivation of a 'harmonised DNEL' for workers (inhalation and dermal) by RAC. However, harmonisation in this context only relates to the REACH Regulation and other reference values remain in place, such as the IOELV established by Commission Directive 2009/161/EU of 17 December 2009 (15 mg/m^3 as opposed to the 'harmonised DNEL' of 6 mg/m^3) that is also legally binding limit value established under OSH legislation in many EU MS. For companies, the different reference or limit values are confusing and the 'harmonised DNEL' does not resolve the differences between REACH-DNELs and OELs.

The differences between legislations are also evident in other examples. In the case of nonyl- and octylphenols, EQS were derived under the Water Framework Directive. These may be considered 'harmonised reference values'. However, based on the RAC statement related to the corresponding nonylphenol and octylphenol ethoxylates (ECHA, 2017), it appears questionable that these EQS may be accepted as a threshold in applications for authorisation. The same is true is even true within a single regulatory area. For example, the DNEL derived by RAC for dibutyl phthalate (DBP) in 2013 may be considered a 'harmonised DNEL'. With the addition of DBP to REACH Annex XIV for endocrine disrupting properties (human health), the validity of this reference value is unclear and RAC was not in a position to derive a DNEL for these effects (ECHA, 2021). Again, diverging OELs are legally in place in several EU MS.

As noted in Annex 4 to this report, reference values established by regulatory agencies are not necessarily lower than those derived e.g. by registrants under REACH. For example, different studies were often available to REACH registrants for deriving PNECs compared to the ones available to the competent authority for the same substance under the BPR. In some cases, REACH registrants have derived lower PNECs than authorities under the BPR and it may not be the most meaningful approach to establish the latter as 'harmonised PNECs'.

It is assumed that the Commission would establish the repository of toxicity reference values as for its commitment as part of the OSOA approach in the CSS, with the aim of promoting the reuse of the values among EU risk assessors and managers. It is also assumed that EU agencies would establish a central coordination mechanism, which would ensure better distribution and coordination of tasks and access to all data by all agencies, as advocated by ECHA and EFSA in their joint position paper.

In the period 2016-2020, there has been a steady increase of CLH for CMR substances (71 in total), leading to the adoption of further RMMs to minimise workers' exposure (ECHA, 2021c). The IRS has accelerated the screening of registered substances and the identification

[60] https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18213ec9e

of those requiring the generation of further data or risk management. Without intervention in the coming years, the performance of the IRS and the rhythm of CLH adoption is assumed to stay constant, as ECHA and RAC work at full capacity and MSCAs' resources remain limited. Also, the workload is assumed to remain uneven, with just a few MSCAs carrying most of the burden.

As of 2022, 4,335 entries[61] have harmonised classifications. Harmonised classifications and labelling of hazardous substances are introduced and updated through the Adaptations to Technical Progress (ATPs), which are issued yearly by the European Commission. Table 13 accounts substances for which the CLH has been revised by subsequent ATPs in the ATP introducing the CLH for the first time.

Table 13: Number of substances with CLH (2008-2022)

ATP	Entry into force	No. of substances
CLP00	2008	3,368*
ATP01	2010	758**
ATP03	2012	11
ATP05	2012	22
ATP06	2014	14
ATP07	2016	19
ATP09	2018	26
ATP10	2018	24
ATP13	2020	16
ATP14	2021	17
ATP15	2022	37

Source: Analysis of all CLH from: https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp
*Notes: *Harmonised classifications implemented under Directive 67/548/EEC; ** ATP01 brought the entries from the 30th ATP & 31st ATP of Directive 67/548/EEC into Annex VI of CLP*

RAC has adopted between 50-60 opinions on CLH since 2017 (previously the average was 35 per year). These cover both CLH for new substances and revisions of existing CLH. In the last 10 years (2012-2022), 209 new substances have received CLH (median of 20.5 per year). Sixty is considered as the maximum number of CLH dossiers that RAC and the ECHA team supporting the CLH procedure can process with the current capacity.[62] Following the adoption of the opinion on the CLH of a substance by the RAC, the European Commission takes a decision and publishes the updated list in an ATP. Table 14 presents the estimate of the number of substances with CLH that could be expected in 2032 and 2042, calculated as the linear forecast of the number of substances with CLH based on the values from ATP03 to ATP17 (2012-2022).[63]

Table 14: Estimates of the number of CLH substances in 2032 and 2042

	2022	2032	2042
Linear forecast	4,385	4,450*	4,600*

*Notes: *rounded to the nearest 50s.*

[61] Some of the entries of Annex VI are group of substances (e.g. the metal compounds), so the number of substances is higher.
[62] ECHA and RAC estimates.
[63] CLP00 and ATP01 introduced the CLHs that were adopted according to the previous legislation. Not all ATPs introduce or revise CLHs.

1.1.5 Self-classification and the CLI

As of 30th November 2021, 751,436 notifications have been submitted to the CLI on 205,903 substances, the majority coming from C&L notifications (656,741) and the remainder coming from REACH Registrations (94,695). Most substances (89%) notified to the CLI originate exclusively from CLP notifications, with 11% originating from REACH registrations. Notification submitters (excluding group members) amount to 22,745 legal entities, of which 14,888 are from REACH Registrations and 12,244 are from CLP notifications. Around 11,055 actual notification submitters are SMEs (48.6% of the total).

A single C&L notification, described as a granular C&L notification, contains a combination of the following:

Substance;
Substance variant (e.g. physical state / form; chemical hydration; composition with an impurity / additive etc);
Classification;
Labelling;
Legal entity.

C&L notifications can be submitted by one legal entity on behalf of a group of manufacturers and importers. For example, the notification submitted on behalf of 50 group members would resolve into 50 granular C&L notifications, and if the group notification contained two substance variants, it would resolve into 100 granular notifications. When the number of granular C&L notifications is taken into account, over 10 million unique notifications have been submitted to the CLI, which come mainly from expanding the group notifications into their constituent C&L notifications from the different group members. Data provided by ECHA shows that on average a group notification contains 44 group members.

The large number of granular C&L notifications that come from group notifications demonstrates that a significant amount of collaboration between duty-holders is already taking place to agree on a single classification, which is illustrated in the graphics below. Figure 55 shows the level of agreement for different classifications and labelling combination for substances in the CLI that have 5 or fewer distinct classifications and labelling combinations.

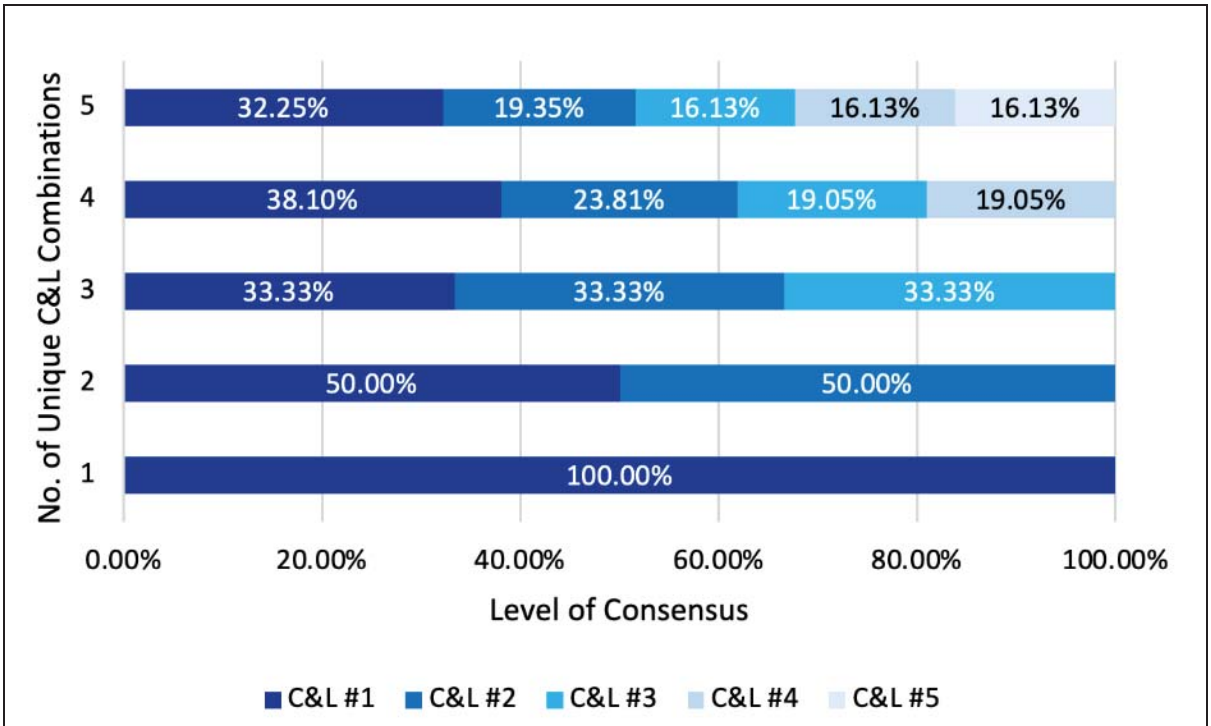

Figure 55: Level of consensus based on individual and lead submissions - Source: ECHA data

Figure 56 factors in the agreement within group notifications is taken into account there is a much higher level of consensus. It also just shows divergence caused by differences in classification only, rather than divergence caused by different combinations of classification and labelling, as substances with the same classification can have two distinct labelling blocks.

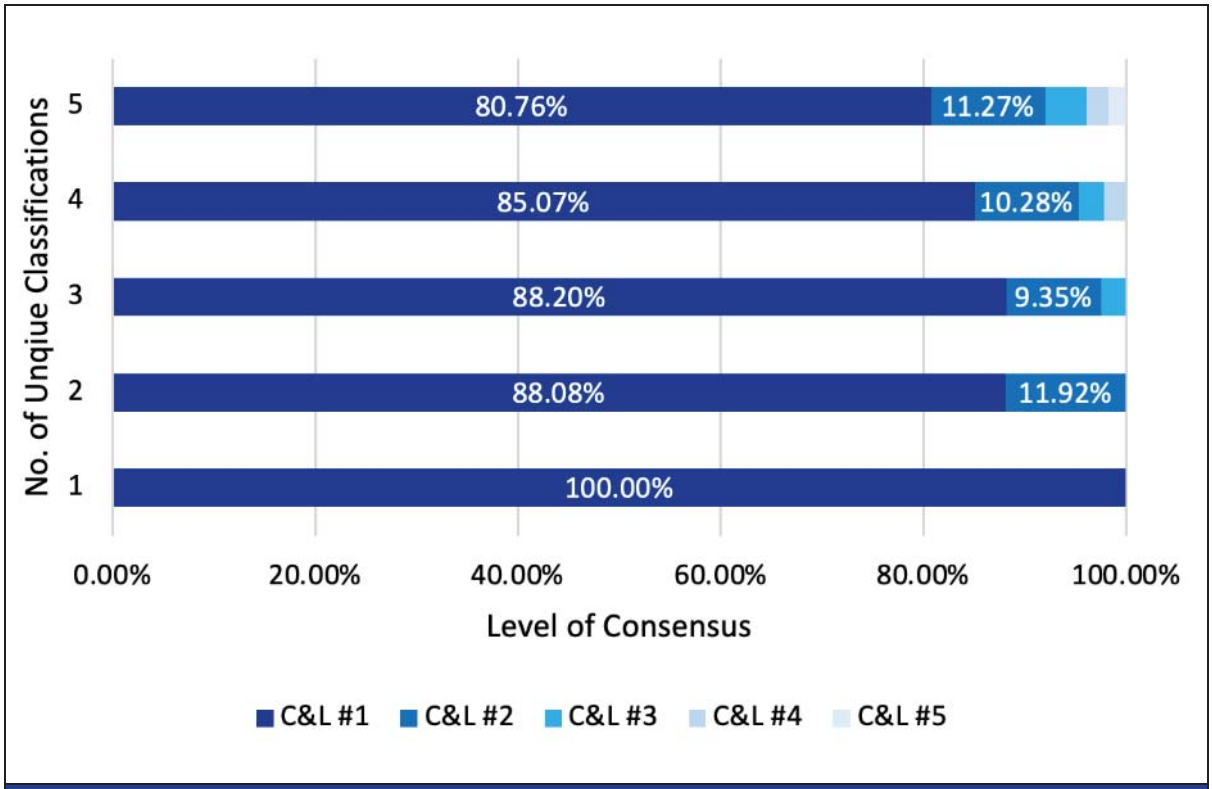

Figure 56: Level of consensus factoring in M/I groups - Source: ECHA data

However, the level of divergence in Figure 56 is not currently displayed in the existing data structure of the CLI. The summaries of notified classification and labelling entries are ordered by number of notifiers, but this only counts M/I groups as one notifier.

78% of substances and 31% of notifications are aligned with a single classification, although divergence amongst the remaining 22% of substances and 69% of notifications can be due to legitimate reasons, such as differences in physical form, presence of impurities etc. ECHA also reports that there is significant agreement for the majority classification (classification most commonly notified) provided for around a quarter of substances with more than one classification. This means that for these substances there is a clear preference for one classification over others. When looking at the level of alignment in granular C&L notifications, which considers agreement within M/I groups, 77% of the 10 million granular C&L notifications agree on a classification.

The data shows that classification divergence affects around 22% of notified substances. Sixty-nine percent (69%) of notifications diverge, but this figure is reduced to 23% once the agreement within group notifications is taken into account, although this is not visible in the CLI public portal.

A redesign of the CLI was initiated in 2019 with the aim to improve how data in the CLI is displayed, structured and made available, in order to bring additional value and improve its ease of use. While this initiative will not directly address the drivers of diverging classifications in the CLI, it aims to provide transparency on the reasons for divergence and aims to make consensus classifications prominent. The redesign is also expected to display agreement within group notifications. When considering the outcome of the changes in the redesign, if the changes are made as described, it is expected for the additional information and the prioritising of consensus classifications to reduce the impacts of the problem. These

changes will not address the source of the divergence. However, the changes, if implemented as described, could help users prioritise the information in the CLI and subsequently find the most relevant data reducing the impact of the incorrect classifications. The outcome of the redesign cannot be fully assessed currently, based on CARACAL discussions, because the redesigned Inventory is expected to be launched in 2023.

1.1.6 Labelling

This subsection presents the expected evolution of the baseline up to 2042 for each of the four categories of products that are affected by the problems investigated, namely:

Substances/mixtures supplied in very small packaging (< 10ml);
Substances/mixtures supplied in bulk;
Substances/mixtures supplied via re-fill; and
Substances/mixtures supplied with very small font size and fold out labels.

Substance/Mixtures Supplied in Very Small Packaging (< 10ml)

How would the problem evolve?

There are two drivers contributing to the problem of hazardous substances/mixtures in very small packaging being unlabelled or incorrectly labelled when placed on the market. The first of these is the impracticality of labelling chemical products in small containers due to the lack of economically feasible exemptions under the CLP Regulation for the labelling of substances and mixtures supplied in small packaging and the complexity they introduce for suppliers of these chemicals. The labelling requirements outlined in the CLP Regulation for bulk and refill chemicals are expected to remain the same in the baseline scenario, and as there is no financial incentive for suppliers to change their behaviour, and given that no change in the level of enforcement surrounding labelling obligations is also expected, the level of non-compliance is expected to remain the same.

The second driver is the existence of regulatory overlaps in labelling provisions of EU chemicals legislation, such as those existing between the CLP Regulation and the Detergents Regulation. The labelling requirements outlined in the CLP Regulation are expected to remain the same in the baseline scenario. However, in light of the ongoing Impact Assessment into the revision of the Detergents Regulation, there is a possibility that changes may be made to labelling requirements applicable to detergents. Ensuring coherence with the CLP Regulation is one of the aims of the Detergents Regulation Impact Assessment, but as of yet there is no final decision as to how the interaction between the two on labelling will be addressed. In the Draft Final Report to the Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling (VVA et al 2022), four policy options are being assessed to allow for alignment of CLP and the Detergents Regulation regarding physical labelling.

One of the policy options is to align the two regulations to address inconsistencies, overlaps and duplications in labelling requirements. No intervention would occur in the CLP Regulation but in the Detergents Regulation: ingredients would only be labelled once, either following CLP or Detergents Regulation rules, which ever is stricter; or removal of all overlapping provisions. Therefore, it is possible that compliance with labelling provisions for hazardous substances/mixtures in very small packaging could become easier for detergent products. However, detergents were not one of the product categories identified as being

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supplied in very small packaging. It should also be noted that compliance is an issue with packaging of less than 125ml and consultation with industry as part of this study revealed that labelling is difficult to fit on packages of up to 200ml in size. In summary, no significant impact on the size of the problem is expected from the removal of regulatory overlaps in labelling provisions in the baseline scenario.

The sales of products supplied in packaging smaller than 10ml that are included in our analysis are expected to slightly increase to 2042, thus maintaining the scale of the problem. This projection is based on data obtained from Prodcom on annual production quantity dating back to 2008 and uses the typical mass per product shown in Figure 5. The compound annual growth rate (CAGR) between 2008 and 2019 was assumed to continue to 2042 for each of the product categories, resulting in an annual growth rate of 1.1% for pens and writing instruments, -5.4% for lighters, 1.2% for essential oils, -3.1% for inks, 4.0% for superglues, and -6.0% for ammunitions. These trends seem to reflect a transition to digital versus printed documents in certain contexts and the decreasing smoking rates. Additionally, an incompliance rate of 50% with labelling requirements has been assumed based on enforcement data from ECHA.

Evidence on poisoning from chemicals in very small packaging is not reported by poison centres, but consultation with the Croatian poison centre provided a datapoint for this in 2021 that has enabled the assumption that each incompliant product sold leads to a rate of 49 poisonings per million products sold. This rate, in the absence of further evidence of the relationship between product labelling and poisoning incidence, will be treated as a permanent relationship that will define the baseline, with the given baseline compliance level, and the policy scenario, with its own compliance level.

The baseline projection of sales of products that include substances and mixtures in very small packaging (< 10 ml) is shown in Figure 57 below, along with the resulting incidence rate of poisonings involving products in very small packaging in the EU-27.

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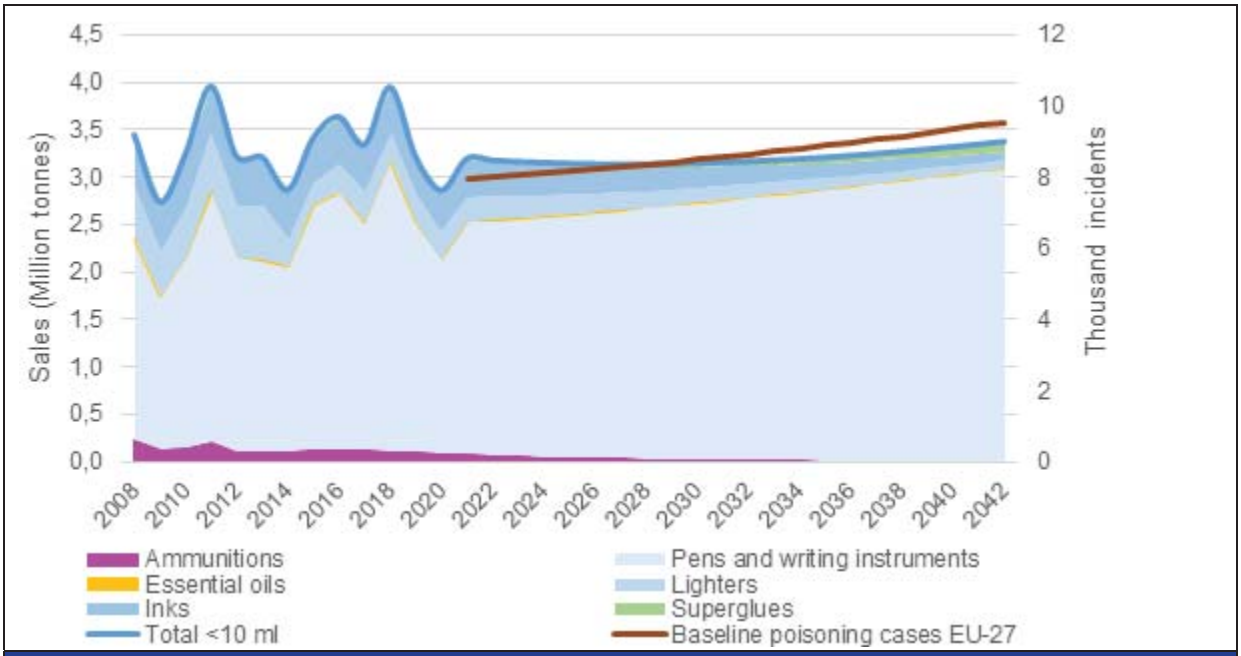

Figure 57: Past series and future projection of the sales of products containing substances/mixtures supplied in very small packaging (< 10ml) by product category and overall, and baseline projection of poisoning cases from products in very small packaging (right axis), 2008-2042.

Substances/Mixtures Supplied in Bulk (i.e. fuels)

How would the problem evolve?

The problem of fuels supplied at fuel stations being unlabelled is caused by unclear labelling requirements under the CLP Regulation for substances supplied in bulk. The lack of specific provisions (i.e. specific rules or exemptions) in the CLP Regulation for bulk substances leads to misinterpretation of the requirements which will not change unless action is taken to amend the legal text of the CLP Regulation, or ECHA guidance on labelling and packaging is updated to clarify labelling rules for how fuels should be labelled under the CLP Regulation. However, it should be noted that the update of guidance may have limited impact on the labelling of bulk chemicals without an explicit mention in the legal text, as it may be viewed as voluntary and would be difficult to enforce. The current level of provision of CLP labelling of fuels at fuel stations is not expected to change without regulatory pressure to do so. This is because provision of labelling represents an addition business cost, and so there is no financial incentive to provide labelling information. Therefore, without any change to the legal text of the CLP Regulation to provide clarity on how fuels should be labelled, no change to the scale of the problem is expected.

While no change in the scale of the problem is expected, the amount of unlabelled fuel placed on the market is expected to decrease, which is expected to have a subsequent impact on the number of poisoning incidents involving fuels.The baseline projection for how the size of the market for fuels used for road and maritime transport will develop up to 2042 will be determined by environmental objectives and fuel regulations in the road transport sector. Building from the historic series of final consumption of fuels in road transport[64], the latest

[64] Eurostat (2021). Supply, transformation and consumption of oil and petroleum products [nrg_cb_oil]. Available at: https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=nrg_cb_oil

projections of oil demand in the EU from the International Energy Agency (IEA, 2021)[65] were used as a reference for the projection of the baseline scenario of substances and mixtures supplied in bulk. Other candidates considered for the projection of the historic series into the future were: (a) IEA's projections of oil demand for passenger cars in advanced economies, discarded on the grounds that past 2030 oil demand for heavy duty transport will be of higher relevance than for passenger cars and probably will follow a different path from them; (b) IEA's projections of energy consumption in road transport in the EU, discarded due to the expected change in the energy mix composition of road transport over the next 20 years.

On the contrary, oil demand in the EU is expected to closely follow oil demand in road transport, being the main source of oil consumption in advanced economies. According to Eurostat[66] 48% of oil consumption in the EU belongs to road transport alone, followed by consumption of oil for non-energy use (14%), for air transport (9%) and water transport (9%). Thus, using current series of final (energy and non-energy) consumption of oil products in road transport in the EU-27 and building from the projected scenario for oil demand in the EU defined by the IEA in its Announced Pledges Scenario, the resulting growth rates between 2020 and 2042 were used to project a baseline for substances and mixtures supplied in bulk. The projection for the overall EU-27 is shown in the figure below. This projection highlights that without any regulatory intervention, the amount of unlabelled fuel being placed on the market is expected to decrease, such that in 2042 less than half the amount of unlabelled fuel will be placed on the market than 2019 levels.

Figure 58 below shows the past series and future projection of consumption quantity of oil products in the road transport sector (i.e., substances/mixtures supplied in bulk) and estimated number of related poisoning incidents in the EU-27 according to the assumed incidence rate calculated.

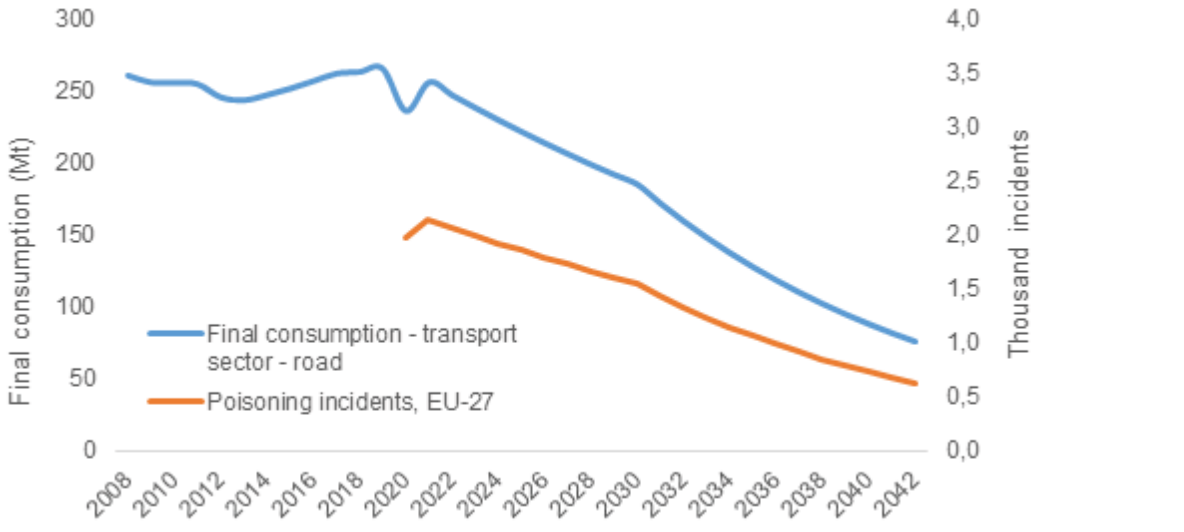

Figure 58: Past series and future projection of consumption quantity of oil products in the road transport sector (i.e., substances/mixtures supplied in bulk) and estimated number of related poisoning incidents in the EU-27 (right axis), 2008-2042.

[65] International Energy Agency (2021). World Energy Outlook 2021.
[66] Eurostat (2021) Oil and petroleum products - a statistical overview https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Oil_and_petroleum_products_-_a_statistical_overview#Consumption_in_sectors

Another factor contributing to the problem is the emergence and increasing trend of consumers purchasing chemicals via re-fill. Refill sales of chemicals are valued for their potential to contribute to sustainability and the circular economy by reducing the amount of packaging waste generated. This is an area of innovation not foreseen when the CLP Regulation was adopted in 2008 and which the Regulation has not kept pace with. A recent study by Eunomia provided a first high-level attempt at assessing market trends of packaging free shops, reporting a central estimate for the EU total turnover from bulk good sales in 2030 of approximately €1.2 billion, and a 'best case scenario' of over €3.5 billion. The authors acknowledged that if radical shifts in the economy or consumer behaviour are also considered, the accurate projections made on the future scale of the bulk and refill sale sector could be greater. Based on these findings, the re-fill sale sector is an area with strong predicted growth over the next 10 years. The number of re-fill chemicals accompanied without correct labelling and packaging and the level of non-compliance by economic operators are only likely to increase if no action is taken.

Substances/Mixtures Supplied via Re-fill

How would the problem evolve?

The problem of re-fill chemicals being unlabelled or labelled incorrectly is caused by unclear labelling requirements under the CLP Regulation for these chemicals. The lack of specific provisions (i.e. specific rules or exemptions) in the CLP Regulation for re-fill chemicals leads to misinterpretation of the requirements which will not change unless action is taken to amend the legal text of the CLP Regulation, or ECHA guidance on labelling and packaging is updated to clarify labelling rules for how re-fill chemicals should be labelled under the CLP Regulation. However, it should be noted that the update of guidance may have limited impact on the labelling of re-fill chemicals without an explicit mention in the legal text, as it may be viewed as voluntary and would be difficult to enforce. The current level of provision of CLP labelling of re-fill chemicals is not expected to change without regulatory pressure to do so. This is because provision of labelling represents an addition business cost, and so there is no financial incentive to provide labelling information.

The labelling requirements outlined in the CLP Regulation for re-fill chemicals are expected to remain the same in the baseline scenario. In light of the ongoing Impact Assessment into the revision of the Detergents Regulation, there is a possibility that changes may be made to the rules for refill detergents. Previous studies have identified problems with the Detergents Regulation not keeping pace with technical and/ or other developments, such as the increase in refill sales of detergents. Ensuring coherence with the CLP Regulation is one of the aims of the Detergents Regulation Impact Assessment, but as of yet there is no final decision as to how the interaction between the two on labelling will be addressed. In the Draft Final Report to the Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling (VVA et al 2022), four policy options are being assessed to allow for alignment of CLP and the Detergents Regulation regarding physical and digital labelling. These include:

1. No change in the current mandatory regulatory framework but the setting of non-mandatory standard on the voluntary use of electronic labels. This option does not allow manufacturers to replace (partially or totally) physical labels with electronic labels.

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2. Aligning the two regulations to address inconsistencies, overlaps and duplications. No intervention would occur in the CLP Regulation but in the Detergents Regulation: ingredients would only be labelled once, either following CLP or Detergents Regulation rules, which ever is stricter; or removal of all overlapping provisions.

3. Revision of the labelling rules to introduce digital labelling, whereby manufacturers could use electronic labels, on a voluntary basis, to provide specific pieces of information as an alternative to having this information on physical labels. This option foresees the regulatory interventions discussed under Policy Option 2 to streamline the regulatory framework.

4. Revision of the labelling rules in the regulations to introduce digital labelling in order to further simplify physical label, and move the majority of information on the e-label.

5. Revision of the labelling rules in the regulations to introduce digital labelling which provides all information in the form of an e-label, for specific products. Under the CLP Regulation it is envisaged that this would refer to re-fill chemicals (fuels to be filled in containers (not tanks), paints etc.); writing instruments and under the Detergents Regulation, refill detergents.

Therefore, without any change to the legal text of the CLP Regulation to provide clarity on how re-fill chemicals should be labelled, no change to the scale of the problem is expected except for that caused by market forces and consumer behaviour.

The volume of re-fill chemicals that are placed is expected to increase as there is a growing trend of consumers purchasing chemicals via re-fill. Refill sales of chemicals are valued for their potential to contribute to sustainability and the circular economy by reducing the amount of packaging waste generated. This is an area of innovation not foreseen when the CLP Regulation was adopted in 2008 and which the Regulation has not kept pace with. A recent study by Eunomia provided a first high-level attempt at assessing market trends of packaging free shops, reporting a central estimate for the EU total turnover from bulk good sales in 2030 of approximately €1.2 billion, and a 'best case scenario' of over €3.5 billion. The authors acknowledged that if radical shifts in the economy or consumer behaviour are also considered, the accurate projections made on the future scale of the bulk and refill sale sector could be greater. Based on these findings, the re-fill sale sector is an area with strong predicted growth over the next 10 years. The number of re-fill chemicals accompanied without correct labelling and packaging and the level of non-compliance by economic operators are only likely to increase if no action is taken.

Looking specifically at re-fill detergents, discussions with industry stakeholders provided insights and access to the growth expectations for the market of re-fill detergents for the next 6 years in a subset of EU-27 countries. Those were extrapolated to the whole EU-27 by criteria of proximity and current observed prevalence of re-fill sales of detergents, also provided by the detergents industry. For years 2027-2042, the compound annual growth rate expected between 2020 and 2026 was used to project future growth. The projected growth is positive and around 2% per year, leading to a steady and moderately growing sector.

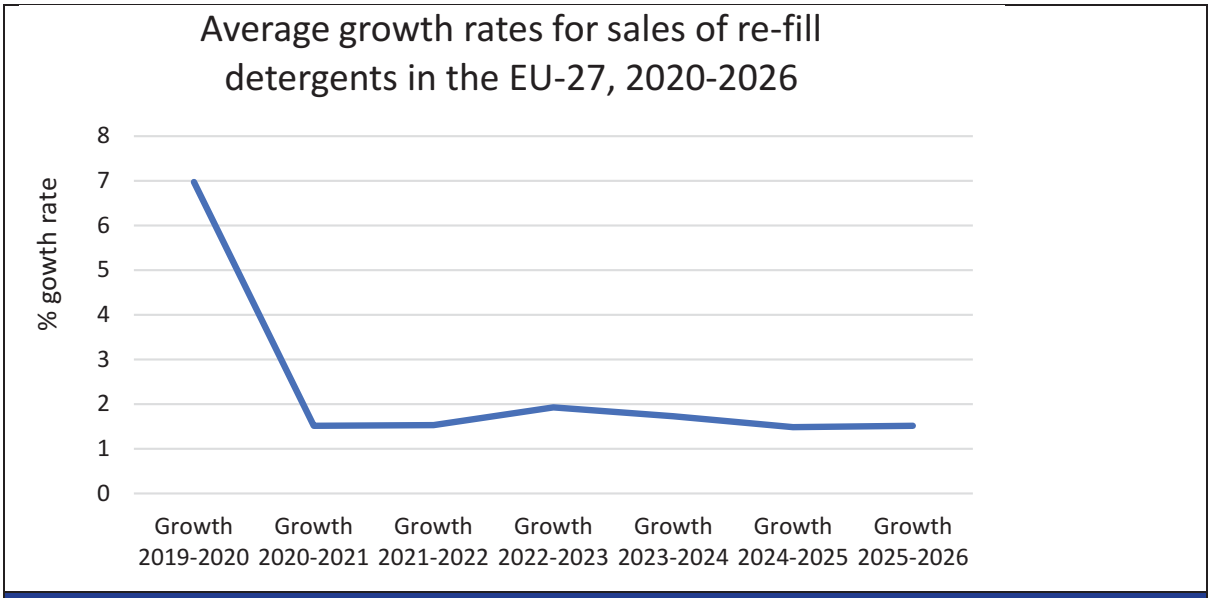

Figure 59: Average growth rates for sales of re-fill detergents as reported by the industry's projected sales in five EU-27 Member States for 2020-2026.

Additionally, an average size per refill was estimated to be 2.9 kg, taking into account the most common bottle sizes for detergents. The series of refills in overall EU-27 is shown in the figure below. This projection highlights that without any regulatory intervention, the scale of the problem of unlabelled detergent being placed on the market will increase, such that in 2042 approximately an additional 30 million refills of detergent will be placed on the market that may be incorrectly labelled or not labelled at all, when compared to 2019 figures (a 50% overall increase). The resulting number of poisoning incidents involving re-fill detergents is also displayed based on the incidence rate calculated.

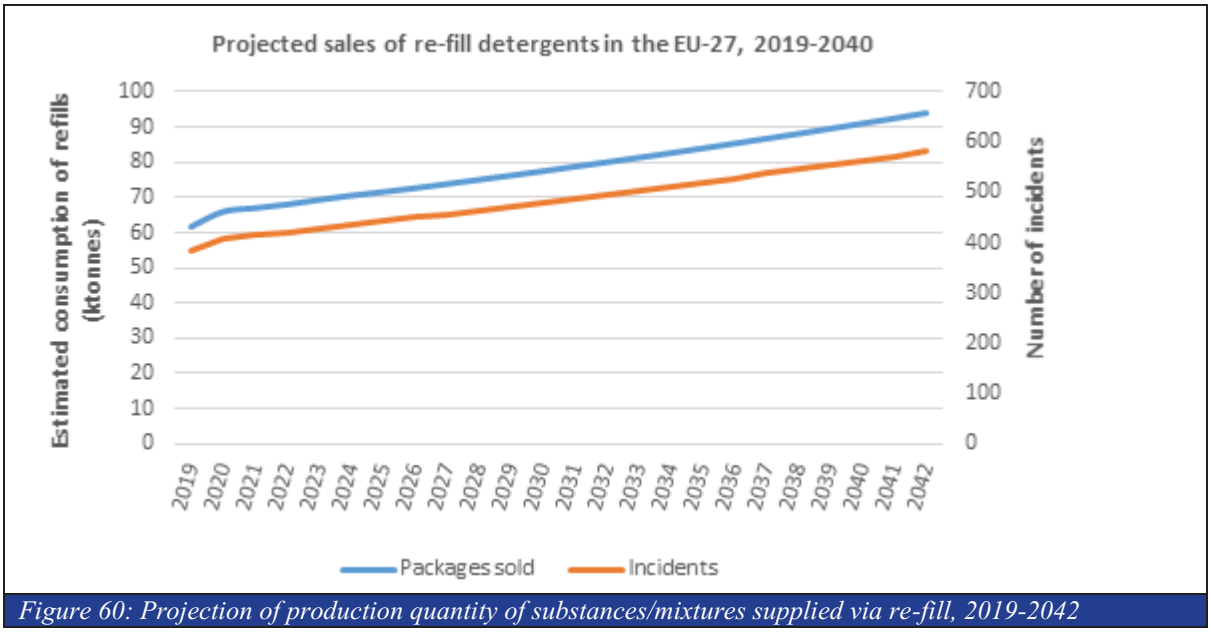

Figure 60: Projection of production quantity of substances/mixtures supplied via re-fill, 2019-2042

Multilingual labels and font size

How would the problem evolve?

There are two drivers contributing to the problem of multilingual labels having poor readability. The first is the restricted use of multi-lingual fold-out labels. The labelling rules outlined in the CLP Regulation for multi-lingual fold-out labels are expected to remain the same in the baseline scenario. Given that there is no financial incentive for limiting the number of languages on a label and producing a separate label for each destination country, the readability issues regarding multilingual labels are expected to remain.

The second driver is the existence of regulatory overlaps in labelling provisions of EU chemicals legislation, such as those existing between the CLP Regulation and the Detergents Regulation. The labelling requirements outlined in the CLP Regulation are expected to remain the same in the baseline scenario. However, in light of the ongoing Impact Assessment into the revision of the Detergents Regulation, there is a possibility that changes may be made to labelling requirements applicable to detergents. Ensuring coherence with the CLP Regulation is one of the aims of the Detergents Regulation Impact Assessment, but as of yet there is no final decision as to how the interaction between the two on labelling will be addressed. In the Draft Final Report to the Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling (VVA et al 2022), four policy options are being assessed to allow for alignment of CLP and the Detergents Regulation regarding physical labelling.

One of the policy options is to align the two regulations to address inconsistencies, overlaps and duplications in labelling requirements. No intervention would occur in the CLP Regulation but in the Detergents Regulation: ingredients would only be labelled once, either following CLP or Detergents Regulation rules, whichever is stricter; or removal of all overlapping provisions. With a reduction in the amount of information legally required, the readability of multilingual labels on detergents could improve under the baseline scenario.

Data from Cefic (2021)[67] presented in Table 15 shows the trend in sales between Member States in the EU27 (intra-EU27 sales) has increased steadily from 2009. This suggests that the number of products sold between Member States is also increasing and highlights the growing international market for chemical products. Therefore, the sale of chemicals products in multiple Member State markets is expected to grow, along with the number of multilingual labels with poor readability and non-compliant with official language requirements.

[67] CEFIC, Facts and Figures of the European Chemical Industry, 2022.

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Table 15: Trends in chemical sales				
Year	**EU27 Total Sales**	**EU27 Home Sales**	**Intra-EU27 Sales**	**EU27 Foreign Sales**
2009	100%	26.2%	44.5%	29.2%
2010	100%	26.5%	44.5%	29.1%
2011	100%	26.1%	45.4%	28.5%
2012	100%	25.6%	44.7%	29.7%
2013	100%	24.8%	45.7%	29.5%
2014	100%	22.3%	47.7%	30.0%
2015	100%	19.8%	48.9%	31.4%
2016	100%	16.5%	50.6%	32.9%
2017	100%	19.4%	49.2%	31.4%
2018	100%	16.0%	52.3%	31.7%
2019	100%	15.0%	52.3%	32.7%
Source: Cefic Facts and Figures 2021				

Area 5: CLP scope exemptions

Table 16 shows the main economic aggregates for the sectors currently exempted from CLP and the forecast for 2032 and 2042.

Table 16: Main economic aggregates (2018 data) for the sectors currently exempted from CLP				
	2018	**2020**	**2032**	**2042**
No. of enterprises				
C10 Manufacture of food products	260,257	255,933	251,211	247,276
C10.9 Manufacture of prepared animal feeds	5,196	5,133	5,572	5,938
C20.42 Manufacture of perfumes and toilet preparations	5,888	6,192	9,206	11,717
C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations**	4,263	4,455	5,609	6,570
Turnover – million euro				
C10 Manufacture of food products	940,137	966,390	1,94,385	1,384,381
C10.9 Manufacture of prepared animal feeds	73,511.7	75,015	84,354	92,137
C20.42 Manufacture of perfumes and toilet preparations	48,093.9	52,821	79,041	102,878
C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations**	277,391	299,581	432,721	543,670
Value added at factor cost – million euro				
C10 Manufacture of food products	182,684.0	188,339	249,166	299,855
C10.9 Manufacture of prepared animal feeds	9,300.5	9,776	12,953	15,601
C20.42 Manufacture of perfumes and toilet preparations	14,000	15,117	25,834	34,764
C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations**	112,511.1	115,415	180,350	234,462
Persons employed – number				
C10 Manufacture of food products	4,100,000	4,051,567	4,556,534	4,977,340
C10.9 Manufacture of prepared animal feeds	123,395	125,287	148,180	167,258
C20.42 Manufacture of perfumes and toilet preparations	173,891	179,791	274,672	352,987
C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations**	605,315	611,363	788,223	935,606
Notes: Eurostat database – Structural Business Statistics **2017 data; **include manufacture of in vitro diagnostics (NACE 21.20); ***2016 data*				

Without policy action, the environmental hazards of **human medicinal products (HMPs) and veterinary medicinal products (VMPs)** will keep being identified through the environmental risk assessments required by the relevant legislation. HMPs and VMPs are accompanied by package leaflets that may also contain important information about the safety of the products, their disposal or any precautionary measures to be taken, but environmental hazards identified through risk assessment may not be necessarily displayed.

In 2016, around 3,000 active pharmaceutical substances were authorised on the EU market (Deloitte et al., 2016). The Union register of medicinal products[68] lists around 12,370 items, between centrally authorised and nationally authorised medicinal products for human and veterinary use and orphan designations. The EMA recommends for authorisation a median of 39 new active substances for human and veterinary medicinal products per year and 97 new human and veterinary medicinal products per year.[69] Table 17 shows the estimates of the

[68] https://ec.europa.eu/health/documents/community-register/html/reg_index_inn.htm

[69] Based on the number of HMPs and VMPs (active substances and products) recommended for authorisation by the EMA between 2015-2020. Source: https://www.ema.europa.eu/en/about-us/annual-reports-work-programmes

cumulative number of HMPs and VMPs (active substances and products) recommended for authorisation by EMA in the period 2015-2020.

Table 17: Estimates of the cumulative number of HMPs and VMPs (active substances and products) on the EU market

		2020	2032	2042
Human and veterinary medicinal products				
New medicines*		**12,100**	**13,350**	**14,300**
New active substances*		**3,150**	**3,650**	**4,050**
*Notes: *Rounded to the nearest 50*				

To tackle the presence of pharmaceuticals and their negative effects on the environment, in 2019 the European Commission has adopted the *Strategic approach to pharmaceuticals in the environment*, which aims to mitigate the environmental issues caused by human and veterinary medicines. Table 18 provides examples of measures to ensure protection from the environmental hazards borne by pharmaceuticals that have been implemented within the Strategic approach to pharmaceuticals in the environment.

Table 18: Overview of measures related to the environmental risk assessment and public awareness of the environmental hazards of pharmaceuticals, compiled from European Commission, 2020	
Measure	**Status**
Action 5.1.1 Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment.	Ongoing
Action 5.1.4 Foster best-practice exchanges between the Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and the choice of therapy more generally, where appropriate.	Ongoing
Action 5.3.1a In collaboration with the European Medicines Agency and the Member States: Seek to improve the level of environmental expertise in the Committees and networks involved in the environmental risk assessment of medicinal products.	Ongoing
Action 5.3.1b In collaboration with the European Medicines Agency and the Member States: Consider developing guidance on the environmental risk assessment of medicinal products for use in aquaculture including, where appropriate, recommendations for risk management measures.	Started
Action 5.3.1c In collaboration with the European Medicines Agency and the Member States: Examine how to improve public access to the main environmental risk assessment results and relevant toxicological thresholds for medicinal products while respecting data-protection rules.	Ongoing
Action 5.3.1d In collaboration with the European Medicines Agency and the Member States: Emphasise to applicants the importance of submitting a completed assessment by the time of the authorisation for marketing human medicinal products, so that adequate risk management measures can be established and published.	Ongoing
Action 5.3.2 Pursuant to the newly adopted Regulation on veterinary medicinal products, report on the feasibility of setting up an EU-wide review system based on active pharmaceutical ingredients, or similar, to support the environmental risk assessment of veterinary medicinal products at the Union level.	Started
Action 5.3.3 Initiate a systematic catching-up procedure for veterinary medicinal products without an (adequate) environmental risk assessment, as provided for in the Regulation on veterinary medicinal products, and take stock of the results of research under the Innovative Medicines Initiative in relation to human medicinal products.	Ongoing
Action 5.4.1b In collaboration with the Member States and the European Medicines Agency: Facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate.	Ongoing
Action 5.4.2 Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal.	Good progress

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Currently, 'the environmental concerns that substances used in cosmetic products may raise are considered through the application of REACH' (Recital 5 of the CPR). Chemical substances used as cosmetic ingredients with adverse effects to the environment can be, for example, subject to authorisations or restrictions. Without policy action, the labelling of the environmental hazards of cosmetic products is not required and, therefore, the only way for consumers to check this information is by consulting the list of ingredients and searching for data online.

The CPR is being reviewed to align the current rules on cosmetics with the objectives of the CSS and ensure better protection of human health and environment in line with boosting innovation. Simplification and digitisation of product label information is one of the possible options to be analysed (European Commission, 2021).[70]

Searching the ECHA registered substances database for substances with notified uses in Product Category (PC) 28 'Perfumes, fragrances' and PC39 'Cosmetics, personal care products' returns 3,248 substances.

Table 19: Registered substances with product categories PC28 'Perfumes, fragrances' and PC39 'Cosmetics, personal care products' per tonnage band

Tonnage band	**Number of registered substances**
1-10 tonnes per year	895
10-100 tonnes per year	719
100-1,000 tonnes per year	618
1,000-10,000 tonnes per year	499
10,000-100,000 tonnes per year	248
100,000-1,000,000 tonnes per year	106
1,000,000-10,000,000 tonnes per year	56
10,000,000-100,000,000 tonnes per year	16
Cease manufacture	48
No longer valid	25
Tonnage data confidential	9
Intermediate use only	9
Total	**3,248**

Source: registered substances database
https://echa.europa.eu/information-on-chemicals/registered-substances

According to these data, a quantity between 229,648,885 and 2,296,488,850 tonnes[71] of substances used as 'perfumes, fragrances' and 'cosmetics, personal care products' is manufactured or imported on the EU market every year. Table 20 shows the classification of registered substances with notified uses in product categories PC28 'Perfumes, fragrances' and PC39 'Cosmetics, personal care products'.

[70] European Commission, *EU Chemicals Strategy for Sustainability - Revision of the Cosmetic Products Regulation*, 2021.
[71] The minimum and maximum quantities are obtained by multiplying the number of substances for the lower-bound and upper-bound of the tonnage band. The average is 1,263,000,000 tpa.

Table 20: Classification of registered substances with product categories PC28 'Perfumes, fragrances' and PC39 'Cosmetics, personal care products'	
Registered substances with product categories PC28 'Perfumes, fragrances' and PC39 'Cosmetics, personal care products	**Number**
Total	3,248
With CLP Notification C&L data for environmental hazards	1,553 (47.8%)
With REACH Registration C&L data for environmental hazards	1,132 (34.9%)
With CLH for any hazard	274 (8.4%)
With CLH for environmental hazards	167 (5.1%)
With recognised properties of concern*	83 (2.6%)
Included in the Candidate list (Art. 57 intrinsic properties)	14 (0.4%)
*Source: registered substances database https://echa.europa.eu/information-on-chemicals/registered-substances Notes: *Recognised as: carcinogenic or mutagenic or toxic to reproduction or respiratory sensitiser or skin sensitiser or persistent, bioaccumulative and toxic or endocrine disrupting or persistent organic pollutants; **ECHA restriction list (February 2022) contains 71 entries including 2,169 substances.*	

Some **cosmetic products**, such as personal care products containing plastic microbeads, siloxanes, synthetic fragrances, UV filters or triclosan, have negative effects on the environment due to their hazardous properties and their releases to the environment during use. Around 8% of the substances (274 out of 3,248) have CLH for different hazard classes. Fifty-six (56) substances have CLH for acute aquatic toxicity and 111 for chronic aquatic toxicity. Some of the environmental hazards of cosmetics ingredients have been and are being addressed through restrictions under the REACH Regulation, such as the restriction of cyclopentasiloxane (D5) and cyclotetrasiloxane (D4), microplastics, etc. (see the supporting study in Annex 4).

It should be noted that there is a **growing interest in the environmental performance of products in general and in providing consumers with transparent information in particular**. Actions such as the Sustainable Products Initiative, Ecolabel and the EcoBeautyScore Consortium[72] can influence communication of the environmental hazards of cosmetic products.

The Sustainable Product Initiative (SPI) was announced by the European Commission in 2020 in the Circular Economy Action Plan. It revises the Ecodesign Directive and covers the environmental performance of goods and services. The aim is to ensure high environmental performance for all products (including cosmetic products) on the EU market. For this purpose, specific environmental requirements and sustainability principles are being developed, addressing the lack of reliable sustainability information about the products. By providing suitable solutions, such as digital product passports, it will improve communication of the environmental performance of the products to consumers and enable them to make informed decisions when buying a product. The revision is planned to be completed in the first quarter of 2022 (European Commission, 2020).[73]

[72] https://www.cosmeticsdesign-europe.com/Article/2021/09/20/Henkel-L-Oreal-LVMH-Natura-Co-Unilever-forming-consortium-for-cosmetics-environmental-impact-system

[73] European Commission (2020). *Sustainable Products Initiative*. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12567-Sustainable-products-initiative_en

In 2021, the European Commission revised the EU Ecolabel criteria for cosmetics and extended them to substances or mixtures that fall under the scope of the CPR and "intended to be placed in contact with the external parts of the human body, or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours" (EC, 2021g, Article 1). The revised criteria for awarding the EU Ecolabel now apply both to rinse-off and leave-on cosmetic products. They include:

Toxicity to aquatic organisms: critical dilution volume (CDV) of rinse-off products;
Biodegradability of rinse-off products;
Aquatic toxicity and biodegradability of leave-on products;
Excluded and restricted substances;
Packaging;
Sustainable sourcing of palm oil, palm kernel oil and their derivatives;
Fitness for use;
Information on EU Ecolabel.

The European Commission has observed a growth in interest in obtaining the EU Ecolabel, mirroring the increasing interest on green products by consumers. According to the European Commission, 2,057 licences have been awarded for 83,590 products in the EU. Twenty-one percent (21%) (118 out of 2,057) were awarded to rinse-off cosmetic products, covering 2,575 products (around 3% of the total number of awarded products) (EC, 2021g).

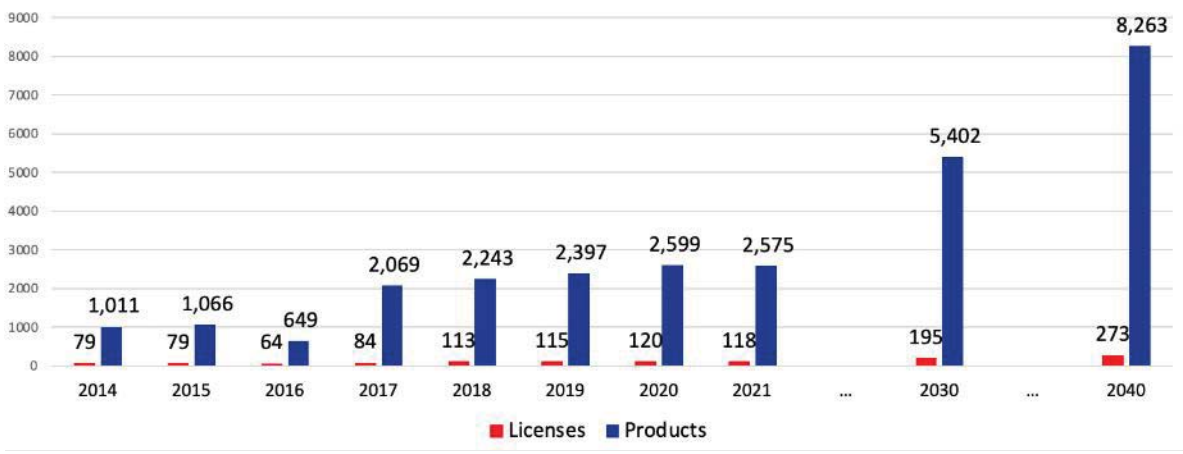

Figure 61: Licences and products

Finally, in 2021, *Henkel*, *L'Oréal*, *LVMH*, *Natura &Co*, and *Unilever* launched a global consortium, open to all cosmetics company, to develop an environmental impact assessment and scoring system for cosmetics products. This initiative aims at providing consumers with comparable and transparent information about the environmental impact of cosmetic products. The assessment and scoring systems will be based on a common product lifecycle assessment methodology for measuring the environmental impacts of a product, common database of environmental impacts and tools to calculate them in line with a harmonized

system for scoring the environmental performance (Unilever, 2021).[74] The initiative has just been launched and it is therefore too early to judge its scope and potential results.

1.1.7 Online sales of chemicals

The evolution of the problem of non-compliance of chemicals sold online with the CLP Regulation over time will be shaped by the development in e-commerce and regulatory and non-regulatory initiatives that have been already undertaken by the Commission.

Data underpinning the trend of increased online sales

Concerning the uptake of e-commerce services by consumers, an increased number of consumer purchases are made online, therefore, chances rise that consumers will be affected by non-compliant chemicals sold online. Data from the EU annual survey on the use of Information and Communication Technologies (ICT) in households and by individuals show that in 2020 and 2021[75] around 8% of all individuals in the EU27 who have used the internet in the three months prior to the survey bought cleaning products or personal hygiene products online[76].

Online shopping behaviour of consumers was also explored by business entities. For instance, in 2018, a research commissioned by Dynamic Parcel Distribution (DPD) to Kantar covered a survey of 24,328 respondents from 21 European countries, while the survey performed by Ipsos for PayPal covered 34,000 customers in 31 countries. The findings of these researches are in line with the data by Eurostat and also provide additional insight into consumer behaviour:

According to PayPal research, 43% of shoppers in Western Europe and 44% in Eastern Europe[77] shop online domestically, while 9% and 10% are, respectively, engaged only in cross-border shopping. **Over 50% of Western and Eastern Europeans prefer large global stores (e.g., Amazon or eBay) when purchasing from another country** (PayPal & Ipsos, 2018).

According to Dynamic Parcel Distribution research, 19% of online shoppers in Europe purchased goods from foreign websites. However, in **some countries the number of online shoppers buying from foreign countries is much higher**, e.g., in Croatia – 29.6%, Ireland – 28.6%, Latvia – 27.9%, Portugal – 27.6%, and Slovenia – 27.5%. 13% of online shoppers in Europe in 2018 purchased online at least once per week (DPD Group & Kantar, 2018).

Also the number of EU companies using e-commerce increases constantly, and web sales through websites, online sales apps, and online marketplaces play an increasingly important role. According to Eurostat, in the period 2010–2019, the number of enterprises with e-sales increased from 15% in 2010 to 21% in 2019. The turnover of enterprises generated from e-sales grew from 13% in 2010 to 20% in 2019. Fifteen percent (15%) of EU enterprises

[74] Unilever, *New cosmetics consortium to co-design environmental impact assessment and scoring system*, 2021.
[75] These are the only years for which data are provided.
[76] Eurostat database: Internet purchases – goods or services (2020 onwards) [ISOC_EC_IBGS__custom_2139201]. This is the only product category reported in the survey which is subject to CLP requirements. The statistics shows large differences between countries, with 24% of Dutch individuals in 2021 having purchased cleaning products or personal hygiene products online, against 1% of all individuals in Bulgaria.
[77] Russian Federation was also included in the group of Eastern European countries.

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conducted e-sales using only websites or apps, while 3% used only electronic data interchange (EDI) for sales and another 3% used both.

Chemicals industry **is increasingly engaged in trading via online marketplaces**. The evolution of chemical online marketplaces could be tracked back to 1996 with the establishment of such platforms as *EC Plaza* in 1996. According to *Accenture*, early chemical online marketplaces were mainly business-to-business services, while much later generalist online marketplaces, such as *Alibaba.com* started to offer chemical products to consumers (Elser & Radel, 2020[78]). In its annual chemical marketplaces report, *Chembid* listed 61 online platforms. According to *Chembid*[79], chemical online marketplaces usually offer up to 10,000 products from up to 25,000 suppliers (Chembid, 2020[80]).

The following trends could be retrieved from a study on cross-border online sales (Cross-Border Commerce Europe, 2020)[81]:

Growing revenues in cross-border online retail sales. The study observed a 14.4% increase in e-commerce revenues compared to 2018 (excluding travel sector). In 2019 the cross-border share was 23.55% of total online sales in Europe (EU16).

The market share of EU and non-EU players in online retail is almost equal: 55% is generated by the EU traders and 45% by non-EU retailers. In 2019, the market share of the EU traders increased by 3% compared to 2018.

Online marketplaces play a significant role in online sales. In cross-border trade within the EU, 25 online marketplaces had a turnover of €10.5 billion in 2019 or 26.4% of total sales and an increase of 17% compared to 2018. According to the study, online marketplaces grow faster than the average market. In online trade by non-EU retailers, 80% of cross-border sales are generated through online marketplaces, with Amazon as a leader with € 32 billion from sales.

Estimations of incompliant chemicals related to the problems outlined above

Data on the CLP incompliances of online chemicals' sales in and outside the EU that are relevant for problem 1 and data on imports that are relevant for problem 2 is not available. The figures below are established based on estimations which bring some uncertainty on the place of origin of sellers (it must be assumed that in reality even more chemicals originate from outside the EU although they are sold by domestic platforms), the overall chemicals' incompliance rate compared to mere samples, the number of consumers exposed to incompliant chemicals[82].

[78] Elser, B. & Radel, T. (2020). *Why digital marketplaces deserve a chance in chemicals*. In *Accenture Chemicals and Natural Resources Blog*. Available at: https://www.accenture.com/us-en/blogs/chemicals-and-natural-resources-blog/elser-radel-digital-marketplaces-deserve-a-chance-in-chemicals

[79] Chembid is an online metasearch engine and intelligence platform for chemical business that compiles a yearly chemical marketplaces report that reviews and compares emerging online platforms.

[80] Chembid (2020). *The chemical marketplaces report 2021*. Available at: https://f.hubspotusercontent40.net/hubfs/6037596/chembids%20Chemical%20Marketplaces%20Report%202021.pdf

[81] The analysis was based on the data from 16 countries from Western Europe and Scandinavia that put limitations on the findings of this study in terms of generalising its result to the EU.

[82] See detailed description of the methodology used in the Appendix.

With respect to CLP non-compliant items from online sellers within the EU:

In 2021, 251 million consumers in the EU purchased goods online from sellers within the EU. These consumers purchased 111 million items from categories of goods for which CLP requirements are relevant for some of the goods.

Based on estimations, 16.6 million of the 111 million items purchased by these consumers from sellers within the EU were not compliant with CLP requirements.

Based on estimations, in 2021, 9.6 million consumers purchased one CLP non-compliant item from sellers within the EU and a further 3.5 million consumers purchased two CLP non-compliant products from sellers within the EU – making a total of 16.6 million CLP non-compliant items purchased from sellers within the EU.

With respect to CLP non-compliant items from sellers outside the EU:

In 2021 there were some 69.5 million consumers in the EU who purchased goods online from sellers outside the EU. These consumers purchased 32.4 million items from categories of goods for which CLP requirements are relevant for some of the goods.

Based also on estimations, 7.3 million of the 32.4 million items purchased by these consumers from sellers outside the EU were not compliant with CLP requirements.

Following the same logic as before, in 2021, 4.2 million consumers purchased one CLP non-compliant item from sellers outside the EU and a further 1.6 million consumers purchased two CLP non-compliant products from sellers outside the EU – making a total of 7.3 million CLP non-compliant items purchased from sellers outside the EU.

The number of non-compliant items and consumers of those items is summarised in the table below for all three scenarios (lower, central and upper).

Table 21: Number of non-compliant items and consumers of those items				
Non-compliance issue	**Location of seller**	**Number of non-compliant items purchased per year (million)**	**Number of consumers purchasing**	
			one non-compliant item per year (million)	**two non-compliant items per year (million)**
Lower scenario				
REACH restriction non-compliant items	within EU	42.5	24.5	9.0
	outside EU	17.0	9.8	3.6
CLP non-compliant items	within EU	11.1	6.4	2.3
	outside EU	4.4	2.6	0.9
Central scenario				
REACH restriction non-compliant items	within EU	70.8	40.9	14.9
	outside EU	31.0	17.8	6.6
CLP non-compliant items	within EU	16.6	9.6	3.5
	outside EU	7.3	4.2	1.6
Upper scenario				
REACH restriction non-compliant items	within EU	110.0	63.6	23.2
	outside EU	64.3	36.9	13.7
CLP non-compliant items	within EU	33.3	19.2	7.0
	outside EU	19.5	11.2	4.1

Description of draft and already applicable EU legislation relevant for solving the problems

Taking into account the dynamic baseline, the following EU legislation should be considered: the draft Digital Services Act[83], the draft General Product Safety Regulation[84], the already applicable Market Surveillance Regulation[85], the Consumer Rights Directive[86] and customs legislation[87].

[83] Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM(2020) 825 final.
[84] Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council, COM(2021) 346 final.
[85] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, OJ L 169, p. 1.
[86] Directive 2011/83/EU on consumer rights, OJ L 304, p.64.
[87] Regulation (EU) No 952/2013 laying down the Union Customs Code ("UCC"), OJ L 269 10.10.2013, p. 1; amendments made in 2019 and 2020 to the UCC Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs, OJ L 343 29.12.2015, p. 1; Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code, OJ L 343 29.12.2015, p. 558.

A description of the interface of those pieces of legislation with the analysed policy options is provided in Annex 15 on online sales (baseline section).

1.1.8 Poison Centers

The baseline from which policy options are assessed is the currently applicable regulatory framework, *i.e.* obligations by downstream users and importers as per Article 45, by distributers and other supplier types as per Article 4(10)[88], and clarifications of those obligations enshrined in ECHA guidance. ECHA guidance already address the problem the best way possible, therefore, improving ECHA guidance was not explored as non-regulatory policy option ("no-policy-change" scenario). To solve the problem, no not yet adopted legislation is relevant, so that only the applicable legislation and guidance should be taken into account for addressing the problem. Based on assumptions, a max. of 50% of distributors who should have to comply by virtue of Article 4(10) adhere to the rules in reality. This reality scenario is not going to change drastically within the next 20 years without any legislative intervention, thus the problem continues existing.

Notifications received by ECHA in 2021

The number of Notifications to Poison Centres (PCNs) received in 2021 was 1,444,290, but submissions to multiple Member States can be made in a single notification. Expanding the number of notifications to include all multiple submissions results in almost 7.7 million notifications. Submission numbers for the next years are expected to be lower given that 2021 was the first applicability date to notify information on consumer mixtures under the new requirements of Annex VIII on poison centres[89].

Trends in chemicals intra-EU trade

In the years to come, intra-EU chemicals sales (and hence distribution as well) are expected to grow, which translates into increasing the scale of the problem of having information loss in certain cases. Figure 62 shows the trend in sales between EU Member States have increased steadily from 44.5% of all chemical sales in 2009 to 52.3% of all chemical sales in 2019.

[88] Article 4(10) of CLP provides for the general obligation to comply with CLP. Based on ECHA guidance, a distributor placing on the market a hazardous mixture, which would jeopardise an appointed body's access to relevant information, would run the risk of breaching Article 4(10) that substances and mixtures can only be placed on the market if they comply with CLP.

[89] Commission Delegated Regulations 2020/1676 and 2020/1677, OJ L 379, p. 1 and 3.

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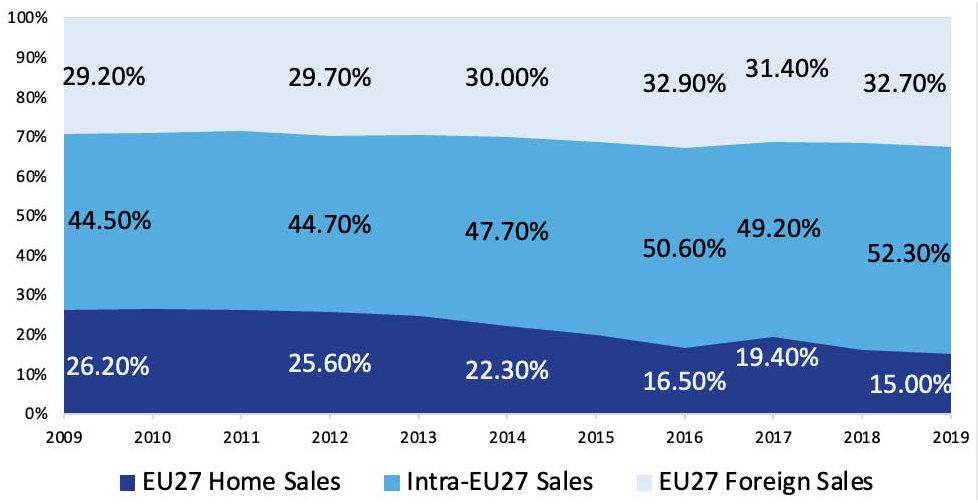

Figure 62: Trend in sales between EU Member States

Data from Eurostat[79] shows that in 2020 intra-EU sales of chemicals accounted for €496 billion in 2020 (up from €207 billion in 2002), which made up 17% of all intra-EU sales.

Number of distributors and distributed products and re-branders/re-labellers and relabelled products

In order to quantitatively assess how many mixtures should be notified to prevent information loss, estimations were carried out which might have their limitations or bring about some levels of uncertainty (see Annex 16).

Estimates further described in Annex 16 conclude that intra-EU distributors place between 220,000 – 560,000 products on another Member States' market and re-branders/re-labellers between 32,500 – 77,500 on their Member States' market. This amounts to between 252,500 – 637,500 products distributed that should be notified. In reality a certain percentage of that range will be notified already due to distributors adhering to Article 4(10) of CLP, hence the number of not notified mixtures leading to information loss will be lower than the range from 252,500 – 637,500 products.

Cost of non-Europe

It is worth mentioning that the entire poison centres format and notification system was already significantly simplified without lowering the level of safety by adopting the latest versions of Annex VIII on poison centres in 2020[90] via delegated act. Before adopting Annex VIII, a study by Kirhensteine et al. (2015) estimated that net cost savings across the EU of €550 million per annum (equivalent to €40,000 per company) could be achieved through harmonisation of the CLP Regulation (cost of Europe non acting).

[90] Commission Delegated Regulations 2020/1676 and 2020/1677, OJ L 379, p. 1 and 3.

2 DISCARDED MEASURES

Table 22 in Annex 7 provides the full list of measures that have been considered but discarded and the rationale behind their screening out from further assessment.

Table 22: Discarded measures on the basis of initial screening

Problem area	Discarded measure	Justification for discarding
Identification and classification of chemical hazards	DM1 Promote the harmonisation of criteria for the new hazard classes (ED, PBT, vPvB, PMT, vPvM) at the UN level (GHS) before introducing them in the CLP	Several industries 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. 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.
	DM2 create a repository of toxicity reference values	Part of the baseline, this measure will be implementted within the One substance, one assessment process initiated by the Chemicals Strategy.
	DM3 create a central coordination mechanism to harmonise toxicity reference values across different chemical regulatory framework	To be assessed by a study focusing on the one substance, one assessment approach. Such a central coordination mechanism, proposed in the ECHA and EFSA Joint position paper on one substance - one assessment,[1] would include a coordinated problem formulation phase (i.e. identifying the correct scientific question that needs to be answered) which would enhance predictability for industry. This may include a public EU coordination registry, potentially developed from ECHA's PACT (Public Activities Coordination Tool), to increase transparency and predictability on substance-specific activities by authorities across different

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		chemical regulatory frameworks.
	DM4 Risk Assessment Committee opinions include the derivation of point of departures (NOAEL/NOAEC) when performing the review of harmonised classification dossiers for the hazard classes under the scope of the harmonised classification dossier	It does not appear meaningful to derive a point of departure without a consideration of the complete toxicological profile of a substance.
Communication of chemical hazards	DM5 Revoke the exemption for the labelling of the human health hazards of medicinal products	Effectiveness and proportionality: Legislation contains comprehensive provisions to assess hazards and risks to human health and to provide relevant information and instructions to users. Additional labelling for human health hazards according to CLP would not contribute to an increased level of protection.
	DM6 Revoke the exemption for the labelling of the environmental hazards of medicinal products	Effectiveness and proportionality: Ample evidence for negative environmental impacts, but legislation contains comprehensive provisions for environmental risk assessment, risk mitigation and provision of information and instructions to users. Ongoing initiatives aiming to further mitigate the environmental impact of medicinal products. Therefore, labelling for environmental hazards according to CLP is not expected to have a significant added value.
	DM7 Revoke the exemption for the labelling of the environmental hazards of veterinary medicinal products	Effectiveness and proportionality: Ample evidence for negative environmental impacts, but legislation contains comprehensive provisions for environmental risk assessment, risk mitigation and provision of information and instructions to users. Ongoing initiatives aiming to further mitigate the environmental impact of medicinal products. Therefore, labelling for environmental hazards according to CLP is not expected to have a significant added value.
	DM8 Revoke the exemption for the labelling of the environmental hazards of medical devices	Relevance and effectiveness: No solid evidence for a negative environmental impact of products. Relevant legislation addresses environmental effects and the provision of information to users. Labelling for environmental hazards according to CLP is not expected to have a significant added value.
	DM9 Revoke the exemption for the labelling of the environmental hazards of cosmetic products	Effectiveness: Solid evidence for negative environmental impacts from certain ingredients. The relevant legislation does not provide for assessment of or information on environmental aspects. While environmental risks posed by cosmetic ingredients can be addressed by the horizontal provisions of REACH, there is a regulatory gap in relation to information on environmental hazards to users, which may be closed by removing the exemption in CLP for cosmetic products. However, the impact of CLP labelling on consumer behaviour (use, purchasing choices) is uncertain, and a number of relevant initiatives (see Annex 14) are currently under way that may significantly change the availability of information of environmental impacts, as well as the impact itself, of cosmetic products. Therefore, it is currently difficult to assess the impact of labelling for environmental hazards according to CLP, and not possible to conclude whether

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		removing the exemption for cosmetic products in CLP is a suitable option.
	DM10 Revoke the exemption for the labelling of the environmental hazards of food or feeding stuffs	No solid evidence for a negative environmental impact of products. Relevant legislation addresses environmental effects and the provision of information to users. Labelling for environmental hazards according to CLP is not expected to have a significant added value.
	DM11 Introduce digital labelling as an alternative to CLP physical label	Significant costs for businesses (SMEs in particular) to implement the new measures (one off and maintenance costs) associated with incomplete access to digital means by EU citizens. This was not widely accepted by stakeholders, particularly National Authorities as this would further deviate from the UN GHS significantly.
	DM12 Introduce mandatory digital labelling for CLP labels	Significant costs for businesses (SMEs in particular) to implement such a measure. This option cannot exclude that some product users, particularly consumers, would not be able to access digital product information due to lack of access to digital tools, lack of digital skills and lack of internet connection.
Implementation of CLP rules	DM13 Introduce obligation to make online platforms the responsible actors for compliance in the EU	Not in line with the draft Digital Services Act[91] as well as the E-Commerce Directive[92] providing for a conditional liability exemption of online platforms.
	DM14: Change the entire system and allow submissions via the ECHA portal only with information storage in ECHA's database and access by all Member States	Very disruptive measure for a system that is only applicable as of 2020; no support from either Member States or stakeholders; measure would solve the problem only partially (not for re-branders/-relabellers).
	DM15 Amend CLP to make online platforms the responsible actor in the EU by default	Too disruptive measure for a just recently introduced system, not appreciated by any Member State nor stakeholder.
	DM16 Improving ECHA guidance on notifications to poison centres	ECHA guidance has been assessed as already addressing the problem, but improvements could not solve the main issues, as distributors continue placing on the market hazardous mixtures supplied cross-border and re-branded.

[91] Proposal for a Digital Services Act and amending Directive 2000/31/EC, COM(2020) 825 final.
[92] Directive 2000/31/EC, OJ L 178/1.

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Annex 8 – New Hazard Classes

CONTEXT

The CSS calls for the strengthening CLP and, more specifically, states that the Commission will 'propose new hazard classes and criteria in CLP to fully address environmental toxicity, persistency, mobility and bioaccumulation' and 'ensure that the CLP is the central piece for hazard classification and allows the Commission to initiate harmonised classifications'[93]. The CLP revision will be closely followed by the revision of REACH and other chemical legislative acts (EC, 2020c[94]) that will benefit from the CLP revision as classification of substances and mixtures trigger legislative actions or direct obligation under downstream legislation.

Several Sustainable Development Goals (SDG) are linked to this problem, especially:

- SDG #3 Good health and well-being – Target 3.9 'By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination': the inclusion of new hazard classes on EDs will contribute to this goal by better protecting human health.

- SDG #6 Clean water and sanitation – Target 6.3 'By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally': all new hazard classes will also participate to this goal, in particular the new hazard classes on PMT and vPvM.

- SDG #9 Industry, innovation and infrastructure – Target 9.4 'By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities': the new hazard classes will help in the identification of sustainable alternatives.

- SDG #12 Responsible consumption and production – Target 12.4 'By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment': the new hazard classes will have downstream consequences, which will at the end impact the full life cycle of this products.

[93] COM(2020) 667.
[94] COM(2020) 667.

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Description of the problems

During the development of the CLP, the intention was to keep the classification and labelling criteria as close as possible to the UN GHS, to facilitate worldwide trade while protecting human health and the environment (CLP recitals 5 to 8, 12, 13, 15 and 42). However, the Fitness Check of chemicals legislation other than REACH[95] found shortcomings in the legislative framework with respect to its coherence, because of the lack of horizontal identification criteria for certain hazard properties. This has resulted in the following identified problems:

- hazard properties not covered by CLP and the UN GHS, not being identified, classified and communicated to downstream users, linked to hazardous substances and mixtures not identified and causing diseases and pollution and consumers and professional users not provided with sufficient information;

- inconsistencies in risk mitigation measures adopted for substances with the same hazards but regulated by different pieces of legislation, linked to insufficient compliance and excessive administrative burden (in particular SMEs);

- failings in triggering risk management provisions in downstream sector-specific regulations and directives referring to CLP hazard classification,[96] linked to hazardous substances not identified and causing diseases and pollution;

- inefficiencies in the use of limited resources, as the same hazard properties are assessed multiple times for the same substances according to different regulations, linked to inefficient procedures for hazard classification and insufficient compliance and excessive administrative burden (in particular SMEs).

Ultimately, these inconsistencies undermine the protection of human health and the environment and have been acknowledged by the CSS which lists, amongst other actions:, to 'propose to establish legally binding hazard identification of endocrine disruptors, based on the definition of the WHO, building on criteria already developed for pesticides and biocides, and apply it across all legislation';, 'propose new hazard classes and criteria in the CLP to fully address environmental toxicity, persistency, mobility and bioaccumulation'; and 'propose to introduce, adapt or clarify criteria/hazard classes in UN GHS' (EC, 2020a[97]).

Endocrine disruption

The World Health Organisation defines an endocrine disruptor (ED) as 'an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes

[95] SWD(2019) 199.
[96] Around 20 different legislative acts referring to CLP classifications were identified and analysed in RPA et al. (2017b).
[97] COM(2019) 640 final. Brussels, 11.12.2019

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adverse health effects in an intact organism, or its progeny, or (sub)populations' (IPCS, 2002).[98]

Over the last 30 years, the endocrine disrupting properties of chemicals have been the focus of increasing scientific research, and the accumulated knowledge identifies EDs as a concern to public and wildlife health (WHO/UNEP, 2013;[99] Vandenberg LN, Turgeon JL, 2021). 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 and cardiovascular diseases, cancer, diabetes and obesity, allergic and autoimmune diseases in adults – have important parallels in some wildlife populations. Evidence on the roles played in the disease outcomes by environmental and other non-genetic factors, including chemical exposure, is growing. Some links have become apparent (e.g. polychlorinated biphenyls' exposure as a risk factor in breast and prostate cancers; relationships between perfluoroalkyl substances and child and adult obesity, impaired glucose tolerance, gestational diabetes, reduced birthweight, reduced semen quality, polycystic ovarian syndrome, endometriosis, and breast cancer) while more research is necessary on the associations between EDs and other endocrine-related diseases (WHO/UNEP, 2013; Kahn et al., 2020).

The interaction between EDs and other environmental stressors is also under investigation, with some research pointing to potential emerging problems (for example, Wu et al., 2022 report on the negative impact on fish populations of the synergetic action of increasing water temperatures due to climate warming and endocrine disruption from plastic pollution). Importantly, only a small proportion of the chemicals on the market have been tested for endocrine effects and the disease risk due to EDs' exposure may be significantly underestimated (WHO/UNEP, 2013). Shaffer et al. (2019) identifies EDs as a high priority class of environmental health risk factors for inclusion in the future iterations of the Global Burden of Disease (GBD) study.[100]

Since 1999, the European Commission has been working on prioritising suspected EDs for evaluation, monitoring exposures and effects, develop and validate new testing methods and increase public awareness on EDs (EC, 2018b[101]).

Identification of known or presumed endocrine disruptors (EDs) is required for actives substances by the Plant Protection Products Regulation (PPPR)[102] and for actives substances and products by the Biocidal Products Regulation (BPR)[103] according to criteria established, respectively, in 2017 and 2018. REACH does not contain identification criteria for EDs, but these are identified as substances of very high concern (SVHCs) on a case-by-case basis

[98] International Programme on Chemical Safety. (2002). Global assessment on the state of the science of endocrine disruptors. World Health Organization. https://apps.who.int/iris/handle/10665/67357

[99] UNEP State of the Science of Endocrine Disputing Chemicals - IPCP-2012, available at: https://www.unep.org/resources/publication/state-science-endocrine-disputing-chemicals-ipcp-2012?_ga=2.148289463.183897156.1643356524-1526509983.1643356524

[100] Shaffer RM et al. (2019): Improving and Expanding Estimates of the Global Burden of Disease Due to Environmental Health Risk Factors. Environmental Helath Perspectives 127(10) October 2019. Available at: https://doi.org/10.1289/EHP5496

[101] COM(2018) 734 final.

[102] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009.

[103] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167 27.6.2012.

following the IPCS/WHO definition and the assessment of the "equivalent level of concern" carried out by the REACH Member State Committee. It should be noted that the same definition and guidelines are used by REACH, BPR and PPPR.

Sector-specific legislation on cosmetic products, medical devices, food contact materials, detergents, toys or on any other chemical products does not require the identification of EDs. However, the use of potential endocrine disrupting substances may be subject to the scientific opinion of expert advisory bodies. For example, while Regulation (EC) No 1223/2009 on cosmetic products[104] (CPR) does not have specific provision for endocrine disruptors, it does ban the use of substances that are toxic to reproduction (which may for some substances also be toxic via an endocrine disrupting mode of action); the scientific committee on consumer safety (SCCS) addresses scientific concerns about the endocrine-disrupting properties (as well as reprotoxicity and other properties of concern) of cosmetic ingredients through specific risk assessments.

Because the lack of CLP on EDs is not filled by systematic identification in other regulations, there is incomplete information on the human health and environmental hazards of these substances. It should also be noted that EDs are not included at UN GHS. As substances and mixtures with ED properties are not systematically identified and classified, these properties are not communicated to downstream users, limiting downstream users' ability to make informed purchase choices and to adopt suitable risk management measures. The lack of identification criteria in CLP may also result in the failure to define risk management provisions in downstream sector-specific regulations and directives referring to CLP hazard classification. Moreover, substances suspected of having ED properties may be assessed multiple times according to different regulations, contributing to the inefficient use of limited resources.

The inclusion of horizontal criteria for the identification and classification of EDs was identified as an area for action in the EU's 7th EAP and their absence has been criticized by many stakeholders (EC, 2020b;[105] EC, 2019e[106]).

It should be noted though that some stakeholders who participated to the consultation activities in the framework of the Fitness Check on endocrine disruptors argue that 'endocrine disruption is a mode of action, while GHS/CLP focus on adverse effects. Adverse effects triggered by endocrine activity are already covered by existing GHS/CLP hazard classes. ED classification would be redundant'. However, not all adverse effects of EDs — for example the effects of obesogens — can be identified within the current existing hazard classes of CLP.

PBT/vPvB properties

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 bioaccumulate. Even at low toxicity, they have the potential to cause severe harm, because they build up, for example in the adipose tissue of mammals, increasing their concentration over time. Once in the food chain, they magnify at each level, leading to higher

[104] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Text with EEA relevance).
[105] SWD(2020) 251.
[106] SWD(2019) 199.

concentrations in top predators and humans. 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: in the case of vPvB substances, 'even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since high but unpredictable levels may be reached in man or the environment over extended time periods' (ECHA, 2017a[107]). Moreover, PBT/vPvB substances have the potential to contaminate remote pristine areas. They also pose particular challenges to the reliability of quantitative risk assessment, as a "safe" concentration in the environment cannot be established with the available methodologies (ECHA, 2017a).

To a certain extent, PBT and vPvB substances are already regulated by REACH: organic substances placed on the market in quantities of 10 tonnes or more per year have to undergo a chemical safety assessment (article 14 of REACH), including a PBT/vPvB assessment according to the identification criteria listed in Annex XIII of REACH. However, any substance, even those that have not been registered, can be identified as PBT/vPvB and included in the Candidate List of substances of very high concern (Annex XIV of REACH) for authorisation of their continued use(s) (article 57 of REACH).

PBT/vPvB substances meeting the criteria set out in paragraph 1 of Annex D to the Stockholm Convention[108] are controlled through the adoption of appropriate measures (article 3(3) of Regulation 2019/1021 on persistent organic pollutants)[109]. Except for explicit exemptions, the manufacturing, placing on the market and use of substances — on their own, in mixtures or in articles — is prohibited or restricted if the substances are included respectively in Annex I or II of the POPs Regulation.

Substances used in veterinary medicinal products and in medicinal products for human use (both outside the scope of CLP) undergo PBT screening according to European Medicines Agency's guidelines[110] which refer to REACH Annex XIII criteria. Also the BPR refers to REACH Annex XIII criteria, but PBT and vPvB substances used in plant protection products are identified according to the criteria listed in the PPPR. This creates a potential for inconsistent PBT/vPvB hazard identification, due to differences in the assessment procedures applied by each legal framework, the interpretation of the criteria, variations in the use of a weight of evidence approach, the availability of data for the assessment and the regulatory consequences. This is in particular the case for substances with PBT/vPvB properties near the trigger values (Rauert et al, 2014; RPA et al. 2017a). Under PPPR, a working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides"[111] has been developed which follow a different approach than the ones followed in other legislations.

[107] 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.
[108] Stockholm Convention on persistent organic pollutants (POPs), available at: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
[109] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants. Available at: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32019R1021
[110] Respectively EMA (2015) and EMA (2018).
[111] https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_fate_evidence_identify-pop-pbt-vpvb-props.pdf

So far, PBT assessments carried out according to the BPR and PPPR have resulted in only one substance being inconsistently identified as a PBT: acetamiprid[112] was identified as "very persistent" and "toxic" under the BPR and therefore included in the list of candidates for substitution and approved for seven years only, while it was not identified as "persistent" under the PPPR and approved for 15 years (EC, 2019e).

The possibility of labelling for PBT/vPvB substances was raised by some MS during the co-decision process leading to the adoption of CLP and supported by some political groups of the European Parliament. The proposal did not gain sufficient support, but the legislator decided to add article 53(2): 'Member States and the Commission shall, in the manner appropriate to their role in the relevant UN for a, promote the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the UN' (UN, 2009).[113] In 2009, the EU put forward a proposal to include PBT/vPvB hazard classes and criteria in the UN GHS, but the UN GHS expert sub-committee concluded that the existing hazard classes for aquatic toxicity would capture any substance with PBT or vPvB properties and ensure adequate classification and labelling (EC, 2019e).

It should be noted that hazard classification as intended in CLP and the UN GHS does not foresee, at the moment, the combination of properties as in PBT or vPvB. 'Such combinations of properties are used to trigger specific actions in terms of risk assessment and risk management' (UN, 2009). Indeed, while PBT/vPvB substances elicit the same level of concern as for example CMRs in REACH, CLP and the UN GHS do not provide for horizontal identification criteria. As a consequence, substances manufactured and imported in quantities below ten tonnes per year with PBT/vPvB properties — and the mixtures containing these substances — are not systematically identified and classified and their PBT/vPvB properties are not communicated to downstream users, limiting their ability to adopt suitable risk management measures and make informed purchase choices. Moreover, substances suspected of having PBT/vPvB properties may be assessed multiple times according to different regulations, contributing to the inefficient use of limited resources. The lack of identification criteria in CLP results in the failure to define risk management provisions in downstream sector-specific regulations and directives referring to CLP hazard classification.

PMT/vPvM properties

Substances with 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[114]. Many PMT/vPvM substances are only partly removed by wastewater treatment processes and can even breakthrough 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. Despite progress, current analytical measurements are inadequate, and monitoring may therefore not detect some of these substances (Hale et al., 2020).

112 EC number: 603-921-1; CAS number: 135410-20-7.
113 UN committee of experts on the transport of dangerous goods and on the globally harmonized system of classification and labelling of chemicals, UN/SCEGHS/18/INF.4, available at https://unece.org/fileadmin/DAM/trans/doc/2009/ac10c4/UN-SCEGHS-18-inf04e.pdf
114 https://enveurope.springeropen.com/articles/10.1186/s12302-020-00440-4

Examples of PMT/vPvM substances are perfluorobutanesulfonic acid (PFBS) and its salts, and GenX[115], which are compounds belonging to the class of per- and polyfluoroalkyl substances (PFAS). In consideration of 'the large number of cases of contamination of soil and water - including drinking water - in the EU and globally, the number of people affected with a full spectrum of illnesses and the related societal and economic costs', the CSS stresses that PFAS require special attention.

The Member State Committee identified two groups of substances (HFPO-DA and PFBS[116]) (2019) and one substance (1,4-dioxane) (2021) as SVHCs and included in the Candidate list for authorisation according to article 57(f) of REACH, because their individual properties as well as the combination of their properties elicit an equivalent level of concern, having probable serious effects to human health and the environment. Hale et al. (2020) applied 16 assessment criteria[117] to three case studies[118] to demonstrate that PMT/vPvM substances elicit an equivalent level of concern of PBT/vPvB substances.

However, neither REACH nor any other legislative framework have identification criteria for substances with PMT/vPvM properties. Since 2009, the German Environment Agency (UBA) has been working on the development of identification criteria[119].

Drivers of the problems

The main drivers of the above problems are:

Missing provisions for identification of critical hazards;
Inefficient procedures for hazard classification.

The missing information about critical hazards to human health and the environment is driven by the lack of horizontal identification criteria and specific hazard classes coupled with insufficient information on modes of action and fate of the substances. These drivers are regulatory failures. As CLP does not require the generation of new information (article 8), the latter driver should be addressed by the revision of the REACH Regulation.

[115] Tradename of HFPO-DA (3: 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid) its salts and its acyl halides.
[116] Remarks: The combined intrinsic properties justifying the inclusion for the Member State Committee as a substance for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern are the following: persistence, mobility, potential for long-range transport, observed adverse effects (at least the following probable effects for human health: effects on the liver, the kidney, and the haematological and immune systems and effects on development; at least the following probable effects for the environment: population relevant effects on birds and mammals); as well as low adsorption potential and high water solubility rendering the substance fully bioavailable for uptake via (drinking) water. Together, these elements lead to a very high potential for irreversible effects
[117] Serious effects to human health (Pose a threat to human health; Irreversible health effects; Delayed health effects; Impaired quality of life). Serious effects to the environment (Irreversible exposure; Irreversible effect; Intergenerational exposure and effect; Unknown/uncertain spatial scale; Disparity between point of release and point of effect; Unknown/uncertain temporal scale; Uncertain/difficult to predict long term fate and toxic effects; Harmful to the aquatic environment; Potential to reach pristine areas). Other effects (Increased societal costs; Negative effect on resources; Need for minimisation of emissions).
[118] PFBS, Gen X and 1,4-dioxane.
[119] Umweltbundesamt, PMT and vPvM substances under REACH, https://www.umweltbundesamt.de/en/PMT-substances

The consequences of having missing information on the hazards of substances and mixtures are that downstream-users may adopt inconsistent and/or inadequate risk management measures. Moreover, they can make purchase choices based on partial information. There is a failure in the functioning of the generic approach to risk management used in many pieces of legislation, which refer directly to CLP hazard classification for triggering certain risk management measures. Finally, the lack of horizontal identification criteria contributes to the inefficient use of the limited resources available.

If the current situation persists, BPR and PPPR will still provide for a systematic identification of endocrine disrupting active substances according to the criteria established in the BPR and PPPR. Without policy intervention, the identification of endocrine disruptors used in other product categories would not be systematic but would still be identified as SVHCs on a case-by-case basis following the IPCS/WHO definition and the assessment of the "equivalent level of concern" carried out by the REACH Member State Committee.

PBT/vPvB substances placed on the market in quantities of 10 tonnes or more per year would be identified according to the criteria listed in Annex XIII of REACH. Even those that have not been registered could be identified as PBT/vPvB and included in the Candidate List of substances of very high concern (Annex XIV of REACH) for authorisation of their continued use(s) (article 57 of REACH).

There are no identification and classification criteria for substances with PMT/vPvM properties in REACH or any other legal framework, even if under PPPR and BPR specific risk assessments is triggered for mobile substances. PMT/vPvM substances would be identified following the assessment of the "equivalent level of concern" carried out by the REACH Member State Committee according to Article 57(f) of REACH.

The pace of identification under REACH of substances with ED, PBT/vPvB or PMT/vPvM properties would be largely dependent on resources allocated to SVHC identification. As a follow-up to the SVHC Roadmap, the IRS started in 2016 with the aim to speed up the identification of substances of concern, having as a target the assessment of all registered substances by 2027, to conclude on whether they are a priority for data generation or whether enough information is available to determine their priority for regulatory risk management (ECHA, 2021b). As revealed by the exercise carried out by ECHA to provide numbers of substances that could potentially be identified and classified with ED, PBT/vPvB and PMT/vPvM properties, for a large number of substances there would be the need for further data generation, as substances registered with Annexes VII and VIII have in general a very limited data set.

Based on ECHA work, '[at] the end of 2020, there were around 1,860 substances of potential concern needing further data generation. […] The generation of the data can take anywhere from less than a year up to several years.' Further details on this exercise and its methodology is available in Annex IV.

CLP works as reference for a number of pieces of legislation, and without the introduction of new hazard classes in CLP, some RMMs which are triggered by harmonised classification and labelling would not be adopted.

Description of the current baseline

CLP is the horizontal reference point for the identification and classification of the physical, health and environmental hazards of chemical substances and mixtures for most EU chemicals and chemicals-related legislation. However, the hazards defined under CLP — and the UN GHS — are not exhaustive, resulting in lack of communication on the hazards not covered by CLP.

As CLP does not contain hazard identification criteria for substances with ED, PBT/vPvB and PMT/vPvM properties, under the baseline these substances will keep being identified through REACH (ED, PBT/vPvB and PMT/vPvM substances), BPR and PPPR (ED, PBT/vPvB substances). The BPR and the PPPR have established identification criteria for EDs. While REACH does not contain identification criteria for EDs, these can be identified as SVHCs on a case-by-case basis following the IPCS/WHO definition and the assessment of the "equivalent level of concern" carried out by the REACH Member State Committee.

REACH requires registrants to carry out a PBT assessment for substances placed on the market in quantities of 10 tonnes or more per year. Any substance under the scope of REACH can be identified according to the criteria listed in Annex XIII of REACH as PBT or vPvB and, as for EDs, may be identified as SVHCs (article 57 of REACH). The BPR refers to REACH Annex XIII criteria, and the PPPR contains PBT/vPvB identification criteria.

Neither REACH nor any other legislative framework have identification criteria for substances with PMT/vPvM properties, but they can be identified as SVHCs under REACH.

ECHA's integrated regulatory strategy brings together the various regulatory processes of REACH and CLP. It is based on the efficient selection of substances and groups of substances that raise potential concern, so that information needed to assess their safety is generated and any remaining concerns addressed through the most suitable regulatory risk management measures. ECHA and MSCAs carry out the following substance-specific activities: data generation and assessment (dossier evaluation, substance evaluation, informal hazard assessment of PBT/vPvB/ED properties); assessment of regulatory needs (ARN); and regulatory risk management (harmonised classification and labelling, SVHC identification, restriction).[120]

Under the baseline, it is assumed that these activities will keep contributing to the identification of ED, PBT/vPvB and PMT/vPvM substances. The assessment of regulatory needs may be based on sufficient available information or on data generated on missing hazard information following compliance checks, testing proposals and substance evaluation. In addition, the ED and PBT expert groups support the identification of ED and PBT/vPvB substances.

ECHA and MSCAs select substances that are to be evaluated to clarify whether their use poses a risk to human health or the environment. The selection is carried out on the basis of risk-based criteria. The substances selected for substance evaluation (Chapter 2 of the REACH Regulation) are included in the community rolling action plan (CoRAP) following the opinion of the Member State Committee. The evaluation of each substance – under substance evaluation – is carried out by a designated Member State by assessing all

[120] Planned, ongoing or completed activities are listed in the Public Activities Coordination Tool (PACT).

registration dossiers from all registrants specific to the same substance or group of substances, considering other sources of information and by requesting and assessing new data from the registrants, typically going beyond the standard REACH information requirements. Following the assessment of all information, if the evaluating Member State considers that the use of the substance poses a risk, it may proceed by proposing: harmonised classification and labelling for certain hazards, identification of the substance as SVHC, an EU-wide restriction, EU-wide occupational exposure limits, national measures or voluntary industry actions.

As of February 2022, the CoRAP includes 392 unique substances/entries.[121] Between 2012 and 2023, Member States evaluated, are evaluating or plan to evaluate 90 substances for their suspected ED properties and 151 substances for their suspected PBT/vPvB properties. Additionally, 23 substances are undergoing an ED assessment under the BPR.[122] No data could be found on the number of substances undergoing an ED or PBT/vPvB assessment under the PPPR.[123] So far, no substances have been included in the CoRAP to investigate suspected PMT/vPvM properties.

Following data generation (or the evaluation of the available information considered sufficient for the purpose), the regulatory needs of substances and groups of substances are assessed.[124] The outcome can be that either there is no need for action or that regulatory risk management at EU level is required. The follow-up regulatory actions are: harmonised classification and labelling, SVHC identification, restriction, or action through other EU legislation. The assessment can also result in a request for additional data (e.g. through substance evaluation).

As of February 2022, the candidate list of substances of very high concern for authorisation includes 444 entries, of which 113 were included because of their ED properties, 114 because of their PBT/vPvB properties and 21 because of their PMT/vPvM properties. It is assumed that Member States or ECHA would keep proposing substances to be identified as SVHCs at the same rhythm. It should be noted that the group approach may result in higher numbers of substances being identified as EDs or with PBT/vPvB or PMT/vPvM properties. Substances and groups of substances can also be identified for restriction rather than authorisation. The effect of the inclusion of groups of substances could be large: for example, the announced intention to submit a restriction proposal for PFAS would affect more than 6,000 substances,[125] although only around 2,000 are currently registered.[126] Finally, biocidal and plant protection active substances that exhibit ED or PBT/vPvB properties should not be

[121] Note that ECHA webpages may indicate a slightly lower number of substances/entries than those listed in the downloadable list, also because group entries are split in different rows. Source: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
[122] https://echa.europa.eu/ed-assessment
[123] It should be noted that the review under BPR and PPPR is systematic, but limited to ED category 1.
[124] As of February 2022, the ARN registry (https://echa.europa.eu/assessment-regulatory-needs) lists 754 entries between substances and groups of substances, for a total of 2,116 substances. In the downloadable spreadsheet, group entries are split in different rows. However, not all groups are split (e.g. PFAS has one single row) and therefore the total number of unique substances is larger. The need for regulatory action, if any, can be identified for the whole group, a subgroup or a single substance.
[125] https://www.rivm.nl/en/pfas/official-start-to-ban-pfas-in-europe
[126] https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas

approved, in principle,[127] for their use in biocidal and plant protection products, in accordance with the BPR and PPPR.[128]

By forecasting numbers of substances through linear regression using the known values for the period 2008-2022, in 2032 the candidate list would include 799 substances, of which 206 for ED properties, 214 for PBT/vPvB properties and 67 for PMT/vPvM properties. In 2042, the candidate list would include 1,126 substances, of which 293 for ED properties, 306 for PBT/vPvB properties and 110 for PMT/vPvM properties (Figure 64).

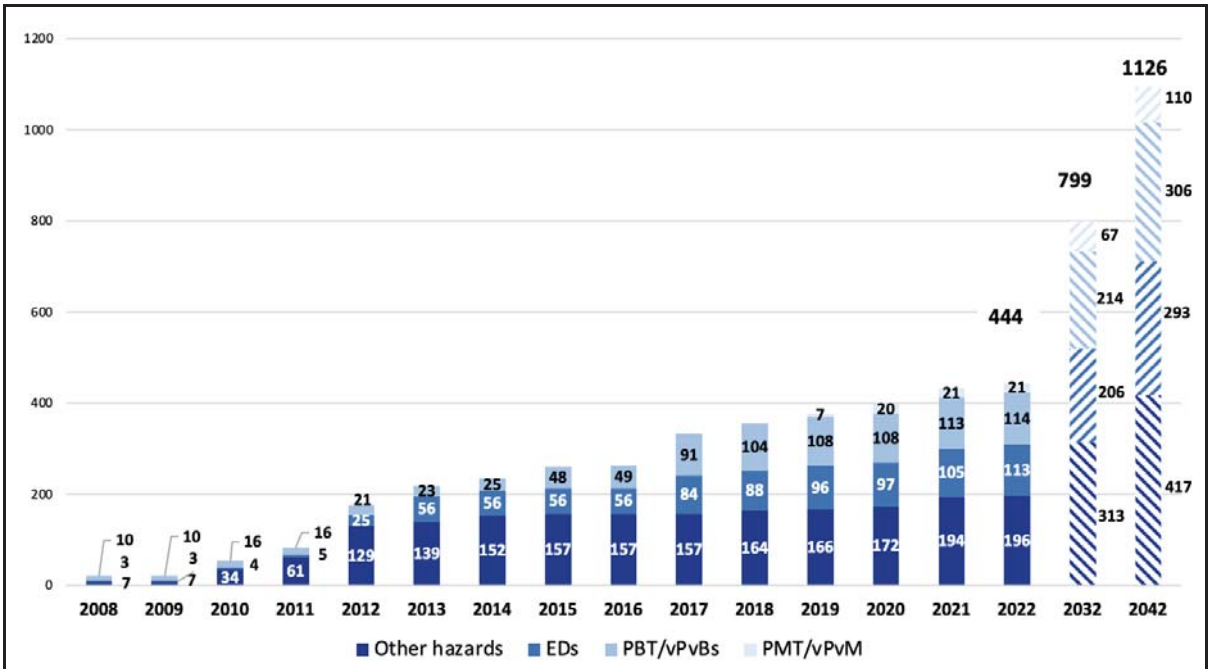

Figure 64: Number of substances included in the candidate list of SVHCs for ED, PBT/vPvB or PMT/vPvM properties or other hazards per year
Source: ECHA Candidate list (projections of the authors)

As most of the substances may be used in more than one mixture, it is necessary to estimate the number of mixtures that would be impacted by the identification of a substance with one or more of the considered properties. Estimating this is difficult for several reasons:

- There is no central repository that compiles information on the number of mixtures for the entire EU;
- Some of the possible information sources are not publicly available, such as the information provided to Poison centres for medical emergency[129] or the German Federal Institute for Risk Assessment (BfR).[130]

Ricardo (2021) estimated that 16,969 substances (including UVCBs) and 190,702 mixtures would be impacted by the extension of the generic approach to risk management to the

[127] Derogations are foreseen.
[128] The reasons for non-approval of active substances are not easily retrieved from ECHA and EFSA databases, if not by checking the opinions one-by-one.
[129] https://poisoncentres.echa.europa.eu
[130] See e.g. https://www.bfr.bund.de/en/notification_of_products-10144.html, accessed November 2021.

following hazard classes: ED, PBT/vPvB, PMT/vPvM, respiratory sensitisation Cat. 1, 1A and 1B, STOT RE/SE Cat. 1 and 2, immunotoxicity, neurotoxicity, CMR Cat. 2, Skin Sensitisation Cat 1, 1A and 1B, aquatic chronic 1 and 2 (Ricardo, 2021, p.50). These estimates imply an average number of mixtures per substance of around 11.

An alternative estimate was derived by analysing the SPIN (Substances of Preparations in Nordic Countries) and extrapolating the result to the EU.[131] The average of five mixtures per substance was multiplied by a factor of five for projection to the entire EU, resulting in an average of 25 mixtures placed on the EU market per single substance. This is consistent with the estimates in the 2017 Fitness Check, which used figures of 99,000 substances and 2.5 million mixtures subject to reclassification, labelling and safety data sheets preparation to produce an average of about 25 mixtures per substance. Applying these two estimates (11 and 25 mixtures per substance) to the numbers of SVHCs in 2022[132] and the estimated number of SVHCs in 2032 and 2042 produces the estimates for the total numbers of mixtures in Table 27.

Table 27: Estimated number of mixtures containing SVHCs with ED, PBT/vPvB, PMT/vPvM properties

	2022	2032	2042
Number of mixtures based on 11 mixtures per substance			
ED	100	2,300	3,200
PBT/vPvB	200	2,400	3,400
PMT/vPvM	100	700	1,200
Total	400	5,300	7,800
Number of mixtures based on 25 mixtures per substance			
ED	300	5,100	7,300
PBT/vPvB	400	5,300	7,700
PMT/vPvM	200	1,700	2,700
Total	900	12,200	17,700

More accurately, the totals provided in the table relate to the number of classifications for mixtures rather than the number of mixtures. This is because some mixtures may meet the classification criteria for more than one of the hazards.

Table 28 summarises the estimates of the numbers of substances and mixtures with ED, PBT/vPvB, PMT/vPvM properties that would be identified and classified under the baseline.

Table 28: Estimated number of substances and mixtures with ED, PBT/vPvB, PMT/vPvM properties that would be identified and classified 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

[131] The methodology and the results are detailed in the section on the policy options.
[132] As of March 2022, only 13 EDs, 15 PBT/vPvB and 7 PMT/vPvM SVHCs are still registered, and therefore on the market.

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*Notes: *rounded to the nearest tens; **rounded to the nearest hundreds*

POTENTIAL POLICY MEASURES

Policy measure 1: Adding new hazard classes.

This measure aims at increasing coherence in the legislation by providing horizontal identification and classification criteria and providing the opportunity to develop CLH dossiers for substances classified for these new hazard classes, in order to promote the adoption of adequate and consistent RMMs for different substance uses, triggering risk evaluations and restrictions in downstream legislation and lowering exposure to hazardous chemicals in a timely manner through increasing the number of CLH substances. A detail of can be found in Table 29.

Table 29: PO1: Adding new hazard classes.

Policy measure	Category	Description
Adding ED, PBT/vPvB, PMT/vPvM hazard classes		
Add HH and ENV EDs Cat. 1/2 hazard classes	Hard, legally binding rules	The Commission to include HH and ENV EDs Cat. 1/2 hazard classes and identification criteria to Annex I of CLP. The requirement should enter into force at the same time of the changes to REACH Annexes to include testing requirements for endocrine disruption.
Add PBT/vPvB hazard class to CLP Annex I		The Commission to include PBT/vPvB hazard classes and identification criteria to Annex I of CLP. The requirement should enter into force at the same time of the changes to REACH Annexes to include testing requirements for PBT/vPvB.
Add PMT/vPvM hazard class to CLP Annex I		The Commission to include PM/vPvM hazard classes and identification criteria to Annex I of CLP. The requirement should enter into force at the same time of the changes to REACH Annexes to include testing requirements for PMT/vPvM.
Including ED, PBT/vPvB, PMT/vPvM for CLH		
Include HH and ENV EDs among the substances subject to CLH	Hard, legally binding rules	The Commission to amend Article 36 of CLP to prioritise CLH to be proposed for EDs.
Include PBT/vPvB substances among those subject to CLH		The Commission to amend Article 36 of CLP to prioritise CLH to be proposed for PBT/vPvB substances.
Include PMT/vPvM substances among those subject to CLH		The Commission to amend Article 36 of CLP to prioritise CLH to be proposed for PMT/vPvM substances.

Options discarded

All options involving neurotoxicity and immunotoxicity hazard classes and substances toxic to the terrestrial environment were discarded at this stage. Indeed, the scale of the problems caused by these hazards need further investigation, before deciding on the best way to tackle the problems linked.

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Stakeholders consultation

In open text responses to OPC, TSS and in interviews, stakeholders provided different opinions with regards to policy options listed in this section. It should be noted that stakeholders provided comments on specific policy options and measures, while some policy options and measures were not in the focus of stakeholders or were not addressed.

Considering the addition of ED, PBT/vPvB, PMT/vPvM hazard classes, stakeholders were cautious about the alignment of the new hazard classes with GHS. Mostly business entities emphasised that the diverging approaches to hazard classes in the EU will put the EU businesses in disadvantaged competitive position in the global trade because of increasing costs to adjust to differences in classification and labelling of costs in the EU and in other countries. Furthermore, stakeholders provided comments about the necessity for clarity in defining category 2 hazard classes for endocrine disruptors. Business entities highlighted that communication of hazards of 'suspected' endocrine disruptors under category 2 will lead to so-called black-listing effect of some products. In turn, it could result in reformulation of products and in some cases, regrettable substitution. Multiple comments with varying opinions about legal wording of category 2 were provided by the members of CASG sub-committee of CARACAL.

Estimation of the number of substances that may be classified as EDs, PBT/vPvB substances and PMT/vPvM substances

The methodological approach described in Annex IV estimates the number of substances expected to be classified for ED, PBT/vPvB or PMT/vPvM properties based on information on 23,751 substances in a combined inventory. It is important to reiterate that there are significant uncertainties on the estimates of the number of substances that may be classified for the new hazard classes.

Number of ED substances

Based on ECHA WF approach, 80 of the 272 substances corresponding to tonnage level of Annex X to REACH in basket 2 with potential ED properties are expected to have these properties confirmed. This estimate implies that ED properties are not confirmed for 192 Annex X substances in basket 2. With the 12 Annex X substances from basket 1, 92 Annex X substances are expected to be classified as ED substances. This figure is multiplied by 11 to obtain the projected number of 1,012 ED substances among all substances in the inventory. ECHA approach estimates the number of substances for which ED properties are already confirmed (basket 1) or are likely to be confirmed (a subset of basket 2). The total of 1,012 substances is therefore expected to represent confirmed (i.e. Cat. 1) ED substances.

Subsequent analyses aim at differentiating ED Cat. 1 and Cat. 2 and assigning substances to the envisaged new hazard classes ED HH & ED ENV.

The WFs applied by ECHA to give a point estimate for basket 2 substances likely to be identified as ED Cat. 1 can be used for deriving lower and upper end estimates of the number of substances likely to be identified as ED Cat. 1 by using different WF cut-off values. The lower and upper end estimates do not differ from the ECHA estimate with respect to basket 1 substances but only with respect to basket 2 substances.

Table 30 shows the assignment of ED Cat. 1 to the WF assigned by ECHA. Note again that this assignment is performed in this impact assessment and was not done by ECHA. The lower end estimate (AA-1) identifies less substances as ED than the upper end estimate (AA-2).

Table 30: WF assigned by ECHA and derivation of lower and upper end estimates

	Substance assigned to category	
Substance-specific WF (all possible values)	**AA-1 (lower end)**	**AA-2 (upper end)**
0.2	Not ED	Not ED
0.25	Not ED	ED Cat. 1
0.5	ED Cat. 1	ED Cat. 1
0.6	ED Cat. 1	ED Cat. 1
0.8	ED Cat. 1	ED Cat. 1

In the alternative analyses, each substance in basket 1 and basket 2 is identified as being ED Cat. 1 or as being not ED. This is a major difference with ECHA approach that does not require the identification of specific substances. The number of substances assigned to each category are counted and can be compared to ECHA's estimate. Table 31 summarises the results of the estimates.

Table 31: Estimated number of substances expected to be identified as ED Cat. 1

Approach	**ED Cat. 1**
AA-1	836
ECHA	1,012
AA-2	1,276

These numbers represent projections based on the 23,751 unique substances in ECHA's combined inventory. Substances identified as ED (ED Total) represent 4.3% (ECHA approach and central estimate) of the total number of substances in the combined inventory, with a lower-end estimate representing 3.5% (AA-1) and upper-end estimate representing 5.4% (AA-2). These analyses suggest a relatively narrow range of the number of substances expected to be identified as ED.

Categorisation (ED cat. 1 and ED cat. 2)

The new ED hazard classes currently under discussion between experts will involve a categorisation into ED Cat. 1 and ED Cat. 2. Estimating the number of ED Cat. 2 substances is associated with a higher uncertainty than the estimate of ED Cat. 1 substances, since there are no data on which it could be based.

Nonetheless, classifications for reproductive toxicity were evaluated to derive these estimates. Reproductive toxicity is chosen because:

- Endocrine-mediated effects may result in reproductive toxicity; and
- Classifications for reproductive toxicity differentiate between confirmed (Repr. 1A and 1B) and suspected (Repr. 2) effects.

It is acknowledged that endocrine-mediated effects may also result in effects on other organ systems and e.g. manifest themselves in repeated dose toxicity. However, classifications for repeated dose toxicity (i.e. STOT RE) do not differentiate confirmed and suspected effects.

Harmonised classifications for reproductive toxicity were extracted from Annex VI of the CLP and the number of self-classifications in REACH registration dossiers was taken from Karamertzanis et al. (2019). This latter source provides numbers of substances classified either as Repr. 1A/1B or Repr. 2 at the end of each quarter (i.e. four values per year). The most recent figures from this publication were used (as per 31 December 2017), but all figures after the second REACH registration deadline (31 May 2013) show an identical fraction of substances classified as Repr. 2 (57%) among all those classified for reproductive toxicity). Table 32 shows the results of these evaluations.

Table 32: Fraction of substances classified as Repr. 2 among all those classified for reproductive toxicity

	CLH	Self-classifications in registration dossiers	Total
Repr. 1A/1B	206	464	670
Repr. 2	148	603	751
Total	354	1067	1,421
Fraction of Repr. 2	42%	57%	53%
Repr. 2 / Repr. 1A/1B	0.718	1.30	1.12

The data show that the fraction of Repr. 2 classifications among all substances with Repr. classifications is lower in CLH (42%) than it is in registration dossiers (57%). This finding is not unexpected, since CLH may have a higher focus on confirmed reproductive toxicants while self-classifications may tend to Repr. 2 classifications, possibly due to a lower degree of conservatism being applied. Consequently, less substances are classified as Repr. 2 than are classified as Repr. 1A/1B in CLH, while the opposite is true in self-classifications from registration dossiers.

The total numbers (i.e. the weighted mean of both datasets) indicate that the number of substances classified as Repr. 2 is 1.12-times the number of those classified as Repr. 1A/1B. This figure is taken to estimate the number of substances expected to be classified as ED Cat. 2. For example, the figure of 1,012 substances identified as ED Cat. 1 in the ECHA estimate is multiplied by 1.12, resulting in 1,133 substances estimated to be ED Cat. 2.

Table 33: Number of substances assigned ED Cat. 1 and ED Cat. 2

Approach	ED Cat. 1	ED Cat. 2	Total ED
AA-1	836	936	1,772
ECHA	1,012*	1,133	2,145
AA-2	1,276	1,429	2,705
*Notes: * Only this figure was estimated by ECHA (2021a); all other numbers in this row are derived as explained in the text.*			

Differentiation by ED effects by impact area (human health, environment)

Two datasets are used to analyse the fraction of substances identified as EDs for the impact areas of human health (HH) or environmental organisms (ENV) among those identified as ED (without impact area):

All substances in ECHA basket 1 (including Annex X substances);
Substances assessed as being ED in ECHA's ED Assessment List. Since this information was also used in ECHA's evaluation (i.e. there is a strong overlap between the ED Assessment List and ECHA's basket 1), only substances from the ED Assessment List that are not included in basket 1 are considered for these analyses.

Note that substances identified as having ED effects in both impact areas (HH & ENV) are assigned to both groups (HH and ENV), since only two hazard classes are envisaged. This approach is meaningful for estimating the fractions assigned to the two intended hazard classes ED HH and ED ENV.

Table 34 presents the number of substances per impact area as well as the corresponding fraction of the total number identified as ED (in brackets) for each of the two datasets. The second last column shows the sum of the number of substances from the two datasets and the corresponding fractions. The last column provides estimated fractions that are roughly based on the fractions obtained for both datasets combined. The last row of the table also indicates the number of substances in each dataset that is included in each of the two impact areas.

Table 34: Derivation of the fractions of ED substances per impact area

Impact area	All ECHA basket 1 substances	ED Assessment List	Total	Estimate
HH	13 (41%)	2 (40%)	15 (41%)	40%
ENV	19 (59%)	3 (60%)	22 (59%)	60%
HH & ENV*	8	2		

*Notes: * Number of substances included in HH and ENV, since these substances are identified as being ED in both impact areas.*

Final estimates

The fractions per impact area derived in the previous section are assigned to the numbers of substances per category estimated above. The same fraction of 40% (HH) and 60% (ENV) is assigned in each category.

Table 35 provides the number of substances expected to be identified as ED differentiated by ED category and impact area among all substances (ECHA basket 3). The last column shows the total number of substances identified as ED already reported above. As noted earlier, the impact areas used here are not mutually exclusive: in other words, any given substance may be counted in HH and ENV.

Table 35: Estimated number of substances expected to be identified as ED with categorisation and differentiation by impact area

Type of estimate	ED Cat. 1		ED Cat. 2		ED Total		
	HH	ENV	HH	ENV	HH	ENV	All
Lower end (AA-1)	334	502	374	562	708	1,064	1,772
Central estimate (ECHA approach)*	405	607	453	680	858	1,287	2,145
Upper end (AA-2)	510	766	572	857	1,082	1,623	2,705

*Notes: * Note again that ECHA only derives the ED Cat. 1 estimate and does not differentiate by impact area. The sum of 1012 ED Cat. 1 substance is included in ECHA (2021a), but the assignment to HH (N=405) and ENV (N=607) is performed in this study.*

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Based on the total number of 23,751 unique substances in ECHA's combined inventory, the central estimate of 1,012 substances identified as ED Cat. 1 represents 4.3%. Using the derived factor of 1.12, an additional 1,133 substances are estimated to be identified as ED Cat. 2 (4.8% of the combined inventory). In total, 2,145 substances (9.0%) are identified as ED in the central estimate.

Overall, the high uncertainty of the estimated figures reflects the fact that the data required for the classification as ED (including categorisation and differentiation by impact area) are not yet available. It must also be stressed that – even if the estimated numbers prove to be close to the real numbers – they would only materialise if all necessary studies have been conducted for all substances. Importantly, information generated by the new Annex VII requirements for ED testing that may be included in REACH following its revision cannot identify ED category 1 and 2: substances that will have positive *in vivo* mechanistic information in the follow-up will not be classified as ED cat 1 or 2 according to CLP. Classification requires both endocrine activity and adversity: *in vivo* positive substances will not meet the CLP criteria for ED category 1 or 2 because data on adversity is missing. However, the new Annex VII requirements would enable the identification of potential EDs (even if not classified/classifiable as EDs) and therefore prevent regrettable substitutions, as industry would be unlikely to substitute a known ED with a substance that as *in vivo* endocrine activity, i.e. a very likely ED.

Moreover, the number of 1,012 potential ED substances was estimated by ECHA by extrapolating to the full registration database of over 23,000 substances, whereas new information requirements about ED properties may affect only a subset of the overall number, leading to the identification and classification of a lower number of substances, and consequently mixtures.

Number of PBT/vPvB substances

Table 36 summarises the relevant numbers included in ECHA (2021a).

Table 36: Summary of the estimated number of PBT/vPvB substances by ECHA

	Annex X substances				All substances
	Basket 1	**Basket 2 total**	**Basket 2***	**PBT/vPvB total****	**PBT/vPvB total**
PBT	1				
vPvB	3				
PBT & vPvB	7				
PBT/vPvB Total	11	99	25	36	396

*Notes: * Application of the ECHA WF approach (see above). ** Sum of basket 1 and basket 2.*

Subsequent analyses are based on the following assumptions:

> The size of the WF assigned by ECHA is assumed to be indicative of whether a substance is identified as PBT/vPvB. This assumption is implicit in the statistical approach applied by ECHA to derive point estimates of the total number of substances having this property.

Direct application of WF cut-offs to differentiate PBT/vPvB substances from those that are not PBT/vPvB at the substance-specific level (rather than in a statistical approach) is valid to derive lower and upper end estimates. This appears a reasonable assumption, since it directly reflects the general approach taken by ECHA.

Table 37 shows the assignment of PBT/vPvB categories in this impact assessment to the WF assigned by ECHA. Note again that this assignment is performed in this impact assessment and was not done by ECHA. The lower-end estimate (AA-1) identifies less substances as PBT/vPvB than the upper-end estimate (AA-2).

Table 37: WF assigned by ECHA and resulting classification

	Substance assigned to category	
Substance-specific WF (all possible values)	**AA-1 (lower end)**	**AA-2 (upper end)**
0.12	Not PBT/vPvB	Not PBT/vPvB
0.3	Not PBT/vPvB	PBT/vPvB
0.8	PBT/vPvB	PBT/vPvB

The number of substances identified as PBT/vPvB is counted and can be compared to the ECHA estimate. Table 38 provides the estimates for all three approaches.

Table 38: Estimated number of substances expected to be identified as PBT/vPvB

Approach	**PBT/vPvB**
AA-1	143
ECHA	396
AA-2	847

Based on the total number of 23,751 unique substances in ECHA's combined inventory, substances identified as PBT/vPvB represent 1.7% (ECHA approach) with a range of 0.60% (AA-1) to 3.6% (AA-2). These analyses suggest a relatively wide range of the number of substances expected to be identified as PBT/vPvB (factor 6 between minimum and maximum estimate). This relatively wide range results from the fact that the majority of the 99 basket 2 substances in the evaluation (N=64, 65%) is assigned a WF of 0.3. These 64 substances are identified as not PBT/vPvB in AA-1, while they are assigned to the PBT/vPvB group in AA-2.

Assignment to hazard classes

The ECHA approach does not differentiate PBT and vPvB properties for basket 2 substances. Since the number of substances per envisaged hazard class (PBT and vPvB) are useful for the impact assessment, the approach for identifying fractions follows the one applied to assign ED substances to impact areas. In the case of PBT/vPvB properties, the following datasets are evaluated:

All substances in ECHA basket 1 (including Annex X substances);[133]
Substances assessed as being PBT and/or vPvB in ECHA's PBT Assessment List.[134]

[133] As noted above, the ECHA evaluation of substances in basket 2 does not differentiate by impact area.
[134] https://echa.europa.eu/de/pbt, accessed 6 November 2021.

As noted for ED properties, there is substantial overlap between these datasets, since the PBT Assessment List was also used as an input for ECHA's basket 1 evaluation. Therefore, substances from the PBT Assessment List were only used in this evaluation, if they are not included in basket 1. Substances identified in these list as being PBT & vPvB (i.e. possessing both properties) are assigned to each of the two intended hazard classes. Their numbers are provided in the last row of Table 39. For example, 17 of the 23 substances identified as PBT among the basket 1 substances are also identified as vPvB. Table 39 summarises the outcome of these evaluations. The percentages given in brackets are the ones for the hazard class as a fraction of the sum of both hazard classes.[135]

Table 39: Fractions of PBT and vPvB substances among those identified as PBT/vPvB

Impact area	ECHA basket 1 substances	PBT Assessment List	Total	Estimate**
PBT	23 (45%)	6 (46%)	29 (45%)	45%
vPvB	28 (55%)	7 (54%)	35 (55%)	55%
PBT & vPvB*	17	2		

*Notes: * Number of substances included in PBT and vPvB, since these substances are identified as being both PBT and vPvB. ** Roughly based on fraction obtained in the evaluation of all three datasets.*

The data show that more than half of the substances identified as PBT are also identified as vPvB (see ECHA basket 1 substances). This is not true for the substances from the PBT Assessment List that are not already included in basket 1, but in this case the sample size is very small. The estimated percentages in the last column of the table are used as a pragmatic approach to assign substances to the envisaged new hazard classes PBT and vPvB, since the fractions obtained in the two datasets are practically identical. However, these fractions involve a high uncertainty, since they are based on small samples. The estimated fractions are assigned to the total number identified as PBT/vPvB, resulting in a final estimate of the number of substances for these hazard classes.

Final estimates and discussion

Table 40 summarises the final estimates, providing the split into the two envisaged hazard classes for the central estimate representing the total number of expected PBT/vPvB substances derived in ECHA (2021a) (N=396) as well as a lower-end (N=143) and an upper-end estimates (N=847). It is important to note that ECHA did not provide separate estimates for PBT and vPvB substances. This allocation was carried out by the consultants supporting the impact assessment.

Table 40: Final estimate on the number of substances expected to be classified as PBT and vPvB

Type of estimate	PBT	vPvB	PBT/vPvB total
Lower end (AA-1)	64	79	143
Central estimate (ECHA approach)	178	218	396
Upper end (AA-2)	381	466	847

[135] Since substances with both PBT and vPvB properties are assigned to both hazard classes, the theoretical number of 'substances' in these evaluations are higher than they actually are. Thus, there are 11 Annex X substances in basket 1: 1 PBT, 3 vPvB and 7 PBT & vPvB). The 7 substances are assigned to both hazard classes, resulting in 8 PBT and 10 vPvB substances. This results in 18 theoretical 'substances', of which 8 (44%) are PBT and 10 (56%) are vPvB.

These numbers represent very rough estimates. As already noted, the apparent accuracy of the estimates is spurious. The calculated numbers are provided to increase transparency and to allow cross-checking of the calculations. The uncertainties of these estimates relate to the following issues:

ECHA (2021a) considers basket 3 estimate (i.e. the figure of 396 substances expected to be identified as PBT/vPvB) as a guestimate and therefore highly uncertain.

Bioaccumulation in air-breathing (terrestrial) animals is currently not fully assessed since assessment approaches are still under development. Substances that do not bioaccumulate in aquatic organisms may do so in terrestrial mammals, potentially increasing the number of PBT/vPvB substances. Also, further developments in bioaccumulation assessment of ionisable substances may also result in changes of the number of substances to be considered as 'B' (both issues are also stated in ECHA (2021a) as limitations).

ECHA evaluation is largely based on sources listing substances with on-going assessments for PBT/vPvB properties. The listing of possible PBT/vPvB is presumably often based on screening criteria and the concerns may not be confirmed upon further investigation. For example, the PBT/vPvB properties of 52 substances assessed by the PBT Expert Group between 2012 and 2018 were only confirmed in 15 cases (29%) (ECHA, 2019a). This is likely to be the reason for the low WFs (0.12 or 0.3) assigned in the ECHA evaluation for many of the sources included.

The split among the two envisaged hazard classes appears robust based on the datasets evaluated. However, it must be noted that the total number of substances in these datasets is small and the assignment to the two hazard classes therefore includes an additional element of uncertainty.

Based on the total number of 23,751 unique substances in ECHA's combined inventory, the 396 substances identified as PBT/vPvB in the central estimate represent 1.7% with a range of 0.60%-3.6%. An earlier screening approach noted a fraction of PBT/vPvB substances of about 3%-5% among 95,000 chemicals (Strempel et al., 2012). Simple screening approaches may identify a higher fraction of substances as PBT/vPvB substances than will be identified upon further investigation.[136] The findings of this screening exercise may therefore not be in contradiction with the numbers estimated here. Finally, the PBT assessment in REACH registration dossiers currently identifies 8,279 entries as not PBT/vPvB and 97 as PBT/vPvB.[137] The latter constitute 1.2% of the total (N=8,376), a figure that falls within the estimated range and close to the central estimate of 1.7%. The assignment to the two envisaged hazard classes is uncertain.

[136] This suggestion also corresponds to the experience of the PBT Expert Group, in which a PBT/vPvB concern identified based on screening approaches was not confirmed.

[137] Based on a simple evaluation of the information given in ECHA's database on registered substances: https://echa.europa.eu/information-on-chemicals/registered-substances, evaluated on 15 November 2021. Entries can be filtered by the 'PBT assessment outcome' and the resulting numbers were extracted for the entries rated as 'PBT/vPvB' and 'not PBT/vPvB'. These numbers only relate to substances for which a PBT assessment according to the REACH Regulation is required. Furthermore, other possible results of the PBT assessment (e.g. when further information is necessary) were not considered.

Number of PMT substances

Table 41 summarises the relevant numbers included in ECHA (2021a).

Table 41: Summary of the estimated number of PMT/vPvM substances by ECHA					
	Annex X substances				**All substances**
	Basket 1	**Basket 2 total**	**Basket 2***	**PMT/vPvM total****	**PMT/vPvM total**
PMT	0				
vPvM	0				
PMT & vPvM	0				
PMT/vPvM Total	0	84	21	21	231
*Notes: * Application of the ECHA WF approach (see above). ** Sum of basket 1 and basket 2*.*					

Subsequent analyses follow the same approach as described above for PBT/vPvB properties. Table 42 shows the assignment of PMT/vPvM categories in this impact assessment to the WF assigned by ECHA. Note again that this assignment is performed in this impact assessment and was not done by ECHA.

Table 42: WF assigned by ECHA and resulting classification		
	Substance assigned to category	
Substance-specific WF (all possible values)	**AA-1 (lower end)**	**AA-2 (upper end)**
0.1	Not PMT/vPvM	Not PMT/vPvM
0.3	Not PMT/vPvM	PMT/vPvM
0.8	PMT/vPvM	PMT/vPvM

The number of substances identified as PMT/vPvM can be compared to the ECHA estimate. Table 43 provides the estimates for all three approaches.

Table 43: Estimated number of substances expected to be identified as PMT/vPvM	
Approach	**PMT/vPvM**
AA-1	0
ECHA	231
AA-2	693

The alternative analysis AA-1 does not identify any substance as being PMT/vPvM, since:

- No Annex X substance with these properties is included in ECHA's basket 1; and
- No substance with a WF of 0.8 exists among Annex X basket 2 substances.[138] While it is entirely unrealistic that no substance will be classified for PMT/vPvM properties, the approach applied in this study does not allow estimating the respective number. Consequently, no lower-end estimate can be provided.

[138] A WF of 0.8 is only assigned to two substances in basket 2 that are not registered under REACH Annex X.

These analyses suggest a relatively wide range of the number of substances expected to be identified as PMT/vPvM (none or almost 700 substances). Like for PBT/vPvB properties, this relatively wide range results from the fact that the majority of the 84 basket 2 substances in the evaluation (N=63, 75%) is assigned a WF of 0.3. These 63 substances are identified as not PMT/vPvM in AA-1, while they are assigned to the PMT/vPvM group in AA-2.

Impact of the log Koc cut-off values and assignment to hazard classes

The current[139] proposal by the European Commission for the mobility assessment suggests a decrease of the cut-off values proposed by the German UBA from log Koc < 4 to log Koc < 3 ('M' criterion) and from log Koc < 3 to log Koc < 2 ('vM' criterion).[140] The impact of such a change is discussed here in the context of the allocation of the number of substances to the two envisaged hazard classes PMT and vPvM.

ECHA evaluation does not differentiate PMT and vPvM properties for basket 1 or basket 2 substances. Furthermore, an assessment based on an ECHA list (as shown above according to the PBT Assessment List) is not possible, since a 'PMT Assessment List' does not exist. Therefore, an evaluation like the one performed for PBT/vPvB properties is not feasible.

Therefore, analyses based on log Koc are performed, which is currently proposed as the sole parameter for the mobility assessment. In principle, such evaluations could be based on log Koc values reported in ECHA's database on registered substances. However, there are several limitations to such an approach:

- For any given substance, several log Koc values may exist. In such situations, the data would need to be evaluated and a single value (or an adequate range) be derived.
- The log Koc values reported may be predicted values in a substantial number of cases and log Koc predictions may also be reported for substances that are outside the applicability domain of the models used. Again, an evaluation/curation step would be necessary prior to using such values for the purpose of this study.

Based on these limitations and the timeframe of this study, a different approach is applied that uses a dataset of substances registered under REACH. This dataset was previously evaluated for a study on emerging chemical risks in the food chain for the European Food Safety Authority (Oltmanns et al., 2019; Oltmanns et al., 2020).[141] The dataset of 2,336 substances (hereinafter 'EFSA dataset') was generated from all substances registered under REACH, excluding intermediate registrations and NONS (considered registered under REACH). The dataset was further limited to substances that have an assigned CAS number and are likely to be within the applicability domain of the models used in the EFSA study to predict biodegradation and bioaccumulation in food or feed. The data curation and evaluation steps excluded metals, metalloids, organometallic substances, inorganic and ionisable substances and ensured that a reliable SMILES notation was available.

The SMILES notations of these 2,336 substances were used to predict log Koc in the KOCWIN (v. 2.01) module of the US EPA's EpiSuite (US EPA, 2011). Both KOCWIN

[139] As of December 2021.
[140] Referred to as 'UBA criteria' and 'COM criteria' below.
[141] The full dataset, including SMILES notations is available at: https://zenodo.org/record/2613616#.YYaDJ7oo-Uk, accessed 5 November 2021.

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models were used: one being based on log Kow and the second one being based on the molecular connectivity index (MCI), resulting in two log Koc values for each of the 2,336 substances. For each substance, the minimum and the maximum value were derived. The following evaluations are performed for both the minimum and the maximum log Koc value per substance. Furthermore, experimental log Koc data in this software were extracted and analysed.

In a first evaluation, the substances identified as M/vM in the EFSA dataset were compared with respect to the origin of the log Koc and the two different criteria for the cut-off. Table 44 provides the results of this evaluation, showing that 66%-75% of the substances have a predicted log Koc <4 and would be considered M/vM according to the UBA criteria. When experimental log Koc values are used, this fraction increases to 80%. These percentages are slightly lower than the fraction quoted in ECHA (2021a) (81%) based on running QSAR models on a very large database (performed by the Dutch RIVM; no further details are provided). The data also show that 49%-62% of the substances have predicted log Koc values <3 and would therefore meet the Commission's criteria. Again, these fractions are somewhat lower than the fraction quoted in ECHA (2021a) (65%), which in turn is lower than the one based on experimental values.

Reducing the log Koc (as in the Commission proposal) results in a decrease of the substances identified as M/vM by 11-25%. While the effect is less pronounced for the experimental log Koc values (from EpiSuite), the dataset is comparatively small (N=136). Giving less weight to this lower percentage, a reduction of the fraction of M/vM substances due to the lower log Koc cut-offs proposed by the European Commission is likely to be in the range of about 15-25% (rounded). This finding is similar to preliminary estimates quoted in ECHA (2021a) from which a reduction by about 20-35% can be inferred.[142] In contrast to the preliminary and unpublished findings quoted in the report, however, the data presented here are based on a single dataset using three different sets of log Koc values.

Table 44: Summary of substances identified as M/vM based on the EFSA dataset

Basis	**UBA criteria***	**COM criteria***	**Reduction by****
Minimum predicted log Koc	1,755 (75%)	1,449 (62%)	306 (17%)
Maximum predicted log Koc	1,534 (66%)	1,145 (49%)	389 (25%)
Experimental (from EpiSuite) log Koc	109 (80%)	97 (71%)	12 (11%)

*Notes: * These percentages refer to the fraction of the total dataset (N=2336; N=136 for experimental data).*
*** These percentages refer to the reduction by applying the COM criteria (e.g. 306 / 1755 = 17%).*

For more detailed analyses, each of the 2,336 substances was rated as 'M' or 'vM' according to the different sources (minimum, maximum or experimental log Koc) and the two classification schemes (i.e. different cut-offs for log Koc). Table 45 summarises the results of these analyses and highlights the fraction of substances considered only mobile (M, but not

[142] The report quotes unpublished evidence that about 81% of chemicals have log Koc < 4, while 65% have a log Koc < 3 and 41% have a log Koc < 2. Thus, lowering the log Koc cut-off from 4 to 3 results in 16% less chemicals being identified as 'M' (a reduction by 16%. A higher reduction can be inferred for vM properties.

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vM) among those considered M/vM. It also shows the total numbers already provided in Table 44.

Table 45: Summary of the mobility assessment of the EFSA dataset according to log Koc criteria and source of the value

Basis		UBA criteria	COM criteria
Minimum predicted log Koc	vM	1,449	936
	M	306	513
	Total M/vM	1755	1,449
	M (but not vM), fraction of total M/vM	17%	35%
Maximum predicted log Koc	vM	1,145	642
	M	389	503
	Total M/vM	1,534	1,145
	M (but not vM), fraction of total M/vM	25%	44%
Experimental (from EpiSuite) log Koc	vM	97	51
	M	12	46
	Total M/vM	109	97
	M (but not vM), fraction of total M/vM	11%	47%
Weighted mean	M (but not vM), fraction of total M/vM	21%	39%
Overall estimate	**M (but not vM), fraction of total M/vM**	**20%**	**40%**
	vM (but not M), fraction of total M/vM	**80%**	**60%**

Use of the maximum log Koc increases the fraction of substances considered 'M' (but not 'vM') compared to use of the minimum log Koc. This finding is not surprising, since a substance with – for example – a minimum log Koc of 1.5 and a maximum log Koc of 2.5 will move from the 'vM' group to the 'M' group under the Commission's criteria. The same trend is observed if the UBA criteria are applied.

Lowering the log Koc cut-offs by one log unit in the Commission's criteria (when compared with the UBA criteria) also has the expected effects of a lower number of substances identified as M/vM and a higher fraction of substances considered 'M' (but not 'vM') among those identified as M/vM. The experimental log Koc show a similar pattern, but the small number of experimental data limit the findings of this evaluation. Overall, the fraction of substances to be considered 'M' (but not 'vM') among those identified as either 'M' or 'vM' is 20% if the UBA criteria are applied and is 40% if the Commission's criteria are applied. Consequently, 80% of these substances are considered 'vM' according to the UBA criteria, and 60% are considered 'vM' according to the Commission's criteria. Combining both the impact of lowering the log Koc cut-offs and assigning substances identified as PMT/vPvM to either of the two envisaged hazard classes is a complex issue. We apply the following approach:

- Although ECHA estimate of the number of substances identified as PMT/vPvM is apparently largely based on the UBA criteria, the total number of 231 is not reduced. This approach accounts for the suggestion in ECHA (2021a) that the number of basket 2 substances 'may to some extent underestimate the number of potential PMT/vPvMs'.

The assignment to either of the two hazard classes is performed based on the fractions derived above with respect to the Commission's criteria and the UBA criteria. Using the Commission's criteria, 40% of the 231 substances identified as PMT/vPvM (N=92) are

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assigned to the PMT group, while 60% (N=139) are assigned to the vPvM group in the ECHA approach.

Table 46 summarises the resulting split between PMT and vPvM substances.[143]

Table 46: Estimated number of substances expected to be classified as PMT and vPvM based on the Commission's criteria and comparison with UBA criteria

Approach	PMT			vPvM		
	EC	UBA	EC-UBA	EC	UBA	EC-UBA
ECHA	92	46	+46	139	185	-46
AA-2	277	139	+138	416	554	-138

Applying the Commission's criteria for log Koc therefore results in a shift of 46 substances from the vPvM group to the PMT group in the ECHA approach (139 substances in the AA-2 approach).

The key assumption in using the figures to differentiate between 'M' and 'vM' substances for these estimates is that a shift from 'vM' to 'M' equals a shift from vPvM to PMT. This assumption is not entirely valid, since it may concern substances that are not toxic. Consequently, such substances would rather move from the 'vPvM' hazard class to no hazard class. This assumption cannot be verified based on the approach of this study since the projections do not relate to specific substances. Such evaluations would in principle be possible for basket 2 substances, but this would require an analysis of log Koc values (see discussion above) as well as a review and evaluation of the toxicity data for each substance. These analyses are not possible given their resource-intensive nature and the timeframe of this study.

Data from a UBA study (Arp and Hale, 2019) aiming to predict the number of substances that would be identified as PMT/vPvM are therefore used to further analyse this issue. This study estimated the number of REACH registered substances (as of 2017) that would be identified as PMT (N=58), vPvM (N=47) and PMT & vPvM (N=155), resulting in a total of 260 substances. If the group PMT & vPvM is added to both the PMT and the vPvM group, 213 substances (51%) are assigned to the PMT group and 202 substances (49%) to the vPvM group (percentages relate to the total of 415 theoretical substances). In contrast to the approach based on the EFSA dataset, these figures better reflect all properties (i.e. persistence, mobility and toxicity) and the underlying dataset also includes some substances excluded from the EFSA dataset (e.g. ionisable substances). However, mobility in this study was assessed on the basis of the UBA criteria for log Koc.

Figure 65 illustrates the division into the two hazard classes for the 231 substances identified as PMT/vPvM in the ECHA approach (left plot) and for the 693 substances from the upper end (AA-2) approach. In both plots:

- the left columns show the estimates derived in this study using the split to PMT and vPvM of 40% and 60%, respectively, derived from dataset of 2,336 substances using the Commission's criteria for log Koc cut-offs;

[143] As explained above, no lower end (AA-1) estimate can be provided.

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- the central columns show the estimates derived in this study using the split to PMT and vPvM of 20% and 80%, respectively, derived from dataset of 2,336 substances using the UBA criteria for log Koc cut-offs; and
- the right columns show the estimates derived in this study using the split to PMT and vPvM of 51% and 49%, respectively, derived from the UBA study (Arp and Hale, 2019).

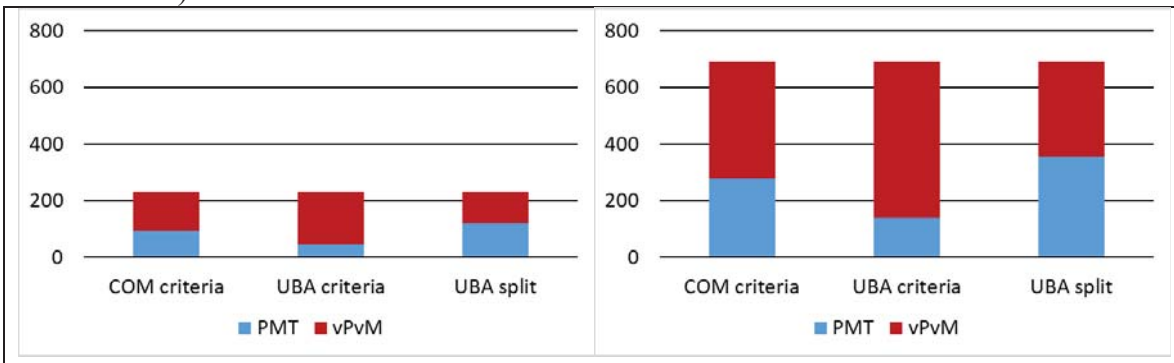

Figure 65: Number of substances assigned to the two hazard classes. Left: total number of PMT/vPvM substances based on ECHA estimate (N=231); right: total number of PMT/vPvM substances based on upper estimate AA-2 (N=693)

The split into PMT and vPvM according to the UBA criteria results in 1.3 times more vPvM substances than the one based on the Commission's criteria, because of the differences noted in the evaluation of the dataset of 2,336 substances (i.e. 80% vs. 60%; see above). The number of PMT substances is consequently lower. In both cases, this split is derived from an evaluation of the EFSA dataset that only addresses log Koc as the mobility criterion with the limitation discussed above. The split from the Arp and Hale (2019) covers all three relevant properties as well as some groups of substances not covered by the EFSA dataset, but is based on the UBA criteria for log Koc. The number of substances assigned to the vPvM group is lower in the UBA split than in both other approaches, reflecting the lower fraction of 49% compared to 60% and 80% based on Commission's and UBA criteria (see above). Table 47 shows the number of substances plotted in Figure 65 for easier reference.

Table 47: Estimated number of substances expected to be classified as PMT and vPvM based on different splits between PMT and vPvM

Approach	PMT			vPvM		
	EC criteria	UBA criteria	UBA split	EC criteria	UBA criteria	UBA split
ECHA (N=231)	**92**	46	119	**139**	185	112
AA-2 (N=693)	**277**	139	356	**416**	554	337

Notes: Unrounded percentages were used for splitting all PMT/vPvM substances between the two hazard classes.

These evaluations demonstrate that the numbers assigned to PMT and vPvM hazard classes based on the Commission's criteria range between those derived with the UBA criteria and the ones calculated using the split derived from the UBA study. The numbers resulting from the split using the COM criteria are used in this study for the following reasons:

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They range between the other two approaches but are closer to the numbers derived by using the split from the UBA study than the ones derived using UBA criteria on the EFSA dataset.

The split derived from the UBA study may be considered somewhat less uncertain than the ones derived from the EFSA dataset (using Commission's or UBA criteria for the log Koc cut-offs). However, the UBA split is based on UBA criteria for log Koc cut-offs, and the number derived using this split are not taken directly. The fact that the numbers estimated using the Commission's criteria are closer to the ones calculated with the UBA split than the ones using the UBA criteria supports the derivation used here.

The central estimate based on the total number of 231 expected to be classified as PMT/vPvM, as derived in ECHA (2021a), results in a lower number of vPvM substances based on the Commission's criteria (N=139) compared to the UBA criteria for log Koc (N=185).[144] However, the upper end estimate derived in this study for this hazard class based on Commission's criteria (N=416) is more than 2-times higher.

Final estimates

Table 48 summarises the final estimates, providing both a central estimate representing the total number of expected PMT/vPvM derived in ECHA (2021a) (N=231) as well as an upper-end estimate (N=693) and the split into the two envisaged hazard classes as derived above. Possible ranges for the split are indicated in brackets but are not used in the impact assessment.

Table 48: Final estimate on the number of substances expected to be classified as PMT and vPvM

Type of estimate	**PMT/vPvM**	**PMT**	**vPvM**
Central estimate (ECHA approach)	**231**	**92** (46-119)	**139** (112-185)
Upper-end estimate (AA-2 approach)	**693**	**277** (139-356)	**416** (337-554)

These numbers represent very rough estimates. As noted earlier, the apparent accuracy of the estimates is spurious, but the numbers are provided to increase transparency and to allow cross-checking of calculations. The uncertainties of these estimates relate to the following issues:

- ECHA (2021a) considers the basket 3 estimate (i.e. the figure of 231 substances expected to be identified as PMT/vPvM) as a guestimate and therefore highly uncertain.
- For PMT/vPvM properties, the ECHA assessment is largely based on lists compiled by other authors with most substances coming from a study by the Danish Technical University (DTU) that almost exclusively relied on predicted data with respect to persistence, mobility and toxicity (Holmberg et al., 2021). In fact, all Annex X substances in basket 2 used to estimate the upper end (N=63 substances, multiplied by 11, resulting in 693 substances) come from this source. Predicted properties are considered uncertain (as is also suggested by the low WF assigned). The upper-end estimate may therefore turn out to be an overestimate.

[144] Note that the 46 substances move from the vPvM to the PMT group under the COM criteria.

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The log Koc values used in the analyses of this study also represent predicted values and the above analyses illustrate the differences between e.g. the use of minimum and maximum log Koc values. The associated uncertainty has an impact on:

- the comparison of Commission's criteria for the mobility assessment with those proposed by UBA;
- the fraction assigned to the envisaged hazard classes PMT and vPvM.

It must be noted, however, that other approaches to estimate the number of PMT/vPvM substances also largely rely on predicted log Koc values. In fact, the DTU study employed three different prediction models to assess mobility, together with two persistence models and several approaches to assess toxicity (Holmberg et al., 2021).

The evaluation of log Koc values in this study and their impacts on the mobility assessment using different cut-offs as well as the assignment to the two envisaged hazard classes is limited by the fact that it covers almost exclusively mono-constituent neural organic substances. This limitation also applies to the DTU study as noted in ECHA (2021a). The complexity of the mobility assessment e.g. for ionisable substances and UVCBs is therefore not covered by this assessment.

The 231 substances identified as PMT/vPvM in the central estimate represent 1% of the total number of 23,751 unique substances in ECHA's combined inventory. This estimate is in line with an earlier estimate by the German UBA that 260 of the 15,469 REACH registered substances (around 1.7%) would be identified as PMT/vPvM substances (Arp and Hale, 2019). If the information from the UBA study is linearly extrapolated to the 23,751 substances in ECHA's combined inventory, 399 substances would be identified as PMT/vPvM substances. This value is substantially lower than the upper end estimate used in this study (N=693). This comparison increases the confidence in the estimates derived in this study.

The DTU study (Holmberg et al., 2021) produces several different outcomes depending on the models chosen to assess persistence and mobility (both entirely based on predictions). The number of substances identified in this screening exercise as potential PMT/vPvM substances in a dataset of 2,073 REACH registered mono-constituent chemicals ranged from 53 (2.6%) to 262 (13%). These fractions are substantially higher than estimated here or in the UBA study (Arp and Hale, 2019). Most likely, this difference is due to the sole reliance of predicted values. Holmberg et al. (2021) considered a set of 29 substances as deserving scrutiny by regulatory agencies, since these substances were identified in the DTU approach as well as in an earlier UBA study performed by the Norwegian Geotechnical Institute (NGI). If these 29 substances are taken as an indication of the substances that would be classified as PMT/vPvM (out of the 2,073 substances evaluated) in the future, the resulting fraction of 1.4% is in line with the estimates presented above.

However, according to Holmberg et al. (2021), the substances identified as PMT/vPvM differed in most cases from the ones by NGI in in the earlier UBA study. The differences noted are due to differences in substance selection and methodological differences in data generation and evaluation. However, even if only substances included in the NGI list and the DTU list are considered, only about one fourth of the substances identified as PMT/vPvM in the NGI list are also identified by DTU as PMT/vPvM (the 29 substances mentioned above). This comparatively low level of agreement is due to the different methods in predicting PMT/vPvM properties.

Overall, given the uncertainties discussed and the different approaches applied to estimate the number of PMT/vPvM, the alignment of the estimates in this study with the ones in the UBA study is noteworthy. The upper-end estimate provided here – although not specifically addressing these uncertainties – may be considered a reflection of the high overall uncertainty in deriving figures for the number of substances with PMT/vPvM properties and the assignment to the two envisaged hazard classes.

SCREENING AND ASSESSMENT OF THE POTENTIAL MEASURES

Economic, social and environmental impacts of policy option 1a: adding new hazard classes

Direct and indirect costs of the introduction of new hazard classes in CLP

A cost-benefit analysis requires that the relevant costs (those with policy action minus the costs of the baseline) accruing to any agent affected by the policy — including manufacturers and importers of chemicals, downstream users, public authorities and consumers — are estimated. Cost also relates to any loss of human wellbeing: for example, if the actors substitute the newly classified chemicals with alternatives that are safer from a human health perspective but are less efficient from a technical perspective, then the loss of beneficial use of the chemicals constitutes a cost. Ideally, understanding and calculating who bears the costs involve a dynamic general equilibrium model of the chemicals sector and beyond. Such a detailed model is not available, and therefore costs are estimated rudimentary by multiplying number of chemical products (substances and mixtures) to be classified, notified and labelled, and the unit costs for classification, notification and labelling. These are referred to as the **direct costs** of CLP.

Table 49 provides the total number of substances under low, main, and high estimate scenarios that are:

Already known to meet the proposed criteria for classification for each hazard;

Are expected to be identified by ongoing assessment (mainly under REACH) as meeting the proposed criteria; and

Are expected to be identified in the future by a combination of further information generation under REACH and/or prioritisation processes yet to be applied to the substances.

The methodological approach to estimating the number of substances expected to be classified for ED, PBT/vPvB or PMT/vPvM properties has been summarised in the sections above. As already mentioned, these numbers have been derived to inform the impact assessment and are associated with substantial uncertainty owing to the fact that the final criteria required for the classification as ED (including categorisation and differentiation by impact area) and for mobility are not yet fully available. Separate legislative proposals to alter the information requirements under REACH to include ED are being examined in the separate study 'Gather further information to be used in support of an Impact Assessment of potential options, for the update of REACH Annexes for inclusion of data requirements on endocrine disruption'. It must be stressed that – even if the estimated numbers prove to be close to the real numbers – they would only materialise if all necessary studies have been conducted for all substances.

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Table 49: Estimated number of substances expected to be identified as ED (with categorisation), PBT/vPvB and PMT/vPvM				
Type of estimate		**Lower end (AA-1)**	**Central estimate (based on ECHA approach)**	**Upper end (AA-2)**
ED Cat. 1	HH	334	405	510
	ENV	502	607	766
ED Cat. 2	HH	374	453	572
	ENV	562	680	857
ED Total	HH	708	858	1 082
	ENV	1 064	1 287	1 623
	All*	**1 772***	**2 145***	**2 705***
PBT		64	178	381
vPvB		79	218	466
PBT/vPvB tot.		**143**	**396**	**847**
PMT		46**	92	277
vPvM		112**	139	416
PMT/vPvM tot.		**158****	**231**	**693**

As noted in Ricardo (2021), 'the inclusion of new hazard classes in CLP will not result in an immediate EU-harmonization of classifications to the new hazard classes. The process will take place gradually, following the harmonised classification and labelling (CLH) processes and subject to the existing or newly generated evidence necessary to support classification, as well as resource availability from authorities'.

It is assumed that policy option 1a would enter into force in 2023 and, as a consequence, those substances already identified as entailing these hazards would have to be classified and labelled accordingly. As presented in the baseline, 113 substances have been identified as having ED properties, but only 13 are still registered and therefore on the market, although for some substances currently classified as toxic to the reproductive system there may be already sufficient information for a classification as EDs. While CLP requirements cover all substances, including those not registered, the main driver to the identification of EDs will be the inclusion of additional testing requirements in REACH and the follow-up activities to the screening of the chemical universe of registered substances to identify substances of concern carried out in the framework of the IRS by ECHA and MSCAs. It is assumed that the inclusion of ED testing requirements in REACH would result in the identification of ED substances over time, as registrants submit testing proposals and generate information, and ECHA carries compliance check, testing proposal examination and substance evaluation and ask for additional data. Indeed, many substances would be identified through follow-up activities by ECHA and MSCAs, e.g. asking for additional or different tests. It is assumed that the new hazard classes — or better, the new endpoints — will be included among those endpoints[145] for which scoping review, compliance check and request of missing information are always performed. As illustrative examples, a typical PBT battery of simulation, bioaccumulation and aquatic toxicity may take between three to five years to carry out. A

[145] So-called 'super endpoints': genotoxicity, repeated-dose toxicity, pre-natal development toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

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basic Extended One-Generation Reproductive Toxicity Study (EOGRTS) study takes minimum two years and requires assessment prior to testing and again afterwards to check test compliance. Moreover, companies may face limited laboratory capacity to contract the testing, further delaying the generation and checking of data.[146]

It is likely that also for PMT/vPvM substances there will be generation of new data, following the revision of REACH information requirements to ensure adequate data for classification.[147] For PBT/vPvB properties, it is assumed that the REACH Annex XIII identification criteria are moved to Annex I of CLP, but the requirement for a PBT/vPvB assessment remain for substances manufactured or imported in quantities of 10 tonnes or more per year per registrant (Article 14 of REACH).

In summary, the substances that are expected to be (self-)classified, labelled and notified for the new hazard classes will be identified through the generation of new data because of new information requirements and follow up activities by ECHA and MSCAs. Table 50 shows the lower end, central, and upper end estimates of the number of substances that could have the considered properties

Table 50: Number of substances expected to be classified for the new hazard classes

	ED	PBT/vPvB	PMT/vPvM
Number of substances – lower end estimate	1,772	143	158
Number of substances - central estimate	2145	396	231
Number of substances – upper end estimate	2,705	847	693

More accurately, Table 50 relates to the number of classifications for substances rather than the number of substances. This is because some substances may meet the classification criteria for more than one of the hazards. To account for such overlap, ECHA's estimates for the Basket 1 (confirmed) and Basket 2 (pending conclusion) substances have been examined. For these Basket 1 and 2 substances the identity of substances is known and hence it is possible to identify which substances meet (or are being considered may meet) classification for one, two or three of the hazards (ED, PBT/vPvB and PMT/vPvM). The extent of this overlap is described in Table 51. This suggests that, of the 936 substances identified in Basket 1 or 2 by ECHA, 801 meet (or may meet) criteria for one hazard, 128 for two of the hazards and 7 for three. Thus, for 801 of the substances, a single hazard is captured in any cycle of re-classification for a substance, for 128, two hazards are captured in any cycle of reclassification and for 7, three hazards are captured resulting in an average of 1.15 hazards per substance. To account for this overlap when calculating costs per hazard identified, costs of the actions required have been adjusted to 87% of the unit costs.

Table 51: Overlap in substances meeting one or more hazard criteria

	Number of substances on Basket 1 or 2	Number of hazards considered
Number with one new hazard classification	801	1
Number with two new hazard classifications	128	2

[146] See the final report of the supporting study to 'Gather Further Information to be Used in Support of an Impact Assessment of Potential Options, for the Update of REACH Annexes for Inclusion of Data Requirements on Endocrine Disruption'.

[147] Currently information requirements for simulation tests in soil and sediment and adsorption desorption can be waived if the substance is not adsorptive.

Number with three new hazard classifications	7	3
Total substances/hazards	936	1,078
Hazards per substance		1.15
Adjustment factor		0.87 (1/1.15)

Economic impacts of PO1a

PO1a: Administrative costs on businesses and conduct of business

Under PO1a, manufacturers and importers of substances meeting classification for one or more of the hazards would be required to classify the substances accordingly. Action would also be required to provide a notification to the CLI and communicate to downstream users by means of labelling and revised SDS. In turn, formulators that are incorporating the substance into mixtures would have to carry out mixture classification and label mixtures accordingly and provide necessary documentation to SDS. Depending on the outcomes, mixtures might also be reformulated. The unit costs of these activities are provided in Table 52 and adjusted by the factor of 0.87 for correct application to information on the number of substances identified with each hazard (see Table 51). The cost of classification and SDS revision of PBT/vPvB substances is not accounted for, as PBT/vPvB assessment is already obligatory under REACH, although it applies to substances manufactured and imported in quantities above 10 tonnes per year per registrant only. Also for EDs, the cost of classification and SDS revision is not accounted for, as 'the inclusion of a substance in the Candidate List for authorisation due to concerns for endocrine disrupting effects triggers additional provisions for risk assessment (Chemical Safety Report) and risk communication (Safety Data Sheet)' (EC, 2020b).

Table 52: Unit costs of actions for manufacturers and importers of substances (per substance par company)

Cost Element	Base value used in calculations	As adjusted (87%)	Euro (2022)
Classification of a single substance according to CLP	€ 400	€ 347.31	€ 378
Cost of re-labelling in line with CLP	€ 388	€ 336.89	€ 367
Cost of notification*	€ 7.20	€ 6.25	€ 7.4
Total cost of classification, labelling and notification of PMT/vPvM substances	**€ 795**		**€ 752**
Total cost of labelling of ED and PBT/vPvB substances	**€ 395**	**€ 367.54**	**€ 374**
Cost of updating and distributing revised SDS	€ 250	€ 217.07	€ 237

Source: RPA et al. (2017b, p. 72)
*Notes: *0.18 hours at €40.5 per hour*

For ED and PBT/vPvB substances, the information is already required to be included in the SDS, so this cost is not accounted for.

Total cost of classification, labelling and notification of substances

The unit costs of classification, labelling and notification are expressed on a per substance per company basis and so require consideration of the number of companies manufacturing/importing each substance. The ECHA information on the identity of the Baskets 1 (confirmed) and 2 (pending) substances has been compared with REACH registration database data on the number of active registrations. From these data, the average number of registrants by company size can be extracted for each of the hazards. These data

are provided in Table 53 and suggest that there are 11.19 companies on average for substances with ED properties, 6.14 for PBT/vPvB and 6.7 for PMT/vPvM.

Table 53: Average number of companies (and percentage) with an active registration per substance by company size

	Micro	Small	Medium	Large	Total
ED	0.16 (1.4%)	0.32 (2.9%)	0.68 (6.0%)	10.03 (89.7%)	11.19
PBT/vPvB	0.04 (0.6%)	0.21 (3.3%)	0.42 (6.9%)	5.47 (89.2%)	6.14
PMT/vPvM	0.05 (0.7%)	0.24 (3.6%)	0.54 (8.1%)	5.87 (87.6%)	6.70
Overall	0.09 (1.1%)	0.27 (3.2%)	0.56 (6.7%)	7.38 (89.0%)	8.30

The data on the number of substances expected to meet each hazard criterion, the average number of companies for each hazard type (Table 53) and unit costs of the activities (Table 52) provides estimates of the total cost of classification, labelling and notification for each one of the three scenarios (Table 54).

Table 54: Total cost of classification, labelling and notification (and SDS revision)

	ED	PBT/vPvB	PMT/vPvM	Total
Lower end estimate	€7,421,125.99	€329,100.23	€1,047,288.48	€8,797,514.70
Central estimate	€8,983,247.89	€911,354.49	€1,531,162.27	€11,425,764.65
Upper end estimate	€11,328,524.72	€1,949,285.99	€4,593,486.81	€17,871,297.52

Total cost of PO1a for substances

Table 55 provides the total cost of all activities in relation to PO1 for manufacturers and importers of substances, combining cost from updating and distributing revised SDS and cost of classification, labelling and notification, assuming that all the substances expected to meet the criteria for classification according to the new hazard classes will be identified over a period of 20 years. Table 55 provides the present value — discount rate of 3% — of the total costs for companies of different size and in total for the number of substances meeting the criteria.

Table 55: Present value of the total cost of PO1-a for substances - (20 years, discount rate: 3%)

Lower end (AA-1)	Micro	Small	Medium	Large	Total
Lower end	€ 8,000	€17,000	€ 36,000	€530,000	€ 591,000
Central estimate	€ 5,000	€26,000	€ 53,000	€685,000	€ 768,000
Upper end	€ 9,000	€43,000	€ 97,000	€ 1,052,000	€ 1,201,000

Costs of PO1a to manufacturers and importers of mixtures

Manufacturers and importers of mixtures containing substances identified as meeting classification for ED and/or PBT/vPvB and/or PMT/vPvM would have to carry out mixture classification and label mixtures accordingly. For PMT/vPvM substance, manufacturers and importers would have to revise and provide necessary documentation in SDS. Depending on the outcomes, mixtures might also be reformulated.

Number of mixtures per substance

Table 56 shows the estimates of the number of mixtures containing substances identified with ED, PBT/vPvB and/or PMT/vPvM properties, obtained by applying the two factors (11 and 25 mixtures per substance) presented in the baseline.

Table 56: Number of mixtures for all substances with new hazard class

Factor: 11	**ED**	**PBT/vPvB**	**PMT/vPvM**
Lower end estimate	19,492	1,573	1,738
Central estimate	23,595	4,356	2,541
Upper end estimate	29,755	9,317	7,623
Factor: 25	**ED**	**PBT/vPvB**	**PMT/vPvM**
Lower end estimate	44,300	3,575	3,950
Central estimate	53,625	9,900	5,775
Upper end estimate	67,625	21,175	17,325

Unit costs

The unit costs of the CLP activities in relation to mixture manufacturers and importers are provided in Table 57 and adjusted by the 0.87 factor to account for the overlap created by some substances having more than one identified hazard. The costs of the activities are largely expressed per mixture per company. For the purpose of this assessment, it has been assumed that each mixture is manufactured uniquely by one company. Thus, all cost expressed per mixture per company are applied on a per mixture basis. The cost of the classification of mixtures containing ED and PBT/vPvB substances and the cost of updating and distributing revised SDS is not accounted for, as part of the baseline.

Table 57: Unit costs for mixtures

Cost Element	**Base value used in calculations**	**As adjusted (87%)**	**Euro (2022)**
Classification of a single mixture according to CLP	€ 200	€ 174.00	€ 190
Cost of re-labelling in line with CLP	€ 475	€ 412.43	€ 449
Cost of updating and distributing revised SDS	€ 250	€ 217.07	€ 237
Cost of classification, labelling and SDS of mixtures containing PMT/vPvM substances	**€ 925**	**€ 803.5**	**€ 876**
Cost of classification and labelling of mixtures containing ED, PBT/vPvB substances	**€ 675**	**€ 586.43**	**€ 639**
Re-formulation of mixtures due to changes in hazard classification	€ 15,000	€ 13,024	€ 14,182

Source: RPA et al. (2017b, p. 72)
Notes: it is assumed that classifying mixtures requires half of the time of classifying substances, as it entails the comparison of concentration limits.

The introduction of new hazard classes in CLP also entails **indirect costs** for businesses, in the form of substitution of chemical substances and reformulation of mixtures and withdrawal from the market of substances and mixtures that may be classified.

As noted by Ricardo (2021), 'These reclassifications could also have indirect impacts, for example, companies may consider product discontinuation or substitution (e.g., as seen for CMR in fast moving consumer goods, fluorinated substances in food packaging in Denmark, etc.). This is driven by non-legislative pressures such as the SIN-list, pressure from retailers, expectations from consumers and professionals, ecolabelling schemes, etc.'.

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There are two basic approaches to risk management often used in combination, in the EU chemicals acquis: one based on specific risk assessment and the other one based on generic risk considerations (GRC). The main difference between these two approaches is the point in time when the exposure assessment is considered and the specificity of the exposure assessment. For risk management based on GRC, the potential exposures and risks are considered generically, prior to the adoption of legislation. The GRC-based approach is built into the legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of the chemical determined under CLP, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. Companies consulted in the context of the Ricardo (2021) study estimated that around 43% of their product portfolio would be affected by the inclusion of new hazard classes to CLP and the extension of the GRC-based approach. Indeed, substances and mixtures reclassified for the new hazard classes would be affected by the application of the GRC-based approach, where a CLH triggers the restriction or ban of a classified substance for some specific or all uses. This impact should be accounted for by the parallel studies supporting the revision of the REACH Regulation.[148]

Some products will not be directly affected by changes to the application of the GRC-based approach, but CLP classification and labelling for the new hazard classes may still put pressure for market withdrawal or substitution and reformulation. The "total potentially affected portfolio" considers the inclusion of hazard classes for immunotoxic and neurotoxic substances in addition to ED, PBT/vPvB and PMT/vPvM, and also the extension of the GRC-based approach to consumer and professional uses via REACH restriction and sector specific legislation to respiratory sensitisers and STOT RE/SE, immunotoxic and neurotoxic substances, skin sensitisers 1, 1A and 1B, CMR 2 and substances toxic to the aquatic environment with long lasting effects (chronic) 1 and 2. The portion of the products that is affected by changes to CLP and not the GRC-based approach is estimated as 31% of the total potentially affected product portfolio in terms of turnover (Ricardo, 2021, p.59).

Moreover, Ricardo (2021) assumes that a quarter (25%) of the products not affected by the GRC-based approach but directly by CLP would face indirect market pressure to substitute and reformulate or withdraw from the market (Ricardo, 2021, p.59). Participants to the bespoke survey of Cefic business members in the context of the Ricardo (2021) study reported that they would be able to substitute and/or reformulate around 35% of the products (in terms of turnover) that may be affected by the changes to the GRC-based approach application and CLP. These two percentages are used as lower (9%)[149] and upper (25%) bounds of the number of mixtures that would be reformulated as a result of the classification for ED, PBT/vPvB and PMT/vPvM properties.

Ricardo (2021) estimates that CLP could be responsible for the reduction of 1% of the total potentially affected portfolio, equivalent to around €5.8 billion.[150] However, this figure should be considered as illustration of the size of the sectors involved rather than an indicator of economic losses. A better measure would be the 'value added foregone', which could be

[148] In particular, the "Study to support the impact assessment for potential amendments of the REACH Regulation, to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation ad restriction" (GRO/IMA/21/2123/12108).
[149] 35% of 25% of mixtures.
[150] Information provided by Cefic in response to a request by the European Commission.

estimated by subtracting the cost of all inputs except capital and labour from the production value. But even this measure cannot be treated as costs in a cost-benefit analysis or cost-effectiveness analysis, and it is certainly 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.

Cost of classification, labelling, SDS revision and reformulation for mixtures

The cost of classification, labelling and SDS revision for mixtures is calculated by combining the estimates of the number of mixtures in Table 56 with the unit costs for mixtures in Table 57. A range between 9% and 25% of the total number of mixtures are assumed to be reformulated. This provides the estimated costs in thousands of euros (Table 58) for numbers of substances identified.

Table 58: Total cost of classification, labelling, SDS revision and reformulation of mixtures

Factor: 11 Reformulation: 9%	**ED**	**PBT/vPvB**	**PMT/vPvM**	**Total**
Lower end estimate	€405,081,092.00	€17,931,330.74	€24,143,460.76	€447,155,883.49
Central estimate	€490,349,290.25	€49,655,992.81	€35,298,350.85	€575,303,633.91
Upper end estimate	€618,365,888.18	€106,208,651.28	€105,895,052.55	€830,469,592.01
Factor: 11 Reformulation: 25%	**ED**	**PBT/vPvB**	**PMT/vPvM**	**Total**
Lower end estimate	€877,537,246.96	€38,845,087.86	€48,932,209.57	€965,314,544.38
Central estimate	€1,062,255,866.10	€107,571,012.53	€71,540,129.18	€1,241,367,007.80
Upper end estimate	€1,339,581,406.90	€230,082,443.46	€214,620,387.53	€1,784,284,237.89
Factor: 25 Reformulation: 25%	**ED**	**PBT/vPvB**	**PMT/vPvM**	**Total**
Lower end estimate	€920,638,845.44	€40,753,024.40	€54,871,501.72	€1,016,263,371.56
Central estimate	€1,114,430,205.12	€112,854,529.10	€80,223,524.66	€1,307,508,258.89
Upper end estimate	€1,405,377,018.58	€241,383,298.36	€240,670,573.99	€1,887,430,890.93
Factor: 25 Reformulation: 25%	**ED**	**PBT/vPvB**	**PMT/vPvM**	**Total**
Lower end estimate	€1,994,402,834.00	€88,284,290.58	€111,209,567.20	€2,193,896,691.78
Central estimate	€2,414,217,877.50	€244,479,573.92	€162,591,202.67	€2,821,288,654.10
Upper end estimate	€3,044,503,197.50	€522,914,644.23	€487,773,608.02	€4,055,191,449.75

Total cost of PO1a for mixtures

Table 58 provides the total cost of all activities in relation to PO1a for manufacturers and importers of mixtures, combining cost from updating and distributing revised SDS and cost of classification and labelling, assuming that a range between 9% and 25% of the total number of mixtures will be reformulated.

Table 59 provides the present value — discount rate of 3% — of the total costs for companies of different size and in total for the number of mixtures meeting the criteria.

Table 59: Present value of the total cost of PO1-a for mixtures (20 years, discount rate: 3%) – rounded to the nearest thousand

Factor: 11 Reformulation: 9%	**Micro**	**Small**	**Medium**	**Large**	**Total**
Lower end estimate	€ 424,000	€ 860,000	€ 1,814,000	€ 26,958,000	€ 30,056,000
Central estimate	€ 230,000	€ 1,294,000	€ 2,650,000	€ 34,496,000	€ 38,669,000
Upper end estimate	€ 409,000	€ 1,999,000	€ 4,527,000	€ 48,885,000	€ 55,821,000

Factor: 25 Reformulation: 9%	Micro	Small	Medium	Large	Total
Lower end estimate	€ 963,000	€1,954,000	€ 4,124,000	€ 61,268,000	€ 68,309,000
Central estimate	€ 522,000	€2,941,000	€ 6,023,000	€ 78,399,000	€ 87,885,000
Upper end estimate	€ 930,000	€4,543,000	€10,289,000	€ 111,103,000	€ 126,865,000
Factor: 11 Reformulation: 25%	**Micro**	**Small**	**Medium**	**Large**	**Total**
Lower end estimate	€914,000	€ 1,856,000	€ 3,917,000	€ 58,197,000	€ 64,884,000
Central estimate	€495,000	€ 2,792,000	€ 5,719,000	€ 74,433,000	€ 83,439,000
Upper end estimate	€880,000	€ 4,294,000	€ 9,727,000	€105,031,000	€119,932,000
Factor: 25 Reformulation: 25%	**Micro**	**Small**	**Medium**	**Large**	**Total**
Lower end estimate	€914,000	€ 1,856,000	€3,917,000	€ 58,197,000	€ 147,464,000
Central estimate	€495,000	€ 2,792,000	€5,719,000	€ 74,433,000	€ 189,635,000
Upper end estimate	€880,000	€ 4,294,000	€9,727,000	€ 105,031,000	€ 272,573,000

Grand total costs of PO1

The grand total cost of the inclusion of the new hazard classes is the sum of the costs of classification, labelling, notification and SDS revision of substances and mixtures and the reformulation of mixtures. The central estimate of the present value (discount rate: 3%) is in the range €39M - €190M, with a lower end estimate of €30M and an upper end estimate of €273M.

Table 60: Present value of the grand total costs of CLP activities on PO1-a (discount rate: 3%)

	Reformulation: 9% of mixtures		Reformulation: 25% of mixtures	
	Based on 11 mixtures per substance	**Based on 25 mixtures per substance**	**Based on 11 mixtures per substance**	**Based on 25 mixtures per substance**
Total – Lower end	€30,647,000	€ 68,900,000	€65,475,000	€ 148,055,000
Total - Central estimate	€39,437,000	€ 88,653,000	€84,207,000	€ 190,403,000
Total - Upper end	€57,022,000	€ 128,066,000	€ 121,133,000	€ 273,774,000

Notes: rounded to the nearest million

The cost estimates are sensitive to the assumptions made on the number of mixtures per substance and the percentage of mixtures that would be reformulated.

Public authorities: Change in costs to the Commission, ECHA and MSCAs

In the coming years, the Commission, ECHA and MSCAs are expected to keep the current level of resources dedicated to chemical risk management. The introduction of new hazard classes in the CLP Regulation — in itself — does not entail a cost for administration but will result in a higher number of substances identified as EDs or with PBT/vPvB and PMT/vPvM properties being subject to further regulatory risk management actions, 'competing' with substances classified for other hazards of concern.

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This subsection presents a discussion over the amount of resources that would be required to prepare CLH dossiers for the number of substances that could be identified as EDs or with PBT/vPvB and PMT/vPvM properties.

ECHA has made an estimate of the resources required for development of CLH dossiers including the average time and other resources required per dossier. The development of a CLH dossier for ED/PMT/PBT hazard classes is of higher complexity than the average CLH. This is summarised in Table 61 and results in an estimated average cost per CLH of €120,500.

In the notes supporting its estimate, ECHA identify that 'dossier development' cost component has two key stages:

- the collection of data for proposing the hazard classes; and
- the drafting of the dossier.

ECHA identifies that the first stage of collecting the data will be the most challenging in respect of time management and experience in literature searching and data collection as it will require the need to acquire/access proprietary data and maybe the necessary access rights to do this. The second stage of drafting the report is identified as being more manageable.

Table 61: ECHA's estimate of resources for supporting the preparation of a complex CLH dossier

	ECHA estimate for CLH
Dossier development	0.5 FTE
RAC opinion making	0.1 FTE
Support services	0.05 FTE
Total FTE	0.65
1 FTE staff costs including 19% overhead cost and infrastructure	€170,000
Total cost of the above	€110,500
Contribution to RAC organisation cost	€10,000
Total	€120,500

The estimate of the average cost of developing CLH for a substance can now be applied to the number of substances. According to the analysis, the following estimated numbers of substances may be identified as meeting classification for each of the identified hazards. As noted earlier, there is overlap between the proposed hazard classes such that some substances may have more than one classification. In earlier parts of the analysis, it was estimated that, on average, each substance may be identified with 1.15 hazard classifications[151]. Thus, the number of substances implied is adjusted to provide the estimated number of CLH dossiers, giving a central estimate of 2,407 (ranging between 1,800 and 3,686). This assumes that there is no grouping of substances, and each substance would require its own CLH dossier. It also does not take account of the fact that some of the substances may already have a hazard classification that requires that a CLH dossier is developed (such as CMR 1A/1B).

Table 62: Number of substances for CLH

	Lower end (AA-1)	**Central estimate (ECHA approach)**	**Upper end (AA-2)**

[151] It is important to note that, considering hazard classes other than ED, PBT/vPvB and PMT/vPvM, the average number of hazard classes covered by a CLH dossier is three (analysis of CLH up to CLP ATP17).

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ED Total	**1,772**	**2,145**	**2,705**
PBT/vPvB total	143	396	847
PMT/vPvM	158	231	693
Total hazard / substance combinations	2,073	2,772	4,245
Implied substances	**1,800**	**2,407**	**3,686**

The resulting cost estimates are provided in Table 63. It should be noted that, whilst the costs provide an estimate of the financial cost of the undertakings, they do not consider the practicality of producing such large numbers of CLH proposals within a framework that currently produces 50 to 60 CLH dossiers per year. Here ECHA notes that **the feasibility of the work needs to be seen in the light of resources that would be available to ECHA as opposed to the total amount of activities (under REACH and CLP) that are foreseen for ECHA to carry out**.

ECHA also notes that the estimates are of limited scalability, meaning that in case of a relatively high demand (e.g. additional >10 CLH per year) additional overhead will need to be looked at.

Table 63: Costs of CLH proposal development under PO1-c

	Number of Substances / CLH proposals	ECHA estimate for CLH cost	Present value (20 years, 3%)
Lower end (AA-1)	1,800	€ 198,900,000	€ 13,400,000
Central estimate (ECHA approach)	2,407	€ 266,000,000	€ 17,900,000
Upper end (AA-2)	3,686	€ 407,300,000	€ 27,400,000

Considering a 20-year period, dossier submitters (ECHA, MSCAs and industry actors)[152] would have to prepare additional 120 CLH dossiers per year (central estimate; 90-184 CLHs per year), and ECHA and RAC would have to process them. Annualised costs (20-year period, 3% discount rate)[153] would sum up to €17.9 million. In terms of human resources, to prepare and process the additional number of CLH dossiers in 20 years, dossier submitters would require additional 60 FTEs per year (ECHA estimate) (CI: 45-92 FTEs), ECHA support services would require 6 FTEs (CI: 5-9 FTEs) and RAC would require additional 12 FTEs per year (CI: 9-18 FTEs).

To put these numbers in perspective with the current capacity, with the current rate of dossier of 50 per year, on the period 2023-2042 (20 years), only 1,000 dossiers will be produced. Assuming that 50% of all CLH dossiers in the next 20 years will cover one or more new hazard classes, dossier submitters would require 13 FTEs per year, ECHA support services would require 1 FTE per year and RAC would require additional 3 additional FTEs per year. The present value is €3.7M (period: 20 years; discount rate: 3%).

In addition, the ED and PBT hazard classes are expected to impact the BPC work on the approval of biocidal active substances. The BPC, based on the peer review of the conclusion of the biocide evaluating Competent Authority, is concluding on ED/PBT identification of biocidal active substances. After the introduction of ED and PBT hazard classes, the hazard

[152] The number of CLH dossiers submitted by industry actors is very small.
[153] As recommended by Tool #64 of the Better Regulation Toolbox (EC, 2021c, p.555).

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identification would rely on the harmonised classification under CLP, at least for the cases where there is a trigger for classification. This would be similar to what happens for CMR classification.

In the review programme there are approximately 200 biocidal active substances that still require ED assessment. The BPC is progressing with the evaluation, and it expects to review a minimum of 15 substances per year. Assuming that the new hazard classes are introduced in 2023, there may be still around 175 substances[154] for review of ED properties. For some substances, the entry in BPC peer review may be delayed awaiting the harmonised ED and PBT classification. The BPC will have to ensure a smooth interplay with the CLH process.

The BPR only refers to substances having endocrine-disrupting properties (article 5(1)(d)), but it is assumed that in analogy with other hazard classifications, only Cat. 1 will be considered for exclusion criteria. For PBT, the confirmation of two criteria (out of the three P, B or T) is enough for being identified as candidate for substitution.

This impact assess for the BPC will impact in a similar way EFSA which asses endocrine-disrupting properties and PBT for active substances in PPP. Moreover, the revision of REACH will touch upon other tasks of public authorities and of RAC. Synergies will be identified. This is why no costs are entitled for PO1a when it comes to public authorities, including ECHA.

Territorial impacts (specific regions)

During the consultation activities for this supporting study, stakeholders have highlighted that some chemical products produced in specific regions of the EU may come within the scope of classification as ED category 2.[155] Many are mainly consumer products, and stakeholders fear that a classification as ED would result in a drastic decrease in the demand for these products, with very severe socio-economic impacts on the economy of the interested regions.

Impacts on SMEs

The overall cost of PO1a according to the different assumptions used (reformulation rate and number of mixtures per substance) has been assessed against the number of persons employed in each enterprise per company size (Table 64),[156] to obtain an 'average cost per employee' (the 'SME test')[157].

Table 64: Main aggregates of NACE code C20 Manufacture of chemicals and chemical products per company size

	Micro	Small	Med.	Large	**Total**
Number of enterprises	19,447	5,242	2,504	793	27,986
Turnover	€ 10,133M	€34,648M	€ 118,957M	€414,870M	€600,000M
Persons employed	47,000	119,331	278,071	735,156	1,200,000
Turnover per person employed	215,596	290,353	427,794	564,330	500,000

[154] There may be 2-3 new active substances per year, although only a fraction of these substances may have positive triggers for ED/PBT harmonised classification.
[155] For example, see Ramsey et al. 2019; Kalyan S, 2007; Dean CJ, 2007.
[156] Eurostat Structural business statistics – Industry by employment size class (NACE Rev. 2, B-E) – NACE code C20 Manufacture of chemicals and chemical products.
[157] In line with Better Regulation Guideline's Tool #23.

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The average administrative burden of PO1a per person employed per year for a large enterprise is €20.1 while for SMEs is €4, assuming a reformulation rate of 9% and 11 mixtures per substance. Assuming a reformulation rate of 25% and 25 mixtures per substance, the average administrative burden of PO1 per person employed per year for a large enterprise would be of €97.2 per year, while for SMEs would of €19.6.

Table 65: Average cost (central estimate) per person employed per company size

Assumptions / company size	**Micro**	**Small**	**Medium-sized**	**Large**
Reformulation 9% - 11 mixtures per substance	€ 1.3	€ 3.3	€ 7.6	€ 20.1
Reformulation 25% - 11 mixtures per substance	€ 2.7	€ 7	€ 16.3	€ 43
Reformulation 9% - 25 mixtures per substance	€ 2.9	€ 7.3	€ 17.1	€ 45.3
Reformulation 25% - 25 mixtures per substance	€ 6.2	€ 15.8	€ 36.8	€ 97.2

The underlying cost estimates suggest no disproportionate effects on SMEs versus large enterprises. It should be noted that small and medium-sized formulators (manufacturers of mixtures), depending on their product portfolio and market (industrial users vs professional users vs consumers) may be significantly affected by the inclusion of the new hazard classes. Concerns have been raised on the inclusion of a category 2 for 'suspected' EDs, which may capture a high number of consumer chemical products put on the market by SMEs, often concentrated in specific EU regions. Such a classification may result in drastic decrease in the demand for these products, with very severe socio-economic impacts on the economy of the interested regions.

Employment, sectoral competitiveness, trade and investment flows

With regard to impacts on particular sectors, despite the fact that cosmetic products are exempted from CLP, the introduction of the ED hazard classes may create a conflict with the CPR, as substances used as cosmetic ingredients only cannot resort to animal testing for classification.

Regarding impacts on trade, the introduction of new hazard classes in CLP prior to their introduction in the UN GHS could pose non-tariff barriers to trade for most sectors and for companies within and outside the EU. GHS follows a "building block approach", aiming at ensuring a certain degree of flexibility with the hazard classes and categories to be implemented while meeting the requirements regarding cut-off values, concentration limits and label elements. RPA et al. (2017c) reported some key differences in:

The adoption of the building blocks;
The transition times for adoption of GHS and GHS biennial revisions;
The labelling and packaging requirements; and
The classification requirements across the countries or regions that have implemented GHS.

All these differences are constraints to the goal of global harmonisation and, effectively, constitute non-tariff barriers to trade. Over 70% of the industry stakeholders participating to the consultation activities carried out in the context of the RPA et al. (2017) study indicated that differences in labelling requirements across countries are key drivers of costs.

There is a vast empirical literature in the environmental economics field investigating the effects of asymmetric environmental regulations on key aspects of firms' competitiveness, including trade, industry location, employment, productivity, and innovation. The first major

review on the topic (Jaffe et al, 1995)[158] concluded that 'there is relatively little evidence to support the hypothesis that environmental regulations have had a large adverse effect on competitiveness, however that elusive term is defined'.

Thanks to the growing number of environmental policies worldwide and the availability of high-quality data, their findings have been tested multiple times around the world. A review of these studies by Dechezleprêtre and Sato (2017)[159] found that the conclusion of Jaffe et al (1995) 'has only become more robust'. Moreover, 'the cost burden of environmental policies has often been found to be very small. The recent evidence shows that taking the lead in implementing ambitious environmental policies can lead to small, statistically significant adverse effects on trade, employment, plant location, and productivity in the short run, particularly in pollution- and energy-intensive sectors. However, the scale of these impacts is small compared with other determinants of trade and investment location choices such as transport costs, proximity to demand, quality of local workers, availability of raw materials, sunk capital costs, and agglomeration'.

These findings have also been confirmed by a study commissioned in 2014 by the European Chemical Industry Council (Cefic) to investigate the prospects of the competitiveness of the European chemical industry.[160] Oxford Economics applied constant-market share analysis to chemical exports coupled with econometric analysis. The authors found that the decrease in extra-EU export market share observed in the preceding two decades is due to declining competitiveness rather than slow-growing destination markets, in particular in the production of petrochemicals and polymers. The change in competitiveness was found to be strongly associated with energy prices, labour costs and research and development intensity. The regulatory burden was not found to be an important driver (no strong statistical relationship).

Finally, the UN GHS has not yet been adopted fully by all countries, nor adopted in a harmonised manner by those who have adopted it (for example, there is no implementation of GHS for consumer products in North America). Therefore, significant differences in labelling requirements continue to exist.

Social and environmental impacts

The ideal model

The benefits of including new hazard classes in CLP are expected to arise from the availability of hazard information and the role that this plays in hazard communication, providing incentives towards the use of safer alternatives and the reduction of exposure to hazardous chemical products. The main benefits for human health and the environment will stem from a reduction in exposures of people and the environment to ED, PBT/vPvB and PMT/vPvM substances — and therefore avoidance of future cases of disease and environmental damage — through risk management measures triggered under various pieces

[158] Jaffe AB, Peterson SR, Portney PR, Stavins RN (1995): Environmental Regulation and the Competitiveness of U.S. Manufacturing: What does the evidence tell us? Journal of Economic Literature, Vol. 33, No. 1 (Mar., 1995), 132-163.

[159] Dechezleprêtre and Sato (2017): The Impacts of Environmental Regulations on Competitiveness. Review of Environmental Economics and Policy, volume 11, issue 2, Summer 2017, pp. 183–206.

[160] Oxford Economics (2014): Evolution of competitiveness in the European chemical industry: historical trends and future prospects. Report for Cefic – October 2014. Available at: https://cefic.org/app/uploads/2019/02/OXFORD_ECONOMICS_competitiveness_chemind_2014.pdf

of downstream legislation and, where applicable, under REACH. These will be delivered through:

Improved cohesion with other legislation, such as REACH, BPR and PPPR;
Improved communication of the hazards of substances and mixtures to downstream users;
Incentives to shift to safer alternatives; and

For some mixtures, reformulation (leading to reductions in exposure and risk of workers and consumers).

The ideal model — ignoring the availability of relevant data — to assess the benefits of the introduction of new hazard classes requires:[161]

Policy effect on exposure. An assessment of the extent to which the CLP revision will reduce human and environmental exposure to chemicals. Refer to this change as ΔX where X refers to exposure. In reality, ΔX is a vector of many different chemicals. For those that are withdrawn completely from the market as a result of the introduction of new hazard classes, $\Delta X = 100\%$.

Exposure-response relationship. The effect on human health can be referred to as ΔH, which is a vector of many different health outcomes. Because there may be differences in the monetary valuation, ΔH can be distinguished in reduced occupational risks (ΔH_O) and reduced public health risks (ΔH_P). The effect on the environment can be referred to as ΔE. The overall impact is therefore: $\Delta I = \Delta H_P + \Delta H_O + \Delta E$

Economic values. Monetary values are used to reconcile the different impacts. These shadow prices[162] (P) reflect individuals' willingness to pay for avoiding the ill-health or negative environmental impact associated with chemicals.

Time and discount factor. Because individuals have time preferences, changes in the future are valued less than near-term changes. To compare monetary values in the future with present values (PV), a discount factor (DF) of 3% is used.[163] Timing is important because the costs of classifying, labelling and possibly substituting/withdrawing chemical products are entailed before the point in time when exposure is reduced, and negative health outcomes are avoided.

Location. Human health and environment impacts are location-specific (e.g. the benefits of risk reduction are higher in heavily populated areas). For convenience, the geographical variation in exposure reduction is ignored and EU averaged values are used instead.

The present value of the benefits of the revision of CLP is:

$$PV\,(B) = \Sigma_{i,j,t}\, \Delta I_{I,t}\, (\Delta X_{j,t})\ x\ DF$$

Where i: different health and environmental outcomes and j: different chemical products

[161] Adapted from Pierce and Koundouri (2003): The social cost of chemicals. The Cost and Benefits of Future Chemicals Policy in the European Union. A WWF Chemicals and Health campaign report.
[162] Prices that would be attached to the reduced risk if there was an overt market in risk reduction.
[163] As recommended by the Better Regulation guidelines.

The CLP revision would pass the cost-benefit test if the PV (B) > PV (C).

The problem with the ideal model is that the following parameters are not known:

The effects of the CLP revision on exposure (ΔX), since this is dependent on the behavioural reaction of producers, users, and regulators to changes in the classification and labelling of chemical products.

The health and environmental exposure-response functions ($\Delta I(\Delta X)$) for the chemical products that may be classified for the new hazard classes, the split between occupational and public health effects and when the reduction of exposure may be realised.

Because of the limitations in the availability of data, another method needs to be devised, which is **determining a benchmark**, i.e. how large the benefits need to be for the CLP revision to pass a cost-benefit test. This procedure requires a range of assumptions, detailed in the following subsections.

The approach to quantifying and monetising the benefits involves:

> Estimating how many substances are identified as having ED, PBT/vPvB and PMT/vPvM properties;
> Identifying the disorders, diseases and impacts that are associated with each of those hazardous properties;
> Applying appropriate economic metrics for the single cases avoided or units of environmental area improved for each type of hazardous properties (in €s); and

Estimating the number of cases of these diseases, disorders and impacts that would have to be reduced in order for the benefits of each information option to outweigh the costs.

A range of disorders, diseases and impacts can be associated with each of the hazardous properties to which can be applied appropriate economic metrics to provide a monetary value for the associated damages. Valuing damages in this way provides a means of estimating the benefits of each option in terms of the damage costs avoided through identification of hazardous properties and appropriate risk management. At the same time, the range of possible outcomes from exposure and environmental releases is much larger than the range of available metrics. As such, valuation must rely on selected 'representative' outcomes.

Estimating the magnitude of such benefits and a 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. There is a lack of detailed health statistics and monitoring data, and the long latency period — measured in years/decades — of some health outcomes between exposure to a causative agent — such as an ED — and diagnosis of disease is an additional complicating factor, with the effect that the benefits of any reduction in exposure achieved via CLP and other chemicals regulation will not be manifested until some point in the future. For the environmental component, very few metrics are available, and this limits the ability of the analysis to assess the full breadth and depth of possible impacts. Thus, by default, assessment of the benefits will tend to underestimate the 'true' environmental benefit.

A break-even approach is adopted to weigh up the likely relative advantages and drawbacks of option 1a and judge whether it is likely to be 'justified' considering the costs. The aim is to answer the following questions:

- What level of benefit would be required to offset the costs?
- What is the minimum number of cases/outcomes that would need to be avoided to achieve this level of benefit?
- Is this minimum number cases/outcomes avoided a plausible outcome of the option?

In order to estimate the economic value of the potential human health damage costs avoided, a cost-of-illness approach has been adopted. This considers medical treatment costs, productivity/earnings losses and, where available, individual's willingness to pay (WTP) to avoid the outcome under consideration.

The following subsections provide an overview of the possible health and environmental outcomes of the exposure to substances with ED, PBT/vPvB and PMT/vPvM properties, and their economic metrics.

Endocrine disruptors

Despite all uncertainties and information gaps, researchers agree that exposure to EDs may lead to substantial societal costs, with estimates in the range of billions of euros for the EU on a yearly basis, with some studies estimating costs in the range of €46-288 billion per year (Rijk et al, 2016).[164] Assuming that the overall burden is broadly correct, the grand total cost of PO1 is approximately one to three thousandths of the overall burden. However, there is a lot of uncertainty associated with the causal link between health effects and EDs' exposure and the corresponding health-related costs. Moreover, only a few ED-associated health effects have been quantified, and therefore any estimate need to be interpreted with care.

Due to the large uncertainties surrounding the monetary evaluation of the health and environmental impacts of EDs, a break-even approach is used to provide an illustration of the number of specific health outcomes that policy option 1 would have to contribute to avoid justifying its costs. This is complemented by an additional benchmark approach, comparing the benefits calculated through predefined population attributable fractions to the costs of the policy option.

Human and environmental exposure to EDs — through multiple routes — is the result of their presence in a wide variety of products, including food packaging, pharmaceuticals, cosmetics and personal care products, pesticides, fabrics and upholstery, electronics, plastic bottles, metal food cans, detergents and toys (Kassotis et al., 2020). EDs can mimic or interfere with the body's endocrine system, and associated effects include impacts on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology.[165] Vulnerable groups, such as young children, are particularly affected by exposure to EDs, which can have life-long impacts and exhibit in adulthood. Rijk et al. (2016) identified more than 80 different health endpoints which have been potentially associated to exposure to EDs. Table 66 reproduces health outcomes attributable to exposure to specific EDs — with strength of human evidence and probability of causation — as reported by Kahn et al. (2020).

[164] 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.

[165] National Institute of Environmental Health Sciences. (n.d.) Endocrine Disruptors. https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm

Table 66: Strength of evidence and probability of causation for outcome-exposure associations		
Outcome	**Strength of human evidence**	**Probability of causation**
Perinatal outcomes		
Low birthweight	Not assessed	Not assessed
Preterm birth	Not assessed	Not assessed
Reduced anogenital distance	Not assessed	Not assessed
Neurodevelopmental		
IQ loss and intellectual disability	Moderate to high	70-100%
Attention-deficit disorder	Low to moderate	20-69%
Autism spectrum disorder	Low	20-39%
Metabolic		
Childhood obesity	Moderate	40-69%
Adult obesity	Low	40-69%
Adult diabetes	Low	40-69%
Reproductive outcomes		
Cryptorchidism	Low	40-69%
Low testosterone, resulting in increased early mortality	Low	40-69%
Male infertility, resulting in increased use of assisted reproductive technology	Low	40-69%
Endometriosis	Low	20-39%
Fibroids	Low	20-39%
Testicular cancer	Very low to low	0-19%
Semen quality	Not assessed	Not assessed
Polycystic ovarian syndrome	Not assessed	Not assessed
Breast cancer	Not assessed	Not assessed
Notes: Kahn et al. (2020) report strength of evidence and probability of causation per specific EDs and time of exposure (prenatal, pregnancy, adult, lifetime). This table reproduces only the highest strength of human evidence and probability of causation among specific EDs and time of exposure.		

Kahn et al. (2020) is part of a series of papers published by Trasande and colleagues starting in 2015[166] estimating the socioeconomic impacts of health outcomes attributable to EDs' exposure. These papers use the population attributable fraction methodology and calculate the attributable costs as the product of disease rate, attributable fraction, population size and cost per case. The cost per case includes health care direct costs, rehabilitation costs and lost productivity. To establish the probability of causation, the authors adapted the Intergovernmental Panel on Climate Change (IPCC) approach, combining the assessment of the strength of the epidemiological and toxicological evidence. Bond and Dietrich (2017) have criticised the methodology used in this series of papers, pointing to a number of criticalities: skewed and non-transparent selection of experts for the panels establishing probability causation for each outcome-exposure association; limited evidence for certain outcome-exposure association; non-transparent selection of the literature evaluated; monetisation of health outcomes with low to moderate probability of causation; insufficient number of experts in the panels. It should be noted that Trasande and colleagues have

[166] Trasande et al. (2015); Bellanger et al. (2015); Hauser et al. (2015); Legler et al. (2015); Hunt et al. (2016); Trasande et al. (2016)

responded to the criticisms,[167,168] defending their methodology and maintaining that the economic estimates are likely to be conservative.

For the purpose of this assessment, a subset of four health outcomes was selected — one outcome for each outcome category:

Low birth weight (perinatal outcomes);
IQ loss and intellectual disability (neurodevelopmental);
Childhood obesity (metabolic);
Male infertility (reproductive outcomes).

A very low weight at birth can have consequences on development, including an increased prevalence of neurosensory problems, behavioural and social competence problems, and intellectual and learning disabilities. As noted in ECHA (2016c), the actual outcomes associated to very low birth weight cannot be known in advance. Alberini and Ščasný (2014) value that the prevention of one case of very low birth weight at €$_{2012}$405,000 (equal to €$_{2021}$450,000)[169] from a public perspective.

Neurodevelopmental disabilities have been associated with IQ productivity losses and other associated health and societal costs. A number of authors[170] [171] [172] have estimated the cost of an IQ point lost as USD$_{2010}$19,269 (equal to EUR$_{2021}$30,500) in discounted lifetime costs. Honeycutt et al. (2004) report average lifetime costs per case of intellectual disability of USD$_{2003}$1,014,000 (equal to €$_{2021}$1,690,000).[173]

Obesity presents significant healthcare costs to society and can result in various related conditions and subsequent reductions in life expectancy. Direct costs considered include drugs, hospitalisations, monitoring and obesity-associated pathologies. Indirect costs are productivity losses, in terms of both presenteeism and absenteeism.[174] Hamilton and Dee (2017) value the total lifetime excess cost per obese child as €$_{2021}$160,000.[175]

There are significant individual and societal costs associated with male reproductive health problems, with costs including medical and fertility treatment. Alberini and Ščasný (2014)

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[167] Hunt et al. (2016): Response to the Letter by G. M. H. Swaen and R. Otter. *The Journal of Clinical Endocrinology & Metabolism*, Volume 101, Issue 11, 1 November 2016, Pages L110–L111, https://doi.org/10.1210/jc.2016-3294

[168] Bellanger et al. (2015): Response to the Letter by Middlebeek and Veuger. *The Journal of Clinical Endocrinology & Metabolism*, Volume 100, Issue 6, 1 June 2015, Pages L54–L55, https://doi.org/10.1210/jc.2015-2221

[169] Rounded to the nearest ten thousand.

[170] Attina TM, Trasande L (2013): Economic costs of childhood lead exposure in low and middle-income countries. Environ Health Perspect 121:1097-1102

[171] Trasande L, Liu Y (2011): Reducing the Staggering Costs of Environmental Disease in Children, Estimated at $76.6 Billion In 2008. Health Affairs 30:863-870

[172] Bellanger et al. (2013): Economic benefits of methylmercury exposure control in Europe: monetary value of neurotoxicity prevention Environmental Health 12

[173] Converted using the purchasing power parities and inflation rates reported by the OECD (https://data.oecd.org/conversion/purchasing-power-parities-ppp.htm) and (https://stats.oecd.org/index.aspx?queryid=82174)

[174] Presenteeism refers to the lost productivity that occurs when employees are not fully functioning in the workplace because of an illness, injury, or other condition. Absenteeism occurs when people are sick, injured, unwell or are unable to come to work due to circumstances.

[175] Rounded to the nearest ten thousand.

estimated the value of a statistical pregnancy among the general population in €$_{2012}$37,900 (equal to €$_{2021}$42,000).

With regard to the environmental impacts of EDs' exposure, while there is strong evidence in specific cases (endocrine disruption in fish), there is limited understanding of the causal associations between EDs and effects on individual animals and wider wildlife populations (Jobling, S., Tyler, C. R., 2006).

Illustrative benefit calculations – EDs

Number of cases to be avoided to justify the costs

The benefits of PO1 are equal to the number of adverse human health and environmental outcomes avoided multiplied by the cost (or value) of each of those outcomes. Regarding the value of the outcomes avoided, the range of possible outcomes from human exposure and environmental releases to EDs is much larger than the range of available metrics. The valuation of the benefits relies on selected 'representative' outcomes which capture some of the possible outcomes. Thus, by default, any assessment of the benefits will tend to underestimate the 'true' benefit. There is no means of predicting how many avoided cases PO1 would result in, and therefore there is no 'case multiplier' to calculate the benefits.

In order to simplify the analysis, the values of the multiple possible outcomes of EDs' exposure have been aggregated to provide a single statistical value, using a weighted average approach based on assumed equal frequency of outcomes (Table 67). The weighted average value has been annualised using a 40-year period to account for the long latency of the considered health outcomes — i.e. the long time that passes between being exposed and having symptoms — and for the fact that some of the health outcomes affect the offspring of the exposed population.

Table 67: Aggregation of values for substances with outcomes

Substance properties	Valuation metric	Monetary value	Relative frequency / weight	Weighted average value to be applied
Endocrine disruption	Low birth weight	€450,000	25%	€585,500 PV = € 25,330 (40y, 3%)
	Intellectual disability	€1,690,000	25%	
	Childhood obesity	€160,000	25%	
	Male infertility	€42,000	25%	

The minimum number of cases/outcomes that would need to be avoided to offset PO1a costs for ED substances is estimated to range between 1,325 – 2,981 in the case of 9% of the substances classified for ED properties being withdrawn from the market because of CLP classification. This equates to 0.6 to 1.4 cases/outcomes to be avoided per substance (Table 68).

Table 68: Illustrative benefits for ED substances

PV total cost of PO1a for ED substances - (9% market withdrawal)	€33,560,000 - €75,510,000 (CI: €27M - €95M)
PV total cost of PO1a for ED substances - (25% market withdrawal)	€72,000,000 - €162,880,000 (CI: €59M - €205M)
Statistical case	
PV (40 years; 3%) of weighted average value of statistical outcome	€25,330
Total number of cases to be avoided to justify PO1a costs for EDs - (9% market withdrawal)	1,325 – 2,981 (CI: 1,095 – 3,759)

Total number of cases to be avoided to justify PO1a costs for EDs - (25% market withdrawal)	2,843 – 6,430 (CI: 2,348 – 8,109)
Number of cases to be avoided per substance - (9% market withdrawal)	0.62 – 1.39
Number of cases to be avoided per substance - (25% market withdrawal)	4.97 – 11.24
Low birth weight	
PV (40 years; 3%) of weighted average value of statistical outcome	€19,468
Total number of cases to be avoided to justify PO1a costs for EDs - (9% market withdrawal)	1,724 – 3,879 (CI: 1,424 – 4,891)
Total number of cases to be avoided to justify PO1a costs for EDs - (25% market withdrawal)	3,699 – 8,366 (CI: 3,055 – 10,551)
Number of cases to be avoided per substance - (9% market withdrawal)	0.8 – 1.81
Number of cases to be avoided per substance - (25% market withdrawal)	6.47 – 14.63
Intellectual disabilities	
PV (40 years; 3%) of weighted average value of statistical outcome	€73,113
Total number of cases to be avoided to justify PO1a costs for EDs - (9% market withdrawal)	459 – 1,033 (CI: 379 – 1,302)
Total number of cases to be avoided to justify PO1a costs for EDs - (25% market withdrawal)	958 – 2,228 (CI: 814 – 2,809)
Number of cases to be avoided per substance - (9% market withdrawal)	0.21 – 0.48
Number of cases to be avoided per substance - (25% market withdrawal)	1.72 – 3.89
Childhood obesity	
PV (40 years; 3%) of weighted average value of statistical outcome	€6,922
Total number of cases to be avoided to justify PO1a costs for EDs - (9% market withdrawal)	4,849 – 10,909 (CI: 4,006 – 13,757)
Total number of cases to be avoided to justify PO1a costs for EDs - (25% market withdrawal)	10,402 – 23,530 (CI: 8,593 – 29,674)
Number of cases to be avoided per substance - (9% market withdrawal)	2.26 – 5.09
Number of cases to be avoided per substance - (25% market withdrawal)	18.19 – 41.14
Male infertility	
PV (40 years; 3%) of weighted average value of statistical outcome	€1,817
Total number of cases to be avoided to justify PO1a costs for EDs - (9% market withdrawal)	18,471 – 41,558 (CI: 15,259 – 52,407)
Total number of cases to be avoided to justify PO1a costs for EDs - (25% market withdrawal)	39,628 – 89,640 (CI: 32,737 – 113,042)
Number of cases to be avoided per substance - (9% market withdrawal)	8.61 – 19.37
Number of cases to be avoided per substance - (25% market withdrawal)	69.28 – 156.71

Table 68 also provides the total number of cases and the number of cases per substance to be avoided to justify the costs of PO1a considering each one of the four health outcomes that have been associated with exposure to EDs. This allows to compare the total number of cases to be avoided with the prevalence of each one of the health outcomes:

Low birth weight: in the EU in 2018, 1 in 15 babies (6.6%) weighed less than 2,500 grammes at birth.[176] There were 4,245,710 live births in the EU27,[177] meaning that around 280,217 babies had a low birth weight according to the WHO definition. The total number of low birth weight cases to be avoided to justify PO1a costs ranges from 1,724 to 8,366 (central estimate), i.e. between 0.6% and 3% of the number of low birth weight cases in 2018.

[176] OECD/European Union (2020): Health at a Glance: Europe 2020: State of Health in the EU Cycle, OECD Publishing, Paris, https://doi.org/10.1787/82129230-en (Figure 3.15)
[177] Eurostat: All data > Population and social conditions > Demography, population stock and balance > Fertility (national level) > Live births (total) by month (DEMO_FMONTH)

Intellectual disabilities: McKenzie et al. (2016) report the prevalence of intellectual disabilities at one percent.[178] Considering an average of 4 million live births per year,[179] around 40,000 babies with intellectual disabilities are born every year. The total number of intellectual disabilities cases to be avoided to justify PO1a costs ranges from 459 to 2,228 (central estimate), i.e. between 1.1% and 5.6% of the number of low birth weight cases every year.

Childhood obesity: 'Nearly one in eight children (12%) aged 7-8 is obese on average in EU countries'.[180] There are around 4,500,000 eight years old each and every year,[181] meaning that around 540,000 eight years old children are obese in the EU each and every year. The total number of childhood obesity cases to be avoided to justify PO1a costs ranges from 4,849 to 23,530 (central estimate), i.e. between 0.9% and 4.4% of the number of childhood obesity cases every year.

Male infertility: According to Agarwal et al. (2015),[182] the prevalence of male infertility in Europe is around 7.5% of the male population. In 2020, there were 2,089,615 male live births in the EU27.[183] This means that, by applying the prevalence rate, there were 156,721 man born with reduced semen quality resulting in infertility. The fertility ratio in the EU27 is 1.50461, so the number of children that will not be born naturally due to reduced semen quality is 235,804. The total number of male infertility cases to be avoided to justify PO1a costs ranges from 18,471 to 89,640 (central estimate), i.e. between 7.8% and 38% of the number of male infertility cases every year.

Predefined population attributable fractions

While the evidence between exposure to endocrine disruptors and negative health outcomes is convicing (although varying in strength), the estimate of the population attributable fractions is associated with large uncertainties, due to their multifactorial nature. WHO/UNEP (2012)[184] attributes 24% of human diseases and disorders globally to environmental factors. Prüss-Ustün, et al. (2016) suggest that around 22% of GBD could be attributed to environmental risks using a range of methods of expert elicitation. How much of this proportion could be attributed to chemicals' exposure — or EDs' exposure — is unclear

[178] McKenzie, K., Milton, M., Smith, G. et al. (2016): Systematic Review of the Prevalence and Incidence of Intellectual Disabilities: Current Trends and Issues. Curr Dev Disord Rep 3, 104–115. https://doi.org/10.1007/s40474-016-0085-7
[179] Eurostat: All data > Population and social conditions > Demography, population stock and balance > Fertility (national level) > Live births (total) by month (DEMO_FMONTH)
[180] OECD/European Union (2018): Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris/European Union, Brussels, https://doi.org/10.1787/health_glance_eur-2018-en (Figure 4.15).
[181] Eurostat: All data > Population and social conditions > Demography, population stock and balance > Population (national level)
[182] Agarwal, A., Mulgund, A., Hamada, A., & Chyatte, M. R. (2015): A unique view on male infertility around the globe. Reproductive biology and endocrinology : RB&E, 13, 37. https://doi.org/10.1186/s12958-015-0032-1
[183] Eurostat: All data > Population and social conditions > Demography, population stock and balance > Fertility (national level) > Live births by mother's age and newborn's sex (DEMO_FASEC)
[184] WHO/UNEP (2012) State of the science of endocrine disrupting chemicals 2012. Edited by Åke Bergman, Jerrold J. Heindel, Susan Jobling, Karen A. Kidd and R. Thomas Zoeller.

and subject to intense research. As illustrative example, Olsson et al. (2014)[185] used three different 'etiological fractions': 1% (low), 20% (medium) and 40% (high), recognising that other environmental factors play a role (e.g. dietary factors, body mass index and waist circumference, obesity, smoking, degree of physical activity and alcohol consumption). Rijk et al. (2016) used 1%, 2.5% and 10%, considering that the first two point estimates are within the lower ranges of fractions attributable to environmental factors — and more specifically to chemicals — presented in WHO and OECD papers. The 10% point estimate is used as high end of the range, which is still conservative if compared to the range used by Olsson et al. (2014). Indeed, Rijk et al. (2016) recognise that 'for some diseases the role of environmental factors in stronger than for other diseases'.

Under this approach, the costs attributable to exposure to EDs are taken as a proxy of the benefits. Table 69 (overleaf) presents the discounted costs (40-year period; 3%) per year of cases attributable to exposure to EDs for four health outcomes. Using a predefined population attributable fraction of 2.5%, the total costs per year amount to over €300 million. The one-off cost estimates of policy option 1a for EDs range between €33 million and €163 million, or around 10% to 50% of the costs of cases of ill-health attributable to EDs' exposure per year. How much of these costs will be saved by the CLP revision only is unknown, but the introduction of identification and classification criteria for EDs in CLP is the prerequisite for the delivery of all benefits, including through the extension of the generic approach to risk management (foreseen in the revision of REACH) and, more in general, through the enhancement of risk management measures to minimise exposure. Moreover, considering that over 80 health endpoints have been associated to exposure to EDs and that the estimates presented refer to a subset of only four health outcomes, hence an underestimation, the omitted benefits are very likely to result in the total benefits being much greater than the costs of this policy option. Environmental impacts have also not been accounted for, although an attempt for PBT/vPvB and PMT/vPvM substances is presented in the following subsection.

[185] Olsson et al. (2014): The Cost of Inaction. A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health. TemaNord 2014:557. Nordic Council of Ministers.

Table 69: Discounted costs per year of cases attributable to EDs' exposure for four health outcomes

Health outcome	Lifetime cost per case	Discounting period	Discount rate	Discounted lifetime cost per case	Prevalence	Population	Cases	PAF	Cases attributable to EDs per year	Cost per year
Low birth weight	€450,000	40	3	€ 19,468.07	6.60%	4,245,710	280,217	2.5%	7,005	€ 136,382,036
Intellectual disabilities	€1,690,000	40	3	€ 73,113.42	1%	4,000,000	40,000	2.5%	1,000	€ 73,113,419
Childhood obesity	€160,000	40	3	€ 6,921.98	12%	4,500,000	540,000	2.5%	13,500	€ 93,446,736
Male infertility	€42,000	40	3	€ 1,817.02	7.50%	2,089,615	235,804	2.5%	5,895	€ 10,711,522
									Total	€ 313,653,713

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Illustrative benefit calculations - PBT/vPvB and PMT/vPvM substances

A core methodological difficulty for estimating (and valuing) the benefits of action to curb or cease emissions of PBT/vPvB (or otherwise address risks) is that 'safe' concentrations of PBT/vPvB and PMT/vPvM substances in the environment cannot be established with reliability. Target compartments and species at risk cannot be identified with sufficient levels of accuracy and, owing to the long-term presence of these substances in the environment, secondary poisoning and multi-generational effects in wildlife cannot be readily predicted.

The inability to estimate the monetary benefits of actions to curb emissions from PBT/vPvB is evidenced by the lack of benefit estimations in the EU REACH restriction dossiers for PBT/vPvB regulated thus far under EU REACH. Few stated preference-based studies have been undertaken with the aim of developing monetary estimates of people's WTP to adopt a precautionary approach with respect to PBT and vPvB. As noted by ECHA (2014), the lack of information on changes in impacts makes it difficult to develop credible change scenarios which could leave survey respondents unclear as to what they are being asked to value.

The most relevant 'off the shelf' estimates are those associated with restrictions brought into force under EU REACH, expressed as costs per kg/tonne of emissions reduced/to be reduced. These are reported in ECHA's (2021) report on the "Costs and benefits of REACH restrictions proposed between 2016 to 2020"[186] but are often simply costs of switching to alternatives. Rarely, restriction dossiers have costs of clean-up in different countries (e.g. Australia with PFAS). None of the available information, then, explicitly values the impacts.

For these reasons, a break-even approach is used to provide an illustration of the quantity of PBT/vPvB and PMT/vPvM substances substituted/withdrawn from the market that policy option 1 would have to contribute to justifying its costs.

The illustrative benefits of the inclusion of PBT/vPvB and PMT/vPvM hazard classes in CLP were calculated assuming that the quantity of PBT/vPvB or PMT/vPvM substances substituted or withdrawn from the market due to CLP classification is equal to 345 tonnes on average per substance. This weighted average was calculated by multiplying the tonnage band distribution shares of basket 1 and basket 2 PBT/vPvB and PMT/vPvM substances multiplied for the lower end of the tonnage bands:

31% of the substances that could be classified for PBT/vPvB or PMT/vPvM properties are currently registered in quantities above 1,000 tonnes per year. This share has been multiplied for 1,000 tonnes;
36% of the substances are registered in quantities above 100 tonnes per year. This share has been multiplied for 100 tonnes;
21% of the substances are registered in quantities above 10 tonnes per year. This share has been multiplied for 10 tonnes;
12% of the substances are registered in quantities above 1 tonne per year. This share has been multiplied for 1 tonne.

[186] ECHA Costs and benefits of REACH restrictions proposed between 2016-2020 February 2021, available at: https://echa.europa.eu/documents/10162/13630/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e

The estimate of 345 tonnes per year as the statistical average quantity of each PBT/vPvB and PMT/vPvM substance on the market is very conservative, as it assumes that all substances are manufactured or imported at the lowest end of the REACH registration tonnage band and does not account for multiple registrants per substance. The present value of the total cost of including hazard classes for PBT/vPvB and PMT/vPvM properties ranges from €5M to €27M (depending on the assumption on the number of mixtures containing one substance), which equate to €0.2-0.74 per kg of PBT/vPvB or PMT/vPvM substances. If the benefits of withdrawing PBT/vPvB and PMT/vPvM substances are €0.7 or above, then PO1 would be justified.

Table 70: Illustrative benefits for PBT/vPvB and PMT/vPvM substances (per year)	
Statistical average quantity of each PBT/vPvB and PMT/vPvM substance on the market	345,000 kg
Number of substances withdrawn from the market due to CLP classification – (9% of all classified PBT/vPvB and PMT/vPvM substances)	56
Number of substances withdrawn from the market due to CLP classification – (25% of all classified PBT/vPvB and PMT/vPvM substances)	156
Total kg PBT/vPvB and PMT/vPvM withdrawn – 9%	19,468,350 kg
Total kg PBT/vPvB and PMT/vPvM withdrawn – 25%	54,078,750 kg
PV total cost of PO1a for PBT/vPvB and PMT/vPvM substances	€5,870,000 - €12,200,000 (based on 11 mixtures per substance) €13,140,000 - €27,520,000 (based on 25 mixtures per substance)
Benefits per kg PBT/vPvB or PMT/vPvM to offset PO1a costs	Minimum €0.2 – 0.7

As noted by SEAC, "data on P, B and T properties does not often allow for quantitative assessment of the human health or environmental impacts. The valuation of benefits via the assessment of the impacts on the environment and human health – the standard 'impact pathways' approach to benefits assessment for chemicals – is therefore not possible, and other options for benefits assessment need to be considered".[187] Accordingly, SEAC has pursued the approach of establishing a benchmark for the proportionality/disproportionality of action to reduce emissions of PBTs considering the cost of past action. Oosterhuis and Brouwer (2015) gathered information on the costs of PBT emission reduction or reductions in the use or exposure to PBT/vPvB substances. In addition, they applied a 'revealed preferences' approach to value the public willingness to pay for such reduction. The authors found that the maximum willingness to pay is difficult to determine, but the 'largest minimum' willingness to pay implied by spent or budgeted investment on PFOS removal is at least €35,000 per kg. Considering potential further investment, this minimum value might increase to between €200,000 and €300,000 per kg. The study identifies values ranging from €1,000 to €50,000 per kg PBT substituted, remediated or emission reduced. The proportionality of these costs depends on the damage potential of the PBT/vPvB substances, which in turn depends on their environmental fate/distribution, characteristics, size and dynamics of the stocks and flows in the environment, the exposure ad hazard potential. Oosterhuis and Brouwer (2015) stress that cost estimates for clean-up / remediation are much higher than cost estimates for substitution, with the values ranging from less than one euro to several millions of euros per kilogramme. Cost estimates for substitution depend on the

[187] Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. SEAC/31/2016/05 Rev.1 (Agreed at SEAC 31). Helsinki, 9 June 2016.

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availability and production costs of suitable alternatives and are specific to the end uses of the substance to be substituted. Moreover, costs per kilogrammes vary hugely depending on the total amount or concentration of the PBT/vPvB substance and whether it is contained in a closed/confined space or widely dispersed.

Nevertheless, comparing the 'grey zone' of proportionality with the cost of €0.2-0.7 per kg of PBT/vPvB or PMT/vPvM substance substituted suggests that the classification of PBT/vPvB and PMT/vPvM substances through CLP is likely to justify the total costs.

RPA & ARCHE (2019)[188] report several examples of costs of remediating sites where contamination of groundwater and soil has occurred due to past use of PFAS: Weber (2016)[189] reports costs of upgrading wastewater treatment works to reduce PFAS concentration in drinking water in the Ruhr and its tributaries of around €100 million, with the works taking several years. The costs of remediating the contamination of Dusseldorf airport due to the use of fire-fighting foams containing PFAS during fire-fighting practices were estimated at €100 million, and the cost of exchanging soil for a different site estimated between €1 billion to €3 billion. Remediation costs for two other PFAS-contaminated airports in Norway were reported at €5.1 million (Evenes airport) and €3.1 million (Oslo Gardermoen airport) (Alling et al. (2017).[190]

[188] RPA & ARCHE (2019): Socio-Economic Assessment of PFHxS and PFHxS-related substances. Final report for the Norwegian Environment Agency.
[189] Weber R (2016): Some lessons learned from PFOS/PFAS management in Germany, Sciene and Policy of Organohalogens pre-Dioxin Symposium, 28 August 2016, Firenze, Italy.
[190] Alling, Vanja, Hartnik, Thomas, & Bjærtnes, Olaug (2017). Two case studies for remediation of PFAS contaminated fire-fighting sites in Norway. Proceedings of the 7th International Contaminated Site Remediation Conference, (p. 633). Australia.

Annex 9 – Harmonised Reference values

CONTEXT

The REFIT evaluation of REACH and Fitness Check of other chemical legislation identified several issues/shortcomings that are related to the components of 'one substance – one assessment process' and that affect proper functioning of the chemical legislation as regards its effectiveness, efficiency or coherence. Addressing these shortcomings together with the experience gained by the Commission and Agencies' staff through past and on-going assessments, while taking into account already on-going activities to improve the assessment processes, will pave the way towards one substance – one assessment process.

As indicated in the chemical strategy for sustainability "The 'one substance, one assessment' approach aims to ensure that methodologies are made more coherent and to the extent possible harmonised" and to "promote reuse and harmonisation of human and environmental health-based limit values among EU risk assessors and managers through a centralised and curated EU repository;".

To this extent, the Commission will ensure that the CLP Regulation strengthens its role as the cornerstone for hazard classification. To reach this aim, the Commission will introduce new hazard criteria, for Endocrine Disruptors, PBTs/vPvBs and other potential SVHCs (e.g., PMT, vPvM). In addition, in order to ensure that regulatory hazard characterization methodologies are applied in a coherent and, to the extent possible, harmonised way, the Commission proposes to add a procedure under CLP to derive and publish harmonised human and environmental toxicological reference values.

The overall goal in harmonising human and environmental toxicological reference values in CLP is to offer a unique reference value that could be used by downstream legislation, when deemed appropriate. These values should support EU risk assessors and duty holders in their specific regulatory framework. This is intended to be particularly relevant for the SDG #3 Good health and well-being – Target 3.9 'By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination'.

PROBLEMS AND DRIVERS

Problems

The risks to the human health and the environment deriving from the exposure to hazardous chemicals are identified and addressed through the assessment procedures set out in the legislation. The main steps of the chemical risk assessment and management process (Figure 66) involve different European agencies and expert committees.

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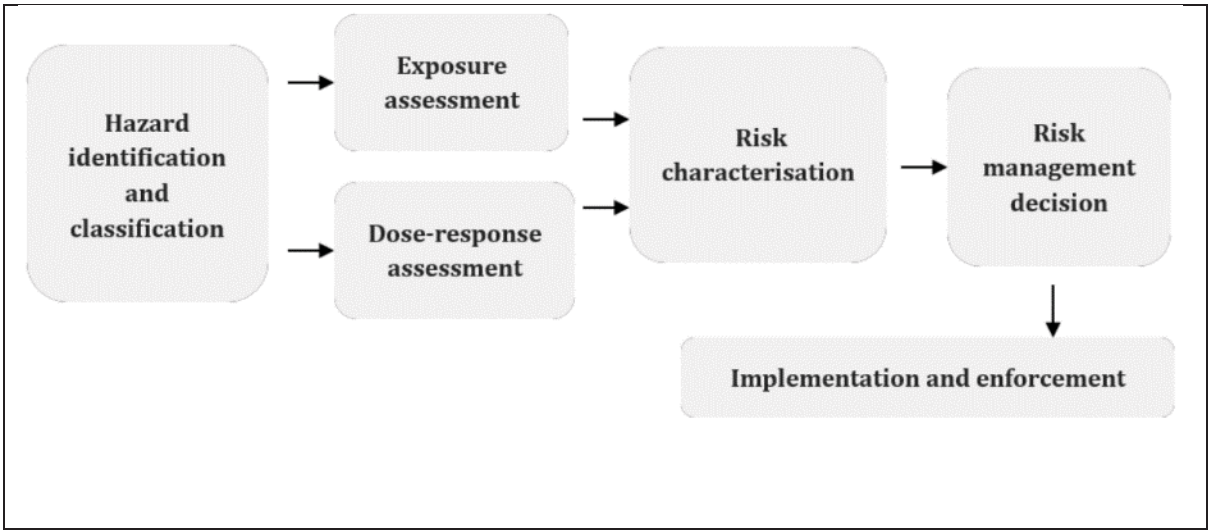

Figure 66: Main steps of the chemical risk assessment and management process – Source: EC (2019e)

When considering the chemical risk assessment and management process, CLP provides only for the first step: hazard identification and classification. Hazard characterization (or dose-response assessment) involves the setting of human and environmental reference values, which expresses the concentration of a substance below which no adverse effects on human health or the environment are expected in case of threshold-substances or the risks are considered acceptable in case of non-threshold substances. There are toxicity reference values which are derived exclusively based on scientific data and considerations, and values which take into account also socio-economic, technical feasibility and other considerations. These include regulatory limits on the concentration in specific products. Table 70 provides a non-exhaustive list of reference values.

Table 70: Non-exhaustive list of toxicity reference values
Derived No-Effect Level (DNEL)
Derived Minimal Effect Level (DMEL)
Predicted No Effect Concentration (PNEC)
Environmental Quality Standard (EQS)
Acceptable or Tolerable Daily/Weekly Intake (ADI or TDI/TWI)
Tolerable Upper Intake Level (UL)
Acute Reference Dose (ARfD)
Acceptable Operator Exposure Level (AOEL)
Acute Acceptable Operator Exposure Level (AAOEL)
Occupational Exposure Limit (OEL)
Indicative Occupational Exposure Limit Value (IOELV)
Binding Occupational Exposure Limit Value (BOELV)
Maximum Residue Level (MRL)
Threshold of Toxicological Concern (TTC)
Maximum Tolerable Dose (MTD)
Average Requirement (AR)
Population Reference Intake (PRI)
Adequate intake (AI)
Maximum Tolerable Daily Intake (MTDI)
Acceptable Intake
Health based exposure limit (HBEL)
Permitted Daily Exposure (PDE)
Source: Call for tenders ENV/2021/OP/0019 - Designing EU repository of health-based limit values and collating information for the first version of the repository

These are derived by companies, competent authorities, EU Commission or international organisations under REACH or other pieces of legislation. Table 71 provides a non-exhaustive list of legislation under which toxicity reference values are set.

Table 71: Non-exhaustive list of legislation under which HBLVs are set
REACH Regulation (EC) 1907/2006
Plant Protection Products Regulation (EC) 1107/2009
Biocidal Products Regulation (EU) 528/2012
Cosmetic Products Regulation (EC) 1223/2009
Food Contact Materials Regulation (EC) 1935/2004
Regulation on contaminants in food (EEC) 315/93
Directive on undesirable substances in animal feed (2002/32/EC)
Food improvement agents Regulation (EC) 1331/2008
Regulation on food additives (EC) 1333/2008
Regulation on food enzymes (EC) 1332/2008,
Regulation on flavourings (EC) 1334/2008
Regulation 234/2011 implementing Regulation (EC) No 1331/2008
Feed additives Regulation (EC) 1831/2003
Maximum Residue Levels of pesticides Regulation (EC) 396/2005
Water Framework Directive (2000/60/EC)
Environmental Quality Standards Directive (2008/105/EC)
Groundwater Directive (2006/118/EC)
Drinking Water Directive (EU) 2020/2184
Marine Strategy Framework Directive (2008/56/EC)
Carcinogens and Mutagens Directive (2004/37/EC)
Chemicals Agents Directive (98/24/EC)
Asbestos at Work Directive (2009/148/EC)
Regulation (EU) 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Source: Call for tenders ENV/2021/OP/0019 - Designing EU repository of health-based limit values and collating information for the first version of the repository

Differences between DNELs for the same substance

With the ECHA Guidance on Information Requirements and Chemical Safety Assessment, R.8 (ECHA, 2012) a detailed methodological guidance for deriving DNELs is available. Nevertheless, in a study on behalf of the Dutch RIVM, the authors found substantial differences depending on the body deriving the DNELs (Schenk et al., 2014). Schenk et al. (2015) noticed large differences in DNELs for 20 substances from registration dossiers, when comparing it to Swedish OELs and to DNELs derived for these substances by the authors themselves, based on the R.8 Guidance document. Differences up to several orders of magnitude were observed. In many cases the authors observed differences in the dose descriptor used (i.e. differences in selection of key study and leading effect).

A statistical approach has been used to further analyse the issue. The DNEL List of the German Social Accident Insurance Association (DGUV)[191] was downloaded that contains

[191] GESTIS DNEL List, Hazardous substance information system of the German Social Accident Insurance, available at: https://www.dguv.de/ifa/gestis/gestis-dnel-liste/index-2.jsp

inhalation DNELs for workers (long-term, local and systemic effects) as of November 2020. This list contains 6,611 entries relating to 5,804 unique chemicals. Of these 5,804 unique chemicals, 5,390 (93%) only have one entry in the DNEL list. In most cases, this entry relates to a DNEL for system effects only, but there are cases for which only a DNEL for local effects is available or a DNEL for local and systemic effects. Among the remaining 414 unique chemicals, the majority has two entries (N=319, 77%) and 90% have between two and four entries (N=374). Two or more entries may result e.g. from different toxicological summaries provided in IUCLID by the lead registrant and members of a consortium or from different submissions. They may still contain identical DNELs and only differ in other respects. If two entries for a substance exist, up to four DNELs may exist (two for local and systemic effects in both entries), but only a local DNEL may exist in one entry and a systemic DNEL in the other entry (which is in fact the case for a substantial number of substances).

An evaluation done on unique chemicals with two (identical or different) workers long-term inhalation DNELs for systemic effects has been performed for the impact assessment. This covers most of the chemicals with more than one entry and the exclusion of DNELs for local effects is acceptable.[192] In total, 214 comparisons are available, i.e. 214 unique chemicals with two workers long-term inhalation DNELs for systemic effects, for which the higher DNEL can be compared with the lower DNEL. For 12 of these substances (5.6%), the two DNELs are identical. This low number is not surprising, since there is no reason to provide diverging toxicological summaries if the DNELs (and all other information) are identical. Large differences of several orders of magnitude are observed in rare cases and the highest difference between the higher and the lower DNEL is by a factor of almost 40,000.[193] This very high value has a large impact on the mean difference between the higher and lower DNEL, as shown in the following table.

Table 72: Summary statistics for the comparison of the higher and the lower DNEL per substance

N	214
AM	204 (18)*
MEDIAN	3.0
GM	4.4
MIN	1.0
MAX	39,837
Higher and lower DNELs within	
a factor of 2	80 (37%)**
a factor of 5	134 (63%)**
a factor of 10	166 (78%)**

*Notes: * Value in brackets after exclusion of the maximum value. ** Percentages relate to the total dataset (N=214)*

The data suggest that DNELs in REACH registration documents may differ substantially in a few cases, but that they do not differ by more than one order of magnitude for more than

[192] Note that if a substance has four entries with two relating only to local DNELs and two to systemic DNELs, the substance was included in the evaluation.

[193] The two DNELs are 0.49 mg/m^3 and 12.3 ng/m3, respectively, for ammonium 2-mercaptopropionate (EC no. 236-526-4). No reason for these diverging DNELs is apparent from the disseminated registration dossier. The experimental data suggest that the higher DNEL is more adequate. Furthermore, there is only a single registrant, and no specific compositions are identified that could explain the lower values. The lower DNEL therefore likely represents an erroneous entry.

three-fourth (78%) of the cases for which two DNELs are available. As noted above, more than one DNEL entry exists only for 7% of the substances on the DNEL list, indicating that the problem is limited to few substances overall. This evaluation has some limitations. For example, it is based on the DNEL list provided by DGUV (as of November 2020) and may include some outdated information. For example, individual cases were noted where one of the DNELs was provided in the dossier by a registrant who in the meanwhile ceased manufacture. Furthermore, this analysis was limited to substances with only two DNELs and other outcomes may be obtained if all substances are included. Finally, substance-specific evaluations of the differences could not be performed due to time constraints. There may be good reasons for differences in DNELs, such as differences in the composition and/or impurity profile of a substances. Therefore, the differences noted above do not necessarily indicate inconsistencies. Apart from different DNELs in REACH registration dossiers, DNELs derived by registrants may also differ from the ones established by RAC for use in applications for authorisation under REACH. In the following table substances are listed, for which RAC recommended DNELs for use in authorisation dossiers. The DNELs as derived in the respective registration dossiers are listed for comparison. For some of the substances, large differences in the numerical values are obvious.

Table 73: RAC reference DNELs[194] and DNELs from registration dossiers for substances in Annex XIV

Substance	**EC No.**	**CAS No.**	**DNEL - Workers - inhalation (mg/m³)***		**DNEL - General population - oral (mg/kg bw/d)***	
			RAC	**Dossier ****	**RAC**	**Dossier ****
Trixylyl phosphate (TXP)	246-677-8	25155-23-1	0.08	2.96	0.008	0.15
1-bromopropane	203-445-0	106-94-5	6.2	0.029***	0.32	-
Diglyme (bis(2-methoxyethyl)ether	203-924-4	111-96-6	1.68	26.8	0.09	1.04
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	9.9	4.36	0.5	0.5
Dibutyl phthalate (DBP)	201-557-4	84-74-2	0.13	0.13	0.007	0.007
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	0.88	1.6	0.034	0.036

*Notes: * DNELs relate to long-term exposure (see text for details). ** REACH Registration dossier. *** DMEL for carcinogenic effects.*

Differences between DNELs and OELs/IOELVs

The restriction under REACH of the aprotic solvent N,N-dimethylformamide[195] to fix a 'harmonised DNEL' for workers (inhalation and dermal) that shall be used by registrants of this substance in their chemical safety report in order to determine the relevant risk management measures for worker protection. However, harmonisation in this context only

[194] https://echa.europa.eu/de/applying-for-authorisation/evaluating-applications
[195] See REACH restriction undefined (europa.eu)

relates to the REACH Regulation and other reference values remain in place, such as the IOELV established by Commission Directive 2009/161/EU of 17 December 2009 (15 mg/m^3 as opposed to the 'harmonised DNEL' of 6 mg/m^3) that is also legally binding limit value established under OSH legislation in many EU member states. For companies, the different reference or limit values are confusing and the 'harmonised DNEL' does not resolve the differences between REACH-DNELs and OELs.) that is also legally binding limit value established under OSH legislation in many EU member states.

A large body of work investigating differences between OELs and DNELs is available. As larger assessment factors are suggested to be used for DNELs (see below), DNELs are expected to be lower than OELs for the same substance. This was observed by Schenk and Johanson using the ECHA R.8 Guidance for several substances and comparing the resulting DNELs with existing OELs as derived by the former Committee on Occupational Exposure Limits (SCOEL) (Schenk and Johanson, 2011). For the example of styrene, Kreider and Spencer Williams (2010) also concluded that the worker long-term DNEL according to the REACH Guidance would be lower than OELs. However, when authors compared national OELs with existing DNELs from registration dossiers no such differences were found. Partly, existing OELs were used instead of deriving own DNELs (Nies et al., 2013; Schenk et al., 2015; Schenk et al., 2014; Tynkkynen et al., 2015).

These analyses are primarily based on comparisons of DNELs with national OELs (from Sweden, Finland and Germany). Therefore, additional analyses were performed by comparing long-term DNELs from REACH registration dossiers (taken from the DGUV list mentioned above) with EU IOELVs. After data curation, 103 substances remained in the analysis. The following table summarises the results of this evaluation and shows similar comparisons of DNELs and IOELVs in two of the studies that also evaluated national OELs.

Table 74: Comparison of DNELs from REACH registration dossiers and IOELVs

	This study		**Tynkkynen et al. (2015)**		**Nies et al. (2013)**	
N (total dataset)	103		87		95	
DNEL = IOELV	58	56%	64	74%	71	75%
DNEL ≠ IOELV	45	44%	23	26%	24	25%
Of those with different DNELs and IOELVs						
DNEL < IOELV	32	71%	18	78%	14	58%
DNEL > IOELV	13	29%	5	22%	10	42%
Combined evaluation of total dataset						
DNEL ≤ IOELV	90	87%	82	94%	85	89%
DNELs < IOELV	32	31%	18	21%	14	15%

This comparison demonstrates that (a) 15-31% of the DNELs are lower than the IOELVs and (b) 87-94% of the DNELs are equal to or lower than the IOELVs. This result contrasts the findings of the studies cited above. The most likely but implicit explanation is that national OELs from Sweden, Finland and Germany are lower than the IOELVs in many cases, but these studies did not compare national OELs with IOELVs.

The quantitative analysis of non-identical IOELVs and DNELs shows that:

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- If IOELVs are higher than DNELs (N=32), the difference is substantial (up to a factor 96) in several cases. For one third of the substances (11/32, 34%), the IOELV is more than 5-times higher than the DNEL;
- If DNELs are higher than IOELVs (N=13), the difference is only about a factor of two on average and a factor of 5 as a maximum.

The following table summarise the results of this evaluation:

Table 75: Comparison of DNELs with IOELVs for non-identical values

	IOELV > DNEL	**DNEL > IOELV**
N	32	13
AM	9.1	2.2
MEDIAN	2.7	1.7
GM	3.7	1.9
MIN	1.0*	1.0*
MAX	96	5.0
Number of substances with a > 5-times higher value	11	0

*Notes: * Rounded to two significant figures (exact values are slightly higher than 1)*

These evaluations support the notion that DNELs are generally equal to or lower than IOELVs. The high level of agreement between DNELs and IOELVs may signal the use of IOELVs as DNELs by registrants rather than deriving DNELs based on the REACH methodology (ECHA, 2012). Such an approach is in agreement with provisions in ECHA (2012) allowing registrants '*to use an IOEL as a DNEL for the same exposure route and duration, unless new scientific information that he has obtained in fulfilling his obligations under REACH does not support the use of the IOEL for this purpose*' (ECHA, 2012). In such a case, the application of assessment factors as specified in ECHA, 2012**.** becomes obsolete. As noted by Tynkkynen et al. (2015), '*registrants have taken advantage of the opportunity to use the IOELV as a DNEL value as such. It can be assumed that at least in some cases, the DNEL would have been significantly lower than the IOELV if the default assessment factors published in the REACH guidance (ECHA, 2012) had been applied.*'

The finding that most of the DNELs differing from an existing IOELV are lower than the IOELV further supports the notion that the application of larger assessment factors will result in DNELs that are lower than IOELVs. However, DNELs derived under REACH may also reflect more recent data that may potentially result in a revision of DNELs (presumably towards lower values in many cases). National OELs may also be lower than IOELVs and a difference between DNELs and national OELs may therefore not be evident statistically.

Differences between DNELs and values in other regulatory areas (AELs, AOELs, ADIs/TDIs)

AOELs (Acceptable Operator Exposure Levels) and AELs (Acceptable Exposure Levels) are derived for workers exposed to pesticides and biocides, respectively, and have similar definitions as DNELs (EC, 2006; ECHA, 2017f)). However, several important differences in their derivation methodology are obvious. For example, no allometric scaling is recommended in the draft guidance for setting AOELs (EC, 2006) and is recommended only as a second tier approach for biocides (ECHA, 2017f). In addition, a higher assessment factor

for intraspecies variability (10) is used in these frameworks compared to REACH (5 for workers in ECHA R.8 Guidance, lower values in national OEL frameworks and in the ECETOC documentation (ECETOC, 2003; 2010)). Finally, AOELs and AELs for workers are generally derived as a dose (in mg/kg bw/d; exceptions apply e.g. for local effects), while workers DNELs for inhalation exposure are typically given as a concentration in mg/m^3 (Schneider and Dilger, 2019). For a detailed assessment of differences, we refer to the results from the BAuA research project F2437.[196]

Similarly, also ADI or TDI values derived for substances in food are derived using a 10 times 10 assessment factor for inter- and intraspecies variability (100 in total), which is numerically in accordance with the factors recommended by ECHA in the R.8 Guidance for DNELs, oral, long-term for the general population, if the POD comes from a chronic rat study. However, for smaller (e.g. mice) or larger species (e.g. rabbit) different factors would result. Nickel salts are an example for substances, for which values are derived both under REACH and by EFSA regarding their role as food contaminants. Recently, EFSA proposed a long-term TDI value of 13 µg Ni/kg bw/day.[197] A similar long-term oral DNEL for the general population of 11 µg Ni/kg bw/day was derived in the registration dossier for nickel dichloride.

To obtained more insight into different reference values in different regulatory areas, worker DNELs derived under REACH were compared with A(O)ELs derived under the BPR for a larger number of substances. Only long-term inhalation reference values were evaluated for this purpose. In addition, the corresponding reference values for the general population were also evaluated as were PNECs for the freshwater ($PNEC_{fw}$) compartment. The following table shows the results of these evaluations. Cells are empty, when no numerical value has been derived. In many cases, a reason is provided in the corresponding documentation.

[196] BAUA, Derivation of occupational exposure limits for airborne chemicals - Comparison of methods and protection levels, available at: https://www.baua.de/EN/Tasks/Research/Research-projects/f2437.html

[197] EFSA, Scientific Opinion, Update of the risk assessment of nickel in food and drinking water, 2020, available at https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2020.6268

Table 76: Comparison of reference values for substances used as industrial chemicals (REACH) and biocides (BPR)

Substance name	CAS no.	Workers (mg/m3)		General population (mg/kg x d)		$PNEC_{fw}$ (mg/L)	
		DNEL	A(O)EL	DNEL	ADI/AEL	REACH	BPR
Acrylaldehyde (acrolein)	107-02-8	0.2	0.019			7×10^{-5}	1.02×10^{-4}
Piperonyl butoxide	51-03-6	1.6	1.4	0.221	0.2	0.001	0.00148
3-iodo-2-propynylbutylcarbamate (IPBC)	55406-53-6	0.023	1.4		0.2	0.001	0.0005
Benzoic acid	65-85-0	0.1 (LOC), 3 (SYS)	35§	16.6	5	0.34	2.5
Biphenyl-2-ol	90-43-7	19.25	2.8	0.4		0.001	0.0006
Boric acid (as mg B)	10043-35-3	1.45	0.7	0.17		2.9	0.18
Bromoacetic acid	79-08-3	2.8	0.054	0.05	0.026	0.01	0.010
Calcium dihydroxide	1305-62-0	1 (LOC)				0.49	0.491
Calcium magnesium oxide	37247-91-9	1 (LOC)				0.32	0.491
Chlorocresol	59-50-7	6.289	2.1§	0.892	0.3	0.015	0.015
Coco alkyltrimethylammonium chloride (ATMAC/TMAC)	61789-18-2	1 (LOC)				0.00068	
Formaldehyde	50-00-0	0.375 (LOC); 9 (SYS)	0.12 (AEC, LOC)	4.1	No ADI (AEL: 0.15)**	0.44	0.0104
Hydrogen cyanide	74-90-8	0.78	0.7	0.018	No ADI (AEL: 0.1)	0.005	4×10^{-5}
Hydrogen peroxide	7722-84-1	1.4 (LOC)	1.25 (LOC)			0.013	0.0126
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one	55965-84-9	0.02 (LOC)	0.02 (AEC)	0.09	0.004	3.39×10^{-3}	4.9×10^{-5}

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Peracetic acid	79-21-0	0.56	0.5 (AEC)	1.25		0.002 (intermittent release)	6.9×10^{-5}
Potassium sorbate	24634-61-5	17.63	93.8§	2	13.4	1	
Propan-1-ol	71-23-8	268	64.4	61	9.2	6.83	2.3
Propan-2-ol	67-63-0	500	125	26	10.7	140.9	2.82

Notes: AEC: Acceptable exposure concentration, LOC: local effects, SYS: systemic effects
** AEL in mg/kg x d multiplied by 70 kg and divided by 10 m3/d; rate and extent of absorption via relevant pathways considered as given in assessment report (100% for both pathways assumed, if no specific data given). ** Non-professional primary use excluded. § ADI derived for non-professional user. No AEL derived for workers.*

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These comparisons of substances assessed both under the BPR and under REACH and biocides can be summarised as follows:

> Reference values derived under REACH (DNELs/PNECs) exist for more substances than reference values under the BPR. This finding is likely due to the fact that such values are derived under the BPR only if they are needed. For example, an ADI is generally derived under the BPR only, if exposure via food or feed is likely.
> While some identical (or very similar) values are derived under the two regulatory frameworks, DNELs and PNECs are generally higher than the corresponding reference values derived under the BPR. This applies to 75% (workers), 80% (general population) and 56% (PNECs) of the cases.
> Larger differences with the reference value derived under REACH being more than 10-times higher than the one derived under the BPR occur in 13% (workers), 20% (general population) and 31% (PNECs) of the cases.

For each substance, a substance-specific assessment would be needed to gain further insight into the reasons for the differences.

It must be noted that A(O)ELs are derived as body doses in most cases and conversions to inhalation exposure concentrations were necessary for this comparison with respect to workers. This conversion was done in a generic way based on the summary absorption rates given in the BPR assessment reports. A substance-specific assessment may have resulted in different outcomes. Interestingly, for the two substances, for which an AEC was reported in the BPR assessment report, these values are practically identical to the DNELs derived under REACH.

Consequences

Companies may use various toxicity values or develop their own where EU-reviewed reference values may already be available. Moreover, within the same reference or limit values, there are often various limit values differentiated by factors such as workers and general populations, adults and children, short- and long-term effects, local and systemic effect and different routes of exposure.

Risk assessment conclusions for the same substance may hence differ depending on the input reference value used and may be perceived as inconsistent even when they are justified. In addition, reference values may be derived using different methodologies, which may lead to incoherent outcomes.

Diverging DNELs or PNECs in different REACH registration dossiers for a substance have been identified. Though the evaluations for worker DNELs do not suggest that the problem is widespread, such divergence seems to come from deviations from the relevant ECHA guidance (Schenk et al., 2015; Schenk et al., 2014). This could lead to incoherent outcomes as these end-points are passed on throughout the supply chain and downstream users may be prevented to place their products on the market as wrongly assumed as not safe or place them on the market, where the use of them is eventually not safe.

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Drivers

Different toxicity reference values for the same substances may lead to inconsistencies in the outcomes of risk assessments and to the inefficient use of limited resources. The existence of different values depends on a range of justified and less justified reasons:

differentiation by workers and general populations, adults and children, short- and long-term effects, local and systemic effect and different routes of exposure;
use of different methodologies;
availability, access and use of different studies;

visibility of EU-reviewed reference values, which may be ignored by companies and/or authorities deriving their own values.

How likely is the problem to persist?

The CSS highlights the "one substance, one assessment" (OSOA) approach as a possible way to produce more coherent results. The Commission committed to create a repository of toxicity reference values to promote their reuse and harmonisation among EU risk assessors and managers. However, a repository can only be the first step, as the various methodologies for deriving reference values in different regulatory areas have been developed historically and may not be easily harmonised. For example, methodologies for deriving OEL values at the EU and Member State levels differ as do DNELs derived under REACH and OELs. Furthermore, even DNELs or PNECs derived by registrants under REACH may differ, because of different assessment factors or points of departure.

EFSA, the Commission and ECHA have already made some efforts to compile and make toxicity reference values available. ECHA has developed and operates the EU Chemicals Legislation Finder (EUCLEF)[198], an online service offering the possibility to navigate through the EU chemicals legislative framework, providing substance-based information from 56 pieces of EU chemicals legislation. EUCLEF lists some health-based limit values derived and applicable under these legislative pieces. EFSA maintains the OpenFoodTox database[199], which summarises the outcomes of all hazard identification and characterisation performed by EFSA on plant protection products and contaminants, food improvement agents and feed additives for human health, animal health and the environment. The Commission (DG SANTE) maintains the EU pesticides database[200], which is the official source for pesticide MRLs in food products. The database also lists AOELs, ARfDs and ADIs.

POTENTIAL POLICY MEASURES

Baseline

Already some initiatives or measures may be envisaged as developing harmonised toxicity reference values and more may be expected in the future. For example, the restriction

[198] https://echa.europa.eu/information-on-chemicals/euclef
[199] EFSA, Chemical Hazards Database, available at: https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox
[200] Pesticides Data base, available at https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en

under REACH of the aprotic solvent N,N-dimethylformamide[201] to fix a 'harmonised DNEL' for workers (inhalation and dermal) that shall be used by registrants of this substance in their chemical safety report in order to determine the relevant risk management measures for worker protection.

The differences between legislations are also evident in other examples. In the case of nonyl- and octylphenols, EQS were derived under the Water Framework Directive. These may be considered 'harmonised reference values'. However, based on the RAC statement related to the corresponding nonylphenol and octylphenol ethoxylates (ECHA, 2017), it appears questionable that these EQS may be accepted as a threshold in applications for authorisation. The same is true is even true within a single regulatory area. For example, the DNEL derived by RAC for dibutyl phthalate in 2013 may be considered a 'harmonised DNEL'. With the addition of this substance to REACH Annex XIV for endocrine disrupting properties (human health), the validity of this reference value is unclear and RAC was not in a position to derive a DNEL for these effects (ECHA, 2021). Again, diverging OELs are legally in place in several EU MS.

The reference values established by regulatory agencies are not necessarily lower than those derived e.g. by registrants under REACH. For example, different studies were often available to REACH registrants for deriving PNECs compared to the ones available to the competent authority for the same substance under the BPR. In some cases, REACH registrants have derived lower PNECs than authorities under the BPR and it may not be the most meaningful approach to establish the latter as 'harmonised PNECs'.

It is assumed that the Commission would establish the repository of toxicity reference values as for its commitment as part of the OSOA approach in the CSS, with the aim of promoting the reuse of the values among EU risk assessors and managers. It is also assumed that EU agencies would establish a central coordination mechanism, which would ensure better distribution and coordination of tasks and access to all data by all agencies, as advocated by ECHA and EFSA in their joint position paper[202].

Policy options

The purpose of harmonising reference limit values is to support EU risk assessors in their specific regulatory framework. They are based on findings that different reference values may exist for a given substance under different regulatory frameworks (or even within the same as for example of different DNELs in registration dossiers). This situation not only lacks transparency for interested stakeholders but may also indicate inefficiency since reference values for the same purpose (e.g. workers protection) may have been derived by different bodies in parallel. Ultimately, different reference values for the same substance may result in different risk assessment conclusions that may be perceived as inconsistent and are difficult to communicate even if they are justified.

Against this background, the OSOA approach has been highlighted in the EU chemicals strategy for sustainability as a possible way to produce more coherent results. In this wider context, harmonised reference values may be an element to support an OSOA approach

[201] See REACH restriction: undefined (europa.eu)
[202] https://www.efsa.europa.eu/en/corporate/pub/osoa

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for use by different bodies in different regulatory areas. Such harmonised reference values may reduce inconsistencies and result in more efficient and effective use of resources.

A detailed discussion of the differences in methodologies for deriving DNELs and PNECs (as well as related reference values) is provided above, including evaluations of substance-specific reference values under different regulatory frameworks and statistical evaluations. For example, methodologies for deriving OEL values in the EU and in Member States differ. In addition, the methodologies for deriving DNELs under REACH are different from the ones applied in OEL derivation in Member States. Furthermore, even DNELs or PNECs derived by registrants under REACH may differ, e.g. by using different assessment factors or points of departure. It is also noted that it may not be meaningful to harmonise all approaches and the CSS specifically notes that the OSOA approach (emphasis added) '*aims to ensure that methodologies are made more coherent and* ***to the extent possible*** *harmonised*'.

Since the Commission proposal considers harmonised DNELs and PNECs particularly valuable for substances with widespread uses in different regulatory areas, the considerations above may serve as a critical appraisal of the proposal. It is also noted that the EFSA/ECHA joint position paper on OSOA does not propose any form of harmonised reference values, but rather three organisational pillars for the OSOA approach by EU agencies (central coordination mechanism, better distribution/coordination of tasks and access to all data by all agencies).

Some CARACAL members suggested to include harmonised NOAELs for toxicological effects and NOECs for ecotoxicological effects in the CLP Regulation rather than DNELs and PNECs. This suggestion is based on the consideration that different assessment factors are used in different regulatory frameworks.

In most regulatory frameworks, reference values are calculated considering results from different key studies by (a) adjusting the experimental POD (point of departure; e.g. a NOAEL, NOEC) to human/environmental exposure and (b) applying assessment factors. The study resulting in the lowest reference value will ultimately be used for deriving the reference value. This may - depending on the substance and the available data – involve many studies for different endpoints, in some cases also a differentiation of local and systemic toxicological effects. Since the approach involves several steps, the study resulting in the lowest reference value may not have the lowest NOAEL/NOEC.

If a harmonised NOAEL is included in the CLP Regulation, different reference values may still be derived under different regulatory frameworks because of non-harmonised methodologies (e.g. different adjustments for human exposure and/or assessment factors being applied). In fact, RAC and SCOEL recognised in their joint report on OEL derivation that in addition to diverging assessment factors 'the way in which the adjustment of the POD for exposure was carried out could be more critical to the final result than previously thought' (ECHA/RAC-SCOEL, 2017).

The most suitable key study and POD may will also depend on the specific reference value it will be used for. If an inhalation reference value is to be derived for a given substance, preference will generally be given to a key study involving inhalation exposure due to the limitations of route-to-route extrapolation (Schneider and Dilger, 2019). If the

same substance is used e.g. in food contact materials and a reference value needs to be derived, preference will generally be given to a key study involving oral exposure.

Provision of NOAELs or NOECs – in some sense – make matters more complicated than inclusion of reference values. For example, benchmark doses (rather than NOAELs) are increasingly used for toxicological endpoints. Benchmark doses may be derived as a central estimate (BMD) or the lower bound of the confidence interval (BMDL). The extent of using benchmark doses and the specific POD used (BMD, BMDL)[203] differ between different regulatory frameworks (Schneider and Dilger, 2019).

These considerations demonstrate that a POD (e.g. a NOAEL) does not exist in a vacuum but must always be seen in the context of its intended application. In some cases, both an inhalation and an oral POD would be needed, and the underlying key studies may differ substantially (e.g. an epidemiological study for the inhalation POD and a study in experimental animals for an oral OEL). The POD may be given as a NOAEL for some substances and as a benchmark dose for other substances. Consequently, substantial contextual information would need to be provided in addition to the value as such.

Even if a single NOAEL could be provided for a given substance, different reference values (e.g. a DNEL under REACH and an A(OEL) under the BPR) may still result due to differences in methodology and/or scientific assessment. Therefore, the OSOA principle appears as not being fulfilled. Ultimately, these considerations suggest that the OSOA principle cannot be simply implemented by providing single values (as long as methodologies are not harmonised), which is also suggested by the proposals of the EFSA/ECHA joint position paper on OSOA.

On the basis of the problem described above as different agencies and expert committees derive toxicity reference values with different methodologies and using different studies: the following policy measures have been identified:

- Provide harmonised toxicity reference values (DNELs/PNECs or N/LOAEC and/or N/LOAEL) in CLP Annex VI (CLH) or new annex;
- RAC opinions include the derivation of point of departures (NOAEL/NOAEC) when performing the review of CLH dossiers for the hazard classes under the scope of the CLH dossier.
- Create a repository of toxicity reference values;
- Create a central coordination mechanism to harmonise toxicity reference values across different chemical regulatory frameworks.

Stakeholders' views

With regard to toxicity reference values, the analysis of the Open Public Consultation position papers has shown a very high variation in opinions with some of them clearly out of the scope this issue. For instance, some respondents discussed the issues of hazard identification or animal testing. Such variance demonstrates that the problem is not sufficiently visible, discussed or understood by the stakeholders. In open questions of the

[203] As an additional element, the benchmark response (also called critical effect size) associated with a BMD or BMDL must be provided, but this issue is not discussed here further.

TSS, the respondents were focused on toxicity reference values; however, many of them pointed out that the issue of hazard quantification is out of the scope of the CLP Regulation. It should be noted, however, that the views of business entities were mostly represented in the TSS due to a very low participation rates of public authorities and non-governmental organisations. In the interviews, the respondents also indicated that the issue is out of CLP scope. However, the interviewees commented that different toxicity reference values emerge due to various reasons (e.g., data or knowledge available as well as different methodology, different levels of scientific quality, etc.).

Similarly, although in general, CARACAL members were supportive to harmonisation of toxicity reference values, they did not see how the issue of diverging toxicity reference values fit the CLP Regulation.

SCREENING AND ASSESSMENT OF THE POTENTIAL MEASURES

Discarded policy options

Include in RAC opinions the derivation of point of departures (NOAEL/NOAEC) when performing the review of CLH dossiers for the hazard classes under the scope of the CLH dossier. While this may entail a lower workload due to the limitation to selected endpoints — although falling on RAC rather than dossier submitters — such an approach has several limitations:

CLH dossiers are usually limited to a consideration of specific endpoints/hazard classes (e.g. CMR properties, respiratory sensitisation and ED properties in the future). The point of departure will only relate to these endpoints. The NOAEL/NOAEC values for other endpoints (i.e. the ones not subject to the CLH dossier) may differ from (and in some cases may be lower than) the one derived under this option. Consequently, the point of departure derived under this option may not be used in the derivation of reference values, which requires a consideration of all endpoints. In essence, providing a point of departure in a CLH dossier will always involve the uncertainty of whether consideration of other endpoints would result in lower points of departure or reference values).

Since CLH dossiers focus on endpoints that are considered (by RAC and other EU institutions) to reflect non-threshold effects in many/most cases (e.g. carcinogenicity, endocrine disruption), deriving a simple point of departure may not be feasible. In such cases, exposure-risk (or dose-response) relationships will need to be established and it will remain unclear how these relate to points of departures for other endpoints.

There may be a complex relationship between pathways of exposure, mechanisms of action and the endpoints considered (e.g. non-threshold carcinogenicity following inhalation, but not dermal, exposure and threshold-based reproductive toxicity involving all pathways of exposure in the case of hexavalent chromium).

Overall, it does not appear meaningful to derive a point of departure without a consideration of the complete toxicological profile of a substance.

Create a repository of toxicity reference values: Assumed to be part of the baseline. The Commission has launched a call for tenders for designing the repository and collating information. This belongs to the baseline.

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Create a central coordination mechanism to harmonise toxicity reference values across different chemical regulatory frameworks: This is to be assessed by a study focusing on the one substance, one assessment approach. Such a central coordination mechanism, proposed in the ECHA and EFSA Joint position paper on one substance - one assessment would include a coordinated problem formulation phase (i.e. identifying the correct scientific question that needs to be answered) which would enhance predictability for industry. This may include a public EU coordination registry, potentially developed from ECHA's PACT (Public Activities Coordination Tool), to increase transparency and predictability on substance-specific activities by authorities across different chemical regulatory frameworks.

Retained policy options

The harmonisation of methodologies is a difficult endeavour and is outside the scope of the CLP Regulation. However, the measures under consideration propose to add a procedure to the CLP Regulation to derive and publish harmonised human and environmental toxicological reference values along the following lines:

'Introduction of the possibility to insert in a CLP CLH dossier or in a stand-alone dossier a proposal for a harmonised value of human and environmental toxicological reference values when considered appropriate by the dossier submitter (e.g. REACH data are available etc.).

The dossier will be assessed by the Agency in the usual way. Once an opinion is provided including a proposal for a harmonised human and environmental toxicological reference values, the Commission will consider its insertion in Annex VI or in a new Annex.

Downstream regulation might want to refer to the harmonised CLP human and environmental toxicological reference values in their specific framework. However, it will be left to these legislations to assess any direct link or specific requirement to follow CLP harmonised values'.

Description of Impacts - Administrative burden on businesses and public authorities

The harmonisation of reference values would lead to increased administrative costs on dossier submitters, and therefore in particular on public authorities. Based on the experience with CLH, it can be assumed that economic operators would only rarely submit dossiers for harmonised DNELs/PNECs or N/LOAECs and/or N/LOAELs. Moreover, businesses wishing to submit proposals may not have access to the same level of data accessible by public authorities.

The following table summarise workload estimates for the dossier submitter under the assumption that a stand-alone dossier is submitted. The workload may be lower if a combined CLH/harmonised DNEL/PNEC dossier is submitted, but this can only be judged on a case-by-case basis and most likely only affects human health. The workload estimates do not change if NOAELs and NOECs are derived instead of DNELs and PNECs. The question whether harmonised DNELs are derived in a stand-alone dossier or together with a CLH dossier. In the latter case, the workload for harmonised DNELs (but not PNECs) may be lower depending on the extent to which the relevant studies for classification and DNEL derivation overlap. However, it is estimated that the additional

workload for RAC to derive NOAELs and NOECs for the hazard classes under the scope of the CLH dossier under AARAC assessment is low.

The impact of the factors mentioned above is far higher than the workload associated with the actual derivation of DNELs and PNECs. Furthermore, resulting reference values need to be calculated anyway for selection of the most adequate NOAEL/NOEC.

Table 77: Workload estimates (in person-days) to derive harmonised DNELs and PNECs or NOAELs and NOECs (derivation only)

Available dataset	Harmonised DNELs*	Harmonised PNECs**	Total person-days (FTEs)
Low	5	5	10 (0.045 FTE)
Medium	15	12	27 (0.123 FTE)
High	25	20	45 (0.205 FTE)

*Notes: * Workers (inhalation and dermal, long-term, systemic effects) and general population (inhalation, dermal and oral, long-term, systemic effects). ** All compartments envisaged in ECHA (2008).*

Due to the various factors affecting the workload, these figures have a high degree of uncertainty, and the 'high' values should not be taken as maximum values. The figures presented in the table above are the estimated additional resources required to derive these reference values by the dossier submitters. Through the analysis of the database of CLHs maintained by ECHA, it is not possible to identify how many CLHs have been submitted by industry and how many by MSCAs. However, a close proxy can be derived through the analysis of the registry of intention for CLHs, which reveals that industry actors submit 2% of CLH dossiers. By considering an average of 55 CLH dossiers being submitted per year, the administrative burden for MSCAs is estimated at 6.8 FTEs per year (or present value of €0.6 million; discount rate: 3%; period: 2023-2043). As noted above, the support services by ECHA and the development of the RAC opinion need to be accounted for. The necessary resources are considered proportional to the time required to derive DNELs and PNECs or NOAELs and NOECs, and are therefore extrapolated from the estimates provided by ECHA on the support and RAC opinion development on CLH dossier.

Table 78: Workload estimates including ECHA support services and RAC opinion development

DNELs/PNECs or NOALEs/NOECs derivation	FTEs	% of required resources to develop a CLH dossier (0.35 FTE)	RAC opinion development	ECHA support services
Low	0.045	13%	0.013 FTE	0.007 FTE
Medium	0.123	35%	0.035 FTE	0.018 FTE
High	0.205	58%	0.058 FTE	0.029 FTE

The additional burdens of 1.9 FTE per year (CI: 0.7 – 3.2 FTEs) for the RAC to develop an opinion on the derived reference values and 1 FTE per year (CI: 0.4 – 1.6 FTE) for ECHA CLP support team to support the process, although low, would impact on the already strained capacity of the RAC and ECHA CLP support team. The present value (discount rate: 3%; 2023-2043) of the costs for RAC opinion development are estimated at €0.4 million and for ECHA support services at €0.2 million.

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Harmonised DNELs have the potential of ensuring a more consistent application of the methodology established under REACH. While the derivation of harmonised DNELs/PNECs may reduce the issue of diverging values observed in REACH registration dossiers (Schenk et al., 2015; Schenk et al., 2014), they would need to be accompanied by additional (regulatory and non-regulatory) clarifications to tackle inconsistencies across different legislative frameworks. In particular, there is the risk that legally binding reference values may contradict legally binding national values under other legislation (e.g. DNELs vs. national OELs based on EU IOELVs), and non-legally binding values may cause confusion, as there may be already legally binding values under different legislation. However, it should be noted that having derived POD (NOAEL, PNEC) by RAC could represent a good starting point for both economic operator or competent authorities to derive their reference values.

If harmonised DNELs or PNECs are derived for substances relevant under REACH and other several regulatory areas (workplace, biocides, plant protection products, food contaminants etc.), for which legislations and guidelines for assessment are in place, the following relevant issues are identified:

Regulatory clarification would be required regarding the status and relevance of harmonised DNELs and PNECs for these regulatory areas. Already under the existing legal framework the obligation to derive DNELs when an OEL is established was identified as a problem for companies (RPA et al., 2017). While the Commission proposal suggests that ‘downstream regulation might want to refer‘ to such harmonised DNELs/PNECs, the legal character would need to be clearly defined:

> If e.g. harmonised DNELs are legally binding, it may contradict legally binding national OELs (based e.g. on an EU IOELV);

If harmonised DNELs/PNECs are not legally binding, it may cause confusion since the classification for the same substance is legally binding.

Harmonised DNELs and PNECs would automatically gain special importance and attention. Therefore, harmonisation of the methods to derive similar health-based values in the various regulatory areas would become necessary to avoid inconsistencies. Setting harmonised DNELs/PNECs or NOAELs/NOECs may then be seen as an incentive to harmonise methodologies across regulatory frameworks. However, if such a methodological harmonisation is not taking place, different values will continue to exist. It may therefore be argued that harmonisation of methodologies – where meaningful – is a prerequisite to obtain more coherent reference values rather than a consequence of harmonised DNELs/PNECs/ NOAELs/NOECs.

The evaluations show that:

IOELVs cannot be taken directly as a basis for harmonised DNELs, since the methodology for their derivation deviates from the DNEL methodology. Noteworthy, DNELs are equal to or lower than IOELVs in 15-31% of the cases based on evaluations performed in this study and by others (Nies et al., 2013; Tynkkynen et al., 2015)

AELs and PNECs derived under the BPR – while derived using similar methods as applied under REACH – often differ from DNELs and PNECs derived under REACH. Illustrative cases of PNEC derivation under both regulatory frameworks suggest that

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differences are not due to differences in methodology (e.g. the application of assessment factors), but rather result from the use of different studies for PNEC derivation. This observation suggests that study/data availability is an element to consider in addition to harmonisation of methodologies as was also noted in the EFSA/ECHA joint position paper on OSOA.

Numerical values of DNELs are subject to changes when new data becomes available. Although harmonised classifications may also require updates with new information becoming available, numerical values are expected to be more likely subject to changes than the qualitative evidence on e.g. CMR endpoints. In contrast to qualitative evidence for classification, harmonised DNELs/PNECs would need to be checked for newly available data and for the potential need for updates on a regular basis (e.g. every two years).

The update of reference values is expected to happen more frequently than updates to CLH dossiers and it would therefore be more difficult. Moreover, their inclusion in Annex VI or separate Annex would not necessarily result in one value for one substance. While it could be an incentive to harmonise methodologies, harmonised methodologies are a pre-requisite to more coherent reference values. In addition, data availability to the dossier submitter needs to be considered.

In summary, it is concluded that the inclusion of reference values in CLP would not add sufficient benefits, if considered against the increased effort required by dossier submitters, ECHA and RAC.

Annex 10 – Allowing COM to initiate CLH & Improving prioritisation of CLH

CONTEXT

CLP is the primary basis for most chemical hazard assessment and classification in the EU. According to the Chemical Fitness Check, the CLP Regulation is effective and is considered by the majority of stakeholders as an improvement over the earlier Directives that it replaced in 2008. Some issues, however, were identified with respect to the pace and focus of harmonised classifications.

The harmonised classification is an important instrument for achieving the safe use and enhancing the substitution of hazardous chemicals[204]. Such classifications are compulsory throughout the EU to ensure adequate information and risk management. It is also linked with various processes laid down in other sectorial regulations, which need a certain and EU-wide harmonised classification as a basis. As an example, the approval processes for plant protection product (PPP) and biocidal product (BP) active substances require a harmonised classification for all hazard classes under the CLP Regulation.

Article 36 of the CLP Regulation requests that substances that fulfil the identification criteria for carcinogenicity, mutagenicity, reproductive toxicity category 1A, 1B or 2 and respiratory sensitisation category 1, substances that are biocidal or plant protection product active substances should be classified and labelled in a harmonised way in the EU. Other substances may also bear a harmonised classification on a case-by-case basis for justified reasons. A harmonised classification (i.e., CLH) dossier may be submitted in order solve diverging self-classifications identified in the Classification and Labelling Inventory (CLI) (see Annex CLI). The procedure for the preparation and submission of CLH proposals is laid out in Article 37 and described below.

The CLH process is usually initiated by an MSCA or manufacturer, importer or downstream user, by submitting a CLH intention, although the latter is not a formal requirement. This is followed by the submission of the CLH dossier – a document that contains sufficient information to allow an independent assessment of physical, health and environmental hazards of a substance. The CLH procedure consists of four main steps:

initiation of the CLH process;
preparation of a CLH dossier for the RAC;
development of RAC opinion; and
Commission's decision concerning the inclusion of the substance and the CLH in Part 3 of Annex VI to the CLP Regulation.

These are preceded by preparatory work (screening/grouping, regulatory risk assessment and generation of further information and assessment) to make the CLH process more targeted and to identify relevant substances for CLH (Figure 68). A more detailed overview of the steps and their efficiency is provided in Annex V.

[204] See chemical Fitness Check, SWD(2019) 199.

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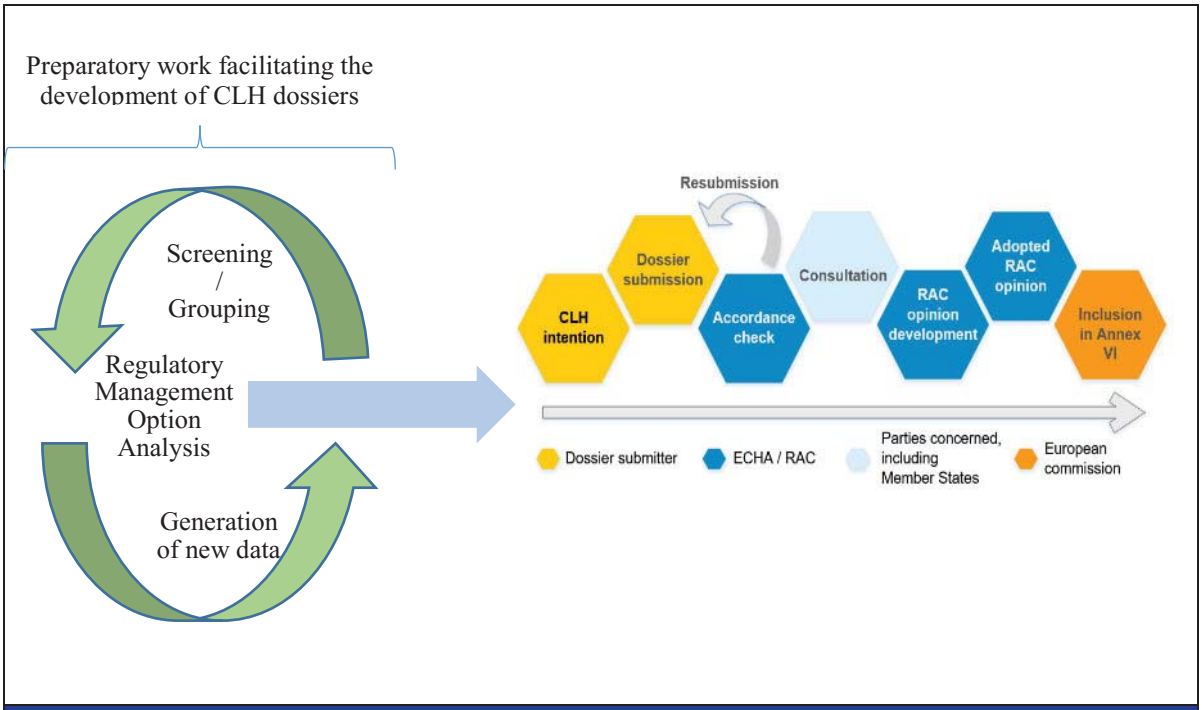

Figure 68: CLH procedure – Adapted from ECHA

DESCRIPTION OF THE PROBLEM

According to the chemicals Fitness Check[197], the number of assessments for harmonised classifications under the CLP Regulation is relatively low compared to the likely number of chemicals which merit a harmonised classification[205]. The speed of the procedures for CLH was assessed as slightly to mostly satisfactory. All categories of stakeholders agreed that there is still rooms for improvement.

Considering harmonised classification and labelling, the feedback to the open questions as well as position papers in the OPC have shown that the respondents[206] did not have a clear understanding about the nature of problems in this area. Such outcome is due to CLH being a specific process that requires certain knowledge to make judgements on it. In the TSS that mostly represented the views of businesses, the latter disagreed in their conclusions about CLH. Two opposite opinions dominated in open comments to the TSS with some respondents considering CLH an inefficient process (e.g., in terms of time, organisation of procedures, etc.), while others believed that CLH is properly organised and shows a good performance. In interviews, some respondents noted the lack of scientific quality and fair prioritisation of substances for CLH, while others were completely satisfied with the CLH procedure. In their written feedback about CLH, some CARACAL members highlighted that ECHA and RAC work to maximum capacity that may indicate the lack of additional resources for CLH.

[205] ECHA "Authorities to focus on substances of potential concern – Roadmap for SVHC identification and implementation of REACH management measures – Annual report' (2018) p. 13

[206] It was noted that many Member State Competent Authorities favoured providing input to the ad-hoc CARACAL consultation rather than replying the Open Public Consultation.

Limited capacity working at full speed

Firstly, RAC has been processing around 50 to 60 dossiers every year since 2017, close to full capacity. ECHA estimates that 60 dossiers are the maximum the ECHA CLH team and RAC can process with the current capacity of 50 members and 5 co-opted members[207]. The timeline and regulatory deadlines for the CLH procedure[208] are always met by RAC, except for 10 opinions in 2020 which were delayed because of the COVID-19 pandemic. The current speed also reflects the need to ensure that all the relevant opinions, including stakeholder views, are taken into account. The transparency with which RAC opinions are developed was highlighted in the Chemical Fitness Check.

The availability of limited resources working at full capacity results in a slow increase of the number of harmonised classifications in Annex VI of the CLP Regulation (Table 79). As of 2022, 4,335 entries[209] have harmonised classifications. Harmonised classifications and labelling of hazardous substances are introduced and updated through the Adaptations to Technical Progress (ATPs), issued yearly by the European Commission. The adoption of the RAC opinions and the inclusion of CLH in Annex VI by the Commission also requires resources and an increase in CLH may result in bottlenecks also at this final step.

Table 79: Number of new substances with CLH (2008-2022)

ATP	Application date	No. of substances
CLP00	2008	3,368*
ATP01	2010	758**
ATP03	2012	11
ATP05	2012	22
ATP06	2014	14
ATP07	2016	19
ATP09	2018	26
ATP10	2018	24
ATP13	2020	16
ATP14	2021	17
ATP15	2022	37

Source: Analysis of all CLH from: https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp
*Notes: *Harmonised classifications implemented under Directive 67/548/EEC; ** ATP01 brought the entries from the 30th ATP & 31st ATP of Directive 67/548/EEC into Annex VI of CLP*

It should be noted that ECHA and RAC have identified the limited resources of RAC as a bottle neck for CLH output[200]. They have come up with the following improvements that are already in place. In 2018, a fast track procedure was introduced by RAC for identifying non- controversial endpoints ahead of the plenary, saving time in the plenary to focus on points that are more difficult. ECHA indicated that since this was introduced, 65% of classification proposals for such endpoints went through without a plenary discussion. In 2021, ECHA set up a working group to RAC for the assessment of CLH

[207] See presentation by RAC at CARACAL 43. It should be noted that currently RAC operates with ony 44 members in total.
[208] Article 37(4) of the CLP Regulation states that RAC should 'adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment.'
[209] Some of the entries of Annex VI are group of substances (e.g. the metal compounds), so the number of substances is higher.

dossiers. This gives more room for detailed discussion. The plenary meeting would then decide on a more mature draft opinion; again saving time.

Secondly, most of the CLH dossiers submitted are developed by Member State Competent Authorities. When covering plant protection product or biocide active substances, only MSCAs can submit CLH dossiers. There are limited resources of Member States resulting also an uneven and limited contribution to CLH proposal submission (see Figure 69:). (Milieu Consulting, 2020; ECHA, 2021b). The situation reported in 2019 (fitness check) is a reflection of the high resource needs (staff/expert capacity) at Member State level for preparing a CLH dossier, combined with reductions in resources and budgets allocated for this work in many Member States, in particular following the 2008 financial crisis. There is also considerable variation between Member States in their capacity and willingness to initiate CLH dossiers with just a few Member States carrying the majority of the burden (see Figure 69:). It is understood that the situation has not improved during the COVID pandemic.

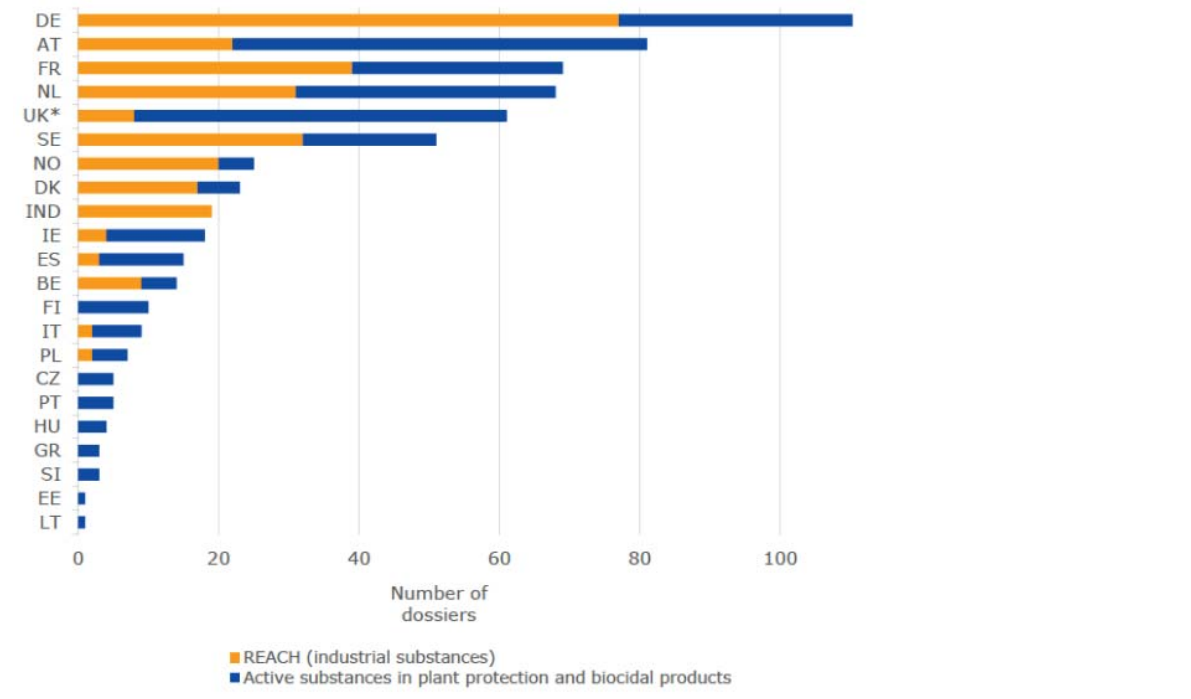

*Figure 69: Number of dossiers submitted per Member State in 2008-2020. Source: reproduced from ECHA (2021b). Notes: *Member State until 31 January 2020*

Out of 27 Member States, only 22 submitted a CLH since the CLP Regulation was adopted. A smaller subset of 13 submitted CLH dossiers for industrial chemicals indicating that out of 27 Member States, only some have resources to perform this task. Only 11 out of the current 27 Member States submitted more than 1 CLH dossier on average per year and 6 of them managed to submit more than 2 per year.

On a more positive note, in 2020, CLH procedures were initiated for a substantial number of substances (100), but even a higher number (125) was pending the initiation of CLH

process, which is far more than what RAC can handle if all intentions are transformed into submitted dossiers.

A high number of substances which deserve a harmonised classification

First, the number of industrial chemicals, which are identified as deserving a harmonised classification according to the current hazard classes in the CLP Regulation, increased every year (see Figure 70). From the figures reported, this development is quicker than what the CLH process can deliver. ECHA's integrated regulatory strategy (IRS)[210] screening and grouping system has resulted in the identification of a long list of substances proposed for regulatory risk management action, including CLH. Significant progress – a ten-fold increase in the number of screened substances per year compared to 2014-2018 – was achieved in 2020 due to the introduction of the grouping approach (ECHA, 2020; ECHA, 2021b).

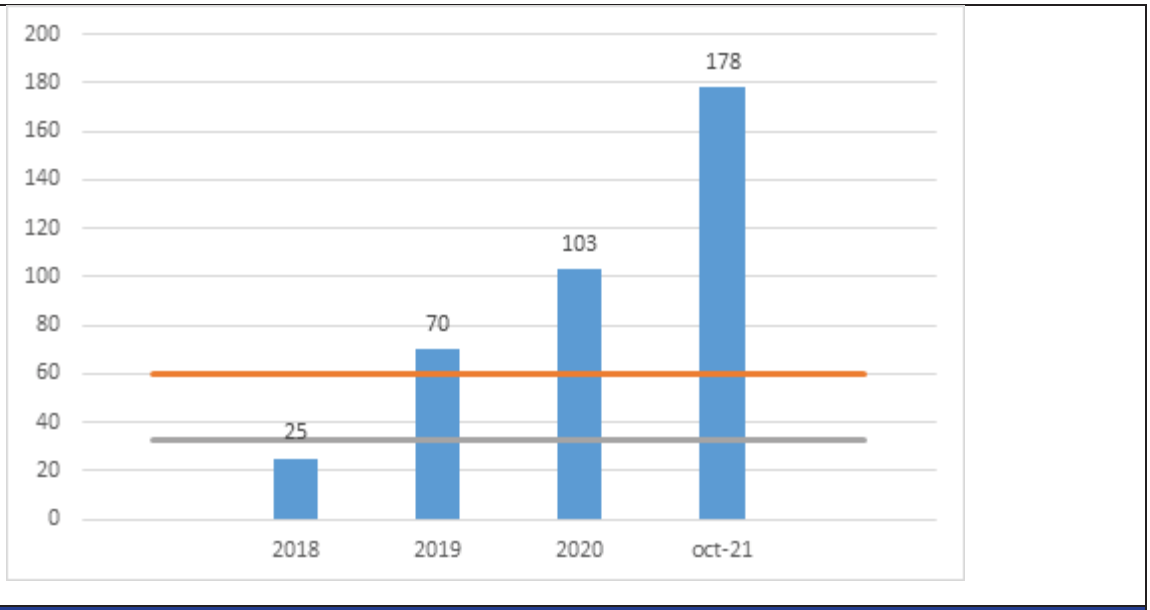

Figure 70: Number of industrial substances requiring CLH identified through the IRS – Source: data provided by ECHA
Red line: 60 RAC opinions per year maximum, grey line: 33 RAC opinions per year maximum for industrial chemicals.

Second, the number of substances for which a CLH dossier is needed may further increase, following deeper checks of available information by ECHA. The rolling out of the following actions from the Chemicals Strategy for Sustainability[211] (CSS) may also increase the number of CLH dossiers. First, more knowledge information may be requested and generated for low-tonnage registered substances. Furthermore, additional hazard classes are proposed to be included in the CLP Regulation. In addition, there is the

[210] Integrated Regulatory Strategy (IRS), which ECHA has been implementing since 2016 as a follow-up to the SVHC Roadmap. The IRS aims "to accelerate data generation, identification of groups of substances of concern, and regulatory action". The goal is "to clarify by 2027 which registered substances are a high priority for regulatory risk management or data generation, and which are currently a low priority for further regulatory action" (ECHA, 2021b).
[211] COM/2020/667 final

need of harmonised classifications to apply generic risk management approach under REACH and other sectorial legislation. The consequence is that more suspected substances of concern may receive harmonised classifications with additional delay in the future, resulting in inconsistencies in risk management measures adopted by the actors along the supply chains but also in a further delayed application of the regulatory Risk Management Measures (RMMs), because of the failure in triggering RMMs in vertical legislation referring to CLP hazard classification.

Second, a large part of the CLH dossiers cover active substances used in plant protection and biocidal products (see Figure 71). This explains the fact that relatively few harmonised classifications have been developed for REACH-registered industrial chemicals and almost none for chemicals not registered under REACH. As shown below, CLH dossiers for active substances represent 45 % of the submitted dossiers. Interestingly, the share of submitted dossiers which don't meet provisions of either Article 36 (1) (CMR or respiratory sensitising substances) or Art 36 (2) (PPP or BP active substances) increased steadily to 16.5 % in 2021. So far, no submitted CLH dossier has been rebutted for not meeting the criterion in Article 36 (3), as justification was always assessed as sufficiently relevant by ECHA and RAC.

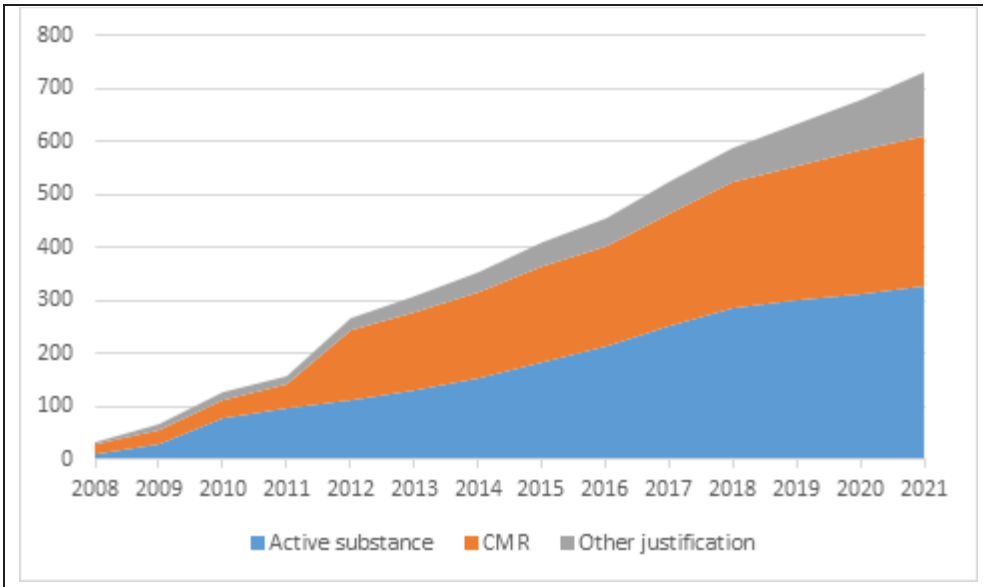

Figure 71: Number of CLH intentions according to the justification according to Art. 36 for CLH (Note: withdrawn intentions out or CLH dossiers submitted without prior intention) ECHA's CLH Registry of Intention, consulted on 24/2/2021)

The main consequence of this 'slow' pace is that not all hazardous industrial chemicals are identified and/or identified in an unambiguous way (see section CLI). This hence may prolong exposure of EU citizens and environment to such hazardous chemicals.

In the period 2016-2020, there has been a steady increase of CLH dossiers for CMR substances (71 in total) (ECHA, 2021c). The IRS has accelerated the screening of registered substances and the identification of those requiring the generation of further data or risk management. Without intervention in the coming years, the rhythm of CLH adoption is assumed to stay constant, as ECHA and RAC work at full capacity and

MSCAs' resources remain limited. Also, the workload is assumed to remain uneven, with just a few MSCAs carrying most of the burden.

Beyond the question on the too small annual volume of opinions, there is a question whether there are synergies to be identified in the current and/or future CLH process. Recently ECHA has improved their screening process by grouping related substances. Such grouping is based on read-across and chemical similarity. The same reasoning could also be applied to CLH dossiers, which could be developed for a group of substances. CLH dossiers take advantage on the approaches mentioned above by using information on similar substances but so far a very limited number of dossiers for grouped substances has been submitted. In 2020 and 2021, RAC issued two opinions on small groups of substances, one for 2-ethylhexanoic acid[212] and its salts and one for 3 lithium salts[213]. It should be noted that so far, grouping under CLH process has been limited to substances sharing the same toxic moiety. The European Commission will soon contract the development of a larger CLH dossier for 40 phthalates, called for by the Roadmap[214] for restriction. If this grouping approach can be applied to CLH processes, the increased pace of IRS will also be addressed by CLH dossiers submitted for groups of substances.

RAC opinions cover both CLH for new substances and revisions of existing CLH. In the last 10 years (2012-2022), 209 new substances have received CLH (median of 20.5 per year). Following the adoption of the opinion on the CLH of a substance by the RAC, the European Commission takes a decision and publishes the updated list in an ATP. Table 80 presents the estimate of the number of substances with CLH that could be expected in 2030 and 2040, calculated as the linear forecast of the number of substances with CLH based on the values from ATP03 to ATP17 (2012-2022).[215]

Table 80: Estimates of the number of CLH substances in 2030 and 2040

	2022	**2030**	**2040**
Linear forecast	4,385	4,450*	4,600*

*Notes: *rounded to the nearest 50s.*

POTENTIAL POLICY MEASURES

According to Recital 16 of CLP, harmonised classification should be available for substances of highest concern and for other substances on a case-by-case basis. Harmonised classification should apply to all manufacturers, importers and downstream users. It also initiates specific and additional risk mitigation measures in downstream regulations, such as additional risk assessment, ban from consumer products.

The objective is to increase the number of harmonised classification entries, not only of substances which are supposed to meet the existing hazard criteria but also for substances which would meet the criteria of the possible new hazard classes over a reasonable period

[212] RAC opinion on 2-EHA metal salts
[213] RAC opinion on 3 lithium salts
[214] Competitiveness Council on 19 February 2013 (europa.eu)
[215] CLP00 and ATP01 introduced the CLHs that were adopted according to the previous legislation. Not all ATPs introduce or revise CLHs.

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of time. To also deliver increased benefits, the submitted CLH dossiers should target identified substances where the need of a CLH dossier has been prioritised.

It is important to focus the resources of the authorities and therefore prioritise the development of CLH dossiers on 'substances of the highest concern with regard to health and to the environment', in line with Recital 52 of the CLP Regulation. A first level of prioritisation criteria is established in Article 36 of CLP, but this is not sufficient. They need to be expanded, also in consideration of the hazard endpoints discussed in Annex 8. Additional or refined criteria could also improve the pace at which hazardous substances are identified.

Two alternative measures are assessed:

> #7 Develop the discussion on prioritisation of candidate substances for CLH dossiers at RIME+;
>
> #8 Prioritise intentions of CLH dossiers at CARACAL level.

Aside an improved focus on the substances that most deserve a harmonised classification, there may be ways to increase the number of CLH dossiers. This would require either a diversion of resources from other processes or an increase in resources. However, due to various factors (level of expertise and qualifications required for RAC members;[216] transparency and independence;[217] efforts to reach consensus;[218] need to give stakeholders the opportunity to provide information and comments), the number of dossiers that can be processed by RAC is inherently limited by the complexity of opinion development, and an increase of resources may not result in a proportional increase of adopted opinions.

The purpose of providing the Commission with the right of initiative for the submission of CLH proposals is to speed up the CLH process and overcome the limited availability of MSCAs' capacity to support the process.

An additional measure, which is complementary, was considered:

#9 Allow the Commission to initiate and fund more CH dossiers, including via a mandate to ECHA;

Under policy measure #9, the Commission would identify substances or groups of substances considered as priorities, where MSCAs have no interest. The Commission would either mandate ECHA to develop such CLH dossiers for those substances or contract such tasks to consultancy. The Commission's right of initiative would not apply to plant protection and biocidal active substances.

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[216] 'Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 77, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise' (Article 87(2) of REACH).

[217] The members of RAC should declare any conflicts of interest that affect their independence as experts (see Articles 87(1)) and 88(3) of REACH).

[218] Article 85(8) of REACH emphasises that 'when preparing an opinion, each Committee [including RAC, NoA] shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members, including their grounds. The minority position(s), including their grounds, shall also be published'.

Again, it is important to stress that the feasibility of the work needs to be seen in the light of resources that will be available to ECHA versus the total amount of activities (in particular, under REACH and CLP) that are foreseen for ECHA to carry out. In addition, these estimates are of limited scalability, meaning that in case of a relatively high demand (e.g. >10 CLH dossiers per year) additional overhead will need to be looked at. One can also note that the CSS calls for a strengthening of the governance of the European Chemicals Agency and an increase the sustainability of its financing.

Prioritising substances for which a CLH dossier is submitted

On prioritisation, under measure #8 ECHA would be asked to screen the registry of intentions for new CLH proposals and to propose a prioritisation list, based on the agreed criteria, on a regular basis. It is assumed that ECHA staff would be able to screen ten substances per day against the agreed prioritisation criteria (e.g. hazard class, tonnage, widespread use, etc.), including the request for additional information to the dossier submitters and the organisation of a discussion at CARACAL level per year. These tasks would require 0.04 FTE per year at ECHA[219]. Again, it is important to note that, since the development of the IRS, the proportion of CLH dossiers that were submitted as a follow-up to previous activities has grown, from 23% during 2010-2015 to 68 % in 2020 (see Table 81). Therefore, the screening of CLH intentions and the request for further information is not expected to bring significant added value as criteria are already integrated in the IRS screening. Furthermore, the effectiveness of such screening at intention level, where part of the work preparing for a CLH dossier has already been undertaken should be put into question. Finally, some stakeholders, amongst them, a lot of the Member States, voiced that such a measure would undermine the right of initiative of Member States. This would hence not be in line with a balanced subsidiarity between Member States and the European Commission.

Table 81. Source of CLH dossiers in 2020

Activity	**Proportion**
REACH compliance check	44%
REACH substance evaluation	32%
RMOA	12%
Group assessment	32%
At least one activity	68%

Source: reproduced from ECHA (2021b)

Policy measure #7 derives from the same starting basis, i.e. the agreement with the MSCAs on a set of prioritisation criteria, but instead of mandating the prioritisation to the Commission (through ECHA), they provide for the development of guidance on the application of the criteria by the dossier submitters. Policy measure #7 would require dossier submitters to illustrate the application of the criteria in their CLH intentions. It is assumed that, at first, the Commission and ECHA would provide a proposal on the prioritisation criteria, to be discussed and agreed upon during subsequent CARACAL

[219] Six days per year to screen CLH intentions and request additional information and four days to organise a CARACAL discussion (10 days = 0.04 FTE).

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meetings. While this process is not expected to entail significant costs, it may overcome the negative feedback on Policy measure #6. Such criteria, when available, would be used to identify the best Regulatory Management Option Analysis (RMOA) in Risk Management and Evaluation (RIME+[220]) platform. There is no additional costs entailed with this change of criteria to be used by RIME+.

Most respondents of the OPC and TSS supported the establishment of a prioritisation mechanism for the development of CLH dossiers. Some stakeholders suggested that the publication of a list of substances of concern to be prioritised could be used to stimulate updating of self-classifications with better information. The prioritisation mechanism should be in line with ECHA's IRS, based on scientific arguments and focus on the hazards that matter the most to ensure high level of protection of human health and environment. The assessment of regulatory needs should be used to identify the best management option prior to the CLH process, when appropriate. The process should consider the various regulatory processes that exist and initiation of multiple, overlapping processes should be avoided.

Some MSCAs noted that if the prioritisation mechanism were to conflict with the right of initiative of the Member States, it would not be acceptable.

ECHA considered that 'an informal and integrated process (with other prioritisation activities) is very likely not only to be less resource intensive and less costly but will also provide more coherent and consistent outcome of the overall chemicals management system while transparency can still be safeguarded'.

Increasing the number of CLH dossiers submitted to ECHA

ECHA has estimated the resources required for the development of CLH dossiers, including the average time and other resources required per dossier. A CLH dossier for a REACH-regulated chemical substance can cover a number of different scenarios and dossier types. They vary in the number of hazard classes, the complexity of the hazard classes and whether it is a data rich substance or of a poor quality/data-lacking substance with incomplete or missing studies inside/outside EU and of low quality/reporting with poor robust study summaries (RSS).

The number and type of hazard classes and the type/quality of available data will together define the quality and the complexity of the dossier preparation and together will effect the resources required for preparing the dossier.

Again, it is important to stress that the feasibility of the work needs to be seen in the light of resources that will be available to ECHA versus the total amount of activities (in particular, under REACH and CLP) that are foreseen for ECHA to carry out (see above).

[220] https://echa.europa.eu/fr/rime

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Table 82. ECHA's estimate of resources for supporting the preparation of a complex CLH dossier	
	ECHA estimate for CLH
Dossier development	0.35 FTE
RAC opinion making	0.1 FTE
Support services	0.05 FTE
Total FTE	0.5
1 FTE staff costs including 19% overhead cost and infrastructure (2021 value)	€170,000
Total cost of dossier development, support services and RAC opinion making	€85,000
Contribution to RAC organisation cost	€10,000
Total (2021 value)	**€95,000**

The 'dossier development' cost component has two key stages:

the collection, validation and evaluation of data for proposing the hazard classes; and
drafting of the dossier.

ECHA considers that the first stage of collecting and assessing the data will be the most challenging in respect of time management and experience in literature searching and data collection as it will require the need to acquire and access proprietary data, which may require the input of the Legal Affairs Unit regarding confidentiality and use of data. The second stage of drafting the report is identified as being more manageable. To estimate the resources necessary to develop a CLH dossier, ECHA has surveyed MSCAs and contractors about the time and financial resources required for the preparation of three 'types' of dossiers:

Simple: the preparation of a dossier with only one to three hazard classes and the less complex hazard classes, such as physical hazards, irritation, or one aspect of environmental hazards.
Medium: the preparation of a dossier with three to six hazard classes and more complex such as CMR and Environment.
Difficult: the preparation of a dossier with seven or more hazard classes including those of a more difficult nature.

On measure #9, the establishment of a team/unit of five FTEs in charge of preparing CLH dossiers at ECHA could be able to develop around 225 dossiers (both simple and complex ones) over the period 2023 – 2040 (see Table 83). This can be summed up as on average 2.5 dossiers per FTE per year.

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Table 83: Estimated number of CLH dossiers over a period of 1-5 years and 1-10 years

Work years	FTE	Dossiers /yr	Total dossiers prepared for the period	Cumulative Total of dossiers prepared in 1- 10 yrs	Cumulative total if an increase in complex/ difficult dossiers
2023-2028	1	3	15		
	3	9	45		
	5	15	75		
2029-2034	1	4	20	35	20-27
	3	12	60	105	60-80
	5	20	100	175	100-140
2035-2040	1	4	28	67	
	3	12	84	189	
	5	20	140	315	
Weighted grand total (2023-2042)				250	

Source: ECHA

The present value of the cost of such a team is €1.1 million. ECHA expects that over time — e.g. three to five years — its resources would acquire experience and would therefore be able to prepare more dossiers. However, if the new hazard classes were to be introduced in CLP, ECHA staff may have to prepare CLH dossiers which are considered to require more time because of their complexity, cancelling out any gain in capacity.

The development of additional CLH dossiers by ECHA would also have an impact on RAC and its secretariat in terms of additional work. The additional burden would be lower in case of CLH developed outside of ECHA. As RAC is currently already running at maximum capacity, any increase of workload would have to be accompanied by a reform of RAC and its membership to cope with additional work. For CLH dossiers, rapporteurs are RAC members and employed as officials by a Member State. Their work is not reimbursed, contrary to other tasks performed by RAC, such as restrictions, applications for authorisation and Occupational exposure limits (OEL) work. Therefore, the financial costs are almost limited to the organisation of the meetings. As another consequence, no co-opted members can be deployed to CLH work as a consequence of the lack of reimbursement.

In addition to the resources needed to develop the CLH proposals and RAC opinion making, there are other ECHA resources that support this work, such as the RAC secretariat, the legal affairs unit, the library services for literature searching, HR, finance, etc. Any additional activity also needs to make a proportionate contribution to the overall administrative costs of running the Agency (building rent, heating, IT infrastructure, etc.). To account for these, ECHA added 19% overhead cost, obtaining a figure of 0.15 FTE per dossier to support the RAC opinion making and administrative overhead (ca. 0.04 FTEs for meeting organisation, 0.06 FTEs for supporting rapporteurs in opinion drafting and 0.05 for other support activities like HR, finance, legal support and library services for literature searching), for a cost of €25,000 (including the 19% overhead cost) plus €10,000 in operational costs to organise the committee meetings (assuming around 50% are remote meetings). Assuming an average of 12.5 CLH dossiers per year (prepared by a team of

five FTEs), over the considered period the present value of these additional costs amounts to €0.3 million.

The Commission could provide additional funding for the preparation of CLH dossiers to contractors, or directly to MSCAs. As noted, also for MSCAs the time to develop one CLH dossier may vary significantly depending on the complexity of the substance (e.g. grouping/read-across), how many hazard classes are evaluated (targeted vs. full), but also on the experience of the staff working on the dossier. The EU27 average labour cost for employees in professional, scientific and technical activities is €71,300. Therefore, the cost of one CLH dossier developed by MSCAs' staff is approximately €28,500. Considering additional 0.15 FTE required for literature searching, HR, finance, etc., the total cost of one CLH dossier developed by MSCAs is approximately €40,000.

External contractors have supported the preparation of CLH proposals for a number of years, typically for CMR endpoints, but also for other hazard classes, such as acute toxicity and STOT RE. Contractors or ECHA's new team are usually asked to carry out the following tasks:

- Literature search;
- Evaluation of information and drafting the CLH dossier;
- CLH dossier update after accordance check;
- Preparation and possible update of RCOM after consultation;
- Support following RAC rapporteur requests/RAC process.

The last task is mostly carried out by the dossier submitter (the supporting MS), although contractors may be asked for some input. Usually, for CMR hazard classes, CLH dossiers require comprehensive summaries of the available information and detailed study descriptions of the key studies and a discussion of all relevant mechanistic, toxicokinetic or other information crucial for the evaluation process. A detailed comparison of the data with the CLP criteria including all arguments pro and con the proposed classification leads to conclusions on the proposed hazard category. One of the main problems faced by contractors is the accessibility of all relevant information from the key studies. Study summaries in the registration dossiers are often not detailed enough to prepare sufficiently robust study summaries for the CLH dossiers and requesting the study reports from the registrant(s) may be time-consuming. In some cases, a separate read-across justification document may need to be prepared as part of the CLH dossier. The average cost of outsourcing the preparation of one CLH dossier is €33,600 (based on the 2020 contracts), although for complex dossiers may arrive to €61,700.

In addition, ECHA and the sponsoring MSCA spend around 0.05 FTE per dossier to organise meetings with the contractors, to contact industry about the full studies, to check the studies, to search data available to ECHA but not to the contractors, to support the public consultation and as a general follow-up and project management. The total cost of outsourcing the preparation of one CLH dossier is therefore approximately €40,000 (33,600 + 6,300 for 2x 0.05 FTE).

As noted, any increase of workload would have to be accompanied by a reform of RAC and its membership to cope with additional work, as a mere provision of additional resources may not take advantage of the synergies of the current setting. Such a reform

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needs to take onboard the ongoing revision of REACH, and in particular of the authorisation and restriction mechanisms as well as the organisation and financing of ECHA foreseen in the CSS. Since March 2021, the RAC established a Working Group to handle CLH dossiers. Its mandate is to support the work of the rapporteurs in discussing the CLH proposals and review opinions for efficient agreements by the plenary meetings of the RAC. The same approach for new hazard classes or specific issues could support RAC.

Summary of the economic impacts

Administrative burden for public authorities:

Mandating the Commission to initiate CLH dossiers entails increased administrative costs for ECHA. The present value of the cost of establishing and maintaining a team/unit of five FTEs in charge of preparing CLH dossiers — which could be able to develop around 250 dossiers over the period 2023 – 2042 (2.5 dossiers per FTE per year) is €1.1 million (discount rate: 3%). Considering that an ECHA staff FTE costs 170,000€, including 19% overhead cost and infrastructure, such ECHA developed CLH dossier would cost 68,000€.

Alternatively, the Commission could provide additional funding for the preparation of CLH dossiers to contractors, or directly to MSCAs following calls of interest. The total cost of outsourcing to external contractors or for funding MSCAs is approximately €40,000 per CLH dossier.

The development of additional CLH dossiers would also have an impact on RAC and its secretariat. As RAC is currently already running at maximum capacity, any increase of workload would have to be accompanied by a reform of RAC and its membership to cope with additional work. Such a reform needs to be thought in the context of the ongoing revision of REACH, and in particular of the authorisation and restriction mechanisms or the identification of Substances of Very High Concern (SVHCs) on the ground of PBT properties or equivalent level of concern (ED properties or PMT properties). The recently set up Working Group for CLH has already improved the flow of CLH assessments. Transforming the existing ECHA WGs on EDs and PBTs into WGs attached to RAC for those properties may also help the development of RAC opinions covering those new hazard classes.

In addition to the resources needed to develop the CLH proposals and RAC opinion making, there are other ECHA resources that support this work, such as the RAC secretariat, the legal affairs unit, the library services for literature searching, HR, finance, etc. These have been estimated in 0.15 FTE per dossier, for a cost of €25,000 plus €10,000 in operational costs. Assuming an average of 12.5 CLH dossiers per year, over the period 2023 – 2042, the present value of these additional costs amounts to €0.3 million (discount rate: 3%).

The costs for the action of the Commission to transform the RAC opinions into a delegated act ATP are supposed to remain equal to the baseline, for as long as the volume of RAC opinions per year is manageable with one annual ATP. Increased consultations with stakeholders or REACH registrants are rather small compared to the CLH development costs.

Table 84: Costs and effectiveness of various options to develop 12.5 CLH dossiers per year (discount rate: 3%)

Who develops CLH dossiers	ECHA with COM mandate	MSCAs with COM funding	Contractors with COM budget	Contractors with COM mandate
Cost per dossier (in thousand €)	68	40	33.6 (up to 61.7)	33.6 (up to 61.7)
Additional cost (coordination meetings, support provided, contracting)**	0*		0.025 FTE MSCA 0.025 FTE ECHA	0.025 FTE ECHA
Present value of the costs for 250 dossiers	1.1m€	0.7m€	0.7m€	0.6m€
Effectiveness (timing, quality)	+++	++	+	++

*Note: * No additional cost foreseen for ECHA as ECHA would work independently. Reports may take place during CARACAL meetings, with no additional cost.*
*** Additional costs to the Commission are not reported as the measures do not create any new tasks or trigger such additional workload that new staff should be hired.*

The introduction of a **mandatory prioritisation mechanism or the improvement of the current one** under CLP for the assessment of CLH dossiers intends to increase effectiveness and ensure the allocation of the limited resources in line with the priorities. The mechanism would complement the prioritisation criteria listed in Article 36 of CLP. Indicatively, the additional prioritisation criteria could be:

Hazard class and category;
Groups of substances vs single substances.
Tonnage;
Exposure (e.g. consumer exposure, widespread dispersive uses);
Divergence in self-classifications.

It should be noted that, currently, ECHA and MSCAs already prioritise substances and groups of substances after the IRS screening stage in the informal meetings RIME+. The prioritisation mechanism would be additional to the IRS step and would act on the CLH intentions as expressed to the registry by the dossier submitters (MSCAs or industry). The indication of the intention to submit a CLH dossier in ECHA's registry of intentions could be made obligatory (at the moment it is voluntary). This additional cost is not significant compared to other costs and hence not reported here.

The prioritisation mechanism would consider, under measure #9, RAC capacity to process CLH dossiers and would result in a list of prioritised CLH intentions to be discussed and confirmed in CARACAL. Those CLH intentions not included in the prioritisation programme would be considered of low priority and placed in a list for further consideration. Additional costs triggered by such additional discussions in CARACAL are expected as Member States have voiced concerns about the limitations to their right of initiative such a measure would bring.

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ECHA would be asked to screen the registry of intentions for new CLH proposals and to propose a prioritisation list, based on the agreed criteria, on a regular basis. It is assumed that ECHA staff would be able to screen ten substances per day against the agreed prioritisation criteria (e.g. hazard class, tonnage, widespread use, etc.), including the request for additional information to the dossier submitters and the organisation of one ad-hoc CARACAL meeting per year. These tasks would require 0.04 FTE per year.[221] Again, it is important to note that, since the development of the IRS, the proportion of CLH dossiers that were submitted as a follow-up to previous activities has grown, from 23% during 2010-2015 to 2016-2020. Therefore, the screening of CLH intentions and the request for further information is not expected to require a significant amount of time.

Table 85: Source of CLH dossiers in 2020

Activity	**Proportion**
Compliance check	44%
Substance evaluation	32%
RMOA	12%
Group assessment	32%
At least one activity	68%

Source: reproduced from ECHA (2021b)

Policy measure #8 moves from the same starting basis, i.e. the agreement with the MSCAs on a set of prioritisation criteria, but instead of mandating the prioritisation to the Commission (through ECHA), they provide for the development of guidance on the application of the criteria by the dossier submitters. Dossier submitters should illustrate the application of the criteria in their CLH intentions. It is assumed that, at first, the Commission and ECHA would provide a proposal on the prioritisation criteria, to be discussed and agreed upon during subsequent CARACAL meetings. While this process is not expected to entail significant costs, it may overcome the resistance of some MSCAs, which during past CARACAL meetings have voiced their concern over a possible conflict between the Commission's mandate to prioritise CLH intentions and the right of MS to initiate CLH dossiers. ECHA considered that 'an informal and integrated process (with other prioritisation activities) is very likely not only to be less resource intensive and less costly but will also provide more coherent and consistent outcome of the overall chemicals management system while transparency can still be safeguarded'.

There are also some expected benefits from harmonising classification and providing a level-playing field amongst manufacturers of the substances with harmonised classification and mixtures containing such substances.

[221] Six days per year to screen CLH intentions and request additional information and four days to organise one ad-hoc CARACAL meeting (10 days = 0.04 FTE).

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Summary of the health and environmental benefits

Article 1 of CLP identifies the establishment of a list of substances with harmonised classifications and labelling elements at the Community level as being one of the key actions that help ensuring a high level of protection of human health and the environment. Harmonised classifications and labelling are the triggers for risk management in much of the downstream legislation and act therefore as one of the key cornerstones of the EU chemicals legislative framework. As an example, harmonised classification for CMR substances of categories 1A or 1B trigger a REACH-based ban in consumer products, preventing exposure of those consumers to CMR substances.

There is also a positive direct impact of harmonised classification for CMR substances, hence replacing possible less critical self-classifications. This would trigger relabelling and possible reformulation to replace the substances at stake, further reducing the exposure of consumers and professional users to hazardous substances. However, quantification or qualification of this positive impact is difficult and uncertain.

Allowing the Commission to initiate CLH dossiers may speed up the process and ensure that the substances of the highest concern are addressed in a timely manner, bringing forward the expected benefits.

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Annex 11 - Convergence of Self-Classification

CONTEXT

The improvement of the Classification and Labelling inventory as an important tool for notification of self-classifications is linked to other actions in the Chemicals Strategy in so far as more accurate and reliable hazard information on chemical substances would allow better risk management.

As to other objectives of the European Green Deal, the initiative is expected to contribute to the zero pollution objective and to a certain extent also the circular economy. Indeed, better knowledge of environmental hazards, if followed by risk management measures, will allow better protection of the environment, whether at the production, use or recycling stage. At the same time, better classification of substances is expected to trigger more appropriate labelling, as both obligations are linked under CLP. As an example, a substance that is classified as acutely hazardous to the aquatic environment should be labelled as 'very toxic to aquatic life'. It should also bear the precautionary statements 'Avoid release to the environment', as well as 'Dispose of contents to/container to…'

In terms of SDG, the envisaged measures are expected to address SDG 9 as well as, indirectly SDG 3, 6 and 12. In general, it must be admitted that the link with these objectives is expected to be mainly indirect, as, to grasp all potential benefits they will require additional actions as e.g. risk management measures, labelling etc. To conclude, these measures will be a necessary, but not a sufficient condition to meet the above mentioned objectives.

PROBLEMS

Article 4 of CLP requires manufacturers, importers and downstream users to classify hazardous substances or mixtures (self-classification) before placing them on the EU market. Self-classification applies only if there is no harmonised classification and labelling, i.e. for those hazard classes or differentiations (i.e. distinction within hazard classes depending on the route of exposure or the nature of the effects) which are outside the scope of that harmonisation. Duty-holders must consider all available information and evaluate the reliability and applicability against the classification criteria for physical, human health and environmental endpoints. They also have to review the classification of substances and mixtures where new scientific or technical developments exist (article 15).

Article 40 of CLP requires duty-holders to notify ECHA a number of classification and labelling data regarding their hazardous substance as well as their identity, to be included in the Classification and Labelling Inventory. The Classification and Labelling Inventory is maintained by ECHA and contains classification and labelling information, whether provided directly by manufacturers or importers, or indirectly via the REACH registration dossiers. In December 2021, the inventory contained ca. 206.000 substances, 4,500 of which had a harmonised classification and the rest being self-classified. The Classification and Labelling Inventory is a publicly available database that receives an average of 16,000 views daily and supports downstream users who otherwise would depend solely on

substance safety data sheets (a sheet which is required under REACH and which contains information on the substance, amongst others on its classification and labelling. It has to be transmitted throughout the supply chain to recipients, being downstream users and distributors).

Table 86 provides an overview of the information that must be notified to ECHA (Article 40) and the information that is publicly available on the Classification and Labelling Inventory (Article 42).

Table 86. Differences between Article 40 (notified information(and Article 42 (publicly available information)

Information to be notified to ECHA under Article 40 C&L Notification	Information published in the Classification and Labelling Inventory according to Article 42
Identity of notifier	Not included
Identity of substance(s)	EINECS name, where applicable
	IUPAC name set out in Article 119(1)(a) of REACH
	Other numerical identifiers where appropriate and available
Classification of substance(s) in accordance with Article 13	Classification of substance(s) in accordance with Article 13
Labelling elements specified in Article (17)(1) points (d)-(f)	Labelling elements specified in Article (17)(1) points (d)-(f)
Specific Concentration Limits (SCL) or M-Factors	Not included
Where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive but insufficient for classification	Not included

The notified information is not subject to review or verification, although the information provided via REACH, which is subject to review and verification, has been used to revise classifications and enhance the reliability of the Inventory. In addition, Article 41 provides that when notifications for the same substance differ, the notifiers or registrants must work together to come to an agreed entry. Article 16 acknowledges that a substance may be classified differently than previously submitted classifications and, if so, the reasoning for this difference must be submitted with the notification. However, this justification does not need to be published according to Article 42 and is not publicly available.

The problem and its scale

In terms of intervention logic, the specific problems described below fall under the more general problem of 'Hazardous chemicals are not comprehensively identified and classified'. This Annex covers only the inefficiencies linked to self-classification, which are all linked to the Classification and Labelling Inventory. Annex 10 covers the

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harmonised classification process**.** One of the aims of the Chemicals Strategy for Sustainability is to coordinate and simplify actions across EU chemicals legislation. This requires a review of the interoperability and accessibility of chemical data, including the self-classification process and the Classification and Labelling Inventory which have been highlighted as areas for improvement.

The Staff working document drafted in the framework of the Fitness Check of the most relevant chemicals legislation (excluding REACH)[222] highlighted the following key issues relating to the quality of data held in the Classification and Labelling Inventory:

As self-classifications are made by the duty holders themselves, there is a possibility of divergence in classifications across actors. In some cases, such divergence may be justified, such as those related to differences in self-classification as a result of impurities, physical state or differentiations. Some divergences are, however, due to differences in data used for classification or lack of agreement between duty-holders on self-classification.

The absence of a tonnage threshold for data requirements for classification can lead to duty holders basing their classification on different levels of toxicological data, particularly in the absence of testing requirements. As there is no quality check, the robustness of information provided is questionable.

As ECHA is not entitled to correct or delete self-classifications that may be incorrect or, in the case of substances which are no longer placed on the market, obsolete, the CLI may end up containing incorrect or irrelevant self-classifications.

Data provided by ECHA found that 78% of substances in the Classification and Labelling Inventory have a single classification, which highlights the potential scale of the issue but further examination of the CLI is needed to determine how many of the remaining substances have incorrect or diverging classifications (see also Figure 72 below).

Furthermore, Amec Foster Wheeler et al.[223], investigated the divergence of classifications of the same substance in the Classification and Labelling Inventory. Based on the responses of companies to a stakeholder consultation questionnaire, the study found multiple reasons for divergence. These include difficulty in interpreting study results, conflicting study results, a lack of agreement amongst companies over how to correctly apply the classification criteria, a need for companies to harmonise classifications based on product ranges with similar substances, and difficulty in consistently filling in the hazard classes in the IUCLID database.

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[222]Commission Staff Working Document. Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, accompanying the document "Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses". SWD(2019) 199 final/2. Brussels, 18.7.2019.

[223] Amec Foster Wheeler et al. (2017): A Study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers. Available at: https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf/7b21b25e-9a11-ef05-30ce-e09a60aa204f

The information available from previous studies combined with the analysis of 2021 Classification and Labelling Inventory data can help determine the scale of incorrect, diverging or obsolete self-classifications in the Classification and Labelling Inventory.

The stakeholder consultation conducted for the Amec Foster Wheeler et al. study[224] found that 59% of companies using the Classification and Labelling Inventory had seen multiple classifications for a single substance. The main reason for these differences was the lack of agreement between companies (28%), with the existence of impurities seen as the second most influential factor.

Most respondents to the targeted stakeholder consultation believe that the obligation of duty-holders to come to an agreed entry in the Classification and Labelling Inventory should be strengthened. Furthermore, there was consensus that diverging and/or erroneous self-classifications and obsolete information in the Classification and Labelling Inventory may hinder the ability of the CLP Regulation to protect human health and the environment.

According to the 2021 data on the Classification and Labelling Inventory provided ECHA provided to the study team of the study underlying this Staff Working Document, 78.39% of substances in the Classification and Labelling Inventory had a single classification and 97.64% have five or fewer classifications (Figure 72). It should be noted that a substance can have multiple classifications for legitimate reasons, such as differences in composition or physical form of the substance. ECHA[225] lists the following justifiable reasons for classifications in the Classification and Labelling Inventory to vary:

Different hazardous impurities, additives or ingredients might be present;
Properties such as the physical form, the pH, the flash point might be different;

Suppliers need to interpret scientific studies when they classify a chemical, and different suppliers might reach a different conclusion, which is sometimes justifiable.

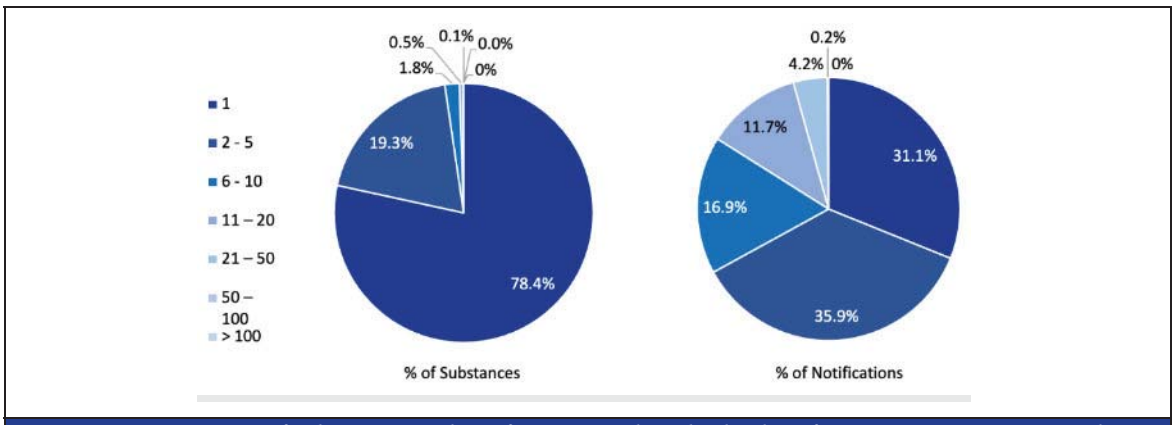

Figure 72. Percentages of substances and notifications with multiple classifications - Source: ECHA data

[224] See footnote 3.
[225] ECHA, Tips for users of Chemicals in the workplace, A short guide for users of chemicals in the workplace on how to get the most from the classification and labelling information you receive, 2016.

The divergence can be analysed further to understand the possible implications, according to the hazards associated with substances holding more than one classification. Figure 73 points to the fact that the majority of the differences in classifications relate to health hazards (over 80%). This suggests that the divergence in classifications in the CLI has the greatest impact on the (mis)communication of hazards relating to human health.

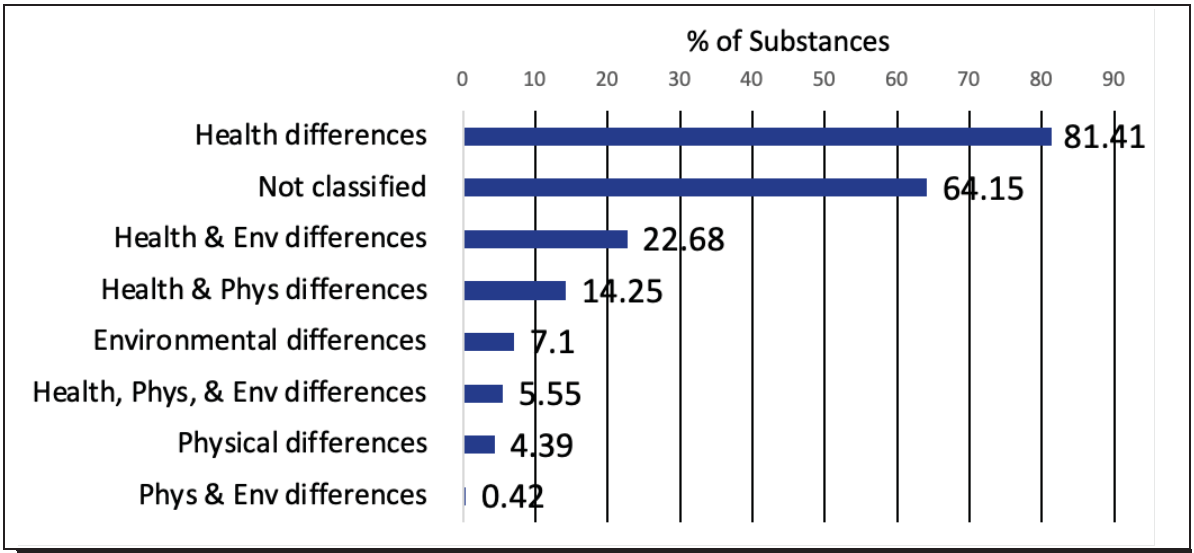

Figure 73. Estimated percentage of substances with multiple classifications due to variation in the hazards listed, in the CLI as of 30th November 2021 - Source: ECHA data

ECHA has recognised the issue of incorrect, diverging or obsolete information in the Classification and Labelling Inventory for some time. Notifiers have been encouraged to communicate with one another to discuss varying self-classification and labelling entries for the same substance, in an effort to obtain consensus on the applicable self-classification (Article 41). Furthermore, ECHA has previously attempted to facilitate these discussions through the introduction of a Classification and Labelling platform. In 2015 ECHA undertook a pilot project on that platform with support from a pilot project team. Approximately 3,985 companies, that had notified 97 substances, were individually contacted and invited to start a discussion using the C&L platform. Prior to the pilot, 25% of all self-classified substances were found to have diverging classifications and the platform was not actively used. It was found that although the number of notifications decreased by close to 1,000 during the pilot, the overall aim to get duty holders to agree on a single self-classification for a certain hazard was not achieved because the number of classifications did not decrease. Less than five percent (5%) of the notifiers contacted used the platform, and the number of classifications did not decrease. The platform was discontinued as a result of lack of use and the pilot was discontinued.

The number of **incorrect, diverging or obsolete self-classifications** have been identified as a key problem of the Classification and Labelling Inventory.

These classifications have a negative impact on the reliability and usefulness of information in the Classification and Labelling Inventory and limit the effectiveness of the inventory as a hazard communication tool. Self-classifications determine the labelling of the substances in the supply chain and the labelling of products (which when under the scope of under CLP are mainly mixtures) containing the substances when placed on the

market. The hazard classification of a substance also determines the appropriate risk management measures that should be applied when using the substance, which aim to control risk by preventing, and protecting against, harmful exposure.

Consequently, the inclusion of incorrect, diverging (if not justified) or obsolete self-classifications in the Classification and Labelling Inventory can lead to negative human health and environmental impacts and a biased internal market for chemicals, because of:

- Decreased value of the Classification and Labelling Inventory as a hazard collection and communication tool; and
- Insufficient risk management measures applied as a result of incorrect classifications.

The problem drivers

The identified problem is a result of four underlying drivers, which represent regulatory and/or technical failures:

No legal basis for ECHA to remove or de-emphasise inactive notifications or correct / delete erroneous notifications and inability for notifiers to remove obsolete Classification and Labelling entries. This driver relates to the lack of a process to remove incorrect or inactive notifications, but they differ with respect to the party involved. Articles 15 and 40 of the CLP Regulation place legal obligations on notifiers to update their notification(s) whenever they become aware of new and reliable information which changes the classification and labelling of their substance(s). Notifiers can inform ECHA if the manufacture or import of the substance has ceased. This will change the notification to "Inactive" but notifiers are not entitled to themselves modify/remove their notification from the inventory as it is ECHA which maintains the Classification and Labelling Inventory. The inventory is automatically updated when a notifier submits data to ECHA. There is no legal basis for ECHA *to correct or delete obvious mistakes* as it is not expected from ECHA to know the exact classification of each substance under self-classification. There is also no legal basis for ECHA to remove entries by companies which no longer exist or for substances which are no longer placed on the market (especially below 1t/y), or to contact notifiers/registrants to initiate these corrections. Finally there is also no obligation for the manufacturer/importer to *check the quality* of the information being notified. Feedback received on CARACAL Document CA/77/2020 on the improvement and re-design of the CLP inventory suggested that multiple classifications for the same substances are to a significant extent caused by the inability to remove classification and labelling entries for substances that are no longer of interest to a notifier. However, when a notifier indicates to cease manufacture/import, the C&L is removed from the public inventory (so in effect it appears as removed).

Shortcomings in ECHA's IT tools for Classification and Labelling notifications, leading to high administrative costs and burden for companies. Notifications to the Classification and Labelling Inventory must be submitted electronically, either through the REACH-IT portal or IUCLID. Previously, the bulk notification tool (Bulk XML) could be used to submit bulk notifications, but this method has recently been replaced with IUCLID cloud and a soon to be released system-to-system platform. The choice of which tool is used to submit a notification to the Classification and Labelling Inventory depends on whether you have a substance with multiple constituents, if a notifier wants to keep the

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IUPAC[226] name confidential when submitting the notification, or the number of substances to be notified. A report on the review of ECHA found shortcomings with ECHA's IT tools (Amec Foster Wheeler et al., 2017[227]), which may act as a deterrent for companies when it comes to updating their Classification and Labelling Inventory notifications, particularly for SMEs. These included:

Frequent IUCLID updates, leading to adaptation costs primarily due to training and increased administrative burdens for companies;
Lengthy and sometimes too complex guidance for IUCLID;
REACH-IT not being accessible on weekends and Finnish public holidays;
IT tools not translated into every EU language; and
Complexity and lack of user-friendliness of the software, particularly IUCLID, leading to time consuming processes and the need for SMEs to use external consultants.

However, it needs to be noted that the three first shortcomings listed above have meanwhile been addressed by ECHA's IUCLID cloud.

Lack of transparency in the Classification and Labelling Inventory regarding the identity of notifiers preventing communication between notifiers of the same substance. The public Classification and Labelling Inventory does not publish the identity of notifiers, and therefore notifiers are unable to identify who has submitted classifications and why they are possibly differing from their own. This lack of transparency regarding the notifier identity acts as a barrier for discussions amongst notifiers. However, ECHA figures (see above) show that the problem is not as huge as originally suspected, especially as many notifiers are part of a 'group' (see next para.) and hence they know the group members' identity. The notifier that submits a notification with a group of companies has to upload a file with the names of the companies, meaning it knows the name of the companies in that group.

No compulsory legal requirement for notifiers to come to an agreement on self-classifications. Article 41 of CLP states that for notifications for the same substances "the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory". However, there is no legal obligation for notifiers and registrants to come to an agreement. Data provided by ECHA on the Classification and Labelling Inventory highlighted that collaboration is already happening to a certain extent. Around one third of notifications are coming from groups of manufacturers and importers, with an average of 44 manufacturers/importers per group. This leaves around two thirds of notifications coming from individuals who are likely to be self-classifying their substances in isolation. However, based on the high usage of the Classification and Labelling Inventory, many are likely to be classifying similarly to already existing notifiers, even if not actively discussing with them. So while the Classification and Labelling Inventory is unlikely to bring existing notifiers to change what they already notified, it is likely to serve as a source for new notifiers. Moreover, some of ECHA's submission tools (online

[226] IUPAC: International Union of Pure and Applied Chemistry.
[227] 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, Available at: https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf/7b21b25e-9a11-ef05-30ce-e09a60aa204f .

dossier tool, subsequently IUCLID cloud) suggest existing classifications when submitting a notification for a substance already in the Classification and Labelling Inventory.

It has been noted by ECHA that the Classification and Labelling Inventory primarily provides transparency on how substances on the EU market have been self-classified by companies and it is not a tool that creates harmonisation after companies have notified their classifications to the inventory. There is no incentive for agreeing on classifications after notifications are submitted to the inventory.

Stakeholders' views[228]

Stakeholder mostly approached the problems from the perspective of actions or measures that could be taken to tackle them. Therefore, most responses were not descriptions of the problems as perceived by the respondents, but rather reactions to potential actions or measures.

With regards to Classification and Labelling Inventory, few reactions were received in position papers and open text responses both in the OPC and Targeted Stakeholders Survey that may indicate less interest of the respondents in this problem. Furthermore, the Targeted Stakeholders Survey respondents (who mostly represented business entities) explicitly stated in their open text comments that they do not see any significant problems in Classification and Labelling Inventory, although acknowledged that the Inventory contains obsolete information and errors and self-classification of the same substance/mixture may diverge. However, the latter could be often justified. Similarly, the interview respondents pointed to the quality of CLI Classification and Labelling Inventory information as well as diverging self-classifications as problems, although as reported such problems did not have any significant effect on stakeholders.

Very few instances of written feedback following the CARACAL meeting on self-classification has been available mostly from the observers.

The baseline

As of 30th November 2021, 751,436 notifications have been submitted to the Classification and Labelling Inventory on 205,903 substances, the majority coming from C&L notifications (656,741) and the remainder coming from REACH Registrations (94,695). Most substances (89%) notified to the Classification and Labelling Inventory originate exclusively from CLP notifications – e.g. due to tonnage thresholds or exemptions -, with 11%[229] originating from REACH registrations.

Actual notification submitters (excluding group members) amount to 22,745 legal entities, of which 14,888 from REACH Registrations and 12,244 from CLP notifications. Around 11,055 actual notification submitters are SMEs (48.6% of the total).

[228] See also Annex IV.

[229] According to ECHA, 2% of substances in the CLI get their data from REACH registrations only. 9% of substances get their data both from C&L notifications and REACH registrations (the logical explanation is that some companies are below 1 tonne).

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A single Classification and Labelling notification, described as a granular C&L notification, contains a combination of the following:

- Substance;
- Substance variant (e.g. physical state / form; chemical hydration; composition with an impurity / additive etc);
- Classification;
- Labelling;
- Legal entity.

Classification and Labelling notifications can be submitted by one legal entity on behalf of a group of manufacturers and importers. For example, the notification submitted on behalf of 50 group members would resolve into 50 granular Classification and Labelling notifications, and if the group notification contained two substance variants, it would resolve into 100 granular notifications. When the number of granular notifications is taken into account, over 10 million unique notifications have been submitted to the Classification and Labelling Inventory, which come mainly from expanding the group notifications into their constituent Classification and Labelling notifications from the different group members. Data provided by ECHA to the study team of the study underlying this Staff Working Document shows that on average a group notification contains 44 group members.

The large number of granular Classification and Labelling notifications that come from group notifications demonstrates that a significant amount of collaboration between duty-holders is already taking place to agree on a single classification, which is illustrated in the graphics below. Figure 75 shows the level of agreement for different classifications and labelling combination for substances in the Classification and Labelling Inventory that have 5 or fewer distinct classifications and labelling combinations.

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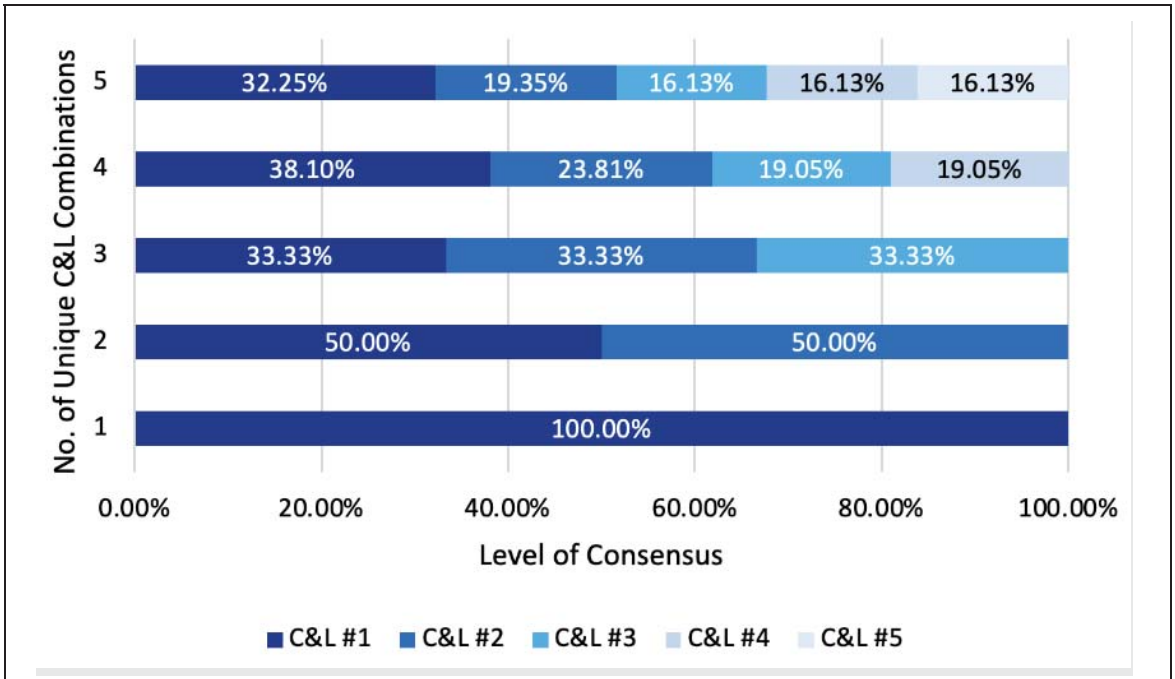


Figure 75: Level of consensus based on submissions by individual notifiers and notifiers representing group notifications - Source: ECHA data

Figure 76 shows that if the agreement within group notifications is taken into account there is a much higher level of consensus. It shows divergence caused by differences in classification only, rather than divergence caused by different combinations of classification and labelling, as substances with the same classification can have two distinct labelling blocks.

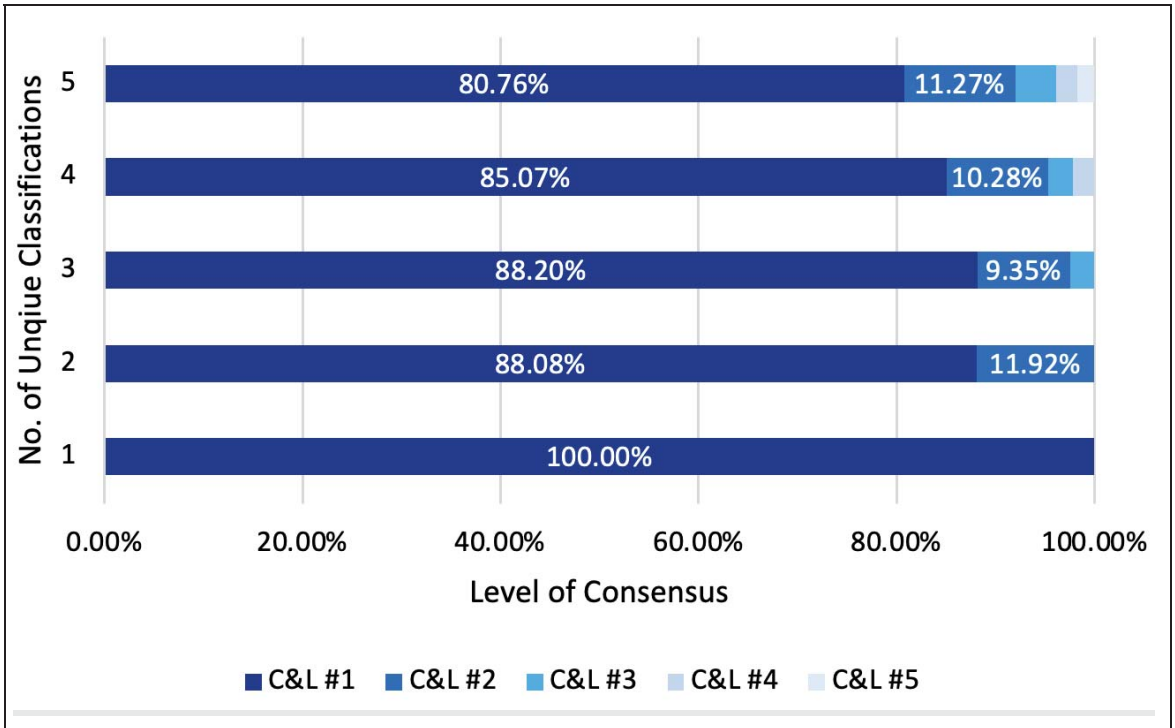


Figure 76: Level of consensus factoring in manufactturers/importers groups - Source: ECHA data

However, the level of convergence within group notifications is not currently displayed in the existing data structure of the Classification and Labelling Inventory. The summaries of notified classification and labelling entries are ordered by number of notifiers, but this only counts M/I groups as one notifier.

As highlighted above 78% of substances and 31% of notifications are aligned with a single classification and divergence amongst the remaining 22% of substances and 69% of notifications can be due to legitimate reasons, such as differences in physical form, presence of impurities etc. Moreover, although sixty-nine percent (69%) of notifications diverge, this figure is reduced to 23% once the agreement within group notifications is taken into account - although this is not visible in the Classification and Labelling Inventory public portal. This means that, when looking at the level of alignment in granular Classification and Labelling notifications, which considers agreement within manufacturers/importers groups, 77% of the 10 million granular C&L notifications agree on a classification.

The data shows that classification divergence affects around 22% of notified substances.

ECHA and the European Commission initiated a redesign of the Classification and Labelling Inventory in 2019. The aim is to improve how data are displayed, structured and made available in the Inventory, in order to bring additional value and improve its ease of use. Discussions held during CARACAL meetings highlighted the difficulties around locating the relevant data from the inventory when small discrepancies lead to multiple entries. CARACAL members noted that the current format highlights the differences and does not focus on the similarities. The redesign of the Inventory is expected to streamline the data set, enhance the data available and provide tools to tailor the results.

The suggested improvements are based on years of operational feedback from MSCAs, users, and Classification and Labelling experts, and work done on other disseminated datasets. The improvements would focus on:

- **Improving structure and display of data to make consensus Classification and Labelling data more prominent** – the ability to use filtering logic is envisaged to assist with removing erroneous entries and corrupt data[230] regularly associated with group self-classifications;

- **Clarifying the source of divergence** – this would involve processing and publishing data on the physical form of a substance and the existence of impurities. This granularity could help users understand why classifications legitimately differ from one another;

- **Publication of notifier names** to encourage convergence; and

- **Revising data access formats** (download, Application Programming Interface).

[230] According to ECHA the data corruptions mostly came from the now discontinued Bulk XML tool, and are not related with the groups (even if also groups have notified with this tool). ECHA is undertaking a project to resolve the corruptions as far as possible; results will be available in the new platform.

It has also been proposed to add the functionality of a "notifiers dashboard" for companies to have an overview of their notifications, the possibility to access them, do modifications in bulk and update when necessary. Another proposal was to eliminate a notification once the notifier has submitted a REACH dossier, as the C&L of the dossier must always have precedence. The latter measure is already in place in the meantime.

The redesigned inventory was initially planned to become operational in 2022. However, ECHA experienced a number of problems with the current dissemination platform, which impacted on the data within the CLI, with instances of some of the publicly available data disappearing. This meant that ECHA has had to delay its roadmap for improving the CLI to focus its resources on "life support" of the current platform to keep it operational. ECHA is currently looking to develop a new data availability solution to host future dissemination activities. Work has begun to scope out the construction of this solution, as an architecture study is currently underway to determine how the new dissemination platform that will be used to host the redesigned CLI will be built. According to ECHA the cost of the redesign is dependent on the findings of this study, which is due for completion in Q3 2022. The resources for the redesign are currently coming out of the ECHA budget. The first version of the new dissemination platform aiming to be made available in 2023, therefore, the redesign of the CLI is expected to be delayed until at least 2023.

In general, it is expected that the new platform will be more stable, more easily maintained (e.g. towards changes in data formats), have improved data access methods (not only visual, but also computer methods). Data flows in the new platform will also be more generic. E.g. identity of submitters will be a standard information element for any type of dossier. Hence, the decision to publish it (for any type of dossier, but also C&L) should not require significant new development in the future platform, as it would have required in the current one.

Specific requirements for C&L data need to be identified, but for example, the following idea exists beyond visually promoting the most common C&L and explaining reasons for divergence:

Making available the most common Classification and Labelling to new/existing submitters preparing dossiers in the various submission tools, in the final data format. This promotes harmonisation, reduces burden of submission, reduces mistakes by avoiding retyping. Although that initiative will not directly address the drivers of diverging classifications in the CLI, it aims to provide transparency on the reasons for divergence and aims to make consensus classifications more prominent, which is expected to allow users to find the most relevant and accurate data with ease. The redesign is also expected to display agreement within group notifications. When considering the outcome of the changes in the redesign, if the changes are made as described, it is expected that the additional information and the prioritising of consensus classifications will reduce the impacts of the problem. These changes will not necessarily address the source of the divergence. However, the changes, if implemented as described, could help users prioritise the information in the CLI and subsequently find the most relevant data reducing the impact of the incorrect classifications. The outcome of the redesign cannot be fully assessed currently, as, based on discussion at CARACAL, the redesigned Inventory is expected to be launched in 2023.

While incorrect or diverging self-classifications may still be notified in the coming years, the redesign of the Classification and Labelling Inventory is expected to emphasise converging self-classifications as described above and classifications derived from REACH registration dossiers. It will highlight the justifications provided for diverging classifications, promote convergence and ease access to the inventory by revising the IT features. All of these improvements are expected to positively address some of the issues discussed so far, although this is dependent on notifier's engagement with the platform[231]. If notifiers make use of the new features it can be predicted that these changes will aid the improvement of the CLI data. The redesign will not address the lack of legal basis for ECHA to remove incorrect or obsolete notifications so this issue will remain, even though the redesign will de-emphasise these notifications. In addition, without stricter enforcement of the requirement for notifiers to come to an agreement on self-classifications of the same substance it is unlikely the increased usability of the CLI will reduce this issue of divergence. Although the convergence will be promoted by the need to provide details and justifications, further encouragement – e.g. enforcement actions - may be required.

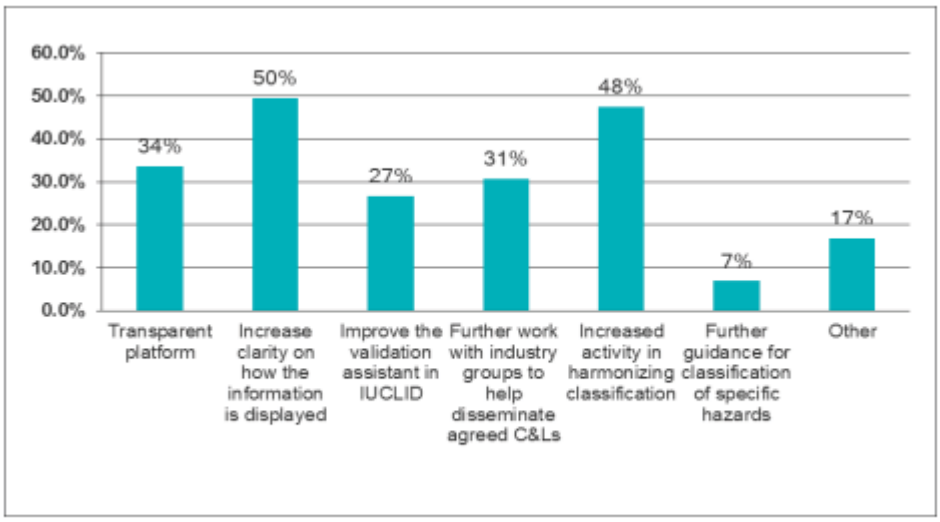
In addition the EU platform which the Commission plans to develop is expected to contain different inventories, such as the CLI. It is expected that further adaptation of the CLI will be needed to ensure its optimal integration in the EU platform.

POSSIBLE POLICY MEASURES

Figure 77 below is an excerpt from a study performed for ECHA in 2017[232] showing which were the respondents' preferred ways to solve the issue of diverging classifications. Measures # 3 (*Require notifiers with classifications that diverge from the entry agreed by most notifiers to update their notifications with a justification for any divergence*) and measure #4 (*make notifiers name public*) try to address the most frequently suggested way forward. Indeed, measure #4 aims to increase transparency and #3 increases the clarity of how the information is displayed.

[231] If some notifiers do not use the new CLI when preparing their notifications or notification updates, but derive their information from other sources, then for their notifications it will not matter however much ECHA improves the prominence of most common C&L, or make available the data in a ready-to-use format etc.

[232] Amec, Foster, Wheeler, 2017, "A study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration dossiers and CLP notification dossiers", p.46.



Number of respondents: 101. Respondents were allowed to select more than one option. Therefore, the sum of percentages is higher than 100%

Figure 77: Feedback from stakeholders on the best options to solve the issue of diverging classification

ECHA has implemented a number of measures to modernise submission systems, make inventory data easier to understand and facilitate the re-use of data both by IT improvements. The simplified submission systems should benefit especially less experienced notifiers. Further improvements will be done, especially to display more prominently certain classifications (e.g. those that have a harmonised classification and labelling, those which are supported by a group or that have been updated in REACH registration dossiers). Ongoing or planned improvements also relate to mentioning elements allowing to better understand the reason for divergence (e.g. data sources REACH/CLP, differences related impurity, grade, form). Some of these improvements are mentioned in Table 87 below (without bold) but they are not subject to this impact assessment as they belong to the dynamic baseline.

Table 87: Overview of possible measures (the measures not in bold belong to the baseline)			
The C&L Inventory contains incorrect, diverging or obsolete information on self-classification, that cannot be removed by ECHA, impacting the reliability and usefulness of information in the C&L Inventory	**ECHA has no legal mandate to remove inactive notifications or correct / delete erroneous notifications**	**#6 Require notifiers to validate/update entries in the C&L Inventory every 2 year(s)**	PO1-b Improving the CLI and promoting convergence of self-classifications
		Redesign the CLI to emphasise up to date C&L notifications and aligned classifications	
		#5 Swift notification updates Require notification of updated self-classifications within a certain deadline after new pieces of evidence are available	
	Shortcomings in ECHA's IT tools for C&L notifications	Add a notifier dashboard to give companies an overview of their notifications and allow ease of access and update. Extend the 'cease of manufacture and import' functionality for registrants in REACH-IT to C&L notifiers	
		Ensure that when a C&L notifier submits a registration dossier, the C&L data provided in the registration dossier replaces any earlier data provided in a C&L notification	
	Notifiers' identities are not published	**#4 Publish contact information for submitted classifications so that notifiers can contact the notifiers of the same substances**	
	Notifiers are not required to come to an agreement on self-classifications	**#3 Require notifiers with classifications that diverge from the entry agreed by most notifiers to update their notifications with a justification for any divergence**	

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Table 88: Impact assessed measures		
#6 Require notifiers to validate/update entries in the C&L Inventory every 2 year(s)	Hard, legally binding rules	The Commission to amend Article 40 of CLP to introduce the requirement for notification update. Notifiers are the only actors that can guarantee their notifications stay up to date. The requirement should come into force with the launching of the redesigned CLI platform.
#4 Publish contact information for submitted classifications so that notifiers can contact the notifiers of the same substances	Hard, legally binding rules	The Commission to amend Article 42 of CLP.
#3 Require notifiers with classifications that diverge from the entry agreed by most notifiers to update their notifications with a justification for any divergence	Hard, legally binding rules	The Commission to amend Article 41 of CLP to require justification of diverging classifications from classifications backed up by REACH registration dossiers or from classifications notified the most. The requirement should come into force with the launching of the redesigned CLI platform.
#5 Swift notification updates Require notification of updated self-classifications within a certain deadline after new pieces of evidence are available	Hard, legally binding rules	The Commission to amend Article 40(2) to add a deadline after which an update is required (from the moment

ECHA has implemented a number of measures to modernise submission systems, make inventory data easier to understand and facilitate the re-use of data both by IT improvements. The simplified submission systems should benefit especially less experienced notifiers. Further improvements will be done, especially to display more prominently certain classifications (e.g. those that have a harmonised classification and labelling, those which are supported by a group or that have been updated in REACH registration dossiers). Ongoing or planned improvements also relate to mentioning elements allowing to better understand the reason for divergence (e.g. data sources REACH/CLP, differences related impurity, grade, form). Some of these improvements are mentioned in Table 87 above (without bold) but they are not subject to this impact assessment as they belong to the dynamic baseline.

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Economic Impact

#4 Publication of the identity of notifiers (i.e. company names and contact details) in the CLI.

One of the policy options to address the lack of convergence of self-classifications analysed below belongs to the measures initially envisaged by the Commission. The Commission at the time, had proposed to systematically publicise the identity of notifiers and make them visible to anyone consulting the C&L inventory. However, before implementing such measure, it was decided to assess its potential impacts in order to check whether it would be relevant to maintain the measure as planned or to modify it and if a change in the legal provisions was necessary – inter alia as ECHA was not planning to implement that measure any more. Hence, though strictly speaking one could argue that this measure belongs to the baseline, it is analysed to check whether this is the best option to address the problem, also in view of other planned new developments in ECHA's tasks.

Table 89 below provides an overview of the costs linked to the measure.

Table 89: Policy measure #4 Publication of the identity of notifiers (i.e. company names and contact details) in the CLI

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent	PV Annualised impacts
Administrative burdens on business	Cost of updating contact details	(o)	Direct	Negligible	One off	Negligible
	Cost of submitting confidentiality requests	(-)	Direct	Total cost of €270,000	One off	€18,148
	Cost of navigating the CLI	(+)	Indirect	Cost saving of €1,750,000 (€1,300,00 for LEs and €450,000 for SMEs)	Recurrent (annual)	€2,352,550 (€1,747,608 for LEs and €362,965 for SMEs)
Positions of SMEs	Increased ability to collaborate	(+)	Indirect	See Administrative Burdens on Business	Recurrent	-
Sectoral competitiveness, trade and investment flows	Increased visibility of company activities	(o)	Indirect	Not quantified	Recurrent	-
Public Authorities	Cost of reviewing	(o)	Direct	Not quantified	Recurrent	-

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Table 89: Policy measure #4 Publication of the identity of notifiers (i.e. company names and contact details) in the CLI						
Impact Category	**Impact**	**Positive or negative**	**Direct or indirect**	**Monetised impacts**	**One off or recurrent**	**PV Annualised impacts**
	confidentiality requests					

Administrative Costs

Cost of updating contact details

Policy measure #4 requires notifiers of single notifications or lead notifiers of group notifications to update their notifications with their company name and contact details. However, these details are already included in the submission when creating a user account and therefore no time or costs are required for the updating of the notifications.

Cost of submitting confidentiality requests

Article 77(2)(e) of REACH tasks ECHA with making the information identified in Article 119(1) and (2) in the database(s) publicly available, free of charge, and over the Internet. The same Article 77(2)(e) explicitly mentions the Classification and Labelling Inventory.I as one of the databases concerned[233]. On this basis, the Commission Services' concluded that the identity of notifiers can be made public[234]. However, Article 77(2) also allows notifiers to the Classification and Labelling Inventory. to have the opportunity to make confidentiality claims if they are considered justified.

Based on discussions at the meeting of the Competent Authorities on REACH and CLP expert group[235], confidentiality requests are expected for around 1% of C&L notifications, based on the rates of claiming confidentiality under REACH. Applying this percentage to the number of notifications received via Classification and Labelling notification (656,741), rather than via REACH registration dossiers (94,695), this would equate to roughly 6,600 confidentiality requests. This percentage is not applied to notifications from REACH Registration dossiers because according to ECHA confidentiality claims made under REACH Registrations would carry over to the Classification and Labelling Inventory.

Under REACH, confidentiality requests must be submitted with a well-substantiated justification for why information should be confidential. Possible justifications for Classifi- cation and Labelling notifications can include:

Natural person
Product and Process Oriented Research and Development (PPORD) activities
Scientific R&D activities

[233] See: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1907
[234] European Commission, 2020, 37th Meeting of Competent Authorities for REACH and CLP (CARACAL) CA/77/2020
[235] See Footnote 234.

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Non-hazardous substance
Revealing company strategic information
Revealing the formulation of products
Revealing involvement in specialty chemicals production
Breaching a non-disclosure agreement

To provide a well-substantiated justification, it is assumed that confidentiality requests will need to be individual to each substance, with limited possibility of grouping substances. The study team for the study underlying this Staff working document considered a reasoned estimate of the time to provide a justification to be one hour. Assuming an hourly rate of €41.126, this leads to a total cost among registrants of approximately €270,000 (6,600 x €41.126 = €271,432).

It should be noted that the number of confidentiality requests under REACH are low, partly because of the significant fee for claiming confidentiality[236] and partly because of the experience companies have in that confidentiality requests are only accepted if they are well substantiated (20-25% of confidentiality requests overall are not accepted, although the success rate is higher for requests on company names). Therefore, there is the possibility that the rates of claiming confidentiality may be higher for Classification and Labelling notifications.

Cost of navigating the Classification and Labelling Inventory.

Each of the three policy measures under consideration aim to address the problem of incorrect, diverging or obsolete information on self-classification in the CLI, in order to make data in the Inventory easier to understand and use. Therefore, an expected benefit to the conduct of business is a reduction in the time taken by Inventory users to find the most relevant and reliable data. The time saving is expected to be greatest amongst inexperienced users, such as SMEs.

Based on stakeholder feedback, the 2017 Fitness Check[237] found 36% of manufacturers, formulators, distributors and importers use the Classification and Labelling Inventory multiple times a week. On average, it was estimated that a large company spends 2 hours per month (24 hours per year) checking the inventory, with a cost of €987 per year (based on an hourly rate of €41.126). SMEs were estimated to spend half the time, and thus incur half the cost (€493.50 per year).

The reduction in time spent using the CLI Classification and Labelling Inventory is dependent on the effectiveness of policy measure #4 in addressing the problem of incorrect, diverging or obsolete information on self-classification in the inventory . Policy measure #4 does not have a direct impact on the improvement of self-classification in the inventory, as it relies on companies using published contact details to collaborate.

[236]The fee for claiming confidentiality on legal identity information in an SDS ranges between €163 for individual submissions for micro enterprises to €3,261 for individual submissions for large enterprises. See: https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02008R0340-20180715&from=EN

[237] Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation, Ref. Ares(2017)1390364 - 16/03/2017.

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Previous initiatives aimed at promoting collaboration have also achieved limited results. Therefore, the cost saving is expected to be small. A small time saving of about 10% could be possible which would equate to a cost saving of €98.7 per large company and €49.3 per SME. Multiplying these figures by the total number of large companies and SMEs gives total annual cost saving of approximately €1,300,000 (€98.70 x 13,485 = €1,330,970) for large companies, €450,000 (€49.35 x 9,260 = €456,518) for SMEs, and a total annual cost saving to all companies of €1,750,000.

SMEs

The costs associated with self-classifications are often high and unaffordable to SMEs, meaning they rely on classification done by larger companies - when they exist. If the names of notifiers are displayed it will be easier for SMEs to contact larger companies – which may be interesting if they have a very similar or same substance. Also for SMES which are often users or importers of mixtures it is beneficial to have more certainty regarding the hazard of the substances – through the fact that notifiers can more easily get into contact with each other – they will use in the mixture as this will ease the classification of their mixture.

Sectoral competitiveness, trade and investment flows

The additional information and transparency on the identity of notifiers is expected to aid competitiveness of EU industry, particularly the competitiveness of SMEs. However, the impact of the measure on its own, is expected to be weak, as its effect relies on companies using published contact details to collaborate. Previous initiatives aimed at promoting collaboration amongst duty holders have also produced very limited results. On the other hand it is not excluded that the measure acts as an incentive for notifiers to contact each other and come to an agreed entry. Moreover, there was agreement to that proposed measure by the Competent Authorities on REACH and CLP expert group, except for substances used for product and process orientated research and development (PPORD).

Public Authority Costs

Cost of reviewing confidentiality requests

At the 37th Competent Authorities for REACH and CLP expert group meeting it was explained that there are no fees for confidentiality requests in C&L notifications, and therefore no resources are expected for ECHA to assess the requests. Also, given the high number of requests that are predicted, it would not be feasible to manually assess them. Therefore, the proposed approach was to provisionally accept all confidentiality requests made, with possible follow-up actions to be agreed later, as required. IT screenings or spot checks would be considered by ECHA as mechanisms to avoid or spot any misconduct. The system to be put in place for updating Classification and Labelling notifications, would recommend that notifiers make confidentiality requests only where needed and would highlight the information needed to justify a request, and which types of reasons are considered invalid. ECHA did not plan to hire additional staff if it were to perform such tasks. Hence, the measure would require ECHA resources to be diverted from other tasks.

As the proposed measure was generally supported by the Competent Authorities on REACH and CLP expert group and because the legal text is not clear on that point, such

measure would require the legal text to be clarified. The measure would allow ECHA to disclose the identity of notifiers, either generally or upon request, subject to a duly motivated confidentiality request by a notifier.

A summary of the costs and benefits of policy measure #4 are provided below.

Summary of cost and benefits of policy measure #4	
Costs - businesses	
Total one-off costs over a 20-year period	€270,000
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	€362,965
PV of one-off costs (20 years; 3%) (annualized)	€18,148
PV of recurring costs (20 years; 3%)	
Total PV – costs - businesses	
Costs – public authorities	
Total one-off costs over a 20-year period	
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	
PV of recurring costs (20 years; 3%)	
Total PV – costs – public authorities	
Total PV cost of policy measure #4	**€362,965**
Benefits (cost savings) - businesses	€33,250,000
PV benefits - businesses	€44,698,446
Benefits (cost savings) – public authorities	
PV – benefits – public authorities	
Benefits - society	
PV - benefits - society	
Total OV - benefits	
Net Present Value - NPV (PV benefits – PV costs)	€44,335,481

A summary of the present value (3% discount) costs and benefits of policy measure #4 are provided below.

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #4 by type			
	Costs		
	Businesses	**Administrations**	**Society**
Direct adjustment costs			
Direct administrative costs	€362,965		
Direct regulatory fees and charges			

Indirect costs						
Benefits						
Description	**Businesses**		**Administrations**		**Society**	
Direct benefits						
Direct cost savings	€44,698,446					
Indirect benefits						

#6 Require notifiers to validate/update entries in the C&L Inventory every 2 year(s)

Another measure that has been considered as possibly improving the data submitted to the Classification and Labelling Inventory is to oblige notifiers to update their notification on a regular basis, e.g. every two years. They would have to look at the data they had submitted before and update, correct or confirm any information from their previous notification. However, in the view of ECHA, this would not trigger an improvement as Classification and Labelling notifications usually do not need regular updates and having permanent updates would not allow to have a stable version of the Classification and Labelling Inventory .

The costs of such measure have been analysed and are provided hereinafter. The benefits are analysed in a separate heading, together with the benefits of the other options.

Table 90: #6 Require notifiers to validate/update entries in the C&L Inventory every 2 year(s)

Impact Category	Impact	Positive (+); negative (-); neutral (o)	Direct or indirect	Monetised impacts	One off or recurrent	PV annualised impacts
Administrative burdens on business	Cost of checking notifications	(-)	Direct	Total cost of €4,900,000	Recurrent (biannual)	€3,293,570
	Cost of re-classification	(-)	Direct	Total cost of €10,400,000 - €20,800,000 Total cost of €1,040,00 - €2,080,000	One-off Recurrent (biannual)	€699,044 - €1,398,087
	Cost of updating and distributing revised Safety Data Sheet (SDS)	(-)	Indirect	Total cost of €17,900,000 - €34,800,000 Total cost of- €1,790,000 - €3,480,000	One-off Recurrent (biannual)	€1,196,440 - €2,406,322

	Cost of re-labelling in line with re-classification	(-)	Indirect	Total cost of €102,000,000 - €200,000,000 Total cost of €10,200,000 - €20,000,000	One-off Recurrent (biannual)	€6,856,002 - €13,443,142
	Cost of navigating the CLI	(+)	Indirect	Cost saving of €8,950,000 (€2,300,000 for SMEs)	Recurrent (annual) from year 2	€12,031,612 (€3,091,923 for SMEs)
Positions of SMEs	Additional burden on SMEs	(-)	Indirect	See Administrative Burdens on Business	Recurrent	-
Sectoral competitiveness, trade and investment flows	Impact on competitiveness of businesses	(+)	Indirect	Not quantified	Recurrent	-
Public Authorities	The reviewing of C&L notifications	(o)	Direct	Not quantified	Recurrent	-

Administrative Costs

Cost of checking notifications

Policy measure #6 requires notifiers to check their notification submissions to the CLI to verify that their self-classifications are correct and up to date. If any self-classification is incorrect or not up to date, either because new adequate and reliable scientific or technical information has become available that affects the classification, or if the notifier no longer manufactures, imports or uses the substance which has been notified, then action will need to be taken to update the notification. This action will either involve re-classification of the substance (see next paragraph) or removal of the notification.

This policy measure will require every notification in the Classification and Labelling Inventory to be validated by the notifier or the lead notifier of a group notification and updated if necessary (the updating costs are presented in the next paragraph). Data on the Classification and Labelling Inventory that was provided by ECHA for the purpose of the study underlying this Staff Working Document, shows that as of 30th November 2021, there were 751,436 notifications in the Inventory. Some 13% of the overall notifications come directly via REACH registration dossiers. REACH registrants would then update those 94,965 notifications via REACH. Hence they are out of the scope of measure #6 (and measure #5 as well).

Therefore, a total of 656,741 notifications were submitted to the C&L Inventory directly from 12,244 notifiers. The data provided by ECHA also provides a breakdown of the number of C&L notifications from large companies (405,713) and SMEs (251,028). This

gives an average of 54 notifications per notifier. Dividing these figures by the number of large notifiers (5,931) and SME notifiers (6,313) gives an average number of 68 notifications submitted by each large company and 40 notifications submitted by each SME.

The 2017 Fitness Check[238] of CLP estimated the average time to submit lower complexity notifications to the Classification and Labelling Inventory was 0.18hrs, which equates to roughly 11 minutes. This was considered a reasonable proxy of the time that would be needed to validate a notification, which does not require any update. In line with the Fitness Check, an hourly rate of €41.126 has been assumed for staff involved in compliance activities. This equates to a cost per notification of €7.40, and an average cost of €400 (€7.40 x 54 notifications) per company, €503 (€7.40 x 68 notifications) per large company, and €296 per SME (€7.40 x 40 notifications). The total biennial cost to large companies would be approximately €3,000,000 (€503 x 5,931 = €2,983,293), €1,900,000 (€296 x 6,313 = 1,868,648) to SMEs and a total biennial cost to all companies of approximately €4,900,000. This cost is based on the assumption that all checks confirm the existing classification. Where a notification should be updated, costs below apply.

Cost of re-classification

The 2017 Fitness Check estimates the average cost of undertaking re-classification activities to be €400, based on feedback from industry stakeholders. This estimate excludes the cost of any associated testing.

Data on the Classification and Labelling Inventory that was provided by ECHA to the study team for the study underlying this Staff Working Document, shows that 3-5% of the 10,000 REACH Registration dossiers that are updated each year provide a change in classification and labelling as one of the reasons for update. The statistics rely purely on the declaration of the registrant as regards the reason for update, as no validation is made by ECHA to determine whether the classification was actually changed. Therefore, there is a degree of uncertainty in this figure.

It is assumed that a similar percentage would apply to all notifications submitted to the Classification and Labelling Inventory (656,741) and which are not regularly updated[239]. 1% of notified substances are already updated regularly (and re-classified where appropriate), so by taking this into account (3-5% minus 1%), it gives an estimate of approximately 13,000 - 26,000 notifications requiring re-classification each year, which when divided by the number of companies that have submitted C&L notifications (12,244), gives an estimate of 1.06 – 2.12 notifications per company. This means that on average each company would incur a re-classification cost of €424 - €848, and a total annual cost to all companies of approximately €5,200,000 - €10,400,000 (€424 - €848 x 12,244). In the two year period between updates proposed by this policy measure, the total cost to all companies would be approximately €10,400,000 - €20,800,000.

By taking the 2-4% range and applying it to the number of notifications submitted by large companies (405,713) and SMEs (251,028), this gives an estimate of approximately 8,100-

[238] See footnote 16.
[239] ECHA informed that 1% of the notified classifications are updated per year.

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16,200 notifications and 5,000-10,000 notifications requiring re-classification by large companies and SMEs respectively each year. This means that on average each large company would have 1.37-2.73 notifications requiring re-classification (8,100-16,200 / 5,931 large companies) and each SME would have 0.79-1.58 notifications requiring re-classification (5,000-10,000 / 6,313 SMEs) and incur a re-classification costs of €548-1,092 (€400 x 1.37-2.73) and €316-632 (€400 x 0.79-1.58) respectively. The total annual costs to large companies are approximately €3,250,000 - €6,500,000 (€548-1,092 x 5,931 = €3,250,188-€6,476,652) and approximately €2,000,000 - €4,000,000 to SMEs (€316-632 x 6,313 = €1,994,908-€3,989,816). In the two year period between updates proposed by this policy measure, the total cost to large companies would be approximately €6,500,000 - €13,000,000 and €4,000,000 - €8,000,000 for SMEs.

Cost of updating and distributing revised Safety Data Sheet (SDS)

Following any re-classifications, companies will be required to update and distribute revised Safety Data Sheet to reflect the new classification. The 2017 Fitness Check estimated an average cost of €250 per substance or mixture of updating an SDS due to a change in classification. SDS help ensure that those who use chemicals in the workplace use them safely without risk of harm to users or the environment. Only companies supplying hazardous substances and mixtures to other companies (downstream users, distributors) are required to provide a SDS, meaning that not all notifiers who re-classify their substances will have to produce a revised SDS. Therefore, only a proportion of notifications requiring re-classification will also require a subsequent revised SDS. A recent economic analysis of the Impacts of the Chemicals Strategy for Sustainability[240] found that just over a quarter of the products identified in the data gathering exercise had an industrial end use and were classified under the following hazard classes: CMR, PBT, vPvB. EDC, respiratory sensitisation, STOT RE, STOT SE, skin sensitisation, aquatic chronic toxicity, immunotoxicity, or neurotoxicity. Although this does not include products classified under all hazard classes, and includes products classified under some hazard classes not currently under CLP, this sample is considered large enough to be representative of the end uses of all hazardous products. This means that approximately 3,250 – 6,500 of the re-classified substances would require an SDS after each year (2,025 – 4,050 for large companies and 1,250 – 2,500 for SMEs), which would lead to a cost per company of €66.25 - €132.50, €85.63 - €170.63 per large company, and €49.38 - €98.75 per SME (these calculations take the average number of notifications per company / large company / SME requiring reclassifications presented in the paragraph above, divide by four and multiple by the unit cost of €250 per SDS). SDS may also need an update for mixtures containing the reclassified substances, where the substance concentration in the mixture would be above the general concentration limit. Such limits vary by several order of magnitude. It was estimated from Annex 8 that for each substance, 11 mixtures are manufactured. To test the variability, frequencies of updates of mixture SDS 10, 30 and 50% were used, though these figures contain uncertainties. This gives total annual costs of approximately €8,900,000 - €17,900,000 (3,250-6,500 x €250 x 11) for all companies, €5,600,000 – €11,100,000 (2,025 – 4,050 x €250 x 11) for large companies, and €3,400,000 - €6,900,000 (1,250 – 2,500 x €250 x 11) for SMEs. In the two year period

[240] Cefic, Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability – Phase 1 Report, 2021.

between updates proposed by this policy measure, the total cost to all companies would be approximately €17,900,000 - €35,800,000, €11,200,000 - €22,200,000 to large companies, and €6,800,000 - €13,800,000 for SMEs.

Cost of re-labelling in line with re-classification

To ensure that customers receive information on hazards, suppliers of substances and mixtures should ensure that they are labelled in accordance with the classification derived for each substance and mixture. CLP labels must include hazard pictograms, hazard and precautionary statements, and signal words derived from a hazard classification. Therefore, a change in classification will require a change in labelling to ensure compliance with labelling provisions under the CLP Regulation and accurate communication of hazard information to users of substances.

Labels are the only tool for direct communication to consumers, but they may also serve to draw the attention of workers to the more comprehensive information on substances or mixtures provided in safety data sheets (SDS). Labelling applies to all substances and mixtures, with the exception of those substances used exclusively in products that are exempt from CLP, such as cosmetics. It is not known what percentage of substances in the Classification and Labelling Inventory are exempt, but the proportion is considered to be a minority, so for the purposes of this analysis all notifications that are updated with revised classifications are assumed to require subsequent re-labelling. However, as mentioned previously one quarter of substances are assumed to be supplied to industrial uses and therefore would not need consumer labelling.

The 2017 Fitness Check[241] estimated the average cost of re-labelling to be €388 per substance and €475 per mixture. Assuming 75% of notifications requiring re-classification each year would result in relabelling, would equate to 9,750 – 19,500 (13,000 – 26,000 * 0.75) for all companies, 6,000 – 12,000 (8,100-16,200 * 0.75) for large companies, and 3,750 – 7,500 (5,000 – 10,000 * 0.75) for SMEs. Again, assuming 11 mixtures are manufactured for each substance, this would equate to annual costs of €51,000,000 – €100,000,000 for all companies, €31,400,000 – €62,700,000 for large companies, and €19,600,000 – 39,200,000 for SMEs.[242] In the two year period between updates proposed by this policy measure, the total cost to all companies would be approximately €102,000,000 - €200,000,000, €62,800,000 – €125,400,000 for large companies, and €39,200,000 – €78,400,000 for SMEs.

Cost of navigating the Classification and Labelling Inventory

Each of the three policy measures under consideration aim to address the problem of incorrect, diverging or obsolete information on self-classification in the Classification and Labelling Inventory, in order to make data in the Inventory easier to understand and use. Therefore, an expected benefit to the conduct of business is a reduction in the time taken by Inventory users to find the most relevant and reliable data. The time saving is expected to be greatest amongst inexperienced users, such as SMEs.

[241] See Footnote 16.
[242] See Footnote 237.

Based on stakeholder feedback, the 2017 Fitness Check found 36% of manufacturers, formulators, distributors and importers use the Classification and Labelling Inventory multiple times a week. On average, it was estimated that a large company spends 2 hours per month (24 hours per year) checking the Inventory, with a cost of €987 per year (based on an hourly rate of €41.126). SMEs were estimated to spend half the time, and thus incur half the cost (€493.50 per year).[243]

The reduction in time spent using the Classification and Labelling Inventory is dependent on the effectiveness of policy measure #6 in addressing the problem of incorrect, diverging or obsolete information on self-classification in the inventory. However, if policy measure #6 led to users of the inventory spending half the time navigating the inventory due to improvements in self-classifications, this would equate to a cost saving of €493.50 per large company and €246.75 per SME. Multiplying these figures by the total number of large companies and SMEs gives total costs of approximately €6,650,000 for large companies, €2,300,000 for SMEs, and a total cost of €8,950,000.

Total administrative burden on businesses

Policy measure #6 foresees that notifications should be reviewed and updated every 2 years. After the first review, the subsequent reviews are expected to incur smaller recurring costs. This is because significantly fewer reclassifications, and subsequent re-labelling and provision of updated safety data sheet, will be required in following reviews, and most are expected to have been performed during the first review. The total cost for the first two-year review period is €125,840,000 – €261,500,000, central estimate: €51,250,000, which is the combined total of the following costs:

cost of validating/updating notifications: €4,900,000
cost of re-classification: €10,400,000 - €20,800,000
cost of re-labelling: €102,000,000 - €200,000,000
cost **of providing updated SDS:** €17,900,000 – €35,800,000

The total annual recurring cost of subsequent two-year review periods are expected to be the same as the cost of reviewing notifications plus the cost of reclassifying a small number of substances. It is assumed that only 10% of the number of substances that required reclassification the first time would require reclassification during subsequent reviews. Therefore, the total annual recurring cost of subsequent two-year review periods is €17,930,000 – €30,560,000, which is the combined total of the following costs:

cost of validating/updating notifications: €4,900,000
cost of re-classification: €1,040,000 - €2,080,000
cost of re-labelling: €10,200,000 - €20,000,000
cost **of providing updated SDS:** €1,790,000 - €3,580,000

The cost of time saved navigating the Classification and Labelling Inventory would be realised every year, and is expected to remain the same, pending the 3% discount rate.

[243] See Footnote 237.

Assuming the obligation under policy measure #6 occurs every 2 years, the total (recurring) cost with a discount rate of 3%, €343,284,062 (central estimate), where the savings from navigating the CLI would equal to €216,569,010 (discount rate 3%).

It needs to be noted however, that, legally speaking, companies are required to update their notifications and communicate to ECHA '*…when… a decision to change the classification and labelling of the substance has been taken*' (Article 40(2) of CLP). The costs associated with the update need therefore to take into account the obligation that notifiers have currently to update their notification when, following a new evaluation of data, they have decided to change the classification. Any subsequent cost triggered by such updating obligation, in terms of re-notification, re-classification and re-labelling should not only be attributed to the obligation to update every two years but also to the existing updating obligation.

For measure #5 – swift Classification and Labelling Inventory update, the same type of costs would apply but only to 4% of notified substances were new data are available as described above. 1% of the notified substances are already regularly updated (and re-classified where appropriate). The costs of measure #5 are those of measure #6 without the notification check for 97% of the notified substances (i.e the cost of validation/updating notifications is avoided). Therefore, the central estimate is €277,412,668. The savings would be the same as for measure #6.

SMEs

The average number of notifications per SME (40) is not much less than the average number of notifications per large company (68). Therefore, there is only a small difference between the cost estimates per company presented above for SMEs and large enterprises. Considering the substantial differences in the profits of SMEs and large companies, the costs of policy measure #6 will be disproportionately felt amongst SMEs. This in turn may negatively impact the competitiveness of SMEs.

Conversely, SMEs rely on public information sources such as the CLI more heavily than larger companies, and therefore improved access to information will benefit the smaller companies more compared to larger companies. Under policy measure #6 SMEs could see a reduction in compliance costs and a subsequent increase in their competitiveness in the long-term.

Sectoral competitiveness, trade and investment flows

The updating and reviewing of notifications aims to harmonise classifications and improve the quality of the CLI data, which in turn will benefit all businesses and increase competitiveness, especially SMEs who rely on public information sources such as the Classification and Labelling Inventory more heavily than larger companies. However, in the short-term the competitiveness of SMEs may be hindered due to the additional burden for smaller companies when reviewing and updating their self-classifications. A weak positive impact is expected.

Public Authority Costs

Cost of reviewing C&L notifications

Based on discussions held at the Competent Authorities for REACH and CLP expert group on the re-design of the CLI, it was stated that ECHA does not have enough available resources for manual screening of C&L data or contacting notifiers. Therefore, they rely on automated IT screening of obvious internally inconsistent data. Discussions between ECHA and the study team revealed that although ECHA would not be checking new notifications, their submission would represent an additional administrative burden to process the notifications (more submissions lead to more company support (technical, regulatory) as well as more IT incidents). ECHA and the Commission are not planning to hire any additional staff for these tasks so this policy measure would result in resources being shifted away from other priorities. This shift of resources may impact ECHA's other activities, for example the redesigning of the CLI. As no increase in staffing levels is expected, the employment costs to ECHA of reviewing C&L notifications will be negligible, however the impact to the organisation and other activities could be significant.

A summary of the costs and benefits of policy measure #6 are provided below.

Summary of cost and benefits of policy measure #6	
Costs - businesses	
Total one-off costs over a 20-year period	€130,200,000 – €256,600,000 (mid-estimate: €193,400,000)
Recurring costs every 1 year	€8,960,000 – €15,280,000 (mid-estimate: €12,120,000)
Total recurring costs over a 20-year period	€166,180,000 – €279,940,000 (mid-estimate: €223,060,000)
PV of one-off costs (20 years; 3%)	€175,029,703 – €344,951,011 (mid-estimate: €259,990,357)
PV of one-off costs (20 years; 3%) (annualized)	€8,751,485 – €17,247,551 (mid-estimate: €12,999,518)
PV of recurring costs (20 years; 3%)	€223,398,126 – €376,327,304 (mid-estimate: €299,862,715)
Total PV – costs - businesses	€398,427,828 – €721,278,315 (mid-estimate: €559,853,072)
Costs – public authorities	
Total one-off costs over a 20-year period	-
Recurring costs every 1 year	-
Total recurring costs over a 20-year period	-
PV of one-off costs (20 years; 3%)	-
PV of recurring costs (20 years; 3%)	-
Total PV – costs – public authorities	-
Total PV cost of policy measure #6	**€398,427,828 – €721,278,315 (mid-estimate: €559,853,072)**
Benefits (cost savings) - businesses	€161,100,000
PV benefits - businesses	€216,569,010
Benefits (cost savings) – public authorities	-

PV – benefits – public authorities	-
Benefits - society	-
PV - benefits - society	-
Total OV - benefits	-
Net Present Value - NPV (PV benefits – PV costs)	€181,858,818 – €504,709,305 (mid-estimate: €343,284,062)

A summary of the present value (3% discount) costs and benefits of policy measure #6 are provided below.

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #6 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs	-	-	-
Direct administrative costs	€6,587,139	-	-
Direct regulatory fees and charges	-	-	-
Indirect costs	€332,556,435 – €655,406,922 (mid-estimate €493,981,678)	-	-
Benefits			
Description	**Businesses**	**Administrations**	**Society**
Direct benefits			
Direct cost savings	€216,569,010	-	-

#3 Require notifiers with classifications that diverge from the entry agreed by most notifiers to update their notifications with a justification for any divergence

Another measure that could be useful for notifiers to understand the reason for divergence in the classification and labelling information would be to require notifiers with classifications that diverge from the entry agreed by most notifiers to update their notifications with a justification for any divergence. The update would be a one off measure. This measure will be eased by ECHA' s planned improvements of the IT tool – belonging to the baseline - i.e. to improve the visibility of the reason for divergence with the information currently available in the C&L inventory. This reason for divergence is however not always known to the notifier: it might be in case the reason is e.g. impurity, additive or form). When the reason is something else (underlying data or interpretation of data), the notifier will not be able to provide such a reason as they would need to know the details of how others derived their classifications.

Table 91: Policy measure #3 Require notifiers with classifications that diverge from the entry agreed by the majority of notifiers to update their notifications with a justification for any divergence in classification

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent	PV annualised impacts
Administrative burdens on business	Cost of justifying diverging notifications	(-)	Direct	Total cost of €1,800,000 across all notifiers	One off	€120,988
	Cost of re-classification	(-)	Indirect	Total cost of €5,200,000 - €10,400,000 (mid-point of €7,000,0000	One off	€349,522 - €699, 043 (mid-point: €524,283)
	Cost of updating and distributing revised Safety Data Sheet (SDS)	(-)	Indirect	Total cost of €8,900,000 - €17,900,000 (mid-point of €13,400,000	One off	€598,220 - €1,203-161 (mid-point of €900,690
	Cost of re-labelling in line with re-classification	(-)	Indirect	Total cost of €51,000,000 – €100,000,000 (mid-point of €75,500,000	One off	€3,428,001 - €6,721,571 (mid-point of €5,074,786)
	Cost of navigating the CLI	(+)	Direct	Cost saving of €8,950,000 (€2,300,000 for SMEs)	Recurrent (annual) from year 2	€12,031,612 (€3,091,923 for SMEs)
Positions of SMEs	Operation of SMEs	(o)	Indirect	Not quantified	Recurrent	-
Sectoral competitiveness, trade and investment flows	Additional information and clarity on self-classifications	(+)	Indirect	Not quantified	Recurrent	-
Public Authorities	Cost of reviewing C&L notifications	(o)	Indirect	Not quantified	Recurrent	-

Administrative Costs

Cost of justifying diverging notifications

Policy measure #3 requires notifiers that have classifications which differ from the consensus classification, to update their notifications with a justification for the divergence or remove the notification if it diverges because it is incorrect. Possible reasons for divergence include:

Different hazardous impurities, additives or ingredients might be present;
Properties such as the physical form, the pH, the flash point might be different;

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Suppliers need to interpret the data from scientific studies when they classify a chemical, and different suppliers might reach a different conclusion, which is sometimes justifiable.

Data on the Classification and Labelling Inventory that was provided by ECHA to the study team of the study underlying this Staff Working Document, shows the level of divergence in the inventory. 21.61% of substances have more than one classification which equates to 68.9% (517,739) of notifications. An estimate of 5 minutes to provide a justification has been assumed by the study team. This is the case when the legitimate reasons for divergence in classifications are well known and it would not be necessary to provide a lengthy explanation. At a recent ad-hoc meeting of the Competent Authorities for REACH and CLP[205], ECHA mentioned that they already hold data on this, such as the presence of impurities / additives, physical states, and hydrated forms, although it is not published in the public CLI[244]. Therefore, a significant number of notifications that diverge may not require any review, and therefore no administrative cost will be incurred.

The maximum total cost of justifying divergence is calculated to be approximately €1,800,000 based on all the 517,739 notifications requiring justification, a time estimate of 5 minutes, and an hourly rate of €41.126. Data on the number of notifiers from which the 517,739 diverging notifications were submitted was not available, so an average cost per company was not able to be reliably calculated.

The aim of the planned re-design of the Classification and Labelling Inventory is to provide clarity on data held in the inventory, which will include publishing the reason for divergence. Therefore, providing information that justifies a diverging classification may become a very efficient tick-box exercise representing a negligible administrative burden to notifiers. In discussions with the study team in charge of the study underlying this Staff working document, ECHA has also highlighted that they already hold information on physical form and impurities, so for those notifiers that have already provided this information, no action from them would be required.

Cost of re-classification

As explained previously, around 2-4% (mid-point of 3%) of C&L notifications are expected to require re-classification each year, which gives an estimate of just over 13,000 – 26,000 notifications. Based on estimates from the Fitness Check[245] that the average cost of undertaking re-classification activities is €400, this gives an approximate total cost range of €5,200,000 - €10,400,000 (mid-point of €7,800,000). However, it should be noted that if only 1% of notifications are being updated regularly, there may be a greater percentage of notifications that would require re-classification.

Although only a proportion of notifications will require review under this policy measure, it is expected that the estimated 13,000 – 26,000 notifications requiring re-classification would come from this subset of notifications.

Cost of updating and distributing revised Safety Data Sheet (SDS)

[244] ECHA publish the fact that a classification is indicated to depend on an impurity/additive. It is assumed that companies systematically indicate this when notifying.
[245] See Footnote 237.

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Following any re-classifications, companies will be required to update and distribute revised SDS to reflect the new classification. The 2017 Fitness Check estimated an average cost of €250 per substance or mixture of updating a safety data sheet due to a change in classification. Safety data sheets help ensure that those who use chemicals use them safely without risk of harm to users or the environment.[246] According to Article 31 of REACH, only companies supplying hazardous substances and mixtures to 'recipients' – defined as downstream users or distributors (Article 3 (34) of REACH - will be required to supply SDS, meaning that not all notifiers who re-classify their substances will have to produce a revised SDS. Therefore, only a proportion of the 13,000 – 26,000 notifications requiring re-classification will also require a subsequent revised SDS. A recent economic analysis of the Impacts of the Chemicals Strategy for Sustainability[247] found that just over a quarter of the products identified in the data gathering exercise had an industrial end use and were classified under the following hazard classes: CMR, PBT, vPvB. EDC, respiratory sensitisation, STOT RE, STOT SE, skin sensitisation, aquatic chronic toxicity, immunotoxicity, or neurotoxicity. Although this does not include products classified under all hazard classes[248], and includes products classified under some hazard classes not currently under CLP[249], it is considered large enough to be representative of the end uses of all hazardous products. This means that approximately 3,250 – 6,500 of the 13,000 – 26,000 re-classified substances would require a safety data sheet each year, which would lead to a cost per company of €66.25 - €132.50, €85.63 - €170.63 per large company, and €49.38 - €98.75 per SME. This gives total annual costs of approximately €8,900,000 - €17,900,000 (3,250-6,500 x €250 x 11) for all companies, €5,600,000 – €11,100,000 (2,025 – 4,050 x €250 x 11) for large companies, and €3,400,000 - €6,900,000 (1,250 – 2,500 x €250 x 11) for SMEs.

Cost of re-labelling in line with re-classification

To ensure that customers receive information on hazards, suppliers of substances and mixtures should ensure that they are labelled in accordance with the classification derived for each substance and mixture. CLP labels must include hazard pictograms, hazard and precautionary statements, and signal words derived from a hazard classification. Therefore, a change in classification will require a change in labelling to ensure compliance with labelling provisions under the CLP Regulation and accurate communication of hazard information to customers.

Labels are the only direct tool for communication to consumers, but they may also serve to draw the attention of workers to the more comprehensive information on substances or mixtures provided in safety data sheets (SDS). Labelling applies to all substances and mixtures, with the exception of those substances used exclusively in products that are exempt from CLP, such as cosmetics. It is not known what percentage of substances in the Classification and Labelling Inventory are exempt, but the proportion is considered to be a minority, so for the purposes of this analysis all notifications that are updated with revised classifications are assumed to require subsequent re-labelling.

[246] See Footnote 237.
[247] See Footnote 240.
[248] According to Article 31(a) of REACH a SDS is required for all substances and mixtures meeting the CLP criteria for classification as hazardous.
[249] EDs, PBTs e.g.

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The Fitness Check of CLP estimated the average cost of re-labelling to be €388 per substance and €475 per mixture. Assuming 75% of notifications requiring re-classification each year would result in relabelling, would equate to 9,750 – 19,500 (13,000 – 26,000 * 0.75) for all companies, 6,000 – 12,000 (8,100-16,200 * 0.75) for large companies, and 3,750 – 7,500 (5,000 – 10,000 * 0.75) for SMEs. Again, assuming 11 mixtures are manufactured for each substance, this would equate to annual costs of €51,000,000 – €100,000,000 for all companies, €31,400,000 – €62,700,000 for large companies, and €19,600,000 – 39,200,000 for SMEs.

Cost of navigating the Classification and Labelling Inventory

Each of the three policy measures under consideration aim to address the problem of incorrect, diverging or obsolete information on self-classification in the CLI, in order to make data in the Inventory easier to understand and use. Therefore, an expected benefit to the conduct of business is a reduction in the time taken by Inventory users to find the most relevant and reliable data. The time saving is expected to be greatest amongst inexperienced users, such as SMEs.

Based on stakeholder feedback, the 2017 Fitness Check found 36% of manufacturers, formulators, distributors and importers use the Classification and Labelling Inventory multiple times a week. On average, it was estimated that a large company spends 2 hours per month (24 hours per year) checking the Inventory, with a cost of €987 per year (based on an hourly rate of €41.126). SMEs were estimated to spend half the time, and thus incur half the cost (€493.50 per year).

The reduction in time spent using the CLI is dependent on the effectiveness of policy measure #3 in addressing the problem of incorrect, diverging or obsolete information on self-classification in the CLI. It is expected that measure #3 will have a positive impact on reducing the number of diverging classifications and improving transparency on the remaining divergence. Therefore, it is realistic to expect that policy measure #3 could lead to users of the CLI to spend half the time navigating the CLI due to improvements in self-classifications, this would equate to a cost saving of €493.50 per large company and €246.75 per SME. Multiplying these figures by the total number of large companies and SMEs gives total costs of approximately €6,650,000 for large companies, €2,300,000 for SMEs, and a total cost of €8,950,000.

Total administrative burden on businesses

The total **one-off** administrative cost of policy measure #3 is €24,215,000 – €32,825,000 (cost of providing justifications + cost of reclassification + cost of relabelling + cost of providing SDS). The recurring cost would apply to new notifications and therefore this cost is expected to be budgeted into the cost of preparing new notifications. However, the cost of time saved navigating the Classification and Labelling Inventory would be realised every year, which needs to be factored into the recurring cost, which equates to €9,950,000.

As in the case of the bi-yearly updates measure described above, it needs to be noted however, that, legally speaking, companies are required to update their notifications and communicate to ECHA '*…when… a decision to change the classification and labelling of the substance has been taken*' (Article 40(2) of CLP). The costs associated with the update

need therefore to take into account the obligation that notifiers have currently to update their notification when, following a new evaluation of data – e.g. because they become aware that they have to re-classify because they had not duly taken into account an impurity - they have decided to change the classification. Any subsequent cost triggered by such updating obligation, in terms of re-notification, re-classification and re-labelling should not only be attributed to the obligation to update in order to display the reason for divergence more clearly but also to the existing updating obligation.

Position of SMEs

Operation of SMEs

Information on the number of diverging classifications per SME and large enterprise was not available. However, assuming a similar distribution amongst SMEs and large enterprises as was observed in the whole dataset of the Classification and Labelling Inventory, the average number of diverging notifications per SME can be expected to be not much smaller than the average number of diverging notifications per large enterprise. Therefore, only a small difference between the cost incurred for SMEs and large enterprises is expected. Considering the substantial differences in the profits of SMEs and large companies, the costs of policy measure #3 would be disproportionately felt amongst SMEs, which in turn may negatively impact the competitiveness of SMEs.

Conversely, SMEs rely on public information sources such as the Classification and Labelling Inventory more heavily than larger companies, and therefore improved access to information will benefit the smaller companies significantly compared to larger companies. Under policy measure #3 SMEs could see a reduction in compliance costs and a subsequent increase in their competitiveness in the long-term. Due to both the positive and negative impacts, overall a limited impact is expected.

Sectoral competitiveness, trade and investment flows

The obligation to review and justify diverging classifications aims to improve the harmonisation of classifications and improve the quality of the Classification and Labelling Inventory data, which in turn will benefit all businesses and increase competitiveness, especially SMEs who rely on public information sources such as the Classification and Labelling Inventory more heavily than larger companies. However, in the short-term the competitiveness of SMEs may be hindered due to the additional burden felt by smaller companies when reviewing and updating their self-classifications. A weak positive impact is expected.

Public Authority Costs

Cost of reviewing C&L notifications

Discussions between ECHA and the study team in charge of the study underlying this Staff working document revealed that ECHA would not have sufficient resources to do manual screening of Classification and Labelling data. IT screening would be more feasible, but would also cost resources as such screening results would need follow-up to generate any effect.

ECHA and the Commission have not planned to hire any additional staff for this task, so this policy measure would result in resources being shifted away from other priorities. As no increase in staffing levels is expected, the employment costs to ECHA of reviewing Classification and Labelling notifications will be negligible but ECHA's other activities are expected to be impacted.

It is envisaged that an additional field would be added to IUCLID (format used for both C&L notification and REACH registration) to allow notifiers to provide their justifications. In discussions with the study team of the study performed for the purposes of this Staff Working Document, ECHA highlighted that this would not represent a significant cost.

Environmental Impacts

Each of the three policy measures under consideration aims to improve the accuracy, transparency, and ease-of-use of information in the CLI. Each measure is therefore expected to result in similar environmental and human health impacts although their magnitude is expected to differ based on their effectiveness.

Improvements in the Classification and Labelling Inventory will enhance the communication of hazard information to consumers, professional users and industrial workers via the inventory, which will allow them to make better decisions on how they use hazardous substances. An increase in the accuracy of self-classifications will also feed into the accurate labelling of hazardous substances and mixtures supplied to consumers, professional users and industrial workers. 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.

More accurate labelling of consumer products may also reduce sales of environmentally harmful chemicals to consumers, as better information will empower consumers to make more informed decisions on their product purchases. Knowing the true hazards of environmentally harmful chemicals might deter consumers from purchasing them in favour of less harmful alternatives.

The environmental benefits from the policy measures are indirect impacts as more accurate information on classification does not automatically lead to improved environmental protection. Subsequent action on re-labelling products and introducing workplace safety measures are required for any benefit to be realised. Therefore, it is not possible to accurately quantify the scale of the environmental benefits from each policy measure. However, the positive impact is expected to be weak for both policy measure #6 and #3 due to the indirect nature of any improvements to environmental protection. Policy measure #4 is also expected to have a limited impact as publication of notifier details relies on subsequent collaboration amongst duty holders and previous initiatives aimed at promoting collaboration have had limited results.

However, the fact that the positive impact on the environment of each of these measures in itself is expected to be low should not constitute a sufficient reason for them not be

pursued, as in fact the exact benefits are unknown in view of the uncertainty of the further measures they need to be combined with.

Table 92: Environmental impacts

Impact Category	Impact	Positive or negative	Direct or indirect	One off or recurrent
The likelihood or scale of environmental and climate risks	Impact on environmental protection	(+)	Indirect	Recurrent

Social impacts

The measures under consideration aim to reduce the level of divergence and improve the transparency of information in the Classification and Labelling Inventory. Each measure is therefore expected to have the same human / social impacts, although their magnitude is expected to differ based on the effectiveness of each policy measure.

Table 93: Social impacts

Impact Category	Impact	Positive or negative	Direct or indirect	One off or recurrent
Employment	Impact on industry jobs	(+)	Indirect	One off
	Impact on public authority jobs	(o)	Indirect	One off
Consumers and households	Impact on consumer awareness	(+)	Indirect	Recurrent
Innovation	Impact on innovation	(+)	Indirect	Recurrent
Public health and safety and health systems	Impact on protection of human health	(+)	Indirect	Recurrent
Working conditions, job standards and quality	Impact on worker protection	(+)	Indirect	Recurrent

Employment

Impact on industry jobs

Companies with a large number of self-classifications may have to increase their number of regulatory staff to accommodate the additional regulatory burden. However, the cost

estimates of each policy measure are not significant enough to cause any discontinuation of business, and therefore each policy measure is expected to have a weakly positive impact on the levels of employment within the EU chemical sector. In addition, the impacts of the policy measures by themselves are not large enough to predict to what extent substitution of hazardous substances with less harmful (non-hazardous) substances will take place. Policy measures #6 and #3 involve the most significant economic costs and are expected to have the most positive impacts on employment.

Impact on public authority jobs

Based on discussion between ECHA and the study team of the study underlying this Staff Working Document, no increase in staff within ECHA is foreseen under any of the policy measures. Therefore, based on this assumption, all policy measures will have no impact. However, the measures is expected to have an impact on ECHA's overall workload - in particular to keep the old dissemination platform operational and in parallel rebuild a new dissemination platform - and hence may require shifting of priorities.

Consumers and households

Impact on consumer awareness

Information on self-classifications in the Classification and Labelling Inventory is used by downstream users to complete their labelling obligations under the CLP Regulation for products they place on the market. Improvements in the accuracy and clarity of self-classifications in the inventory is therefore expected to improve the accuracy of labelling elements of consumer products (provided they are not excluded from the scope of CLP in accordance with Article 1(5) of CLP and the product specific legislation does not refer to CLP labelling provisions). This will ensure consumers are correctly informed on the hazards associated with a product and can make more-informed decisions on product purchases.

Making the identity of the notifiers public – subject to duly motivated confidentiality requests - will increase transparency.

Innovation

Impact on innovation

A vast and credible data set of hazard information will provide industry with useful information to guide their innovation and the confidence to make innovation decisions without having to conduct expensive research internally. A weakly positive impact on innovation is expected.

Public health and safety and health systems

Impact on protection of human health

Improvements in the accuracy of classifications will lead to the use of improved consumer product labels and thus will ensure that consumers are correctly informed on the hazards associated with the products they purchase. This is expected to lead to the safer use,

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storage, and disposal of chemical products, thus resulting in improvements in the protection of human health.

In addition, the enhanced accuracy of the information in the Classification and Labelling Inventory will be used by poison centres to provide more valuable medical advice. When notifying mixtures to poison centres, notifiers must include the classification of each substance within the composition. Often, formulators rely on the information and classifications provided by the substances' suppliers. However, different suppliers of the same substance can provide differing classifications, which can be the result of impurities within the substance, differing access to data, or lack of agreement on self-classification. In these cases, it is difficult for the notifiers to select one dataset over another. ECHA's current practice is to advise notifiers to go back to their suppliers to reconcile these differences. However, this is unlikely to be a practical solution and can be time consuming.

These conflicting classifications for identical substances could result in inconsistent medical advice given for exposure incidents involving the same substance(s), within the same Member State or across Member States. For example, two product notifications that have identical formulations (except minor concentration differences) submitted by two different companies, could result in a poison centre advising specific medical advice for one product and not for the other, based on diverging classifications of substances within the product's formulation. Therefore by improving the data in the Classification and Labelling Inventory, poison centres can use the inventory to resolve these differences and deliver consistent and reliable medical advice.

The human health benefits from the policy measures are indirect impacts as more accurate information on classification does not automatically lead to improved protection for human health. Subsequent action on re-labelling products and introducing workplace safety measures are required for any benefit to be realised. Therefore, it is not possible to accurately quantify the scale of the human health benefits from each policy measure. The positive impact is nevertheless expected to be weak. Policy measure #4 is expected to have a limited impact in itself as publication of notifier details relies on subsequent collaboration amongst duty holders and previous initiatives aimed at promoting collaboration have had limited results. However, it is expected to still have a positive impact if combined with collaboration.

Impact on worker health

Improvements in the accuracy and clarity of self-classifications in the Classification and Labelling Inventory are also expected to improve the accuracy of labelling elements of chemicals supplied to industrial and professional users. This may lead to more appropriate risk management measures being implemented in the workplace, leading to greater protection of worker health.

However, it is not because the positive impact on human health of each of the measures on its own is weak that it should not be pursued, because the exact benefits are unknown in view of the uncertainty of the further measures they need to be combined with.

Transparency

Making the identity of notifiers public will have a certain benefit for transparency. However that impact will be limited as there are around 10 million companies in the groups (not all different companies - still associated with notified substances), whereas only 750,000,000 notifier names would become public.

It will also allow aligning with substances registered under REACH - for which the names of the registrants are public, subject to duly motivated confidentiality requests.

There were several reasons which drove ECHA, supported by the Commission, to make the registrant's names public under REACH, *inter alia* as it was justified by reference to Article 119(2) (d) of REACH according to which ECHA should give access to any information included in the Safety Data Sheet (SDS) – subject to a duly motivated confidentiality request – which SDS includes the name of registrants. The objective of REACH regarding transparency with regard to risks and hazards of substances and industry responsibility in managing such risks also justified such interpretation. That transparency objective fits with the access to environmental information under the Aarhus Convention, which encompasses information of an administrative nature.

To be noted that Article 77(2) of REACH which provides for ECHA's competence in establishing and maintaining REACH and CLP databases, refers to Article 119(1) and (2) of REACH regarding the obligation to make information of these databases publicly available. This supports that a parallel measure to REACH would be implemented. Recital 58 of CLP confirms that information provided for the CLI and under REACH should benefit from the same degree of accessibility and protection of information.

A summary of the costs and benefits of policy option #3 are provided below.

Summary of cost and benefits of policy option #3	
Costs - businesses	
Total one-off costs over a 20-year period	€66,900,000 - €130,100,000 (mid-estimate: €98,500,000)
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	€89,314,851 - €174,275,506 (mid-estimate: €131,795,178)
PV of one-off costs (20 years; 3%) (annualized)	€4,496,731 - €8,744,764 (mid-estimate: €6,620,747)
PV of recurring costs (20 years; 3%)	-
Total PV – costs - businesses	-
Costs – public authorities	
Total one-off costs over a 20-year period	-
Recurring costs every 1 year	-
Total recurring costs over a 20-year period	-
PV of one-off costs (20 years; 3%)	-
PV of recurring costs (20 years; 3%)	-
Total PV – costs – public authorities	-
Total PV cost of policy option #3	**€89,314,851 - €174,275,506**

	(mid-estimate: €131,795,178)
Benefits (cost savings) - businesses	€161,100,000
PV benefits - businesses	€216,569,010
Benefits (cost savings) – public authorities	-
PV – benefits – public authorities	-
Benefits - society	-
PV - benefits - society	-
Total OV - benefits	-
Net Present Value - NPV (PV benefits – PV costs)	€41,673,739 – €126,634,393 (mid-estimate: €84,154,066)

A summary of the present value (3% discount) costs and benefits of policy measure #3 are provided below.

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #3 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs	-	-	-
Direct administrative costs	€2,419,765	-	-
Direct regulatory fees and charges	-	-	-
Indirect costs	€89,314,851 – €174,275,506 (mid-estimate: €131,795,178)	-	-
Benefits			
Description	**Businesses**	**Administrations**	**Society**
Direct benefits			
Direct cost savings	€216,569,010	-	-

Stakeholder Opinions

#6 Require notifiers to validate/update entries in the Classification and Labelling Inventory every 2 year(s)

Of the stakeholders that responded to policy measure #6 one Trade Association was supportive in suggesting a general improvement in creating a legal obligation to delete inactive entries, for example after 2-3 years of inactivity. However a public authority also noted that under the proposed policy measure #6 there would be significant time and cost investment required from individual members of group submissions, which the public authority has suggested is responsible for the majority of notifications to the C&L inventory. The requirement for group members to take action could result in a need for a

"complete restart of the inventory". Furthermore a Public Authority and a Member State Competent Authority have indicated that from their experience regular updates don't necessarily provide any benefit to the accuracy of the Inventory or even provide any new relevant information. One industry association suggested a softer approach with a simple update mechanism rather than a full re-submission, as full re-submissions should only be required as a last resort.

#4: Publication of the identity of notifiers (i.e. company names and contact details) in the CLI

Of the two stakeholders that responded in support of this measure, one industry association noted that they understand the concerns in regard to protecting confidential business information, especially with activities relating to research and development such as Product and Process Oriented Research and Development (PPORD) and SR&D substances. Nevertheless, they do support the publication of names as long as there is a provision to protect confidentiality where appropriate or provide exemptions, this specific provision to the measure is also supported by a group of industry representatives and one trade association. A Member State Competent Authority who is in support of the measure indicated that the measure would facilitate communication between submitters and the supply chain, so long as the names were made in direct relation to the submitted classification and labelling, else there would be less added value to publishing submitter's names.

Overall the majority of stakeholders against the measure cite confidentiality reasons. For example and in line with the above concern regarding research and development substances, an industry association explained that the publication of a notifiers name against substances could imply the research and development portfolio of the notifier, which is considered confidential business information and its indirect publication could discourage innovation. Furthermore, one trade association, one public authority and one Member State Competent Authority all suggested that there would be little added benefit or limited usage to this measure, which one trade association suggesting it would come with additional IT costs that could otherwise be spent on more effective measures.

A Public Authority recommended to simply publish the identity of the individual data submitter where groups have agreed on single classifications, because the requirement of every member would involve significant overall investments on their behalf.

#3: Require notifiers with classifications that diverge from the entry agreed by the majority of notifiers to update their notifications with a justification for any divergence in classification

Stakeholders were largely in support of this measure but provided further suggestions to focus on. Two Member State Competent Authorities agreed that it is important to address the legitimate differences such as the physical state or impurity/additive profile of a substance and its influence on classification and labelling and supports the making available of contextual information. Furthermore, in cases where there are legitimate reasons for deviation that results in a more stringent classification, then the visibility of data sources should be considered, because if outlier classifications are added via a drop-down menu, then they may been deemed of lower reliability. It is noted however that the self-classification by industry may be correct and more stringent than the harmonised

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classification because Member States may not have the resources to update the harmonised classification (example environmental classification of some cobalt compounds). It was also suggested that the registrant may not classify based on absence of data, where a notifier may have data resulting in classification. Therefore, the approach should be clear to the user of the inventory and the consequences explained.

Of the stakeholders that were unsupportive of the measure, the question of value in providing these justifications was raised. A Public Authority indicated that ECHA would not have the resources or information to decide what represents a good or bad justification. One Member State is of the opinion that before making any new requirements, industry should wait for the new version of ECHA database to be published. Additionally, one industry association believes that the usefulness of this measure depends on the percentage of substances affected and that other higher impact measures should be prioritised. Other suggestions for improvements to the C&L Inventory include:

Alignment of new entries:

- A Trade Association has suggested a simple system to improve the alignment of new entries with existing ones could be of benefit for new notifications e.g. a comparable approach to REACH-registrations and the stricter technical implementation of the one substance one assessment principle. With that, in practice, a new notifier could only join an existing group of notifiers and accept their C&L-entry or opt-out. For an opt-out there could be a pull-down-menu with the most common reasons for divergences (e.g. impurity, additive or other data), from which they could pick and which would then be visible in the public CLI.

Quality Control:

- A Trade Association has also suggested that quality could be improved by letting users of the CLI act as reviewers e.g. a correction button could be installed into the CLI directly and if the user disagrees with a specific entry, he could flag it to ECHA and/or the notifier. To avoid abuse of this system, only registered users would get the role as reviewers.

- Three Industry representatives have supported the implementation of some simple validation rules for new notifications. An Industry Association has also commented on the quality of notifications and the need for this to be assessed. They have proposed to work along the modalities used in the Horizon Europe Framework, where the Commission has established a system where participants interested in joining a call for projects could give their availability without naming the existing consortia, and the consortia get a notification and can decide to reply. In other words, the system allows people to get in contact without disclosing identities. Something similar could be set up:

    - The tool could include a possibility for registrants to click on an existing notification to indicate that they would like to discuss/address the divergences;

- The notifiers behind those notifications get an automatic alert via ECHA and they can decide to get in contact with consortia that would like to address the divergency;

- This could be combined with a flagging system to publicly display which notifications have been challenged, regardless of whether they have accepted or not to reply to the request for discussion;

- To avoid misuse of this system, the flag could be implemented if raised by the notifiers with the majority of aligned notifications. In other words, majority groups have the possibility to publicly flag problematic minority positions, not the opposite.

- One Industry Association has suggested that obvious errors in the Classification and Labelling Inventory should be corrected or deleted directly by ECHA. If there are legal reasons to the contrary, ECHA could contact the respective notifier in order to initiate a correction, as only ECHA has the necessary information available. Furthermore, entries that are not updated any more as the notifying companies do not exist any longer, or respective products are not on the market anymore, should systematically be deleted or inactivated. An easy-to-use process to flag obsolete entries should be established.

Data download options:

- One Industry Association expressed concern regarding the proposal to make every part of the Inventory available to be freely downloadable in a structured re-usable format. They suggested that such provision of data can only take place if there is no link or connection between the information and the data of the respective notifiers. Otherwise it will provide a full overview of the portfolio of those companies that notified to the Classification and Labelling inventory, including those substances that are manufactured or imported for the purposes of Scientific R&D (SR&D) or product and process oriented research and development (PPORD) and which are exempted from registration under REACH. This means that confidential business information would be revealed by ECHA and would be available for anyone to see.

Notifiers dashboard:

- One Industry Association has highlighted the need for companies to have an overview of their notifications, access them, and do modifications in bulk, update when necessary, etc. This could be achieved via a notifiers dashboard.

Consensus classification and labelling:

- One Member State Competent Authority has noted that the document defines the consensus classification and the consensus labelling as the most consistent groupings of classification and of labelling data. The word consensus may suggest that all the notifiers agreed to the same classification. Therefore, some other wording is suggested such as “dominant” or “majority” unless there is real consensus. It is also unclear whether “consensus” is based on individual hazard

classes or overall classification. A minimum level (%) should be considered to justify including a "consensus" classification.

COMPARISON OF THE MEASURES, REGARDING THEIR RESPECTIVE IMPACT.

Economic impacts

Administrative burden on businesses and public authorities:

All policy measures would lead to increased administrative costs on duty holders who use substances that meet the classification for one or more of the hazards and are required to classify them accordingly, and who have the obligation to notify these classifications to the Classification and Labelling Inventory. Under policy measure #4, notifiers would need to provide contact details in the inventory or submit confidentiality requests. This policy measure presents the lowest administrative burden on businesses and is expected to lead to a small, annualised cost saving of €1.74 million due to time saved by users of the inventory in finding the relevant information. Policy measure #6 and #5 are also expected to lead to a small, annualised cost saving of up to €1.79 million, or an annualised cost of 0.36 million, depending on the effectiveness of the policy measure. Policy measure #3 would lead to the greatest increase in administrative costs, which are estimated to be approximately €7 million to – €7.5 million of annualised cost.

Under all policy measures, ECHA would be required to divert resources from other priorities, such as the ongoing re-design of the inventory. The need for resources would be highest in policy option #6 and #3, followed by #4 and #5.

Impacts on SMEs:

Under policy measure #6 SMEs are expected to benefit from the time saved spent trying to find relevant information in the Classification and Labelling Inventory and could see a subsequent increase in their competitiveness in the long-term. Under policy measure #4, it is expected that SMEs will benefit from the publication of notifier contact details more than larger companies, as it is expected that SMEs are less likely to notify as a group. Policy measure #3 is expected to be disproportionately felt amongst SMEs, which in turn may negatively impact the competitiveness of SMEs, although there is some uncertainty as information on the number of diverging classifications per SME and large enterprise was not available.

Sectoral competitiveness, trade and investment flows:

All policy measures aim to harmonise classifications and improve the quality of the Classification and Labelling Inventory data, which in turn will benefit all businesses and increase competitiveness. They are therefore expected to have a positive impact on sectoral competitiveness.

Social and environmental impacts

The three measures are expected to have positive impact on human health and the environment from the provision of more accurate information on human health and environmental hazards of classified substances. This is turn would lead to more

appropriate workplace risk management measures being implemented and more accurate information communicated down the supply chain and to end-users. However, these impacts would be indirect and therefore their magnitude is not possible to quantify. A weak positive impact is expected on employment levels from the increased regulatory requirements.

Annex 12 – Hazard labelling

CONTEXT OF HAZARD LABELLING

Labels provide essential information on safety to chemicals users (both consumers and workers). The compulsory labelling of hazardous chemicals is the most important element in CLP to communicate this information. The label includes essential information on the potential harmful effects on people and/or on the environment that could be caused by a specific chemical; in addition, it includes information on how to store, dispose and use the chemical safely, as well as information on how to react in case of poisoning or accidental exposure. They also facilitate emergency health response by medical staff in case of exposure or intoxication. Where applicable, they provide contact information of services that can provide further assistances (Poison centres).

Since the introduction of CLP labels are based on the United Nations' Globally Harmonized System of Classification and Labelling of chemicals (GHS[250]). At the same time, the CLP Regulation retains some of the labelling requirements taken over from former legislation on chemicals[251], such as the small packaging exemptions. In order to accommodate certain hazard information not yet covered by the GHS, as well as further label elements that are required by other EU legislation, CLP introduces also the concept of "supplemental information" to be put on the label.

CLP labels play an important role to ensure the free movement of chemicals in the single market but also on a global basis: alignment between CLP and GHS ensures reduced compliance costs, as industry can use the same classification and labelling principles when exporting chemicals, thereby increasing the competitiveness of EU industry and international trade of goods.

According to CLP, labelling of hazardous substances and mixtures must contain the following relevant information, as set out in Article 17 and detailed further in Articles 18 to 28:

- Name, address and telephone number of the supplier(s);
- Product identifiers (i.e. name of the substance or mixture and/or identification number);
- Nominal quantity of the substance or mixture in the package made available to the general public (unless specified elsewhere on the package);
- Hazard pictograms (graphics that combine symbols and other elements to denote the type(s) of hazard associated with a chemical);

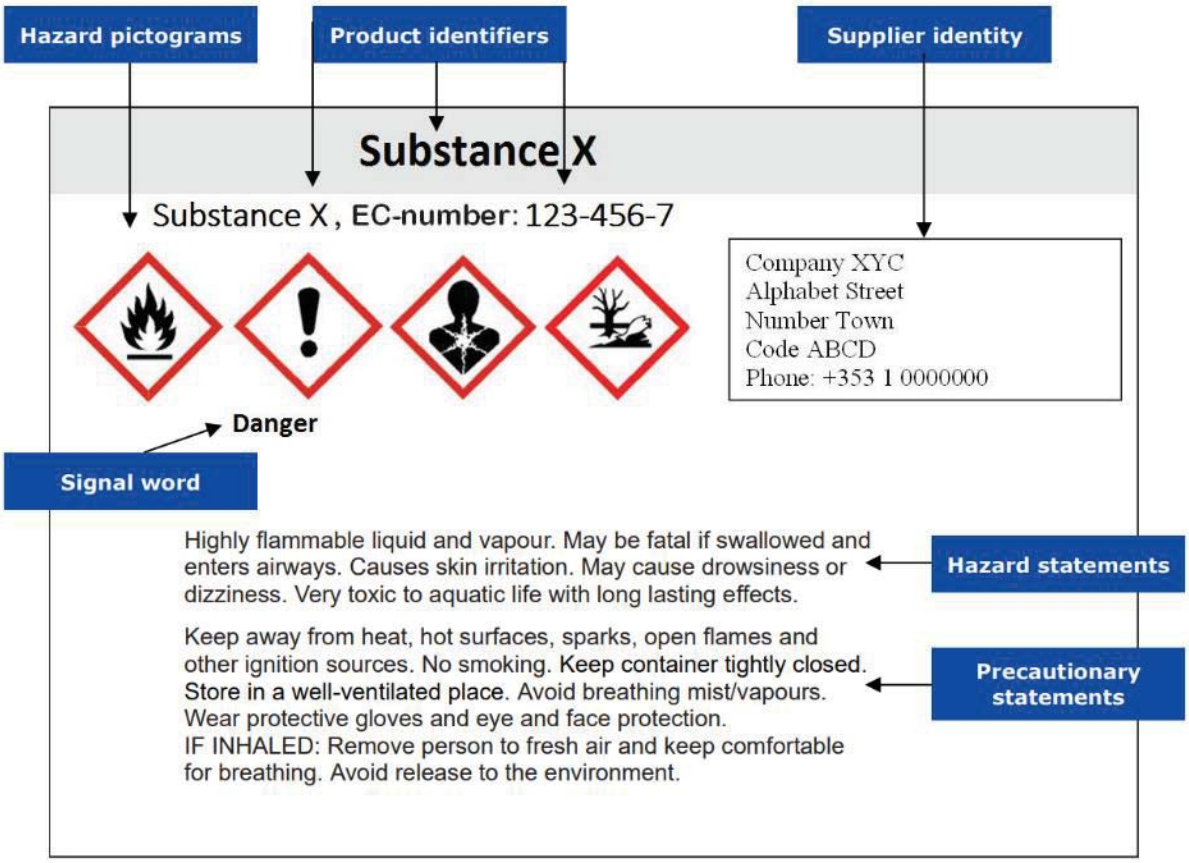
[250] See UNECE, About GHS, https://unece.org/about-ghs

[251] Such as the Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1–98 (http://data.europa.eu/eli/dir/1967/548/oj) or Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.7.1999, p. 1–68 (http://data.europa.eu/eli/dir/1999/45/oj)

- Hazard statements (a set of standardised phrases about the hazards of chemical substances and mixtures);
- Precautionary statements (a set of standardised phrases indicating how the chemical should be handled to minimise risks to the user, others and the environment);
- Signal words for the level of hazard ('warning' or 'danger'); and
- Supplemental information (as necessary for special cases, including also information required by other legislation).

Figure 78 provides an example of a typical CLP label.[252]

Figure 78: Example of a typical CLP label



PROBLEMS AND DRIVERS RELATED TO HAZARD LABELLING

Problems

The chemicals Fitness Check identified some problems in which CLP labelling does not provide sufficient information, including due to:

[252] ECHA guidance on CLP labelling and packaging: https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

frequent non-compliance with the CLP labelling provisions or ambiguity of the text in CLP, resulting in the absence of a label in certain cases, such as chemicals in very small packaging (e.g. writing instruments containing hazardous inks), chemicals supplied to consumers in bulk (e.g. fuel for cars) or chemicals placed on the market for self-refill (e.g. detergents),

inefficient hazard communication resulting from a limited readability of the labels, for example due to the amount of information to be affixed on the label, or a small font size, or chemical names that are not meaningful to consumers,

insufficient compliance and unnecessary administrative burden (in particular for SMEs) leading to poor application of labelling rules such as absence of CLP labelling in cases where the obligations are clear (i.e. other than the cases listed above) and leading to a limited use of fold out labels, thus not exploiting the full benefits of the single market.

The above problems can directly harm public health or the environment since consumers or workers could be exposed to hazardous chemicals in the absence of the required safety information (for instance the label can inform on the need to use of gloves for a corrosive substance or how to correctly dispose a chemical that is toxic to the aquatic environment). The insufficient level of compliance can also have negative effects on the internal market competitiveness since non-compliant economic operators could have undue competitive advantages versus compliant companies (e.g. better market perception due to the absence of CLP label and pictograms, lower internal costs for labelling etc.). At the same time, the lack of some information on consumer goods affects the consumers' ability to make informed choices.

There is evidence showing that the size of the problem is related to the level of non-compliance with the CLP labelling requirements. The evidence reported below is the result of European enforcement projects carried out by several EU countries under the coordination of the European Chemical Agency (see ECHA FORUM website for additional information[253]); the following quantitative data on compliance levels are available:

2019 European Chemicals Agency FORUM Report on the Pilot project on cooperation with customs in enforcement of REACH restrictions and CLP labelling[254]. Compliance with CLP labelling duties was checked for 150 products in 9 EU countries, 107 of the inspected products (corresponding to 71% non-compliance rate) had labelling issues. The most common violation was the absence of the use of national language on the label, followed by wrong or absent pictograms and signal words, and by the absence of a CLP label altogether.

[253] See ECHA FORUM https://echa.europa.eu/about-us/who-we-are/enforcement-forum

[254] ECHA FORUM Report on the pilot project on cooperation with customs in enforcement of REACH restrictions and CLP labelling, Operational Phase: March–November 2019, available at: https://echa.europa.eu/documents/10162/13555/customs2_project_report_en.pdf/5a2c3795-7ed9-5900-fe28-540228abc7c1

2018 European Chemicals Agency FORUM REF-6 Project Report Classification and labelling of mixtures[255]. The Forum conducted the REF-6 enforcement project that focused on controlling CLP duties. 27 EU and EEA countries and Switzerland reported on the results of inspections. The project checked the hazard labels of mixtures for compliance with CLP. In total, 1,732 inspections were conducted and 3,189 mixture labels were checked. 1,067 of the labelling elements of the checked mixtures, labelling information was missing and/or had errors or deficiencies (corresponding to 33.5% non-compliance rate).

2018 Sub section Forum REF-6 Project on labelling exemptions (mixtures in small packaging, fold out labels etc). 17 EU countries conducted checks on 355 mixtures. Despite the use of fold-out labels, tie-on tags or an outer packaging, in 32.1 % of the checked mixtures the full labelling information was not provided. For mixtures in small packaging (below 125 ml) about 10% of the checks found non-compliances and for mixtures in very small packaging (less than 10 ml) 9 out of 14 mixtures had labelling issues (corresponding to about 60% non-compliance rate).

These EU enforcement projects found a high level of non-compliance in terms of CLP labelling (from 33.5% up to 71%). Therefore, in the framework of this Impact Assessment, it is possible to broadly estimate an ***average level of non-compliance in terms of CLP labelling of about 50% of all chemicals placed on the EU market.***

Furthermore, the chemicals Fitness Check pointed out that the existing provisions and requirements do not take into account opportunities offered by digitalisation which could help reaching consumers more effectively (see Annex XIII on digital label for further elements).

Additional evidence on the effectiveness of hazard communication via the CLP label was assessed via two recent large Eurobarometer surveys:

A 2016 Eurobarometer survey on chemicals safety[256] indicated that 70% of EU citizens find information on the hazards of chemicals on the label useful.

However, the 2017 Eurobarometer survey on environment[257] also found that less than half of the respondents (45%) feel well informed about the potential dangers of the chemicals contained in consumer products.

Therefore, in the framework of this Impact Assessment, it is possible to broadly estimate that an average level of about 55% EU citizens consider that they are not well informed about the hazards of the chemicals contained in consumer products.

The above information provides strong evidence on the magnitude of the problem and of its European dimension. The problems described above are affecting:

Actors that are responsible for implementing the labelling rules;

[255] See https://echa.europa.eu/documents/10162/17088/ref-6_project_report_en.pdf/bfa9fc69-fdfd-2f52-bf96-5174d7e29cf8?t=1576499164990

[256] 2016 Special Eurobarometer 456 https://data.europa.eu/euodp/data/dataset/S2111_86_3_456_ENG

[257] 2017 Special Eurobarometer 468 https://europa.eu/eurobarometer/surveys/detail/2156

Consumers and workers using the CLP label to obtain safety information on the hazards related to a chemical;

Competent authorities in charge of enforcing CLP.

Drivers

The main drivers of the problems in hazard labelling are:

Regulatory failure driver due to poor application of current rules due to complexity of labelling provisions - Certain CLP labelling requirements are difficult to apply which sometimes results into a failure to label certain chemicals. This concerns in particular chemicals placed on the market in very small packaging (e.g. writing instruments, lighters, super glues), chemicals supplied to consumers in bulk (e.g. car or boat fuel at filling stations). The labelling requirements are also not sufficiently clear for modern sales practices (e.g. refill of detergents by the consumer).

Market failure driver due to inconsistent hazard communication across the supply chain - Many companies are placing chemicals on the market in multiple countries and, therefore, provide the information on the label in a number of different languages. This often results in very small font sizes (i.e. reducing readability) or making a suboptimal use of novel form of labelling such as fold out labels. This can result into an inefficient hazard communication and consumers and, subsequently, workers are not sufficiently informed on the hazards related to a chemical and/or face difficulties in reading and understanding the content of the label.

How likely is the problem to persist? / Baseline

The main problems identified above are:

- ***Consumers and workers do not have sufficient information*** due to the absence of CLP labelling for certain chemicals or inefficient communication.

- ***Insufficient compliance and unnecessary administrative burden***.

The rules on classification, labelling and packaging of hazardous chemicals are harmonised at EU level via the CLP Regulation. Therefore, the above problems will continue to persist in absence of EU action. In addition, the evidence collected via the 2019 chemicals Fitness check, 2016 and 2017 Eurobarometer surveys and the European FORUM enforcement projects clearly indicates a European dimension of the described labelling issues.

Considering the long-term developments and trends, the following paragraphs contain an assessment of how the problems will persist in the absence of EU policy intervention:

Labelling and packaging issues with chemicals placed on the market for refill – This refers to a novel practice of offering unpackaged consumer chemicals in stores where the consumers brings its own reusable container into which the chemical is filled, thus reducing packaging waste. This practice is already more common for food but this is also introduced for chemicals, so far mostly detergents and home care products and corresponds to about 2% of total market for those products (about 179,000 t/year). This

figure encompasses refill detergents made available to all users; considering the average range of delivered quantity per transaction can be estimated to range from 89.5 million to 8.95 million individual sales per year for refill of chemicals. By 2040 it is expected that this practice will increase up to over 265,000 t/year accounting for about 132.5 million to 13.25 million individual sales per year for self-refill of chemicals. Therefore, assuming a rate of non-compliance of 50% for CLP labelling, it can be assumed that by 2040 from 6.62 to 66.2 million purchases of refill chemicals will happen in absence of the appropriate labelling information and further hamper the effectiveness of hazard communication, thus increasing the risk of consequences for health or the environment. In addition, there is concern that this practice would not only be limited to chemicals with less severe hazards. Allowing this practice for corrosive chemicals such as drain cleaners could result in severe accidents, for example, involving consumers at the point of sale. However, restricting the refill to less hazardous chemicals requires modifications in CLP.

Labelling issues with chemicals placed on the market with multi-language labels – The European Chemicals Agency estimated that on average each chemical is placed on the market in 5 EU countries. The Agency also determines those Member States where the scale of the problem is likely to be greatest. Member States with the greatest number of neighbouring countries such as Germany (9 neighbours), France (8) and Hungry (7) will likely experience the export and sale of chemicals products to other Member States to a greater degree than those with fewer borders. Data from the chemicals industry shows that the trend in sales between Member States has increased steadily from 2009. This suggests that the number of products sold between Member States is also increasing and highlights the growing EU market for chemical products. Therefore, the sale of chemical products in multiple Member State markets is likely to grow, along with the scale of the problem of poorly readable multilingual labels and high rates of non-compliance with official language requirements.

Labelling issues with chemicals placed on the market for consumers in bulk (without packaging) - This concerns mostly fuel for transport purposes purchased at filling stations and pumped directly into a tank of a vehicle. To a lesser extent, this also concerns the supply of fuel additives (e.g. “Ad-blue”) and other fluids for use in vehicles. The difference to the refill scenario described above is that the chemicals are directly pumped into a tank from where it is not intended to be removed again by the consumer. Therefore, there is a smaller risk of exposure or accidents, and that unsuitable receptacles are used. This is also not a novel practice. Currently over 235,578 Kt per year of fuel are placed on the EU market, considering the significant development of alternative mobility solutions (electric cars), by 2040 it is expected to decrease to less than 100,000 Kt per year. This remains a very significant quantity of chemicals placed on the market in bulk every year in EU with sub optimal or no CLP labelling. The current levels of non-compliance vary significantly between Member States. Some Member States have set up guidelines on how the labelling requirements are to be applied in those cases (i.e. established a requirement to put the label on the fuel pump) and in those Member States there are high levels of compliance. Other Member States have not acted on this and fuel pumps are typically not labelled.

Labelling issues with chemicals placed on the market with small packaging (e.g. writing instruments, lighters, essential oils). Those products are broadly commercialised and purchased in the EU: between about 734 to 898 billion units are placed on the EU

market every year. By 2040 this number is expected to slightly increase. Considering a level of non-compliance of CLP labels of about 50%, from 367 up to 449 billion units of chemicals in small packaging might be placed on the market every year with sub optimal or no CLP labelling. The CLP Regulation requires that those items must have the labelling on the packaging but in practice items like writing instruments using hazardous inks or lighters are often sold without packaging. Given the parallel objective of reducing packaging waste, a balanced approach is needed between the need for appropriate hazard communication and circular economy objectives.

For labelling issues, it is likely that the size of the problem will increase or at best will continue to be significant at EU level. Guidance on Labelling[258] was first issued in 2011 by the European Chemicals Agency and has been updated six times. Despite appropriate guidance documents and multiple updates the above problems continue to be significant. Therefore, it cannot be expected that guidance will suffice to address the problems.

DESCRIPTION OF POLICY OPTION AND/OR SUB-OPTIONS FOR HAZARD LABELLING

The following policy options have been assessed to facilitate compliance with the CLP Regulation and to improve the protection of health and the environment.

[258] See https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

Table 94: PO2a and PO2b – Hazard communication and labelling		
PO2 Hazard communication and labelling		
Policy measure	**Category**	**Description**
PO2a Update and prepare guidance		
#11 Guidance on labelling	Soft regulation	The European Chemicals Agency to update guidance to clarify the applicability of the CLP Regulation and the corresponding rules for chemicals supplied: in very small packaging (e.g. writing instruments); to consumers in bulk (e.g. fuels); via refill of containers (e.g. detergents).
PO2b Improving labelling and making it more flexible		
#12 Improving readability	Hard, legally binding rules	The Commission to amend Section 1.2 Annex I to introduce general provisions for a minimum font size and other provisions to improve the readability of the label, based on current ECHA guidance.
#14 Facilitating refill sales through proper labelling and other related requirements	Hard, legally binding rules	The Commission to address the new practice of refill sales explicitly in the CLP Regulation to provide clarity to retailers on the applicable rules for labelling, thus providing flexibility and legal certainty and boostering a sales method that contributes to circular economy objectives. To avoid that this leads to an unacceptable risk for health and the environment by doing so (e.g. risks of serious incident during the refill process or later use at home), the practice should be limited to chemicals with less severe hazards.
#15 Facilitating the use of fold-out labels.	Hard, legally binding rules	The Commission to amend Article 29(1) and section 1.5.1.1 of Annex I of CLP 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.
#16 Labelling exemptions for chemicals sold in bulk to consumers and in very small packaging	Hard, legally binding rules	The Commission to amend: • Article 23 to include a labelling derogation for chemicals sold in bulk to consumer at filling station indicating that in such cases a label on the pump will suffice. • Article 23 and Annex I Section 1.3 to extend the current exemption under Article 29 and Annex I Section 1.5 for the inner packaging of contents not exceeding 10ml from chemicals used for scientific R&D or quality control analysis to all hazardous chemicals that have less severe hazards (the inner packaging must be contained within outer packaging that meets the requirements of Article 17).

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Description of impacts

The areas of intervention that have been assessed against the policy options are the following:

Improving label readability

Facilitating refill sales through proper labelling and other related requirements

Facilitating the use of fold-out labels.

Labelling exemption for chemicals sold to consumers in bulk (e.g. fuel at filling stations).

Labelling exemption for chemicals sold in very small packaging (e.g. writing instruments, lighters, super-glue).

POLICY MEASURE #14: REFILL CHEMICALS

Economic impacts

Next to improvements for health and the environment, policy measure #14 aims at facilitating the introduction of this rather novel distribution method to support circular economy objectives and to encourage more actors to exploit business opportunities. An explicit mentioning of this distribution method in CLP will clarify the rules for how re-fill chemicals should be labelled, packaged and limit this sales method to chemicals that have less severe hazards.

Currently, no guidance or legal requirements for the labelling of refill chemicals exist under the CLP framework. Therefore, chemicals sold this way are at risk of having no or an incorrect label and not being suitably packaged. Policy measure #14 would reaffirm that also re-fill chemicals need to comply with the requirements of CLP for labelling and packaging (e.g. suitable packaging material). There are several options for how compliance could be achieved. For example, labelling could be provided via stickers that can be applied to containers brought by consumers, or a copy of the label could be provided with the receipt. Suitable and properly labelled containers may also need to be provided at the point of sale at a cost to the supplier. The supplier may be obliged to update labels on containers brought in by consumers. There are currently no indications that this sales method would be used for chemicals with more severe hazards, although it can be expected that this would become practice given the increasing no-packaging trend. Therefore, for action at this point there should be no or only very limited cost linked to those policy measure.

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. The chemicals Fitness Check also cites an impact assessment supporting the adoption of GHS and implementation of CLP, and further work carried out for International Association for Soaps, Detergents and Maintenance Products (AISE), which estimated the average cost of re- designing and modifying labels to be compliant with

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CLP to be around €300 per formulation, based on experiences under the Dangerous Preparations Directive. However, for SMEs these figures may be higher as a significant number of companies (11% and 24% of companies for the cost of classify substances and mixtures respectively) consulted during the chemicals Fitness Check gave costs between €500 and €1,000 per substance/mixture, and these companies tended to be SMEs.

Detergents are one of the most common types of re-fill chemicals, with the growth of this sector being acknowledged in the Commission's Evaluation of the Detergents Regulation[259]. The Evaluation estimated the one-off cost, per detergent product, of producing new labels (to comply with the Detergents Regulation) to be between €200 and €3,000. Based on both estimates, a figure of €1,000 is assumed, which sits at the upper end of the Fitness Check estimate and the middle of the estimate provided in the Evaluation of the Detergents Regulation.

RPA et al. (2018) states that there were between 31,500 and 51,500 consumer detergent products that had to be relabelled as a result of the Detergents Regulation. It was also estimated that re-fill detergents make up just over 2% of the overall market of detergent products. Therefore, it is estimated that there are between 630 – 1,030 re-fill products on the EU market. Considering an assumed rate of non-compliance with the CLP label of 50%, the estimated amount of re-fill products impacted by the measure is 315-515 re-fill products on the EU market. This would lead to a total one-off cost of between €315,000 and €515,000 that would be necessary to return to compliance.

RPA et al. (2017a) give a total one-off cost of throwing label stock away of €3.2 million to €9 million. Applying the estimate of 2% of detergent market being re-fill detergents and a 50% rate of non-compliance gives a cost estimate of €32,000 – €90,000 for throwing re-fill label stock away. This leads to a total one-off cost of €347,000 – €605,000. However, changes in the labelling requirements come with transition periods during which existing stock can be consumed to avoid the disposal of old labels.

In summary ensuring compliance with existing requirements could result in total one-off cost of €347,000 – €605,000 and recurring costs of €15,500 – €36,000 per year.

Estimates provided earlier assessed the quantity of re-fill detergents sold in the EU to be approximately 179 million kilograms per year. This figure encompasses re-fill detergents made available to all end-users. It is expected that a typical sale of re-fill detergent would range from 2L – 20L, although large quantities would be purchased during business-to-business sales. This would provide a range of 89.5 million to 8.95 million individual sales per year. Considering those figures, it can be calculated that the costs for the sellers of re-fill chemicals to return into compliance are:

Scenario (89.5 million transactions)	
One off costs per year and transaction	€0.0038 – €0.0067
Recurrent costs per year and transaction	€0.00017 – €0.0004

Scenario (8.95 million transactions)

- One off costs per year and transaction €0.038 – €0.067

[259] RPA et al. (2018) Evaluation of the Detergents Regulation

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- Recurrent costs per year and transaction €0.0017 – €0.004

In the highest range the increase of costs due to one off and recurrent costs is expected to be less than €0.07 per transaction (only the first year), in the following years the recurring costs are expected to be less than €0.004 per transaction. Considering the relatively higher market price for refill products compared to the traditional products it is expected that the estimated increase will have very limited impact on businesses.

A negative impact on **market size and profitability** could only be postulated for the new restriction of refill sales for chemicals with more severe hazards. However, as this market currently does not seem to have developed yet, such cost should be minor and not significant. At the same time, an improved legal framework may offer business opportunities.

For the reasons outlined above, there should be no noteworthy impact on the **operation of SMEs** unless they are currently not complying with the existing rules.

Policy measure #14 should not have a noteworthy impact on **consumers and households price of consumer goods**. The measure should not place additional costs on suppliers of refill chemicals in ensuring their products are appropriately labelled and packaged, unless they are currently not complying with the existing rules. Cost to return into compliance may be borne by the supplier, or alternatively they may be passed onto consumers through increased price of consumer goods. The resulting impact on the price of consumer goods cannot be assessed at this stage since it will depend on business decisions. Nevertheless, the additional cost per transaction has been estimated to be rather small (less than €0.07 per transaction only the first year, less than €0,004 per transaction in the following years).

There is currently a perceived lack of clarity on the labelling obligations for refill chemicals under CLP. Therefore, enforcement activities in this area are not likely to be high. With #14 the supply of refill chemicals may become an area in need of enforcement. Consequently, **enforcement cost of public authorities** is expected to increase slightly under policy measure #14. The ECHA (2019f) REACH-EN- FORCE- 6 (REF 6) project on classification and labelling of mixtures carried out 85 inspections as part of an optional module on rules applicable to Liquid Laundry Detergent Capsules (LLDC). An enforcement project of similar magnitude would be likely to be sufficient for enforcing the rules for refill chemicals. Therefore, the number of inspections carried out on Liquid Laundry Detergent Capsules is a proxy to estimate the cost of enforcement of re-fill chemicals. This gives a recurring cost of €74,715 (85 x €879). It is not expected that a specific enforcement project on refill chemicals would occur every year and, therefore, the annual cost would be even lower (a factor 3 is applied providing a cost of €25,000 per year per enforcement project).

Policy measure #14 is expected to have a positive impact on the **functioning of the internal market and competitiveness.** It will clarify the applicable rules for refill chemicals, which will help ensure that all Member States take the same approach regarding compliance of refill chemicals with CLP. This is expected to help level the playing field for businesses across the EU by ensuring they all incur the same (unit) compliance costs.

Table 95: Comparison of impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised Impact	One off or recurrent
Conduct of Business	Labelling Costs	(-)	Direct	Annual recurring costs (disposing of old label stock): €7,500 – €21,000 One-off cost (re-labelling disposing of old label stock) of €347,000 to €605,000. Annual recurring cost (re-labelling): €8,000 to €15,000	Recurrent and one off
	Packaging Cost	(-)	Direct	Negligible	Recurrent
	Impact on market size	(-)	Indirect	Negligible	Recurrent
Public Authority Costs	Enforcement Costs	(-)	Direct	Approx. €25,000 per enforcement project	Recurrent
Functioning of the Internal Market and Competition	Level of Enforcement across Member States	(+)	Indirect	Not quantified	Recurrent
Position of SMEs	Operation of SMEs	(-)	Indirect	Not quantified	Recurrent
Consumers and Households	Price of Consumer Goods	(-)	Indirect	Not quantified	Recurrent

Environmental impacts

Currently there is no guidance or legal requirements that deals specifically with refill chemicals Therefore these chemicals are often not labelled or labelled incorrectly (about one out of two refill chemicals are expected to have no or insufficient hazard information)

and wrongly packaged. This poses risks for to the environment as consumers and workers are not provided with information on the environmental hazards of the products they are purchasing, e.g. on how to properly dispose them. Policy measure #14 aim to ensure that suppliers of refill chemicals label and package them correctly. Therefore, this will have a significant positive impact on the protection of the environment.

Policy measure #14 is expected to have a slightly negative impact on **resource use**, as they foresee the requirement for suppliers of refill chemicals to ensure their products are appropriately labelled and packaged. This means suppliers of refill chemicals who supply labels, will increase resource use and packaging waste, if they are not in compliance yet. Estimates provided earlier assessed the quantity of refill detergents sold in the EU to be approximately 179 million kilograms and policy measure #14 could result in impacting about 45 to 4.5 million transactions every year This figure encompasses refill detergents made available to all end-users, consumers and workers. At the same time, refill practices are likely to have environmental benefits due to the reuse of packaging and related reduction of resources needed to produce new packaging. It could be argued that the benefits of reusing a packaging can offset the impacts related to the use of resources to produce new CLP compliant labels.

Table 96: Environmental impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised Impacts	One off or recurrent
Sustainable consumption and production	Impact on Resource Use	(neutral)	Indirect	Not quantified	Recurrent
	Impact on the protection of the environment	(+)	Indirect	Not quantified	Recurrent

Social impacts

No guidance or legal requirements for the labelling of refill chemicals is currently provided. Therefore, these refill chemicals are often not labelled or labelled incorrectly and not safely packaged. This negatively affects **public health and safety and health systems** as consumers and workers are not provided with information on the human health hazards of the products they are purchasing and using. The policy measures could result in providing the necessary information on safety of a high number of hazardous chemicals (up to 4.5 million products placed on the market every year). Policy measure #14 aims to ensure that suppliers of refill chemicals label and package correctly. Therefore, the policy measure will have a positive impact on the protection of human health, but the quantification is problematic and was not quantified in terms of public health.

Policy measure #14 is expected to have a slightly positive impact on **employment** levels in the refill sector. Making the existing requirements explicit will provide legal certainty to this novel sector and likely provide a more level playing field for actors. This is likely

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to encourage more businesses to engage in the refill sector, also beyond the detergents sector that is currently starting to exploit this option.

Policy measure #14 is likely to have a slightly positive impact on the number of **public authority jobs**, as clearer labelling rules for re-fill chemicals will lead to a new area requiring enforcement, which may increase the number of enforcement officers required.

Table 97: Social impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent
Public health and safety and health systems	Impact on the protection of human health	(+)	Direct	Not quantified	Recurrent
Employment	Impact on industry jobs in the re-fill chemical sector	(+)	Indirect	Not quantified	Recurrent
	Impact on public authority jobs	(+)	Indirect	Not quantified	Recurrent

A summary of the costs and benefits of policy measure #14 are provided below.

Summary of cost and benefits of policy measure #14	
Costs - businesses	
Total one-off costs over a 20-year period	347,000 – 605,000 (mid-estimate: 476,000)
Recurring costs every 1 year	15,500 – 36,000 (mid-estimate: 25,750)
Total recurring costs over a 20-year period	294,500 – 684,000 (mid-estimate: 489,250)
PV of one-off costs (20 years; 3%)	466,477 – 813,310 (mid-estimate: 639,894)
PV of one-off costs (20 years; 3%) (annualized)	23,324 – 40,666 (mid-estimate: 31,995)
PV of recurring costs (20 years; 3%)	395,901 – 919,511 (mid-estimate: 657,706)
Total PV – costs - businesses	862,378 – 1,732,821 (mid-estimate: 1,297,599)
Costs – public authorities	
Total one-off costs over a 20-year period	-
Recurring costs every 1 year	25,000

Total recurring costs over a 20-year period	475,000
PV of one-off costs (20 years; 3%)	-
PV of recurring costs (20 years; 3%)	638,549
Total PV – costs – public authorities	-
Total PV cost of policy measure #14	**1,500,927 – 2,371,370 (mid-estimate: 1,936,148)**
Benefits (cost savings) - businesses	-
PV benefits - businesses	-
Benefits (cost savings) – public authorities	-
PV – benefits – public authorities	-
Benefits - society	-
PV - benefits - society	-
Total OV - benefits	-
Net Present Value - NPV (PV benefits – PV costs)	-1,500,927 – -2,371,370 (mid-estimate: -1,936,148)

A summary of the present value costs (3% discount) for policy measure #14 are provided below.

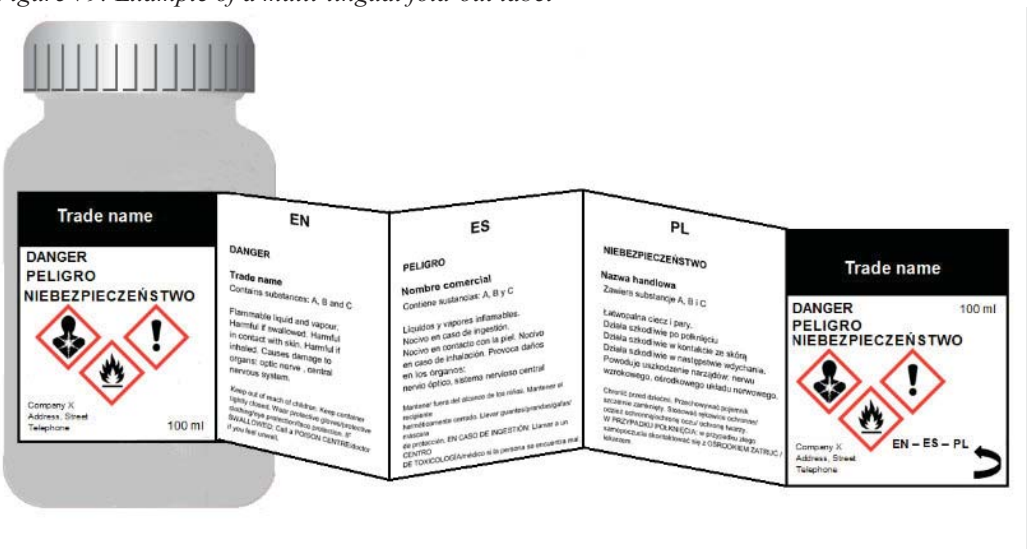
Summary of costs and benefits (PV; 20 years; 3%) of policy measure #14 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs	-	-	-
Direct administrative costs	€1,500,927 – €2,371,370 (mid-estimate: €1,936,148)	€638,549	-
Direct regulatory fees and charges	-	-	-
Indirect costs	-	-	-
Benefits			
Description	**Businesses**	**Administrations**	**Society**
Direct benefits			
	-	-	-

POLICY MEASURE #15: FOLD-OUT LABELS

Policy measure #15 would allow the use of fold-out labels also for chemicals with normal size packaging (currently this applies only to small packaging and packaging in special forms). Currently, suppliers of chemicals delivered into multiple Member States put several languages on the same label to exploit economies of scale. This often leads to a small font size, often becoming almost illegible, in particular for consumers and workers with visual impairments. Furthermore, this also leads to overloaded labels, where consumers experience difficulties in finding the information relevant to them. If suppliers

of chemicals in multiple Member States want to overcome this, they would currently have to produce containers with different labels for the various markets. Considering that policy measure #12 would introduce minimum requirements, the problem would be further aggravated and could lead to competitive disadvantages. In turn allowing the use of fold-out labels also for chemicals with normal packaging sizes, would compensate the impact of policy measure #12 and allow the use of multilingual labels whilst improving the readability of the label in line with policy measure #12. There is to same degree a trade-off between the inconvenience of a fold-out label and the improvement of the readability, so overall the impact on the safety level is probably neutral. Improvements in the technology and reliability of fold-out labels give sufficient assurance that they are equally reliable as classical labels and is now acceptable not only in exceptional cases. The possibility of using more language versions could also be used to include languages which are widely spoken in a Member State but not official languages. This could cater in particular communities with a migration background and may provide business opportunities.

Figure 79: Example of a multi-lingual fold-out label



Source: European Chemicals Agency guidance on CLP labelling

Options to extend the scope of multilingual fold-out labels have been previously discussed at CARACAL[260] where it was also suggested to include certain related quality requirements either in Annex II of CLP or in ECHA guidance to ensure the quality, readability and accessibility of information (as now included in policy measure #12). While the majority of Member States were in favour of extending the scope of multi-lingual fold-out labels, some proposed certain restrictions should be considered, including minimum readability requirements on top of those in the ECHA guidance.

Economic impacts

For estimating the **Conduct of Business** cost it is important to note that policy measure #15 will not mandate the use of a fold-out label. It will only provide an option to use it. Therefore, the use of a fold-out label versus a standard label would be a voluntary business choice of the relevant supplier. It is likely that suppliers will only opt for a fold-

[260] See CA/05/2015, CA/51/2015, CASG-LP/03/2015

out label where it actually is economically beneficial for them. The following information about cost is, therefore, informative but actually, it can be assumed that the economic benefits of using fold-out labels will practically always outweigh the associated cost.

An initial cost for transitioning to fold-out labels would be incurred. The chemicals Fitness Check estimates the average cost of re-labelling each substance and mixture to be €388 and €475 respectively. Due to the increased size and material use of fold-out labels as opposed to standard on-pack labels, the cost of producing fold-out labels is likely to be higher. In the chemicals Fitness Check, a significant number of companies indicated re-labelling costs of between €500 - €1,000 per product, which is considered to be more likely to be representative of the cost of producing fold-out labels. The number of products that are sold across Member States is not known so it is not possible to quantify the total cost of transitioning to fold-out labels.

The use of fold-out labels could provide significant economic advantages: the greater the maximum number of languages allowed, the higher the saving in labelling costs. Assuming a maximum number of six languages to be affixed, the maximum saving in labelling cost would equate to the need to only produce one fold-out label, rather than 6 on-pack labels. Taking the re-labelling costs represented in the Fitness Check, the average cost of producing 6 on-pack labels would be €2,328 – €2,850 (depending on whether they are for substance or mixtures), whereas the cost of producing a fold-out label has been estimated to be in the region of €500 to €1,000. This represents a long-term cost saving of between €1,328 – €2,350 per product.

Information from poison centre notifications suggest that, on average, hazardous mixtures are supplied to five Member States. Based on the calculations above, this would mean each company on average would have a cost saving of €1,375 to €1,875 (5 x €475 minus €500 to €1,000).

Consultation with a large supplier of chemical products indicated that their most widely sold products require 15-16 different labels on average. For large enterprises, this is likely to be representative of most products in their portfolios, whilst the estimate of five different labels provided above is likely to be more representative of SME, as most are likely to sell in fewer Member States. If wider use of fold-out labels was introduced, with a maximum number of six languages per label, large enterprises could see the number of different labels required to place each product on the market reduced to 3, while SMEs could use a single label per product. This would lead to a cost saving of €4,125 – €5,625 (15 x €475 minus (€500 to €1,000 x 3)).

Taking the detergents industry as a case study, the Evaluation of the Detergents Regulation provides an estimate of the number of large enterprises and SMEs and the number of consumer detergent formulations each places on the market on average. This data has been used to calculate the cost saving per enterprises from wider use of multilingual labels and the total cost for all enterprises.

Table 98: Savings estimations based on broader use of fold out labels

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Enterprise Type	No. of Enterprises	No. of Consumer Detergent Formulation per Enterprise	Average No. of Labels Required per Product	Average No. of multilingual labels	Cost Saving per Product	Total Cost Saving per Enterprise	Total Cost Saving	Annualised Cost Saving
Large enterprise	50	150-250	15	3	€4,125 – €5,625	€618,750 – €1,406,250	€30,937,500 – €70,312,500	€11,834,000 – €26,895,000
SME	600 – 650	40 – 60	5	1	€1,375 – €1,875	€55,000 – €112,500	€33,000,000 – €73,125,000	€12,623,000 – €27,970,000
Total	650 - 700	31,500 – 51,500	-	-	-		€64,000,000 – €144,000,000	€24,000,000 – €55,000,000

Using the detergents sector as an example, multilingual labels with a maximum of five languages would require large enterprises to use three different labels required for each product on the market instead of 15, while SMEs could use one label instead of five (one per product). This is estimated to reduce costs savings (annualised) for the detergents sector only by €24,000,000 to €55,000,000. About half of those savings are related to SMEs (€12,623,000 – €27,970,000).

The baseline information show that intra-EU sales of chemical products are in the hundreds of billions of Euros and represent the majority of total sales in the EU. Therefore, it can be assumed that a large number of products are sold across multiple Member States and would benefit from wider use of fold-out labels. The cost savings are thus expected to be significant and a strong positive impact on administrative costs to business is likely.

Data from Eurostat[261] shows that across the EU-27, on average 56% of intra-EU exports of goods for each Member State were supplied to their three largest EU partners. For Luxembourg and Portugal, 71% and 72% of their intra-EU exports of goods respectively are to their three largest EU partners, while Germany exports only 38% of its intra-EU goods to its three largest EU partners. This highlights that a fold-out label accommodating up to five languages would cover the majority of each Member State's intra-EU traded goods.

No change in **public authority costs enforcement costs** is expected under policy measure #15 as enforcement is already carried out to check compliance of fold-out labels and compliance of labels with official language requirements, for example as part of various enforcement projects of the European Chemicals Agency.

[261] See https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Intra-EU_trade_in_goods_-_main_features#Intra-EU_trade_in_goods_by_Member_State

Policy measure #15 is expected to have a positive impact on the **functioning of the internal market and competition** as it will establish readability criteria on labels and clearer rules on multilingual labels and help ensure their implementation is harmonised across all Members States. Allowing wider use of multilingual labels will also level of the cost of business across the EU by reducing the administrative burden on companies, which will have a positive impact on competitiveness of EU businesses and promote the free movement of goods.

The wider user of fold-out multilingual labels would bring the greatest benefit to companies operating across many Member States, which are typically large companies. The **position of SME operation** was discussed during a 2014 workshop organised by the European Commission on the safe use of chemicals by SMEs. This addressed the challenges related to the implementation of CLP by SMEs: The restricted use of multi-lingual fold-out labels was mentioned by stakeholders as an important challenge for SMEs because of the high administrative burden posed by the frequent re-labelling required when distributing a product in multiple Member States. This indicates that wider use of fold-out labels would also bring significant benefit to SMEs: about half of total savings are related to SMEs (€12,623,000 – €27,970,000).

As regards to **consumers and households price of consumer goods**, consumers currently are confronted with the high levels of non-compliance with the requirement under Article 17(2) that labels "*shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market*" (see explanations above). Although the reason for the infringements of Article 17(2) are not known, this may be in part due to the cost of re-labelling a product sold in multiple Member States being perceived as too high. Wider use of fold-out multilingual labels would reduce label costs, which is expected to make it easier for companies to comply with the requirement under Article 17(2). Greater compliance with official language requirements coupled with the establishment of minimum readability criteria will improve communication of hazard information to consumers and empower EU consumers and professional users through better access to more relevant and understandable product information, leading to more informed decision making on the purchase and use of chemical products.

Table 99: Economic impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised Impact	One off or recurrent
Conduct of Business	Labelling Costs	(+)	Direct	€24-55 million annualised	Recurrent
Public Authority Costs	Enforcement Costs	(o)	Direct	Not quantified	Recurrent
Functioning of the Internal Market and Competition	Level of Enforcement across Member States	(+)	Indirect	Not quantified	Recurrent
	Free Movement	(+)	Indirect	Not quantified	Recurrent

	of Goods				
Position of SMEs	Operation of SMEs	(+)	Direct	€12-27.9 million	Recurrent
Consumers and Households	Consumer Information, Knowledge, Trust or Protection	(+)	Direct	Not quantified	Recurrent

Environmental impacts

Greater use of fold-out multilingual labels coupled with improved readability criteria **improve the protection of environment**. This is because that would allow a greater number of languages to be provided on product labels, which would increase the comprehension rate of labels. Multilingual labels are important in ensuring that purchasers of products on-line from other Member States, and EU workers and citizens in Member States other than their own, receive information on environmental hazards of products in their native language. Policy measure #15 is expected to have a neutral **impact on resource use**. Fold-out labels consist of multiple pages and subsequently use more paper in their manufacture than on-pack labels. However, as discussed below, fold-out labels improve planning and reduce the amount of surplus labelling and packaging stock.

Greater use of fold-out labels is expected to lead to a reduction in **labelling and packaging waste**, as on-pack labels would not have to be re-designed when products are sold in multiple Member States. Greater flexibility in planning and logistics resulting from a single label, as opposed to multiple labels, would result in less labelling and packaging being scrapped. At the same time, a fold-out label can also replace several traditional labels. At previous discussions at CARACAL in 2015 [262] on the quality and design of fold-out labels, there was agreement on the importance of ensuring sufficient quality of fold-out labels, with the exact manner in which the quality and robustness is ensured left to the duty holder. It was agreed that guidance should state that the fold-out label should be durable (e.g. by using plasticised pages) and that it should be attached to the packaging in a robust way. Therefore, some level of plasticisation of fold-out labels would be required, which would increase plastic waste. It should also be noted that fold-out labels consist of multiple pages and subsequently will use more paper in their manufacture. Overall, policy measure #15 is expected to have a neutral or small positive impact on labelling and packaging waste.

Table 100: Environmental impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent
Sustainable consumption and	Impact on Resource Use	(o)	Direct	Not quantified	Recurrent

[262] European Commission (2015): 18th Meeting of Competent Authorities for REACH and CLP (CARACAL) – 23 – 24 June 2015 CA/51/2015

production	Impact on the protection of the environment	(+)	Indirect	Not quantified	Recurrent
Waste production, generation and recycling	Impact on Labelling and Packaging Waste	(o)	Direct	Not quantified	Recurrent

Social impacts

The impact of the more frequent use of fold-out labels on the **public health and safety and health systems** is likely to be positive. During previous discussions at CARACAL, the value of multilingual labels has been expressed by several group members, due to the increasing amount of international internet sales and the growing number of workers active across borders within the EU. Multilingual labels are important in ensuring that purchasers of products on-line from other Member States, and EU workers and citizens in Member States other than their own, receive information on the human health hazards of products in their native language. Greater use of fold-out multilingual labels would allow a greater number of languages to be provided on product labels, which would increase the comprehension rate of labels and thereby improve the protection of human health.

Policy measure #15 is unlikely to have implications on **employment**.

Table 101: Social impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent
Public health and safety and health systems	Impact on human health	(+)	Direct	Not quantified	Recurrent
Employment	Impact on industry and public authority jobs	(o)	Indirect	Not quantified	Recurrent

A summary of the cost and benefits of policy option #15 are presented below.

Summary of cost and benefits of policy measure #15	
Costs - businesses	
Total one-off costs over a 20-year period	€64,000,000 – €144,000,000 (mid-estimate: €104,000,000)
Recurring costs every 1 year	€24,000,000 – €55,000,000

	(mid-estimate: €39,500,000)
Total recurring costs over a 20-year period	€456,000,000 – €1,045,000,000 (mid-estimate: €750,000,000)
PV of one-off costs (20 years; 3%)	€86,036,106 – €193,581,238 (mid-estimate: €139,808,672)
PV of one-off costs (20 years; 3%) (annualized)	€4,301,805 – €9,679,062 (mid-estimate: €6,990,434)
PV of recurring costs (20 years; 3%)	€613,007,253 – €1,404,808,289 (mid-estimate: €1,008,907,771)
Total PV – costs - businesses	€699,043,359 – €1,598,389,527 (mid-estimate: €1,148,716,443)
Costs – public authorities	
Total one-off costs over a 20-year period	
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	
PV of recurring costs (20 years; 3%)	
Total PV – costs – public authorities	
Total PV cost of policy measure #15	**€699,043,359 – €1,598,389,527 (mid-estimate: €1,148,716,443)**
Benefits (cost savings) - businesses	
PV benefits - businesses	
Benefits (cost savings) – public authorities	
PV – benefits – public authorities	
Benefits - society	
PV - benefits - society	
Total OV - benefits	
Net Present Value - NPV (PV benefits – PV costs)	€699,043,359 – €1,598,389,527 (mid-estimate: €1,148,716,443)

A summary of the present value costs (3% discount) for policy measure #15 are provided below.

Summary of costs and benefits (PV; 20 years; 3%) of policy option #14 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs			
Direct	699,043,359 –		

administrative costs	1,598,389,527 (mid-estimate: 1,148,716,443)					
Direct regulatory fees and charges						
Indirect costs						
Benefits						
Description	**Businesses**		**Administrations**		**Society**	
Direct benefits						

POLICY MEASURE #12: IMPROVING READABILITY

Note: Policy measure #12 is linked but not limited to policy measure #15.

CLP only includes general instructions concerning the formatting of the label. Article 31 only specifies that:

the colour and presentation of any label shall be such that the hazard pictogram stands out clearly.

The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.

Guidance[263] by the European Chemicals Agency explains that readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background.

Readability has continuously been point for discussion, as highlighted by the chemicals Fitness Check which found evidence to indicate that labels can become overloaded with information. That makes it difficult for consumers and workers to focus on essential hazard and use information, reducing the effectiveness of hazard communication, particularly on products supplied in small packaging and when multilingual labels are required. It was found that consumers and workers are often faced with unattractive labels with too much text in too small font size, in particular in relation to multilingual labels restricts the comprehensibility of the information displayed.

In the Commission Expert Group on REACH and CLP further suggestions were made to improve the readability of labels such as grouping information by language, or mandating a logical order of the languages (e.g. alphabetical).

[263] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2 March 2021, https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

The unspecific rules also hamper enforcement efforts as different interpretations are possible e.g. of what "size and spacing as to be easily read" actually means. Despite the existing guidance, the problem persist, as the guidance is not legally binding. Without further action, the problem will persist or even increase.

Policy measure aims to improve the readability of the label, thus improving hazard communication, by introducing legally binding rules in CLP. To this extent it is possible Commission to amend Section 1.2 Annex I to introduce general provisions for a minimum font size and other provisions to improve the readability of the label, based on current ECHA guidance.

Economic impacts

The impacts of this measure have not been separately assessed but in conjunction with policy measure 15. As outlined therein, formatting requirements would come together with allowing a wider use of fold-out labels. However, they would also apply to standard labels.

The aim of CLP is to ensure both a well-functioning single market for chemicals and a high level of protection of human health and of the environment. To achieve this, information on the hazards and safe use of chemicals must be effectively communicated to consumers and end-users of chemical products, the primary vehicle for which is labelling. To ensure the free circulation of chemicals in the internal market, labelling of chemical products must not be too onerous or represent an undue administrative burden, and labelling requirements must be harmonised across the EU and internationally to prevent the need for different labels for each national market. Setting clearer formatting rules for labels will provide a more level playing field and limit competition over safety.

Adjusting to a new labelling format would incur initial **conduct of business cost**. However, as policy measure 12 is not a stand-alone measure, the cost will occur anyway as a result of other changes. Potential cost could also be compensated by taking advantage of the wider possibilities to use fold-out labels. It is not likely that policy measure 12 would have an **impact on the market size**.

Public Authority Cost are more likely to decrease because policy measure 12 will facilitate enforcement with its clear rules. Clear rules also mean that there is less likelihood for non-compliance.

The **functioning of the internal market and competition** is likely to improve once policy measure #12 enters into force. There may be a slightly positive impact due to an improved level playing field.

SME did not express a particular opinion on policy measure #12.

Price of consumer goods are unlikely to be significantly influenced by policy measure #12.

Table 102: Economic impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised Impact	One off or recurrent

Conduct of Business	Labelling Costs	(o)	Direct	Not quantified	Recurrent
	Impact on market size	(o)	Indirect	Not quantified	Recurrent
Public Authority Costs	Enforcement Costs	(-)	Direct	Not quantified	Recurrent
Functioning of the Internal Market and Competition	Level of Enforcement across Member States	(+)	Indirect	Not quantified	Recurrent
Position of SMEs	Operation of SMEs	(-)	Indirect	Not quantified	Recurrent
Consumers and Households	Price of Consumer Goods	(-)	Indirect	Not quantified	Recurrent

Environmental impacts

Labels that are difficult to read pose a threat to the environment, as consumers and workers may not be able to take note of the use and disposal instructions. In particular if they have visual impairments. While, it is not possible to quantify this effect, it is likely that improved readability will have a neutral or slightly positive impact on the environment and resource use.

Table 103: Environmental impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent
Sustainable consumption and production	Impact on Resource Use	(o)	Direct	Not quantified	Recurrent
	Impact on the protection of the environment	(+)	Indirect	Not quantified	Recurrent
Waste production, generation and recycling	Impact on Labelling and Packaging Waste	(o)	Direct	Not quantified	Recurrent

Social impacts

Poorly legible labels negatively affect **public health and safety and health systems** as consumers and workers may not be able to take not of information on the human health hazards of the products they are purchasing and using. In particular when they are having visual impairments. Policy measure #12 aims to ensure labels are legible. Therefore, the policy measure will have a positive impact on the protection of human health, but the quantification is problematic and was not quantified in terms of public health.

Policy measure #12 is unlikely to have a noteworthy impact on **employment** and equally unlikely to have a noteworthy impact on the number of **public authority jobs**.

Table 104: Social impacts					
Impact Category	**Impact**	**Positive or negative**	**Direct or indirect**	**Monetised impacts**	**One off or recurrent**
Public health and safety and health systems	Impact on human health	(+)	Direct	Not quantified	Recurrent
Employment	Impact on industry and public authority jobs	(o)	Indirect	Not quantified	Recurrent

POLICY MEASURE #16 CHEMICALS SOLD IN BULK TO CONSUMERS

Note: policy measure #16 includes actions on labelling exemption for chemicals sold in bulk to consumers and in very small packaging. This chapter only addressed chemicals sold in bulk to consumers. The labelling exemption for very small packaging is addressed in the next chapter.

Policy measure #16 grants a derogation from labelling obligations under the CLP Regulation for chemicals sold in bulk to consumers, such as fuel sold at filling stations. This concerns cases where the chemical is directly pumped into a receptacle (such as a vehicle's fuel tank) from where it is not intended to be removed by the consumer and where the consumer cannot get in touch with the chemical due to the way the chemical is transferred (i.e. nozzle entering the receptacle). Under this derogation, it would suffice to provide a label on the pump for each of the chemicals dispensed via the related nozzles (e.g. one label for petrol and one label for diesel at a fuel pump).

Economic impacts

Policy measure #16 aims to clarify the rules how unpackaged chemicals supplied in bulk to consumers should be labelled. While CLP does not discriminate between forms of sale, currently there is no guidance or dedicated legal requirements for the labelling of unpackaged chemicals sold to consumers (except for those covered by Article 29(3) which currently only covers ready mixed cement and concrete in a wet state). Therefore, these chemicals are often not labelled or labelled incorrectly, also because the current provision are difficult to apply to such forms of sales given the absence of a packaging. Policy measure #16 would require suppliers of bulk chemicals to ensure compliance with any specific CLP labelling requirements. As policy measure #16 represents additional **conduct of business cost** for those suppliers that are currently chemicals in bulk to consumers and not complying to current rules. The assessment of economic impacts below focuses on quantifying the impacts of fuel labelling as a case study. This is believed to be by far the largest share of the market but does not quantify the total impacts of labelling all unpackaged chemicals supplied in bulk (i.e. not including other fluids provided in bulk to consumers such as "AdBlue").

A cost-effective option would be providing labelling as an extension to a receipt. However, this may not be sufficient as consumers do not always choose to take a receipt and in these instances, consumers would not receive labelling information. Although this could be combated by removing the option to decline a receipt being issued, this could face backlash from consumers who are moving away from receipt due to environmental

concerns. Instead, within CARACAL, the provision of a sticker at a fuel pump with the correct label elements was deemed to represent a sufficient solution, and it would be left to the consumer to take note of the sticker, or take home a copy of the sticker. It was stated at CARACAL that self-service filling stations should not be required to verify that every customer uses the sticker on their jerry can, but they would be required to at least make the sticker available. It is relevant to note that in some Member States it is already obligatory to label the pumps accordingly.

As of the end of 2018, there were approximately 67,000 filling stations in the EU-27 (FuelsEurope, 2019), the number of individual fuel pumps being several times greater.

A recent impact assessment by the UK Department of Transport (UK DOT, 2019) on the adoption of standard labels for the type and biofuel content of road transport fuels in response to the EU's Alternative Fuels Infrastructure Directive (AFID) provides a central estimate of 239,212 for the number of fuel nozzles in the UK in 2019, based on information provided by associations from the automotive and fuel industry. The impact assessment provided a cost range of €0.14 – €1.36 to label a single fuel nozzle, with a mid-point of €0.75 (estimates converted to Euros and 2021 prices).

As of 2019, the UK had a population of 66,647,112, which is approximately 15% that of the EU-27 (446,446,444) (Eurostat, 2019). If we use this proportion to extrapolate the number of fuel nozzles in the UK to give as estimate of the number in the EU, it gives an estimate of approximately 1,520,000 million fuel nozzles. When dividing this figure of the number petrol stations in the EU-27 from FuelsEurope, it gives an average of roughly 24 fuel nozzles per station, which based on 3 nozzles per fuel pump (2 petrol; 1 diesel), would give a figure of 8 pump per stations on average, which is considered a realistic estimate. 1.6 million fuel nozzles would give a relabelling cost of €212,800 - €2,067,200 based on the costs provided above, with a central estimate of €1,200,000. The costs of new fuel nozzle labels are expected to be one off cost. Following initial labelling, replacement labels would be factored into maintenance of branding schedules with only marginal additional costs expected.

An additional cost incurred by fuel retailers would be the integration of the labels into their existing point of sale branding. Estimates form the UK DOT (2019) give a cost of €374 per fuel station (estimate converted to Euros and 2021 prices), although it notes that smaller filling stations will spend significantly less and not choose to incorporate labels into existing branding. Therefore, a median estimate of €155 per fuel station is provided (estimate converted to Euros and 2021 prices). This would be a cost of €10,385,000, based on 67,000 fuels stations across the EU. However, including the label in existing branding would be a voluntary business choice, in addition to a simple label that would suffice to comply with policy measure 16. Therefore, this cost is informative but not relevant for this impact assessment.

A further cost highlighted by the UK DOT (2019) is the cost of training staff to understand the labelling information and help answer any queries from fuel pump customers. Using the time taken for training legal and accounting staff as a proxy for training sales and customer service occupations, the UK DOT arrived at a central estimate of €16.75 per fuel station (estimate converted to Euros and 2021 prices). Based on 67,000 fuel stations across the EU, this would equate to a cost of approximately €1,122,250.

The cost outlined above would only occur in Member States that do not already require a labelling of the pump and only where multinational chains do not label their pumps anyway as part of their corporate policy. Furthermore, it needs to be taking into account that policy measure #16 would not mandate a label per nozzle. Typically, one label of petrol and one label for diesel on the pump would suffice, independent of the number of actual nozzles per fuel type. Therefore, those cost estimations constitute a maximum.

Public authorities' enforcement cost are influenced by the fact that there are currently no dedicated labelling obligations for chemicals sold in bulk to consumers under the CLP Regulation. Therefore, enforcement activities in this area are currently dependent on national rules. If labelling obligations are imposed though amendment of the legal text of the CLP Regulation, the supply of fuels will become an additional area in need of enforcement in Member States that do not have such rules yet. Consequently, the level of resources needed by enforcement authorities is expected to increase under policy measure #16.

The ECHA (2019f) REACH-EN- FORCE- 6 (REF 6) project on classification and labelling carried out 194 inspections as part of an option module on exemptions from labelling and packaging requirements. This optional module targeted mixtures supplied in small packaging, which have specific labelling rules under CLP. If specific labelling rules for chemicals sold in bulk to consumers are established, a similar level of enforcement is likely to be sufficient as that carried out on mixtures supplied in small packaging. Therefore, we can use the number of inspections carried out on mixtures supplied in small packaging as a proxy to estimate the cost of enforcement of re-fill chemicals. This gives a recurring cost of €170,526 (194 x €879 per on-site inspection). It is not expected that a specific enforcement project on refill chemicals would occur every year and, therefore, the annual cost would be even lower (a factor 3 is applied providing a cost of approximately €57,000 per year per enforcement project).

Policy measure #16 is expected to have a positive impact on the **functioning of the internal market and competitiveness**. The policy measure aims to clarify rules on the labelling of chemicals sold in bulk to consumers, which will help ensure that all Member States take the same approach regarding compliance of bulk chemicals with CLP. This is expected to help level the playing field for businesses across the EU by ensuring they are all subject to the same compliance costs. The positive impact is expected to be very weak as the oil sector (NACE C19.2) is dominated by a few large companies, with the average turnover in 2018 being €562,000,000 (Eurostat, 2018). Therefore, the compliance costs are not expected to be significant to competition.

Labelling chemicals sold in bulk to consumers is not expected to have a negative impact on the **operation of SME** as suppliers of fuel are typically, but not exclusively, large multinational companies or cooperatives and therefore SMEs are not expected to be significantly or disproportionately impacted.

Table 105: Economic impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised Impact	One off or recurrent
Conduct of Business	Labelling Costs	(-)	Direct	**Fuels** One-off cost of	One-off

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				€11,700,000 – €13,700,000	
Public Authority Costs	Enforcement Costs	(-)	Direct	Approx. €57,000 per enforcement project	Recurrent
Functioning of the Internal Market and Competition	Level of Enforcement across Member States	(+)	Indirect	Not quantified	Recurrent
Position of SMEs	Operation of SMEs	(o)	Indirect	Not quantified	Recurrent

Environmental impact

So far, legal clarity on the labelling of unpackaged chemicals is only provided by Article 29(3) and guidance by the European Chemicals Agency on labelling and packaging related to that provision. Since no specific provisions exist for fuels and similar cases, these chemicals are often not labelled or labelled incorrectly. This increases the **environmental impact** of such sales as consumers are not provided with information on the environmental hazards of the products they are purchasing. Policy measure #16 would require all suppliers of bulk chemicals to ensure they are labelled and packaged correctly. Thereby, policy measure #16 will have a slightly positive impact on the protection of the environment.

Policy measure #16 is expected to have a neutral impact on **sustainable consumption and resource use,** as it foresees the requirement for suppliers of chemicals in bulk to ensure their products are appropriately labelled and packaged. As this would happen once at the level of fuel pump, it is not expected to create a noteworthy impact in the resource use and **packaging waste**.

Table 106: Environmental impacts					
Impact Category	**Impact**	**Positive or negative**	**Direct or indirect**	**Monetised impacts**	**One off or recurrent**
Sustainable consumption and production	Impact on Resource Use	(neutral)	Indirect	Not quantified	Recurrent
	Impact on the protection of the environment	(+)	Indirect	Not quantified	Recurrent

Social impacts

Currently **public health and safety and health** systems can be negatively affected because there is no dedicated guidance or legal requirements for the labelling of chemicals sold to consumers in bulk. Therefore, these chemicals are often not labelled or labelled incorrectly. This reduces the level of protection for human health as consumers are not provided with information on the human health hazards of the products they are purchasing.

Policy measure #16 is not likely to have any significant impact on **employment** levels. The additional cost of conducting business is expected to be negligible.

A summary of the costs and benefits of introducing labelling for fuels is provided below

Summary of cost and benefits of policy measure #16 (fuel labelling)	
Costs - businesses	
Total one-off costs over a 20-year period	€11,700,000 – €13,700,000 (mid-estimate: €12,700,000)
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	€15,728,476 – €18,417,104 (mid-estimate: €17,072,790)
PV of one-off costs (20 years; 3%) (annualized)	€786,424 – €920,855 (mid-estimate: €853,639)
PV of recurring costs (20 years; 3%)	
Total PV – costs - businesses	€15,728,476 – €18,417,104 (mid-estimate: €17,072,790)
Costs – public authorities	
Total one-off costs over a 20-year period	
Recurring costs every 1 year	€57,000
Total recurring costs over a 20-year period	€1,083,000
PV of one-off costs (20 years; 3%)	
PV of recurring costs (20 years; 3%)	€1,455,892
PV of recurring costs (20 years; 3%) (annualized)	€76,626

Total PV – costs – public authorities	
Total PV cost of policy measure #16 (fuel labelling)	**€17,260,994 – €19,949,622 (mid-estimate: €1,455,892)**
Benefits (cost savings) - businesses	
PV benefits - businesses	
Benefits (cost savings) – public authorities	
PV – benefits – public authorities	
Benefits - society	
PV - benefits - society	
Total OV - benefits	
Net Present Value - NPV (PV benefits – PV costs)	€17,260,994 – €19,949,622 (mid-estimate: €1,455,892)

A summary of the present value (3% discount) costs and benefits of introducing labelling for fuels is provided below.

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #16 (labelling fuels) by type						
Costs						
	Businesses		**Administrations**		**Society**	
Direct adjustment costs						
Direct administrative costs	€15,728,476 – €18,417,104 (mid-estimate: €17,072,790)		€1,455,892			
Direct regulatory fees and charges						
Indirect costs						
Benefits						
Description	**Businesses**		**Administrations**		**Society**	
Direct benefits						

POLICY MEASURE #16 CHEMICALS IN VERY SMALL PACKAGING

Note: policy measure #16 includes actions on labelling exemption for chemicals sold in bulk to consumers and in very small packaging. This chapter only addresses the labelling exemption for very small packaging. The labelling exemption for chemicals sold in bulk to consumers is addressed in the previous chapter.

CLP currently requires that chemicals in very small packaging should be labelled and the environmental hazards communicated to end-users. However, the applicability of CLP to some chemicals in very small packaging is contested by some industry actors. For example, EWIMA is of the opinion that writing instruments (e.g. single-use pens/markers) are considered as articles according to the definition laid down in the EU regulation

REACH, and, therefore, CLP would not apply (EWIMA, 2017). Whereas it is of the understanding of the European Chemicals Agency and the Commission that writing instruments are 'mixtures in containers', following a discussion in the 27th Meeting of Competent Authorities for REACH and CLP[264], *"COM replied that it is of the opinion that writing instruments are mixtures in a container and that the container constitutes packaging pursuant to Article 2(36) of CLP. However, the notion of packaging under CLP does not necessarily spill over in the Waste Packaging Directive"*. The Commission subsequently followed up by stating that they would not re-open this discussion in CARACAL as long as no new information becomes available which could change COM's conclusion.

Policy measure #16 grants an exemption from labelling obligations under the CLP Regulation for the inner packaging of chemicals supplied in very small packaging (below 10 ml), by extending the current exemption provided under Article 29, which currently only applies to chemicals used for scientific R&D or quality control analysis, to all chemicals that exhibit less severe hazards. As it is currently already the case for chemicals used for scientific R&D or quality control analysis, the exemption would be granted subject to the condition that the inner packaging is contained within an outer packaging that meets the requirements of Article 17. Writing instruments and other chemicals supplied in very small packaging that contain chemicals that exhibit more severe hazards remain covered by all current obligations in CLP (i.e. Article 29). However, it is assumed that only a small proportion of writing instruments contain chemicals that exhibit more severe hazards.

Economic impacts

A position paper by EWIMA (2017) provided information on the **cost of conducting business**, in response to discussion held previously on the labelling of writing instruments at CARACAL. The paper reports that manufacturers of writing instruments would have one-off costs of between €500,000 – €7,000,000 and annual recurring costs of €4,000,000 – €14,000,000 to comply with CLP labelling provisions.

Assuming the costs identified for writing instruments would apply to other products containing hazardous chemicals in very small packaging that are currently unlabelled, policy measure #16 would lead to a cost saving estimate of between €500,000 - €14,000,000 per manufacturer.

Data received from the Open Public Consultation estimated the number of products placed on the market which contain hazardous chemicals in very small packaging to be between 735 million and 898 million, which would all not require labelling under this policy option. Over 95% of these are writing instruments, such as pens. Therefore, a labelling exemption will significantly reduce labelling costs.

EWIMA (2017) also reports that because of the low sale price of pens, typically around €0.15 per pen, and the long-term practice of selling them as single items, labelling and

[264] European Commission (2018): 27th Meeting of Competent Authorities for REACH and CLP (CARACAL) –18 June 2018 CA/72/2018

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packaging costs would be too expensive and would mean that certain single-sold writing instruments would have to be withdrawn from the market.

Public authority cost are the result of enforcement activities that are currently carried out to check the compliance of chemicals sold in small packaging. For example, the REF-6 enforcement project carried out 194 checks on mixtures sold in small packaging. If an exemption was granted for these products, enforcement in this area could be reduced and resources could be diverted to areas of higher relevance for health and the environment. Based on the cost estimate of €879 for carrying out an on-site inspection, the REF-6 project on mixtures in small packaging is estimated to cost approximately €170,000, which would present the cost saved on enforcement under policy measure #16. It is not expected that a specific enforcement project on refill chemicals would occur every year and, therefore, the annual cost would be even lower (a factor 3 is applied providing a cost of €57,000 per year per enforcement project).

The introduction of a labelling exemption and a clarification of the applicable rules chemicals in very small packaging is expected to have a positive impact on the **functioning of the internal market**, as labelling rules would be more harmoniously applied across all Member States. The removal of the labelling obligation would also reduce the cost of business and reduce barrier to trade, particular for small items such as pens sold in multiple Member States, as it is practically not possible to apply multilingual labels to the inner packaging of such small items due to the limited space.

The **position of SME** is that the costs of complying with current CLP labelling provisions are significant, and place a very high administrative burden on any SME. Policy measure #16 provides an exemption from labelling and would, therefore, have a significant positive impact on SMEs.

As mentioned previously, the cost of complying with current CLP labelling provisions would lead to an increase in the price of writing instruments and could see certain writing instruments withdrawn from the market and no longer available to consumers. Policy measure #16 would, therefore, have a positive impact on the **price of consumer goods** as price increases would no longer be necessary. Price increases for other products containing chemicals in small packaging (e.g. essential oils, superglues, lighters, printing inks) have higher price points and therefore are not expected to be impacted by increased consumer prices, and the increased production costs due to labelling can be more easily absorbed.

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Table 107: Economic impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised Impact	One off or recurrent
Conduct of Business	Labelling Costs	(+)	Direct	One-off cost saving of €500,000 – €7,000,000 per manufacturer Annual cost savings of €4,000,000 – €14,000,000	One-off & Recurrent
	Product Withdrawal	(+)	Direct	Not quantified	Recurrent
Public Authority Costs	Enforcement Costs	(+)	Direct	Approx. €57,000 cost saving	Recurrent
Functioning of the Internal Market and Competition	Level of Enforcement across Member States	(+)	Indirect	Not quantified	Recurrent
Position of SMEs	Operation of SMEs	(+)	Indirect	Not quantified	Recurrent
Consumers and households	Price of Consumer Goods	(+)	Indirect	Not quantified	Recurrent

Environmental impact

Policy measure #16 would have a positive impact on **resource use** and **packaging and labelling waste**, as the use of stickers, leaflets, blister cards, and additional packaging would in most cases no longer be needed to meet CLP labelling provisions. Information presented in previous sections estimated that between 734 and 898 million products containing chemicals in very small packaging were placed on the EU market in 2019. Over 95% of these are pens and writing instruments. Although the quantity of these products that are currently sold as single unpackaged and unlabelled items is not known, if this was even a small percentage of the total, a significant amount of additional packaging and labelling material would be required for them to remain on the market without policy measure #16.

The CLP Regulation currently requires that all chemicals in very small packaging should be labelled and the environmental hazards communicated to consumers. Policy measure #16 sets exemptions for certain chemicals meaning information on **environmental hazards** will no longer be communicated in cases where environmental hazards are relevant (unless the hazards of the chemical in question exhibits severe hazards), which

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might reduce the level of protection for the environment, as end-users would have limited information on safe use and disposal. This may have a slight negative impact on environmental protection is expected. However, this impact is expected to be small in reality because these items are already today largely sold without a label and the quantities in question are small (although accumulated, e.g. over all writing instruments, not insignificant). Furthermore, the exemption would not apply for chemicals with more severe hazards. On the flip-side, this small reduction of the level of protection for the environment is probably offset by the significant savings on resource use and waste that would be necessary when ensuring compliance with CLP without policy measure #16. As policy measure #16 would clarify rules on these chemicals and, therefore, a greater rate of labelling is expected for the chemicals that remain subject to labelling because they exhibit more severe hazards. This means better communication of information on environmental hazards, which will increase the level of protection for the environment, as end-users will have more information on safe use and disposal. Furthermore, producers or producers of writing instruments that contain chemicals with more severe hazards might be encouraged to substitute those chemicals due to market pressures. Therefore, overall, a positive impact on environmental protection is expected.

Table 108: Environmental impacts

Impact Category	Impact	Positive or negative	Direct or indirect	Monetised impacts	One off or recurrent
Sustainable consumption and production	Impact on Resource Use	(+)	Direct	Not quantified	Recurrent
	Impact on the protection of the environment	(+)	Indirect	Not quantified	Recurrent
Waste production, generation and recycling	Impact on Packaging and Labelling Waste	(+)	Direct	Not quantified	Recurrent

A summary of the costs and benefits of exempting labelling of items in very small packaging are presented below:

Summary of cost and benefits of policy measure #16 (labelling of very small packaging)	
Costs - businesses	
Total one-off costs over a 20-year period	
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	
PV of recurring costs (20 years; 3%)	
Total PV – costs - businesses	
Costs – public authorities	

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Total one-off costs over a 20-year period	
Recurring costs every 1 year	
Total recurring costs over a 20-year period	
PV of one-off costs (20 years; 3%)	
PV of recurring costs (20 years; 3%)	
PV of recurring costs (20 years; 3%) (annualized)	
Total PV – costs – public authorities	
Total PV cost of policy measure #16 (labelling of very small packaging)	
Benefits (cost savings) - businesses	€76,500,000 – €273,000,000 (mid-estimate: €174,750,000)
PV benefits - businesses	€102,840,033 – €366,997,763 (mid-estimate: €234,918,898)
PV benefits – businesses (annualized)	€5,142,002 – €18,349,888 (mid-estimate: €11,745,945)
Benefits (cost savings) – public authorities	€1,083,000
PV – benefits – public authorities	€1,455,892
Benefits - society	
PV - benefits - society	
Total OV - benefits	
Net Present Value - NPV (PV benefits – PV costs)	€104,295,925 – €368,453,656 (mid-estimate: €236,374,790)

A summary of the present value (3% discount) costs and benefits of exempting labelling of items in very small packaging are presented below:

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #16 (labelling fuels) by type						
Costs						
	Businesses		**Administrations**		**Society**	
Direct adjustment costs						
Direct administrative costs						
Direct regulatory fees and charges						
Indirect costs						
Benefits						
Description	**Businesses**		**Administrations**		**Society**	
Direct benefits						
Direct administrative cost savings	€102,840,033 – €366,997,763 (mid-estimate: €234,918,898		€1,455,892			

STAKEHOLDERS VIEWS ON POLICY OPTION 2

With regard the policy options 2 related to hazard communication, the respondents to the open public consultation generally welcomed the consideration to allow a broader use of multilingual fold-out labels and introduce tailored labelling rules where there is insufficient space on the packaging. The open public consultation, targeted stakeholder surveys and interview respondents 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, targeted stakeholder surveys and interview respondents emphasised the importance of proper CLP labelling of refill chemicals to ensure that customers get all safety information. Similar concerns were raised in the discussion during CARACAL meeting and in the written feedback.

STAKEHOLDERS VIEWS ON SPECIFIC PRODUCTS: CLP LABELLING OF AMMUNITION

Under the public consultation, the defence industry sector provided a position paper related to CLP labelling of ammunition and requested to:

- Have a general exemption to place UFI code(s) on ammunition since there would be no added value in terms of providing emergency health response;
- Adjust the labelling requirements for ammunition in order not to label the immediate packaging layer containing it, but the outer one, to ensure good functioning and security;
- Provide for a CLP labelling exemption in deployment scenarios of camouflage needs;
- Better regulate the SDS requirements applying to articles by proposing a specific format.

The Commission did not assess the specific impacts of this request since it wanted to keep policy options at a general basis – and not sector limited – as well as due to time constraints.

Moreover, the Commission understands that this request is very sector specific and does not have impacts on the overall CLP labelling system.

MONITORING

For some specific objectives of the revision of the CLP Regulation, a number of additional streams will also be important:

EU barometer surveys: these surveys provide very useful information on how well informed citizens/consumers feel about the dangers and safety of chemicals and on their level of understanding of labelling. As the last EU barometer 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 corresponding questions to assess progress.

EU enforcement projects: the level of compliance with CLP rules is regularly monitored by the Forum for Exchange of Information on Enforcement (the Forum), a network of authorities responsible for the enforcement of the REACH, CLP, PIC, POP and Biocidal Product regulations. The Forum has been driving in the past years a number of EU wide enforcement studies (led by the European Chemical Agency), which have been instrumental to identify the level of non-compliance with the CLP Regulation across 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, monitoring progress on those areas through targeted Forum's activities should take place. Those data will also feed the overall enforcement and compliance indicators that are currently under development as part of the future framework of indicators on chemicals.

PRACTICAL IMPLICATIONS OF THE OPTION OR SUB-OPTION

Summary of costs and benefits

Table 109: Comparison of measures for hazard communication.

Options	Effectiveness	Key impacts			Benefit/cost ratio	Efficiency	Coherance
		Economic	Social	Environmental			
PO2a Update/prepare guidance	Limited extension of clarifications	Minimal positive	Minimal positive	Minimal positive	Very limited benefits with very limited costs	Low	Not relevant
PO2b Improving and making more flexible existing labels	High – in tackling absence of labels and improved hazard communication	Negative costs for business €0.34-0.6 million Negative impacts for font size (undetermined)	Highly positive (increased safety information available to users)	Slightly positive (more information available to users)	Positive	High	Not relevant

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Annex 13 – Digital labelling

INTRODUCTION & CONTEXT

On top of the detailed section on labelling (Annex 12), this Annex focusses specifically on a new area of amendment to the CLP Regulation, which looks at possibilities of providing certain labelling elements digitally. As this area of labelling intervention was supported by a comprehensive and separate Impact Assessment supporting study, it is presented in a stand-alone Annex.

Context

During the course of 2019, the European Commission published the Fitness Check of the most relevant chemicals legislation[265] (excluding REACH, hereafter 'the Fitness Check'). This evaluation provides a comprehensive assessment regarding the performance of the EU chemicals legislation in light of its objectives of protecting human health and the environment, ensuring the efficient functioning of the single market and enhancing competitiveness and innovation. While concluding that legislation is overall fit for purpose, it also pointed to several issues with current labelling requirements and hazard communication measures. Certain findings (among others) showed that:

1. there is room for simplification in the communication of hazard and safety information to consumers and for improvement in terms of its effectiveness and efficiency; and

2. the use of innovative digital tools for the communication of such information is currently suboptimal.

3. there are some regulatory overlaps, which lead to confusing and overloaded labels.

Digital labelling under the CLP Regulation was investigated in the broader context of the European Green Deal[266], the European Union's strategy to set up a sustainable climate neutral and circular economy by 2050 and the EU industrial strategy[267] for a competitive, green and digital Europe which published on 10 March 2020 to address the twin challenge of the green and the digital transformation. Further, this initiative aims to contribute to the high level European Commission priority (2019-2024) of a 'Europe fit for the digital age', as the Commission is determined to make this Europe's "Digital Decade". As a priority,

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[265] REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses (COM/2019/264 final): https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN

[266] European Commission, 2019, *The European Green Deal*. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF.

[267] European Commission, 2020, A New Industrial Strategy for Europe. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0102

Europe is strengthening its digital sovereignty and setting standards with a focus on data, technology, and infrastructure.

Further, in the context of the European Green Deal, the European Union's strategy to set up a sustainable climate neutral and circular economy by 2050, the EU industrial strategy for a competitive, green and digital Europe was published on 10 March 2020 to address the twin challenge of the green and the digital transformation. Also in the context of the European Green Deal, the Chemicals Strategy on Sustainability was published on 14 October 2020 and it sets objectives to ensure a better protection of human health and the environment from hazardous chemicals, as well as to boost innovation for safe and sustainable chemicals, and to enable a transition to chemicals that are safe and sustainable by design. In order to further achieve the goals of the European Green Deal, the Circular Economy package and the proposal for a Regulation on Eco-design for Sustainable Products was adopted on 30 March 2022[268]. The proposal establishes a Digital Product Passport (DPP) which will hold information on all regulated products and their value chains. The objective of the DPP is to support sustainable production, to enable the transition to circular economy, to provide new business opportunities to economic actors, to support consumers in making sustainable choices and to allow authorities to verify compliance with legal obligations. This initiative is particularly relevant for digital labelling under CLP, because it foresees the mandatory adoption of digital ways of communicating information about products, including those covered by CLP.

The safe and sustainable use of chemicals within the Sustainable Development Goals

Improving the regulatory framework of chemicals to better protect human health and the environment is also in line with larger economic, societal and environmental challenges and objectives, such as the United Nations' 2030 Agenda for Sustainable Development which defines the Sustainable Development Goals (SDGs).

Firstly, protecting consumer health as set out in the European Union's Chemical Strategy for Sustainability, contributes to the SDG 3 which aims to ensure healthy lives and promotes well-being for all, at all ages. More specifically, target 3.9 sets a goal to substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water, and soil pollution and contamination by 2030. Digitalisation offers opportunities to reach more and in particular vulnerable consumer better. Digital labels would facilitate the integration of labelling information in digital tools that assist e.g. elderly or disabled consumers. Digitalisation also offers opportunities to provide more language versions of labels, in addition to those that are obligatory on the physical label.

Secondly, the objectives of the Chemical Strategy for sustainability is to better protect the environment also relate to SDG 6 which aims to ensure the availability and sustainable management of water and sanitation for all, and more specifically to target 6.3, to improve water quality by, among other things, eliminating dumping and minimizing the release of hazardous chemicals and materials by 2030.

[268] European Commission, 2022, *Communication on making sustainable products the norm*. Available at: https://ec.europa.eu/environment/publications/communication-making-sustainable-products-norm_en

Finally, the regulatory framework for chemicals should also contribute to the fulfilment of SDG 12, to ensure sustainable consumption and production patterns, and more specifically, to target 12.4 which aims for environmentally sound management of chemicals throughout their cycle and to reduce their release into air, water, and soil in order to minimize adverse impacts on human health and the environment.

The importance of chemicals and waste management to achieve the SDGs is also aligned with the overall objective of the Strategic Approach to International Chemicals Management (SAICM).[269] Supported by the United Nations Environment Programme, the SAICM is an international policy framework to promote chemical safety around the world, and support the sound management of chemicals throughout their life cycle to minimise their adverse impacts on the environment and human health.

Legal basis:

Article 114 of the Treaty on the Functioning of the European Union (TFEU)[270] confers upon the EU institutions the competence to lay down appropriate provisions which have as their object the establishment and functioning of the internal market.

Regarding consumer protection, Article 169 TFEU provides that, to promote the interests of consumers and ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests, and that these objectives can be reached through measures adopted pursuant to Article 114 in the context of the completion of the internal market.

Therefore, according to Article 114 TFEU introducing any digital labelling under the CLP regulation is subject to the shared competence of the EU. In this situation, Article 5 TEU and the principle of subsidiarity[271] provide that the Union shall act only if, and in so far as, the objectives can be better achieved at Union level than by Member States. Since the objectives of the regulations concerned in this study necessitate common provisions throughout the EU, Article 114 TFEU can serve as the appropriate legal basis for this initiative.[272]

Subsidiarity: Necessity of EU Action

The simplification of labelling requirements for chemicals and the use of digital labelling aim at improving consumer understanding and awareness of chemical labels, by making optimal use of digital tools to communicate product information. The overarching

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[270] Treaty on the Functioning of the European Union. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC_2&format=PDF.

[271] Treaty on European Union. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC_1&format=PDF.

[272] Recital 2 of the CLP Regulation provides that "the efficient functioning of the internal market for substances, mixtures and those articles can be achieved only if the requirements applicable to them do not differ significantly between Member States". This reasoning can also be find in Recital 2 of the Detergents Regulation.

objectives are to ensure that all consumers in the EU enjoy a high level of protection when using chemical products while taking into account the current digitalisation trend.

Currently, there is room for improvement in terms of the understanding and awareness of chemical labels across the EU. Especially as the classification, labelling and packaging of substances and mixtures under the CLP Regulation is harmonised at Union level, it is appropriate that the digital labelling under the same regulation continue to be regulated at EU level to achieve their objectives, i.e. to increase the protection of consumers while ensuring the free movement of chemicals in the internal market.

At the same time, national action and/or absence of EU level action could create inequalities and asymmetries between the protection of consumers in different Member States. It could also increase costs for industry to adapt to different labelling requirements in different Member States and hinder the good functioning of the internal market for chemical products. Differing approaches would also make it more difficult for consumer to obtain the relevant information.

EU action is also needed because of the strong cross-border dimension of the problem: as explained above, Europe is the second largest chemicals producer in the world and chemicals products supply almost all sectors of the economy. It is estimated that around 543 € billion worth of chemicals are produced annually and move freely within the EU thanks in part to the CLP Regulation, and to sector-specific regulations such as the Detergents Regulation. The magnitude and cross-border nature of the sector indicate that action in this sector should be taken at EU level.

Subsidiarity: Added value of EU action

The added value of EU action is to improve the current legislative framework at the EU level to address the problems identified in this Annex, while also taking into account the current market developments of the sector.

Specifically, the digital readiness of the EU regulatory framework surrounding chemical products cannot be efficiently tackled at national level and needs to be harmonised in order for industry to reap the benefits of digitalisation in the communication of product information. Also EU action will ensure that consumers have the same access to information wherever they purchase or use chemical products in the EU. The use of digital tools is not limited to a single Member State, and rules fit for the digital age are needed across all of Europe to foster cross-border activity and competition. Digital improvements to the current legislation, such as including the possibility for some labelling requirements to be provided digitally, could improve the functioning of the internal market and the protection of consumers if they are undertaken at EU level.

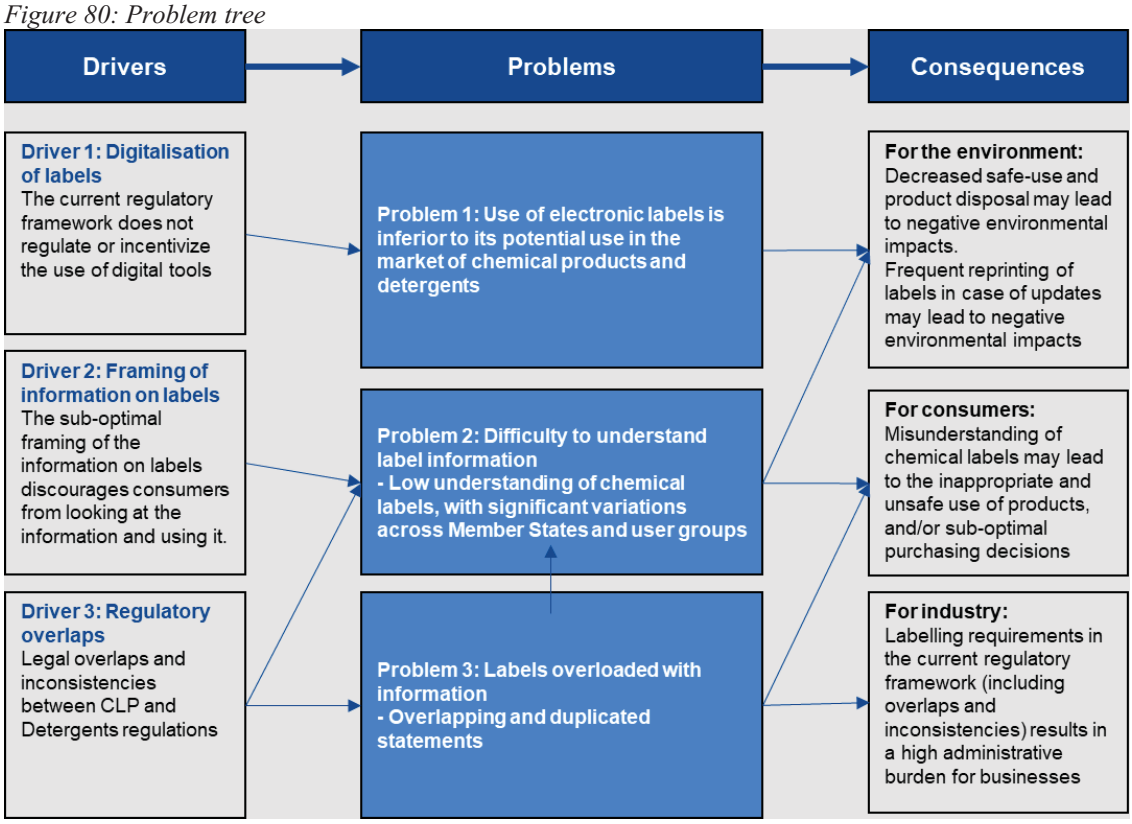
Finally, the added value of EU action also lies in the existence of economies of scale in the chemical industry. The harmonisation of labelling requirements across the EU allows manufacturers to use multi-lingual labels and to distribute the same products (with the same label) in more than one Member State.

PROBLEMS AND DRIVERS

As demonstrated by the Fitness Check, even if chemicals legislation is overall fit for purpose, there are still several issues with current labelling requirements, reducing the effective communication of hazard and safety information.

The link between problems identified their drivers and consequences is visualised in the problem tree below:

Figure 80: Problem tree



Findings of the Fitness Check

The Findings of the Fitness Check showed that chemical legislation is overall fit for purpose, but proposed several suggestions for improvement, including in the communication of hazard and safety information. Based on the Special Eurobarometer survey[273] number 456 the Fitness Check reports that *"a low level of understanding of certain pictograms, labels, and precautionary statements partially due to the overload of information"*[274].

[273] Special Eurobarometer 456, 2017. Available at: https://europa.eu/eurobarometer/surveys/detail/2111.
[274] Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses, p.9. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0264&from=EN

The level of understanding is influenced by the amount of information on chemical labels. This is affected by having too much text or technical language that consumers are not familiar with, text in multiple languages, as well as repeating text caused by overlaps in legal requirements (e.g. between, CLP and Detergents Regulation and/or the Cosmetic Products Regulation). The Fitness Check also pointed out that the current approach to the labelling of allergens could be improved so that consumers are better protected and informed in case of allergies. The Fitness Check further identified the opportunity to improve the communication of product information by including the use of technologies such as QR codes. Potential burden reduction for SMEs, were also presented as potential benefits of increased use of digital technologies. Potential burden reduction for SMEs, as well as an improvement of enforcement and compliance by the relevant competent authorities (e.g. Market Surveillance Authorities, customs) were also presented as potential benefits of such improvements.

Problem drivers

Three key problem drivers to the current labelling requirements of CLP, in the context of digital labelling have been identified:

1. Market development:

Since the entry into force of the CLP regulation, digitalisation has led to the development of new labelling technologies which are not adequately captured by the current scope of the regulatory framework. Currently no mention is made in the regulation of the possibility to use e-labelling solutions to communicate product information to users. This is despite the increasing use in Europe of mobile devices and internet.[275] The digital readiness of the regulatory framework surrounding chemical products needs to be addressed in order for industry and consumers to reap the benefits of digitalisation in the communication of product information.

2. Sub-optimal framing of information on labels, discouraging consumers from reading and using it:

A second driver identified in this study is the **sub-optimal framing of the information on chemical labels discouraging consumers from looking at the information and using it**. In particular, two characteristics have been identified: the complexity of information provided for the average consumers, and the use of multi-lingual labels leading to the need for small font size.

Some of the information provided on chemical labels contains technical and scientific terminology, not used in the day-to-day lives of consumers. This creates a lack of understanding of the link between this chemical terminology and their meaning in the context of the label (i.e. their properties in the product). In particular, the use of chemical names can sometimes be seen as an obstacle for consumer understanding of chemical labels.

[275] Eurostat, Digital Society statistics at regional level. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Digital_society_statistics_at_regional_level#Internet_users

At the same time, the behavioural experiment conducted for this study shows that, overall, consumers are able to interpret the Status Quo Label correctly (i.e. regarding hazards) and that CLP-relevant information items are rated as both easy to understand as well as easy to find. These results can also be explained by the fact that in the experiment, consumers were incentivised to read the label, thus increasing their understanding in comparison to day-to-day situations. This suggests that one attention is paid to finding the relevant labelling elements and reading them carefully, overall they are effective. Digitalisation could help with that by moving less critical information from the physical label to the digital label, so that information can better be found.

Secondly, the Fitness Check pointed out that consumers and workers do not understand some of the CLP pictograms (in particular GHS04 – gas cylinder and GHS07 – exclamation mark pictograms). Similarly, in the Special Eurobarometer participants were least familiar with the serious health hazard symbol – 20% reported having seen the symbol before – and only 17% understood the exclamation mark symbol. This was confirmed by some stakeholders during the interviews for this study. At the same time, it should be noted that the purpose of pictograms is to catch attention and complement the text on the label. They also work, to a certain degree, on their own, for people that are illiterate, so that they realise that they may have to seek more information. Therefore, it is not necessary that the pictogram is fully understood. Additionally, for professional users who should be more knowledgeable about pictograms, they can provide a quicker means of communication compared to reading the text.

Furthermore, under the CLP Regulation, the legal requirements specify that information on labels should be available in the official language(s) of the country in which the product is distributed. While this makes multilingual labels mandatory only in countries with more than one official language, such labels are a common practice in the industry across all EU countries.

Multilingual labels are used to achieve economies of scale, by allowing the industry to distribute one product with the same label across several countries. This is especially useful in smaller countries (e.g. in the Baltic countries). Thus, multilingual labels save money and material, they allow for flexibility in planning, and they reduce waste. In addition, it was highlighted that separate production for each market might be so complex that companies could decide to abandon smaller markets. However, the use of several languages to comply with labelling requirements also takes more space on labels and leads to a smaller font size to be used to communicate information, and makes information more difficult to find.

3. Regulation overlaps, duplications and inconsistencies

The third driver concerns **legal overlaps, duplications, and inconsistencies** between the CLP and Detergents regulations[276]. These issues are due to the fact that the Detergents Regulation was designed before GHS was developed by the United Nations, and therefore, before the CLP Regulation entered into force. These overlaps are explained below to extensively illustrate the problem of understanding chemicals labels, however, it should be

[276] A full legal analysis was conducted during this study and is available in Annex 13c.

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noted that such overlaps will be addressed in the sectorial legislation (i.e. in this case in the Detergents Regulation[277]) and not in the horizontal regulation (CLP).

This driver can be divided into 3 issues:

First of all, under the CLP, ingredient substances that present certain hazards must be included on the product label using a chemical name (e.g., MEA-dodecylbenzene sulfonate), whereas under the Detergents Regulation ingredients can be listed under a generic name (e.g., anionic surfactant). Complying with the labelling requirements of both Regulations results in the listing of the same ingredient twice, and in some cases using different names.

Secondly, the Detergents Evaluation revealed some legislative overlaps between the Detergents Regulation and the CLP with regard to the labelling of allergenic fragrances. Other overlaps also exist e.g., on the labelling of surfactants[278] and allergenic preservatives when CLP thresholds are met.

Thirdly, the Detergents Regulation requires the label to include the allergenic fragrances listed in Annex III to the CPR and which are added to detergents at concentrations exceeding 0.01% by weight. The labelling of these fragrances shall be done using the International Nomenclature of Cosmetic Ingredients ("INCI names"). In parallel, the CLP requires the inclusion of skin sensitisers[279] (i.e., allergenic substances like preservatives and fragrances) in the list of ingredients that need to figure on the product label when they are present above certain thresholds.[1] These thresholds are different from the thresholds provided in the Detergents Regulation. As most allergenic fragrance ingredients under the Cosmetic Products Regulation are also classified as skin sensitisers under the CLP, this may lead to the labelling of the same substance twice, once following the Detergents Regulation and once following the CLP.

The three drivers above lead to three overarching problems:

The **potential of electronic labels is not fully exploited** in the market of chemical products and detergents.

There is a certain **lack of awareness and understanding of chemical labels** in the EU, which can be an issue for consumer health.

Chemical labels can become overloaded with information and they could be streamlined and simplified to facilitate their understanding and reduce the administrative burden for industry related to labelling requirements.

Each of these problems are described below.

[277] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0648&from=EN.
[278] A full legal analysis was conducted during this study and is available in Annex 13c.
[279] Special Eurobarometer 456, 2017. Available at: https://europa.eu/eurobarometer/surveys/detail/2111.

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Problem definition

Problem 1: The potential of electronic labels is not fully exploited in the market of chemical products and detergents.

Due to the lack of regulations or incentives in the chemical legislative framework to use digital tools, the use of electronic labels is currently inferior to is potential use in the market of chemical products and detergents.

Indeed, besides the obligation for manufacturers to provide a full ingredient list on a website under the detergents regulation, the CLP and the Detergents regulations do not include the possibility to use digital labelling solutions to communicate product information to users.

Therefore, the current use of digital labelling for chemical products, including detergents, is only limited to ad hoc voluntary initiatives by manufacturers, and it remains unharmonised across Europe.

Problem 2: Difficulty for consumers to understand the hazard and safety communication on chemical labels

One of the problems that needs to be tackled is the current low understanding of chemical labels among consumers in Europe, with significant variation across user groups and Member States.

In Special Eurobarometer 456, less than half of respondents (45%) felt informed about the potential dangers of chemicals in consumer products. In consultations carried out for this study, all stakeholder groups (except public authorities) indicated that the clarity and understanding of chemical labels could be improved. Similarly, during interviews, a majority of stakeholders from both the business sectors and consumer associations stated that chemical labels as they are now are not well understood by consumers, for a variety of reasons.

Furthermore, consumer understanding of chemical labels is very heterogeneous across Europe. Indeed, in the Special Eurobarometer survey, Northern Europeans reported feeling more informed compared with Southern Europeans. This heterogeneity was also highlighted during the interviews where, for example, two stakeholders from both the business and consumer sectors highlighted the fact that in Denmark there is a high awareness and understanding of chemical labels among consumers. This can be explained by a highly-educated population, consumer associations and national authorities that actively inform consumers, and a high-level of digital literacy with consumers willing to look for further information online.

Finally, understanding of chemical labels also varies between consumers and professional users and industrial workers. All categories of stakeholders pointed out that there is a clear difference in understanding of hazard and safety instructions communicated on chemical labels between these different user groups. This difference is explained by the fact that professional and industrial workers are trained to understand the information on the label and that they have access to additional tools (e.g. the Safety Data Sheet). Moreover, around two-thirds of companies also provide additional training on chemical products or

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substances, e.g. on hazards or precautions of safely using these products. A combination of these measures explains the higher level of understanding of chemical labels among professional users and industrial workers compared to the consumers.

Problem 3: Labels overloaded with information

Sub-problem 1: Overlapping and duplicated ingredients

The current labelling requirements in the CLP Regulation can lead, in some cases, to an **overlap or a redundancy of information between ingredients**. Under CLP, ingredients that present a chemical hazard should be included on the product label using the chemical name (e.g., MEA-dodecylbenzene sulfonate), whereas under the Detergents Regulation ingredients can be listed under a generic name (e.g., anionic surfactant). Complying with the labelling requirements of both Regulations results in the labelling of the same ingredient twice, and in some cases using different names.

The Detergents Regulation requires the label to include the allergenic fragrances listed in Annex III to the CPR and which are added to detergents at concentrations exceeding 0.01% by weight on detergents' labels. The labelling of these fragrances shall be done by using the International Nomenclature of Cosmetic Ingredients ("INCI names").

In parallel, the CLP requires the inclusion of skin sensitisers (i.e., allergenic substances like preservatives and fragrances) in the list of ingredients that need to figure on the product label when they are present above certain thresholds. These thresholds are different from the thresholds provided in the Detergents Regulation, the latter being lower than the former. As most allergenic fragrance ingredients under the Cosmetic Products Regulation are also classified as skin sensitisers under the CLP this may lead to the labelling of the same substance twice, once with its INCI name following the Detergents Regulation and once following the CLP with its chemical name.

Addressing this redundancy could increase the efficiency of hazard and safety communication on chemical labels and improve their understanding, and reduce administrative burden.

A full analysis of the legal overlaps, inconsistencies and duplications can be found in Annex 10c.

Sub-problem 2: A lot of information communicated through written texts

In addition to legal inconsistencies, the sub-optimal framing of information as described in driver 2 also contributes to overloaded labels because a lot of information is communicated through written text which takes a lot of space on labels.

Information overload makes it difficult for users to focus on the most relevant information on the label. In particular, the long hazard (H) and precautionary (P) statements on multi-lingual labels can result in a significant amount of information that can become difficult to read and understand. In addition, the overload of labels lead to texts being written in very small print/font size which hampers readability. While multi-lingual labels foster the single market and they can be beneficial economically for businesses, the overloaded label clashes with consumer protection by hindering labels' readability.

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Furthermore, while a lot of information are written on the labels, it can be argued that consumers spend little time reading the information provided on chemical labels. According to a study commissioned by A.I.S.E, consumers spend 22 seconds on average to read chemical labels, irrespective of the content.[280] Interviews conducted for this study confirmed that consumers usually spend only a few seconds reading labels, except in case of accidents. In comparison, the behavioural experiment for this study showed that, on average, 62 seconds for laundry detergent and 78 seconds for the glue were required for consumers to answer a set of questions about the content of the label. For both products, there was a positive and significant relationship between the time spent reading the label and the chances of a correct answer to questions on product hazards. In summary, without an incentive to do so, consumers do not spend sufficient time reading the current chemical labels to understand them. This can lead to gaps in consumer protection, especially in conjunction with some labelling requirements, such as long written statements, that are difficult to understand quickly.

Magnitude and EU dimension of the problem

The magnitude of the problems described above can be first assessed by looking at the size of the chemicals sector in Europe, and therefore at the size of the market of impacted products. Europe is the second largest chemicals producer in the world with 499 billion euros (7,5% of EU manufacturing by turnover) and 14,4% of global sales. In terms of allocation across Europe, two thirds of these sales are made in four Member States: Germany (32,1%), France (13,5%), Italy (10,7%) and the Netherlands (8,9%). In addition, the sector is responsible for the direct employment of about 1,2 million people in Europe and it supplies almost all sectors of the economy (textiles, construction, agriculture, transport, health, hygiene, housing, food…) because 56% of EU chemicals are sold as an input to other industrial sectors.

The important place of the chemical sector in the European economy and the use of multilingual labels to allow for economies of scale and to foster the internal market in Europe contribute to the EU dimension of the problems described above. More information on the size of the market of chemical products in EU is provided under the description of the baseline in Chapter 5.

The extent to which European consumers are impacted by the above mentioned problems also needs to be considered. According to the Special Eurobarometer 456, less than half of respondents (45%) felt informed about the potential dangers of chemicals in consumer products. Similarly, the behavioural experiment shows that for the current label, the objective understanding of product hazards, precautionary measures and ingredients were rather poor.

Finally, since only voluntary industry initiatives exist at EU level to use digital labels, there are only ad hoc practices by manufacturers, and therefore a very limited and inconsistent use of such labels across all EU Member States.

[280] Maggie Geuens, Dominic Byrne, Geert Boeije, Virginie Peeters and Bert Vandecasteele, 2021, "Investigating the effectiveness of simplified labels for safe use communication: The case of household detergents". International Journal of Consumer Studies, DOI: 10.1111/ijcs.12662.

Stakeholders affected by the problem

The (sub)problems identified lead to a variety of consequences:

Consumers: the apparent lack of understanding of the information on chemical labels is a significant issue as these are the primary tool for communicating the hazards associated with the use of certain products. Misunderstanding of their meaning may lead to the inappropriate use of products, potentially resulting in negative impacts to human health and/or the environment. Indeed, the main sources of information for consumers on the potential dangers of chemicals are product labels (used by 70%) and the media (53%).[281] A lack of understanding of chemical labels by consumers, leads to a lack of awareness about the dangers of chemicals, with a potential detriment for their health and safety.

Environment: in addition to the impacts on consumers' health, the inappropriate use of products can have negative effects on the environment, especially if the rules on dosage or disposal of the product, as communicated on the label, are not respected. Understanding of chemical labels is therefore of primordial importance to ensure a sustainable use of chemical products in the environment.

Industry: a cumulative costs assessment study found that certain chemical industries, in this case the detergents industry, faces a relatively high administrative burden to comply with EU legislation compared with other sub-sectors within the EU chemicals industry.[282] Further, an evaluation of the detergents regulation[283] found that labelling requirements are an important part of such administrative burdens and concluded that, in light of the above challenges, there may be a need to consider more innovative communication approaches to reduce information overload and to enable consumers to access additional information on the properties of products and on their safe use. In particular, the use of digital tools was put forward as a possible solution.

How will the problem evolve?

Without any interventions, the problems described above will continue to exist, and to have social, economic, and environmental consequences.

The foreseen revisions of CLP and the Detergents Regulation could have a positive impact and contribute to diminishing the problems related to the understanding of hazard and safety information by consumers and labels overloaded with information in the future. However, without any interventions to regulate and promote digital labelling, its use will remain inferior to its potential, with dispersed ad hoc practices by manufacturers across Europe.

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[281] Special Eurobarometer 456, 2017. Available at: https://europa.eu/eurobarometer/surveys/detail/2111.

[282] European Commission, 2016, Cumulative cost assessment for the EU Chemical Industry. Final Report. https://ec.europa.eu/docsroom/documents/17784/attachments/1/translations/en/renditions/pdf. See also A.I.S.E Factsheet, Findings for the detergents and maintenance products industry. https://www.aise.eu/documents/document/20161024164027-cumulative_cost_assessment_aise_factsheet_oct_2016_final.pdf

[283] Commission Staff Working Document, Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents: https://ec.europa.eu/docsroom/documents/36289

The description of how the problems will evolve in the future without intervention is further expanded in the Chapter 5, in the description of policy option 0.

The ongoing developments in the context of the Digital Product Passport and the development of a GHS framework for digitalisation means that eventually there would the risk of future inconsistencies or shortcomings in EU legislation.

OBJECTIVES

The general objective of the digitalisation of labelling requirements under the CLP regulation is **to ensure and improve consumer safety, in light of the digitalisation trend**. In other words, the policy options developed under this initiative must ensure a higher or at least the same level of safety for consumers using chemical products, while allowing industry and society to reap the benefits of digitalisation for chemical labels.

This general objective is in line with the objectives of the CLP Regulation, to ensure a high level of protection of human health and environment as well as the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation.[284]

This general objective is also aligned with the general Treaty-based objective of good functioning of the internal market and protection of consumers as enshrined in the TFEU and with the Commission's long-term objective to make Europe fit for the digital age, allowing citizens and businesses in Europe to seize the potential of digitalisation.[285]

More specifically, the objective of this annex is to explore the possibilities of setting up a future proof regulatory framework allowing the use of digital tools, and to improve consumer understanding and awareness through improved communication of product information.

The public consultation on the revision of the CLP Regulation found that respondents across all stakeholder groups believe the inclusion of digital labels such as QR codes to be useful, and agreed that there would be cost savings from providing some mandatory information digitally rather than physically on the packaging. In particular, respondents providing position papers across all stakeholder groups (except for 'EU and Non-EU citizens') supported digitalisation of labels to improve communication of relevant product information, even though it was highlighted that care must be taken as not all users may have access to digital information.

Furthermore, concerning chemical labelling in general, the public consultation on the revision of the CLP Regulation found that, when given the option to provide less but clearer information on labels or 'as much information as possible', most respondents (80%) indicated that they would prefer less but clearer information. In addition, companies and business associations in particular (but also some citizens, public authorities and civil society organisations) expressed concern that hazard and precautionary statements need to be simplified.

[284] Recital 1 of the CLP Regulation.
[285] European Commission, A Europe fit for the digital age. https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age_en

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BASELINE

Establishing a baseline

The baseline scenario allows for a comparison of the expected effects of the identified policy options against environmental, economic and social trends, as well as legal and political developments, including on global level. In particular, the implementation, in the European Union, of the latest GHS revision and the activities stemming from the Strategic Approach to International Chemical Management, in particular related to waste management.

For the forecast analysis, a 20-year period for the projections has been considered.

The following chapters describe the current situation concerning the critical developments in the EU population, technological uptake of consumers and enterprises and the size of the chemical industry in the EU.

Population

Developments in the EU population described in the paragraph below are highly important to this study considering the prospects of using digital labels in the future by vulnerable consumers. Analysis of using digital labels needs to be performed in terms of considering the impact of digital labels to the consumers with visual, hearing and mobility impairments as well as older consumers, or consumer with limited to no access to the internet.

Concerning vulnerable consumers, the population of the European Union is ageing rapidly. According to Eurostat data, physical and sensory functional limitations increase by age group: on an average 26.8% of population experience a form of limitation (e.g. seeing, hearing or walking). This share increases to 37.1% for the age group above 75 years old[286]. As an example, at current projections, assuming a constant share of over 75 years olds with physical and sensory functional limitations, the number of EU citizens affected would increase from 16.2 million in 2020, to 20 million in 2030 and 25 million in 2040. This trend is in line with one of the "megatrends" identified Commission's Megatrends Hub namely "Increasing demographic imbalances"[287]

According to Eurostat projections, the overall population in the EU27 is expected to slightly decrease in the 20-year period taken into account, from around 447,7 million (2020) to 446,7 (2040). However, more significant changes are expected in terms of age composition. In particular, the share of the population above 65 years old, which in 2020 accounts for 21% of the overall population, is expected to increase to 28% in 2040. In particular, the population above 75 years old, which today accounts for 45 million citizens, should increase by 11 million by 2040.

Figure 71: Physical and sensory functional limitations by sex, age and educational attainment level

[286] Most recent Eurostat data available for the year 2014.
[287] See: Increasing demographic imbalances | Knowledge for policy (europa.eu)

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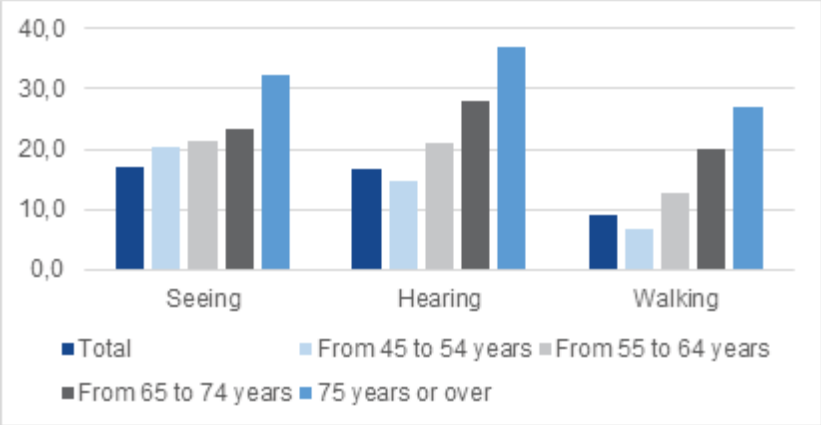


Source: Eurostat ([hlth_ehis_pl1e]), VVA elaboration

Technological uptake of consumers

Technological uptake is relevant for the analysis of a regulatory intervention that would entail the use of electronic labels on chemical products. For this analysis we have considered statistics on the use of the internet in the last 3 months. The trends that are described in more detail in the paragraphs below correspond to one of the megatrends in the Commission's Megatrends Hub namely "Accelerating technological change and hyperconnectivity". *According to the latest Eurostat data[288], the percentage of individuals increased considerably in the last 10 years, going from 72% of the EU27 population in 2012 to 89% in 2021. This technology update has seen a strong increase also amongst older groups of citizens. The percentage of individuals in the age group between 55 and 64 years old increased by 34% between 2012 and 2021 and doubled the percentage of individuals in the age group between 65 and 74 years old (from 28% in 2011 to 61% in 2021). According to this trend, it is expected that in the next 10 to 20 years nearly the whole EU27 population will use the internet regularly. Further, digital inclusion is an EU-wide effort to ensure that everybody can contribute to and benefit from the digital world. The EU is fostering digital inclusion through several policy areas, including digital skills and social inclusion. The use of electronic labels could be of particular relevance for online purchases. According to most recent data on e-commerce , the share of European population that reported having made an online purchase in the previous 12 months, in 2021 was 66%. A share that decreases from an average of 81% for the age groups between 16 and 34 years old, to 54% for the age group 55-64 and around 35% for the age group 65-74. According to a trend analysis, however, it is expected that, at this rate, the share should increase up to 100% in less than 15 years from now.*

Another relevant aspect of the technological uptake relevant for the definition of the baseline for this study is the percentage of EU27 population that uses a smartphone. This is particularly relevant if the proposed electronic labels would require the use of these devices able to scan and access data provided online.

[288] Eurostat, Individuals - internet use [isoc_ci_ifp_iu]

According to the latest available data[289] the percentage of EU27 population that accessed internet with the use of a mobile phone was 71%. Lower shares for older groups of citizens (i.e. 45% in the age group 55-74 years old). Also this indicator has shown a steady increase in the last 10 years. However, the data in this case are also strongly influenced by the availability on the market of mobile devices with internet capabilities.

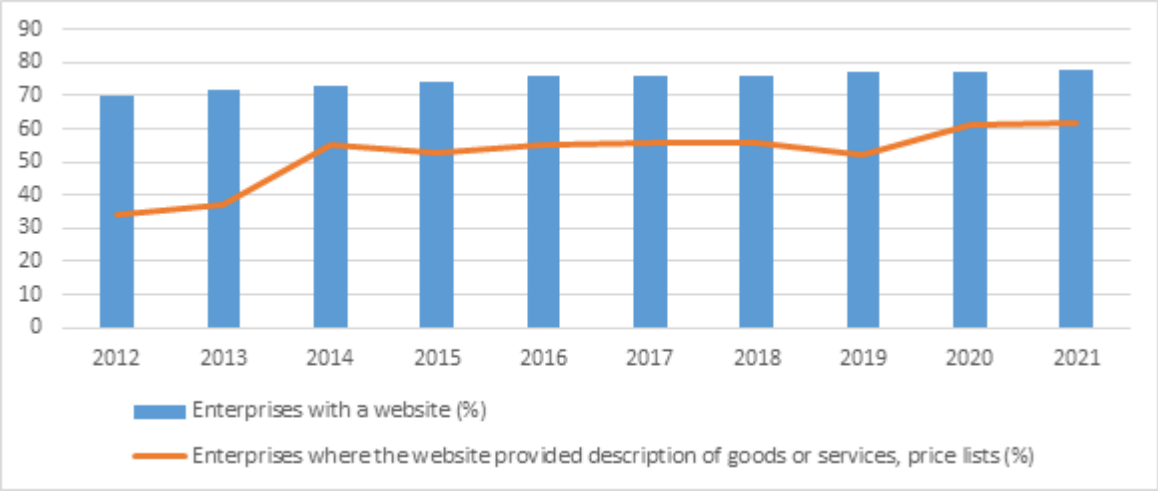
These trends suggest that, in the next 10-20 years, the share of the population accessing the internet via mobile phone will increase substantially. This assumption, however, does not necessarily imply universal access or smartphone use: as mentioned by a consumer organisation, people living in remote areas where internet is not available, or economic reasons may mean that some population groups remain digitally excluded. Any regulatory change, must therefore ensure that safety standards are not lowered, for any category of stakeholder.

Technological uptake of enterprises

Digitalisation of businesses is a critical aspect for the uptake of electronic labels by enterprises. As for consumers, the trends described below are related to the Commission's Megatrends Hub namely "Accelerating technological change and hyperconnectivity" .

Statistics show a small, but steady, increase of the share of companies that have a website. More importantly, is the data on the percentage of enterprises that use their website to provide description of goods and services and price lists amounts to 62% across all sectors, and 76% for chemical manufacturers. This is a good indicator of the potential readiness of businesses for the uptake of electronic labels.

Figure 81: Digitalisation of enterprises



Moreover, data from 2021 shows that 78%[290] of businesses use websites to provide information about their products or services and their prices. This share increases to 94%

[289] Eurostat, Individuals - mobile internet access [isoc_ci_im_i]
[290] Digital economy and society statistics, Enterprises with a website [isoc_ciweb]

amongst manufacturers of chemical products[291]. In addition, 76% of manufacturers in the chemical sector, provide online descriptions of their goods and/or price lists.

For what concerns digital tools and innovative communication methods, it is important to take into account the following aspects:

1. **Industry experience with online ingredient information**: according to the Detergents Regulation, manufacturers already have the obligation to publish on a website the ingredient datasheet of their products. This means that manufacturers already deliver activities related to the collection of information and publication of these data online. The costs related to the collection of these information should not be additional for the provision of electronic labels;

2. **Increased market penetration of digital tools** such as barcodes, QR codes and websites to convey product information. This trend has increased the awareness of consumers on the use of these tools. In particular, during the recent pandemic, QR codes have been widely used, for example as an integral part of the EU Digital COVID certificate. It can, therefore, be assumed that a large share of the population is familiar with the use of this technology;

3. **The GHS has embarked on defining a framework for digital labelling which would be followed by implementation at EU level**. Discussions started in 2019 regarding the possibility of digitalisation of information for chemical products. Thus, even in the absence of a direct intervention at EU level now, digital labels might eventually be introduced in the EU market through a revision of GHS standards. Preparing EU businesses early will allow spreading investments over a longer period of time and provide a competitive advantages once the relevant GHS standards become applicable;

4. **Increased rules at EU level on communication of product information via digital tools** (i.e. for the labelling of wine , electronic instructions for use of medical devices and digital labelling for batteries), as well as the upcoming **Digital Product Passport** (under the Sustainable Products Initiative) will set out the rules for digital provision of suitability criteria of products. These parallel initiatives on the introduction of digital labels in the EU suggest that electronic labelling would be introduced for chemical products even if not directly related to a revision of the CLP or Detergents regulations; and

5. The industry is already starting to **voluntarily develop and use digital labels** which could lead to market fragmentation (i.e. a multitude of different systems at national level or even at company level) if no common framework is established.

Chemical Sector Statistics

Analysis of the current size and magnitude of the chemical industry in the EU is crucial to understand the market that is affected by the problems outlined in Chapter 2 and would be

[291] Digital economy and society statistics, Enterprises with a website [isoc_ciweb], Manufacture of chemicals and chemical products (10 or more employees and self-employed persons).

subject to the policy options. The size and structure of this market will have a strong impact on the economic costs and benefits that any regulatory intervention entails. As described in more detail in the tables below, throughout the EU, there are over 21 thousand chemical enterprises, directly employing over a million of EU citizens and generating over a billion EUR of turnover annually. These statistics, however, do not take into account the businesses that are indirectly linked to the chemical industry, either up- or downstream in the supply chain (e.g. retailers) and should therefore be seen as a very conservative estimate of the market size.

For the analysis conducted in this study, in particular concerning impacts on costs, the sectors in scope are the ones subject to CLP and Detergents Regulations, in particular manufacturers of chemicals and chemical products (NACE C20), manufacturers of coke and refined petroleum products (NACE C19), manufacturers of rubber and plastic products (NACE C22).

In particular, according to the NACE rev.2 classification, the sectors in scope are:

Manufacture of refined petroleum products (CLP)
Manufacture of other inorganic basic chemicals (CLP)
Manufacture of other organic basic chemicals (CLP)
Manufacture of plastics in primary forms (CLP)
Manufacture of synthetic rubber in primary forms (CLP)
Manufacture of paints, varnishes and similar coatings, printing ink and mastics (CLP)
Manufacture of soap and detergents, cleaning and polishing preparations (CLP and Detergents)
Manufacture of explosives (CLP)
Manufacture of glues (CLP)
Manufacture of essential oils (CLP)
Manufacture of other chemical products n.e.c (CLP).
Manufacture of basic iron and steel and of ferro-alloys (CLP)

The table below presents market data in terms of the number of enterprises, turnover, production value, value added and persons employed.

Table 110: Chemical sector statistics 2018

	Enterprises - number	Turnover - million euro	Production value - million euro	Value added at factor cost - million euro	Persons employed - number
Manufacture of refined petroleum products	814	457.631,4	381.931	30.119,7	161.678
Manufacture of other inorganic basic chemicals	912	26.166,5	24.620	7.651,0	63.508
Manufacture of other organic basic chemicals	1.885	185.876,6	159.483	44.264,4	224.137
Manufacture of plastics in primary forms	2.263	99.386,4	92.239	18.892,0	133.112
Manufacture of synthetic rubber in primary forms	179	4.755,5	4.569	1.167,2	7.225
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3.356	41.987,8	37.859	11.266,8	150.384
Manufacture of soap and detergents, cleaning and polishing preparations	3.877	21.903,4	19.855	5.904,9	85.544
Manufacture of explosives	501	2.080,6	1.936	830,2	12.983
Manufacture of glues	481	4.360,8	3.962	1.152,7	13.977
Manufacture of essential oils	773	7.379,7	7.085	2.257,7	20.655
Manufacture of other chemical products n.e.c.	3.968	62.203,8	52.499	15.230,5	119.762
Manufacture of basic iron and steel and of ferro-alloys	2.616	161.636,4	159.856	29.308,0	331.670

Source: Eurostat

Amongst the sectors in scope, the manufacture of chemicals and chemical products is the largest with a total number of enterprises close to 28.000 in 2018. Most of these companies are SMEs as shown in the table below.

Table 111: Number of enterprises by size (2018)

Enterprise number	Total	From 0 to 9 persons employed	From 10 to 19 persons employed	From 20 to 49 persons employed	From 50 to 249 persons employed	250 persons employed or more
Manufacture of coke and refined petroleum products	868	522	92	97	78	79
Manufacture of chemicals and chemical products	27.986	19.447	2.732	2.510	2.504	793
Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	8.346	5.549	813	793	861	330
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3.356	1.998	468	408	364	119
Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	9.765	7.568	793	617	609	178
Manufacture of other chemical products	5.723	3.863	586	607	549	119

Source: Eurostat

Baseline scenario

Under the baseline scenario no further policy intervention would be introduced. The purpose of the baseline is to have a comparison for the estimate for the impacts of the other policy options and assess the costs and benefits of the "status quo" to which other policy options are compared to.

The findings of a legal analysis, the interviews, and the behavioural experiment, conducted under the VVA 2021 study on digital labelling[292], findings indicate that the labelling requirements of the CLP Regulation are still relevant in fulfilling their objective of communicating hazard and safety information as well as use instructions to users. More specifically, the legal analysis shows that the labelling provisions of the Detergents Regulation are "without prejudice" to the provisions of the CLP and, where applicable, they will be added to the CLP requirements.

For what concerns digital tools and innovative communication methods, it is important to take into account the following aspects:

[292] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and use of e-labelling

1. The increased market penetration of digital tools such as barcodes, QR codes and websites to convey product information. This trend has increased the awareness of consumers on the use of these tools. In particular, during the recent pandemic, the use of QR codes has been widely used, for example as integral part of the EU Digital COVID certificate.[293]

2. The GHS has embarked on defining a framework for digital labelling. Potentially, in case of a definition of an international GHS framework on digital labelling, a subsequential implementation at EU level would follow up. Discussions have started in 2019 regarding the possibility of digitalisation of information for chemical products.[294] Development on this topic suggest that, even in absence of a direct intervention at EU level, the use of digital labels will have to be introduced in the EU market though a revision of the GHS standards.

3. Increased rules at EU level of the communication of product information via digital tools (i.e. for the labelling of wine[295], electronic instructions for use of medical devices[296] and digital labelling for batteries[297]), as well as the upcoming Digital Product Passport (under the Sustainable Products Initiative)[298] which will set out the rules of digital provision of suitability criteria of products. Parallel initiatives on the introduction of digital labels in EU suggest that electronic labelling could be introduced in EU for chemical products even if not directly related to a revision of the CLP or Detergents regulations;

4. The industry is already starting to develop and use digital labels which could lead to market fragmentation (i.e. a multitude of different systems at national level or even at company level) if no common framework is established.

All of these developments point towards the fact that digital labels will be necessary in the future to present and/or sell products online, and that therefore, the costs to develop these

[293] EU Digital Covid Certificate: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

[294] (AC.10/C.4) ECOSOC Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (38th session). Report available at: https://unece.org/info/events/event/19153

[295] Regulation (EU) 2021/2117 of the European Parliament and of the Council of 2 December 2021 amending Regulations (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products, (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2117&qid=1645715904558

[296] COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226, of 14 December 2021, laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2226

[297] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020, COM/2020/798 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0798&qid=1639045049210

[298] Work in progress, for more information please see: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12567-Sustainable-products-initiative_en

digital labels will occur in any event. However, without a common framework at EU level, the market fragmentation would likely lead to higher costs.

Regarding the use of e-labels, this policy option would foresee no changes in the status quo meaning that industry would continue to provide mandatory information on physical labels. Manufacturers would continue to adopt e-labels according to their own preferences and with no specific measure regarding the type of IT solution to be used, or the quality of information provided.

Physical vs electronic label under the baseline

In the current regulatory framework, the use of electronic labels is not regulated, thus, manufacturers are not allowed to replace (partially or totally) the physical labels with electronic ones.

The use of e-labels is voluntary and not regulated. As previously mentioned, however, some requirements already exist for duty holders that are relevant for our analysis, in particular:

Safety Data Sheets that need to contain the labelling information of the CLP Regulation pursuant to Article 31 of the REACH Regulation need to be provided by suppliers who place a substance or mixture on the market[299]; This is increasingly (but not always) done in an electronic manner;

Under Article 40 of CLP, manufacturers or importers, or a group of manufacturers or importers, are obliged to notify information to the European Chemicals Agency (ECHA) on the substances they place on the market;

Under Article 45 of CLP, downstream users and importers are obliged to notify nationally or to ECHA relevant information to provide emergency health response, which shall be received by national appointed bodies (poison centres).

These processes involve largely or fully the digital processing and/or communication of labelling elements. Therefore, we assume that there is already an "administrative burden" related to notifications to be carried out electronically for duty holders due to the provision of information under CLP Articles 40 and 45 to a public authority. This implies at least that duty holders have the relevant labelling elements on the substances and mixtures they place on the market already available in an electronic format and that it is unlikely that additional significant cost for digitalisation of physical labels will occur.

Description of Policy Measures

The legal analysis, the interviews and the behavioural experiment provided the basis for the identification of the policy options to simplify and streamline current labelling requirements, and to introduce the use of digital tools for parts of the labels falling within the scope of CLP and the Detergent Regulations.

[299] See Article 31 of the REACH Regulation read in combination with Annex II of that Regulation.

Policy measure 0: No new policy actions

Under this measure, no further policy intervention would be introduced. The purpose of the baseline is to establish a benchmark against which the impacts of the other policy options can be compared,

The findings of the legal analysis, the interviews, and the behavioural experiment, indicate that the labelling requirements of CLP are still relevant in fulfilling their objective of communicating hazard and safety information to users. The legal analysis suggests that the labelling requirements of the two Regulations (detergents and CLP) complement each other as both Regulations aim to protect the health of consumers, industrial and professional users. Indeed, as described above, the European chemical legislation is spearheaded by the REACH Regulation and the CLP Regulation which are setting the science-based horizontal legislative framework, and complemented by sector specific legislation (e.g. the Detergents Regulation), using the general framework to establish risk management measures as necessary.

However, some legislative overlaps between the CLP and the Detergents Regulations exist, notably regarding the labelling of allergenic fragrances, the labelling of surfactants and allergenic preservatives when CLP thresholds are met. These overlaps may create duplications in labelling requirements and consequently, redundant information that reduce the readability of a label and confuse users. For instance, labels of detergents, falling by default under both regulations, contain a duplication in labelling of substances (e.g. allergenic fragrances), and in addition they need to be indicated under different names (INCI names for preservatives and allergenic perfume ingredients according to Detergents Regulation, and chemical names according to CLP). More details on the regulatory overlaps are provided in the regulatory analysis in Annex 3.

Regarding the use of digital labels, this policy option would foresee no changes in the status quo meaning that industry would continue to provide mandatory information on physical labels. Manufacturers would continue to adopt digital labels according to their own preferences and with no specific measure regarding the type of IT solution to be used, or the quality of information provided, possibly even using proprietary systems that are incompatible with other systems used.

Physical vs electronic label under the baseline (option 0)

In the current regulatory framework, the use of electronic labels is not regulated, thus, manufacturers are not allowed to replace (partially or totally) the physical labels with electronic ones.

The use of digital labels is voluntary and not regulated. As previously mentioned, however, some requirements already exist for duty holders[300] that are relevant for our analysis, in particular: the Safety Data Sheets, notifications to ECHA, providing information for emergency health response and the obligations under the Detergents Regulation to make some information available on a website.

[300] Manufacturers, suppliers, importers, and downstream users of the products defined in the CLP and Detergents Regulations.

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These processes involve largely or fully the digital processing and/or communication of labelling elements. Therefore, we assume that there is already an "administrative burden" related to notifications to be carried out electronically for duty holders due to the provision of information under CLP Articles 40 and 45 to a public authority and a substantive cost of setting up a dedicated website due to Annex VII to the Detergents Regulation.

Furthermore, it is expected that the Digital Product Passport will already lead to the development of relevant databases and communication platforms that could be re-used for digital labelling elements under CLP and the Detergents Regulation.

Table 112: Policy measure 1: Non-legislative measures: Physical labels and voluntary use of e-label

Summary
Policy Measure 1: Non-legislative intervention which foresees no changes in the current mandatory regulatory framework. The intervention of the European Commission would be limited to the provision of a guidance document which would set non-mandatory standards (e.g. on how to present information) on the voluntary use of electronic labels (e.g. with recommended practices for better readability of information on the electronic label). Manufacturers would not be allowed to replace (partially or in total) physical labels with electronic ones. This option might also include the promotion of information campaigns on chemicals in consumer products to improve consumer understanding of dangers and information available on labels. Intervention: Policy measure: to create a new section/heading under ECHA's Labelling and Packaging Guidance with recommendations on the implementation of existing labelling requirements and effective communication for digital labelling.

Under Policy Measure 1, only non-legislative action to set out common practices in the implementation of existing labelling requirements will be taken. It should be noted that guidance documents were already developed by ECHA on the CLP Regulation[301]. While this guidance is appropriate it may be necessary to widen the communication efforts about the guidance to stipulate its use. In the next review of the guidance it could also be explored to elaborate further on the interaction between CLP and other relevant legislation such as the Detergent Regulation.

Commission or ECHA guidelines could provide more practical examples and informal notes on how to convey obligatory information (under the CLP Regulation) on the label without overwhelming users, in particular consumers, for example by simplifying and streamlining labels. However, such solutions would not remove any regulatory overlaps or inconsistencies as such. Furthermore, such guidelines could include best practices examples of the interplay between the CLP and the Detergent Regulations regarding labelling provisions. Nevertheless, such solution would not remove any regulatory overlaps or inconsistencies as such.

Regarding the use of digital labelling, the current legal labelling requirements do not allow duty holders to provide information only digitally, and digital communication on product

[301] ECHA, Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, March 2021. https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

labels is done only on a voluntary basis and supplementary to the physical label. Considering the opinions expressed so far in the Sub-Committee of the GHS, it likely that this will remain the norm for CLP.

However, guidelines and good practices examples on effective communication for digital labelling could support the industry in the uptake of digitalisation on a voluntary basis, e.g. to respond to market demands.

Regarding how to provide the above mentioned guidelines on how to convey obligatory information on the label and on effective communication for digital labelling, Policy Measure 1 considers to create a new section/heading under ECHA's Labelling and Packaging Guidance[302], designed to assist manufacturers in the effective application of the CLP Regulation, with new recommendations. As they are now, these guidelines provide a general overview of the CLP Regulation with explanations of the requirements for labelling and packaging, as well as practical examples illustrating different situations that may be encountered when designing labels. With this policy measure, this document could be completed with additional recommendations, especially on how to convey obligatory information without overwhelming users (and especially consumers), thus increasing the efficiency of the hazard communication to users without modifying the legal requirements. This additional guidance would aim to tackle the issue of the overloaded character of labels and the long texts in small prints, which, as highlighted by a majority of stakeholders during the interviews, reduce the readability and understandability of labels.[303] In addition, ECHA's Labelling and Packaging guidance could also include practical examples of effective communication for digital labelling, in order to incentivise a voluntary but standardised way of communicating information digitally. This part of the policy measure would address the objective (SO2) of setting up a framework allowing the use of digital tools to communicate product information. However, it must be noted that with this policy measure, this guidance would constitute a non-regulatory framework. Policy Measure 2: Revision of the labelling rules in the regulations: align the two regulations and address inconsistencies on the physical label only.

[302] ECHA, Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, March 2021. https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

[303] See Annex 1, Stakeholder consultation - Synopsis report, findings from the interviews.

Table 113: Policy Measure 2: Revision of the labelling rules in the regulations

Summary
Policy Measure 2: This policy measure would entail a regulatory intervention when revising the Detergents regulations to address inconsistencies, overlaps and duplications (also with CLP). This policy measure would not entail any possibility for manufacturers to replace (partially or in total) physical labels with electronic ones and the use of electronic labels would remain voluntary and with the provision, at EU level, of guidelines on the use of digital tools. • Interventions on CLP Regulation: None. • Interventions on Detergents Regulation: ○ Sub-measure 2a: the Detergents Regulations provides that the identified overlapping provisions are to be labelled only once, either following the CLP or Detergents Regulation, based on the stricter rules; Sub-measure 2b: all overlapping provisions are removed from the Detergents Regulation.

This policy measure would entail a regulatory intervention when revising the Detergents Regulation to address the identified legal overlaps, inconsistencies and duplications. This policy option contribute to the achievement of the first specific objective identified (SO1), to improve consumer understanding and awareness of labels, especially for vulnerable consumers, by simplifying and streamlining the existing labelling requirements in the Detergents Regulation only.

This policy measure would not entail any possibility for manufacturers to replace (partially or in total) physical labels with digital ones, and the use of digital labels would remain voluntary and with the provision, at EU level, of guidelines on the use of digital tools (as described under Policy measure 1).

This policy measure would not necessitate any regulatory interventions on the CLP Regulation. The legal overlaps, inconsistencies and duplications identified would be addressed with a regulatory intervention when revising the Detergents Regulation. Although no regulatory changes would be made to the CLP regulation, addressing the issues in the Detergents Regulation, will address overlaps identified in both Regulations.

First, labelling requirements under the Detergents Regulation that would need to be streamlined to avoid overlaps, inconsistencies and duplications with the CLP Regulation. These regulatory changes include the following:

Where labelling provisions of CLP (hazard pictograms, hazard statements, precautionary statements, etc.) fulfil the requirements of the Detergents Regulation, Article 11(3), the standard phrases under the CLP Regulation would be used to warn consumers, industrial and professional users;

Ensure that for mixtures the provisions of Annex VII C of the Detergents Regulation do not duplicate those of Article 45 and Annex VIII of the CLP;

Secondly, this policy measure aims to simplify and clarify the rules on labelling of allergenic fragrance ingredients in a way that the same fragrance ingredient falling within the scope of both Regulations is not labelled twice or thrice on the same label. This simplification should also consider the existing differences between the two Regulations

in the identification of a substance, i.e., the name (and identification number) under which the sensitising fragrance is to be labelled. To this purpose, this policy option is declined under two sub-options, as follows:

Sub-measure 2a: the Detergents Regulations provides that the remaining overlapping provisions are to be labelled only once, either following the CLP or Detergents Regulation, based on the stricter rules;

Sub-measure 2b: all overlapping provisions are removed from the Detergents Regulation.

These overlaps concerns the inclusion of skin sensitisers (i.e. allergenic substances like preservatives and fragrances) in the list of ingredients that need to figure on the product label when they are present above certain thresholds, considering that most allergenic fragrance ingredients under the Cosmetic Products Regulation are also classified as skin sensitisers under CLP. These thresholds in CLP are lower than those provided in the Detergents Regulation. Therefore, according to sub-measure 2a, when these substances are present in a detergent, they should be labelled according to the stricter rules provided in the Detergents Regulation (i.e. labelled as soon as the lowest threshold is reached). However, in the sub-measure 2b, the labelling requirements concerning the allergenic fragrance ingredients will be removed from the Detergents Regulation and when these substances are present in a detergent, they would be labelled according to the CLP Regulation. To this regard, in sub-measure 2b, less allergenic substances would be labelled (due to higher thresholds to reach).

The analysis and impacts of this policy measure are included in the parallel Staff Working Document of the Detergents Regulation targeted revision.

Policy measure 3: Revision of the labelling rules in the regulations, introducing digital labelling: keep basic information of labelling requirements on physical labels, and move certain labelling requirements on the digital label only.

Table 114: Policy measure 3

Summary
Policy measure 3: This policy measure would entail a regulatory intervention to allow manufacturers to use electronic labels, on a voluntary basis, to provide specific pieces of information to users in alternative to physical labels. This policy measure does not allow for a complete replacement of the physical label. Still, it will enable manufacturers to provide some mandatory details online while keeping basic mandatory information on the physical label. From Policy measure 3 onwards, the policy options would also include the regulatory interventions discussed under Policy measure 2 to streamline the regulatory framework under the Detergents Regulation. In addition, this policy measure would entail the introduction of a common framework for digital labelling in each piece of legislation (i.e. in the CLP and Detergents Regulation, but also in other legislation such as the Fertilising Product Regulation). This common framework for digital labelling would need to be kept aligned between the relevant legislation. Such a framework would include mandatory principles on the provisions of this information to ensure higher consumer protection standards. Such principles would need to be common to all digital labelling solutions. **Labelling requirements under the CLP regulation** that would be allowed to be moved on a digital label under Policy measure 3: o Supplemental labelling information: a) EUH statements as per sections 1.1. and 1.2. of Annex II (Art. 25(1)) b) Other supplemental labelling information than that in paragraphs (1) and (2) of Art. 25 (Art. 25(3)) c) EUH statements as per Part 2 of Annex II for certain mixtures (Special rules for supplemental label elements for certain mixtures, Art. 25(6))

This policy measure is the first to introduce the possibility for duty holders to partially replace physical labels with digital labels for the provisions of some specific pieces of information which are currently mandatory. Providing information electronically would remain voluntary.

From Policy measure 3 onwards, the policy options also include the regulatory interventions foreseen under Policy measure 2 in the Detergents Regulation, which are needed to streamline the regulatory framework and remove inconsistencies and duplications.

It must be noted that the framework for digital labelling would need to be introduced in each piece of legislation (i.e. in the CLP and Detergents Regulation, but also in other legislation such as the Fertilising Product Regulation). This common framework for digital labelling would need to be kept aligned between the legislation. Alternatively, the framework for digital labelling could also be included in CLP, with downstream legislations (e.g. the Detergents Regulation) making reference to these overarching rules. This option would allow the digital labelling framework to remain consistent over time and the potential revisions without having to amend each downstream legislations.

The possibility for manufacturers to adopt digital labels would also require the introduction of mandatory principles on the provisions of this information to protect end-users and to ensure the accessibility and the availability of the digital information. Such principles should ensure accessibility of information and further assist in enforcing the rules.

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Digital labelling should *at least* comply with the following general requirements:

The obligation for the digital label to include the full set of labelling information (i.e. there should not be a split of information between the physical and digital label), to ensure that the information provided online is meaningful;

The obligation to provide all digital data in one place, separately from other commercial information (e.g. the mandatory information shall not be displayed together with other information intended for sales or marketing purposes). Coherence should also be sought with other digital provision of information of products (e.g. under the Digital Products Passport);

The format of the data provided digitally must be appropriate (e.g. rules on font size, the content of the digital label must be searchable);

The protection of personal data (e.g. prohibition of collecting and tracking user data or using that information for commercial purposes) in accordance with Regulation (EU) 2016/679[304];

Accessibility of the data both in terms of ease of access (e.g. "two-click" maximum rule to access the information), and in terms of accessibility for users (e.g. also for users with disabilities). Access to the digital label must be free and without a need for prior registration or a password, or prior download of applications. Access limitations for certain user groups (e.g. geo-blocking in accordance with Regulation (EU) 2018/302[305]) are not allowed;

Minimum technical requirements are to be complied with, in order to ensure technological neutrality of IT solutions used. The IT solution must be easily readable via widely used digital technologies. It must be ensured that the data can be accessed, navigated and read on, and is compatible with all major operating systems and browsers. Information must also be available for old browser version and operating systems;

The information must be provided equally in all official languages of the EU Member States in which the product is marketed. Additional languages are permitted; Users must have the possibility to select their language of choice, regardless of their physical location.

Appropriate alternative ways of providing information must be available in case of lack of digital tools or skills, or in the absence of network access (e.g. a print-out label at the point of sale);

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[304] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0679-20160504

[305] Regulation (EU) 2018/302 of the European Parliament and of the Council of 28 February 2018 on addressing unjustified geo-blocking and other forms of discrimination based on customers' nationality, place of residence or place of establishment within the internal market and amending Regulations (EC) No 2006/2004 and (EU) 2017/2394 and Directive 2009/22/EC: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32018R0302

The IT solution must be printed or placed physically, visibly and legibly on the product. When appropriate under the overall labelling requirements of the product in question, where this is not possible or not warranted on account of the nature and size of the product, the IT solution shall be affixed to the documents accompanying the product.

The data contained under the digital label must remain accessible as long as the product that it refers to, are sold and used in the European Union, or as long as the conformity assessment documentation is required to be kept, where relevant. The data present on the digital label must remain available even after the bankruptcy, the liquidation or the cessation of activity in the EU of its originator;

Further, the overarching principle that guides the selection of *what* information could be moved to an online label is to ensure that it does not lower the level of safety and therefore decrease consumer protection. In this regard, the results of the behavioural experiment show that a simplified label can perform, in terms of consumers' safety, as well as the current physical labels.

Commitments of the EU under GHS limit the option to move information exclusively to the digital label because GHS mandates the use of a physical label. Statements made during the discussions on a digitalisation framework suggest that the presence of the information on a physical label is considered essential for safety and it is currently considered unlikely that the future GHS framework on digitalisation would change that.

Labelling requirements under the CLP regulation that would theoretically be allowed to be moved on a digital label under Policy measure 3 are the supplemental labelling information[306], as provided in Article 25 of the CLP Regulation (as this information as not covered by GHS). More specifically, these would include:

- EUH statements as per sections 1.1. (physical properties) and 1.2. (health properties) of Annex II of the CLP regulation. These include statements that shall be assigned in accordance with Article 25(1) to substances and mixtures classified for physical, health, or environmental hazards.

- Other supplemental labelling information, in accordance with Article 25(3). These include supplemental information included by the supplier to provide further details on the label elements referred to in Article 17(1) (a) to (g), i.e. the name, address, and telephone number of the supplier(s), the nominal quantity of the substance or mixture, the product identifiers, the hazard pictograms, the signal words, the hazard statements, and the appropriate precautionary statements.

- According to Article 25(6), EUH statements as per Part 2 of Annex II for certain mixtures containing any substance classified as hazardous.

However, it must be noted that this does not concern the supplemental information coming from other legislation (e.g. biocides, ODS).

[306] This does not include the supplemental information coming from other legislation (e.g. Biocidal Product Regulation).

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Policy measure 4: Revision of the labelling rules in the regulations, introducing digital labelling: further simplify physical label, and move additional information on the digital label

Table 115: Policy measure 4

Summary
Policy measure 4: Similar to policy measure 3, policy measure 4 would entail a regulatory intervention to allow manufacturers to use electronic labels, on a voluntary basis, to provide specific pieces of information to users in alternative to physical labels. As provided under Policy Measure 3, Policy measure 4 would also include the regulatory interventions discussed under Policy measure 2 to streamline the regulatory framework under the Detergents Regulation. In addition, as under Policy Measure 3, this policy option would entail the introduction of a common framework for digital labelling in each pieces of legislation, as well as common principles on the provisions of this information to ensure higher consumer protection standards. This policy measure does not allow for a complete replacement of the physical label. Still, it will enable manufacturers to provide mandatory details online while keeping basic mandatory information on the physical label. Policy measure 4 would be a further extension of the possibilities offered to manufacturers under policy option 3 to provide additional information on a digital label. Regarding **the labelling requirements under the CLP Regulation**, Policy Measure 4 foresees that in addition to the information allowed to be provided online under Policy Measure 3, the list of information that could be provided only online is extended to: Hazard statements (Art. 21 CLP); Precautionary statements (Art. 22 CLP).

The Policy Measure would also include the regulatory interventions discussed under Policy measure 2 to streamline the regulatory framework under the Detergents Regulation.

This policy option foresees the possibility for manufacturers to introduce additional information, further to that specified under Policy measure 3.

From a legal point of view and in the context of the CLP Regulation, Policy measure 4 would deviate from the GHS quite significantly in the context of CLP labelling. Therefore, it must be emphasised that this policy option is included in order to assess the impacts of its policy measures, as put forward by stakeholders, but is unlikely to be implemented under the revision for the CLP regulation.

As provided under Policy measure 3, this policy measure would entail the introduction of a framework for digital labelling in each pieces of legislation (i.e. in the CLP and Detergents Regulation, but also in other legislation such as the Fertilising Product Regulation). This common framework for digital labelling would need to be kept aligned between the legislation.

The possibility for manufacturers to adopt digital labels would also require the introduction of mandatory principles on the provisions of this information to ensure higher consumer protection standards. Such principles (as developed in Policy measure 3) would need to be common to all digital labelling solutions.

Regarding the information that could be provided digitally, Policy measure 4 includes the labelling information as provided and described in Policy measure 3. In addition, under

Policy measure 4, the list of labelling requirements from the CLP Regulation that could be provided only online is extended to the following:

- The relevant hazard statements, as per Article 21 of CLP;
- The relevant precautionary statements, as per Article 22 of CLP.

Policy measure 5: Revision of the labelling rules in the regulations, introducing digital labelling: In specific cases, option of providing all information on digital label

Table 116: Policy measure 5

Summary
Policy measure 5: This policy measure entails the possibility for manufacturers of providing mandatory information exclusively on electronic labels in specific cases and/or specific products (e.g. products which are sold without original container, or products for which a container is too small to physically include all mandatory information). As provided under policy measure 3, Policy measure 5 would also include the regulatory interventions discussed under Policy measure on 2 to streamline the regulatory framework under the Detergents Regulation. In addition, similarly to policy measure 3, this policy measure would entail the introduction of a common framework for digital labelling in each piece of legislation, as well as mandatory principles on the provisions of this information to ensure higher consumer protection standards. Regarding **the products falling under the CLP Regulations**, this option should be assessed only for: • Re-fill chemicals (e.g. , detergents, fuels to be filled in jerry-cans (not in tanks), paints etc.) • Writing instruments including hazardous inks (pens, highlighters etc.) • Lighters

Under Policy Measure 5, in addition to the previous policy option, manufacturers would be allowed, for some specific products or types of sale, to provide the mandatory information under the CLP and Detergents Regulations exclusively on digital labels.

As provided under Policy measure 3, this policy option would also include the regulatory interventions discussed under Policy measure 2 to simplify and streamline the regulatory framework under the Detergents Regulation. It also entails the introduction of a framework for digital labelling in each pieces of legislation (i.e. in the CLP and Detergents Regulation, but also in other legislation such as the Fertilising Product Regulation). This common framework for digital labelling would need to be kept aligned between the legislation.

The possibility for manufacturers to adopt digital labels would also require the introduction of mandatory principles on the provisions of this information to ensure higher consumer protection standards. Such principles (as developed in Policy measure 3) would need to be common to all digital labelling solutions.

This policy measure applies only to products where the packaging is either in such a shape or form or is so small that it is impossible to meet the labelling elements under Article 17 (products falling under Art. 29(1) of CLP, where the label elements may be provided *on*

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fold-out labels, tie-on tags, outer packaging"). Such a change would require a specific labelling provision for those products. In practice these products are currently very often not labelled at all, despite the legal obligations due to practical difficulties to comply with the rules. While allowing for digital labelling in those cases would not offer the same level of protection compared to a physical label, it would increase the safety level compared to the *de-facto* absence of a label.

As these products usually contain only very small amounts of hazardous substances and contact with them is limited, a digital label may be an acceptable compromise between consumer protection and the additional cost to ensure appropriate labelling, which would in the end result into higher consumer prices. In addition, enforcing proper labelling would in most cases mean that the products would need to be individually packaged thus creating a huge amount of packaging waste that may in turn increase the environmental and climate footprint of the product.

Regarding **the labelling requirement set up in the CLP**, Policy measure 5 considers the possibility to provide all mandatory labelling requirements digitally for the following specific products only:

- Re-fill chemicals: detergents, fuels to be filled in containers (not in tanks), paints;
- Writing instruments (e.g. pens, highlighters etc.);
- Lighters.

The problems related to the labelling of those items are discussed exhaustively in Annex 12. This policy measure will, therefore, be significantly influenced by the policy option and measure selected under that the general CLP labelling rules.

DESCRIPTION OF IMPACTS

In alignment with the provisions of the Better Regulation Toolbox, the first step in the assessment of impacts is the identification of all relevant impacts under the different policy options. The identification of the impacts is based on data and information collected during the previous tasks (i.e. interviews, behavioural experiment, survey and analysis of OPC responses). The research collected qualitative information and quantitative data on social, economic and environmental impacts related to the identified policy options.

Socio-economic and environmental impacts identified have been categorized according to the following criteria:

- **Economic impacts**, in particular focusing on conduct of business (BR Tools #21-25), sectoral competitiveness, trade and investment flows (BR Tools #21, 27), impact to the SMEs (BR Tool #21), technological development / digital economy (BR Tool #28), and impact to public authorities (BR Tool #58);
- **Social impacts**, focusing consumers and households (BR Tool #33);
- **Environmental impacts**, in particular focusing on sustainable consumption and production (BR Tool #36).

The impacts that have been taken into account for this analysis are considered to be the most relevant and the ones for which consulted stakeholders were able to provide insights. A dedicated survey targeting public authorities, consumer organisations and industry

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representatives (associations and businesses), presented the individual policy options and asked participants to provide a direct feedback. The opinions of stakeholders have been triangulated with other data sources used in the study.

This section provides an assessment for each identified impact that is relevant to the assessment of the options and the identification of a preferred option.

Table 117: Assessment of impacts

Colour coding	--	-	O	+	++	U
Qualitative	Strongly negative	Weakly negative	No or limited impact	Weakly positive	Strongly positive	Undefined

Policy measure 0: No new policy measures

The status quo has been extensively discussed in the previous chapters. This analysis highlighted the following issues:

There are a number of overlaps and inconsistencies in the labelling requirements between CLP, Detergents and other relevant legislative acts;
In some cases, there are difficulties for consumers to understand information provided by labels.

In addition, the current legal (mandatory) requirements do not incentivise the use of more innovative techniques and digital tools (i.e. digital labelling) and when it happens, industry uses these digital tools on a voluntary and unharmonised basis, in addition to the physical labels required by law.

This policy measure would not address any of the problems identified in Chapter 2 and it would continue to lead to improper use of detergents by consumers, burdensome administrative activities for businesses and a wrongful disposal of chemical products that can be harmful for the environment. Moreover, this policy measure is not in parallel with recent market developments and ongoing initiatives in the EU described in more detail in chapter 5.1.4, "other policy developments" of the SWD, that aim to promote the use of digital labels and reduce the severity of some of the problems identified in Chapter 2.

Taking into consideration the previously mentioned issues, stakeholders have been consulted regarding their overall assessment of the current regulatory framework (CLP and Detergents) with the objective of having a benchmark to assess the proposed policy options.

The overall opinion of the consulted stakeholders on the status quo is not particularly positive, with public authorities having a slightly more positive view than industry stakeholders[307].

[307] Based on the findings from the online survey on Policy Options. On a scale from -5 to 5, 12 survey respondents belonging to public authorities, on average, have rated the current framework as fairly positive (2.5), while 54 respondents from the industry, on average, have rated the status quo as fairly negative (-1.5).

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Table 118: Economic impact assessment Policy Measure 0

Type of impact	Assessment	Score
Conduct of business (Tools #21-25)	Based on the findings from the behavioural experiment, according to 90% of consulted representatives of Public Authorities and 70% of industry representatives, the information currently provided on labels and SDS are adequate to ensure a safe use of products. Very few respondents (6%) gave a negative opinion. Findings from the online survey for professionals and industry users strongly support this argument as 74% of respondents from industry think that information currently provided on labels is easy to understand and only 10% of professional and industry users think that information provided on product packaging is difficult to understand. Taking into consideration of these results, professional users are overall content with the pieces of information currently available on the labels and the understandability of this information. Industry respresentative pointed out that frequent legislative changes incur annual cost for disposal of old labels which are considered by a large majority of the industry stakeholders (70%, 27 out of 38) as high or very high. Companies that have provided estimates mentioned that, in total, these costs reach up to 1 % of annual turnover. I should be noted though that changes in CLP that affect the classification of chemicals always come with a transition period during which old labels can still be consumed. Furthermore, labelling changes are not only triggered by legislation but also done for marketing purposes. The information provided did not allow to distinguish what factors exactly are causing the costs mentioned.	Weakly negative
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	This policy measure should have no particular impact for the competitiveness of the industry considering that it would not entail any regulatory change and the provision of information would still remain on physical labels and safety data sheets.	Neutral
SMEs (Tool #21)	This policy measure does not have any specific impact on SMEs as cost of conducting business for SMEs would remain unchanged.	Neutral
Technological development / Digital economy (Tool #28)	Amongst industry respondents to our survey comparing the policy options (in large part, large enterprises), 60% indicated to be using a form of digital tool (e.g. QR codes) to provide information to consumers and 90% see the use of such tools positively. Businesses in the chemical industry are already highly involved in using digital tools to provide information to the consumers. The absence of regulatory support to foster the transition towards digital labelling tools could thus have negative consequences on the development of the digital economy. Under Policy measure 0, in the same survey, stakeholders were asked to indicate their preference on the form of database providing electronic labels. Public authorities expressed a general preference either for a centralised EU database provided by an EU wide authority/provider, but they also responded positively to electronic labels handled by manufacturers through their websites for their own products. For industry respondents, on the other hand, the preferred option would be to have an electronic label directly on their own website in order to have greater control about the information provided to consumers. However, it is important to consider that most industry respondents in the study were large enterprises. Creation of the online database, particularly the decentralised database, would be aligned with the aims of the Digital Product Passport (DPP) since, according to the Sustainable Products Initiative, it will be mandatory for companies to adopt digital ways of communicating information about products. Hence, under the adoption of DPP, companies will have to handle additional costs anyway to comply with this measure and communicate the information about their products online. Therefore, when calculating the costs for the companies to place their digital labels online (if the decentralised database approach was selected) it is important to highlight that development costs would be mandatory under the DPP and, thus, only the costs of adding the CLP module in their databases should be taken into account.	Weakly negative
Public authorities (Tool #58)	This policy measure would have no impact on public authorities.	Neutral

Table 119: Social impact assessment Policy measure 0

<table>
<tr><th>Type of impact</th><th>Assessment</th><th>Score</th></tr>
<tr><td>Consumers and households (Tool #33)</td><td>Based on the findings from the survey on the policy measures, the consulted public authorities in general reported a very positive opinion on the importance of information currently required on the labels[308] (on a scale from -5 to +5 the average response was 4) apart from ingredients that, despite the wide range of opinions, on average scored only moderately positive in terms of the safe use of products.
Industry stakeholders (associations and companies) thought that the most important information in terms of safe use of products are the general product information and the signal words, followed by the hazard communication information and the precautionary statements. Dosage information imposed by the Detergents Regulation follows with a moderately positive score. As above, ingredients scored lowest among industry stakeholders.
Table 120: To what extent is the current information provided to consumers on labels able to ensure safe use of the products? (Please consider -5 as the least appropriate ; 0 as neutral and +5 as the most appropriate.)[309]
<table>
<tr><th></th><th>Public authorities</th><th>Industry representatives</th></tr>
<tr><td>General product information[310]</td><td>4</td><td>3</td></tr>
<tr><td>Ingredients[311]</td><td>2</td><td>-3</td></tr>
<tr><td>Hazard communication (including pictograms and statements)[312]</td><td>4</td><td>2,5</td></tr>
<tr><td>Precautionary statements[313]</td><td>4</td><td>2,5</td></tr>
<tr><td>Signal words[314]</td><td>4</td><td>3</td></tr>
<tr><td>Dosage (Detergents Regulation)[315]</td><td>4</td><td>2</td></tr>
</table>
Considering the importance of these pieces of information present in the label, the consulted stakeholders were asked to assess how problematic current labels can be for consumers with vision, colour blindness, cognitive/learning and mobility or physical impairments. According to 58% or respondents of public authorities and 64% of respondents from industry, current labels are problematic for consumers with vision impairment[316]. 45% of respondents from public authorities and 41% from industry, report a negative impact on consumers with colour blindness.[317] Current labels are considered also problematic by half of respondents (both public authorities and industry representative) for consumers with learning/cognitive impairments. More neutral the opinion for consumers with other impairments.</td><td>Weakly negative</td></tr>
</table>

[308] General product information, Ingredients, Hazard communication (including pictograms and statements), Precautionary statements, Signal words, Dosage.
[309] Results provided in the table represent average rating of the piece of information in terms of its importance to ensure safe use of the products
[310] 12 responses from public authorities, and 46 responses from the industry representatives.
[311] 12 responses from public authorities, and 52 responses from the industry representatives.
[312] 13 responses from public authorities, and 53 responses from the industry representatives.
[313] 13 responses from public authorities, and 51 responses from the industry representatives.
[314] 12 responses from public authorities, and 48 responses from the industry representatives.
[315] 12 responses from public authorities, and 37 responses from the industry representatives.
[316] Based on the findings from the online survey on Policy Options. Seven out of 12 respondents belonging to public authorities, and 30 out of 47 respondents representing the industry.
[317] Based on the findings from the online survey on Policy Options. Five out of 11 respondents belonging to public authorities, and 20 out of 49 respondents representing the industry.

Table 121: Environmental impact assessment Policy Measure 0

Type of impact	Assessment	Score
Sustainable consumption and production (Tool #36)	Concerning environmental aspects, the analysis is limited to awareness of consumers about the impacts of dispersion of substances in the natural environment. The analysis does not include an estimate of waste generated by regulatory changes since legislative revisions include, where relevant, long enough transition periods during which old labels and packaging can be used to avoid costs for duty holders and the creation of waste. Under the Baseline Policy Option, digital labelling would remain voluntary, and no such waste in this case should not apply anyway. Based on the findings from the survey, both public authorities and industry representatives believe that current labels have a positive or very positive impact on the awareness of consumers about the impact of dispersion of harmful substances in the natural environment (82% of public authorities, 50% of industry representative[318]).	Weakly positive

Policy measure 1: Non-legislative measures: Physical labels and guidelines for the voluntary use of digital label

Overall assessment

There were opposing views among stakeholders on the introduction of industry guidelines for the use – albeit voluntary – of electronic labels. In general, while consumer organisations and public authorities see this policy measure positively, this assessment was not shared by industry representatives.

More specifically, policy measure 1 would entail interventions on the CLP regulation, summarised in:

- **Policy measure:** Create a new section/heading under ECHA's Labelling and Packaging Guidance with recommendations;

Regarding this policy measure, public authorities, on average, responded positively to the adaptation of the guidelines (80% gave a positive score), while industry representatives, on average, saw this intervention slightly negative. Industry representatives argue that this Policy measure does not address the requirements on the safety use of the physical labels nor does it incentivise companies to use digital labels (60% of the industry stakeholders).

The views gathered concerning this policy measure by stakeholders is similar to the preceding policy measure: on average public authorities responded positively to the adoption of guidelines (89% gave a positive score), while industry representatives expressed overall a negative appreciation (56% gave a negative score). Overall, industry representatives provided that this policy measure would not incentivise manufacturers' adoption of digital tools for those who do not already use them (60% answered negatively).

[318] Based on the findings from the online survey on Policy Options. 10 out of 12 respondents from public authorities, and 25 out of 51 respondents from the industry.

Table 122: Economic impact assessment Policy measure 1

Type of impact	Assessment	Score
Conduct of business (Tools #21-25)	Compared with PM0, this policy option should have no particular impact for professional users considering that it would not entail any regulatory change and the provision of information would still remain on physical labels and safety data sheets. The cost of conducting business remain the same as per the baseline scenario.	Weakly negative
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	This policy option should have no particular impact for the competitiveness of the industry considering that it would not entail any regulatory change and the provision of information would still remain on physical labels and safety data sheets.	Neutral
SMEs (Tool #21)	Just as with professional users, PM1 would have no impact on SMEs. The cost of conducting business remain the same as per the baseline scenario.	Neutral
Technological development / Digital economy (Tool #28)	According to 45% of public authorities, the use of guidelines is considered strongly positive (on average, the option received a score of 8/10 in terms of digitalisation). Industry stakeholders thought that such guidelines would not be very coherent with the digitalisation trends and assign an average score of 2/10.	Neutral
Public authorities (Tool #58)	In this specific policy option, considering that the intervention would mean updating the ECHA guidance for CLP and the FAQ for detergents, no specific enforcement costs for public authorities were considered. Public authorities and industry associations indicated that updating guidelines carries relatively low costs. None of the participating stakeholders indicated a high cost for the development of such guidelines.	Neutral

Table 123: Social impact assessment Policy measure 1

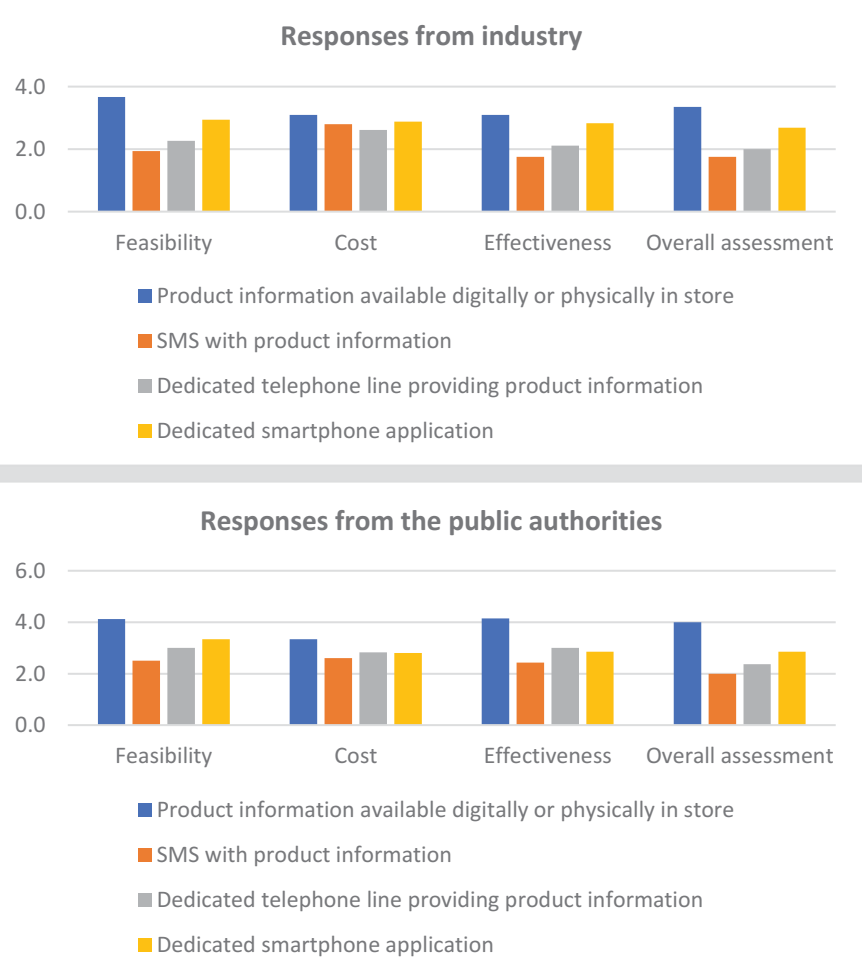
Type of impact	Assessment	Score
Consumers and households (Tool #33)	The update of guidelines – according to public authorities - would have a marginal, yet positive, impact on consumer awareness. Indeed, public authorities responding to the survey thought that the introduction of guidelines might have a positive impact in terms of increased safety for consumers, awareness and consumer choice. However, for more than half of industry respondents, the use of guidelines would have no impact on consumer safety. Regarding the impact on vulnerable consumers, for a third of public authorities and half of industry representatives, PM1 would have no impact on this group with slightly positive effects, according to public authorities, for consumers with visual and cognitive/learning impairments. Only a third of industry participants to the survey consider PM1 as potentially having a positive impact on consumers with visual impairments, colour-blind and with cognitive/learning difficulties. The analysis included also the assessment of potential alternative solutions. In general, consulted stakeholders from industry reported an overall preference for the availability in store of information on products (either digitally or physically). This option is considered the most feasible by stakeholder but also the most costly. The most cost-effective solution would be a dedicated telephone line providing the required product information, while the least cost-effective solution being the use of SMS with product information. **Figure 82: Stakeholders assessment of backup solutions (responses from the industry and public authorities)** 	Weakly positive

Table 124: Environmental impact assessment Policy measure 1

Type of impact	Assessment	Score
Sustainable consumption and production (Tool #36)	Regarding the impact of PM1 on consumer awareness about the impact of dispersion of harmful substances in the natural environment, the survey shows that both public authorities and industry representatives consider this policy option as relatively neutral. Half of participating public authorities believe the guidelines might have a minor positive effect, while 84% of industry respondents consider PM1 as potentially having a neutral or slightly positive effect.	Neutral

Policy measure 2: Revision of the labelling rules in the regulations: align the two regulations and address inconsistencies in the Detergents Regulation on the physical label only

Overall assessment

The consulted stakeholders had an overall positive view about the alignment of the two regulations and the revision of the Detergents Regulation to address inconsistencies, overlaps and duplications on the physical label. All of the stakeholders representing public authorities (11) assessed policy measure 2 as positive with eight out of 11 stakeholders assessing the policy measure as very positive and rating the assessment of the policy measure as 4 or 5 out of 5. On the other hand, industry representatives had a slightly less positive opinion on the policy measure, with 62% of these stakeholders (16 out of 26) assessed policy measure 2 as positive.

The legal intervention foreseen under Policy measure 2 to streamline the labelling requirements between the CLP Regulation and the Detergents Regulation between the two regulations was agreed by all categories of stakeholders during the interviews, especially by industry representatives who insisted on the benefits of this intervention to remove duplications of information on chemical labels and thus create more space for other information to be conveyed in a more readable manner.

First, labelling requirements under the Detergents Regulation would need to be streamlined to avoid overlaps, inconsistencies and duplications with the CLP Regulation. In addition, policy measure 2 aims to simplify and clarify the rules on labelling of allergenic fragrance ingredients in a way that the same fragrance ingredient falling within the scope of both Regulations is not labelled twice or thrice on the same label. This simplification should also consider the existing differences between the two Regulations in the identification of a substance, i.e., the name (and identification number) under which the sensitising fragrance is to be labelled.

For this purpose, this policy measure is declined under two sub-options, as follows:

- Sub-measure 2a: the Detergents Regulations provides that the remaining overlapping provisions are to be labelled only once, either following the CLP or Detergents Regulation, based on the stricter rules;

- Sub-measure 2b: all overlapping provisions are removed from the Detergents Regulation.

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Regarding the assessment of these two sub-options in the survey, it must be noted that public authorities and consumer organisations had no particular preference on either of these sub-options, while industry representatives expressed a slight preference for sub-measure 2b arguing that sub-measure 2b would be more straightforward to apply for industry. However, it must be noted that removing the overlaps between the two regulations would also mean that the thresholds for labelling some allergenic fragrances would be higher, thus indicating a potential concern that consumers might be less informed about the presence of these substances in detergents.

In addition, one of the findings from the Open Public Consultation was that stakeholders, in general, believe that the most effective method to increase the communication of information on labels of chemicals is by simplifying the text on labels[319], while, on the other hand, one of the least effective ways to increase the communication, according to the respondents, was having more detailed information provided on the on-pack label (e.g. more detailed use instructions, etc.)[320]. Moreover, the most popular response to the question on how the information on detergents label could be simplified was "Avoiding that the same ingredient is listed multiple times on the label"[321], which stresses the importance of simplifying physical labels and avoiding the duplications due to overlaps between the CLP and Detergent Regulations.

Provides information about the impact of Policy measure 2. However, as outlined above, these impacts will occur due to changes in the Detergents Regulation, not due to changes in CLP. The impacts are, therefore, not considered for this impact assessment and provided here only for information. The changes in the Detergents Regulation will address the issues identified in the chemicals Fitness Check.

[319] Most popular option among the stakeholders with 24% of the votes (160 out of 675 total votes)
[320] Third least popular option among the stakeholders with 3% of the votes (19 out of 675 total votes)
[321] Most popular option among the stakeholders with 22% if the votes (113 out of 522 total votes)

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Table 125: Economic impact assessment Policy measure 2

Type of impact	Assessment	Score
Conduct of business (Tools #21-25)	Based on the findings from the survey on the policy options, around 80% of the consulted stakeholders from public authorities think that addressing the inconsistencies, overlaps and duplications on the physical label would have a positive impact on professional users in terms of label readability, and overall safety of products dedicated to professional and industrial users. On the other hand, only around half of the industry stakeholders believe that this policy measure would bring positive impact to professional users concerning these aspects. Concerning the costs, according to the large majority (around 80%) of consulted industry stakeholders, the costs or benefits of the revisions under policy measure 2 would generate **none to very low impact on enterprises**. More specifically, around 50% of industry stakeholders believe that the clarifications under policy measure 2 **would not generate relevant costs for companies**, and 31% consider that such revisions would generate **low costs**. Consulted stakeholders from the companies that sell detergents argue that the costs associated with policy measure 2 would be one-off cost related to the disposal of the non-compliant labels, however, companies would not face any recurring annual costs after this has been done. These costs, although low in scale, would vary greatly depending on the size of the production and the timeline designated for the implementation of the regulatory changes. In terms of benefits, only 20% of industry respondents consider the revisions under policy measure 2 to provide economic benefits to businesses arguing that although the communication of the safe use of the product would increase under the policy measure, all impacted product physical labels would still need to be updated to comply with the new regulation, therefore, increasing costs even if low. In the long term, however, industry stakeholders see the possibility of **less re-labelling in the future due to new fragrances falling under CLP Sub measure 2b**. This way, there is a potential for less re-labelling and recreation of labels for skin sensitisers (i.e. sensitising) substances like preservatives and fragrances as fewer of these substances would need to be labelled.	Neutral
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	Large part of consulted stakeholders could not provide an opinion on the expected impact of policy measure 2 on competitiveness. Amongst respondents, according to 45% of consulted public authorities, policy measure 2 would not have an effect on competitiveness of European companies. 26% of industry representatives also consider that policy measure 2 would not have an impact on competitiveness of enterprises, while 10% of respondents consider the possibility that policy measure 2 would have a negative impact. In conclusion, consulted stakeholders generally estimate that the impact of policy measure 2 on competitiveness would be minimal and negligible.	Neutral
SMEs (Tool #21)	According to consulted stakeholders, the majority (both public authorities and industry representatives) consider that the provisions under policy measure 2 would not impact SMEs disproportionately in comparison to larger enterprises.	Neutral
Technological development / Digital economy (Tool #28)	Policy measure 2 is a regulatory alignment of the Detergents Regulation and it does not include the use of digital labels. Therefore, there is no information on the alignment with digitalisation trend.	Neutral
Public authorities (Tool #58)	The majority of consulted stakeholders (82%) estimate that the provisions of policy measure 2 would not generate costs – or very low costs – for public authorities. On the other hand, nearly half (45%) of consulted public authorities reported that policy measure 2 would generate a benefit thanks to the simplification and streamlining of the regulatory framework. Representatives from the public authorities argue that changes under policy measure 2 would not require extra surveillance from them, yet, aligning the regulations and inconsistencies could make it more simple for end users and consumers to read and understand the label of certain products, which would in turn simplify the guidance of national authorities.	Strongly positive

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Table 126: Social impact assessment Policy measure 2

Type of impact	Assessment	Score
Consumers and households (Tool #33)	In terms of the impact of the proposed policy measure 2 on the awareness of consumers, addressing inconsistencies, overlaps and duplications on the physical label – according to both public authorities and industry representatives – would have an overall positive impact on consumers. More specifically, label readability would be improved according to a large majority of public authorities (90%, 11 out of 12) and of industry representatives (85%, 22 out of 26).	Weakly positive

Table 127: Environmental impact assessment Policy measure 2

Type of impact	Assessment	Score
Sustainable consumption and production (Tool #36)	Based on the survey findings, the majority of public authorities (55%) answered that addressing the inconsistencies overlaps and duplications on the physical label would bring a positive impact to the awareness of consumers on the effects of dispersion of harmful substances in the natural environment. However, a majority of the industry representatives (over 80%) think that this Policy Option would not bring any positive impact to the environment. Stakeholders from industry claim that current overlaps between CLP and Detergents Regulation do not specifically consider environmentally hazardous substances.	Neutral

Policy measure 3: Revision of the labelling rules in the regulations, introducing optional digital labelling: keep basic information of labelling requirements on physical labels, and move certain labelling requirements on the digital label only.

Overall assessment

According to consulted stakeholders, the average assessment of Policy measure 3 for both public authorities and business representatives is positive. Public authorities have, on average, a more positive view with half of respondents reporting a very high score for Policy measure 3. Industry representatives, on average, also reported an overall positive position with more than 80% of participants in the survey assessing the policy option positively.

More specifically, policy measure 3 entails specific provisions affecting CLP (e.g. the possibility to provide overlapping information between precautionary statements and hazard statements and supplemental labelling information online), and the proposal of principles of application of digital labels. During interviews, stakeholders from all categories agreed that hazard information (encompassing notably the hazard statements) was one of the most useful information to be conveyed to consumers. However, they also noted that in some cases there could be an overlap or a redundancy of information given between the hazard statements and the precautionary statements, and that this redundancy could be addressed to simplify and optimise space on the label. This findings was confirmed by the feedback collected in the survey where, according to public authorities, this intervention on the CLP Regulation under Policy Measure 3, is considered positively by 73% of participants. A large majority of industry representatives (82%) also confirmed this positive assessment. However, the study did not identify any noteworthy overlap.

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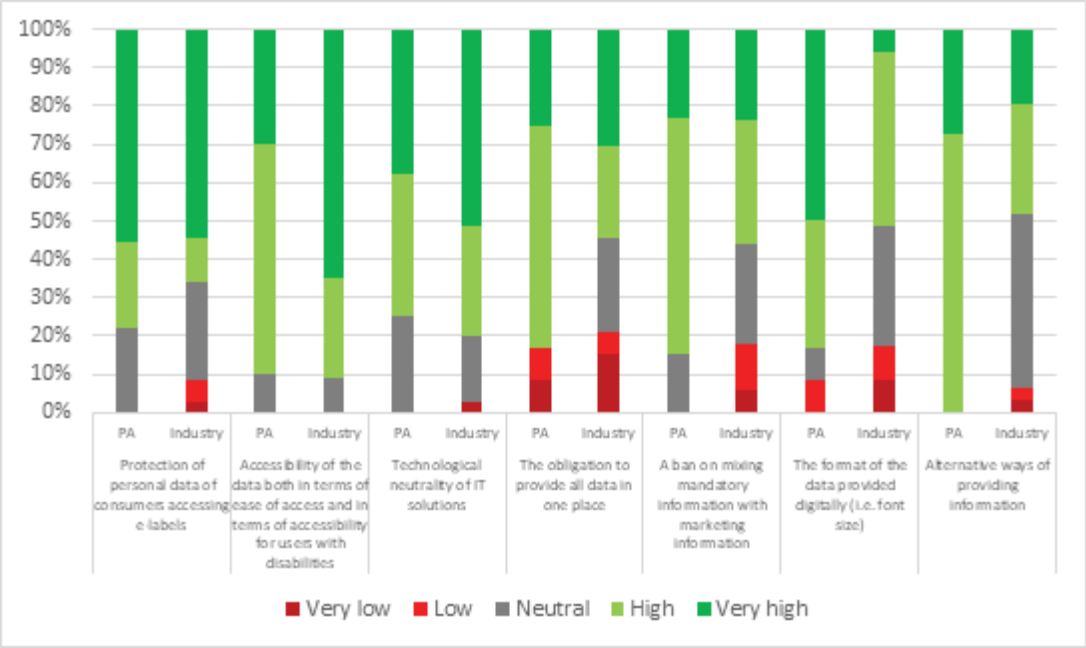
In the survey, consulted stakeholders were also asked to provide an assessment of the proposed principles for the use of digital labels. The overall feedback is that all the proposed principles are highly relevant. As shown in the chart below, the principles with the highest agreement are:

1. Accessibility of data in terms of ease of access (i.e. "two-click" maximum rule to access the information) and accessibility for users with disabilities;

2. Technological neutrality of IT solutions (i.e. minimum technical requirements to be complied with in order to ensure technological neutrality); and

3. Protection of personal data.

Figure 83: Feedback of consulted stakeholders on digital labelling principles[322]



Source: Online survey on the policy options.

Stakeholders had mixed opinions regarding the obligation to provide all data in one place and on the format to be used for the provision of digital data (i.e. font size) with around 20% of industry respondents expressing a negative view on the mentioned principles. However, overall also for this principle there was overall support.

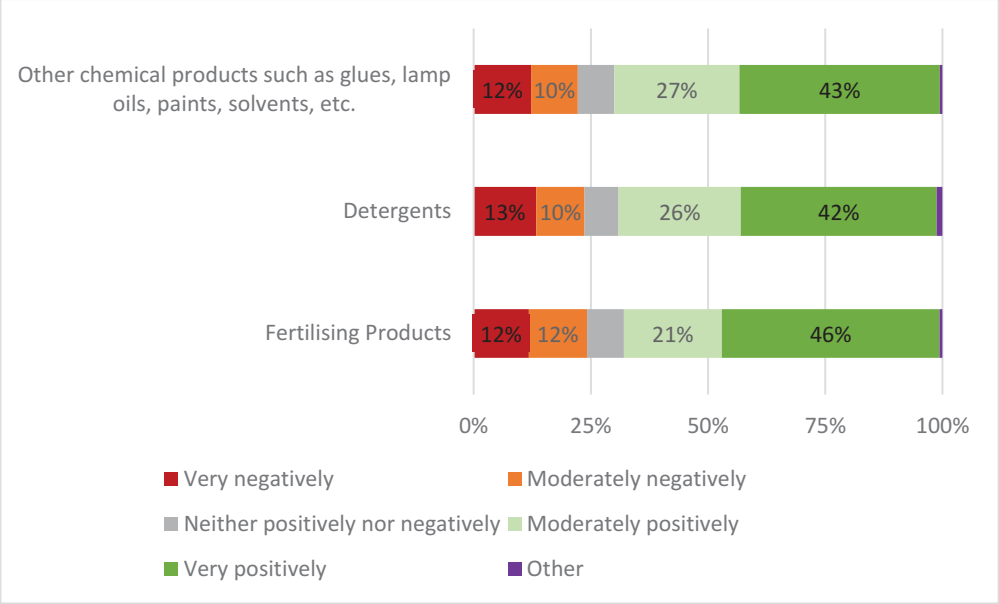
Some industry representatives also expressed a negative view about a centralised EU database for providing information digitally. Such a database would force companies to adopt a digital solution, the structure of which would be managed externally. Since

[322] Protection of personal data of consumers accessing e-labels: PA = 9, industry = 35 ; Accessibility of the data both in terms of ease of access and in terms of accessibility for users with disabilities: PA = 10, industry = 34; Technological neutrality of IT solutions: PA = 8, industry = 35; The obligation to provide all data in one place: PA = 12, industry = 33; A ban on mixing mandatory information with marketing information: PA = 13, industry = 34; The format of the data provided digitally (i.e. font size): PA = 12, industry = 35; Alternative ways of providing information: PA = 11, industry = 31.

companies work differently, it could take a long time to establish such a centralised database.

Furthermore, based on the findings from the Open Public Consultation, the majority of the consulted stakeholders[323] think that, in the context of detergents, fertilising products, and other chemical products, removing some of the information from the on-pack label to the digital labels would have a moderately positive or a very positive effect overall.

Figure 84: In the context of the below chemical products, how would you evaluate it if some information was removed from the on-pack label and could only be obtained via digital labels?



Source: Open Public Consultation. Respondents: N = 153 for Fertilising Product, N= 165 for Detergents, and N = 180 for other chemicals.

However, citizens and consumer organisations had mixed views on moving the information from physical to digital labels as around half of the stakeholders representing consumers supported the process of moving the information, while the other half opposed this action.[324]

In terms of the benefits associated with digital labelling, the majority of the respondents rated all the listed benefits[325] as moderately beneficial or extremely beneficial with "Better

[323] 125 out of 180 respondents who have answered to a part on the other chemical products such as glues, lamp oils, paints, solvents, etc., 112 out of 165 respondents who have answered to a part on the detergents, and 103 out of 153 respondents who have answered to a part on the fertilising products.
[324] For 'other chemicals', 25 out of 52 respondents expressed a very negatively or a moderately negatively impact, and 24 out of 52 expressed a moderately positively or very positively impact. For detergents, 21 out of 49 respondents expressed a very negatively or a moderately negatively impact, and 22 out of 48 expressed a moderately positively or very positively impact. For fertilising products, 23 out of 47 respondents expressed a very negatively or a moderately negatively impact, and 18 out of 47 expressed a moderately positively or very positively impact.
[325] The listed benefits included: "Better management of fast changing label information", increased ease of complying with labelling requirements", better targeted communication" and "cost savings".

management of fast changing label information" considered most beneficial[326], and "cost savings" as least beneficial".[327]

Concerning challenges, around half of respondents assessed "Increased costs associated with training"[328] and "Increased costs associated with changes to design /packaging"[329] as **little challenging or not challenging at all**, while around half of the respondents rated the "Implementing IT solutions"[330] as **moderately or extremely challenging**. Overall, only a minority of respondents considered the introduction of digital labelling as extremely challenging.

Table 128: Economic impact assessment Policy measure 3

Type of impact	Assessment	Score
Conduct of business (Tools #21-25)	Regarding the possible impacts of policy measure 3 measures on professional users, the opinion of consulted stakeholders changes marginally in comparison to the assessment for consumers. More specifically, the survey finds that around 60% of PA respondents consider the possibility to provide on digital labels only overlapping information on p-statements (Art. 22 CLP) with H-statements (Art.21 CLP) as positive for professional user safety (30% estimate a negative impact). A large share of industry representatives reported a neutral position on this measure (39% of industry respondents) and 57% indicated a positive impact on safe use of professional users. In addition, 71% of professional users view the possibility of using online electronic labels for chemical products positively. **Overall, stakeholders expect a generally positive impact of PO3 CLP measures.** In terms of costs, industry stakeholders generally (66%) believe costs for individual manufacturers to comply with policy measure 3 would be slightly higher than the benefits (59%) and this holds true for both the revisions in CLP and Detergents Regulations. Although it is difficult to estimate the costs of introducing a digital label and moving some of the information online, stakeholders from the industry explained that it would take around **three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level**. It is important to highlight though that under policy measure 3, businesses would have to decide themselves if they want to turn to digital labelling as it would be done on a voluntary basis. In regards to other costs that are related to the compliance with the regulatory changes (implementation of IT solutions, maintaining website for the e-labels, managing different data formats, costs associated with changes to design/packaging, etc.), currently, manufacturers are already providing a digital version of their products information, either on the digital versions of the SDS or for the information obligations towards the poison centres. In addition, market data show that a large majority of businesses already have an online website which could host such information. In addition, once set up and automated maintenance costs would be expected to be minimal. Thus, even if the potential operational costs and benefits under policy measure 3 could not be monetised, the overall assessment suggests that the costs would be	Weakly positive

[326] 111 out of 124 respondents (90%) have selected options "Extremely beneficial" or "Moderately beneficial".
[327] 65 out of 117 respondents (56%) have selected options "Extremely beneficial" or "Moderately beneficial".
[328] 61 out of 122 total responses (50%).
[329] 66 out of 128 total responses (52%).
[330] 63 out of 127 total responses (49.5%).

Type of impact	Assessment	Score
	negligible or low. In addition, market practices suggest that, in most cases, enterprises out-source and use third-party software for the management of information on labels. Therefore, third-party software would be likely to financially benefit from this policy measure. In terms of the benefits of the revisions under policy measure 3, industry stakeholders consider the possibility to reduce the frequency of changes in physical labels, and better management of fast changing label information. These potential benefits, however, could not be estimated quantitatively due to the wide range of variables affecting labels (e.g. size of the label, number of ingredients, type of chemical product, etc.).	
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	A large share of stakeholders could not provide an opinion on the expected impact of policy measure 3 on competitiveness (72% of public authorities, 71% of industry representative). Amongst respondents, according to 27% of consulted public authorities, policy measure 3 would have a positive effect on competitiveness of European companies. 17% of industry representatives believed policy measure 3 would have a positive effect on competitiveness of EU enterprises while 12% of respondents believe that these measures would have a negative impact.	Neutral
SMEs (Tool #21)	Regarding the impact of policy measure 3 on SMEs, a large share of respondents could not provide an answer. According to most industry representatives (65%), the introduction of digital labels would not have a disproportionate impact on SMEs in comparison to large enterprises. However , amongst public authorities, the number of those expecting higher costs for SMEs is higher than those that would expect no difference.	Neutral
Technological development / Digital economy (Tool #28)	In general, the opinion of consulted stakeholder about the coherence of policy measure 3 with market digitalisation trends is particularly high for both PA respondents (6,5/10 score) and industry representatives (7/10 score). Industry respondents were also asked if, under policy measure 3, they would see an incentive for businesses to use digital labels. There was a positive response from 75% of respondents.	Strongly positive
Public authorities (Tool #58)	According to the majority of consulted stakeholders (75%), the provisions of policy measure 3 would not generate costs – or very low costs – for public authorities. Nonetheless, only around one-third (30%) of consulted public authorities reported that policy measure 3 would generate a benefit for monitoring activities of Market Surveillance Authorities. Hence, impact to public authorities is negligible.	Neutral

Table 129: Social impact assessment Policy measure 3

Type of impact	Assessment	Score
Consumers and households (Tool #33)	Concerning the provision of supplemental labelling information on digital labels, the opinion of a large majority of stakeholders is positive: 78% of PA and 83% of industry representatives. The use of digital labels could have a negative impact on the well-being of groups of population without access to these digital tools (e.g. smartphone, internet access or other technical difficulties). According to consulted stakeholders, the majority (54%) of consulted public administrations and industry representatives considered this an important drawback to be taken into account. However, for those population groups the physical label with all critical information on it would remain available as today. The use of digital labels for the provision of product information is considered, by a majority of the consulted stakeholders, a solution that could improve the well-being of consumers with visual impairments. According to 70% of PA respondents and 64% of industry representatives, the impact on this group of consumers could be positive. According to stakeholders, the effect of electronic labels could be positive also for people affected by colour-blindness (40% of PA respondents and 57% of industry representatives). More neutral is the position of the majority of respondents regarding the potential impact of policy measure 3 and the use of digital labels on the well-being of consumers with other types of impairments (cognitive/learning and physical/mobility disabilities or others).	Strongly positive

Table 130: Environmental impact assessment Policy measure 3

Type of impact	Assessment	Score
Sustainable consumption and production (Tool #36)	Regarding the potential effects of policy measure 3 on consumer awareness about the impact of dispersion of harmful substances in the natural environment, half (50%) of PA respondents would expect a partially positive impact, while 30% had a neutral view. Similar views were expressed by industry respondents, where 61% would expect a positive impact and 35% had a neutral position.	Weakly positive

Policy measure 4: Revision of the labelling rules in the regulations, introducing digital labelling: further simplification of physical labels, and move additional information on the digital label

Overall assessment

The overall assessment of policy measure 4 is mixed and varies considerably between public authorities and industry representatives. While for public authorities the possibility for manufacturers to provide additional mandatory information exclusively on e-labels would have a quite negative impact, the average feedback from industry representatives is very positive.

According to participating public authorities, the assessment of the intervention under Policy measure 4 on the CLP Regulation is negative while a positive average assessment is reported by industry representatives. During interviews, stakeholders from all categories agreed that hazard information (encompassing notably the hazard statements) was one of the most useful information to be conveyed to consumers. In addition, communicating information on the safe and appropriate use of products to consumers – notably through precautionary statements – was also agreed by all stakeholders to be the most important

type of information to be communicated on chemical labels. Therefore, findings from the interviews rather point to the fact that stakeholders from all categories would asses negatively the possibility to provide this information exclusively on a digital label. Furthermore, it must be noted that, according to the findings of the behavioural experiment, for both products tested (glues and detergents), the hazard and precautionary statements on the label were the most relevant reason for rating the product as dangerous (69% for both product types) for consumers, which suggests that they are indeed most useful for consumers to be provided on pack.

Table 131: Economic impact assessment Policy measure 4

Type of impact	Assessment	Score
Conduct of business (Tools #21-25)	The opinion of stakeholders regarding the impact on professional users is similar to the views provided in general for consumers. Based on the survey findings, a majority of public authorities see the impact on professional users negatively while industry representatives see the provisions under PO4 as potentially positive. In fact, 71% of the professional and industry users view the possibility of using the online electronic labels for chemical products positively. More specifically, concerning the P-statements (Art. 22 CLP) and H-statements (Art.21 CLP), around 70% of the professional and industry users think that moving these pieces of information from physical to digital label would have no detrimental effects to workers' safety. Therefore, the opinion on the impact of PO 4 to the professional users has been marginalised across different categories of stakeholders as consumers and public authorities view the provisions under PO4 as negative. Concerning the costs, according to the large majority of consulted industry stakeholders, the proposed measures under PO4 would generate a high cost for companies (68%) which would however be compensated by larger benefits (79%). The costs for the implementation of a digital solution for individual companies under Policy measure 4 do not differ from the calculations made under Policy measure 3. Thus, the same type of costs should be considered for the assessment of this policy option. Nevertheless, the share of companies that would transfer some of the information from physical to digital labels would be larger as using digital labels would no longer be voluntary but mandatory. Thus, as under Policy Measure 3, industry stakeholders explained that it would take around **three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level**. In regards to other costs that are related to the compliance with the regulatory changes (implementation of IT solutions, maintaining website for the digital labels, managing different data formats, costs associated with changes to design/packaging, etc.), even if the potential operational costs and benefits under PO 4 could not be monetised, the overall assessment would suggest that size of the costs would be negligible or low. In regards to the benefits, according to consulted stakeholders, in addition to already mentioned benefits under Policy measure 3 (reducing the frequency of changes in physical labels, and better management of fast changing label information) Policy measure 4 would increase the share of information provided only on digital labels which would allow for more space on physical labels for multiple languages. This would allow for more cost-effective product distribution across EU markets and thus a larger benefit under Policy measure 4 than under Policy measure 3. These potential benefits, however, could not be estimated in monetary terms due to the wide range of variables affecting labels (e.g. size of the label, number of ingredients, type of chemical product, etc.).	Weakly positive
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	A large share of stakeholders could not provide an opinion on the expected impact of Policy measure 4 on competitiveness. There is no clear position of industry representatives on the effect on competitiveness of Policy measure 4 with half of respondents estimating a positive effect and another half estimating a negative effect. The position of	Neutral

Type of impact	Assessment	Score
	public authorities is clearer with 67% estimating a positive effect on competitiveness of EU enterprises under Policy measure 4.	
SMEs (Tool #21)	Regarding the impact of Policy measure 4 on SMEs, the opinion of consulted stakeholders is similar to Policy measure 3. Most public authorities would expect a disproportionate impact on costs for SMEs in comparison to larger enterprises because larger companies have more resources to successfully implement digital labels and, thus, have an advantage in providing information and marketing through digital labels when compared to SMEs. For industry representatives, no clear position is expressed, with half of respondents estimating disproportionate costs for SMEs and the other half estimating that there would be no difference between SMEs and larger companies.	Weakly negative
Technological development / Digital economy (Tool #28)	Both public authorities and industry representatives agree that Policy measure 4 is in line with digitalisation trends. While for public authorities the assessment of Policy measure 4 in terms of digitalisation is not higher than PO3, for industry representatives Policy measure 4 measures represent a higher level of alignment to digitalisation trends.	Strongly positive
Public authorities (Tool #58)	According to around one-fourth of the public industry stakeholders (23%), the provisions of Policy measure 4 would generate high or very high costs for public authorities. Nonetheless, only 9% of consulted public authorities reported that Policy measure 4 would generate a benefit for the monitoring activities of MSAs. According to the consulted public authorities, the benefits for public authorities would concentrate on the simplification and clarification of labelling requirements which would make the monitoring and the inspection process for the public authorities and the compliance process for the businesses equally easier. The benefit, however, is considered to be minimal even though the costs are not considered to be very high as well.	Strongly negative

Table 132: Social impact assessment Policy Measure 4

Type of impact	Assessment	Score
Consumers and households (Tool #33)	In general, policy measure 4 is considered as potentially **negative or very negative** according to 70% of participating public authorities. In contrast industry stakeholders estimate the expected impact on consumer safety as strongly positive (78%). Overall, stakeholders from the public authorities[331] and industry[332] both expressed support for the proposed interventions **on the Detergents Regulation** rather than the CLP regulation under Policy Measure 4. Moreover, respondents were asked to provide an individual assessment of the potential impact of CLP measures on consumer safety. The possibility of allowing H-statements and P-statements exclusively on digital labels is considered negatively by a large majority of public authorities: 78% against H-statements on digital labels and 64% against P-statements on digital labels. The position of public authorities on the possibility of providing supplemental labelling information on digital labels is mixed with only a third of respondents having a negative view on this possibility. The view of industry stakeholders is largely in favour of the CLP revisions under Policy measure 4. 73% of respondents are in favour of placing H-statements on digital labels, 70% in favour of P-statements on digital labels and 77% in favour of supplemental information on digital labels. In general, around a fifth of the consulted industry representatives see the possibility of having H and P statements exclusively on digital labels as being potentially negative for consumer' safety. Similarly to Policy measure 3, the opinion of all the consulted stakeholders is that the possibility of having digital labels would have a positive impact on consumers with visual impairments (50% approval rate from the public authorities and 76% approval rate from the industry representatives).	Weakly negative

Table 133: Environmental impact assessment Policy measure 4

Type of impact	Assessment	Score
Sustainable consumption and production (Tool #36)	According to 60% of the consulted public authorities, the provisions under Policy measure 4 would have a negative impact on the disposal of harmful substances in the environment arguing that the awareness impact of the consumer is dependent on end-user knowledge of the changes and where to find information, and consumers are not trained to understand all the chemical information and they do not have the same awareness as professional users. Industry stakeholders had the opposite view with 64% of respondents (18 out of 28) considering Policy measure 4 having a positive impact on consumer awareness on disposal of harmful substances.	Neutral

[331] Five out of nine stakeholders from public authorities viewed the interventions on the Detergents Regulation as positive, while only three out of nine stakeholders from the public authorities viewed the interventions on the CLP as positive.

[332] 15 out of 18 stakeholders from the industry viewed the interventions on the Detergents Regulation as positive, while 24 out of 31 stakeholders from the industry viewed the interventions on the CLP as positive.

Policy measure 5: Revision of the labelling rules in the regulations, introducing optional digital labelling: in specific cases, providing all information on the digital label

Overall assessment

Concerning Policy measure 5, stakeholders were consulted on the possibility for manufacturers of providing mandatory information exclusively on electronic labels in specific cases and/or specific products. This concerns

products which are sold to consumers in bulk (i.e. without a container), such as fuels at filling stations

products for which the label or packaging is too small to physically include any or all mandatory information, such as writing instruments (e.g. pens, highlighters).

It must be noted that this concerns product which are already subject to labelling today. The fact that they are currently often not labelled due to practicalities associated with the labelling constitutes a non-compliance. Costs associated with Policy measure 5 are part of the baseline. They are assessed as policy option due to stakeholder interventions.

Overall, based on the findings from the online survey on the Policy measures, public authorities had a slightly positive opinion on Policy measure 5 and its proposed interventions on the CLP Regulation and on the Detergents Regulation[333]. Similarly, industry stakeholders also expressed a positive opinion on Policy measure 5 (83% assessed Policy measure 5 positively[334]), preferring the interventions proposed on the CLP Regulation[335] to the interventions proposed on the Detergents Regulation[336].

Table 134: Economic impact assessment Policy measure 5

Type of impact	Assessment	Score
Conduct of business (Tools #21-25)	Policy measure 5 does not consider the impact the policy measures of Policy measure 5 would have on the professional users. In terms of costs and benefits, around a third of consulted stakeholders consider that policy measure 5 measures would generate **benefits that exceed the costs of the option.** In particular due to the interventions under the CLP, a majority of respondents (78%) believed that the policy option would bring benefits and less than half (43%) think that compliance with the regulatory changes under policy measure 5 would carry costs for them. Costs for implementation of a digital solution for individual companies under policy measure 5 do not differentiate from the calculations made under policy measure 3 or policy measure 4. Thus, same type of costs should be considered for the assessment of this policy measure. Nevertheless, the share of companies that would transfer some of the information from physical to digital labels would be larger compared to policy measure 3 as using digital labels would no longer be voluntary but mandatory. In addition, the share of information that	Strongly positive

[333] Six out of 10 stakeholders from the public authorities have assessed PO 5 as positive, seven out of nine stakeholders have assessed the proposed interventions on the CLP Regulation under Policy Option 5 as positive, and five out of nine stakeholders have assessed the proposed interventions on the Detergents Regulation under Policy Option 5 as positive.
[334] 25 out of 30.
[335] 21 out of 26 (81%)
[336] Nine out of 14 (64%)

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Type of impact	Assessment	Score
	would have to be placed on the digital labels would also increase compared to policy measure 4, therefore, costs[337] and benefits stemming from policy measure 5 should be higher than the ones from policy measure 4. Although it is difficult to estimate the costs of introducing digital labels and moving information on specific products online in monetary terms, stakeholders from the industry explained that it would take around **three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level**. For other costs that are related to the compliance with the regulatory changes (implementation of IT solutions, maintaining website for the e-labels, managing different data formats, costs associated with changes to design/packaging, etc.), even if the potential operational costs and benefits under policy measure 5 could not be monetised, the overall assessment would suggest that size of the costs would be negligible or low. For the benefits, according to consulted stakeholders, in addition to already mentioned benefits under policy measure 3 and 4 (reducing the frequency of changes in physical labels, better management of fast changing label information, improving the possibility of increasing the amount of information only on electronic labels) policy measure 5 would allow better understanding of the hazard classification, and an improved and faster way of communicating changes in hazard classification. These potential benefits, however, could not be estimated quantitatively due to the wide range of variables affecting labels (e.g. size of the label, number of ingredients, type of chemical product, etc.).	
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	A large share of consulted stakeholders (both public authorities and industry representatives) believe that the measures under policy measure 5 would not have competitiveness impacts.	Neutral
SMEs (Tool #21)	Regarding the impact of policy measure 5 on SMEs, the opinion of consulted stakeholders diverges considerably between public authorities and industry representatives. While the large majority of PA consider policy measure 5 having a disproportionate effect on SMEs in comparison to larger companies, less than a third of industry representatives share a similar view (thought it should be noted that the majority of industry respondents were from larger companies).	Neutral
Technological development / Digital economy (Tool #28)	Similarly to other policy measure that include the use of digital labels, according to the majority of public authorities and industry, policy measure 5 would have a positive impact on coherence with digitalisation.	Strongly positive
Public authorities (Tool #58)	Considerably small group of consulted public authorities (three out of 12, or 25%), estimate the provisions of policy measure 4 would generate high or very high costs – for public authorities. Nonetheless, only one stakeholders reported that policy measure 5 would generate a benefit for the monitoring activities of MSAs. According to the consulted public authorities, the benefits for the public authorities would concentrate on the simplification and clarification of the labelling requirements which would make the monitoring and the inspection process for the public authorities and the compliance process for the businesses equally easier. The benefit, however, is considered to be minimal even though the costs are not considered to be very high as well.	Strongly negative

[337] Operational costs, although at the low level, should increase, however, costs related to the familiarisation activities should remain the same.

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Table 135: Social impact assessment Policy measure 5

Type of impact	Assessment	Score
Consumers and households (Tool #33)	The possibility for manufacturers to provide mandatory information on electronic labels in specific cases and/or specific products would fill a current information gap (since this information is currently not provided on physical labels for these products). Industry representatives (around 70%) believe that this policy option would have a positive impact on general consumer safety. The majority of industry stakeholders (around 60%) and 40% of stakeholders from public authorities think that Policy measure 5 would have a positive impact on visually impaired consumers because communication on digital labels can transfer all the relevant information online in an easily readable way rather than have all this information in small letters in a very limited space on a can, tin or a tube.	Weakly positive

Table 136: Environmental impact assessment Policy measure 5

Type of impact	Assessment	Score
Sustainable consumption and production (Tool #36)	According to the majority of the public authorities (55%), this measure would have a negative impact on the awareness of consumers on the effects of dispersion of harmful substances in the natural environment. Around half of industry representatives think that this policy measure would have no impact on the environment.	Weakly negative

COMPARISON OF IMPACTS AND PREFERRED OPTION

Overall comparison of the assessment criteria

The analysis in the previous chapter allows for an overall comparison of the proposed policy measures for digital labelling. The following tables summarise the assessments of the policy measures described in the previous section. Each impact is colour-coded as shown in Table 137. Description of the analytical methods used in preparing the impact assessment measures together with the robustness and limitations of the analysis presented in this chapter is available in Annex 13e.

Effectiveness

To assess the effectiveness of each Policy Measure, firstly, we need to assess them vis-à-vis two specific objectives of digital labelling, namely:

SO1: **improve consumer understanding and awareness of labels, by simplifying and streamlining the existing labelling requirements in the Detergents regulation.**

SO2: **set up a future proof regulatory framework allowing the use of digital tools to communicate product information**.

Note: The impacts under SO1 will be incurred by the Detergents regulation, not by CLP. The impacts are presented here for information only and for transparency reasons.

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Table 137: Assessment of the Policy measures vis-à-vis the specific of objectives of the study

Specific objective	Policy measure 0 (baseline)	Policy measure 1	Policy measure 2	Policy measure 3	Policy measure 4	Policy measure 5
SO 1	No or limited impact	No or limited impact	Weakly positive	Strongly positive	Strongly negative	Weakly positive
SO 2	No or limited impact	No or limited impact	No or limited impact	Strongly positive	Strongly positive	Strongly positive

Based on the findings from the survey, public authorities and industry representatives have expressed a very positive opinion on the impact policy measure 3 would have on the overall consumer and end-user label readability, and safe use of the products for consumer in comparison to the current situation. According to the consulted stakeholders, Policy measures 2 and 5 would have a slightly positive and Policy measures 0 and 1 would have limited or no impact on the readability and safe-use of the products. Considering Policy measure 4, stakeholders mentioned that this policy measure would entail the possibility for manufacturers to provide H and P statements on online labels. This possibility is considered by public authorities and consumer representatives as potentially dangerous for consumers and users in general. For this reason, the assessment is strongly negative.

When it comes to the distinction of the impact from the Policy measure to the CLP and Detergents Regulations, the interventions foreseen under policy measures 3 and 5 concerning consumer understanding and awareness of labels are seen positively both for CLP and Detergents with no significant differences in the level of support from stakeholders. In regards to Policy measure 4, stakeholders from public authorities and industry both expressed support for the proposed interventions on the **Detergents Regulation** rather than the CLP regulation under Policy Measure 4.

The second part of the assessment of effectiveness consists of analysing economic, social, and environmental impacts.

Table 138: Assessment of the Policy measures vis-à-vis economic, social, and environmental impacts

Type of impact	Policy Measure 1	Policy Measure 2	Policy Measure 3	Policy Measure 4	Policy Measure 5
Economic	No or limited impact	No or limited impact	Weakly positive	No or limited impact	Weakly positive
Social impacts	Weakly positive	Weakly positive	Strongly positive	Weakly negative	Weakly positive
Environmental	No or limited impact	No or limited impact	Weakly positive	No or limited impact	No or limited impact

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In terms of the economic impacts[338], none of the Policy Measures would bring strongly positive economic impact. Nonetheless, **Policy Measures 3 and 5** received the highest score of all options. The full overview of the assessment of economic impacts is available in the table below.

Table 139: Assessment of the Policy measures vis-à-vis specific economic impacts

Economic impacts	Policy Measure 1	Policy Measure 2	Policy Measure 3	Policy Measure 4	Policy Measure 5
Conduct of business	Weakly negative	No or limited impact	Weakly positive	Weakly positive	Strongly positive
Sectoral competitiveness, trade and investment flows	No or limited impact	No or limited impact	No or limited impact	No or limited impact	No or limited impact
Impact to the SMEs	No or limited impact	No or limited impact	No or limited impact	Weakly negative	No or limited impact
Technological development / digital economy	No or limited impact	No or limited impact	Strongly positive	Strongly positive	Strongly positive
Impact to public authorities	No or limited impact	Strongly positive	No or limited impact	Strongly negative	Strongly negative

In terms of social impacts[339], Policy Measure 3 scored highest as stakeholders considered this Policy Measure to have an overall positive impact on the safe use of products by the consumers. There was a preference for the revisions to the CLP compared to the Detergents Regulation. Meanwhile, Policy Measure 1, 2, and 5 received a positive feedback from public authority stakeholders, and neutral or negative feedback from industry stakeholders. Policy Measure 4 received the lowest score in this assessment because - even though industry stakeholders estimated an overall positive impact on consumer safety under Policy Measure 4 - this option would entail the possibility for manufacturers to provide H and P statements on online labels. This possibility is considered by public authorities and consumer representatives as potentially dangerous for consumers and users in general, hence, the lower score for Policy Measure 4 in terms of its impact on consumers.

Considering the environmental impact, none of the Policy Measure received very positive feedback from the consulted stakeholders. However, industry and public authorities had an overall positive opinion on Policy Measure 3 in terms of its impact on the awareness of consumers of the impact of dispersion of harmful substances in the natural environment.

[338] Conduct of business (BR Tools #21-25), Sectoral competitiveness, trade and investment flows (BR Tools #21, 27), Impact to the SMEs (BR Tool #23), Technological development / digital economy (BR Tool #28), and Impact to public authorities (BR Tool #58)
[339] Impact to consumers and households (BR Tool #33).

Public authorities estimate a positive impact of Policy Measure 2 and a negative impact of Policy Measure 4 on the environment, while industry stakeholders hold the exact opposite view. Policy Measure 1 is considered to have no effect to the environment, while Policy Measure 5 is considered to have a negative impact on the environment by both types of stakeholders.

Efficiency

The assessment provides information regarding the potential costs and cost-effectiveness for businesses. It should be noted that monetisation of costs was not feasible in all cases. In particular, operational costs related to introducing and maintaining digital labels (costs related to the implementation of IT solutions, maintaining website for the e-labels, managing different data formats, costs associated with changes to design/packaging, etc) could not be quantified. There was a similar challenge with regard to the benefits of introducing digital labelling which could not be estimated due to the wide range of variables affecting labels (e.g. size of the label, number of ingredients, type of chemical product, etc.).

A table describing the above mentioned costs in detail is provided below.

Table 140: Analysis of the quantifiable costs

Businesses	Policy Measure 1	Policy Measure 2	Policy Measure 3	Policy Measure 4	Policy Measure 5
Familiarisation activities (digital labelling)	Undefined	Undefined	Three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level. Note: under Policy measure 3, businesses would have to decide themselves if they want to turn to digital labelling as it would be done in a voluntary basis	Three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level. Note: under Policy measure 4, familiarisation activities would be mandatory.	Three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level. Note: under Policy measure 5, familiarisation activities would be mandatory.

Source: Survey on Policy Options

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Most policy measures entail non-mandatory measures (i.e. the use of electronic labels is always a choice of individual manufacturers and – by definition – if a company choses to invest in the use of a digital tool such as an electronic label, the expected benefits would outweigh the costs). Stakeholder perception on the costs-benefits ratio[340] under each Policy Measure is presented in the table below.

Table 141: Stakeholder perception on the cost-benefits ratio per policy option

Type of stakeholder	Policy measure 1	Policy measure 2	Policy measure 3	Policy measure 4	Policy measure 5
Industry	Undefined	Undefined	Overall: -7% CLP: -77% Detergent: -3%	Overall: 14% CLP: 14% Detergent: 7%	Overall: 34% CLP: 35% Detergent: 11%
Public authorities	Undefined	Overall: 27%	Overall: 0%	Overall: -14%	Overall: -16%

Source: Survey on Policy Options

Coherence

In terms of coherence, the criteria for the assessment of the policy *measures are:*

Coherence between CLP and Detergents regulations;

Coherence with digitalisation trends in the economy and other EU level and international initiatives on the topic[341].

Table 142: Assessment of coherence sub-criteria

Effectiveness criteria	Policy measure 1	Policy measure 2	Policy measure 3	Policy measure 4	Policy measure 5
Coherence between CLP and Detergents	No or limited impact	Strongly positive	Strongly positive	Weakly positive	Strongly positive
Digitalisation trend	Weakly positive	Undefined	Strongly positive	Strongly positive	Strongly positive

Concerning the first criterion, one of the specific objectives of the regulatory intervention is to streamline and reduce overlaps or duplications due to incoherence between the two regulations. The legal analysis, in Annex 13c, presents inconsistencies affecting physical labels. All policy options, except Policy Measure 1, entail a streamlining of the two regulations leading to increased coherence of the overall regulatory framework.

[340] Ratio of stakeholders who have indicated that cost and benefits under the Policy Option are high or very high. If the ratio is negative it means stakeholders estimate higher costs than benefits under the option.
[341] Results on the stakeholders' perception on the coherence with the digitalisation trends is also included as one of the economic impacts, namely "Technological development / Digital economy (Tool #28)".

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Regarding the comparison of the proposed policy options in terms of coherence with market digitalisation trends, Policy Measure 1 and Policy Measure 2, the ones that do not entail the possibility for manufacturers to provide information exclusively on electronic labels, score lower in comparison to options that allow the use of electronic labels to replace (even if only partially) physical labels. From Policy Measure 3 onwards, the possibility to use electronic labels would be coherent with other similar initiatives of the European Commission related to the digitalisation of product information (i.e. the sustainable product initiative and the digital product passport), but also with recent discussion of the GHS about the possibility for a digital communication of hazards for chemical products.

A table comparing the overall assessment of key stakeholders and the median rating (from -5 to +5) of the Policy Measures is presented in the table below.

Table 143: Stakeholders' opinion on the Policy Measures

Type of stakeholder	Policy measure 1	Policy measure 2	Policy measure 3	Policy measure 4	Policy measure 5
Public authorities	Overall: 4 CLP: 4 Detergents 4	Overall: 4 Sub-option 2(a): 4 Sub-option 2(b): 4	Overall: 4 CLP: 3 Detergents 4	Overall: -2 CLP: -1 Detergents 2	Overall: 2 CLP: 1 Detergents 1
Industry	Overall: -3.5 CLP: -3 Detergents: -3	Overall: 1.5 CLP: 3 Detergents 4	Overall: 3 CLP: 2 Detergents 3	Overall: 5 CLP: 4 Detergents 5	Overall: 3 CLP: 3 Detergents 2.5

Source: Survey on Policy Options

The preferred policy option

According to the analysis performed, Policy Measure 3 is the overall preferred option because it combines the necessary and widely requested simplification and streamlining interventions foreseen under Policy Measure 2 with the possibility for businesses to adopt digital labels. This solution as a first step,is considered positively by the majority of the consulted stakeholders and strongly in line with the digitalisation trends. Summary of the costs and benefits under the preferred option are in line with the Better Regulation Guidelines, and is available in Annex 13d.

Policy Measure 3 is the only option that would have a strongly positive impact on both specific objectives (SO) of this initiatve, namely:

SO1: improve consumer understanding and awareness of labels, by simplifying and streamlining the existing labelling requirements in the Detergents regulation.

SO2: set up a future proof regulatory framework allowing the use of digital tools to communicate product information.

In terms of effectiveness, Policy Measure 3 was ranked as the most effective Policy Measure in terms of addressing social, and environmental impacts. Concerning social impacts, consulted stakeholders consider the revisions under Policy Measure 3 to have an overall positive impact on the safe use of products (with a preference for revisions to the Detergents Regulation compared to the CLP). Moreover, Policy Measure 3 is as effective as Policy Measure 5 in terms of its economic impacts.

In terms of the efficiency, industry stakeholders considered Policy Measures 4 and 5 as more cost-effective than Policy Measure 3. Nonetheless, when it comes to public authorities' perception on costs and benefits of the Policy Measures that promote the use of digital labels, Policy Measure 3 was the only option that did not receive an overall negative assessment.

Most importantly, Policy Measure 3 was the only Policy Measure that received a very positive overall assessment (median ≥ 3) from industry and public authority stakeholders. Public authorities assessed the overall impact of Policy Measure 1, 2, and 3 as strongly positive, while the industry had a general preference towards Policy Measure 3, 4, and 5. Therefore, Policy Measure 3 is the only option that was assessed positively both by the industry and public authorities.

To conclude, the analysis has shown that Policy Measure 3 is the overall preferred option. It scores the highest overall in effectiveness and coherence, and is the most cost-effective Policy Measure promoting the use of the digital labels according to the public authority stakeholders.

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