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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2022) 435 final, Part 5/5
Subject:	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

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

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EUROPEAN
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Brussels, 19.12.2022
SWD(2022) 435 final

PART 5/5

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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Q18. To what extent could the information of fertiliser be removed from the on-pack label and transferred to a digital label?

First of all, the majority of the respondents across all stakeholder groups are of an opinion that for the production date[1], and the function of the product[2], **all information should remain on the on-pack label.**

Then, regarding the possibility to move some information on a digital label, the majority of the respondents think that the information from the on-pack label **should be transferred to a digital label** concerning: coating agents (for coated fertilisers)[3], Low in cadmium statements[4], Poor in chloride statements[5], and the List of ingredients[6].

In addition, respondents provided that at least basic information could be provided on pack and more details on a digital label for the following category of information[7]: solubility of phosphorus; reference to inhibitors, chelating and complexing agents; measures to mitigate risks; product storage instructions; and product use instructions.

In regards to the other parts of the information, the respondents had different views on what kind of information should remain on the on-pack label, should be kept on the on-pack label and more details provided via a digital label, or transferred to a digital label completely. The full overview of the responses to this question is provided in the table below.

[1] 55 out of 100 total responses.
[2] 58 out of 103 total responses.
[3] 50 out of 92 total responses.
[4] 58 out of 95 total responses.
[5] 51 out of 95 total responses.
[6] 56 out of 103 total responses.
[7] Based on the combined answers given for "basic information should be kept on pack and more details provided via a digital label" and "information should move to a digital label".

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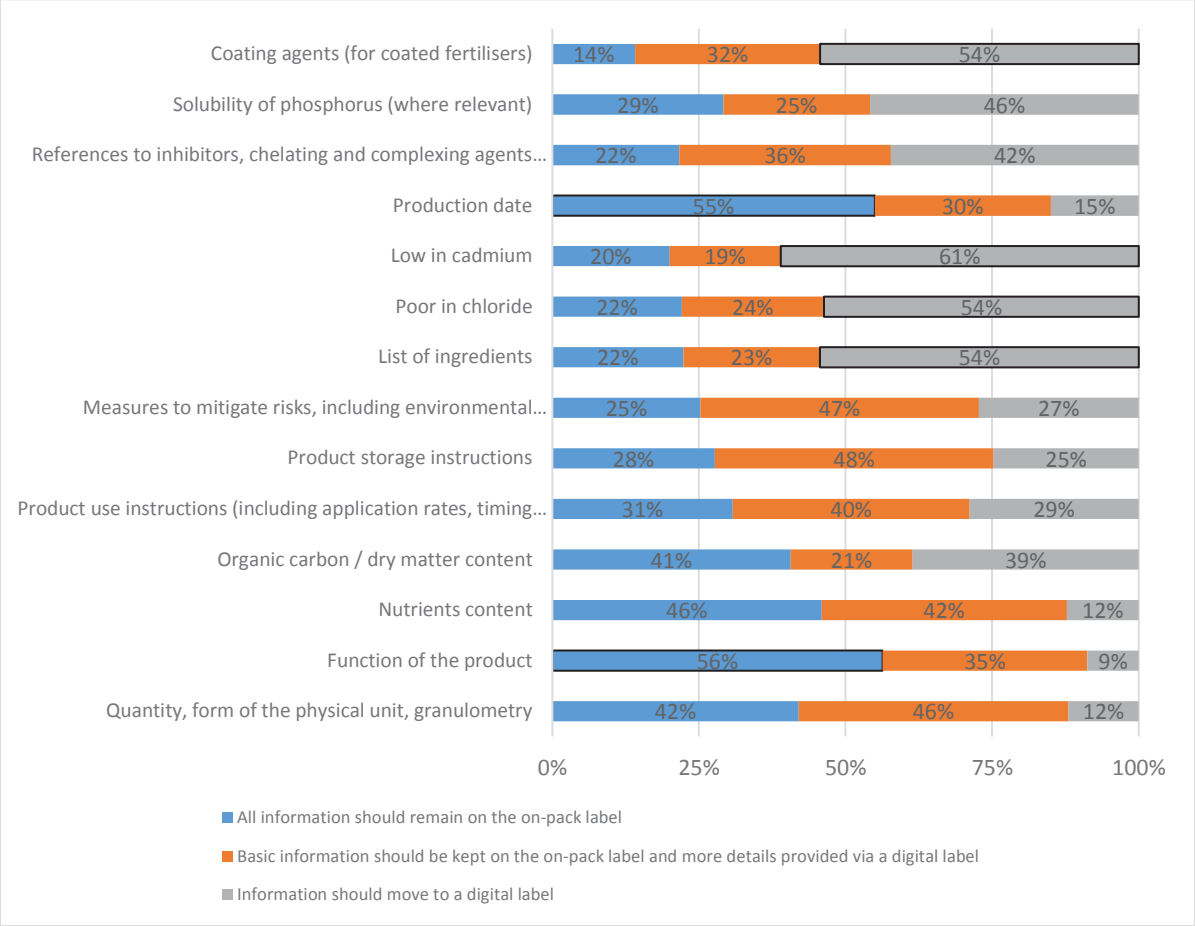

However, regarding the answers given specifically by stakeholders representing consumers, the answers are more divided and no consensus can be found regarding a category of information that should move completely to a digital label. According to the answers given by this stakeholder group, information could be moved online if basic information are kept on pack and only more information are provided on a digital label, for the following categories of information[8]: product use instructions; product storage instructions; nutrients content, organic carbon / dry matter content; poor in chloride; low in cadmium; references to inhibitors, chelating and complexing agents; solubility of phosphorus; and coating agents.

Q18a-e. To what extent could the information of a fertilising product mentioned below be removed from the on-pack label and transferred to a digital label?

Overall, the analysis did find substantial differences, and answers were consistent among the different fertilising products.- Respondents agreed that the following information needed to stay on pack for all products: quantity (and granulometry/volume where relevant) and the function of the product. In addition, other categories of information relevant for:

1. liming material: the calcium oxide and magnesium oxide, as well as reactivity of the product;
2. soil improver: dry matter content, pH value, nutrients content and organic Carbon (Corg) content;
3. growing medium: the production date;

[8] Based on the combined answers given for "basic information should be kept on pack and more details provided via a digital label" and "information should move to a digital label".

4 biostimulant: the physical form, production date and expiry date.

Were indicated to be kept on-pack.

Regarding information that could be moved to a digital label, respondents indicated for all types of fertilising products that the list of ingredients and poor in chloride could be moved digitally. In addition, for liming material, respondents indicated the information on neutralising value cold be moved online.

Finally, respondents also indicated a consensus for all products categories to keep some basic information on pack, and provide more details via a digital label for the following categories of information: the product use instructions, the products storage instructions, and the measure to mitigate risks, including environmental statements.

Compared to the stakeholders from the industry, consumer representatives were, in general, less keen to transfer from the on-pack label and to digital label. These stakeholders supported keeping the information on pack, especially for the inhibitors, soil improvers and, generally, the information regarding the quantity and the function of the products, and keeping basic information on the on-pack label and having more details provided via a digital label, particularly for bio stimulants and, generally, product storage instructions of fertilising products.

Q19. To what extent do you think that the following pieces of information could be removed from the on-pack label of a detergent and transferred to a digital label?

The majority of the respondents believe that the **name of the product should remain on the on-pack label**[9], while for use instructions the majority of the respondent indicated that basic information **should be kept on the on-pack label and more details could be provided via a digital label**[10]. Similarly, the majority of the respondents stated that basic information on special precautions, where required, should be kept on pack while the details should be moved to a digital label.

In regards to the other parts of the information, the respondents had different views on what kind of information should remain on the on-pack label, should be kept on the on-pack label and more details provided via a digital label, or transferred to a digital label completely. For none of the items there was a majority to move all information to a digital label though for the list of ingredients this group was particular large. The full overview of the responses to this question is provided in the table below.

[9] 102 out of 151 total responses.
[10] 79 out of 150 total responses.

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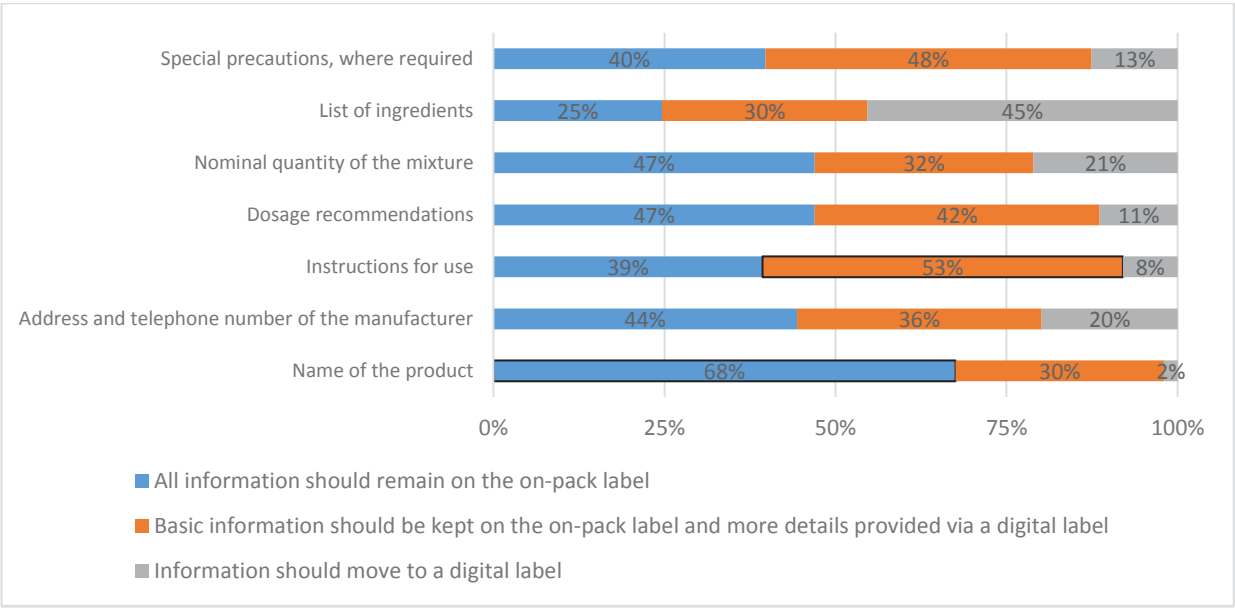


This finding needs to be mitigated by the aswers given specifically by consumer representatives, who were in general less inclined to move information online.Within this stakeholder group, the majority of respondents indicated that all information should remain on pack for the following categories of information: name of the product[11], instructions for use[12], dosage recommendations[13], nominal quantity of mixtures[14], and special precautions[15]. Finally, consumer representatives expressed different/mixed views regarding the following pieces of information: address and telephone number of the manufacturer[16] and list of ingredients[17].

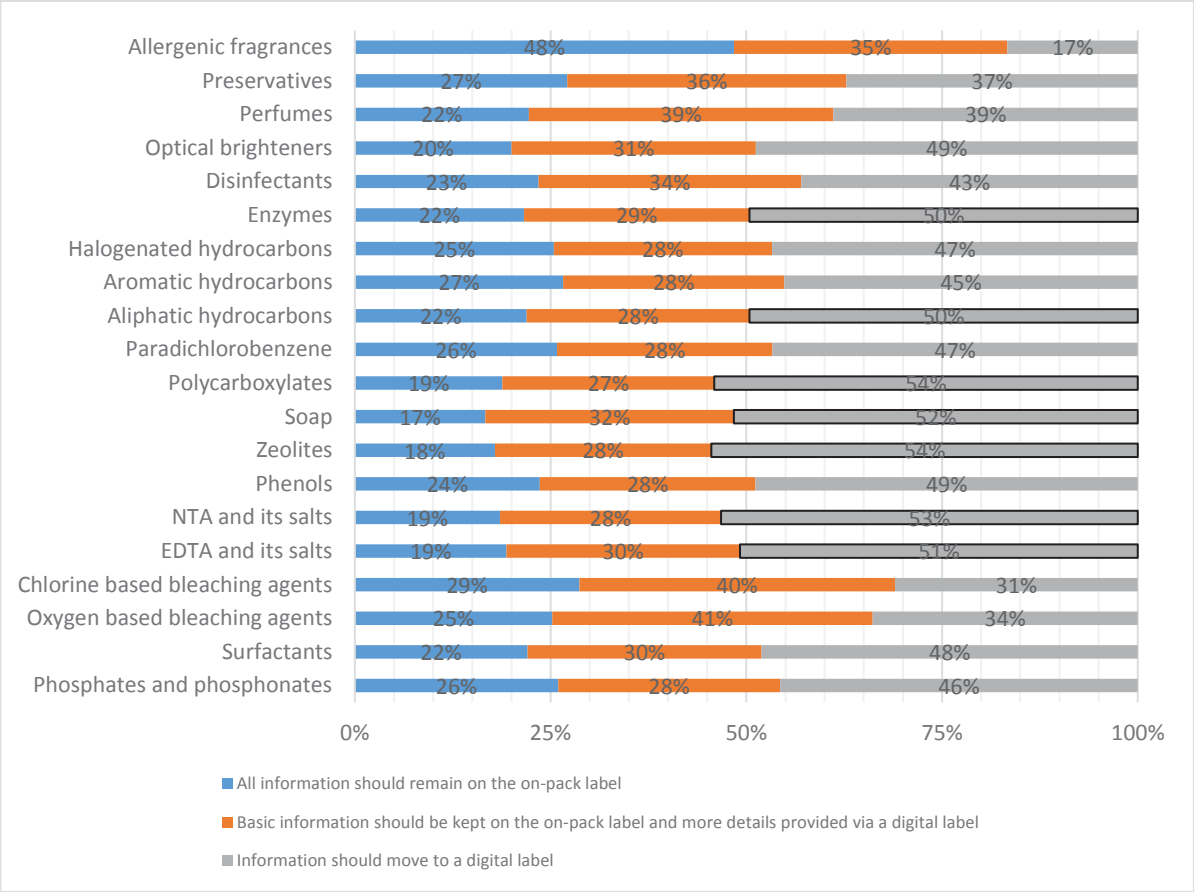
Q19a. For information that you would like to see listed on-pack, please explain why this is:

There was no clear consensus among the respondents on the key reasons why certain information should be listed on-pack, however the most popular option between the respondents was "Because this information allows me to use the product safely"[18].

Among consumer representatives, the most popular option was "because this information helps me make a purchase decision"[19], followed by "because this information allows me to use the product safely"[20], and "because I consider some ingredients to be dangerous/harmful"[21].

[11] 33 out of 52 answers within this stakeholder group.
[12] 29 out of 52 answers within this stakeholder group.
[13] 30 out of 52 answers within this stakeholder group.
[14] 27 out of 51 answers within this stakeholder group.
[15] 27 out of 52 answers within this stakeholder group.
[16] N=52, 19 answered that "All information should remain on pack"; 19 answered that "basic information should remain on pack and more details provided via a digital label"; and 14 answered that "Information should move to a digital label".
[17] N=51, 21 answered that "All information should remain on pack"; 14 answered that "basic information should remain on pack and more details provided via a digital label"; and 16 answered that "Information should move to a digital label".
[18] 122 out of 413 total choices.
[19] 41 out of 52 answers.
[20] 39 out of 52 answers.
[21] 34 out of 52 answers.

Q20. To what extent could the following ingredients be removed from the on-pack label of a detergent and transferred to a digital label?



Around half of the stakeholders (mostly industry stakeholders) believe that the information from the on-pack label of a detergent should be **moved to the digital label** for the following ingredients: Enzymes[22]; Aliphatic hydrocarbons[23]; Polycarboxylates[24]; Soap[25]; Zeolites[26]; NTA and its salts[27]; EDTA and its salts[28].

In regards to the other ingredients, the respondents had different views on what kind of information should remain on the on-pack label, should be kept on the on-pack label and more details provided via a digital label, or transferred to a digital label completely. The full overview of the responses to this question is provided in the table above.

However, the answers given by citizens and consumer organisations indicates less willingness to move information to a digital label. No categories of information received a majority of answers to move information online. The only consensus expressed within this stakeholder category is the need to keep allergenic fragrances on pack.[29]

Q20a. For information that you would like to see listed on the on-pack label, please explain why this is:

[22] 66 out of 125 total responses.
[23] 61 out of 123 total responses.
[24] 66 out of 122 total responses.
[25] 65 out of 126 total responses.
[26] 67 out of 123 total responses.
[27] 66 out of 124 total responses.
[28] 63 out of 124 total responses.
[29] 29 out of 47 answers.

There was no clear consensus among the respondents on the key reasons why certain ingredients should be listed on-pack, however, the most popular option between the respondents was "Because this information allows me to use the product safely"[30].

It must be noted that the most popular option among respondents from citizens and consumer organisations was "because I consider some ingredients to be dangerous/harmful"[31], followed by "because this information helps me make a purchase decision"[32].

Q21. In what ways do you think that the information on the detergents label could be simplified: (multiple choice possible)

Likewise, there also was no clear consensus among the respondents on the ways that the information on detergents label could be simplified. Nevertheless, the most popular option between the respondents also for respondents from citizens and consumer organisations[33] was "Avoiding that the same ingredient is listed multiple times on the label[34]",

Q22. To what extent could the following ingredients be removed from the on-pack label of a chemical product (such as a glue, lamp oil, paint, solvent, etc.) and be transferred to a digital label?

The majority of the respondents, including consumer representatives[35] think that all information should remain **on the on-pack label** concerning the: identification code for poison centers[36]; hazard statement or signal word[37]; and pictogram showing the risk[38].

In regards to the other sources of information, the respondents (including consumer representatives) had different views on what kind of information should remain on the on-pack label, should be kept on the on-pack label and more details provided via a digital label, or transferred to a digital label completely. The full overview of the responses to this question is provided in the table below.

[30] 84 out of 304 total choices.
[31] 38 out of 44 answers.
[32] 35 out of 44 answers.
[33] 45 out of 53 answers.
[34] 113 out of 522 total choices.
[35] 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 centers".
[36] 106 out of 158 total responses.
[37] 109 out of 156 total responses.
[38] 121 out of 157 total responses.

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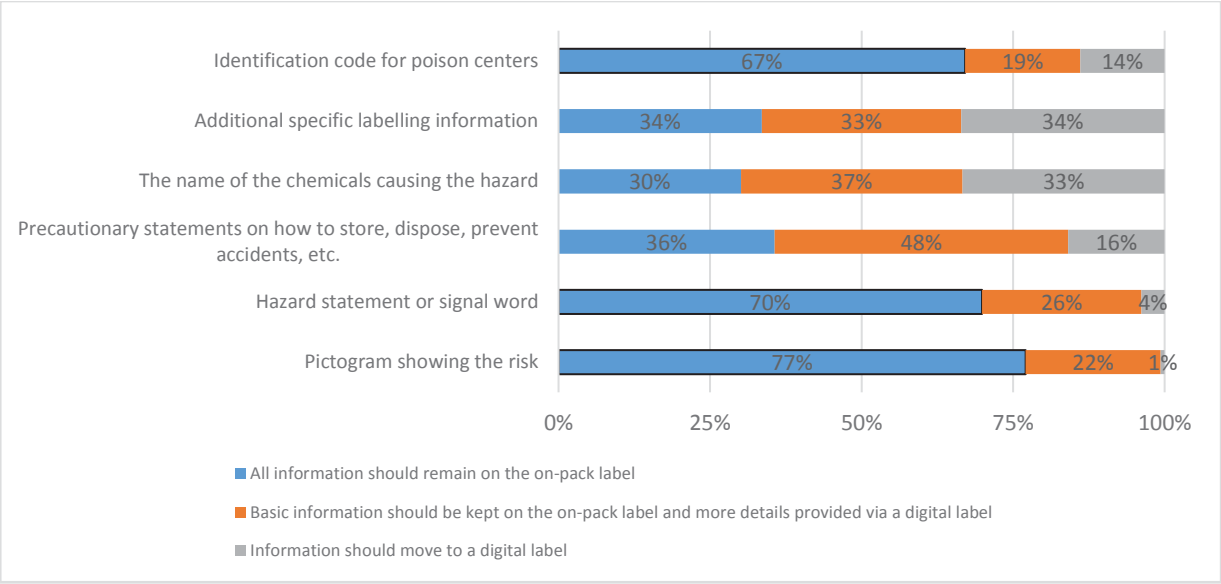
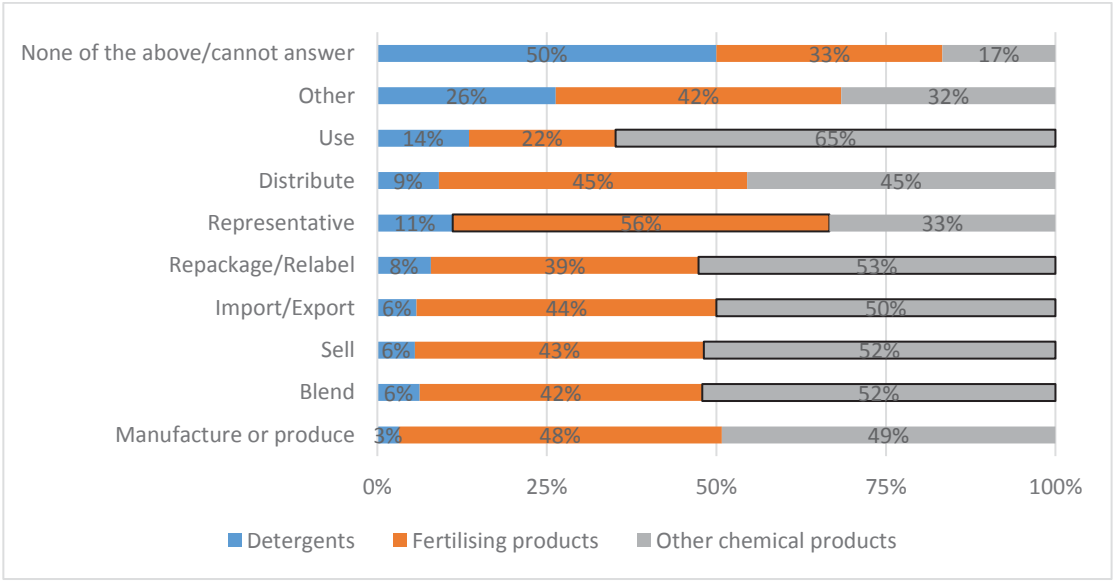


SPECIFIC QUESTIONS FOR PROFESSIONALS AND INDUSTRY

In this part of the questionnaire, all industry stakeholders were asked to answer the questions related to the practicalities of using digital labelling.

Q23. Industry stakeholders were asked to give more information about the type of organisation they represent, and in which sectors (multiple choice is possible).

Most industry representatives indicated their organisation was active in the sector of 'other' chemical products[39] (in other words, 'other to fertilising products or detergents'), followed by fertilising products[40], while least were active in the detergents[41] sector. Please see more details in the table below on the different types of industry stakeholders:



The following questions were asked to all industry stakeholders responding to the survey:

[39] 182 out of 368 total choices (49%) across the 10 terms.
[40] 154 out of 368 total choices (42%) across the 10 terms.
[41] 32 out of 368 total choices (9%) across the 10 terms.

Q24. Do you currently provide any product information via IT solutions or digital tools?

The majority of the industry stakeholders (74%[42]) do provide information about their products via IT solutions or digital tools. Almost half of the respondents from the industry provide additional/complimentary information to an on-pack label, while around one-quarter of the respondents provide the same information online that was presented on the on-pack label.

Q25. What are the main reasons for providing information online? (multiple choice possible)

There was no clear consensus among the industry stakeholders on the key reasons to provide information online, however, the most popular option between the respondents was "Improved customer service"[43].

Q26. Please rate the main benefits of introducing a regulatory framework on digital labelling of chemicals for your organisation?

The majority of the industry stakeholders have rated all of the listed benefits[44] as moderately beneficial or extremely beneficial with the benefit called "Better management of fast changing label information" as the most beneficial[45], followed by ", "Increased ease of complying with labelling requirements"[46], "Better targeted communication"[47], and "Cost savings" as the least beneficial" option[48].

Q27. How would you see the following challenges if digital labelling was introduced?

Around half of the industry stakeholders have assessed the challenges associated with the "Increased costs associated with training"[49] and "Increased costs associated with changes to design /packaging"[50] as **a little challenging or not challenging at all**, while around half of the respondents have rated the challenge of "Implementing IT solutions"[51] as **moderately or extremely challenging**. The opinion of the stakeholders on other challenges proved to be more diverse and marginalised. However, only a minority of respondents considered the introduction of digital labelling as extremely challenging.

[42] 123 out of 167 total responses.
[43] 97 out of 390 total choices.
[44] The listed benefits included: "Better management of fast changing label information", increased ease of complying with labelling requirements", better targeted communication" and "cost savings".
[45] 111 out of 124 respondents (90%) have selected options "Extremely beneficial" or "Moderately beneficial".
[46] 106 out of 125 respondents (85%) have selected options "Extremely beneficial" or "Moderately beneficial".
[47] 106 out of 125 respondents (85%) have selected options "Extremely beneficial" or "Moderately beneficial".
[48] 65 out of 117 respondents (56%) have selected options "Extremely beneficial" or "Moderately beneficial".
[49] 61 out of 122 total responses (50%).
[50] 66 out of 128 total responses (52%).
[51] 63 out of 127 total responses (49.5%).

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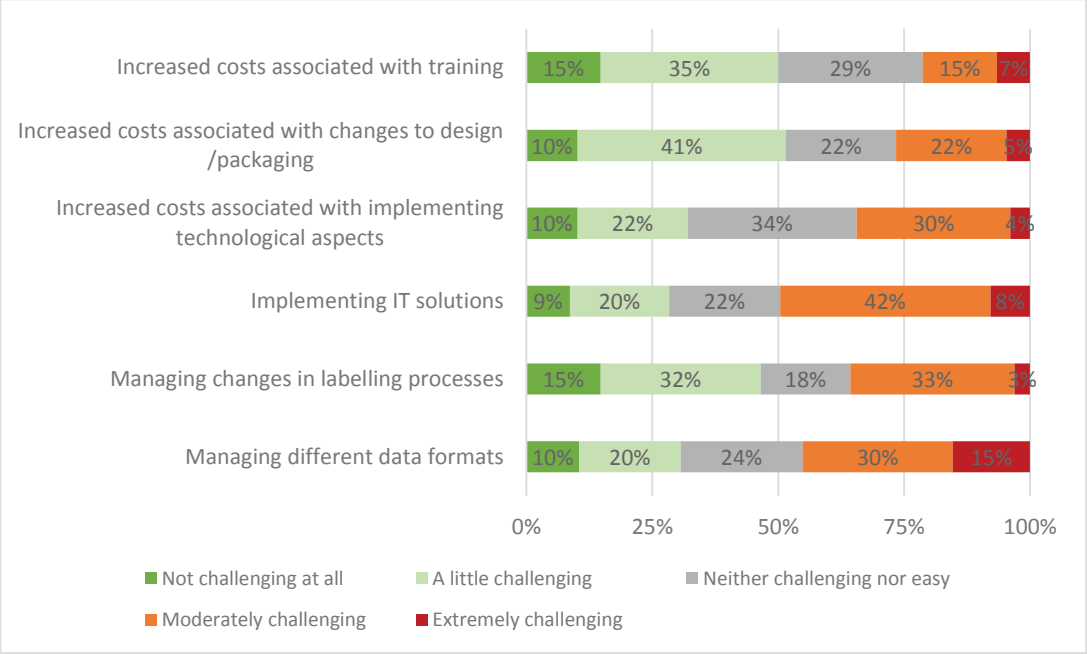

Q28. Would your organisation implement digital labelling if it were an option under the revised regulations?

More than two-thirds of the industry stakeholders (94 out of 135) think that their organisations would implement digital labelling if it were an option under the revised regulations.

Q29. In your view, how should any label information presented via IT solutions be organised?

The majority of the industry stakeholders (56%, 89 out of 156) would prefer a decentralised database, operated individually by each manufacturer following standardised templates or guidelines

Annex 13c - Legal Analysis (digital labelling)

This Annex provides a summary of existing labelling requirements under Classification, Labelling and Packaging Regulation (CLP) and Detergents Regulations, including labelling examples and the identification of duplications and legislative overlaps between different pieces of EU legislation.[52]

The analysis of the relevant regulation, in conjunction with the exchanges incurred with the Commission, also allowed the research team to define a "baseline" label[53] to be used in the behavioural experiment as described in Annex 4.

[52] CLP, Detergents Regulation, Cosmetic Products Regulation and Biocidal Products Regulation.
[53] The baseline label is a regulatory-compliant test label which will be tested in the experiment to assess the behaviour and understanding of consumers of specific products (in this experiment detergents and glues) under the currently applicable legislation.

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GENERAL OVERVIEW

Labelling obligations for substances and mixtures fall under the Classification, Labelling and Packaging Regulation (Regulation (EC) No 1272/2008) **in case a substance or mixture is classified as hazardous**.

The manufacturers, importers, downstream users (including formulators) and distributors (including retailers) must label and package any hazardous substance or mixture before it is placed on the market in accordance with Titles III and IV of the CLP (CLP Article 4(4))[54]. Following the rules of the CLP a substance or mixture contained in packaging must be labelled in accordance with the CLP rules when:

the substance or the mixture itself is classified as hazardous; or

if it is a mixture containing one or more substances classified as hazardous above the concentrations referred to in Part 2 of Annex II to the CLP, even if the mixture itself is not classified overall as hazardous. In this case, the supplemental labelling as set out in Part 2 of Annex II to the CLP applies (CLP Article 25(6)); and

if it is an explosive article as described in Part 2.1 of Annex I of the CLP.

The hazard classifications are set out in parts 2 to 5 of Annex I to the CLP. In general, there is an obligation to classify substances and mixtures for their physical, health or environmental hazards. Each class includes one or more hazard categories. For example, explosives, flammable gases, flammable aerosols, and aerosols are classified under CLP *Physical hazards* class. Some examples *under Health hazards* class are "acute toxicity", "skin corrosion/irritation", "serious eye damage/eye irritation", "respiratory or skin sensitisation". Under *Environmental hazards* class fall "Hazardous to the aquatic environment" and "Hazardous to the ozone layer" classifications.[55]

The CLP is the primary basis for identifying hazards, providing hazard classification across almost all other pieces of EU legislation as well as labelling and other risk and hazard communication measures. The aim of the CLP is that consumers[56], industrial[57] and professional users[58] should be provided with relevant and adequate information that allows them to recognise the real hazard of a product and get relevant safe use guidance.

The labelling requirements of the Detergents Regulation is the primary means by which the Regulation aims to achieve its objective of ensuring the protection of human health. The information included in detergents labels serves as a means of communicating information on the content of detergents[59] (e.g., fragrance allergens, enzymes, disinfectants, optical

[54] 'Where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is labelled and packaged in accordance with Titles III and IV, before placing it on the market.'

[55] The Hazard class table, available at https://www.reach24h.com/en/service/chemical-service/eu-clp.html provides full information for all CLP Hazard Classes and Categories.

[56] The consumer is a member of the general public who may primarily be exposed to hazardous substances or mixtures by using a consumer product.

[57] Industrial users – people involved in manufacturing, handling and/or packaging of actives or products in industry.

[58] Professional users – people using end-products outside industry.

[59] There are eighteen specific constituents listed in the Annex VII A to the Detergents Regulation, which must be stated on the label if present as a constituent in the detergent at greater than 0.2% by weight for example all surfactant types, phosphates and aliphatic hydrocarbons.

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brighteners, perfumes, and preservation agents) and use instructions to consumers thus allowing them to make more informed choices.

Whether a particular product falls within the scope of the Detergents Regulation **depends on its purpose** (cleaning function or not) and **not on its composition** (containing surfactants or not).[60] Further, the labelling of ingredients according to the Detergents Regulation is not dependent on whether these ingredients are hazardous or non-hazardous.

The labelling and packaging of all detergent products (i.e., both those intended for consumer use and those intended for professional and industrial use) must comply with the requirements of the Detergent Regulation. All detergent products which are **classified as hazardous** must be **hazard labelled** in accordance with CLP. Where the detergent has a **biocidal function[61] or contains a preservation agent**, the packaging must also contain labelling information as required by the **Biocidal Products Regulation (BPR)[62]**. In addition, the Detergents Regulation makes reference to the Cosmetics Products Regulation (CPR)[63] for the labelling of **allergenic fragrances[64]**.

Labelling elements under CLP Regulation

Under the CLP (Article 17(1)) **in case a substance or mixture is classified as hazardous** the mandatory pieces of information the label has to provide to users are:

identification and contact details of the supplier(s);

the quantity of hazardous substance/mixture (on the label or on the package), and

the product identifier.

Depending on the hazard severity (**hazard category**) the label may include:

- hazard pictograms;
- signal words;
- precautionary statement; and
- a section for supplemental information:

[60] Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, 6.1 Criteria for deciding whether a product falls within the scope of the Regulation, p. 11. Available at: https://ec.europa.eu/docsroom/documents/33168/attachments/1/translations/en/renditions/pdf

[61] A biocidal function, by analogy with the definition of a biocidal product, means the function of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. CA-Sept13-Doc.5. i.e., "Note for guidance Subject: Frequently asked questions on treated articles", answer to Q. 10, p. 6. Available at: https://circabc.europa.eu/sd/a/d7363efd-d8fb-43e6-8036-5bcc5e87bf22/CA-Sept13-Doc%205.1.e%20%28Rev1%29%20-%20treated%20articles%20guidance.doc

[62] 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. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528

[63] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223

[64] According to Annex VII A of the Detergents Regulation, the allergenic fragrances as listed by the 7th amendment (2003/15/EC) of Directive 76/768/EEC shall be mentioned on the label if they have been added to detergents sold to the general public at concentrations exceeding 0.01% by weight. This list of allergenic fragrances, to be found in Annex III, Part 1 of Regulation (EC) No 1223/2009 can be adapted to technical progress.

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- *obligatory:* information which comprise of hazard statements provided for in other parts of the CLP [65] and/or taken over from previous chemical legislation, e.g., EUH001 Explosive when dry and EUH204 "Contains isocyanates. May produce an allergic reaction"; and
- *non-obligatory:* not part of the legal labelling requirements under CLP, for example, instructions for use. Such information must not distract from nor contradict the obligatory label elements and statements, for example "non-toxic" or "non-polluting" must not be used;

a Unique Formula Identifier (UFI[66]), if applicable, must also be added to, i.e., printed on or affixed to, the label of mixtures falling under the scope of Article 45 and Annex VIII to the CLP on poison centres.

The CLP implements the use of the hazard statements, precautionary statements, and pictograms provided for by the United Nations Globally Harmonised System (GHS). The CLP also includes the use of the two GHS signal words "Danger" and "Warning" to indicate the severity of a hazard.

Section 1.2 of Annex I to CLP defines the label size, setting out minimum dimensions for the label, with the pictogram size being linked to these minimum dimensions. Nevertheless, the label should be large enough to contain all the label elements defined by the CLP while remaining legible. As a result, the label may need to be larger than the minimum area specified. The table below demonstrates the minimum dimensions of labels and pictograms under the CLP. The size of the pictogram relates here to the dimensions of the pictogram itself, and not to the size of the virtual square into which the pictogram is placed.

Table 156: Minimum dimensions of labels and pictograms under the CLP Regulation[67]

Capacity of the package	Dimensions of the label (in millimetres) for the information required by CLP Article 17	Dimensions of the pictogram (in millimetres)
≤ 3 litres	If possible, at least 52 x 74	Not smaller than 10 x 10 If possible, at least 16 x 16
> 3 litres but ≤ 50 litres	At least 74 x 105	At least 23 x 23
> 50 litres but ≤ 500 litres	At least 105 x 148	At least 32 x 32
> 500 litres	At least 148 x 210	At least 46 x 46

The CLP requires that the label elements as referred to in CLP Article 17(1) be of such size and spacing as to be easily read[68]. Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of

[65] For example, the listing of surfactants and perfumes according to the Regulation (EC) No 648/2004 on detergents, as amended; the authorisation number of the biocidal product according to the Biocidal Products Regulation (EU) No 528/2012.

[66] Mixtures for consumer or professional use must be submitted before 1 January 2021. Mixtures for industrial use are due three years later, by 1 January 2024.

[67] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.

[68] CLP, Article 31(3) 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.

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the letters, the surface of the material and significant contrast between the print and the background[69].

The exact size of the letters of the signal words, hazard statements, precautionary statements and any supplemental information is not further defined in the legal text, i.e., it is up to the supplier to determine the size of the letters that allows the label elements to be easily read. However, the minimum letter size of 1.2 mm ('x-height') can be used as a reference[70]. A supplier may decide whether to increase the letter size with the overall volume of the packaging and dimensions of the label, or to fix it more or less for all volumes and labels. Similarly, a supplier may decide whether to have larger letter sizes for certain label elements while others are presented in smaller letters[71].

The labelling elements described above must be clearly and indelibly marked on the labels. The labels should be firmly affixed to one or more surfaces of the packaging immediately containing the hazardous substance or mixture (CLP Article 31). They should be readable horizontally when the package is set down normally.

A label may accommodate more language(s) than those required by the Member State where the substance or mixture is placed on the market. As long as the label complies with the (minimum) dimensions set out in Table 2 above and as long as legibility of the text elements is warranted, the decision on the number of languages is at the discretion of the respective supplier.

All hazard statements must appear on the label unless there is obvious duplication or redundancy. The colour and presentation of the labels must allow the hazard pictogram and its background to be clearly visible. Hazard pictograms are the shape of a square set at a point (diamond shape) and must have a black symbol on a white background with a red border (section 1.2.1 of Annex I to CLP). The CLP links the size of the hazard pictograms to the minimum dimensions of the label. Each hazard pictogram should cover at least one fifteenth of the minimum surface area of the label, but the pictogram area for the smallest capacity of the package should be at least 16 mm x 16 mm, if possible, but must never be less than 1cm^2.

It is important to note that in order **to reduce the number of substance** ('chemical') names on the label, **no more than four names** should be provided on the label for a mixture, unless necessary due to the nature and severity of the hazards[72]. If the trade name or the designation of the mixture already includes the name(s) of the substance(s) contributing to the classification of the mixture as defined in paragraph 3(b) of CLP Article 18, they do not need to be repeated. Moreover, **if the supplemental information on the label already contains the chemical name of the substance, e.g., in the list of allergens and preservatives required by Regulation (EC) No 648/2004 on detergents, it is advisable to use the same name[73].**

[69] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.
[70] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021, p.45.
[71] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.
[72] CLP, Article 18 (3)
[73] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.

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Article 32 of CLP provides some limited rules defining the location of information on the label. However, further details as to how label elements are arranged are left to the discretion of the person responsible for compiling the label. As a general rule, the information should be structured in a way that is easy to read and understand or in other words the labels may be organized in any way that leads to best clarity. **However, the hazard pictograms, signal word, hazard statements and precautionary statements should be kept together on the labels.** The supplier may decide the order of the hazard and precautionary statements. Normally it is required to group them together on the label by language (CLP Article 32). In case more than one language is used on the label, the hazard and precautionary statements of the same language should be treated as one package and grouped together on the label. This should allow the reader to find all relevant hazard and safety information in one place.

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Table 157: CLP labelling requirements versus discretion of the supplier

CLP requirement (Article 32)	Example of decision left to the discretion of the supplier
The hazard pictograms, signal word, hazard statements and precautionary statements must be kept together on the label.	The supplier is free to choose the arrangement of the pictograms.
Hazard statements must be grouped together on the label.	The supplier may choose the order of the hazard statements. The supplier may choose whether these groups are to be presented on the left, on the right or elsewhere on the label.
Precautionary statements must be grouped together on the label.	The supplier may choose the order of the precautionary statements but should ensure that they are grouped with the hazard statements. The supplier may choose whether these groups are to be presented on the left, on the right or elsewhere on the label.
In case more than one language is used on the label, the hazard and precautionary statements of the same language must be grouped together on the label.	Where the supplier needs to use alternative means to meet the requirements of CLP Article 31 in relation to the language(s) required in a particular Member State, he may choose whether to accomplish this using fold-out labels, tie-on tags or on an outer packaging, in accordance with section 1.5.1 of Annex I to CLP.
Any supplemental information as referred to in CLP Article 25 must be included in the section for supplemental labelling and placed alongside the label elements referred to in CLP Article 17(1)(a)–(g).	The supplier may choose how to visibly separate this section from the section containing the label elements referred to in CLP Article 17(1)(a)-(g). He may also decide to place this information in more than one location on the label.
The label elements must be easily readable (Article 31(3)).	It is recommended to keep full sentences together and in one line, if possible. The font size and spacing must be large enough and in relation to the dimensions of the label.

Principles of precedence

For hazard pictograms

Where the classification of a substance or mixture would result in more than one pictogram on the label, rules of precedence are applied to reduce the number of pictograms required (CLP Article 26). As a general rule, the label must include those **pictograms** which indicate **the**

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most severe hazard category of each hazard class. This would also apply in case a substance has both harmonised[74] and non-harmonised[75] classifications (CLP Article 26(2)).

In case a substance or mixture is assigned the supplemental hazard statement EUH071 ("Corrosive to the respiratory tract"), a corrosivity pictogram (GHS05) may be assigned (see Note 1 of Table 3.1.3 in Annex I to CLP). Where this is done, the pictogram GHS07 (exclamation mark) for specific target organ toxicity SE category 3 ("Respiratory tract irritation") must be omitted from the label, as well as the hazard statement H335 ("May cause respiratory irritation").

For hazard statements

If a substance or mixture is classified within several hazard classes or differentiations of a hazard class, all hazard statements resulting from the classification shall appear on the label, unless there is evident duplication or redundancy (CLP Article 27). For example, if the hazard statement H314 ("Causes severe skin burns and eye damage") is assigned, H318 ("Causes serious eye damage") may be omitted. Similarly, if the hazard statement H410 ("Very toxic to aquatic life with long lasting effects") is assigned, H400 ("Very toxic to aquatic life") may be omitted.

Duplication or redundancy should also be avoided for a substance or mixture that is assigned the supplemental hazard statement EUH071 "Corrosive to the respiratory tract". In this case, the hazard statement H335 ("May cause respiratory irritation") for STOT SE category 3 ("Respiratory tract irritation") should be omitted from the label.

For precautionary statements

Not more than six precautionary statements shall appear on the label, unless more are necessary to reflect the severity of the hazards. To provide flexibility in the application of precautionary phrases, combinations or consolidations of precautionary statements are encouraged to save label space and improve readability. If the substance or mixture requires labelling and is to be sold to the **general public,** the label must include **one precautionary statement** on the **disposa**l of the **substance** or **mixture**, as well as the **disposal** of the **packaging** (CLP Article 28).

Exemptions from labelling and packaging requirements

In general substances and mixtures, especially those supplied to the general public, should be supplied in packaging together with the necessary labelling information. Labelling information and other relevant hazard information are provided through other means than a label where **unpackaged** materials are supplied to **professional users**, usually in the Safety Data Sheets (SDS). SDS are the main hazard communication tool aside from product labelling

[74] Harmonised classification applies to substances only.

[75] Under the CLP, a substance must be self-classified by manufacturers, importers or downstream users when it has no harmonised classification in Annex VI to the CLP and it presents hazardous properties. This classification and labelling information for the substances to be placed on the market is then notified by manufacturers and importers to the Classification and Labelling Inventory (CLI) held by European Chemicals Agency. Mixtures must always be self-classified before being placed on the market, as they are not subject to harmonised classification and labelling.

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required and regulated under REACH[76]. Annex II of the Regulation sets out detailed information which must be provided in a SDS under 16 required headings.

In exceptional circumstances, substances and mixtures may also be supplied to the general public unpackaged. In case the substance or mixture is listed in Part 5 of Annex II to CLP (currently only cement and concrete in the wet state), a copy of the labelling elements is always required, for example on an invoice or bill (CLP Article 29(3), Part 5 of Annex II to CLP).

Small packages where the contents do not exceed 125 ml

CLP Article 29(1) and section 1.5.1 of Annex I to CLP provide derogations for a packaging that is so small or in such a shape or form that it is impossible to meet the requirements of CLP Article 31 (General rules for the application of label). In this case the label elements may be provided in one of the following ways: (a) in fold-out labels; (b) on tie-on tags; or (c) on an outer packaging. ***The label on any inner packaging shall contain at least hazard pictograms, the product identifier and name and telephone number of the supplier of the substance or mixture.***

The hazard statements and the precautionary statements linked to hazard categories may be omitted from the label elements 1) where the contents of the package **do not exceed 125 ml** and 2) the substance or mixture is classified in one or more of 17 hazard categories (section 1.5.2.1.1. of Annex I to CLP). Amongst them fall "Skin irritation" of category 2 and "Eye irritation" of category 2.

The pictogram, the signal word, the hazard statement, and the precautionary statement linked to hazard categories may be omitted from the label elements where 1) the contents of the package do not exceed 125 ml and 2) the substance or mixture is classified as "Corrosive to metals" hazard categories.

The label elements may be omitted from soluble packaging intended for single use where 1) the content of each **soluble packaging does** not exceed **a volume of 25 ml;** 2) the classification of the contents of the soluble packaging is exclusively one or more of the hazard categories in 1.5.2.1.1 (b), 1.5.2.1.2 (b) or 1.5.2.1.3 (b); and 3) **the soluble packaging** is contained within outer packaging that fully meets the requirements of Article 17 CLP.

The label elements may be omitted from the inner packaging where 1) the contents of the inner packaging do not exceed 10 ml; 2) the substance or mixture is placed on the market for supply to a distributor or downstream user for scientific research and development or quality control analysis; and 3) the inner packaging is contained within outer packaging that meets the requirements of Article 17 CLP.

The below figure presents an example of hazard label for supply to general public demonstrating the required elements according to the CLP.

Figure 89: Example of Hazard Label for Supply[77]

[76] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

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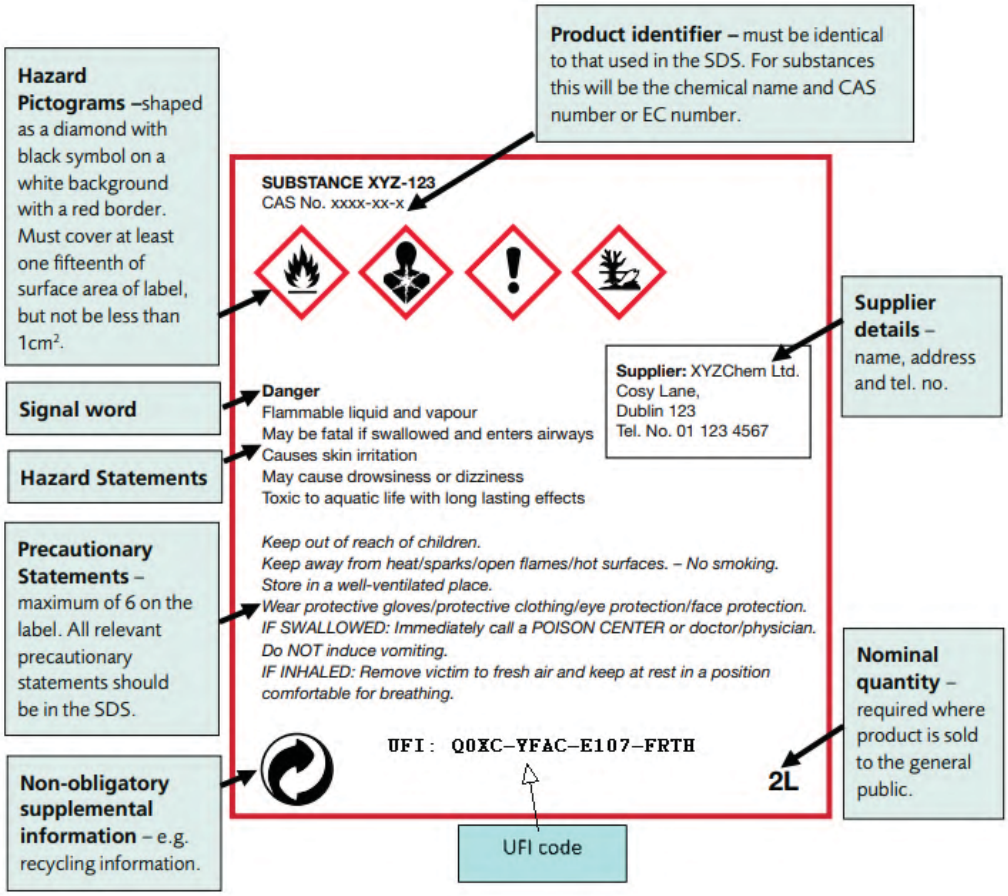

Labelling of Detergents

The labelling of detergents follows three separate regulations: Detergents Regulation 648/2004, CLP Regulation 1272/2008 and Biocidal Products Regulation 528/2012.

A difference exists in the terminology regarding the hazard communication in form of labelling between CLP and the labelling requirements of Detergents Regulations. The **CLP** refers to a **label on the packaging**, while **Detergents Regulation** refers to **information** that has to appear **on the packaging**[78]. The CLP Regulation, Article 17(1) states that if a substance or mixture is classified as hazardous (and contained in packaging), **the label** shall include the elements described in letters (a) to (h). The Detergents Regulation, Article 11(2) elaborates the **information** that must appear on the packaging in which the detergents are put. However, the different terminology does not have any impact or consequences on the labelling of detergents and the communication of the relevant and adequate information to consumers, allowing them to recognise the real hazard of a product, get relevant safe use guidance and make more informed choices.

The labelling information on the packaging of detergents that are put up for sale to consumers include:

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[77] Source: Hazard Labelling & Packaging according to the CLP Regulation Information Sheet. Available at https://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/CLP_info_sheet.pdf

[78] Support to the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation), p. 72. Available at: https://op.europa.eu/en/publication-detail/-/publication/ad2fa114-e952-11e8-b690-01aa75ed71a1

A section dedicated to the **CLP Regulation labelling requirements and elements**;
A section for the additional labelling information according to the **Detergents Regulation; and**

A section for the labelling requirements of the **Biocidal Products Regulation,** where relevant[79].

In particular, the section related to the Detergents Regulation includes the following:

the name and trade name of the product;
the name or trade name or trademark and full address and telephone number of the party responsible for placing the product on the market;
the address, email address, where available, and telephone number from which the ingredient datasheet can be obtained[80];
a list of specific constituents if present in concentrations >0.2% in the product e.g., phosphates, aliphatic hydrocarbons. A weight percentage range must be provided;
names of any enzymes, disinfectants, perfumes, optical brighteners, preservatives irrespective of the concentration in which they are found in the product;
names of any allergenic fragrances (as listed in Annex III of the Cosmetics Products Regulation)[81];
the indication of instructions for use and special precautions;
dosage instructions[82];

website of the manufacturer where the ingredient datasheet is available[83].

Detergents might also contain voluntary information (not required under different EU pieces of legislation) such as safe use icons and phrases. The International Association for Soaps, Detergents and Maintenance Products (A.I.S.E) has developed a set of safe use icons complemented with related sensible advice text in order to improve and further develop clear messages for consumers on how to use A.I.S.E. consumer products[84]. These safe use icons and phrases intend to help the consumers to use and store household detergents and maintenance products safely. They can be found on the label and provide safe use instructions in a simple and user-friendly way[85]. In addition, there are voluntary icons and tips providing information to consumers how to clean more sustainably saving water, energy, CO2 and money.[86]

The Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 – March 2021)[87] provides an example of a single language label for a mixture

[79] For detergents disinfectants and detergents that are also treated articles and which fulfil the labelling requirements of BPR.
[80] Detergents Regulation, Article 11.
[81] If present at greater than 0.01% by weight (or at a replacement limit), for example Citral, d-Limonene, Oak moss and tree moss extract and Linalool.
[82] The packaging of consumer laundry detergents and consumer automatic dishwasher detergents shall bear the information provided for in section B of Annex VII to Detergents Regulation.
[83] "The website address, from which the list of ingredients mentioned in section D of Annex VII can be obtained, shall be given on the packaging." Annex VII A to Detergents Regulation as amended by COMMISSION REGULATION (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Ann exes III and VII thereto. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R0907
[84]https://www.aise.eu/documents/document/20140129161815-final_draft_aise_safe_use_guidelines_revjan2014.pdf
[85] https://www.cleanright.eu/en/safe-use.html#safe-use
[86] Such examples can be found at https://www.cleanright.eu/en/sustainable-use.html
[87] https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf

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containing both obligatory and non-obligatory supplemental information (supplied to the general public). The example label given below illustrates the supply and use label for a typical consumer product (detergent).

All obligatory labelling information is shown, i.e., the product identifiers (trade name and designation of the mixture; one of them would have been sufficient), the identity of the supplier, the signal word, the UFI code, the hazard and precautionary statements in accordance with CLP and the obligatory supplemental information, in accordance with Detergents Regulation. The supplemental labelling information according to the CLP is grouped together. The UFI can alternatively be placed outside the label (e.g., printed or affixed on the inner packaging) but in proximity to the other obligatory CLP label elements.

As the product is supplied to the general public, its nominal quantity is also provided on the label. Beyond the obligatory supplemental information, also non-obligatory supplemental information is shown. The non-obligatory supplemental labelling information, the content of which is at the discretion of the supplier, is not part of the labelling requirements under the CLP[88]. No P-statement on disposal is given as this is not required for a mixture classified as eye irritant.

The label shown is primarily drafted for inner packaging. If the chemical is contained in combination (= inner + outer) packaging, the same information has to be shown on the outer packaging, unless the information on the inner packaging can be seen through the outer packaging.

[88] Suppliers may need to include certain elements on the label that are not obligatory but are necessary for the handling and use of the product, for example specific product information, basic instructions for use or P-statements that do not arise directly from the classification of the product (e.g., “Read label before use” or “Do not get in eyes” for eye irritant mixtures).

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Figure 90: Example of detergent label. Hazard class "Eye Irritation"[89]

The below figure presents an example of the regulatory requirements according to **CLP and Detergents Regulations** for a product bleaching detergent supplied to the general public (consumers). The text in the pink boxes relates to the labelling elements required for

[89] Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 – March 2021); p. 63.

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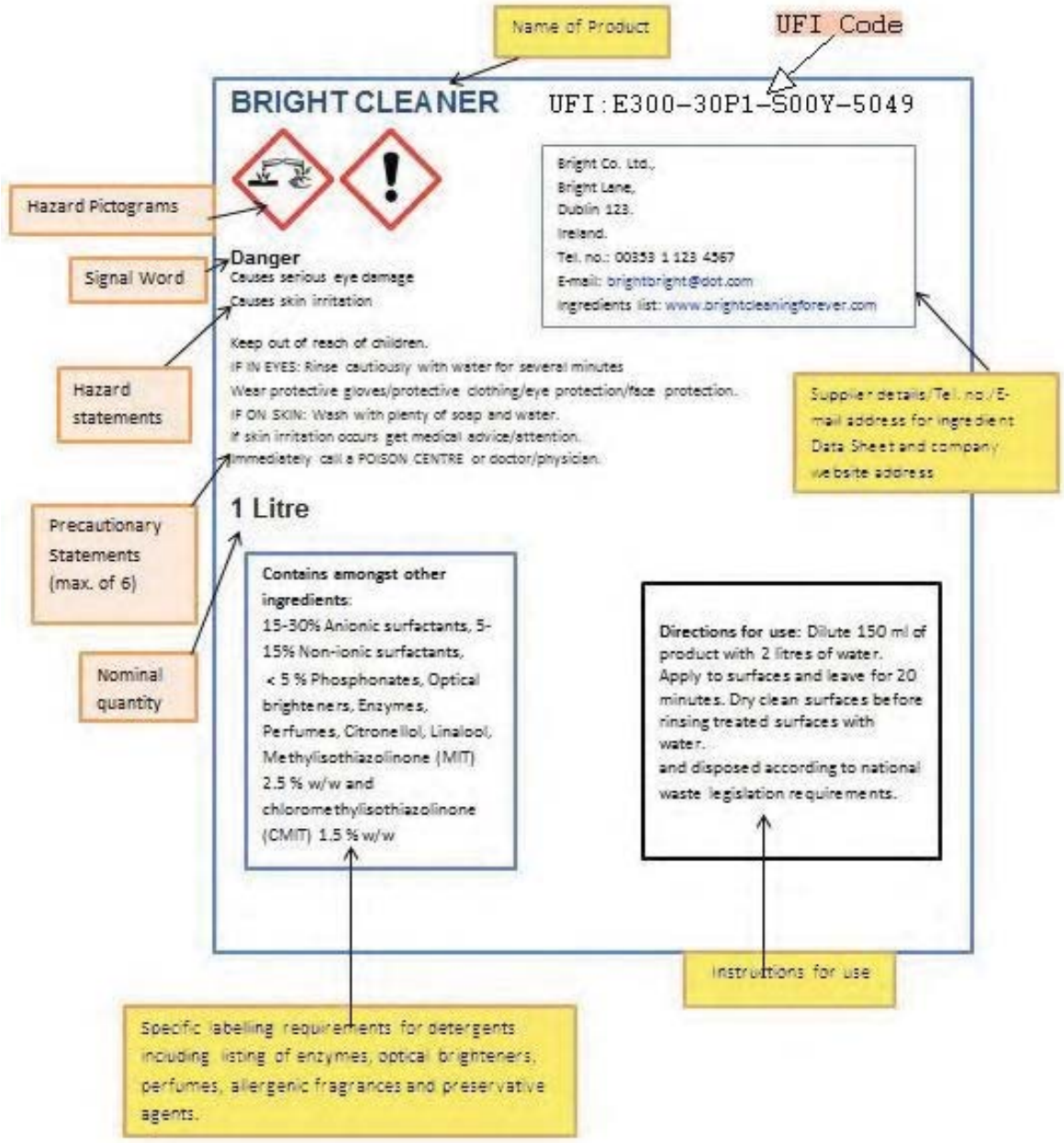
detergents under CLP while the text in the yellow boxes relates to information requirements under Detergents Regulation.

Figure 91: Example of detergent label. Hazard class "Serious eye damage/skin irritation"[90]



Detergents labelling under Biocidal Products Regulations

There are two types of **detergents** falling under the scope of **Biocidal Products Regulations:** detergents that are also disinfectants (biocidal products) and detergents containing an in-can

[90] HSA Detergent Labelling & Packaging Requirements, **available at:** https://www.hsa.ie/eng/Your_Industry/Chemicals/Legislation_Enforcement/Detergents/Detergent_Labelling_Packaging_requirements/

preservative[91] (treated articles), both subject to different definitions and different labelling provisions. The rules apply to both laundry and dishwasher detergents as well as other detergent types, covering detergents for consumer, professional and industrial use.

Article 3.1(a) of BPR defines as 'biocidal product' any substance or mixture of it "capable of preventing the action" or carrying out a control action on any harmful organism by any means other than mere physical or mechanical action. In brief, biocides are products that destroy harmful organisms through chemical/biological processes.

Article 3.1(l) of BPR defines 'treated article' as "any substance, mixture or article which has been ***treated with, or intentionally incorporates***, one or more biocidal products." The definition refers to the explanation of biocidal product in Article 3.1(a) of BPR and it is important to note that the definition of a biocidal product indicates that: ***a treated article that has a primary biocidal function shall be considered a biocidal product***. A liquid laundry sanitizer (with a biocidal claim e.g., kills bacteria) is an example of a treated article with primary biocidal function.

In addition to the requirements specified in the Detergent Regulation the labelling information on the packaging of detergents that contain biocidal active substance/s[92] (e.g., disinfectant, antimicrobial or sanitising product) should contain **all the relevant elements** specified in Article 69 of the BPR. The label of a detergent that is also a biocide namely with a biocidal function such as antibacterial, antimicrobial, antifungal, sanitizing, and disinfectant etc. "must show clearly and indelibly the following information":

- the name(s) of the biocidal active ingredient(s) and its concentration in the product[93];
- the notification or approval number (e.g., PCS 9xxxx or IE/BPA 7xxxx)[94]. Only notified or approved biocides have such a number;
- the type of product formulation[95];
- what the product is approved for[96];
- the formulation batch number or designation and the expiry date relevant to normal conditions of storage[97];
- details of any restricted users i.e., for general public or professional/industrial use only[98];
- instructions on handling, storage, application, use and disposal of the biocide[99];
- details of any protective clothing or equipment which must be worn when using the biocide; and
- whether access to treated areas needs to be restricted[100].

[91] Used to preserve water-based formulations such as laundry detergents, surface cleaners, hand dish washing liquids, etc…

[92] Biocidal substances are incorporated into detergents to give them antibacterial, antimicrobial, disinfecting or sanitizing properties with the intention to destroy, make harmless or control harmful organisms such as bacteria or viruses by means other than mere physical or mechanical action.

[93] BPR, Article 69 (2) (a) the identity of every active substance and its concentration in metric units;

[94] BPR, Article 69 (2) (c) the authorisation number allocated to the biocidal product by the competent authority or the Commission;

[95] BPR, Article 69 (2) (e) the type of formulation;

[96] BPR, Article 69 (2) (f) the uses for which the biocidal product is authorised;

[97] BPR, Article 62 (2) (k);

[98] BPR, Article 69 (2) (m) where applicable, the categories of users to which the biocidal product is restricted;

[99] BPR, Article 69 (2) (g), (j),

[100] BPR, Article 69 (2) (l).

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The figure below presents the information that must be contained on the package of a detergent that is also a biocide. The text in the **green** boxes relates to the information requirements for biocidal detergent products (**BPR**), the text in the **pink** boxes relates to the labelling elements required for detergents under **CLP** while the text in the **yellow** boxes relates to information requirements under **Detergents Regulation.**

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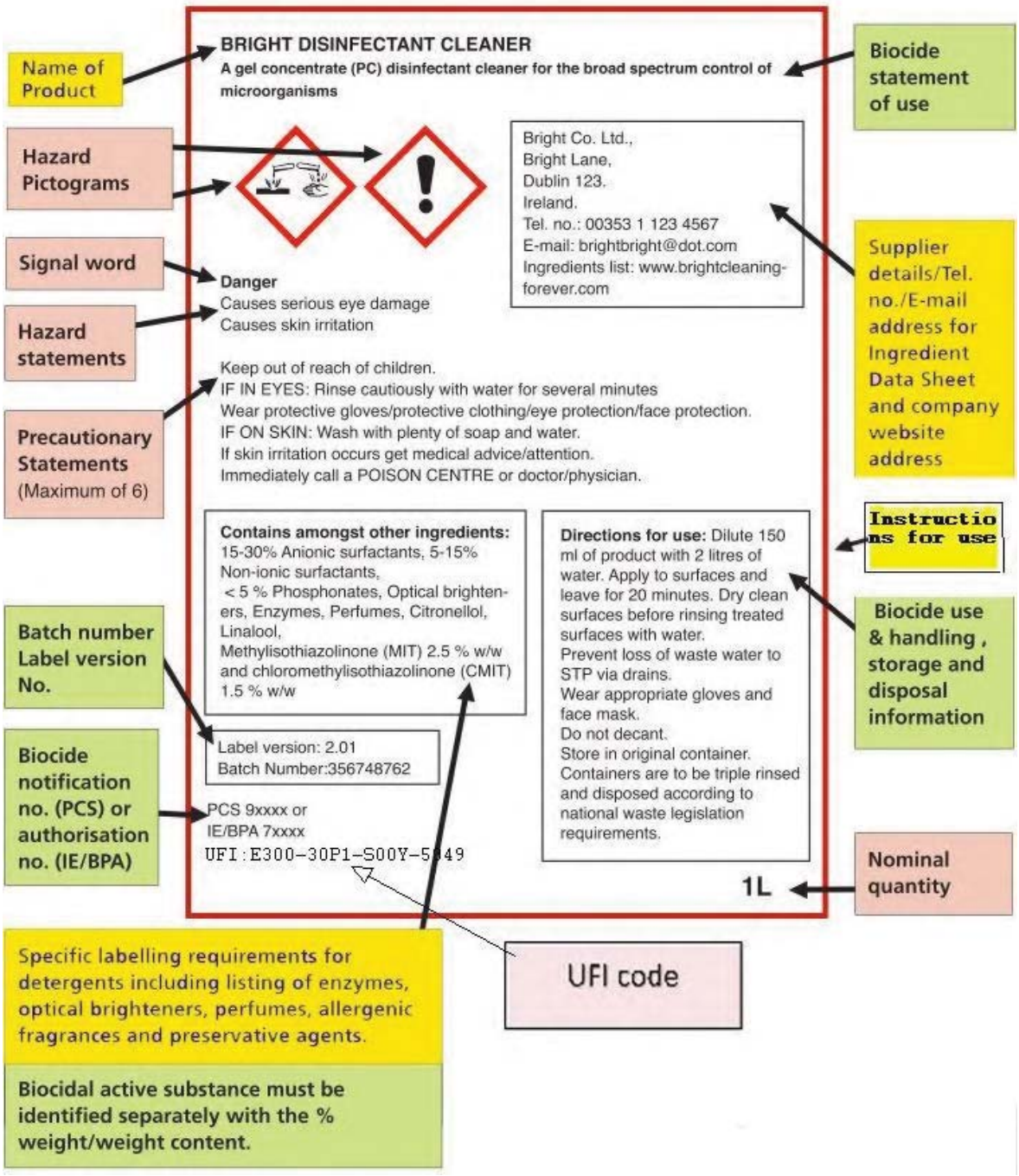
Figure 92: Example of the information that must be contained on a Detergent package containing a Biocide[101]



A laundry liquid detergent formulated with an in-can preservative[102] **having a preserving function[103] in the final product** is an example of a detergent that is also a treated article in accordance with BPR.

[101]https://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/Detergents_Info_Sheet.pdf

[102] For example, under the brand names vinkocide, grotan®, grotanol®, parmetol®.

[103] A preservative's function is to ensure that products are safe to be used by consumers over a long period of time and to maintain the appearance of the product.

According to the Commission guidance on treated articles[104], detergents, containing an additive, which had an in-can preservative added in order to protect it during storage, where this **preservative has no further preserving function in the final product** are not considered as treated articles and **are not a subject** to the BPR labelling provisions listed in Article 58(3). According to the same guidance document detergents, containing what are often referred to as "carry over" preservatives i.e., preservatives that were not added by the manufacturer as such but by a supplier to protect a specific ingredient used for the formulation of a detergent) and which are found in the detergent in very small concentrations are also not subject to BPR labelling provisions. However, Annex VII A of the Detergents Regulation stipulates that "if added, preservation agents shall be listed, irrespective of their concentration". Thus, even if under BPR some treated articles might not be labelled, under the Detergents Regulation they would always be labelled irrespective of the concentration in which they are added in the detergent.

In case the treated articles for which the active substance meets the criteria to be classified as a skin sensitizer category 1 or sub-category 1A in accordance with CLP, the provisions of BPR Article 58(3) should apply[105]. This specific labelling provision will be imposed through the substance approval decision.

The requirements for labelling information for treated articles placed on the market are elaborated in BPR Article 58(3) and are different from the information the label of biocidal product must show[106]. Treated articles have to be labelled according to Article 58(3) in case that:

- A claim is made about the biocidal properties of the treated article e.g., biocide is added intentionally, with claim and/or market positioning regarding its biocidal properties gained from using biocides (e.g., mould resistant polish);[107]

- When the conditions associated with the approval of the active substance concerned require specific labelling provisions.

The label of the placed on the market detergent product (in case of treated articles) must provide:

a statement that the treated article incorporates biocidal products;

the biocidal property attributed to the treated article, where substantiated;

the name of all active substances contained in the biocidal products;

the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets[108];

any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates[109].

[104] Appendix 1; Commission note on guidance on treated articles, CA-Sept13-Doc.5. I.e., (Revision 1, December 2014).
[105] Commission note CA-May15-Doc.6.1-Final.
[106] BPR, Article 69.
[107] It should be pointed out that the majority of 'regular/ normal' detergents & cleaning products are not subject to this requirement.
[108] Preservatives for products during storage PT6 biocidal products are very unlikely to contain nanomaterials.

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Identified overlaps, duplications, and inconsistencies

As mentioned in the previous section legal analysis shows a difference in the terminology regarding the hazard communication in form of labelling between CLP and the labelling requirements of Detergents Regulations. The Detergents Regulation refers to placing information "on the packaging" of the detergent product (e.g., Article 11(2)), while CLP refers to placing information "on the label". However, no evidence has been found for any practical consequences or impact of the different terminology on the hazard communication to consumers, professional or industrial users.

The Detergents Regulation is clear on the fact that its labelling provisions are "without prejudice" to the provisions of the CLP, i.e., they come in addition to CLP requirements. For example, where applicable[110], the section containing the labelling elements dedicated to the CLP might include on the label hazard pictograms, signal words, hazard statements and **precautionary statements** that, to some extent, overlap with Article 11(3) of the Detergents Regulation specifying that "the packaging of detergents shall indicate […] instructions for use and **special precautions**, if required".

In practice, the compliance with the labelling provisions of CLP (hazard pictograms, hazard statements, precautionary statements, etc.) has as an effect to, in part, fulfil the requirements of the Detergents Regulation, Article 11(3), although this is not explicitly stated in the legal text of the Regulation. It might be noted that the CLP and Detergents Regulation complement each other in the sense that both Regulations aim to protect the health of consumers, industrial and professional users [111]. If a substance is regulated or presents a hazard, then there are standard phrases under CLP that can be used to warn consumers, industrial and professional users.

Detergents Regulation, Article 9(3) obliges manufacturers placing on the market the mixtures covered by this Regulation to make available, upon request, without delay and free of charge, to any medical personnel, an ingredient datasheet as stipulated in Annex VII C[112]. For mixtures (such as detergents, paints, and household chemicals) subject to submission requirements under Article 45 and Annex VIII to CLP, a unique formula identifier (UFI) must be provided. The poison centres can identify the exact product and its composition through the submitted UFI. In this regard there is a duplication between these requirements in the sense that the ingredient data sheet under the Detergents Regulation serves a similar purpose as the harmonised information provided to poison centres under the Annex VIII to the CLP.

Further, a certain inconsistency exists between the Detergents Regulation and REACH regarding the information that needs to be included in the safety data sheet for industrial and institutional detergents. This inconsistency results from the fact that the safety data sheet is compiled in accordance with the requirements stipulated in REACH, which are different from the labelling requirements of the Detergents Regulation.

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[109] The CLP Regulation requirements for informing and warning users about potential hazards and related precautions to be taken - for example H317 "May cause an allergic skin reaction" and EUH 208 "Contains … May produce an allergic reaction".

[110] If a substance is regulated or presents a hazard.

[111] 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

[112] Annex VII C requires "The common chemical name or IUPAC name, the CAS number, and, where available, the INCI name, and the European Pharmacopoeia name, shall be given for each ingredient". However, this requirement only applies for the ingredient datasheet (to be provided on request).

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The listing of allergens (fragrances and preservatives) "on the packaging" of the detergent product aims to protect and inform all end-users on hazards, including those already sensitized. The Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents[113] reveals 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[114] and allergenic preservatives when CLP thresholds are met.

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.

In the public consultation of 2014 the Commission proposed, among others, to Amend Annex III to the CPR ('List of substances which cosmetic products must not contain except subject to the restrictions laid down') by submitting additional 62 contact allergens to the obligation of individual labelling, in addition to the 25[115] allergens already listed in Annex III. Should the Commission introduce the obligation to label additional 62 fragrance ingredients the number of fragrance allergens to be labelled would increase to 87 substances. The labelling of additional fragrance allergens will have an impact on products regulated by the Detergents Regulation[116] resulting in more allergens being listed on the packaging.

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")[117].

In parallel, the CLP requires the inclusion of skin sensitisers[118] (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.[119] *These thresholds are different from the*

[113] 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. Available at: https://ec.europa.eu/docsroom/documents/36289

[114] The word "surfactant" is an abbreviation of the phrase 'surface active agent'. A surfactant is a chemical compound that reduces the interfacial tension between water and other liquids such as fats and oils. Surfactants are common ingredients in topical products, which can cause both irritant and allergic contact dermatitis.

[115] One of the 26 allergens currently subject to labelling HICC (3 and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde) have been excluded from these calculations as it was banned by Regulation 2017/1410 of 2 August 2017. Transition periods for the ban end on 23 August 2019 (for placing the substance on the market) and 23 August 2021 (for making it available on the market).

[116] Inception impact assessment - Ares (2018)6241542. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2009-Labelling-fragrance-allergens_en

[117] The International Nomenclature Cosmetic Ingredients (INCI) name is mandatory in the European Union (EU) according to Regulation (EC) No 1223/2009 for labelling the names of ingredients on cosmetic products. Article 19(1)(g) of the Regulation requires the labelling information on cosmetic products to include a list of ingredients. The ingredients are to be expressed using the common ingredient name set out in a glossary compiled and updated by the Commission pursuant to Article 33 of that Regulation. The glossary takes account of internationally recognised nomenclatures including the International Nomenclature of Cosmetic Ingredients. Since 2004, the INCI system is mandatory in the EU for labelling of preservatives and allergenic perfume ingredients according to the Detergents Regulation (EC) No 648/2004.

[118] A skin sensitizer is "a substance that will induce an allergic response following skin contact".

[119] Under CLP, skin sensitisers must be indicated on the label if added at concentrations exceeding 1.0% (skin sensitiser Category 1), 0.1% (skin sensitiser Category 1A) and 1.0% (skin sensitiser Category 1B).

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.

In addition to the different thresholds for the labelling of allergenic fragrances between the Detergents Regulation and the CLP two more differences exist, namely:

The product identifier of the substance, i.e., the name (and identification number) under which the allergenic fragrance is to be labelled, **is different** under these two Regulations: as the **Detergents Regulation refers to the Cosmetic Products Regulation** for the labelling of allergenic fragrances, the latter are listed on detergents' labels with their **INCI** name. Contrary to that, the **CLP** requires that substances are **labelled with either the name and identification number** given in Part 3 of Annex VI to the CLP Regulation[120] or, in case the substance is not part of the list of substances provided therein, with the name and identification number given in the classification and labelling inventory. If neither of these product identifiers exists, then the substance is labelled either with its CAS[121] number together with its IUPAC[122] name or only the IUPAC name in case that the substance doesn't have a CAS number. Finally, under certain conditions, substances can also be listed with their EC names[123].

For mixtures not classified as sensitising but containing at least one skin sensitiser (e.g., an allergenic fragrance) above a pre-defined concentration threshold, (as is commonly the case for detergents), the CLP requires that a EUH208 statement[124] is included in their label.

Based on the above it appears that one and the same allergenic fragrance contained in a detergent is very likely to be indicated twice on the detergent's label and in some cases under different names.

The example below demonstrates that there can be duplication between – on the one hand – the product identifier of the mixture or EUH statement and – on the other hand – the supplemental information mandated by the Detergents Regulation (i.e., the list of allergens and preservatives, which may be referred to by an INCI name also included in the Classification and Labelling Inventory).

Figure 93: Example of dual labelling of ingredients.

[120] Part 3 of Annex VI to the CLP provides a table on the harmonised classification and labelling of hazardous substances.
[121] CAS Registry Number is a unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature.
[122] The IUPAC nomenclature of organic chemistry is a systematic method of naming organic chemical compounds as recommended by the International Union of Pure and Applied Chemistry (IUPAC).
[123] The EC number, i.e., EINECS, ELINCS or NLP, is the official number of the substance within the European Union.
[124] EUH 208 'Contains (name of sensitising substance). May produce an allergic reaction'.

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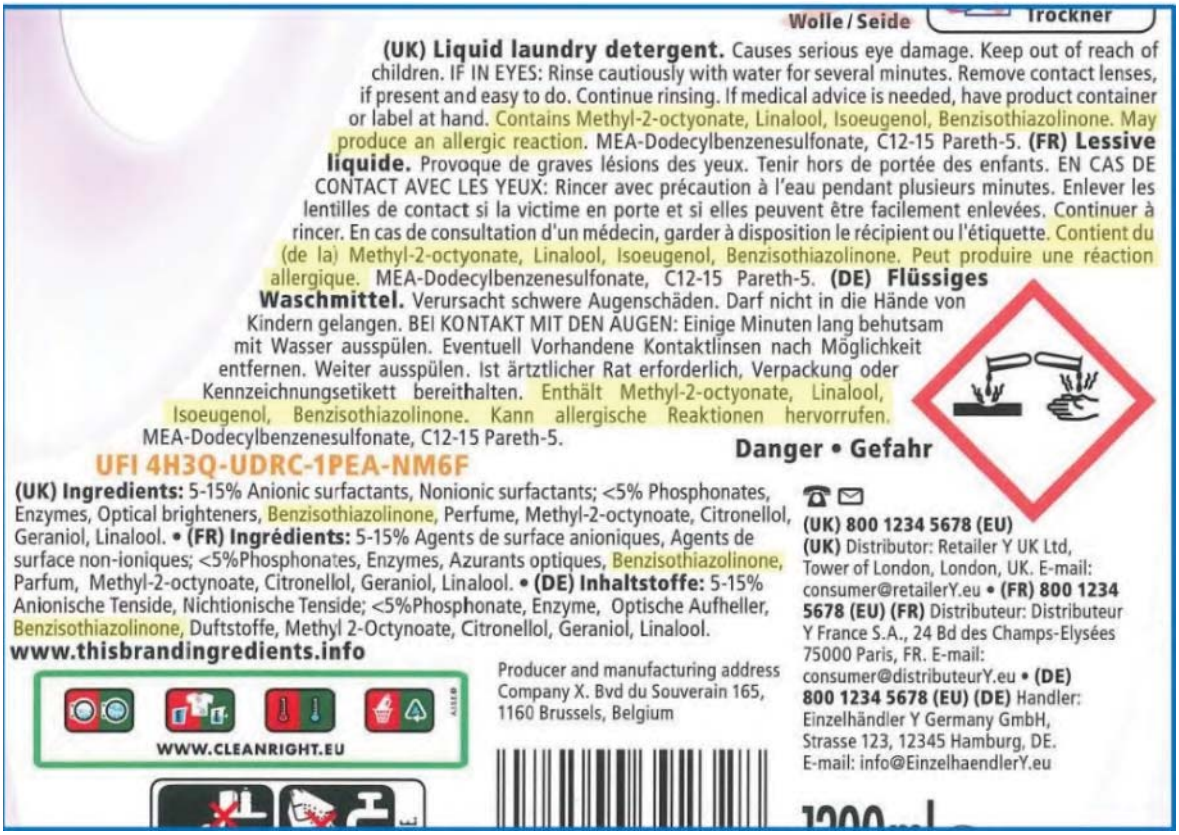

It should be noted that three EU regulations guide the labelling of (sensitizing) preservatives: the Detergents Regulation, BPR and CLP.

The Detergents Regulation requires information on the presence of preservative/s regardless of the concentration and BPR requires information on the preservative/s used in the 'treated article'. The BPR requirement for the label to provide (in case of treated articles) the name of all active substances contained in the biocidal products is already covered by the Detergents Regulation labelling requirements: name of the in-can preservative(s) is listed on the label (INCI name).

The CLP requires hazard statement for Induction H317 *"May cause an allergic skin reaction"* and *"(substance name)"* or Elicitation EUH208 *"Contains (substance name). May produce an allergic reaction". If a EUH statement needs to be included, then the same* ***allergenic fragrance is labelled thrice,*** *i.e., twice under the CLP (product identifier + EUH statement) and once under the Detergents Regulation.*

The below figure is an example of a typical detergent label highlighting the duplication and inconsistencies between CLP and Detergents Regulations[125].

[125] The detergents regulation and opportunities to improve communication of safety information to consumers; GIULIA SEBASTIO International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.),

Figure 94: Typical Detergent Label and a Highlight of the Duplication and Inconsistency

Annex 13d – Overview of costs and benefits under the preferred option

Overview of Benefits (total for all provisions) – Preferred Option		
Description	**Amount**	**Comments**
Direct benefits		
Improved consumer safety and label readability	N/A	Possibility to move supplemental labelling information[126] under CLP, and labelling requirements[127] under the Detergents Regulation to digital labels, would simplify the labels overall and would improve the well-being of consumers with visual impairments.
Benefits for the manufacturers	N/A	Benefits for the manufacturers include: Better management of fast changing label information, and; More space on physical labels for multiple languages which would allow for more cost-effective product distribution across EU markets.
Administrative cost savings related to the 'one in, one out' approach		
Possibility to reduce the frequency of changes in physical labels	N/A	Currently, annual costs related to the disposal of labels reaches around 1 % of manufacturers' annual turnover with the frequency of disposing the labels around 3-4 times per year. Under Policy Option 3, these costs would likely to be reduced, however, quantification of such theoretical reduction is not possible.

[126] EUH statements as per sections 1.1. and 1.2. of Annex II (Art. 25(1)); Other supplemental labelling information than that in paragraphs (1) and (2) of Art. 25 (Art. 25(3)); EUH statements as per Part 2 of Annex II for certain mixtures (Special rules for supplemental label elements for certain mixtures, Art. 25(6)).

[127] Detailed dosage instructions, with only simplified dosage instructions kept on pack; Some categories of ingredients (e.g. surfactants) while other categories are kept on pack (e.g. enzymes, bleach); Other labelling information such as the address and telephone number of the manufacturer.

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	Citizens/Consumers		Businesses		Administrations	
Type of cost	**One-off**	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Familiarisation activities	N/A	N/A	N/A	Three to four FTEs who would need 10 to 20 working days to conduct familiarisation activities (e.g. training, consulting) at the company level.	N/A	N/A
Disposal of labels	N/A	N/A	One-time cost of disposing the labels to comply with the new regulatory requirements under Policy Option 3 is estimated to reach 0.25% to 0.33% of companies' annual turnover.	Currently, annual costs related to the disposal of labels reaches around 1 % of manufacturers' annual turnover with the frequency of disposing the labels around 3-4 times per year. Under Policy Option 3, these costs would likely to be reduced, however, quantification of such theoretical reduction is not possible.	N/A	N/A
Enforcement costs	N/A	N/A	N/A	N/A	N/A	The information which will be provided digitally will not be a point of compliance check by the authorities. Under Policy Option 3, the provision of a digital label will be in voluntary basis.

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Annex 13e – Description of the analytical methods used in preparing the impact assessment (digital labelling)

This Annex provides a description of an approach to the prospective analysis whose results are described in the main body of this report. The aim of the prospective analysis was to (1) assess the problems identified and its drivers, provide the reasons for the EU action, set general and specific objectives of the new initiative, develop policy options tackling these objectives, assess the developed policy options in terms of their economic, social, and environmental impacts and, finally, compare the policy options under effectiveness, efficiency, and coherence criteria.

OVERVIEW OF THE METHODS

The prospective analysis was carried out between December 2021 and March 2022. The work was structured around seven main tasks, each of them containing various activities. This part summarises the work under the key evidence-gathering and analysis activities.

Problem Tree Definition

The definition of the problem and its problem tree were identified and refined based on information collected at the Inception Phase of the study and discussions with the Commission. The final version of the problem tree containing the key drivers behind the problems identified and the consequences of these problems to the environment, consumers, and the industry is presented in Chapter 2.

Subsidiarity analysis

Each of the key problems identified as part of the problem tree definition were carefully assessed with respect to subsidiarity, more specifically, the necessity and added value of EU action.

Policy Objectives Identification

Following the definition of the problems, and the necessity and added value of EU action, the objectives of the policy action were defined, including the general objectives covered in this study, namely:

CLP Regulation: to ensure a high level of protection of human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation;[128]

Detergent Regulation: to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health.

And the specific objectives of this study, namely:

[128] Recital 1 CLP Regulation.

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- SO1: to improve consumer understanding and awareness of labels, by simplifying and streamlining the existing labelling requirements in the Detergents regulation;

- SO2: to set up a future-proof regulatory framework allowing the use of digital tools to communicate product information.

Definition of the policy options

The definition of the policy options started with defining the baseline policy option based on a projection of the status quo. The definition of the baseline scenario involved understanding, qualifying, quantifying, and monetising (to the extent possible) the key elements of 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. Subsequently, the data collected combined with the results of the problem definition and the opinions provided by stakeholders under targeted stakeholder consultation contributed to refining the five policy options developed to tackle these objectives.

Assessment of the policy options

In alignment with the Better Regulation Toolbox, the first step in the assessment of impacts was the identification of all relevant impacts under the different policy options. The identification of the impacts was based on data and information collected during the previous tasks (i.e. interviews, behavioural experiment, surveys, 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 were categorized according to the following criteria:

- **Economic impacts**, in particular focusing on the conduct of business (BR Tools #21-25), sectoral competitiveness, trade and investment flows (BR Tools #21, 27), impact on the SMEs (BR Tool #21), technological development / digital economy (BR Tool #28), and impact to public authorities (BR Tool #58);

- **Social impacts**, focusing on consumers and households (BR Tool #33);

- **Environmental impacts**, in particular focusing on sustainable consumption and production (BR Tool #36).

The impacts that were taken into account for this analysis were 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 representatives (associations and businesses) presented the individual policy options and asked participants to provide direct feedback. The opinions of stakeholders were triangulated with other data sources used in the study. The impacts were modelled in quantitative terms (and monetary terms, whenever possible), and in qualitative terms. The modelling of the impacts involved assessing each option against the baseline scenario, based on the expected evolution of key external trends in the absence of any new policy measures.

Comparison of the policy options

As a final step of the impact assessment, after assessing the identified socio-economic and environmental impacts of each policy option, policy options were compared under effectiveness, efficiency, and coherence criteria.

Concerning the effectiveness criteria, policy options were assessed vis-à-vis the two specific objectives of this study, and economic, social, and environmental impacts identified previously. In the analysis, a comparison of the policy options vis-à-vis each specific objective and socio-economic and environmental impact was illustrated in the following method:

Table 158: Colour coding

Colour coding	--	-	O	+	++	U
Qualitative	Strongly negative	Weakly negative	No or limited impact	Weakly positive	Strongly positive	Undefined

In terms of efficiency, the analysis consisted of two parts:

Presentation and comparison of monetizable costs and benefits identified in this study, and;

Presentation and comparison of stakeholder perception on the costs-benefits ratio under each policy option.

In terms of coherence, the criteria used for the assessment of the policy options were:

Coherence between CLP and Detergents regulations;

Coherence with digitalisation trends in the economy and other EU level and international initiatives on the topic;

Overall assessment of stakeholders' opinion on the policy options.

Following the comparison of the options, the preferred policy option was selected, namely – Policy Option 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.

LIMITATIONS ENCOUNTERED AND MITIGATION MEASURES

Limited availability of updated, EU-level, comparable quantitative data

The limitations of quantitative data were the most evident concerning data related to the operational costs i.e. set-up and maintenance of systems supporting digital labelling. Using this data in the assessment and comparison of the policy options would have been really useful, in particular, for monetising the economic impact (conduct of business) and the expected costs to the chemical industry under Policy Options 3, 4, and 5. The majority of the consulted industry stakeholders mentioned that they do not have this information available and the timeline to collect it at company level was too short. Furthermore, although, during the targeted stakeholder consultation, businesses identified specific benefits of transferring

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information from physical to digital labels, these potential benefits 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.). The combination of these factors resulted in a limited cost-benefit and cost-effectiveness analysis of the policy options that include the use of digital labels.

Similarly, although consulted public authority stakeholders provided input concerning the cost-benefit ratio for national authorities for each policy option, during the course of the study, no concrete quantifiable data was found concerning, for example, additional FTEs needed from public authorities under each policy option to perform enforcement and monitoring activities. It is difficult to estimate the costs each policy option would include to public authorities, especially considering the current lack of clarity on the digital infrastructure that would be used to store the information on digital labels[129].

The analysis of impacts on consumers focused on assessing the impact on safety (i.e. safe use of products) and label readability. The study gathered valuable qualitative input from the targeted stakeholder consultation. However, the perception on these issues from stakeholders representing consumers (i.e. consumer organisations) is not complete due to the lack of responses from such stakeholders to the survey on the policy options. Nonetheless, data triangulation and the use of other data sources (i.e. OPC, interviews, and behavioural experiment) countered this problem to an extent.

Likewise, the assessment of the environmental impacts also was essentially qualitative and focused on the impact on the awareness of consumers about the impacts of dispersion of substances in the natural environment. Thus, the analysis did not include an estimate of waste (i.e. disposal of waste) generated by regulatory changes. In this case, however, policy options 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. Hence, quantitative estimation of the impact on the environment was considered not relevant.

In conclusion, the limitations on quantitative data constrained the strength of the argument on the scale of some identified problems and implications of future policy options. In some cases, estimations were corroborated by existing evidence underpinning the key assumptions through alternative data. In addition, for some options where quantification of costs and benefits was not feasible, a qualitative approach was chosen instead.

The low response rate from consumer stakeholders regarding the survey on policy options

Response rate across all consultation activities, across all major stakeholder categories (industry, public authority, and consumers) was high. Hence, the findings from these activities can be considered, overall, representative. Nonetheless, the most important source of data for the impact assessment part – the online survey on the policy options, had limitations in terms of representativeness. This is particularly the case for stakeholders representing consumers, and, to a lesser extent, public authorities. The survey received a significant number of responses from industry stakeholders (n=67), but a relatively small number from public authorities (n=13), and an insignificant number of responses from consumer organisations (n=2). The low number of responses from consumer organisations

[129] Possible options would include EU centralised database of e-labels held by EU wide public authority/provider; EU centralised database of e-labels held by third-party provider; Independent providers of e-label services (EU or national); Manufacturers' websites with e-labels of own products.

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resulted in an overall lower level of representation of consumers in terms of assessing the impact on consumer safety (i.e. safe use of products), and label readability. To counter this issue, other sources of data (i.e. OPC, interviews, and the behavioural experiment) were used to add to overall representativeness.

Several factors explain the low response rate from consumer stakeholders consulted for this study, notably: the timeline of the assignment, the overlap with other consultation activities on the same topic (i.e. interviews, behavioural experiment, public consultation), resulting in stakeholder fatigue. The lack of interest from the consumer stakeholders in this initiative, especially compared to the response rate from the chemical industry, was noticeable in other stakeholder consultation activities as well. To boost the response rate of the online survey, the study team sent reminders to consumer organisations to complete this survey, however, this did not result in a significantly higher participation rate.

Annex 14 – Exemption from the scope of CLP for certain products

CONTEXT

The 2019 Fitness Check on chemicals reports that, during consultation activities, some Member States and NGOs pointed to potential gaps and inconsistencies regarding identification and communication of hazards in some sectorial legislation such as cosmetic products, medical devices, food and feed additives. For instance, these stakeholders emphasised that in the case of Cosmetic Products Regulation (CPR), the focus on human health protection could result in not considering environmental hazards and fate of cosmetic ingredients. Additional discussions on this topic took also place at the REACH and CLP competent authorities meeting in 2013[130].

Relevant SDG

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';

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'.

Societal trends:

Consumers and professional users concerned about hazardous chemicals

Growing environmental awareness of society, move towards more sustainable products

PROBLEMS

The hazards of certain chemical substances and mixtures are not optimally communicated

The CLP Regulation provides that all substances and mixtures displaying hazardous properties must be labelled and packaged according to their classification (see also Annex 12 on labelling); this aims to protect human health and the environment and to ensure free movements of chemicals in the single market. Through the identification and communication of the hazards of substances and mixtures, the CLP Regulation provides key information thereby enabling professional users and consumers to adopt all necessary precautions during its use, storage and disposal; in addition, this allows them to make informed decisions when purchasing a product.

[130] Document CA/40/2013, 13th Meeting of Competent Authorities for REACH and CLP (CARACAL), 26-28 November 2013

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The CLP Regulation generally covers all chemicals supplied in the EU, including products sold to consumers. It also addresses a full range of hazards to human health and to the environment, as well as physical hazards (e.g. flammability, explosiveness). However, Article 1(5) of CLP exempts a number of substances and mixtures, in the finished state and intended for the final user, from its scope. These scope exemptions concern human[131] and veterinary[132] medicinal products, medical devices[133], cosmetics products[134], and food and feeding stuffs[135]. Recital 11 of CLP further clarifies that these exemptions are based on the premise that the exempted sectorial legislations lay down more specific rules on classification and labelling.

The exempted product categories have a paramount impact on human health because they enter, or come into close contact with, the human body, e.g. by ingestion or application to skin. Therefore, the sectorial legislation exempted by Article 1(5) of CLP is primarily oriented at the protection of health, and uses different measures to assess and ensure the safety for users (e.g. negative and positive lists of substances that can be used in products, risk assessments and authorisation processes, pre-defined lists of products that can be placed on the market, classifications of products according to their complexity and inherent risks to human health, etc.). These legislations may also include the possibility to provide warnings or instructions for safe use to the user through labelling or packaging inserts, but usually information on the hazards of a product is not available to the customer.

While all exempted legislations require a safety assessment for human health, and communication on necessary precautions is covered by the respective legislation, environmental aspects are addressed only in some of those areas. The quality and quantity of evidence about the negative environmental impacts of the chemical products exempted from CLP varies substantially. However, the analysis[136] shows that all exempted product categories (except food and feed where there is no solid evidence) can cause a certain degree of environmental damage. It is important to note here that in some cases adverse environmental effects may be caused by illegal or inappropriate disposal practices (e.g., flushing or pouring pharmaceuticals down the drain), while in other cases it is just the consequence of their use (excretion of medicines).

There is solid quantitative evidence that **human and veterinary medicinal products** can negatively affect the environment due to their hazardous properties[137], use and overuse but also users' inappropriate disposal practices (e.g., flushing unused or expired medicines directly to household sewers).

Medical devices is a diverse product category with an estimated 5,000 to 24,000 different types of products (most of which are articles and thus not subject to CLP provisions). There is currently not enough evidence to identify the full spectrum of environmental issues that may be caused by their use, storage and disposal for the whole group of medical devices.

[131] as defined in Directive 2001/83/EC
[132] as defined in Directive 2001/82/EC
[133] as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC
[134] as defined in Directive 76/768/EEC
[135] as defined in Regulation (EC) No 178/2002 including when they are used (i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC; (ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC; (iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003; (iv) in animal nutrition within the scope of Directive 82/471/EEC.
[136] Annex 7 of RPA report
[137] Zhou et al. (2019). *Environment international*, *128*, 1-10; O'Flynn et al. (2021). Analytical Methods, 13(5), 575-594; Barbosa et al. (2016). *Water Research*, *94*, 257-279.

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However, human health and environmentally hazardous substances can be used in some medical devices when their use is justified and the benefits clearly outweigh the risks.[138] While there are examples of hazardous substances being used in medical devices (e.g. octylphenol ethoxylate), no comprehensive evidence has been found on the environmental hazards and effects of in-vitro diagnostics and other medical devices composed of substances and mixtures.

A number of extensive literature reviews[139] highlight that **cosmetics** that contain ingredients hazardous to the environment may have a substantial impact on the environment. Release into the environment occurs in particular from rinse-off products that enter the wastewater system and sunscreen products that are directly released into surface waters. Some cosmetic products, such as personal care products containing plastic microbeads, siloxanes, synthetic fragrances, and UV filters or triclosan, have negative effects on the environment due to their hazardous properties and their releases to the environment during use.

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. Around 8% of the substances have CLH for different hazard classes. Fifty-six (56) substances have CLH for acute aquatic toxicity and 111 for chronic aquatic toxicity. When self-classifications are included, ca 35% of substances with notified uses in the above product categories have self-classifications for environmental hazards, based on REACH registration data.

An ongoing study[140] which assesses the feasibility of an extended producer responsibility (EPR) scheme for micropollutants[141] in the context of the revision of the Urban Waste Water Treatment Directive (UWWTD) identified pharmaceuticals and personal care products (PCPs) as the main sources of micropollutants reaching urban waste water treatment plants, albeit the contribution from PCPs was lower than from pharmaceuticals. It was estimated that PCPs constitute 26% of the total PNEC toxicity load (pharmaceuticals 66%).

There is solid evidence of adverse environmental effects arising from **food** waste, which, in turn, originates from improper use, storage and disposal of food products. However, the problem of food waste is not related to the environmental hazardous properties of food, but rather the volume of food waste. Scientific peer-reviewed papers discuss the environmental hazards of some food antioxidants (e.g., synthetic phenolic antioxidants[142]). In 2015, butylated hydroxytoluene (BHT) was included in the first Watch List for potential pollutants of surface and ground waters in the EU[143].

[138] EC, (2019). Why are potential dangerous phthalates allowed in medical devices, and who decides if their use is warranted? Available at: https://ec.europa.eu/health/sites/default/files/scientific_committees/docs/citizens_phthalates_en.pdf

[139] Vita et al. (2018). *Toxicology letters*, 287, 70-82; Bom et al. (2019). Journal of Cleaner Production, 225, 270-290; Juliano and Magrini (2017). *Cosmetics*, 4, 11-29; Brausch and Rand (2010). *Chemosphere*, 82, 1518-1532

[140] Bioinnovation Service, 2022. Feasibility of an EPR system for micro-pollutants. Study for DG ENV, Unit C2 (under publication, exact ref to be added)

[141] Micropollutants are substances found in water bodies or waste water with some toxic activity to humans or ecosystems; some of them are toxic even in small concentrations (e.g. endocrine disruptors) and there is concern about their chronic effect and about so-called cocktail effects when combining diffuse exposition to multiple pollutants.

[142] Wang et al. (2021). Environmental Research, 111531.

[143] Negrão De Carvalho, R. et al. (2015). Publications Office of the European Union; 2015. JRC95018.

Problem drivers: Exemption of human and veterinary medicines, medical devices, cosmetics and food and feed from the scope of CLP

The CLP Regulation provides information about the environmental hazards of substances and mixtures to their recipients, i.e., professional users and consumers. The sectorial legislation covers environmental aspects to a varying degree, but generally does not provide hazard information to the users as it is required by the CLP Regulation on environmental endpoints. The products which are exempted from CLP are equally exempted from the provisions in REACH concerning information in the supply chain (Title IV), which i.e. provides that professional users can request a safety data sheet, which could provide information on hazardous properties of a mixture.

Human and veterinary medicinal products

The effects of human medicinal products (HMPs) and veterinary medicinal products (VMPs) on the environment are addressed in the environmental risk assessment which must be submitted as part of the marketing authorisation dossier. In cases where the environmental risk assessments identifies a potential risk to the environment that cannot be avoided, the applicant has to propose a risk mitigation strategy, including information about the environmental risks of the medicinal product, appropriate use, storage and disposal indicated on the label or in the package leaflet.[144] However, the environmental hazards of HMPs and VMPs are not communicated as such as it is required for other chemical products in the scope of the CLP Regulation.

The review of evaluation studies, as well as scientific and technical reports, did not find any conclusive evidence that more extensive labelling of medicines (based on CLP environmental hazards) would substantially contribute to the mitigation of the environmental hazards of pharmaceuticals. Furthermore, the systematic literature reviews did not identify a clear link between environmental awareness and positive change in consumer behaviour[145] and indicated that more factors – e.g., availability of medicine take-back programme, advice by doctors and pharmacists etc. shape the behaviour of consumers with regard to the proper disposal of medicines[146].

Medical devices

The relevant legislation on Medical Devices and In Vitro Medical Devices[147] does not explicitly focus on environmental hazards; however, some safety requirements addressing the safety of disposal of and emissions from medical devices (incl. in vitro medical devices) might be relevant to the protection of the environment. Professional users and consumers do not have access to information about environmental hazards of medical devices, although some information on the environmental hazards is provided for in vitro medical devices containing substances or mixtures which may be considered dangerous. The labels and instructions for use of medical devices

[144] EMA (2018). Guideline on the environmental risk assessment of medicinal products for human use. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-environmental-risk-assessment-medicinal-products-human-use-revision-1_en.pdf

[145] Kusturica et al. (2016). Reviews of Environmental Contamination and Toxicology, 240, 71-104.

[146] Makki et al. (2019). Pharmacy, 7(2), 61.

[147] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, OJ L 117, 5.5.2017, p. 1–175; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, OJ L 117, 5.5.2017, p. 176–332

communicate relevant information on safe use, storage, handling and disposal of the devices, where necessary.

Cosmetic products

The Cosmetic Products Regulation (CPR)[148] does not contain any specific requirements related to the identification, and assessment of the environmental hazards of cosmetic ingredients or products, nor on the communication related to such hazards. As stated in Recital (5) of CPR, the environmental concerns for cosmetics products are to be addressed by REACH. While the Annexes of CPR prescribes labelling for certain ingredients, including specific instructions for use, these are limited to the human health related aspects under the scope of this legislation.

According to REACH, manufacturers and downstream users are obliged to assess identified uses, including in cosmetic products, in a chemical safety report. Moreover, REACH can place restrictions on certain uses of substances, including on cosmetic ingredients. However, only a limited number of relevant cosmetic ingredients have yet been addressed through restrictions under REACH (e.g. Octamethylyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5), microplastics (under development)).

Studies about environmental concerns and cosmetics purchasing behaviour show multiple interacting factors that shape consumer behaviour. In the systematic review of 80 research papers published in 2011-2017, One publication[149] showed different types of motivational factors and their interplay in purchasing decisions of green personal care products and colour cosmetics. According to the study, in buying green personal care products, health concerns are the main deciding factor that also influences other motivational factors, such as internal (environmental attitudes, values, environmental consciousness and attitude towards environmental consumption), social (social pressure, family, friends' attitudes etc.) and external (environmental awareness, price, supply, etc.). Differently, when buying colour and styling cosmetics, which is considered a luxury product, brand and quality play a dominant role and influence other motivational factors.

Food and feed stuffs

In food legislation, the Regulation on genetically modified food and feed[150] requires the identification of environmental hazards is a part of the environmental risk assessment. Other food legislation does not directly cover environmental risk assessment, although some legal acts specify that environmental factors may be considered, if relevant, in the approval of authorisation applications or as a part of scientific risk assessments. All analysed animal feed legal acts provide an explicit requirement for animal feed and animal feed additives to be safe for the environment. The analysis of the effects on the environment must be provided in authorisation applications. The review of the food and feed legislation did not find any specific labelling requirements addressing the environmental hazards covered by CLP.

[148] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209

[149] Liobikienė, G. and Bernatonienė, J. (2017). *Journal of Cleaner Production*, 162, 109-120.

[150] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1–23.

How likely is the problem to persist?

Human and veterinary medicinal products

Pharmaceutical consumption is growing worldwide. In the EU, due to an aging population, the consumption of drugs to treat ageing-related and chronic diseases is expected to remain significant, although a reduction in the consumption of all pharmaceuticals has been observed since 2015. Due to the inappropriate management, treatment, and disposal, discharges of pharmaceuticals and their metabolites into the environment are expected to increase[151]. The European Commission has a number of ongoing initiatives to address environmental pollution from medicinal products. The Strategic approach to pharmaceuticals in the environment and the Farm to Fork Strategy aim to mitigate the environmental issues caused by both human and veterinary medicines. 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. The strategy provides many measures for improving the environmental risk assessment of medicinal products and raising public awareness about proper use and disposal.

Cosmetics

The global market for cosmetics has grown at an average rate of 4% in the period 2011-2019.[152] The European market is expected to follow the global trends, both in terms of growth of the different business segments (skincare, haircare, makeup, fragrances and hygiene products) and channels (strong growth of online sales).

There are ongoing regulatory initiatives that can have an impact on mitigating the environmental risks of chemicals including cosmetic products:

Currently, the CPR is being reviewed to align the current rules on cosmetics with the objectives of the Chemicals Strategy for Sustainability.

The Sustainable Product Initiative (SPI), a legislative framework, announced in 2020 in the Circular Economy Action Plan, targets the environmental performance of goods and services. By revising the Ecodesign Directive, high environmental performance will be ensured for all products (i.e. covering cosmetic products as well) on the EU market. For this purpose, specific environmental requirements and sustainability principles will be developed. SPI will address the current lack of reliable sustainability information about the products. By offering relevant solutions, such as e.g., digital tagging, digital product passports, it will improve communication of the environmental performance of the product 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.

The Introduction of new hazard classes in CLP (intervention area 1), in conjunction with the revision of REACH in 2022 which i.e. aims at extending the use of the Generic approach to risk management

[151] González Peña et al. (2021). Int. J. Environ. Res. Public Health 2021, 18, 2532.
[152] L'Oreal, Cosmetics Market 2020. https://www.loreal-finance.com/en/annual-report-2020/cosmetics-market-2-1-0/

The ongoing revision of UWWTD included a feasibility study of establishing an Extended producer responsibility (EPR) scheme for products responsible for introducing contaminants of emerging concern into waste water. Following the polluter-pays principle, this would ensure that those who place the concerned products on the EU market (producers, importers, retailers, etc.) are responsible for the complete lifecycle of the products, including reduction of discharges into the environment. Such a scheme could improve product composition so that their environmental impacts at the end of life is eliminated or reduced, and/or finance additional costs for removing pollutants from waste water by additional cleaning steps.

There is a growing interest in the environmental performance of products in general and providing consumer with transparent information in particular. In 2021, the European Commission revised the EU Ecolabel criteria for cosmetics. The revised criteria for awarding the EU Ecolabel now apply both to rinse-off and leave-on cosmetic products and include i.a. toxicity to aquatic organisms and biodegradability of rinse-off products and leave-on products, specific exclusions and restrictions of hazardous ingredients, packaging and sustainable sourcing of certain oils. Growing interest in getting the EU Ecolabel has been recently observed. According to the European Commission, 2,057 licences have been awarded for 83,590 products in the EU. Of those, the share of 21% (118) of licenses were awarded to rinse-off cosmetic products with 3% (2,575) of products in this group granted the EU Ecolabel (EC, 2021g).

Cosmetics Europe argues in its environmental sustainability report[153] that many members of the association have been systematically reporting their environmental performance on their websites and provides some examples of environmental performance assessment in some cosmetics companies. Finally, in 2021, a global consortium of cosmetic manufacturers launched an initiative to develop an environmental impact assessment and scoring system for cosmetics 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.[154] This initiative is under preparation and in a recent press release[155] (23 February 2022) the consortium announced that *"A footprinting and scoring prototype is targeted for end of 2022, providing the environmental scoring for a selection of product categories at first.*"

Stakeholders' views

According to the findings of two recent Eurobarometer surveys, the European citizens are highly concerned about the environmental issues and would like to be informed about them. A recent survey on the attitudes of Europeans towards the environment has shown that most Europeans (94%) think that protecting the environment is important to them personally, while over half (53%) believe that it is very important. Moreover, 90% of Europeans are worried about the impact of chemicals present in everyday products on the environment[156]. The Eurobarometer survey on chemical safety demonstrated that slightly less than half Europeans feel well-informed about chemicals contained in products such as paints, detergents,

[153] Cosmetics Europe, 2019
[154] Unilever, 2021
[155] ecobeautyscore-consortium--pr--english-version.pdf (loreal.com)
[156] Kantar (2020). *Special Eurobarometer 501: attitudes of European citizens towards the environment*. Available at: https://europa.eu/eurobarometer/surveys/detail/2257

cosmetics, etc. Yet, the main sources about potential dangers of chemicals in products are product labels (for 70% of respondents) and the media (for 53%)[157].

A recent behavioural experiment[158] assessed the objective understandability of labels by Europeans from selected countries. It concluded that when the label information was available the majority of participants were able to identify less harmful products much better than in cases when there was no label information. Similarly, when the label information was available the experiment participants performed much better in correctly identifying the hazards of a product than when no label information was presented.

A large group of OPC respondents, including citizens, public authorities and civil societies felt that the provision of information on the environmental hazards of veterinary medicines, medical devices, cosmetics, and food or feed, was 'an issue which should be immediately solved' (see also synopsis report in Annex 2). Differently from other respondents, business entities and associations felt that there is an issue to be immediately solved only for human medicines, 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 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 draw conclusions about predominant view within these groups.

The analysis of the position papers in the OPC has shown a very low number of position papers dedicated to the issue of CLP scope exemptions. The findings from the analysis of open questions in TSS demonstrated conflicting opinions on the problem in this intervention area. While some respondents believed that the sectorial legislation regulating the exempted products is fit for purpose, others indicated that the exempted products are not properly regulated under sectorial legal acts. However, in the latter case, no substantial argument was provided on the gaps in the sectorial legislation. 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.

POTENTIAL POLICY MEASURES

The problem that consumers (as well as professional users of certain products) do not receive optimal information on the hazards of certain chemical substances could be addressed by amending Article 1(5)(a) of CLP to revoke the exemption for the labelling for the hazards of these products. Sub-options of this measure would be to selectively revoke the exemption for a certain product area i.e. human medicinal products, veterinary medicinal products, medical devices, cosmetic products or food and feeding stuff.

[157] TNS opinion & social (2017). *Special Eurobarometer 456: chemical safety*. Available at: https://europa.eu/eurobarometer/surveys/detail/2111

[158] VVA Economics & Policy, ConPolicy, Ecorys (2021). Impact assessment study on the simplification of the labelling requirements for chemicals and the use of the e-labelling. Available at: in press.

The option to extend the human health labelling to chemicals that are currently excluded from the scope of CLP was discarded as the analysed legislation contains comprehensive provisions to assess hazards and risks to human health and to provide relevant information and instructions to users. Therefore, additional labelling for human health hazards according to CLP would not contribute to an increased level of protection

The option of amending Article 1(5)(a) of CLP to revoke the exemption for the labelling of the environmental hazards of all or individual exempted product categories was discarded and not further pursued in the impact assessment on the following grounds:

Human and veterinary medicinal products

There is abundant evidence on the presence of pharmaceuticals in the environment, and for their negative effects. The relevant legislation already contains provisions for environmental risk assessment, risk mitigation and provision of information and instructions to users. To mitigate the environmental issues caused by both human and veterinary medicines, the Commission adopted the Strategic approach to pharmaceuticals in the environment[159] in 2019, which includes numerous measures for improving the environmental risk assessment of medicinal products and for raising public awareness about proper use and disposal. The analysis done (see Appendix to this Annex) did not reveal any solid evidence that hazard labelling according to CLP would substantially contribute to the mitigation of the environmental hazards of pharmaceuticals. The current provisions on environmental hazard assessment and communication to consumers in the relevant legislation, as well as already ongoing initiatives, sufficiently address the problem and that the extension of additional classification and labelling measures under CLP is unlikely to provide a significant added value.

Medical devices

While environmental hazardous substances are used in some medical devices, there is no solid evidence for a significant environmental impact from the diverse group of medical devices (most of which are not substances and mixtures). The relevant legislation addresses, to a certain degree, environmental effects and the provision of information to users. Therefore, labelling for environmental hazards according to CLP is not expected to have a significant added value.

Cosmetic products

A number of regulatory initiatives, including the revision of the CPR itself, as well as revision of other legislations that may have an influence on the environmental hazard of cosmetic products (Sustainable Product Initiative, Revision of the Urban Waste Water Treatment Directive), make it difficult to conclude at this point in time on the possible impacts and the appropriateness of revoking the exemption from CLP for cosmetic products.

There is solid evidence for negative environmental impacts from certain ingredients. The relevant legislation does not provide for assessment of or information on environmental

[159] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. European Union Strategic Approach to Pharmaceuticals in the Environment. Available at: https://ec.europa.eu/environment/water/waterdangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

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. Furthermore, a number of relevant initiatives are currently under way, including the revision of the CPR itself, revision of other legislations that may have an influence on the environmental hazard of cosmetic products (Sustainable Product Initiative, Revision of the Urban Waste Water Treatment Directive), as well as actions of the concerned industry to assess the environmental impact of products. These initiatives may significantly change the availability of information on environmental impacts, as well as the impact itself, of cosmetic products. Therefore, it is currently difficult to assess the likely effect of labelling for environmental hazards according to CLP, and not possible to conclude whether removing the exemption for cosmetic products in CLP is a suitable option.

Food and feeding stuff

There is no solid evidence for a negative environmental impact of such products. Furthermore, the relevant legislation addresses, to a certain degree, environmental effects and the provision of information to users. Therefore, labelling for environmental hazards according to CLP is not expected to have a significant added value for most of these products. However, regarding feed additives, the current revision of Feed Additive Regulation addresses the environmental safety of feed additives as well as labelling issues (EC, 2020e).

Appendix – Exemption from the scope of CLP for certain products: Legislative Analysis and Literature Review[160]

INTRODUCTION

The objective of this evidence collection exercise is to support the review of the scope of exemptions from the CLP Regulation. According to Article 1(5) of the CLP Regulation, it covers all chemicals placed on the market except for those excluded from its scope. Veterinary and human medicinal products and medical devices fall out of the scope of the CLP Regulation, as well as cosmetics products, feed and food (*senso largo*). As provided by Recital 11 of CLP, this exemption is based on the assumption that sectorial legislation provides for specific classification and labelling rules ("*This Regulation should, as a general principle, apply to all substances and mixtures supplied in the Community, except where other Community legislation lays down more specific rules on classification and labelling ...*"). However, the hazards borne by those excluded products, especially environmental hazards, may not be covered to the extent provided by the CLP Regulation. Moreover, it may not be clear how the exclusion provisions must be applied in all cases, because some definitions diverge between the CLP Regulation and specific products legislation (in particular the wording of 'in the finish state' and 'intended for the final user') and for other reasons.

In consultation activities carried out for the supporting study to the Fitness Check of chemicals legislation (RPA et al., 2017), Member State authorities and NGOs have identified gaps and inconsistencies in identification and communication of health and environmental hazards caused by cosmetic products, food and feeding additives and medical devices. However, the Fitness Check of chemicals legislation did not cover all exempted areas. Only the CPR and the Medical Devices Directives were extensively covered by the analysis. Few other legal acts concerning human and veterinary medicines and food additives were briefly considered without a thorough examination.

The following research questions are investigated:

RQ1: Does the sectorial legislation that regulates the exempted products provide the same level of protection from the environmental hazards borne by these products as the CLP Regulation?

RQ2: Do the definitions in the CLP Regulation and sectorial legislation covering the exempted products (particularly those related to 'in the finished state' and 'intended for the final user') provide sufficient clarity to decide whether the CLP exemptions apply to a product?

For several reasons, this study does not cover health hazards borne by the products that are exempted from the CLP Regulation. All exempted products have a paramount impact on human health because of close contact with and use by humans. Therefore, the sectorial

[160] Performed in the context of the 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" (group led by RPA Europe). See Annex 1

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legislation covered by Article 1(5) of the CLP Regulation is specifically oriented at the protection of health and uses a lot of different measures for this purpose comparable to classification and labelling – e.g., negative and positive lists of substances that could be used in products, extensive risk assessments and rigorous authorisation processes, the pre-defined lists of products that could be placed on the European market, extensive classifications of products in according to the complexity and inherent risks to human health, etc. So far, previous review and evaluation activities of chemical legislation do not provide any solid quantitative evidence of gaps in protecting human health from the hazards borne by the exempted products.

For the reasons outline above, this analysis is focused on the classification and labelling requirements related to the environmental hazards borne by the products exempted from the CLP Regulation.

Article 1(5) of the CLP Regulation states:

This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

> *(a) medicinal products as defined in Directive 2001/83/EC;*
>
> *(b) veterinary medicinal products as defined in Directive 2001/82/EC;*
>
> *(c) cosmetic products as defined in Directive 76/768/EEC;*
>
> *(d) medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;*
>
> *(e) food or feeding stuffs as defined in Regulation (EC) No 178/2002 including when they are used:*
>
> > *(i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;*
> >
> > *(ii) as a flavouring in foodstuffs within the scope ofDirective 88/388/EEC and Decision 1999/217/EC;*
> >
> > *(iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003;*
> >
> > *(iv) in animal nutrition within the scope of Directive 82/471/EEC.*

To answer the research questions **two methodological approaches** – analysis of legislation and rapid literature review of the evidence available in the scientific peer-reviewed and grey literature sources – are applied.

METHODOLOGY

To answer the research questions outlined in the introduction specific methodological approaches were developed. Each research question was detailed into relevant sub-questions, tasks necessary to collect relevant evidence, methods to collect the evidence and data sources. Figure 95 shows the structural scheme of the suggested research methodology.

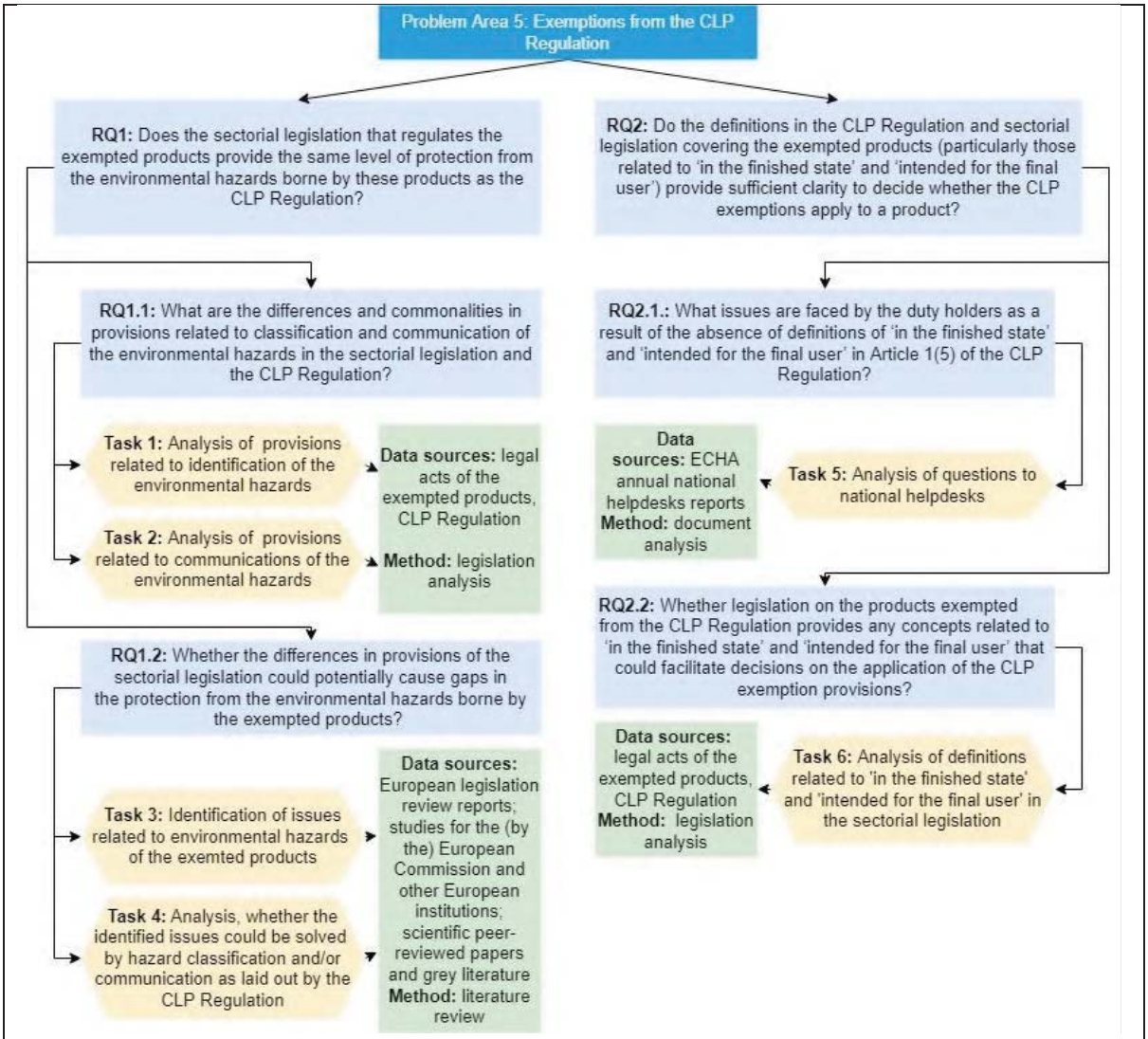

Figure 95: Structural scheme of research methodology

RQ1 was divided into two sub-questions, investigating:
the differences/commonalities in provisions related to identification and communication of hazards of the exempted products in the sectorial legislation and the CLP Regulation (**RQ1.1**);
whether the differences identified in answering RQ1.1 could cause gaps in the protection from the environmental hazards borne by the exempted products (**RQ1.2**).

To answer **RQ1.1**, the sectorial legislation regulating the exempted products was analysed. For each product type, the legislative framework has been identified by consulting the thematic websites of the European Commission. Regulations, Directives and guidelines were screened for general safety requirements, product market authorisation and environmental risk assessment procedures, including labelling requirements. Twenty-two relevant legal acts were identified and analysed (see Table 159).

Table 159: Legal acts regulating the exempted products

Product	Legal acts

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Table 159: Legal acts regulating the exempted products	
Human and veterinary medicinal products	Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation on Authorisation and Supervision of Medicinal Products) Medicinal Products Directive 2001/83/EC Veterinary Medicinal Products Regulation 2019/6 (will come into force on 28 January 2022)
Cosmetics	Cosmetics Regulation 1223/2009
Medical devices	The Medical Devices Regulation 2017/745 In Vitro Medical Devices Regulation 2017/746
Food and feed	*General:* Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Regulation on food law) Regulation 1829/2003 on genetically modified food and feed (Regulation on GM food and feed) Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms (Regulation on traceability and labelling of GMO in food and feed) *Food–specific obligations and procedures:* Regulation 1169/2011 on the provision of food information to consumers (Regulation on Food Information to Consumers) Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (Regulation on a common authorisation procedure) *Specific food products:* Regulation 2015/2283 on novel foods Regulation 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Traditional Foods Regulation) Regulation 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Regulation 2017/2469 on requirements for novel foods applications) Regulation 1333/2008 on food additives (Food Additives Regulation) Regulation 1332/2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (Food Enzymes Regulation) Regulation 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (Food Flavourings' Regulation) *Feed:* Regulation 767/2009 on the placing on the market and use of feed (Feed Regulation) Regulation 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (Regulation on the Implementation rules) Regulation 1831/2003 on additives for use in animal nutrition (Regulation on additives in animal nutrition)

To answer **RQ1.2**, in the first place, the European Commission legislation evaluations and checks as well as other studies conducted for and by other European institutions were analysed. This analysis was necessary to understand if any regulatory gaps on hazard identification and communication in the sectorial legislation (as detected through the legislation analysis) could lead to issues in protection from the environmental hazards of the exempted products. Furthermore, where relevant we identified the EU policy documents supported by evidence and used them as a source for evidence collection (e.g., Strategic Approach to Pharmaceuticals in the Environment, Farm to Fork Strategy, etc.). The analysis of the relevant EU documents and studies was followed by the investigation of scientific peer-reviewed and grey literature publications. For each exempted product, the analysis followed four main steps, shown in Figure 96.

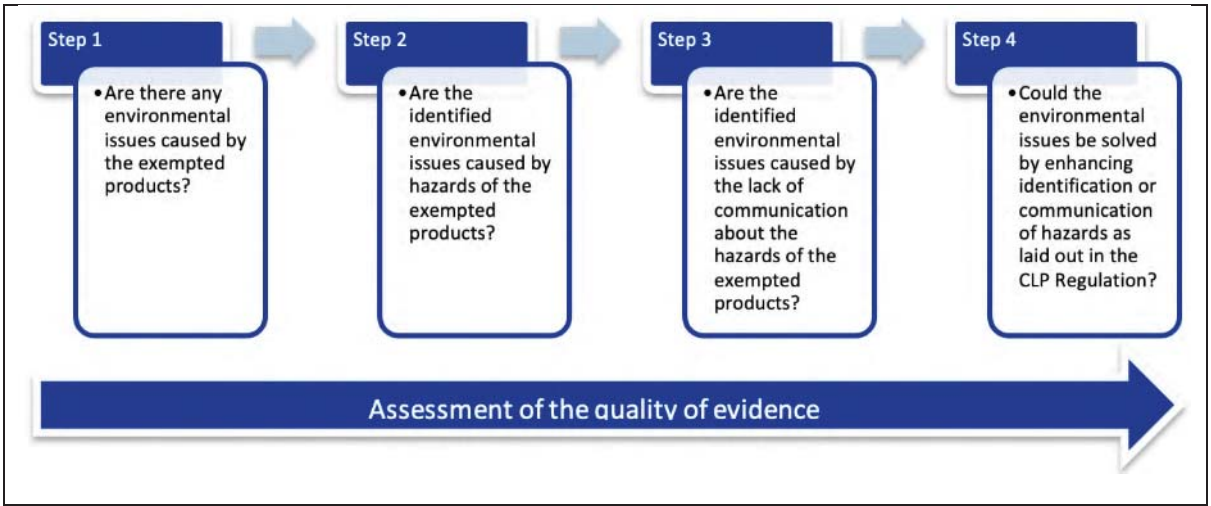

Figure 96: Main steps of analysis to answer RQ1.2

At each step, the quality of evidence was assessed to understand whether available evidence is sound. For this purpose, the guidance provided by Better Regulation Tool #4 (EC, 2021c) combined with the hierarchy of evidence suggested by Evans (2003) was used. The quality of the evidence is understood as its strength in terms of the influence of the research design on the generalizability and argumentation of research results. For instance, the results of international cross-sectional quantitative survey could be representative of the European Union if it covers relevant countries, while the findings of a national survey could not. The following grading framework has been applied:

Excellent – large-scale studies that cover international datasets of substantial quantity and diversity. E.g., systematic literature reviews, international cross-sectional quantitative surveys (e.g., for studying attitudes, perceptions and behaviour).

Good – results obtained by direct observation or survey studies of a lesser scale, such as, e.g., national quantitative surveys.

Fair – studies that do not cover large audiences even at national level and/or does not provide a reproducible quantitative methodology. These are for instance, narrative literature reviews (i.e. without a systematic approach to collection and selection of evidence), qualitative research (focus groups, interviews).

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Poor – expert opinions expressed in expert working groups, dedicated events or through stakeholder surveys, case studies with a qualitative methodology.

N/A – legal acts, guidelines and policy documents were not assessed for the quality/strength of evidence.

Evidence assessment matrix for all evidence sources used in this study is provided in Appendix 1 to Annex 4.

To answer **RQ2**, it was divided into two sub-questions (detailed motivation is provided in the analysis section):

RQ2.1: what issues are faced by the duty holders as a result of the absence of definitions of 'in the finished state' and 'intended for the final user' in Article 1(5) of the CLP Regulation?

RQ2.2: Whether legislation on the products exempted from the CLP Regulation provides any concepts related to 'in the finished state' and 'intended for the final user' that could facilitate decisions on the application of the CLP exemption provisions?

To answer **RQ2.1,** annual reports on the activities of national helpdesks published by ECHA in 2018, 2019 and 2020 were analysed to understand what the most frequent and relevant questions to the helpdesks are. Furthermore, questions related to the definitions in ECHA's Q&A section were investigated.

To collect evidence on **RQ2.2**, an analysis of definitions in the sectorial legislation regulating the exempted products was conducted. The quality of available evidence was evaluated based on the recommendations of Better Regulation Tool #4 (EC, 2021c).

The main **limitation** of the evidence analysis is that it does not give an exhaustive evidence review on each product exempted from the CLP Regulation. Due to the broadness of topics addressed (i.e. human and veterinary medicinal products, cosmetics, medical devices, food and feed), a thorough systematic literature review on each exempted product is not possible within the scope of this supporting study. Therefore, this **evidence collection exercise aimed to identify the main trends and evidence sources** related to each product. The evidence search was focused on several types of sources:

systematic literature reviews,

narrative literature reviews, where systematic ones were not available,

EU-wide quantitative surveys, and

national surveys or case studies if the sources covering EU were not available.

This approach was adopted from the hierarchy of evidence by Evans (2003); in his model, systematic literature reviews are the best sources of evidence in terms of effectiveness, appropriateness, and feasibility. Systematic literature reviews provide a transparent and reproducible methodology for including publications under analysis and assessing their quality. They cover substantial periods and number of publications (usually, from 5-10 years and several dozens to hundreds of publications) to reflect the main trends in scientific knowledge and gaps. Similarly, international surveys provide stronger evidence than national surveys and case studies.

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Legislative framework

Three legal acts focused on veterinary medicinal products (VMP) and medicinal products for human use (HMP) were identified (see Table 160). A market authorisation is needed for placing these types of products on the market. Common market authorisation procedures for veterinary medicinal products and medicinal products for human use are laid out in Regulation 726/2004 on Authorisation and Supervision of Medicinal Products. Specific requirements for each type of medicinal product are provided in Medicinal Products Directive 2001/83/EC and Veterinary Medicinal Products Directive 2001/82/EC. Regulation 2019/6 lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products. This repeals Directive 2001/82/EC and amends the provisions of Regulation (EU) 726/2004 relating to the authorisation and supervision of veterinary medicines, which currently governs the centralised marketing authorisation procedure for both human and veterinary medicines. Regulation 2019/6 will apply since 28 January 2022; therefore, the Directive 2001/82/EC was not included in the analysis.

Table 160: Overview of medicinal and veterinary medicinal products legislation

Type of products	Legislation
Medicinal and medicinal veterinary products	Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation on Authorisation and Supervision of Medicinal Products)
Medicinal products for human use	Medicinal Products Directive 2001/83/EC
Veterinary medicinal products	Veterinary Medicinal Products Regulation 2019/6 (will come into force on 28 January 2022)

Legal acts' search identified several specific regulations on medicinal products, namely, Regulation 141/2000 on medicinal products for rare diseases, Regulation on medicinal products for children 1901/2006 and Regulation on advanced therapy medicinal products 1394/2007. These regulations complemented the requirements set in Regulation 726/2004, Directive 2001/83/EC and did not contain any additional provisions focused on the identification, classification and communication of the environmental hazards, so these are not covered in this mapping exercise.

Identification and classification of environmental hazards

In medicinal and veterinary medicinal products legislation, environmental hazards of products are identified in the environmental risk assessment (ERA), which is carried out as a part of activities in preparing a dossier for marketing authorisation. Marketing authorisation can be granted through various procedures, such as centralised, mutual recognition, decentralised or national procedure. However, an ERA is required for all new marketing authorisation applications for a medicinal product through all these procedures (EMA, 2018).

The common procedure for marketing authorisation of medicinal (HMPs – human medicinal products) and veterinary medicinal products (VMPs) is laid out in Regulation 726/2004, while Medicinal Products Directive 2001/83/EC and Veterinary Medicinal Products' Regulation 2019/6 provide specific requirements. For both HMP and VMP, an environmental risk assessment is therefore required for placing a product on the market.

Applicants who intend to place either HMP or VMP on the market are obliged to submit an environmental risk assessment as a part of the authorisation dossier. Table 161 summarises provisions regarding the environmental risk assessment found in the legal acts.

Table 161: Provisions regarding identification and classification of environmental hazards in medical devices

Legislation	Provisions
Regulation 726/2004 on Authorisation and Supervision of Medicinal Products	Article 6(2) states that in the case of a medicinal product for human use containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC, the application shall be accompanied by: (a) a copy of the competent authorities' written consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes where provided for in Part B of Directive 2001/18/EC or in Part B of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1); (b) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC; (c) **the environmental risk assessment** in accordance with the principles set out in Annex II to Directive 2001/18/EC; and (d) the results of any investigations performed for the purposes of research or development. Article 31(2) specifies that in the case of a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC, the application shall also be accompanied by: a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC or in Part B of Directive 90/220/EEC; the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC; **the environmental risk assessment** in accordance with the principles set out in Annex II to Directive 2001/18/EC; and the results of any investigations performed for the purposes of research or development.
Medicinal Products Directive 2001/83/EC	Under Article 6(1), no medicinal product may be placed on the market of a Member State unless a **marketing authorisation has been issued** by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (2) and Regulation (EC) No 1394/2007. According to Article 8(3), the application for a marketing authorisation of a medicinal product must be **accompanied by:** (ca) **evaluation of the potential environmental risks posed by the medicinal product**. This impact shall be assessed and, on a case-by-case basis, specific arrangements to limit it shall be envisaged. (g) **reasons for any precautionary and safety measures** to be taken for the storage of the

Table 161: Provisions regarding identification and classification of environmental hazards in medical devices	
Legislation	**Provisions**
	medicinal product, its administration to patients and for the disposal of waste products, together with **an indication of potential risks presented by the medicinal product for the environment**. (iaa) **The risk management plan describing the risk management system which the applicant will introduce** for the medicinal product concerned, together with a summary thereof. Annex I, Part I, Module I, 1.6 specifies that where applicable, applications for marketing authorisations shall include **a risk assessment overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions**. The environmental risk connected with the release of medicinal products containing or consisting of GMOs (Genetically Modified Organisms) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of modified organisms and repealing Council Directive 90/220/EEC (1) shall be addressed.
Veterinary Medicinal Products Regulation 2019/6	Article 5(1) states that a veterinary medicinal product shall be placed on the market only when a competent authority or the Commission, as applicable, has granted a **marketing authorisation** for that product in accordance with Article 44, 47, 49, 52, 53 or 54. Article 8(1) specifies the requirements to the content of a marketing authorisation. It refers to Annex I of the Regulation for the documentation requirements. Article 8(2) defines additional requirements for antimicrobial medicinal products as follows: (a) documentation on the direct or indirect risks to public or animal health or to the environment of use of the antimicrobial veterinary medicinal product in animals; (b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of the veterinary medicinal product. Annex I sets the requirements for the particulars and documents accompanying an application for marketing authorisation. Title I of Annex I, Requirements for veterinary medicinal products other than immunological veterinary medicinal products, Part 3: Safety and residues tests, Section 6: Environmental risk assessment describes the procedure of the **environmental risk assessment** for products containing/not containing genetically modified organisms. Sub-section 6.1 states that an **environmental risk assessment** shall be performed to assess the potential harmful effects, which the use of the veterinary medicinal product may cause to the environment and to identify the risk of such effects. The assessment shall also identify any precautionary measures which may be necessary to reduce such risk. Sub-section 6.2 outlines that in the case of a veterinary medicinal product containing or consisting of genetically modified organisms the application shall also be accompanied by the documents required under Article 2 and Part C of Directive 2001/18/EC. Title II of Annex I, Requirements for immunological veterinary medicinal products, Part D. Environmental risk assessment, Part 3: Safety tests, Section D. Environmental risk assessment describes the procedure of the environmental risk assessment. It states that the purpose of **the environmental risk assessment** is to assess the potential harmful effects, which the use of the product may cause to the environment and to identify any precautionary measures, which may be necessary to reduce such risks.

The requirements and process of the environmental risk assessment of medicinal products for human use are described in the guidelines by the European Medical Agency (EMA, 2018).

According to EMA (2018) 'It is mandatory for the dossier for the marketing authorisation of HMP to include an ERA. This ERA is based on the use of the product and the physicochemical, ecotoxicological, and fate properties of its active substance'. The ERA should be updated if there is an anticipated increase in environmental exposure. It is important to stress that the ERA focuses on the properties of the active substance. EMA (2018) clarifies that 'excipients do not generally require an ERA unless there is a specific toxicological effect to suggest an environmental risk under the product's conditions of use.'

All medicinal products, in principle, require an ERA and a PBT assessment. An ERA may also consist of a justification for not submitting ERA studies. The ERA consists of two phases: in Phase I, 'the potential for environmental exposure is assessed based on the nature of the active substance and the intended use' and 'products that require a more extensive Phase II risk assessment – either standard or tailored - are identified'.

ERA Phase I results in a predicted environmental concentration in surface water (PEC_{SW}) value. If the value is above 0.01 µg/L, the medicinal product active substance needs to undergo ERA Phase II. Phase II requires the determination of the physicochemical properties, fate and ecotoxicity. These need to be determined by applying GLP tests following OECD test guidelines. A number of methods are based on methods described in REACH and the Water Framework Directive Environmental Quality Standards. Phase II results in the calculation of predicted no-effect concentration (PNEC) values for different environmental compartments and risk quotients (RQ = PEC / PNEC). If RQ is equal to or above 1, the risk to the environmental compartment cannot be excluded and therefore the applicant should propose adequate precautionary and safety measures to protect soil ecosystems.

The PBT assessment follows the criteria for the identification of PBT and vPvB substances specified in Annex XIII of the REACH Regulation.

Finally, for active substances with a specific mode of action (e.g. antibiotics and endocrine active substances), EMA (2018) requires tailored assessments.

ERA results in assigning a medicinal product to one of the following categories that lead to specific labelling requirements:

> No significant risk to the environment or Current ERA data does not suggest a potential risk to the environment.

ERA has identified a potential risk to the environment.

In cases, when ERA identified a potential risk to the environment and it cannot be avoided, the applicant should propose a risk mitigation strategy, including information about the environmental risks of the medicinal product, appropriate use, storage and disposal indicated on the label or in the package leaflet. Provision of such information on the label or in the packaging leaflet considered on case-by-case basis depending on the specific risk (EMA, 2018).

ERA of the veterinary medicinal products (VMPs) is a two-phase process that is detailed in the guidelines describing the requirements and content of each phase (EMA, 2000). Similarly to HMPs, ERA considers only the use of the VMP and physicochemical, ecotoxicological

and fate properties of its active substance. The results of ERA trigger specific risk mitigation measures and appropriate labelling to inform users and professionals.

Phase I is focused on the assessment of the environmental exposure of a VMP and determines if an ecotoxicological assessment is necessary. Phase I assessment considers active substance and other constituents (excipients) of a VMP, its methods of administration, target species and proposed pattern of use. This assessment is mandatory for all VMPs. The decision if Phase II assessment is necessary is taken based on the predicted environmental concentration of a VMP in soil for the terrestrial compartment and environmental introduction concentration for the aquatic compartment and intended use and intrinsic properties of a VMP. For VMPs with predicted environmental concentrations below 100 µg/kg or environmental introduction concentration 1 µg/L, Phase II assessment is not required. However, because of concerns related to the intrinsic properties of a VMP and their effects on the environment, a tailored risk assessment might be needed.

Phase II covers a three-tiered ecotoxicological assessment, which is based on risk quotient (RQ), which is a ratio between predicted environmental concentration and predicted no-effect concentration in terrestrial and aquatic compartments. If RQ is lower than 1, no further testing is needed, while if the RQ is equal or above one, assessment moves to tier B to generate more data on the environmental compartments where RQ is higher than one. If the tier-B assessment concludes that a VMP poses a risk to the environment, tier-C assessment based on more realistic scenarios is required. Physicochemical properties, environmental fate and environmental effects studies should be performed following the OECD guidelines and by applying Good Laboratory Practice. If Phase II assessment concludes that a VMP poses an unacceptable risk to the environment, the applicant should propose measures to reduce the risk to an acceptable level.

The guidelines for specific aspects of assessing veterinary medicinal products are under development. In the recent concept paper, the European Medicines Agency acknowledged that 'while the available guidance documents (see above for details) provide detailed information on how to estimate the environmental exposure of VMPs intended for use in terrestrial animals, they do not provide comprehensive guidance on how to perform an ERA for VMPs intended for use in aquaculture facilities' (EMA, 2021a).

Labelling and communication of the environmental hazards of the products to downstream users

In all legal acts 'labelling' is treated broadly as any information provided on the outer or immediate packaging of the products (see Table 162). HMPs and VMPs are also accompanied by a package leaflet that may also contain important information about the safety of the products, their disposal or any precautionary measures to be taken.

Table 162: Labelling and related definitions

Legislation	Definitions
Regulation 726/2004 on Authorisation and Supervision of Medicinal Products	Article 2 specifies that the definitions laid down in Article 1 of Directive 2001/83/EC and those laid down in Article 1 of Directive 2001/82/EC shall apply for the purposes of this Regulation.
Veterinary Medicinal Products	Article 4 provides the following definitions: (24) 'labelling' means information on the immediate packaging or the outer packaging; (25) 'immediate packaging' means the container or any other form of packaging that is in

Regulation 2019/6	direct contact with the veterinary medicinal product; (26) 'outer packaging' means packaging in which the immediate packaging is placed; (27) 'package leaflet' means a documentation leaflet on a veterinary medicinal product which contains information to ensure its safe and efficacious use;

Medicinal Products Directive 2001/83/EC indicates that the label must contain specific precautions relating to the disposal of unused medicinal products or waste derived from them. However, such requirement is absent in the newer Veterinary Medicinal Products Regulation 2019/6.

*Table 163: Provisions on the communication of product hazards to the environment to users**

Legislation	Provisions
Regulation 726/2004 on Authorisation and Supervision of Medicinal Products	No specific requirements related to the environmental hazards are mentioned.
Medicinal Products Directive 2001/83/EC	Article 54 specifies the content of the medicinal product label. Among other required content it must contain: (g) a special warning, if this is necessary for the medicinal product; (i) special storage precautions, if any; (j) **Specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products**, where appropriate, as well as reference to any appropriate collection system in place. Annex I, Part I, Module I, 1.6 specifies the content requirements of the risk assessment and indicates that applications for marketing authorisations shall include a risk assessment **overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions**. Article 62 states that the outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful for the patient, to the exclusion of any element of a promotional nature. According to Article 63(1), the particulars for labelling listed in Articles 54, 59 and 62 shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.
Veterinary Medicinal Products Regulation 2019/6	Recital (52): In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, **simplified rules should be laid down as to how their packaging and labelling are to be presented**. The textual information provided should be reduced and, if possible, pictograms and abbreviations could be developed and used as an alternative to such textual information. Pictograms and abbreviations should be standardised across the Union. **Care should be taken so that those rules do not jeopardise public or animal health or environmental safety**. Article 10(1) specifies the requirements for information on the immediate packaging of veterinary medicinal products. Among other required information it must contain (g) **special storage precautions**, if any. Article 14(1) sets the requirements for information provided in the package leaflet of a veterinary medicinal product. Among other required information it must contain (i)

*Table 163: Provisions on the communication of product hazards to the environment to users**	
Legislation	**Provisions**
	information essential for safety or health protection, including **any special precautions relating to use and any other warnings**.
*NOTE: *User may include professional users and consumers*	

Table 163 shows that some legal acts put requirements to provide information related to storage precautions, special warnings and disposal of the product. However, other environmental hazards identified through risk assessment may not be necessarily displayed.

According to the VMP Regulation, information on the label and leaflet as well as special precautions for the protection of the environment and other product features are provided in the summary of product characteristics (Article 33(1), Article 35(1)). Summaries of product characteristics are provided in the Union VMP database which is accessible to the general public (Article 55(1) and (2); Article 56(3)).

Evidence on the gaps in protection from the environmental hazards

Firstly, evaluation, impact assessment and technical and scientific studies that related to HMP and/or VMP legislation were identified and screened to find evidence of potential gaps in protection from the environmental hazards borne by human and/or veterinary medicinal products.

The research presented in the studies recognised that **inappropriate use and disposal of medicinal products and gaps in the environmental risk assessment** are among the reasons why medicines occur in the environment. The pharmaceuticals used by humans and animals are excreted with the urine, veterinary medicinal products occur in the environment with animal feed surplus, while human medicines are often disposed of through household sewers or trash bins. The rates of human medicines' consumptions are high. For instance, in 2008, the consumption of active pharmaceutical ingredients in the EU varied from 50 to 150 g of API per capita annually (with average world consumption of 15 g of API per capita). High quantities of veterinary medicinal products were also reported in the EU farms (BioIntelligence Service, 2013; Deloitte, INERIS, Mileu, LSE, 2016). Trends in sales of veterinary antimicrobial agents have been systematically reported by the European Medicines Agency (EMA). According to the recent report, 5577.8 tonnes of antimicrobial veterinary medicines were sold in 31 European countries in 2020 with the largest amounts of penicillins (with proportion of 31.1% of total amounts sold in mg per population correction unit), tetracyclines (26.7%) and sulfonamides (9.9%). However, a substantial decrease (43.2%) in sales, especially in high selling countries was observed between 2011 and 2020 (EMA, 2021c).

The evidence for pharmaceuticals in the environment was collected through extensive literature reviews in scientific and technical reports (BioIntelligence Service, 2013; Deloitte, INERIS, Mileu, LSE, 2016; European Commission, 2014). The recent report also focused on the feasibility aspects of the environmental risk assessment of pharmaceuticals (Schwonbeck et al., 2021).

The effects on the environment vary by individual pharmaceuticals, among documented impacts are decreasing vulture population due to poisoning with diclofenac, impaired reproduction of fish due to contraceptive Ethinylestradiol, and many others (BioIntelligence

Service, 2013). Based on the growing scientific evidence on the presence of pharmaceuticals in the environments, some of them have been monitored as **potential pollutants in surface and groundwaters** under the Watch List of priority substances in the field of water policy (European Parliament and Council, 2013) that aims to determine the risks of these substances to the aquatic environment across the EU. The Watch List has been periodically updated. The first Watch List was published in 2015 and contained one synthetic and two natural hormones, a pain killer diclofenac, and three macrolide antibiotics (EC, 2015b). The Watch List was revised in 2018 and covered two new antibiotics – amoxicillin and ciprofloxacin, while the pain killer diclofenac was removed (EC, 2018d). In 2020, the Watch List was updated for the third time and included several new pharmaceuticals – antibiotics (sulfamethoxazole and trimethoprim), antidepressant venlafaxine and its metabolite O-desmethylvenlafaxine, and three azole pharmaceuticals (clotrimazole, fluconazole and miconazole) (EC, 2020f). Substances for the watch list have been selected based on various criteria, including scientific evidence and expert consultations. Proposals of substances and related evidence are documented in the reports by the Joint Research Centre (Gomez Cortes et al., 2020; Loos et al., 2018; Negrão De Carvalho et al., 2015). The Watch List is an important measure for identifying the emerging pollutants and gathering reliable data for identifying their risk posed across the EU.

Scientific literature provides abundant evidence about the occurrence of both human and veterinary pharmaceuticals in the environment and their adverse effects. The volume of literature (including literature reviews) is very high; therefore, only some examples of relevant systematic literature reviews are discussed here:

O'Flynn et al. (2021) examined over 100 scientific publications covering the 2009-2020 period, to understand the whole lifecycle and the concentrations of six pharmaceuticals (azithromycin, ciprofloxacin, sulfamethoxazole, gemfibrozil, diclofenac, and venlafaxine) in the EU surface waters. The researchers emphasised that azithromycin, ciprofloxacin and sulfamethoxazole are of particular concern due to their ability to encourage the growth of antimicrobial-resistant organisms in an environmental setting. Various factors, such as obesity, population growth and an ageing population led to the increased usage of many pharmaceuticals such as gemfibrozil, diclofenac and venlafaxine.

According to the systematic literature review of papers published in 1998-2016 that analysed pharmaceuticals in the environment by Zhou et al. (2019), approximately 60% (284) of the analysed substances were positively detected in one or more of 33 European countries. Forty-five analysed compounds showed a potential environmental risk to aquatic ecosystems, 12 of them were indicated to have high environmental risk in aquatic environments, while 17 and 7 compounds showed moderate and small-scale environmental risks.

In the systematic literature review, Barbosa et al. (2016) summarised the occurrence, adverse effects on the environment and removal in aqueous matrices of 10 substances and group of substances listed in the Second EU Watch List and discussed in the research papers published in 2005-2015. Among the discussed substances – steroid hormones (EE2, E2 and E1), diclofenac, and macrolide antibiotics.

In the systematic literature review of 1166 scientific publications, Tim aus der Beek et al. (2015) analysed the global occurrence of human and veterinary pharmaceuticals. Residues of 16 human and/or veterinary pharmaceutical substances were detected in the surface, drinking, and groundwater of all analysed regions. Diclofenac was the most widely available pharmaceutical due to its frequent use for humans and animals. However, other

pharmaceuticals, such as carbamazepine (antiepileptic), sulfamethoxazole (antibiotic), ibuprofen, and naproxen (both analgesics) were found almost as often as diclofenac.

With regard to **veterinary medicinal products**, the recent scientific review paper by the European Medicines Agency found that the environmental risk assessment of 108 VMPs in the EU conducted during the centralised authorisation procedure was terminated after Phase I assessment in 95% of cases. Only one negative opinion for a VMP – LONGRANGE, was issued due to a serious long-term risk for dung fauna that could not be mitigated to an acceptable level. The authorisations veterinary medicines containing zinc oxide and Pharmasin were withdrawn because of their environmental risks (Fabrega & Carapeto, 2020).

Considering the abundant evidence on the presence of pharmaceuticals and their negative effects on the environment, the *Strategic approach to pharmaceuticals in the environment* was adopted by the European Commission in 2019, which aims to mitigate the environmental issues caused by both human and veterinary medicines (EC, 2019g). To implement the *Strategic approach to pharmaceuticals in the environment* many measures for improving the environmental risk assessment of medicinal products and raising public awareness about proper use and disposal of them were foreseen. Table 164 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 164: 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

According to the recent Inception Impact Assessment (EC, 2021e), the ongoing evaluation and revision of pharmaceuticals' legislation cover the improvements in the environmental risk assessment.

Some of the identified reports focused on the measures to protect the environment from the hazards borne by pharmaceuticals. For instance, the study supporting the *Strategic approach to pharmaceuticals in the environment* proposed a revision of the CLP Regulation to remove the exemptions on medicinal products (EC, 2019h). However, this option was mainly based on the stakeholder consultation findings (Deloitte, 2017). It is important to note that only 20% of the respondents to public consultation believed that clear labelling of environmental risks to allow informed choices of equivalent therapeutic options were most effective actions to limit negative environmental impacts of medicines. Similarly, the expert workshop organised in 2009 by the European Environment Agency came up with a proposal to classify environmental hazards and improve the labelling of pharmaceuticals (EMA, 2010). Again, this proposal was based on the expert opinion of the workshop participants. However, the analysis of **review, evaluation and revision studies, as well as scientific and technical**

reports, did not reveal any solid quantitative evidence that more extensive labelling of medicines will substantially contribute to the mitigation of the environmental hazards of pharmaceuticals.

Controversial views on the environmental hazards of human and veterinary medicines were collected in consultation activities. A large group of business entities and associations (53%, 94) felt that the provision of information on the environmental hazards of human medicines was 'an issue which should be immediately solved' (see Annex 2 for OPC response analysis). Similarly, in TSS consultation, business entities and associations were of the view that the environmental hazards of the exempted products are properly covered by sectorial legislation. However, the OPC findings showed that in the groups of citizens and civil societies different opinions prevailed. Fifty-seven per cent (134) of citizens and 67% (42) of civil societies felt that provision of information on the environmental hazards of human medicines is not an issue. Differently, in case of veterinary medicines, 54% (127) of citizens and 65% (40) of civil societies believed that the provision of information on the environmental hazards of VMP requires an immediate solution. The group of respondents representing public authorities was too small both in OPC and TSS to draw any conclusions. This was also the case for citizens respondent group in TSS.[161]

Furthermore, to understand the links between classification and labelling of pharmaceuticals mitigation of their environmental hazards, a search of scientific and grey literature was performed by using Google Scholar and PubMed search engines for scientific publications. This search focused on the studies of consumer behaviours regarding pharmaceuticals and means to prevent medicines to occur in the environment.

Many studies focused on human pharmaceuticals are available; however, most focus on the non-European countries where the legislative framework and consumer behaviour may substantially differ from the European Union. Therefore, only fourteen studies related to the EU in general and the specific Member States were included. Five of them were grey literature reports published by the international (e.g., OECD) and national (e.g., German Environment Agency, Finnish Environment Institute, etc.) bodies, while nine – scientific peer-reviewed publications. Furthermore, reports and papers published earlier than 2010 were not included as well, since consumer habits, as well as regulatory and non-regulatory measures, evolve.

Surveys of consumers of HMP in various countries (Dias-Ferreira et al., 2016; Rogowska et al., 2019; Vellinga et al., 2014; Zorpas et al., 2018; Finnish Environment Institute, 2020; noPILLS, 2015) and systematic literature reviews of such studies (Kusturica et al., 2016; Makki et al., 2019) revealed significant differences in storage and disposal of HMP by consumers. High awareness and proper disposal of HMP was observed in Sweden, Finland, Portugal, and France, while the behaviour of disposing of HMP through household sewage or trash bins was more common in Poland, Latvia, Lithuania, Ireland and Cyprus. However, the surveys were conducted in different periods, so cannot be compared. Different methodologies were used, e.g., questionnaire surveys and interviews. Most national studies were not representative of the whole country because they focused on particular regions (e.g., Vellinga et al., 2014) or applied non-probability sampling (e.g., Rogowska et al., 2019; Zorpas et al., 2018). The systematic literature reviews **did not identify a clear link between**

[161] As for all other intervention areas, OPC and TSS results need to be interpreted with caution. Both surveys did not apply a random sampling approach, and the number of respondents in each stakeholder group varies substantially, meaning that the results are not representative for each group of stakeholders.

environmental awareness and positive change in consumer behaviour (Kusturica et al., 2016) and **indicated that more factors – e.g., availability of medicine take-back programme, advice by doctors and pharmacists etc. shape the behaviour of consumers with regard to proper/inappropriate disposal of medicines** (Makki et al., 2019). In some cases, environmental awareness did not preclude the inappropriate disposal of medicines (Rogowska et al., 2019). Surveys of pharmacies in Romania (Bungau at al., 2018) revealed that pharmacies may play a significant role – the findings showed that due to unclear regulatory framework and responsibilities, pharmacies refused to collect unused medicines from citizens. The findings of the survey of the European authorities whose work is related to medical waste indicated that combined measures of raising awareness of the citizens would be applied to reduce the streams of household pharmaceutical waste (Vollmer, 2010).

Several studies referred to the example of classification of environmental hazards of pharmaceuticals introduced in Sweden and used for advising healthcare professionals on prescribing the medicines (OECD, 2019; Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, 2019; UBA, 2014). However, all these reports did not provide any reliable evidence of the contribution of this approach to changing the behaviour of Swedish consumers.

The literature search did not detect any studies on the disposal behaviours related to VMP in the EU. The scarcely available studies focused on the USA and UK (e.g., Vatovec, 2021; Lam et al., 2018; Higham et al., 2018). Therefore, no conclusions can be made for consumer behaviour related to VMP.

To summarise, the current studies show that the issues underlying the occurrence of pharmaceuticals in the environment to a large extent relate to their use. However, the proper use and disposal of human medicinal products depend on multiple factors that include the availability of collection systems for pharmaceuticals, literacy and motivation of consumers to dispose of medicines in appropriate ways as well as active engagement and advice to consumers from other actors – e.g., pharmacists, healthcare professionals. Current activities to mitigate the challenges caused by pharmaceuticals in the environment cover a variety of regulatory and non-regulatory measures to raise public awareness of the issue and influence consumer behaviour as well as to improve the environmental risk assessment of VMP and HMP. **Therefore, it can be concluded that the current provisions on environmental hazard assessment and communication to consumers are sufficiently addressed in the current legislation and that there is no evidence that the extension of additional classification and labelling measures under CLP Regulation would provide benefits.**

COSMETIC PRODUCTS

Legislative framework

The Cosmetics Regulation 1223/2009 is the main legal act that establishes rules for cosmetic products available on the EU market. The Regulation aims to ensure the functioning of the internal market and a high level of protection of human health.

Identification and classification of environmental hazards

Before being placed on the market, a cosmetic product must undergo a safety assessment based on potential human health effects (Article 10). Annex I of the Regulation sets the requirements to the content of a safety assessment report. Several annexes of the Regulation list substances that are authorized for specific uses or that are prohibited or restricted under certain conditions:

Annex II lists substances that are prohibited in cosmetic products;
Annex III lists the substances that cosmetic products must not contain except subject to specified restrictions;
Annex IV lists the substances allowed to be used as colourants;
Annex V lists the substances allowed to be used as preservatives; and
Annex VI –lists the substances allowed to be used as UV filters.

There are no specific requirements related to the identification and classification of the environmental hazards in the Cosmetics Regulation. As stated in Recital (5) the environmental concerns for cosmetics products are addressed by the REACH Regulation.

Table 165: Provisions regarding identification and classification of environmental hazards in medical devices

Legislation	Provisions
Cosmetics Regulation 1223/2009	Recital (5): The **environmental concerns** that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, which enables the assessment of environmental safety in a cross-sectoral manner. The content and requirements to a cosmetic product safety report are specified in Annex 1 of Regulation 1223/2009. The annex does not contain specific provisions for assessing the risk of cosmetic products to the environment.

Labelling and communication of the environmental hazards of the products to downstream users

In compliance with Recital 5, the Cosmetics Regulation 1223/2009 does not define specific provisions for classification and labelling for environmental hazards; otherwise, there are substantive labelling requirements for cosmetic products in the Regulation. The analysis of the legal requirements did not identify specific provisions on the communication of the environmental hazards to cosmetics users. In addition to information placed on the label, Recital (53) and Article 21 outlines conditions when the users can access relevant information about cosmetic products. However, it does not consider specific information about environmental hazards.

*Table 166: Provisions on the communication of environmental hazards of cosmetic products to users**	
Legislation	**Provisions**
Cosmetics Regulation 1223/2009	Annex V Preamble Point 2: All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05 %. Recital (53): In addition to the labelled information, consumers should be given the possibility to request certain product-related information from the responsible person in order to make informed product choices. Pursuant to Article 21, without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as **existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means**. The **quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances** in accordance with Article 3 of Regulation (EC) No 1272/2008. (Article 21).
*NOTE: *User may include professional users and consumers*	

Evidence on the gaps in protection from the environmental HAZARDS

Studies on evaluation, impact assessment as well as supporting studies that cover Cosmetics Regulation were identified and screened to find evidence of potential gaps in protection from the environmental hazards borne by cosmetics products. Only two studies address the environmental hazards of cosmetic products. "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" (RPA, European Commission, 2017) provides the opinion of some public authorities in the Member States and NGOs on the lack of classification and labelling requirements for environmental hazards under the Cosmetics Regulation. "Study for the strategy for a non-toxic environment of the 7th Environment Action Programme" (2017) discusses the environmental effects of chemicals used in cosmetic products. The report reviewed the negative environmental effects of siloxanes that are often used in cosmetic products. However, it should be noted that a proposal for restriction of the following siloxanes – Octamethylcyclotetrasiloxane (D4) Decamethylcyclopentasiloxane (D5) Dodecamethylcyclohexasiloxane (D6) (ECHA, 2019a) based on the negative effects on the environment was adopted.[162]

Furthermore, studies supporting initiatives by the European Commission regarding protection of the environment by raising customer awareness through labelling have been identified. The first initiative was the EU Ecolabel, a voluntary environmental labelling scheme. The EU Ecolabel is granted to the products for their environmental excellence, covering high environmental performance of a product at different stages of its lifecycle (e.g., manufacturing, distribution, disposal, etc.). The EU Ecolabel Regulation sets the rules for establishing and applying this scheme. In 2021, the Joint Research Centre carried out a technical study to support the revision of EU Ecolabel criteria for rinse-off cosmetic products. It outlined several criteria for granting Ecolabel based on the environmental performance of a cosmetic product. For the purposes of formulating criteria, the CLP Regulation and REACH

[162] https://echa.europa.eu/substances-restricted-under-reach

were consulted. Based on the findings, the European Commission revised the EU Ecolabel criteria for cosmetics and extended them to substances or mixtures that fall under the scope of Cosmetics Regulation 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 contain the following:

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.

Growing interest in getting the EU Ecolabel has been recently observed. According to the European Commission, 2,057 licences have been awarded for 83,590 products in the EU. Of those, the share of 21% (118) of licenses were awarded to rinse-off cosmetic products with 3% (2,575) of products in this group granted the EU Ecolabel (EC, 2021g).

The further literature search identified abundant research on the environmental issues of microplastics and especially plastic micro beads in cosmetic products as well as regulatory initiatives to ban and/or reduce their use (Anagnosti et al., 2021). For instance, Eunomia (2016) estimations that **microplastics** from cosmetic products contribute up to 4.1% or between 2,461 and 8,627 tonnes of microplastics entering the marine environment from Europe every year. However, according to the authors of the report, this estimate was very uncertain due to the limited availability of data. The intentional use of microbeads in cosmetic products was also discussed in the report "Intentionally added microplastics in products" delivered at the request of the European Commission (Scudo et al., 2017). Based on Eunomia (2016) research and other sources, the study estimated that 1250-1910 tonnes of intentionally added plastic microbeads (5 mm or less) that are water insoluble plastic particles are used in personal care products annually. However, this estimate is also uncertain due to substantial gaps in data. The study usefully distinguished between rinse-off and leave-on cosmetic products. Rinse-off products are washed off shortly after their application and enter the environment via wastewater streams or by direct human uptake, while leave-on products can also enter the environment via solid waste pathways (Scudo et al., 2017).

The issue of the environmental pollution by microplastics (including by plastic microbeads in cosmetic products) was addressed in *A European Strategy for Plastics in a Circular Economy* in 2018. Intentional use of plastic microbeads was also voluntarily reduced by the cosmetics industry and microbeads were subject to national bans (EC, 2018g). In January 2019, ECHA proposed a wide-ranging restriction on microplastics in products placed on the EU/EEA market to avoid or reduce their release to the environment. ECHA's Committee for Risk Assessment (RAC) adopted its opinion on the proposal in June 2020 with some recommendations, while the Committee for Socio-economic Analysis (SEAC) – in December 2020. The European Commission decision is currently under preparation.[163] According to the

[163] https://echa.europa.eu/hot-topics/microplastics

estimations of the impact assessment study on intentionally added microplastics in products, a restriction on the use of all synthetic polymers in personal care products could affect approximately 18% of all EU personal care products (Scudo et al., 2017).

As the reports of the European Commission and other institutions lacked information on the environmental issues of cosmetic products, scientific peer-reviewed and grey literature searches were conducted to identify adverse effects of cosmetic products on the environment. Several extensive literature reviews (Vita et al., 2018; Bom et al., 2019) highlight **that personal care - especially rinse-off - products that contain ingredients hazardous to the environment may have a substantial impact on the environment** because they could be found in the household sewage shortly after their application. Some personal care products, such as sunscreens, enter the aquatic compartment directly because of their use (e.g., use of sunscreens during recreational activities) (Vita et al., 2018; Bom et al., 2019).

There is a growing interest of researchers in the environmental impacts of **UV filters** (Huang et al., 2021) and their occurrence in water compartments (Cadena-Aizaga et al., 2020). Currently, 45 UV filters are allowed in cosmetic products (ECHA, 2021e). Specific organic UV filters in different concentrations were found on the seacoasts in Spain and the Netherlands (Cadena-Aizaga et al., 2020), in the North and Baltic seas (Apel et al., 2018), and French Mediterranean beaches (Labille et al., 2020). One of the widely used substances in sunscreens, a sun blocking agent 2-Ethylhexyl 4-methoxycinnamate (EHMC), was included in the EU Watch List of potential water pollutants (EC, 2015b). According to the scientific evidence collected by the Joint Research Centre, EHMC was ubiquitous in the European environment and was detected in surface water, sediment and biota (Negrão De Carvalho et al., 2015). According to the JRC report, EHMC was included in the Draft Community Rolling Action Plan (CoRAP) with several reasons of concern, such as environment/suspected PBT, potential endocrine disruptor, wide dispersive use, environmental exposure and high (aggregated) tonnage. In the systematic literature review, Barbosa et al. (2016) noted that previous studies documented the presence of EHMC in the lake and rivers sediments and concentrations in diverse organisms. According to Barbosa et al. (2016), little is known about the removal of EHMC from aquatic environments.

The literature search identified four papers that experimented with the **classification** of the ingredients of personal care products and sunscreens by applying the criteria of the CLP Regulation (for details see Appendix 1 to Annex 4). The papers addressed the classification of the environmental hazards of UV filters (Sobek et al., 2013) and personal care products (Klaschka, 2012; Klaschka, 2015; Klaschka, 2016). All papers were case studies that applied either classification and labelling criteria for investigating ingredients of cosmetic products or used information on ingredients available in Classification and Labelling Inventory. The studies stressed that some of the analysed ingredients were hazardous for the environment; however, this information was not properly communicated to consumers of the cosmetic products. Although all studies were based on empirical data collection, they were qualitative small-scale case studies, so they do not provide enough evidence to cover different groups of cosmetic products and ingredients.

To understand the role of hazard communication through **labelling information**, a search was performed for relevant consumer research. Studies of the role of labelling information about the environmental hazards of cosmetic products in their purchasing or use behaviour are rare and mostly qualitative. For instance, Labille et al. (2020) conducted interviews of 471 visitors at three different Mediterranean beaches in France to analyse their habits of using sunscreens, while Anderson et al. (2016) carried out four focus groups with 20 participants to

understand the perceptions considering microplastics in cosmetic products. However, the studies provided quite different results. Labille et al. (2020) found that most of the respondents (60±6%) were aware of the environmental effects of the sunscreens they used, but there were no products labelled as eco-friendly among those they used. Although the composition of the sunscreen was an important selection criterion for the respondents, 19% of consumers cared about the composition of the product because of the possible effects on their health, while only 3% of them expressed environmental concerns. Differently, Anderson et al. (2016) found varying levels of awareness of the participants about the environmental effects of plastic microbeads in cosmetic products and their readiness to change their behaviour after getting information about the environmental hazards. However, as noted by Anderson et al. (2016) the sense of urgency of the environmental issue also depended on other factors: "Microbeads were seen as competing for attention with a number of other environmental and societal issues and relatively low down the list of the public's priorities".

More general studies about environmental concerns and cosmetics purchasing behaviour show **multiple interacting factors that shape consumer behaviour**. For instance, in the systematic review of 80 research papers published in 2011-2017, Liobikiene and Bernatoniene (2017) showed different types of motivational factors and their interplay that stimulate a decision to purchase green personal care products and colour cosmetics instead of selecting non-green cosmetics. According to the study, in buying green personal care products, health concerns are the main deciding factor that also influences other motivational factors, such as internal (environmental attitudes, values, environmental consciousness and attitude towards environmental consumption), social (social pressure, family, friends' attitudes etc.) and external (environmental awareness, price, supply, etc.). Differently, when buying colour and styling cosmetics, which is considered a luxury product, brand and quality play a dominant role and influence other motivational factors.

When asked about possible gaps in information provision on the hazards of cosmetic products ('when buying or using the product categories listed below, you might not be informed that they could be hazardous to the environment. What is your opinion?'), most citizens (61%), public authorities (67%) and civil societies (69%) who participated in the open public consultation considered that this issue should be immediately solved.

To summarise several conclusions can be made:

- The screened studies provided sufficient evidence that some cosmetic products have a negative effect on the environment due to hazardous properties of their ingredients. The environmental effect of some of them has been addressed by REACH restrictions. Scientific peer-reviewed sources show that there are environmental issues caused by specific cosmetic products, such as, e.g., sunscreens containing UV filters and personal care products, that favour their release into household sewage or directly into water compartments. REACH restrictions have been issued or are on the way on the grounds of their harm to the environment for siloxanes and plastic microbeads that have been used in cosmetics.

- The adverse effects of cosmetic product to the environment result from their use, while appropriate measures of storage, safe use or disposal do not play a substantial role in reducing their harm to the environment. Leave-on and rinse-off cosmetic products follow similar ways to the environmental compartments through wastewater and/or solid waste streams for leave-on cosmetics or may directly enter the

environment because of their use (e.g., in case of sunscreens). Often the only way to avoid harm to the environment is to refuse using the product.

- Information about properties of the cosmetic products or its environmental performance does not play a dominant role in consumer purchasing behaviour. Although some qualitative studies highlight consumer opinions about the importance of awareness about environmental effects of the cosmetic products, the studies of consumer behaviour show that purchasing decisions are shaped by multiple factors. There is a lack of evidence on how these factors interact and whether the informed choice based on the awareness about the environmental hazards would result in purchasing environmentally sustainable cosmetic products. It should also be noted that current sources on green purchases emphasize that environmental awareness does not play yet a dominant role.

The evidence search did not provide any additional data to change the conclusion made by the Commission in the Staff working document on the evaluation of chemicals legislation: "the focus of the Cosmetic Products Regulation solely on human health aspects was identified as a legal gap by NGO stakeholders. While it may impact consumer ability to differentiate between products in terms of their environmental performance (due to the lack of labelling requirements on environmental hazards) and, therefore, to make better informed purchases, in principle, any potential environmental risks arising from cosmetic ingredients are addressed under REACH, for example, via authorisations or restrictions." (European Commission, 2019: p. 78-79).

MEDICAL DEVICES

Legislative framework

The term 'medical device' covers a wide range of products that could be instruments, equipment, appliances, software, chemicals, etc. That are intended to be used for human beings in order to fulfil certain medical purposes, such as diagnosis, prevention, monitoring, treatment of disease or injury, alleviation or compensation for a disability, investigation or modification of different physiological or pathological conditions or processes, in vitro examinations of specimens derived from the human body (see Medical Devices Regulation 2017/745).

Different types of medical devices could be distinguished. Some medical devices are composed of substances or combination of substances (i.e., mixtures). For classification purposes, the Medical Devices' Regulation (MDR) introduced the notion of "medical devices composed of substances or combination of substances" (see MDR, Annex VIII, Chapter III. Classification rules, Section 7. Special rules, rule 21). Based on it, medical devices as substances and mixtures could be distinguished from medical devices that are articles. Examples of medical devices composed of substances or mixtures include saline nasal drops or sprays, dental fillings, disinfectants (e.g., iodine solution), syrups or throat sprays, lubricants, artificial tear drops, bone cement, etc. Such medical devices are distinguished from medicinal products based on their mode of action. Medical devices achieve the intended result by physicochemical means (e.g., mechanical action, physical barrier, etc.), while medicinal product reach the intended effect by pharmacological, immunological or metabolic means (EC, 2015d; Racchi & Govoni, 2020). Furthermore, medical devices composed of substances and mixtures should be distinguished from medical devices that are articles, i.e. where the function of such device is determined by their shape, surface or design

rather than chemical composition. Examples of medical devices that are articles include contact lenses, catheters, blood glucose meters and many others (Mereu & Lantres, 2022).

According to Article 1(5) of the CLP Regulation, only medical devices that are substances and mixtures which are invasive or used in direct physical contact with the human body and are in the finished form and intended for the final user are exempted from the CLP Regulation.

The search for legislation identified two legal acts regulating medical devices in the EU:

The Medical Devices Regulation 2017/745 sets rules concerning the placing on the market, making available on the market or putting into service medical devices for human use and accessories for such devices in the Union. It also applies to clinical investigations concerning such medical devices and accessories conducted in the Union. The Regulation came into force on 26 May 2021, following a four-year transition period.

In Vitro Medical Devices Regulation 2017/746 lays down rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices for human use and accessories for such devices in the Union. This Regulation also applies to performance studies concerning such *in vitro* diagnostic medical devices and accessories conducted in the Union. The Regulation 2017/746 will apply from 26 May 2022, following a five-year transition period. Currently, manufacturers can opt to place in-vitro diagnostic devices on the market under Directive 98/79/EC or under the new Regulation if they fully comply with it (EMA, 2021b). In this mapping exercise, we will not consider the Directive 98/79/EC.

Under Regulations 2017/745 and 2017/746, medical devices must undergo a conformity assessment to demonstrate their safety and ability to perform as intended. Environmental hazards are not explicitly considered by both legislations.

Identification and classification of environmental hazards

Under Regulations 2017/745 and 2017/746, medical devices must undergo a conformity assessment to demonstrate their safety and ability to perform as intended. Some of the safety requirements consider the safe disposal of these devices. The Regulation 2017/745 also contains a provision on emissions from medical devices.

According to Article 51 of (MDR), all medical devices are classified considering their intended purpose and inherent risks. The devices could be divided into classes I, IIa, IIb and III in accordance with Annex VIII of the MDR. In addition, and according to Article 52(7)(a), (b) and (c), Class I devices can be further subdivided into Is – sterile condition, Im – measuring function and Ir – reusable surgical. Although all devices must comply with all relevant obligations of the MDR; some requirements depend on the device classification (MDCG, 2021).

Similarly, in accordance with Article 47 of In Vitro Medical Devices Regulation (IVDR), devices are divided into classes A, B, C and D, based on the intended purpose of the devices and their inherent risks. Specific procedures of conformity assessment depend on the classification of a device (MDCG, 2020).

Safety assessment is an important part of the conformity assessment of the device in both Regulations. As outlined in Annex I of Regulation 2017/745 on Medical Devices and in

Annex I of Regulation 2017/746 on In Vitro Medical Devices, safety relates to the safety of patients, safety and health of users and where applicable other persons. It means that both regulations are not explicitly focused on environmental concerns.

Table 167: Provisions regarding identification and classification of environmental hazards in medical devices

Legislation	Provisions
Regulation on Medical Devices 2017/745	Article 5 specifies the conditions that a medical device must satisfy to be placed on the market. Following Article 5(2), a device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose. In Annex 1 General Safety and Performance Requirements, Chapter I General Requirements, environmental hazards/risks are not explicitly mentioned: Paragraph 1: Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. However, some safety requirements specified in Annex 1 are relevant to the protection of the environment. For instance, Annex 1, Chapter II Requirements to design and manufacture: Paragraph 10.4.1. indicates that devices shall be designed and manufactured in such a way as to reduce as far as possible **the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device**. Paragraph 14.7 specifies that devices shall be designed and manufactured in such a way as to facilitate **their safe disposal and the safe disposal of related waste substances by the user, patient or other person**. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed of after use.
Regulation on In vitro Medical Devices 2017/746	Article 5 specifies the conditions that an in vitro medical device must satisfy to be placed on the market. Following Article 5(2), a device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose. In Annex 1 General Safety and Performance Requirements, Chapter I General Requirements, environmental hazards/risks are not explicitly mentioned: Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. However, some safety requirements specified in Annex 1 are relevant to the protection of the environment. For instance, Annex 1, Chapter II Requirements regarding performance, design and manufacture, Paragraph 13.6 specifies that **devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person**. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely

Table 167: Provisions regarding identification and classification of environmental hazards in medical devices	
Legislation	**Provisions**
	disposed of after use.

However, under safety requirements in both regulations, manufacturers should ensure that medical devices are manufactured in such a way that facilitates their safe disposal as well as safe disposal of related substances by users or other persons. Furthermore, MDR Regulation 2017/745 indicates that devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. However, all safety requirements are targeted at the protection of the patients, users and other persons involved in the use and disposal of the devices.

Compliance with the general safety requirements is supported with CEN-EN ISO 14971:2019 *Medical devices — Application of risk management to medical devices*. This standard aims to assist manufacturers of medical devices to identify hazards related to a medical device, carry out assessment, mitigate, and control the associated risks. ISO 14971:2019 applies to all phases of life cycle of a medical device and covers both in vitro diagnostic medical devices and medical devices. Risk management activities include identification of hazards and hazardous situations associated with a medical device, risk assessment, risk control, monitoring the effectiveness of the risk control measures. During the risk identification and evaluation stages, hazards and hazardous situations are determined, and it is analysed to what types of harm they may lead. In turn, 'harm' is defined as "injury or damage to the health of people, or damage to property or the environment". So, the environmental safety aspects are considered; however, in Annex C that informs about hazards, hazardous situations and harm, the focus on health aspects of harm prevails. The standard refers to the environment in a sense of immediate surroundings or space where a medical device has been exploited – e.g., 'use environment', 'inappropriate environmental conditions' (CEN, 2019).

Currently, in accordance with the Commission's standardisation request M575, the standard has been aligned with the medical device legislation; therefore, now CEN-EN ISO 14971:2019 does not apply to medical devices (EC, 2021h).

Labelling and communication of the environmental hazards of the products to downstream users

Both regulations use the same definition for "label", meaning the written, printed or graphic information appearing either on the device itself or on the packaging of each unit or the packaging of multiple devices (Regulation 2017/745, Article 2(13); Regulation 2017/746, Article 2(13)).

Information communicated to users on the label mainly considers safe use, storage and handling of the devices. Information of their safe disposal and related precautions are provided in the instructions for use. According to the MDR, devices of class I and IIa may be supplied without instructions for use if such devices can safely be used without the instructions and no other provisions of Annex I Section 23 state otherwise (MDCG, 2021).

*Table 168: Provisions on the communication of product hazards to the environment to users**	
Legislation	**Provisions**
Regulation on Medical Devices 2017/745	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed of after use. Such procedures shall be **described in the instructions for use** (Annex I, Chapter II, Paragraph 14.7). According to Annex I, Chapter III, Section 23.1, the **label** must contain: (k) an indication of any special storage and/or handling condition that applies; (m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users; Following Annex I, Chapter III, Section 23.4, this information should be provided in the **instructions for use**: (v) warnings or precautions to be taken in order to facilitate **the safe disposal of the device**, its accessories and the consumables used with it if any. This information shall cover, where appropriate: — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and — physical hazards such as from sharps. If in accordance with Section 23.1(d) no instructions for use are required, this information shall be made available to the user upon request. According to Article 32(1), for implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a **summary of safety and clinical performance**. Pursuant to Article 32(2)(h), the **summary of safety and clinical performance**, must include, among other requirements, information on any residual risks and any undesirable effects, warnings and precautions.
Regulation on In vitro Medical Devices 2017/746	According to Article 29(1), for class C and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance. The manufacturer shall mention **on the label or instructions for use where the summary is available**. Pursuant to Article 29(2)(h), the **summary on safety and performance** must include, among other required elements, information on any residual risks and any undesirable effects, warnings and precautions. Following Annex I, Chapter II, Section 20.1(i), in the case of devices containing **a substance or a mixture which may be considered as being dangerous**, taking account of the nature and quantity of its constituents and the form under which they are present, relevant **hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply**. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use. Annex I, Chapter II, Section 20.2 lists information that must be provided on the **label**. Among other requirements, it includes: (k) an indication of any special storage and/or handling condition that applies; (m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum

*Table 168: Provisions on the communication of product hazards to the environment to users**	
Legislation	**Provisions**
	in which case more detailed information shall appear in the instructions for use, taking into account the intended users; In accordance with Chapter II, 13.6, devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed of after use. Such **procedures shall be described in the instructions for use**. Following the provisions of Annex I, Chapter III, Section 20.4.1, the following information should be provided in the **instructions for use**: (ac) warnings or precautions to be taken in order to facilitate the **safe disposal of the device**, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate: (i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin; (ii) **environmental hazards** such as batteries or materials that emit potentially hazardous levels of radiation; (iii) physical hazards such as explosion.
*NOTE: *User may include professional users and consumers*	

Warning or precautions related to the environmental hazards are required in the instruction for use by the IVD Regulation 2017/746. For in vitro medical devices that contain substances or mixtures that may be considered dangerous, Regulation 2017/746 already requires applying hazard pictograms and labelling requirements of the CLP Regulation.

Storage and handling precautions and other information that requires the immediate attention of the user of a medical device or any other person involved must be provided on the label. Information and precautions related to the safe disposal of the device must be given in the instructions for use.

Additional sources of information are so-called summaries of safety and clinical performance of the device.

Evidence on the gaps in protection from the environmental hazards

The literature search identified only one study on the review of chemical legislation prepared for the European Commission that mentioned the environmental hazards of medical devices and potential gaps in legislation. The study drew attention to the gap in hazard communication in the legislation on medical devices, where hazards are communicated through safety data sheets that may not be understandable to the user. However, this finding was based on the opinion of NGOs and Member States authorities in the stakeholder consultation (RPA et al., 2017). Furthermore, the search did not detect any scientific and technical reports or peer-reviewed scientific papers that discuss this issue. Therefore, an overview of available literature that highlights environmental issues and their possible reasons is provided.

The EU market for medical devices is worth €140 billion. The EU medical device industry is composed of over 33,000 companies (of which 95% are SMEs) employing over 760,000 people. It is characterised by a high rate of innovation, ranking first among the sectors filing patent applications, around 9% more than the computer and technology industries and 66% more than the pharmaceutical industry.[164] The medical devices' industry is very diverse in terms of complexity, purposes of use and features of the devices that may range from simple products, such as syringes, catheters, face masks, to complex products, e.g. ultrasound and CT scanners, anaesthesia machines equipment, etc. According to the WHO, there are between 5,000 to 24,000 types of medical devices under different classification and nomenclature systems (WHO, 2021). MedTech Europe refers to over 500,000 medical technologies available in hospitals, community care and household settings.[165] Therefore, not all issues and solutions apply to each type of medical device.

There is growing attention to the sustainability and environmental impact of medical devices (Arun Kumar, 2021; Sousa et al., 2021; WHO, 2016; McGain & Naylor, 2014; Dalenstam et al., 2012). However, the **scientific literature search** (+"medical devices" +environment) **revealed that the papers focus on medical devices that are articles, while the research specifically addressing the environmental hazards or impact of medical devices composed of substances or mixtures is not available**. Lifecycle assessment studies have been conducted to evaluate the environmental impacts of specific medical devices (Sousa et al., 2021; Dalenstam et al., 2012). Environmental impacts and related costs have also been investigated in case studies (see e.g., Piccoli et al., 2015).

Different sources emphasised that a large amount of solid waste is generated by medical devices, in particular single-use devices (Sousa et al., 2021; WHO, 2016; McGain & Naylor, 2014). For instance, the WHO highlights that every year an estimated 16 billion injections are administered worldwide, but not all of the needles and syringes are properly disposed of afterwards (WHO, 2018).

According to WHO, about 85% of waste generated in healthcare activities is not hazardous and can be recycled, while 15% constitutes infectious, chemical, or radioactive waste (WHO, 2018). Furthermore, reprocessing of specific single-use medical devices is allowed by Article 7 of the Medical Devices Regulation 2017/745. Complementing Regulation 2020/1207 on reprocessing of single-use medical devices laid out common specifications for such activities.

When asked about possible gaps in information provision on the hazards of medical devices ('when buying or using the product categories listed below, you might not be informed that they could be hazardous to the environment. What is your opinion?'), many citizens (55%), public authorities (44%) and civil societies (67%) who participated in the open public consultation considered that this issue should be immediately solved. However, qualitative inquiries about medical devices in targeted stakeholder questionnaire and interviews did not result in specific examples or references to the environmental hazards or effects of medical devices on the environment.

To summarise the analysis of the available evidence, several conclusions can be made:

> Available scientific and technical reports as well as peer-reviewed scientific **papers do not provide any information about the environmental hazards and,**

[164] Information provided by MedTech Europe.
[165] https://www.medtecheurope.org/wp-content/uploads/2021/06/medtech-europe-facts-and-figures-2021.pdf

consequently, impacts of medical devices that are composed of substances or mixtures. Most research focuses on medical devices that are articles. Therefore, currently, it is not possible to provide any sound argument about the hazards of medical devices that are substances or mixtures.

To get sound evidence on the environmental hazards and effects of medical devices composed of substances and mixtures a targeted systematic literature search and review is necessary based on the exhaustive lists of such medical devices and search keywords derived from specific groups/names of specific devices that are substances or mixtures.

Similarly, although medical devices enter the streams of healthcare waste, the **study did not identify any evidence about the share of medical devices that are substances/mixtures in this type of waste and their impact to the environment**. Furthermore, the review of the available literature did not allow to identify estimates of the volumes and composition of medical device waste and its environmental impacts in Europe.

FOOD AND FEEDING STUFFS

Legislative framework

Sixteen legal acts that cover the issues of identification and communication of the environmental hazards in food and feed were identified through the analysis of the European Commission websites and EUR-Lex database (see Table 169).

Table 169: Overview of food and feed legislation

Type of products	Legislation
Food & feed	**General**
	Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Regulation on food law)
	Regulation 1829/2003 on genetically modified food and feed (Regulation on GM food and feed)
	Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms (Regulation on traceability and labelling of GMO in food and feed)
Food	**Focused on specific obligations and procedures**
	Regulation 1169/2011 on the provision of food information to consumers (Regulation on Food Information to Consumers)
	Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain
	Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (Regulation on a common authorisation procedure)
	Focused on specific food products
	Regulation 2015/2283 on novel foods
	Regulation 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Traditional Foods Regulation)
	Regulation 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Regulation 2017/2469 on

Table 169: Overview of food and feed legislation	
Type of products	**Legislation**
	requirements for novel foods applications) Regulation 1333/2008 on food additives (Food Additives Regulation) Regulation 1332/2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (Food Enzymes Regulation) Regulation 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (Food Flavourings' Regulation)
Feed	Regulation 767/2009 on the placing on the market and use of feed (Feed Regulation) Regulation 1831/2003 on additives for use in animal nutrition (Feed additives Regulation) Regulation 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (Regulation on the implementation rules) Regulation 2019/4 on the manufacture, placing on the market and use of medicated feed (Medicated feed Regulation)

Three legal acts give **general provisions that are relevant to other food and feed legislation**. Regulation 178/2002 on food law is focused on common principles and responsibilities, organisational arrangements and procedures in the field of food and feed safety. Regulation 1829/2003 on GM food and feed sets out the procedures for authorisation of and supervision of as well as labelling of genetically modified food and feed. Regulation 1830/2003 on traceability and labelling of GMOs in food and feed establishes a framework for tracing the products that contain GMOs, and food and feed produced from GMOs to facilitate labelling, monitoring the environmental and human health effects, risk management and, if necessary, withdrawal of products.

Nine legal acts cover the **food domain**. Three of them relate to specific obligations and procedures, such as the provision of food information to consumers (Regulation 1169/2011), risk assessment in the food chain (Regulation 2019/1381), and authorisation of food products (1331/2008). Another three legal acts lay out specific provisions relevant to food additives, food flavourings and food enzymes. The rest three regulations cover novel foods that include any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the categories provided in Article 3(2)(a) of Regulation 2015/2283. Novel foods also include traditional foods from third countries (Regulation 2017/2468).

Search and review of relevant websites identified four legal acts related to **animal feed**. Regulation 767/2009 covers placing on the market and use of feed. Regulation 1831/2003 on additives in animal nutrition (a legislative proposal revising this Regulation is under preparation) sets out a procedure for authorising the placing on the market and use of feed additives, while Regulation 429/2008 (discussions on amendments to this Regulation are ongoing) provides detailed rules for the implementation of Regulation 1831/2003. Regulation 1831/2003 also lays down rules for the supervision and labelling of feed additives and

premixtures. Finally, Regulation 2019/4 sets out specific provisions regarding medicated feed and intermediate products.

Furthermore, two legal acts identified by search were excluded from the analysis. It is Directive 2002/32 on undesirable substances in feed and Regulation 183/2005 on feed hygiene. According to Article 2(l) of the Directive 2002/32, undesirable substance is "any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production". Undesirable substances may occur in feed products in different ways, e.g., because of environmental or other contamination in food and feed chain. However, these substances are not intentionally added to feed products; therefore, they are out of the scope of this analysis. Regulation 183/2005 lays down the general rules for feed hygiene that is understood as "the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use" (Article 3(a), Regulation 183/2005). However, hazard control is associated with specific operations by feed businesses that may cause hazards (e.g., contamination of feed): "Feed business operators responsible for primary production of feed shall ensure that operations are managed and carried out in such a way as to prevent, eliminate or minimise hazards with the potential to compromise feed safety" (Regulation183/2005, Annex 1, Part A, Section I). However, the Regulation 183/2005 does not address hazards of chemical substances/mixtures; therefore, it is out of the scope of this study.

Identification and classification of environmental hazards

Regulation 178/2002 on food law lays out general requirements to risk analysis and assessment of food. However, it explicitly mentions the protection of human health and life as an objective to be reached through these actions (Article 6). Other food legislation mentions environmental factors in different contexts (see Table 170).

Table 170: Provisions regarding identification and classification of environmental hazards in food	
Legislation	**Provisions**
General food legislation	
Regulation on Food Law 178/2002	Article 14 lays out general food safety requirements. Pursuant to Article 14(1), **food shall not be placed on the market if it is unsafe**.
Regulation 1829/2003 on genetically modified food and feed	Article 4(1) specifies that (a) food referred to in Article 3(1) **must not have adverse effects** on human health, animal health or **the environment**. no person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied; no GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article. Article 5 lays out provisions for applications for authorisations. Article 5(5) specifies that in the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by: **the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment** carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision; a **monitoring plan for environmental effects** conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.
Regulation 1830/2003 on traceability and labelling of GMO in food and feed	N/A
Specific food legislation	
Regulation 2015/2283 on novel foods	Recital (2): A high level of protection of human health and of consumers' interests and the effective functioning of the internal market needs to be assured in the pursuit of Union food policies, whilst ensuring transparency. **A high level of protection and improvement of the quality of the environment** are among the objectives of the Union as established in the Treaty on European Union (TEU). It is important that all relevant Union legislation, including this Regulation, take those objectives into account. Recital (29): **New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production**, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured.
Traditional foods Regulation 2017/2468	The Regulation does not contain any explicit links to the assessment of the environmental risks. Only health risks to consumers are considered in the Regulation.
Regulation 2017/2469 on requirements for novel foods applications	The Regulation does not contain any explicit links to the assessment of the environmental risks. Only health risks to consumers are considered in the Regulation.
Regulation on a	Recital (14): It is recognised that, in some cases, **scientific risk assessment alone**

Table 170: Provisions regarding identification and classification of environmental hazards in food	
Legislation	**Provisions**
General food legislation	
common authorisation procedure 1331/2008	**cannot provide all the information** on which a risk management decision should be based, and that **other legitimate factors relevant to the matter under consideration may be taken into account**, including societal, economic, traditional, ethical and **environmental factors** and the feasibility of controls.
Food Additives' Regulation 1333/2008	Article 4(1) specifies that **only food additives included in the Community list in Annex II** may be placed on the market as such and used in foods under the conditions of use specified therein. Article 4(2) provides that **only food additives included in the Community list in Annex III** may be used in food additives, in food enzymes and in food flavourings under the conditions of use specified therein. Pursuant to Article 6(1), **a food additive may be included in the Community lists** in Annexes II and III **only if it meets the following conditions** and, where relevant, other legitimate factors, **including environmental factors**: (a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed; (b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and (c) its use does not mislead the consumer.
Food Flavourings' Regulation 1334/2008	The Regulation does not contain any explicit links to the assessment of the environmental risks. Only health risks to consumers are considered in the Regulation.
Food Enzymes Regulation 1332/2008	Recital (6): Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes must be safe when used, there must be a technological need for their use and their use must not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. **The approval of food enzymes should also take into account other factors** relevant to the matter under consideration including societal, economic, traditional, ethical and **environmental factors**, the precautionary principle and the feasibility of controls.

Regulation 1829/2003 requires **genetically modified food and feed to be safe for the environment**. The authorisation dossiers must contain environmental risk assessment and monitoring plans for environmental effects in accordance with this legal act.

Regulation 2015/2283 on novel foods refers to the goal of a high level of protection of the environment in recitals, however, protection of the environment is not referenced elsewhere in this regulation. In a similar vein, there are no references to the protection of the environment in other legal acts regulating novel foods (i.e. Regulations 2017/2468 and 2017/2469).

Regulation on a common authorisation procedure 1331/2008 specifies in the recital part that environmental factors may be considered where relevant. The same references are found in Food Additives' (1333/2008) and Food Enzymes Regulations (1332/2008). Other food legal

acts do not contain explicit links to the environment and identification of the environmental hazards.

Animal Feed Regulation 767/2009 explicitly states that only feed that does not have a direct adverse effect on the environment or animal welfare can be placed on the market (Article 4(1)). Annex III provides a list of restricted or prohibited materials for use for animal nutritional purposes. In turn, feed intended for particular nutritional purposes may only be marketed as such if its intended use is included in the list of intended uses established by the Commission in the Regulation (EU) 2020/354. The list can be updated by submitting to the Commission an application demonstrating that a feed product has no adverse effects on animal health, human health, the environment or animal welfare.

Feed legislation that regulates genetically modified organisms in the feed also sets a general requirement for feed products to be safe and do not have adverse effects on human health, animal health or the environment. The compliance with these requirements is to be proved by the results of the risk assessment (including environmental risk assessment).

Table 171: Provisions regarding identification and classification of environmental hazards in animal feed

Legislation	Provisions
	General feed legislation
Regulation 178/2002 on Food Law	Article 15 sets out general safety requirements for animal feed. According to Article 15(1), **feed shall not be placed on the market or fed to any food-producing animal if it is unsafe**.
Animal Feed Regulation 767/2009	Article 4(1) lays out the requirements for animal feed to be placed on the market. According to Article 4(1), feed may only be placed on the market and used if: (a) it is safe, and (b) it does not have a **direct adverse effect on the environment or animal welfare**. The requirements set out in Article 15 of Regulation (EC) No 178/2002 shall apply, *mutatis mutandis*, to feed for non-food producing animals Pursuant to Article 6(1), feed shall not contain or consist of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited. The list of such materials is set out in Annex III. Following Article 9, feed intended for particular nutritional purposes may only be marketed as such if its intended use is included in the list of intended uses established in accordance with Article 10 and if it meets the essential nutritional characteristics for the respective particular nutritional purpose outlined in that list. According to Article 10(2), the list of intended uses can be updated by the submission to the Commission of an application by a natural or legal person established in the Community or by a Member State. **A valid application shall include a dossier demonstrating that the specific composition of the feed fulfils the particular intended nutritional purpose and that it has no adverse effects on animal health, human health, the environment or animal welfare**.
Regulation 1829/2003 on genetically modified food and feed	Article 16 specifies that: Feed referred to in Article 15(1) must not: (a) have adverse effects on human health, **animal health or the environment**; No person shall place on the market, use or process a product referred to in Article 15(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied. No product referred to in Article 15(1) shall be authorized unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

Table 171: Provisions regarding identification and classification of environmental hazards in animal feed	
Legislation	**Provisions**
General feed legislation	
	Article 17(5) specifies that in the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by: **the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment** carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMOs has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision; a **monitoring plan for environmental effects** conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.
Regulation 1830/2003 on traceability and labelling of GMO in food and feed	N/A
Specific animal feed legislation	
Regulation 1831/2003 on Additives in Animals Nutrition	Article 5 sets the requirements to feed additives to be placed on the market. Pursuant to Article 5(2)(a), a **feed additive must not have an adverse effect on animal health**, human health or **the environment**. Article 7(3)(d) indicates that a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(2) and (3) must be submitted as a part of an authorisation application.
Regulation 429/2008 on the implementation rules of Regulation 1831/2003	Annexes II and III set requirements for the dossier accompanying the application for authorisation and studies to be included in it. The general requirements of Annex II specify that safety assessment is to be based on studies intended to demonstrate the safety of the use of the additive in relation to <…> (e) **the environment**, as a result of the additive itself or products derived from the additive, either directly and/or as excreted by animals. Annex II, Section III: Studies concerning safety of the additive, part 3.4 describes that **to determine the environmental impact of additives**, a stepwise approach shall be followed. All additives have to be assessed through Phase I to identify those additives which do not need further testing. For other additives, a second phase (Phase II) assessment is needed to provide additional information, based upon which further studies may be considered necessary. These studies shall be conducted according to Directive 67/548/EEC [= replaced by the CLP Regulation – author note] <…>Paragraph 3.4.1. The purpose of Phase I assessment is to determine if a significant **environmental effect of the additive** or its metabolites is likely and whether a Phase II assessment is necessary. <…>Paragraph 3.4.2. The aim of Phase II is to assess the potential for additives to affect non-target species in the environment, including both aquatic and terrestrial species or to reach groundwater at unacceptable levels.
Medicated feed Regulation (2019/4)	No additional requirements are provided. However, all general requirements laid out in feed legislation apply. Pursuant to Article 1, the provisions of Medicated feed Regulation are additional to Union legislation on feed and apply without prejudice in particular to Regulations (EC) No 1831/2003, (EC) No 183/2005 and (EC) No 767/2009 and Directive 2002/32/EC.

Regulation 1831/2003 on Feed additives specifies in Article 5 that to be placed on the market a **feed additive must not have an adverse effect on animal health**, human health or **the environment**. In turn, Regulation 429/2008 sets the requirements for authorisation dossiers to be submitted by applicants intending to place a feed additive on the market.

The guidance on the safety assessment of feed additives by the EFSA details that an environmental risk assessment (ERA) should be conducted for (1) terrestrial compartment (via spreading of animal manure contaminated with feed additives on agricultural soils), (2) the aquatic compartment (via drainage and run-off from agricultural fields to surface water, via a direct discharge of waste water from land-based fish farms to surface water, or via excreta from fish farmed in cages to sediment), and (3) the groundwater compartment (via leaching from the soil) (Bampidis et al., 2019) (see Paragraphs 3.4.1.1. and 3.4.1.2. of Annex II, Section III).

If the EFSA's opinion concludes that the additive is not safe for the environment, one of the conditions for authorising the additive (laid down in Article 5 of Regulation 1831/2003) is not met and the measure to be adopted by the Commission on the basis of Article 9 must take it into account (cf Article 9(1) of Regulation 1831/2003), either by denying the requested authorisation or by requiring specific conditions/restrictions linked to the authorisation.

No specific additional **REQUIREMENTS** were set in Regulation 2019/4 on Medicated feed.

Labelling and communication of the environmental hazards of the products to downstream users

Following the review of food and feed legislation two definitions of labelling were identified:

Regulation 1169/2011 on food information to consumers: '**label**' means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food (Article 1(i)); '**labelling**' means any words, particulars, trademarks, brand name, pictorial matter or symbol relating to food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food (Article 1(j)).

Animal Feed Regulation 767/2009: '**labelling**' means the attribution of any words, particulars, trademarks, brand name, pictorial matter or symbol to a feed by placing this information on any medium referring to or accompanying such feed, such as packaging, container, notice, label, document, ring, collar or the Internet, including for advertising purposes (Article 3(2)(s)); '**label**' means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of feed (Article 3(2)(t)).

It is important to note that Regulation 178/2002 on Food Law specifies in Articles 14(1) and 15(1) that no food or feed products must be placed on the market if they are not safe.

Regulation 1169/2011 and 767/2009 provide extensive guidance on labelling food and feed products, respectively:

Regulation 1169/2011 on food information to consumers specifies that the provision of food information shall pursue **a high level of protection of consumers' health** and interests by providing a basis for final consumers to make informed choices and to make safe use of food,

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with particular regard to health, economic, **environmental**, social and ethical considerations (Article 3(1)).

Regulation 767/2009 sets the objective to harmonise the conditions for the placing on the market and the use of feed, to ensure a high level of feed safety and thus a high level of protection of public health, as well as **to provide adequate information for users and consumers** and to strengthen the effective functioning of the internal market. In Articles 15-22 it sets extensive requirements for labelling of feed products; however, the Regulation 767/2009 does not provide specific required label elements for addressing the environmental hazards of feed.

Regulations related to specific feed products, such as feed additives and medicated feed provide some label elements that may potentially address the environmental hazards:

- Regulation 1831/2003 on Additives in Animals Nutrition provides one labelling requirements that can potentially relate to communication of the environmental hazards. Pursuant to Article 16(1)(e), "directions for use, and any safety recommendations regarding the use" must be provided on the label of feed additives and premixtures.

- Regulation 2019/4 on medicated feed lays out specific labelling provisions in Article 9(1), which indicates that medicated feed must comply with the labelling requirements listed in Annex III. In turn, Annex III gives a list of specific particulars that must be present on the label. Among various elements, the label must include "information that inappropriate disposal of medicated feed poses serious threats to the environment and may, where relevant, contribute to antimicrobial resistance" (Annex III, Specific labelling requirements referred to in Article 9(1), (10)).

The review of legal acts did not find any substantial and systematic approach to labelling requirements for communicating the environmental hazards of the food and feed.

Evidence on the gaps in protection from the environmental hazards

Evaluation, impact assessment and technical and scientific studies that related to food and feed legislation were identified and screened to find evidence of potential gaps in the protection from the environmental hazards borne by food and/or feed products. The *Farm to Fork Strategy* (EC, 2020g) highlighted several environmental issues throughout the whole food chain. Analysis of the evaluation and other relevant reports revealed several topics related to the environmental hazards of food and/or feed products:

Shortcomings in **public communication about risks** caused by food/feed products by EFSA (EC, 2018e; EC, 2018f). This criticism originated from the public consultation with the stakeholders in the course of the re-fit evaluation of the General Food Law. Public authorities and citizens expressed opinions on the lack of clarity and adjustment to different needs of target audiences in communication, in some cases, communicating contradictory information as well as the lack of transparency in some communication processes. This issue relates to the effectiveness of communication of EFSA but it does not consider that risk communication has specific shortcomings due to regulatory gaps.

The *Farm to Fork Strategy* (EC, 2020g) highlighted **sustainability challenges in the food production chain**, including the use of chemical pesticides and nutrients that cause air, water

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and soil pollution and harm to plants and animals, greenhouse gas emissions in the course of agricultural activities, excessive use of antimicrobials in animals. Similarly, a recent Eurobarometer survey (2019) showed that EU citizens are well-aware and concerned about such issues as antibiotic, hormone or steroid residues in meat (44%), pesticide residues in food (39%), environmental pollutants in fish, meat or dairy (37%). Forty-three per cent of Europeans (43%) think that food products are full of harmful substances (Kantar, 2019).

The **Food waste issue** is in part pre-conditioned by wasteful behaviour of consumers and has been caused by misunderstanding of food date ('best before' and 'use by') labels (EC, 2020h; Purnhagen & Schebesta, 2019; Anthesis et al., 2018; EC, 2015c; European Court of Auditors, 2016). EC (2020h) referred to the findings of the Eurobarometer survey 2015, which suggested that less than one in two consumers understand the meaning of date marking: "use by", which indicates the ultimate food safety date, and "best before", which refers to the date food retains its optimal quality. The study performed by Anthesis et al. (2018) for the Commission concluded about 10% of all food waste generated in the EU could be related to date marking on the product labels. The Joint Research Centre study carried out for the Commission in 2020 indicated that the effect of labels on the consumer decision may lessen when several concurrent labels (e.g., environmental and nutrition) are presented on the package. Furthermore, JRC pointed out that the environmental effect of food labels has not been widely researched. The review of date marking on labels has been included within the scope of the revision of Regulation (EU) No 1169/2011 on the provision of food information to consumers (EC, 2020h).

Insufficient information to professionals and end-users of food and feed on the hazards borne by these products (RPA et al., 2017). The findings of the stakeholder survey in the report supporting the impact assessment of chemicals legislation (except REACH) revealed that public authorities and NGOs considered that current information on labels of food and feed is not sufficient to disclose hazards of these products to their users. This opinion was not supported by any quantitative evidence.

The analysis of the European Commission policy documents and studies showed that **the issues of sustainability in the food chain and food waste are not related to the scope of the CLP Regulation** because the reason of the environmental harm is not due to hazardous properties of food, but the peculiarities of food production activities, volumes of food waste produced by inappropriate consumer behaviour and other reasons.

Similarly, the issues of food-wasting behaviour of consumers and labelling are associated with the volumes of produced waste that becomes an environmental problem. The scientific papers and grey literature dedicated to the food-wasting behaviour of consumers are voluminous. This search concentrated on literature reviews and European level quantitative studies. The search identified four extensive systematic literature reviews covering the period of 1980 – 2019 and between 112 to 309 papers (Principato et al., 2021; Boulet et al., 2021; Schanes et al., 2018; Hebrok et al., 2017), one quantitative modelling research of the datasets of Eurobarometer surveys (Toma et al., 2020) and two legislation and literature reviews (Bremmers & Purnhagen, 2018; Wunder et al., 2018). Although **all these analyses consider consumer food-wasting behaviour and labelling, they do not attribute food-wasting behaviour to the lack of or inappropriate food hazard communication to the consumer**.

When asked about possible gaps in information provision on the hazards of food or feed, such as additives ('when buying or using the product categories listed below, you might not be informed that they could be hazardous to the environment. What is your opinion?'), many

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citizens (59%), public authorities (45%) and civil societies (69%) who participated in the open public consultation considered that this issue should be immediately solved.

DEFINITIONS RELEVANT TO THE APPLICATION OF EXEMPTIONS

Problem and its scope

The initial research hypothesis for this study was that "it is not always clear how the exclusion provisions must be applied, *inter alia*, because some definitions diverge between CLP and specific products legislation (in particular the wording of 'in the finish state' and 'intended for the final user')".

According to the reports on the national helpdesk activities published by ECHA, in 2018, 2019 and 2020, the theme 'scope and exemptions of CLP' was in the list of ten hot topics that cover most asked questions by the customers of helpdesks. There is no uniform system for tracking questions to national helpdesks, so the annual reports are compiled by surveys of national representatives of helpdesks and the answers reflect their opinion and practical experiences. In 2018, 2019 and 2020 (in 2019 and 2020 the theme was combined with another topic 'general questions on CLP') this topic was the fifth on the list (ECHA, 2021b, 2020, 2019b). **The available evidence does not allow to confidently conclude that the issues of CLP scope exemptions were among the most significant for duty holders** who contacted helpdesks.

When addressing this issue, it is important to consider that:

In Article 1(5) addressing the application of exemptions, the CLP Regulation does not define the legal wordings 'in the finish state' and 'intended for the final user', although they are intended to serve for making a distinction between products that are exempted from the CLP Regulation or those that must comply with it. This circumstance poses a problem for making a proper distinction between the above-mentioned products.

Scopes and objectives of the legislation regulating the exempted products are broad and cover a lot of issues within and beyond hazard identification and communication. Therefore, the concepts applied in the CLP Regulation may diverge and be used differently or not used at all.

Based on these observations, two questions need to be answered to clarify the issue of the application of the CLP exemption provisions:

What issues are faced by the duty holders because of the absence of definitions of 'in the finished state' and 'intended for the final user' in Article 1(5) of the CLP Regulation?

Does on the products exempted from the CLP Regulation provide any concepts related to 'in the finished state' and 'intended for the final user' that could facilitate decisions on the application of the CLP exemption provisions?

Analysis of relevant definitions

To answer the questions introduced in the previous section the following research was performed:

Analysis of the practical examples of uncertainties that might occur in deciding whether in some cases the CLP Regulation applies to the products listed in Article 1(5) (medicinal and

veterinary medicinal products, cosmetics, food and feed, medical devices). Practical examples and their interpretations were collected from the Questions & Answers section by ECHA (see Appendix 2 to Annex 4).

Analysis of definitions related to products 'in the finished state' and/or 'intended for the final user' in the legislation regulating the exempted products.

The analysis of practical examples related to the application of the CLP Regulation to the products listed in Article 1(5) has shown **two major uncertainty areas: a) changes to the product that determine its finished/unfinished condition; b) circumstances that should be considered as (non)final use situation**. Interpretation of practical examples by ECHA suggests that a product is in its finished state when no alterations to its chemical composition occur. Following this approach, for instance, bulk cosmetics or medicinal products are in the finished state, even if they are further processed by packaging. In turn, a product is intended for the final user when it is placed on the market to be sold to professional end-users or consumers, but not other business entities that could further process it for developing other products. Depending on circumstances, the same product may be interpreted as intended or not intended for the final users. For instance, essential oils may be offered to end-users as a cosmetic product or may be used as an ingredient for cosmetic products. In the first case, essential oils are intended for the final users, while in the second case – not.

Based on the practical understanding of the CLP references to products 'in the finished state' and 'intended for the final user', the legal acts regulating the exempted products were analysed to find relevant definitions (see Table 172).

Table 172: Definitions of the product condition and uses in the exempted products' legislation	
Regulation	**Definition**
Product users	
Cosmetics Regulation 1223/2009	'End user' means either a consumer or professional using the cosmetic product (Article 2(1)(f)).
Regulation on Medical Devices 2017/745 and Regulation on In vitro Medical Devices 2017/746	'User' means any healthcare professional or lay person who uses a device (Article 2(37) of the Regulation 2017/745 and Article 2(30) of the Regulation of 2017/746).
Regulation 178/2002 on General Food Law	'**Final consumer**' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.
Food Additives' Regulation 1333/2008	Distinguishes between '**food additives not intended for sale to the final consumer**' (Article 21) and **'food additives intended for sale to the final consumer**' (Article 23), but does not provide a definition
Food Flavourings' Regulation 1334/2008	Distinguishes between '**flavourings not intended for sale to the final consumer**' (Article 14) and '**flavourings intended for sale to the final consumer**' (Article 17), but does not provide a definition
Food Enzymes Regulation 1332/2008	Distinguishes between '**food enzymes and food enzyme preparations not intended for sale to the final consumer**' (Article 10) and '**food enzymes and food enzyme preparations intended for sale to the final consumer**' (Article 12)
Regulation 1831/2003 on Additives in Animal Nutrition	'Premixtures' means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, **not intended for direct feeding to animals** (Article 2(2)(e).
Product state or condition	
Medicinal Products Directive 2001/83/EC	According to Article 3(4), this Directive shall not apply to **intermediate products** intended for further processing by an authorized manufacturer (Article 3(4)).
Veterinary Medicinal Products Regulation 2019/6	According to Article 2(7)(e), this Regulation shall not apply to medicated feed and **intermediate products** as defined in points (a) and (b) of Article 3(2) of Regulation (EU) 2019/4. Regulation 2019/4 provides the following definition of 'intermediate products' that is focused on medicated animal feed (Article 3(2)(b)): '**Intermediate product**' means a feed, which is not ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products with feed materials or compound feed, exclusively intended to be used for the manufacture of medicated feed.

Regulations of most products, except legal acts on medicinal products, define a user and refer to final/end-use situations. In legislation on cosmetics and medical devices users are understood as professionals and consumers/lay persons. The most extensive definition of the final consumer that could be useful for understanding the conditions for CLP exemptions under Article 1(5) is the definition of the final consumer in the Regulation on General Food Law. It emphasises that the situation of the final consumption excludes any use of a product in business operations or activities. ECHA recognised the usefulness of this definition in practice when deciding whether a specific product should be treated as an exemption from the

CLP Regulation.[166] The definition of the final user in the Regulation on General Food Law applies to other sectorial food and feed legislation. Subsequently, food and feed legal acts distinguish between products intended/not intended for the final user. This distinction serves various purposes, for instance, in food legislation different labelling requirements are provided for food additives, flavourings and enzymes in cases when they are intended or not intended for a final consumer.

In the inception impact assessment of the Feed additives Regulation 1831/2003 the insufficient legal clarity with the CLP Regulation was mentioned with regard to feed additives and premixtures that may lead to contradictory directions when both regulations apply simultaneously (European Commission, 2020). The lack of legal clarity and application of both regulations to feed additives and premixtures is going to be addressed in evaluation of the Feed additives Regulation. The consultation activities to support the revision of the CLP Regulation, including expert interviews, did not demonstrate any issues for the duty holders in this domain.

Veterinary and medicinal products legislation introduces a concept of intermediate products. This definition serves the purpose of defining the products to which the legal acts do not apply. Intermediate products are those that require further processing of a product before being used by a final consumer (e.g., before being directly fed to animals). Although this definition brings more clarity, it, however, does not refer to the nature of processing that a product undergoes. Analysis of ECHA questions and answers indicates that the nature of processing activities is important for deciding whether a product must comply with the CLP Regulation.

In sum, the **definitions provided in the exempted products legislation do not bring more clarity for understanding**, which legislation applies to a product. In the exempted products' legislation, the definitions that can potentially relate to the concepts 'in the finished state' and 'intended for the final user' serve different purposes than linking with the provisions of the CLP Regulation.

CONCLUSIONS

In this section, the information is organised in form of answers to the two research questions.

RQ1: Does the sectorial legislation that regulates the exempted products provide the same level of protection from the environmental hazards borne by these products as the CLP Regulation?

The analysis revealed that **identification of the environmental hazards** is addressed in the legislation referring to human and veterinary medicinal products, genetically modified food and feed, and animal feed in general. In all these legal acts, environmental risk assessment, which combines the assessment of hazards and exposure, is required. In food legislation, environmental factors may be considered, if relevant. The legal acts concerning cosmetic

[166] *CLP:* scope and exemptions under CLP. Questions & Answers. Available at: https://echa.europa.eu/support/qassupport/browse?p_p_id=journalqadisplay_WAR_journalqaportlet&p_p_lifecycle=0&_journalqadisplay_WAR_journalqaportlet_topic=CLP&_journalqadisplay_WAR_journalqaportlet_scope=Scope+and+exemptions+under+CLP&_journalqadisplay_WAR_journalqaportlet_backURL=https%3A%2F%2Fecha.europa.eu%2Fsupport%2Fqassupport%2Fbrowse%3Fp_p_id%3Djournalqadisplay_WAR_journalqaportlet%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview [Accessed on: 30 November 2021]

products, medical devices and food (as well as food additives) do not have a special focus on the identification of the environmental hazards. However, in legislation on medical devices and food some environmental hazards may be still considered if relevant. In addition, Environmental concerns for cosmetic ingredients are tackled by REACH (e.g. via restrictions based on hazard and risks for the environment). For a summary see Table 173.

Regarding **communication of the environmental hazards**, specific precautions or warnings related to the safe use, storage and disposal are required for human and veterinary medicinal products on the label or in the instructions for use, while communication of the environmental hazards related to safe disposal of in vitro medical devices is required as well. For other products, the analysis of legal acts has not identified specific labelling requirements, except for feed additives and medicated feed. For a summary see Table 173.

Table 173: A summary of environmental hazard identification and communication in the legislation on the products exempted from the CLP Regulation

Product	Identification of environmental hazards	Communication of environmental hazards
Medicinal products for human use	Required through ERA	Precautions on use, storage, disposal on the label
Veterinary medicinal products	Required through ERA	Precautions on use, storage or any other important information on the label or in the instruction for use
Medical devices	No specific focus on the environmental hazards	For in vitro medical devices, warnings or precautions related to environmental hazards that facilitate the safe disposal of the device must be provided in the instructions for use. In case a device contains a substance or a mixture that may be considered dangerous, relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.
Food	Required through ERA for genetically modified food. May be considered where relevant in risk assessments and application dossiers for food additives and food enzymes	No specific requirements
Animal feed	Required through ERA	No specific requirements, except for feed additives (directions for safe use) and medicated feed (disposal recommendations)
Cosmetics	Reference to REACH for environmental considerations (e.g. REACH restriction)	No specific requirements

In summary, the following requirements apply to the different types of exempted products:

Human and veterinary medicinal products. The effects of HMPs and VMPs on the environment are addressed in the environmental risk assessment, which must be submitted as a part of the marketing authorisation dossier. The assessment of environmental risks considers the evaluation of environmental hazards of chemicals and their environmental exposure. The outcomes of the environmental risk assessment of a HMP or a VMP lead to specific labelling requirements and risk mitigation measures. Hazard communication requirements for HMPs and VMPs cover use, storage and disposal precautions. In some

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cases, information can be provided in the instructions for use. Therefore, labels of such products do not provide information on the environmental hazards of the products to the extent as in the CLP Regulation.

Cosmetics. The CPR does not address the identification and communication of the environmental hazards by explicitly stating in Recital 5 that the environmental concerns are addressed under REACH in a cross-sectoral manner.

Medical devices. The Regulations on Medical Devices (2017/745) and In Vitro Medical Devices (2017/746) does not explicitly focus on environmental hazards; however, some safety requirements to medical devices (incl. in vitro medical devices) addressing the safety of disposal and/or emissions might be relevant to the protection of the environment. It is important to note, however, that the safety assessment of medical devices is focused on the protection of the health of patients, users and other persons involved in the use and disposal of a device. Differently from the CLP Regulation, the label or instruction for use of a medical device, following the regulations 2017/745 and 2017/746, communicates information relevant to safe use, storage, handling and disposal of the device. So, the professional user or a consumer does not have access to information about environmental hazards on the label. An exception are in vitro medical devices containing substances or mixtures, which may be considered dangerous. In such cases, hazard pictograms are put on the label and other information under the CLP Regulation should be provided in the instructions for use.

Food and feed. In food legislation, the identification of environmental hazards is a part of the environmental risk assessment required by Regulation 1829/2003 on genetically modified food and feed. Other food legislation does not cover environmental risk assessment, although some legal acts, e.g., Regulation on a common authorisation procedure 1331/2008, Food Additives' (1333/2008) and Food Enzymes (1332/2008) Regulations specify that environmental factors may be considered if relevant in the approval of authorisation applications (Regulations 1333/2008 and 1332/2008) or as a part of scientific risk assessments (Regulation 1331/2008). All analysed animal feed legal acts provide an explicit requirement for animal feed and animal feed additives to be safe for the environment. The analysis of the effects on the environment must be provided in authorisation applications. The analysis of food and feed legislation did not detect any specific labelling requirements addressing the environmental effects, except general safe use recommendations in Feed Additives Regulation (1831/2003) and disposal precautions in Medicated feed Regulation (2019/4).

Analysis of the available evidence revealed that some exempted product types may have adverse effects on the environment (see Table 174 for a summary of evidence analysis). For **medicinal products and food, there is solid quantitative evidence on the negative effects on the environment**. However, **food waste or sustainability gaps in the food production chain are not caused by hazardous properties of food**. Scientific peer-reviewed studies and some grey literature reports reveal the adverse effects of plastic microbeads (to be mentioned that those ingredients are affected by the REACH restriction on microplastics) and UV filters both used in personal care cosmetic products. However, no estimate of the overall environmental impact of cosmetic products on the environment was found. No evidence about the environmental hazards of medical devices could be found.

Table 174: A summary of the findings of an analysis on potential gaps in protection from the environmental hazards

Question	HMP & VMP	Cosmetics	Medical devices	Food and feed

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Are there any environmental issues caused by the exempted products?	Yes, pollution of aquatic environments by pharmaceuticals	No solid and quantitative evidence of all issues: UV filters and plastic microbeads are visible in the research	No evidence, difficult to distinguish common issues for a highly diverse group of devices	Food waste No evidence for issues caused by feed
Are the identified environmental issues caused by hazards of the exempted products?	Yes	At least for UV-filters and plastic microbeads used in cosmetic products, there is some evidence	No evidence	No evidence, food waste is a problem mainly due to its volume
Are the identified environmental issues caused by the lack of communication about the hazards of the exempted products?	No evidence	No evidence	No evidence	No evidence
Could the environmental issues be solved by enhancing identification or communication of hazards as laid out in the CLP Regulation?	No evidence, although hazard communication by label information could be one of the measures	No evidence	No evidence	No evidence

The adverse environmental effects of the medicinal products (intended for human use in particular) are caused by the hazardous properties of these products and mostly result from the inappropriate disposal behaviour of such products in households. However, the studies of disposal behaviours are fragmented and non-representative. Besides, the **available empirical research of consumer behaviour does not prove the link between the lack of awareness/information about the environmental effect of medicines as a cause of inappropriate disposal habits**. Instead, controversial results from different research suggest that medicine disposal behaviour depends on multiple interrelated factors and is not limited to the level of environmental awareness. Interestingly, the research about consumer behaviour in purchasing cosmetic products and consumer food-wasting behaviour also indicate that there is no direct causal link between the level of awareness of the environmental issue and purchase and use behaviour, which is affected by multiple complex factors.

Furthermore, it is useful to mention that regulatory initiatives aimed at improving the environmental risk assessment and influencing medicines' disposal behaviour are foreseen in the forthcoming revision of pharmaceutical legislation. Similarly, a restriction proposal for plastic microbeads has been submitted by ECHA, also covering cosmetic products.

RQ2: Do the definitions in the CLP Regulation and sectorial legislation covering the exempted products (particularly those related to 'in the finished state' and 'intended for

the final user') provide sufficient clarity to decide whether the CLP exemptions apply to a product?

There is no solid evidence that the application of the CLP exemptions under Article 1(5) causes uncertainties or issues to the duty holders. The only source about duty holders' concerns – annual reviews of national helpdesks activities published by ECHA – do not allow to conclude that duty holder experience any issues related to the concepts of 'in the finished state' and 'intended for the final user'. Sectorial legislation on the exempted products provides some definitions related to the final use or finished state of the product, however, these definitions serve different purposes than making a link with the CLP Regulation. The Question & Answer section maintained by ECHA provides all necessary explanations to duty holders how to interpret Article 1(5).

The lack of legal clarity and inconsistencies between the Feed Additives Regulation and the CLP Regulation have been addressed by the Commission in the ongoing evaluation of the Feed Additives Regulation 1831/2003 in order to avoid regulatory gap and to bring regulatory simplification.

Therefore, there is no evidence to justify the need for a regulatory action.

Annex 15 – Information on online sales of chemicals

CONTEXT

The objective of the matter described in this annex to adapt CLP to online sales and to ensure safe purchase and use of chemicals sold online is closely linked to Green Deal's goal of having a green and digital transition of the EU industry whilst ensuring consumer and environmental protection. It also links to SDGs #3 Good health and well-being and SDG #9 Industry, innovation and infrastructure as outlined under Section 1.1. of the SWD.

The relevance of online sales has been steadily growing both for individuals and businesses. According to Eurostat, in 2020, 73% of Internet users in the EU shopped online, while online purchases increased by 20% in comparison to 2010. Thirty-one per cent (31%) of online shoppers bought goods from sellers in other EU countries (Eurostat, 2021).[167] According to the EU consumer survey, in 2018, 18.4% of Europeans purchased services or goods online outside of the EU (GfK Belgium, 2018). One in five EU enterprises made online sales in 2020, amounting to 18% of total turnover of companies that employ 10 or more people[168]. The trend of increased online sales, in particular to consumers, is also noted in UN's Global Chemicals Outlook (UNEP, 2019).[169]

The Fitness check of the most relevant chemicals legislation (excluding REACH) states that: "Regarding online chemicals sales, several enforcement surveys show that various non-authorised chemicals and related products are increasingly being offered for sale via the Internet. As chemicals legislation does not distinguish between different types of trade, all provisions regulating chemicals apply in principle also to Internet trade. Currently, however, access to websites and relevant information on transactions, vendors or service providers for monitoring authorities is difficult and therefore hampers their investigations"[170].

The findings to the Fitness check[171] report that "articles imported into the EU, including via online sales, still represent a particular challenge for market surveillance authorities for ensuring both overall consumer protection as well as fair competition".

Section 2.3.2. of the Chemicals Strategy for Sustainability (CSS) mentions that "currently almost 30% of the alerts on dangerous products on the market involve risks due to chemicals, with almost 90% of those products coming from outside the EU and imported articles and *online sales representing a particular challenge*". And further that "The Commission is considering which additional measures could be put in place to strengthen the enforcement of REACH at the EU's borders, as well as to promote cooperation with online market platforms" as well as "the Commission will: […] target known areas of high risk of non-compliance, *in particular online sales*, imported articles, classification and labelling and restrictions".

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[167] Eurostat (2021). *E-commerce statistics for individuals*. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=E-commerce_statistics_for_individuals#General_overview

[168] European Commission, Online sales continue to grow among EU enterprises - Products Eurostat News - Eurostat (europa.eu)

[169] United Nations Environment Programme, Global Chemicals Outlook II – From Legacies to Innovative Solutions: Implementing the 2030 Agenda for Sustainable Development, 2019, p. 550-551.

[170] Commission's Staff Working Document, SWD(2019) 199 final/2, p. 19.

[171] COM(2019)264.

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For the purpose of clarity of this annex, the term chemicals refers to substances and mixtures covered under CLP.

PROBLEM DEFINITION, PROBLEM DRIVERS, CONSEQUENCES

Two problems were identified in relation to closing communication gaps for online sales.

First (problem 1), consumers are unable to make informed choices when purchasing chemicals online, since online offers/advertisements do not have to display all labelling info and the consumer is not immediately made aware of the hazards, in comparison to brick-and-mortar sales. This leads to an uneven level playing field between companies offering chemicals online and companies offering them in traditional shops, whereby online shops have a competitive advantage over traditional shops, as well as to insufficient protection of consumers who may only be able to check the labels once they receive the chemical, i.e. only after the termination of the sale.

The concepts of offers and advertisements need to be distinguished. The former is intended to conclude a purchase contract so that when the offer is accepted by the buyer the sale is concluded, while the latter covers promoting messages before the offer and the actual sale. Offers should contain more hazard information than advertisements given the different purpose of the two. CLP currently only provides for a provision on advertising for all types of sale and does not mention online offers explicitly.

Incompliances of online advertisements with advertisement provisions of CLP (Article 48, advertisement[172]) amount to very high numbers. Strictly speaking, incompliances with CLP provisions in the case of online offers, on the other hand, could not possibly be researched in the first place, given that currently CLP does not provide for any explicit obligation on how to display labelling information when offering online. Hence, the best available benchmark to reveal the scale of the problem is data on advertisement incompliances. Findings of international e-commerce enforcement projects suggest that **non-compliance with CLP provisions regarding advertisements is found in chemicals sold both by EU and non-EU actors online**. International research projects focused on online sales by the Forum for Exchange of Information on Enforcement, responsible for enforcement of chemical legislation, found[173] that 75% of 2752 inspected products in 29 EEA countries were non-compliant with Article 48 (ECHA, 2021e), 82.4% of 1314 inspected products in 15 EU countries were non-compliant with Article 48(2) on advertisement of mixtures (ECHA, 2018). A collaborative project by national enforcement authorities of Sweden, Norway, Finland and Denmark revealed that 75% (25 products) of 33 chemicals inspected for compliance with Article 48(2) of the CLP Regulation[174] were not compliant (Klar et al.,

[172] Article 48: 1. Any advertisement for a substance classified as hazardous shall mention the hazard classes or hazard categories concerned.
2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) which allows a member of the general public to conclude a contract for purchase without first having sight of the label shall mention the type or types of hazard indicated on the label.
The first subparagraph shall be without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (1).

[173] The most recent study (ECHA, 2021e) declared in the methodology that many EU countries adopted a risk-based approach to the check, meaning that they targeted products for which risks could be high. This resulted in higher rates of non-compliance being found.

[174] Risk-based approach to product sampling for investigation was applied (i.e. products that posed higher risks as experienced in previous research were included), which means that the sample is not generalisable to the whole market.

2020). However, in this case, the number of inspected products was very low to reflect the situation in the countries covered by the project. Those projects did not differentiate between online sales made by sellers outside the EU and sellers in the EU.

Second (problem 2), consumers are exposed to chemicals with no or incorrect classification, labelling and packaging when buying from non-EU actors shipping chemicals directly into the EU. CLP does not apply to those non-EU actors.. Thus, when they directly ship chemicals to the EU consumers there is no intermediary in the EU who qualifies as importer with the result that the consumer becomes the importer[175]. This again leads to an uneven level playing field, i.e. to a competitive advantage for non-EU actors operating online and a disadvantage for EU actors such as importers (the latter not including consumers, as their purchases do not qualify as commercial transactions), downstream users, distributors and manufacturers who have to comply with CLP, as well as to insufficient protection of consumers, human health, and the environment.

Incompliances with CLP of chemicals purchased from non-EU sellers are expected to be high considering the available data from the enforcement reports indicated above on Article 48 of CLP, which, however, do not specifically distinguish between intra-EU and imported chemicals (see above). From an example given in ECHA's enforcement report on REACH restrictions, incompliances of goods coming from outside the EU are even higher and there is no indication that for CLP such tendencies would be different[176]. Based on estimations, 7.3 million incompliant products from outside the EU directly reached the EU consumer in 2021[177].

Regarding both problems 1 and 2, the findings of consultation activities show that all stakeholders indicate problems arising in online sales of chemicals. In the open public consultation, 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 hazardous chemicals purchased online. In the targeted stakeholder survey, all groups of stakeholders 'strongly agreed' or 'agreed' that the lower level of protection from hazards of chemicals sold online hinders the ability of the CLP Regulation to reach its goals. Similarly, the interview respondents indicated that non-compliance with classification and labelling as well as Article 48 requirements of the CLP Regulation is a problem in online sales of chemicals. The interviewees stressed that non-EU traders, especially small business entities engaged in e-commerce, are common sources of the problem. CARACAL members and observers acknowledged the problem of non-compliance of chemicals sold online with the CLP Regulation in their written feedback to the meeting on this topic.

The problem driver of both problems is that CLP is not sufficiently equipped for **keeping pace with globalisation, technological development and new means of sale such as online sales**. According to OECD (2019), in 2015 there were, for example, over 2 million sellers worldwide on Amazon marketplace, while the eBay online platform operated almost 30 international websites in 2018. E-commerce enables traders to introduce products that comply

[175] Among the issues are difficulties in identifying responsible persons for compliance of the substance/mixture sold online with the legislation, applying enforcement measures to companies located outside the EU, identifying non-compliance cases in vast streams of online content, as these issues were reported by public authorities (Kemi, 2021; Klar et al., 2020; Kemi, 2018; feedback by CARACAL members).

[176] For example, of all incompliances found for non-compliant products containing lead, 60% of the online marketplaces were not established in the EU. See ECHA enforcement report, Ref. 8, p. 30.

[177] See baseline section below.

with the legal requirements of a non-EU country where they were manufactured to be sold to global markets, where product safety and chemical legislation requirements may substantially differ (Kemi, 2021). In EU28 countries many small and medium enterprises have been actively engaging in e-commerce activities as an easy way to access new markets and expand customer reach (OECD, 2019). The share of turnover from business-to-consumer web sales in EU28 countries in 2017 was higher in small firms (43%) compared to 41% in large firms and 34% in medium-sized ones. New business models, including variety of intermediary services (e.g., social media, online marketplaces) that connect online sellers and buyers, increase the engagement in e-commerce of even more diverse players worldwide (Kemi, 2021). The findings of a 2015 Eurobarometer survey (TNS Political & Social, 2015) show that EU companies do not see the lack of knowledge as a major problem for getting engaged in online sales. Not knowing the rules that a company must follow in online sales was not perceived as a problem by 56% of respondents that sold online to other EU countries in the past or at the time of the survey, while only 15% of them considered it a major problem.

As mentioned above, CLP does not apply to non-EU based economic actors, who can today easily reach and sell directly to consumers in the EU and does not take into account that in those situations consumers become *de jure and de facto* importers by buying online from non-EU actors. Moreover, current CLP provisions do not, or do not exhaustively, address online offers or advertisements, *i.e.* they do not impose an obligation to display labelling information in online offers and they do not sufficiently clarify obligations for online advertisements.

In the future, the two specific problems will be positively affected by horizontal draft and already applicable legislation related to product safety, digital services and customs legislation as well as by non-regulatory initiatives. Although this legislation will have a positive impact on ensuring that consumers are better able to make informed choices upon purchase and use of chemicals sold online, they will not entirely eliminate the problem, in particular as the number of online sales is increasing (see figures in the baseline heading below).

Baseline

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[178] 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[179].

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

[178] These are the only years for which data are provided.

[179] 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.

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[180] 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 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[181]). In its annual chemical marketplaces report, *Chembid* listed 61 online platforms. According to *Chembid*[182], chemical online marketplaces usually offer up to 10,000 products from up to 25,000 suppliers (Chembid, 2020[183]).

The following trends could be retrieved from a study on cross-border online sales (Cross-Border Commerce Europe, 2020)[184]:

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).

[180] Russian Federation was also included in the group of Eastern European countries.

[181] 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

[182] 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.

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

[184] 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.

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[185].

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.

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

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 175: 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

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

Taking into account the dynamic baseline, here is a short description of the horizontal draft and already applicable legislation to be considered: the draft Digital Services Act[186], the draft General Product Safety Regulation[187], the already applicable Market Surveillance Regulation[188], the Consumer Rights Directive[189] and customs legislation[190].

[186] 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.
[187] 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.
[188] 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.
[189] Directive 2011/83/EU on consumer rights, OJ L 304, p.64.
[190] 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

Customs legislation – relevant for problem 2

Given that in problem 2 consumers are exposed to chemicals with no or incorrect classification, labelling and packaging when buying from **non-EU actors shipping chemicals directly into the EU**, who do not have to comply with CLP, customs legislation becomes relevant as, before reaching consumers, those chemicals have to pass through customs and be released for free circulation. Before goods are released for free circulation in the EU, a customs declaration needs to be submitted by the importer or its representative according to the Union Customs Code[191]. The **importer under customs legislation can be a consumer or other natural or legal person**, depending on the applicable rules for low value consignments, other consignments, etc.[192]. So, when the consumer is the importer under customs legislation, chemicals pass through customs, are released for free circulation and directly reach the "natural person responsible for import" in the EU, *i.e.* the consumer.

The dynamic baseline takes into account:

The recently adopted VAT e-commerce package that introduced a financial liability for the online platforms which facilitate the sale of low value goods dispatched from a third country to consumers in the EU for the collection of VAT on those sales, applicable as of 1 July 2021.

Draft General Product Safety Regulation (GPSR)/Market Surveillance Regulation (MSR) – both relevant for problems 1 and 2

Considerations relevant to solve problem 2

In order to ensure that chemicals sold on-line by non-EU actors are properly labelled and packaged (following proper classification), one option would be to introduce the obligation to have a responsible economic actor in the EU by default, so that an economic actor in the EU, who should always ensure compliance with CLP requirements before chemicals reach consumer, is inserted in the supply chain. Draft GPSR and MSR already contain similar provisions which however do not cover CLP and would hence not solve the problem.

MSR provides for the need to have a person responsible for compliance by default in the EU for listed pieces of legislation, but does not include CLP in that list[193]. Draft GPSR

(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.

[191] Article 127, Article 158 of the UCC.

[192] For low value consignments of goods with a value not exceeding EUR 22, new VAT and customs e-commerce rules are applicable for their import as of 1 July 2021 to ensure fair competition for EU businesses and reduce the VAT losses resulting from the importation of low value consignments from third countries. The VAT exemption for imported goods below EUR 22 is abolished and an import declaration will be required for all goods entering the EU, regardless of their value.
Further, the UCC Delegated Regulation (EU) 2015/2446 of 28 July 2015 was modified in 2019 and 2020 to adapt to a new form of customs declaration for release for free circulation of goods in consignments not exceeding EUR 150 (super-reduced dataset) to facilitate and speed up the process of dealing with a high volume of parcels. This customs declaration is available to any person (consumers, business, postal or express operators).
According to the guidance on "Importation and Exportation of low value consignments – VAT E-Commerce Package" the customs' importer could be a private or legal person who declared for itself or uses a representative who may act in the name and on behalf of the person represented (direct representation) or in his/her own name and on behalf of the person represented (indirect representation).

[193] See Article 4(5) of CLP MSR.

establishes the principle of having a responsible person to ensure product safety and extends it to all products[194]. However, that particular provision is not applicable to CLP, since it excludes Union harmonisation legislation - including CLP - from its scope[195]. A change of MSR to extend the responsible person for compliance by default to CLP would be quite complicated since the definitions in both legislations of actors (importers, distributors etc.) and of placing on the market are different and do not match exactly.

To sum up, CLP is not covered by either MSR or draft GPSR in relation to having a person responsible for compliance in the EU by default (other than the consumer). Therefore, it would be for CLP itself to address the problem of ensuring chemicals sold from outside the EU are safe by means of another economic actor in the EU who would bear compliance obligations. Consequently, **such action would not be part of the dynamic baseline**.

Considerations relevant to solve problem 1 on online offering

In contrast to problem 2, Chapter III, Section 2 and Chapter IV of draft GPSR (Online marketplaces) apply to CLP and help consumers to make informed choices when they purchase chemicals online (problem 1). Rules are provided for economic operators to indicate product safety information in online offers[196] as well as for online marketplaces to design and organise their online interface in a way that enables traders to provide useful information[197].

[194] Chapter III, Section 1 of draft GPSR provides for the obligations of economic operators and sets forth the need of having a person responsible for compliance in the EU (Article 15, Responsible person for products placed on the Union market) by default.

[195] Following Article 2(1) of the draft GPSR, Union harmonisation legislation as listed under Annex I of MSR – that includes CLP – is excluded from the applicability of Chapter III, Section 1 of draft GPSR, see draft GPSR, Article 2 (Scope):

1. This Regulation shall apply to products defined in Article 3(1), placed or made available on the market in so far as there are no specific provisions with the same objective in rules of Union law which regulate the safety of the products concerned. Where products are subject to specific safety requirements imposed by Union legislation, this Regulation shall apply only to the aspects and risks or categories of risks not covered by those requirements. In particular, as regards products subject to specific requirements imposed by Union harmonisation legislation as defined in Article 3(25),

(a) Chapter II shall not apply insofar as the risks or categories of risks covered by Union harmonisation legislation are concerned;

(b) Chapter III, Section 1, Chapters V and VII, Chapters IX to XI shall not apply.

[196] Chapter III, Section 2, Article 18 of draft GPSR, which isapplicable to CLP states that "where products are made available on the market online or through other means of distance sales by the relevant economic operators, the relevant offer of the product shall clearly and visibly indicate at least the following information: […] (d) any warning or safety information that is to be affixed on the product or to accompany it in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers".

[197] Chapter III (rules for online marketplaces) Art. 20(5) draft GPSR: For the purpose of the requirements of Article 22(7) of Regulation (EU) […/…] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC, online marketplaces shall design and organise their online interface in a way that enables traders to provide the following information for each product offered and ensures that it is displayed or otherwise made easily accessible by consumers on the product listing:

(a) name, registered trade name or registered trade mark of the manufacturer, as well as the postal or electronic address at which they can be contacted;

(b) where the manufacturer is not established in the Union, the name, address, telephone number and electronic address of the responsible person within the meaning of Article 15 (1);

(c) information to identify the product, including its type and, when available, batch or serial number and any other product identifier;

Those obligations, applicable to economic actors and online marketplaces, **will be taken into account as a baseline scenario for the CLP revision**. This impact assessment will examine whether CLP requires a specific reference to the applicable provisions to enhance compliance and for coherence between the different legislations.

Draft DSA (relevant for problems 1 and 2) and E-Commerce Directive[198], Consumer Rights Directive (relevant for problem 1)

Considerations relevant to solve problem 1

Draft DSA, the E-Commerce Directive and the Consumer Rights Directive contain provisions on online advertisement and offers that help solving problem 1 and ensuring correct communication of hazards to consumers.

Draft DSA provides for obligations of online platforms to trace their traders when they promote messages or offer products to consumers (see Article 22 draft DSA). Further, it contains a provision on online advertising transparency (Article 24). Draft DSA also defines "advertisement" as "information designed to promote the message of a legal or natural person, irrespective of whether to achieve commercial or non-commercial purposes, and displayed by an online platform on its online interface against remuneration specifically for promoting that information"[199]. This definition should also be used under CLP to cover online advertisements and to clearly distinguish advertisement from offers.

The E-Commerce Directive provides for rules that (advertising) information to be provided for commercial communications must follow (Article 6), to clearly identify its commercial content[200].

Further, also the Consumer Rights Directive contains rules on information requirements for distance and off-premises contracts, including online sales, which also apply to CLP[201].

CLP should take into account all those applicable rules and this assessment should examine the need of making cross-references to those pieces of legislation and providing that any rules under CLP are without prejudice to these provisions of the other pieces of legislation (this would also include an update of the reference to Directive 97/7/EC on the protection of consumers in respect of distance contracts under Article 48 which was repealed by the Consumer Rights Directive).

Hence, **those provisions are part of the dynamic baseline**.

Considerations relevant to solve problem 2

(d) any warning or safety information that is to be affixed on the product or to accompany it in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers.

[198] Directive 2000/31/EC, OJ L 178/1.

[199] Article 2(n) draft DSA.

[200] The E-Commerce Directive provides that national governments must ensure that advertising follows certain rules: - it is clearly identifiable as advertising; - the person or company responsible for it is clearly identifiable; - promotional offers, games or competitions are clearly identifiable, and the conditions are easily accessible and presented in clear and simple terms.

[201] See Article 6 of the Consumer Rights Directive.

Pursuant to Chapter II of the draft DSA (Liability of providers of intermediary services), the liability of intermediary services, such as online platforms[202], is conditional. For instance, they can only be held liable for the illegal content on their websites if they were made aware of such illegal content and they did not remove it. Also, under Article 15 of the E-Commerce Directive, Member States are not allowed to introduce a general obligation of intermediary service providers to monitor the information they store or transmit for non-compliance with legal requirements.

CLP does not provide for any specific obligations of online platforms regardless if they are established in or outside the EU. Those platforms would only have obligations under CLP if they met the definitions of the CLP actors, *i.e.* importers, manufacturers, distributors (including retailers), downstream users and this is very unlikely. Thus, if a non-EU actor sells directly to an EU consumer even via a platform established in the EU, that platform would neither have an obligation under CLP to comply with it (while the non-EU sellers themselves would also have no such obligation), nor any liability under the draft DSA or the E-Commerce Directive. **Hence, the problem of supplying unsafe chemicals from outside the EU to consumers persists**.

This impact assessment takes into account the general liability exemption under draft DSA and the E-commerce Directive **and will not deviate from that general principle**. Therefore, the option to have a responsible actor in the EU by default and include online platforms as such an actor will be discarded (see below).

Other initiatives

The baseline also takes into account already existing measures at EU level to ensure compliance of online sales, such as:

Product Safety Pledge: This voluntary initiative was issued by the European Commission in 2017 and signed by large online marketplaces. It includes voluntary commitments to consult the Product Safety Gate (former RAPEX) for information on recalled/dangerous products, react within two working days on government notices about unsafe products and cooperate with EU Member State authorities in identifying dangerous products[203].

The platforms committed to collaborate with public authorities and contribute to identifying and removing non-compliant products. Key performance indicators to monitor the implementation of commitments were developed and are reported by online platforms (Table 176).

Table 176: Examples of performance data of online marketplaces under the Product Safety Pledge

Key performance indicator 1: product listings removed based on governmental notices			
Reporting period	**Online platforms**	**No. of governmental notices**	**No. of removed product listings**
1 December 2020 to 31 May 2021	AliExpress, Allegro, Amazon, CDiscount, eBay, Rakuten France, Wish, eMag and bol.com	2,732	13,555
1 June 2020 to 30	AliExpress, Amazon, eBay, Rakuten	2,033	12,267

[202] See Article 2(f) of draft DSA which defines the different intermediary services and further distinguishes between "mere conduit", "caching" and "hosting". "Online platforms" are hosting service providers.
[203] Online marketplaces participating are: Joom, Etsy, bol.com eMAG Wish.com, AliExpress, Amazon, eBay, Rakuten France, Allegro and Cdiscount.

Table 176: Examples of performance data of online marketplaces under the Product Safety Pledge			
November 2020	France, Allegro and CDiscount		
Key performance indicator 2: product listings removed based on the monitoring of recall websites			
Reporting period	**Online platforms**	**No. of detected alerts**	**No. of removed product listings**
1 December 2020 to 31 May 2021	AliExpress, Allegro, Amazon, CDiscount, eBay, Rakuten France, Wish, eMag and bol.com	885	27,717
1 June 2020 to 30 November 2020	AliExpress, Amazon, eBay, Rakuten France, Allegro and CDiscount	1,760	70,273
Sources: Progress reports on the implementation of the product safety pledge. 2021 report available at: https://ec.europa.eu/info/sites/default/files/5th_progress_report_product_safety_pledge.pdf 2019 report available at: https://ec.europa.eu/info/sites/default/files/4th_progress_report_product_safety_pledge_-_final_0.pdf			

However, the performance data of online marketplaces show that safety pledge commitments could hardly provide any substantial contribution to solving the problem of non-compliance of chemicals with the CLP Regulation. The performance data refers to all product safety non-compliances with different pieces of legislation. To compare, in 2015-2019 Member States performed 288,280 controls of compliance with the CLP Regulation and identified 68,898 cases of non-compliance (Milieu Consulting, 2020).

EU Product Compliance Network (EUPCN): This network aims to structure the coordination and cooperation between market surveillance authorities in EU countries, and streamline market surveillance practices within the EU that facilitate the implementation of joint enforcement activities by member state authorities, such as joint investigations. Amongst the initiatives or activities listed by the EUPCN's work programme 2021-2022 is the introduction of a web crawler, *i.e.* a computer programme that automatically searches information on the web and can hence be used to identify information on incompliant products. It is highly unlikely that such an initiative would solve the problem of non-compliance of chemicals with the CLP Regulation, due to its broad scope.

DESCRIPTION OF POLICY MEASURES

To solve problem 1, the following policy measures were identified:

#17: Amend or update CLP to refer to horizontal provisions on online offering and advertisement (e.g. draft GPSR, draft DSA, E-Commerce Directive and Consumer Rights Directive)

This would entail either an amendment of Article 48 (Advertisement) of the CLP when it comes to referring to the horizontal provisions on advertisement or mentioning those horizontal provisions in a recital with regards to distance contracts.
Article 48 could also be revised to lay out the same requirements for substances and mixtures to be provided when advertising (currently they are different, provided under par. 1 and 2 respectively) as suggested by stakeholders in the different consultations[204].

[204] For substances any advertisement shall mention the hazard class and categories and for mixtures the type or types of hazard indicated on the label if a member of the general public concludes a contract before having first sight of the label. See Article 48 CLP.

This would also entail addressing online offers in CLP, for instance by adding an article that the rules in the draft GPSR, and in particular rules imposing obligations on economic operators to display product safety information (Article 18 draft GPSR) and on online marketplaces to allow traders to provide that information (Article 22 draft GPSR), need to be adhered to (e.g. add Article 48a on online offers).

#22: Periodically run consumer awareness raising campaigns on chemicals offered and advertised online

This would entail running campaigns at Union wide level making consumers aware that they need to pay particular attention when buying chemicals online and they could be organised by ECHA. This measure is aimed at reaching out to consumers with the purpose of providing information about hazard identification and communication requirements for products sold online. To be effective such measures use various communication media and provide information in an attractive and simple way[205].

To solve problem 2, the following policy measures were identified:

#18: Introduce the obligation to have a responsible economic actor in the EU by default under CLP
This would entail a change of the CLP in order to introduce the obligation of always having a responsible economic actor for CLP compliance in the EU. Such actor should carry out a commercial activity (and therefore would not include the consumer), and could be a natural or legal person. Except for the case outlined above under problem 2, where the consumer buys directly from a seller outside the EU and there is no economic actor in the EU involved in commercial activity, in all other cases (of imports) such an economic actor is already established in the EU.
DM 13: Introduce the obligation to have a responsible economic actor in the EU and include online platforms as such responsible actors

This would entail the same change under CLP as measure 1, with the difference that online platforms established in the EU would be explicitly qualified as responsible economic actors for compliance in case non-EU actors sell chemicals to EU via online means.

Taking into account the general liability exemption of online platforms under draft DSA and E-Commerce Directive, **this measure is discarded**.

Below a table outlining the different policy measures:

Table 177: Policy measures

	Specific objective	Policy measure	Regulatory or non - regulatory?	Alternative option? Preference?	Retained or discarded?	Why retained or discarded?
1	Ensure comprehensive communication for online offers/advertising	#17 Amend or update CLP to cross-refer to horizontal provisions	regulatory	#22 - PO.	Retained	

[205] Similar measures are discussed in OECD (2016) and EC (2015).

		on online offering and advertisement (e.g. draft GPSR, Consumer Rights Directive)				
		#22 Raise consumer awareness campaigns on chemicals offered and advertised online	non-regulatory	#22	Retained	
2	Ensure products sold on-line by non-EU economic actors reaching directly EU consumers are properly labelled and packaged (following proper classification)	#18 Introduce the obligation to have a responsible economic actor in the EU by default under CLP	regulatory	#18 - PO	Retained	
		#DM13 Introduce obligation to have a responsible economic actor in the EU and make online platforms such responsible actors	regulatory	#18	Discarded	Not in line with draft DSA and E-Commerce Directive

Description of impacts

Social and health impacts

The social and health benefits of the measures are associated with both a reduction in the number of CLP and REACH non-compliant products purchased online and a consequent reduction in the exposure of individuals and the environment to potential hazards.

#22 and #17 relating to consumer awareness and CLP cross-referencing reduce non-compliance for both intra-EU and import sales. The table below provides the central estimate of the impact of these two options on reducing the sale of non-CLP compliant items and products that are CLP relevant and are also non-compliant with REACH restrictions.

*Table 178: PO8: Reduction in number of non-compliant items and exposed consumers per year for CLP referencing and consumer awareness measures based on 2021 figures**

		Number of items purchased per year (number)	Number of consumers purchasing	
			one item per year (number)	two items per year (number)
#17 CLP cross-referencing				
REACH restriction non-compliant items	Within EU	1 109 816 (1.6%)	641 456 (1.6%)	234 180 (1.6%)
	Imports	243,306 (0.8%)	139,619 (0.8%)	51,843 (0.8%)
CLP non-compliant items	Within EU	3,329,449 (20%)	1,924,369 (20%)	702,540 (20%)
	Imports	729,918 (10%)	418,858 (10%)	155,530 (10%)
REACH restriction non-compliant items	**Total**	1,353,122 (1.3%)	781,075 (1.3%)	286,023 (1.3%)
CLP non-compliant items	**Total**	4,059,367 (17%)	2,343,227 (17%)	858,070 (16.9%)
#22 Consumer awareness				
REACH	Within EU	554,908 (0.8%)	320,728 (0.8%)	117,090 (0.8%)

restriction non-compliant items				
	Imports	243,306 (0.8%)	139,619 (0.8%)	51,843 (0.8%)
CLP non-compliant items	Within EU	1,664,725 (10%)	962,184 (10%)	351,270 (10%)
	Imports	729,918 (10%)	418,858 (10%)	155,530 (10%)
REACH restriction non-compliant items	**Total**	798,214 (0.8%)	460,347 (0.8%)	168,933 (0.8%)
CLP non-compliant items	**Total**	2,394,643 (10%)	1,381,042 (10%)	506,800 (10%)
** Values are calculated based on sales of online goods in 2021. There was 1.1% growth in online sales between 2020 and 2021. Thus, the annual values in this table could be expected to increase over time.*				

The responsible economic actor obligation (measure #18) affects only import sales (and not online purchases from sellers within the EU). The table below provides the central estimate of the impact of the responsible economic actor obligation on options on reducing the sale of non-CLP compliant items and products that are CLP relevant and are also non-compliant with REACH restrictions. Estimates of the reduction in the number of consumers exposed to non-compliant products are also provided.

*Table 179: PO8: Reduction in number of non-compliant imported items and exposed consumers per year for the responsible economic actor measure based on 2021 figures**			
	Number of items purchased per year (number)	**Number of consumers purchasing**	
		one item per year (number)	**two items per year (number)**
#18 Responsible economic actor obligation			
Import of REACH restriction non-compliant items	811,020 (0.8%)	465,398 (0.8%)	172,811 (0.8%)
Import of CLP non-compliant items	2,433,059 (10.2%)	1,396,194 (10.1%)	518,433 (10.2%)
** Values are calculated based on sales of online goods in 2021. There was 1.1% growth in online sales between 2020 and 2021. Thus, the annual values in this table could be expected to increase over time.*			

Environmental impacts

It was not possible to assess environmental impacts quantitatively. However, from a qualitative point of view, positive environmental impacts are expected from all sub-measures, albeit with different magnitudes in terms of their effectiveness. It is plausible that especially the expected reduction in imports of non-CLP compliant products will have a quite substantial positive impact. The more incompliant chemicals purchased and used are reduced, the better for the environment, because this implies less spillage, fewer emissions, less pollution from wrongly classified substances.

Economic impacts

#17 CLP cross-referencing: The option would not require a change to the physical label or the packaging to which it is attached. Rather, information from the label would need to be included in future online adverts/offerings and this might, for example, be achieved simply by including a photograph of the label/information in the series of photos already provided on most online adverts/offerings or by copying and pasting the information into the item description. Such actions are unlikely to have any perceptible impact on the costs. Regardless, such costs would need to be borne already by online traders and platforms in order to comply with draft GPSR (see above). This sub-measure would just better link the CLP obligations with the ones under draft GPSR to ensure coherence and clarity. Costs for enforcement authorities would already be alleviated by the draft GPSR because they would be better able to check compliance.

#22 Consumer awareness raising campaigns: The costs of the measure are associated with the operation of a consumer awareness campaign. This could be included within existing campaigns (such as the European Interactive Digital Advertising Alliance) or could be standalone. As the intended target of such a campaign would be online consumers, operation of a digital campaign would be the method of choice, making it relatively inexpensive to operate. Assuming €150,000 in staff costs (3 FTEs) and €150,000 for equipment and operational costs would imply costs of around €300,000 per year.

#18 Responsible economic actor obligation: Sellers based in the EU would not incur any costs, but sellers based outside the EU would have to sell via a new or already established EU based responsible economic actor and are likely to have to pay a commission to that

responsible actor. These same costs (to outside sellers) would bring benefits to the existing or newly established responsible economic actors in the EU. With 7.3 million items at a value of €20 each (consistent with the €22 VAT free cut-off that applied until July 2021) and a commission of 2%, this equates to an EU benefit of around €2.9 million per year for items that are non-compliant at present. A commission of 5% would equate to benefits to the EU of around €7.3 million per year. As requirements would also apply to products that currently comply with CLP (as well as those that don't), such values should be regarded as minimum and conservative estimates.

Moreover, sellers from outside the EU would have to bear the compliance cost of adhering to the CLP rules and this would level the playing field between sellers from in and outside the EU, with sellers from inside the EU benefitting from the resulting fairness in competition. It was impossible to quantitatively assess how much it costs to comply with CLP rules or how much the EU-based sellers would gain from enhanced competitiveness.

COMPARISON OF IMPACTS AND PREFERRED OPTION

CLP cross-referencing (#17) does not imply any additional economic costs for both online traders/platforms and market surveillance authorities. Those costs would be inexistent due to the measures in draft GPSR. Societal and environmental impacts of the measure are positive as they would grant certainty to consumers regarding various aspects of online sales (from advertisement to offers) and thus allow consumers to be better informed. Consumer awareness raising campaigns (#22) are not so costly either, but they would have a lesser positive societal and environmental impact than #17. The responsible economic actor obligation (#18) has no negative economic impacts for EU actors. To the contrary, (i) it levels the playing field between EU and non-EU actors and (ii) brings new job opportunities to the EU. Sub-measure 2.1. also has positive environmental and social impacts since it reduces the number of incompliant products circulating in the market, leading to consumers being less exposed to incompliant products and to less spillage or pollution from wrongly classified chemicals in the environment.

The preferred options are measures #17 (CLP cross-referencing) and measure #18 (introduce a responsible economic actor obligation).

APPENDIX

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.

No specific data are collected on the actual number of online sales, the location of sellers or the products sold. However, Eurostat does produce an e-commerce dataset that describes the percentage of (all individuals) across the EU that have made purchases in the preceding 3 months. These data are organised into different data areas including:

> Percentage of individuals that have purchased items within the last three months from sellers within their nation, from another EU Member State, from sellers in the rest of the world (RoW) or where country is not known;[206]

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

Percentage of individuals making 1-2, 3-5, 6-10 or more than 10 online purchases in a three-month period;[207]
Percentage of individuals making purchases of different value categories in the three-month period; and
Percentage of individuals that have purchased each of 16 different types of physical goods and 13 different types of services.[208]

The organisation and presentation of some of these sets (notably identity of items purchased) is different and more expansive/explicit for the years 2020 and 2021 compared with the preceding years.

Total number of online purchases/transactions

Whilst, as noted, no specific data on the volume of sales are available, using the Eurostat data it is possible to develop best estimates of the number of items sold online by multiplying the relevant percentages of (all individuals) by the total number of individuals (i.e. the population). Table 180 provides the total number of online purchases/transactions over three months (all types of purchase) implied by the data. The table provides data for the full suite of categories of online purchases, including those that are not CLP (or REACH) relevant. This is to allow the total numbers of purchases derived by consideration of Eurostat data on individual product categories (in Table 180) to be compared with total numbers of purchases derived from other statistical breakdowns produced by Eurostat (such as numbers of purchases made). In this way, the comparison provides a means to assess the consistency and reasonableness of the estimates of items purchased (including CLP relevant products).

[207] Eurostat, Internet purchases by individuals (2020 onwards), available at: https://ec.europa.eu/eurostat/databrowser/view/isoc_ec_ib20/default/table?lang=en
[208] https://ec.europa.eu/eurostat/databrowser/view/isoc_ec_ibgs/default/table?lang=en

Table 180: Implied total number of online purchases/transactions over three months (all types of purchase)				
	Percentage of individuals making online purchases within a three-month period		**Implied number of purchases/transactions within a three-month period**	
	2020	**2021**	**2020**	**2021**
Clothes (including sport clothing), shoes or accessories	33%	38%	147,615,572	170,314,137
Sports goods (excluding sport clothing)	11%	13%	49,205,191	58,265,363
Children toys or childcare items	9%	11%	40,258,792	49,301,461
Furniture, home accessories or gardening products	15%	16%	67,097,987	71,711,216
Music as CDs, vinyls etc.	4%	3%	17,892,797	13,445,853
Films or series as DVDs, Blu-ray etc.	4%	3%	17,892,797	13,445,853
Printed books, magazines or newspapers	14%	14%	62,624,788	62,747,314
Computers, tablets, mobile phones or accessories	14%	13%	62,624,788	58,265,363
Consumer electronics or household appliances	10%	10%	44,731,992	44,819,510
Medicine or dietary supplements such as vitamins (online renewal of prescriptions is not included)	12%	11%	53,678,390	49,301,461
Deliveries from restaurants, fast-food chains, catering services	15%	17%	67,097,987	76,193,166
Food or beverages from stores or from meal-kits providers	10%	10%	44,731,992	44,819,510
Cosmetics, beauty or wellness products	14%	15%	62,624,788	67,229,265
Cleaning products or personal hygiene products	8%	8%	35,785,593	35,855,608
Bicycles, mopeds, cars, or other vehicles or their spare parts	5%	5%	22,365,996	22,409,755
Other physical goods	10%	11%	44,731,992	49,301,461
Online purchases (3 months) from private persons: any physical goods	18%	18%	80,517,585	80,675,117
Music as a streaming service or downloads	13%	14%	58,151,589	62,747,314
Films or series as a streaming service or downloads	17%	17%	76,044,386	76,193,166
e-books, online-magazines or online-newspapers	7%	7%	31,312,394	31,373,657
Games online or as downloads for smartphones, tablets, computers or consoles	9%	9%	40,258,792	40,337,559
Computer or other software as	9%	9%	40,258,792	40,337,559

Table 180: Implied total number of online purchases/transactions over three months (all types of purchase)				
	Percentage of individuals making online purchases within a three-month period		**Implied number of purchases/transactions within a three-month period**	
downloads including upgrades				
Apps related to health or fitness (excluding free apps)	4%	4%	17,892,797	17,927,804
Other apps (e.g. related to learning languages, travelling, weather) (excluding free apps)	4%	4%	17,892,797	17,927,804
Tickets to sport events	3%	1%	13,419,597	4,481,951
Tickets to cultural or other events	12%	5%	53,678,390	22,409,755
Subscriptions to the internet or mobile phone connections	8%	7%	35,785,593	31,373,657
Subscription to electricity, water or heating supply, waste disposal or similar services	6%	5%	26,839,195	22,409,755
Household services (e.g. cleaning, babysitting, repair work, gardening)	2%	2%	8,946,398	8,963,902
Total			**1,261,442,163**	**1,263,910,173**
Notes: Based on combination of EUROSTAT population data (https://ec.europa.eu/eurostat/databrowser/view/demo_pjan/default/table?lang=en) of 447 319 916 for 2020 and 448 195 097 for 2021 and E-Commerce and digital economy and society data (https://ec.europa.eu/eurostat/databrowser/view/isoc_ec_ibgs/default/table?lang=en)				

Clearly, the values in Table 180 are derived from the number of individuals who have purchased at least one of each of the listed items in the three-month period. As many consumers may have made more than one purchase in that period, the numbers of items as calculated in Table 180 may represent a minimum. However, Eurostat also provide data on the percentage of (all) individuals making:

1 to 2 (average 1.5) online purchases within three months;
3 to 5 (average 4) online purchases within three months;
6 to 10 (average 8) online purchases within three months; and
More than 10 online purchases within three months.209

Applying these percentages to the number of individuals and number of purchases provides a second estimate of the total number of purchases/transactions in a three-month period for comparison with the total numbers of purchases of 1.264 billion (2021) and 1.261 billion (2020) from Table 180. For three of the four frequency categories the number of purchases is established. However, for the category of 'more than 10 purchases', the number is not defined but can be varied in the calculations to adjust the returned number of transactions from the frequency data until it matches the totals given in Table 180. Cross-checking the

209 Eurostat, Internet purchases by individuals (2020 onwards), available at: https://ec.europa.eu/eurostat/databrowser/view/isoc_ec_ib20/default/table?lang=en

numbers in this way suggests that the 'more than 10' category would have to equate to an average of around 14 purchases in three months for the two sets of numbers to agree. This, in turn, equates to a weighted average of 2.8 purchases per individual across all individuals making purchases within the three-month period.

As, from the cross-checking, this does not seem unreasonable it is assumed that the calculation total number of purchases/transactions across all categories of purchases in Table 180 is relatively unaffected by the possibility that multiple individuals may have made multiple purchases from the same category of product. Applying a 'common sense' approach, for multiple purchases from the same individuals to significantly affect the data and the estimate of the total number of purchases/transactions, multiple individuals would have to be making multiple purchases of the same category of item. Whilst this is possible, the numbers in Table 180 represent the best available estimate of online purchases/transactions, and it is assumed that the estimates in relation to the CLP (and REACH) relevant categories are a reasonable reflection of the reality.

Online purchases from sellers outside the EU

Eurostat also produce data describing the percentage of (all) individuals who have made an online purchase from sellers in their own nation or in different country categories.[210] The data for 2020 and 2021 are provided in Table 181. These data can be used to describe both the percentage of (all) individuals making purchases from EU versus non-EU sellers and also the fraction of items sold by EU versus non EU sellers. Concerning the implied origin of products, this is only an assumption one can make given that online platforms in one Member State may very well sell goods not originating from that Member State but from a third country. So, in reality, the number of products originating from third countries might be much higher.

Table 181: Purchases made from sellers in different locations

	Percentage of individuals making purchases (from EUROSTAT)		**Fraction of items from sellers in different locations types***	
	2020	**2021**	**2020**	**2021**
Online purchases: from national sellers over three months	47%	47%	59%	56%
Online purchases: from sellers from other EU countries over three months	17%	18%	21%	21%
Online purchases: from sellers from the rest of the world (non-EU) over three months	12%	12%	15%	14%
Online purchases: from sellers with unknown country of origin over three months	4%	7%	5%	8%

*Notes: * These percentages are calculated from the percentage of individuals data*
Source: Eurostat data https://ec.europa.eu/eurostat/databrowser/view/isoc_ec_ibos/default/table?lang=en

Number of individuals 'exposed'

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

From Table 181, at least[211] 12% of (all) individuals made a purchase from the RoW in 2020 and 12% in 2021. By the same token, at least 4% of (all) individuals made a purchase from an unknown country in 2020 and 7% in 2021. Some individuals in the statistics may have made purchases from both a country in the RoW and an unknown country and some individuals may have only made purchases from either the RoW or from an unknown country. Thus, the total percentage of (all) individuals making purchases from the RoW or an unknown country for 2021 ranges between 12% (based on all individuals making in one or both so the maximum of the two categories applies) and 19% (based on all individuals making either purchases from RoW or from an unknown country so the total applies = 12% + 7%).

Applying the percentages and approaches to the number of individuals provides the total number of individuals in the EU making purchases from sellers within and outside the EU in Table 182. Whilst the numbers in the table are derived from three-month statistics, for the purpose of the IA it will be assumed that they represent the total number of people making purchases annually. This would be to assume that the individuals making purchases in each of the four three-month blocks are the same individuals, a fair assumption given that assuming that they are all different would produce annual numbers larger than the EU population.

Thus, the numbers in Table 182 provide the total EU population purchasing goods coming from territories outside the EU in 2020 and 2021. A proportion of these consumers will be exposed to inaccurate and/or incomplete information in advertisements/offers and/or exposure to substances that are restricted in the EU.

Table 182: Number of individuals making online purchases from within and outside the EU

	2020	**2021**
Online purchase from outside the EU		
Online purchases: from sellers from the rest of the world (non-EU)	53,678,390	53,783,412
Online purchases: from sellers with unknown country of origin	17,892,797	31,373,657
Total assuming different people between two categories	71,571,187	85,157,068
Total assuming same people some of whom also make purchases from both categories	53,678,390	53,783,412
Total individuals making extra EU purchases (assuming average of the two cases above)	**62,624,788**	**69,470,240**
Online purchases from within the EU		
Online purchases: from national sellers	210,240,361	210,651,696
Online purchases: from sellers from other EU countries	76,044,386	80,675,117
Total assuming different people between two categories	286,284,746	291,326,813
Total assuming same people some of whom also make purchases from both categories	210,240,361	210,651,696
Total individuals making EU purchases (assuming average of the two cases above)	**248,262,553**	**250,989,254**

Source: Based on combination of EUROSTAT population data (https://ec.europa.eu/eurostat/databrowser/view/demo_pjan/default/table?lang=en) and E-Commerce and digital economy and society data https://ec.europa.eu/eurostat/databrowser/view/isoc_ec_ibos/default/table?lang=en

Number of products from outside versus inside the EU

[211] Because the statistics are over a three-month period

In Table 181 the percentage of individuals making purchases in different locations has been used to derive the implied distribution of products by origin. Whilst it could be argued that the statistics by individual do not explicitly describe the proportion of purchases made by location, there is no better data on which to base the assessment and the resulting percentage split between locations so derived seems plausible.

The resulting percentages (in Table 181) have been applied to the total number of purchases of physical goods in a three-month period (in Table 180) to make a split between purchases of physical goods from EU sellers and extra EU sellers. The resulting values have been multiplied by four to convert them from three-month figures to annual figures and are provided in Table 183. As can be seen from the table, certain physical goods (such as deliveries from restaurants) are unlikely to have been purchased from outside the EU and this has been accounted for in the calculations.

The resulting total number of physical items purchased online from outside the EU is estimated as around 583 million in 2020 and 693 million in 2021. In terms of comparison of this with other data points, in 2017 it was estimated that around 150 million small consignments imported free of VAT into the EU each year[212]. The number of online purchases/transactions has increased since that time. Using available and comparative data from EUROSTAT for 2017 and 2021 suggests a multiplier of 1.375 to convert the 2017 estimate of 150 million into a 2021 estimate of around 206 million small VAT free consignments for 2021. This represents some 30% of the 693 million total number of items. In other words, the comparison would suggest that, in 2021, 30% of online purchases from sellers outside the EU would be of a value less than €22 (the VAT free cut-off that applied until July 2021). This does not seem unreasonable.

A further sense check of the data on both the number of purchases and the number of consumers (in Table 182) is provided by calculating the average number of purchases per consumer suggested by the data. As can be seen from Table 183, this comparison suggests around 11 purchases per consumer per year on average for purchases from EU countries and 9 or 10 per consumer per year for extra EU purchases. This, gain, does not seem unreasonable. Given the sense checks, the data in Table 183 are taken to be a fair representation of the numbers and flow of physical goods to consumers from online purchases and the number of consumers.

[212] European Commission, Memo 2017 - Modernising VAT for e-commerce https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_3746

Table 183: Purchases of physical goods online from within versus outside the EU (purchases/items per year)				
	Within EU		**Outside EU**	
	2020	**2021**	**2020**	**2021**
Clothes (including sport clothing), shoes or accessories	472,369,831	527,162,805	118,092,458	154,093,743
Sports goods (excluding sport clothing)	157,456,610	180,345,170	39,364,153	52,716,280
Children toys or childcare items	128,828,136	152,599,759	32,207,034	44,606,083
Furniture, home accessories or gardening products	214,713,560	221,963,286	53,678,390	64,881,576
Music as CDs, vinyls etc.	57,256,949	41,618,116	14,314,237	12,165,295
Films or series as DVDs, Blu-ray etc.	57,256,949	41,618,116	14,314,237	12,165,295
Printed books, magazines or newspapers	200,399,322	194,217,875	50,099,831	56,771,379
Computers, tablets, mobile phones or accessories	200,399,322	180,345,170	50,099,831	52,716,280
Consumer electronics or household appliances	143,142,373	138,727,054	35,785,593	40,550,985
Medicine or dietary supplements such as vitamins (online renewal of prescriptions is not included)	171,770,848	152,599,759	42,942,712	44,606,083
Deliveries from restaurants, fast-food chains, catering services	268,391,950	304,772,666	0	0
Food or beverages from stores or from meal-kits providers	178,927,966	179,278,039	0	0
Cosmetics, beauty or wellness products	200,399,322	208,090,581	50,099,831	60,826,477
Cleaning products or personal hygiene products	114,513,898	110,981,643	28,628,475	32,440,788
Bicycles, mopeds, cars, or other vehicles or their spare parts	71,571,187	69,363,527	17,892,797	20,275,492
Other physical goods	143,142,373	152,599,759	35,785,593	44,606,083
Total purchases	**2,780,540,598**	**2,856,283,325**	**583,305,170**	**693,421,843**
Total individuals making online purchases	**248,262,553**	**250,989,254**	**62,624,788**	**69,470,240**
Average purchases per consumer per year	11.2	11.4	9.3	10.0

Number of non-compliant transactions

While not all of the categories of physical goods set out in Table 183 are entirely relevant from the perspective of EU safety standards in general or requirements on chemicals under CLP and REACH specifically, some are relevant.

A proportion of these goods will have been non-compliant, and the objective of the interventions is to address this and ensure greater compliance in the future. For the IA, then, an estimate of the percentage/number of REACH/CLP non-compliant online products needs to be established for the following types of relevant products listed in Table 183 to establish a baseline for the assessment:

Clothes (including sport clothing), shoes or accessories
Children toys or childcare items
Furniture, home accessories or gardening products
Computers, tablets, mobile phones or accessories
Consumer electronics or household appliances
Cosmetics, beauty or wellness products
Cleaning products or personal hygiene products
Bicycles, mopeds, cars, or other vehicles or their spare parts

To inform this estimation of non-compliance, available surveillance information on online products has been gathered from a variety of consumer reports and enforcement projects. Data on notifications to Safety Gate/RAPEX that was previously compiled for the IA of GPSD has also been reviewed for relevance. However, as the GPSD IA Staff Working Document identifies that only 25% of the notifications in the period from 2013 to 2019 included reference to a 'chemical risk' it was concluded that the data were not useful for the current analysis.

The results of surveillance studies on online products have been collated as Table 184:. The table provides information on reasons for non-compliance where this includes both chemically relevant variables (relating to, for example, presence/concentration of restricted substances or hazard information) and also other non-compliance issues (such as electrical safety, choking hazards, etc.).

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
Non-compliance with chemicals related requirements						
Online Cosmetics			21%	Non-compliant - often owing to lack of information on alergens	DGCCRF (Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes) 2020 survey	2020
Online Cosmetics for adults	39	22	56%	No list of ingredients and company information	BEUC report	2021
Online Cosmetics for adults	39	1	3%	Illegal substances	BEUC report	2021
Online Teeth whitening products	11	7	64%	Hydrogen peroxide limits	BEUC report	2021
Online Teeth whitening products	11	11	100%	Labelling and no manufacturer/batch labels	BEUC report	2021
Online Children's make-up	11	1	9%	425 x legal limit for lead	BEUC report	2021
Online Children's make-up	11	2	18%	Legal limits on antimony	BEUC report	2021
Online Children's make-up	11	3	27%	Legal limits substances	BEUC report	2021
COSMETICS - average			**37%**	**Restrictions**		
Online Toys	193	18	9%	Pthalate levels	June 2020 Toy industry survey	2020
Online Toys	193	7	4%	Boron migration	June 2020 Toy industry survey	2020

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Table 184: Collated information on online product non-compliance

Product	Reference number/ Number tested/assessed	Non-compliant	Non-compliant (%)	Requirement/reason	Source	Year
Online Toys	82	12	15%	Noncompliance with restriction: Entry 51: Phthalates (DEHP, DBP, BBP,	ECHA Ref 8 report	2020
Online Toys	94	2	2%	Noncompliance with restriction: Entry 52: Phthalates (DINP, DIDP,	ECHA Ref 8 report	2020
Online Balloons	5	5	100%	nitrosamines and/or nitrosatable substances	BEUC report	2021
Online Balloons	5	2	40%	15 x limit for nitrosamines, 27 x limit for nitrosatable substances	BEUC report	2021
Soft plastic toys	29	9	31%	Above legal limits for one or more Phthalates	BEUC report	2021
Online Acoustic toys	23	0	0%	Legal limits on substances	BEUC report	2021
Online Acoustic toys	23	4	17%	German limits on PAHs	BEUC report	2021
Online Toys and childcare items			24%	Not conforming to restrictions on substances (KEMI enforcememnt 2014-2019)	Kemi - Increased e-commerce – increased chemicals risks?	2016
Online Toys and childcare items			23%	Not conforming to restrictions on substances (Nordic e-commerce project 2019)	Kemi - Increased e-commerce – increased chemicals risks?	2016
Online Childcare articles	24	0	0%	Noncompliance with restriction: Entry 51: Phthalates (DEHP, DBP, BBP,	ECHA Ref 8 report	2020
Online Childcare articles	28	0	0%	Noncompliance with restriction: Entry 52: Phthalates (DINP, DIDP,	ECHA Ref 8 report	2020

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
TOYS AND CHILDCARE ITEMS - average			**20%**	**Restrictions**		
Online Electrical products			31%	Not conforming to restrictions on substances (KEMI enforcememnt 2014-2019)	Kemi - Increased e-commerce – increased chemicals risks?	2016
Online Electrical products			57%	Not conforming to restrictions on substances (Nordic e-commerce project 2019)	Kemi - Increased e-commerce – increased chemicals risks?	2016
ELECTRICAL PRODUCTS - average			**44%**	**Restrictions**		
Solder (for use in soldering) - inside EU			40%	Restrictions on lead	ECHA Ref 8 report	2020
Solder (for use in soldering) - outside EU			60%	Restrictions on lead	ECHA Ref 8 report	2020
Online Jewellery	340	79	23%	Noncompliance with restriction: Entry 23: Cadmium	ECHA Ref 8 report	2020
Online Jewellery	302	16	5%	Noncompliance with restriction: Entry 27: Nickel in jewellery	ECHA Ref 8 report	2020
Online Jewellery	337	31	9%	Noncompliance with restriction: Entry 63 Lead	ECHA Ref 8 report	2020
Online Jewelery	7	5	71%	nickel and or cadmium	BEUC report	2021
JEWELERY - average			**27%**	**restrictions**		
Online Leather articles	1	0	0%	Noncompliance with restriction: Entry 43: Azocolourants and azodyes	ECHA Ref 8 report	2020
Online Leather articles	76	6	8%	Noncompliance with restriction: Entry 47. 5-7: Chromium VI in leather articles	ECHA Ref 8 report	2020

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
Online Textiles	31	0	0%	Noncompliance with restriction: Entry 43: Azocolourants and azodyes	ECHA Ref 8 report	2020
LEATHER AND TEXTILES – average			**3%**	**Restrictions**		
Online Plastic material	6	2	33%	Noncompliance with restriction: Entry 23: Cadmium	ECHA Ref 8 report	2020
Online Binoculars	17	16	94%	Chlorinated paraffins, phthalates, PAHs	BEUC report	2021
Online products (substances, mixtures, artcles)	5,730	5,047	88%	Noncompliant for one or more reasons	REF-8 (2020)* as reported in ECHA Ref 8 report	2020
Online products (substances, mixtures, artcles)	3,391	1,398	41%	Noncompliant for one or more reasons	REF-6[2] (2018)* as reported in ECHA Ref 8 report	2018
Online products (substances, mixtures, artcles)	2,629	2,042	78%	Noncompliant with REACH restrictions	ECHA Ref 8 report	2020
Online products (substances, mixtures, artcles)	5,625	1125	22%	Noncompliant with REACH restrictions	REF-411 (2016)* as reported in ECHA Ref 8 report	2016
Online products (substances, mixtures, artcles)	1,225	211	17%	Noncompliant with REACH restrictions	Cooperation with customs 2 project [1] (2019)* as reported in ECHA Ref 8 report	2018
Online Substances/mixtures	1,974	1,876	95%	Non compliance with restriction	ECHA Ref 8 report	2020
Online Articles	655	164	25%	Non compliance with restriction	ECHA Ref 8 report	2020

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
Online Articles	7	2	29%	Noncompliance with restriction: Entry 63 Lead	ECHA Ref 8 report	2020
REACH (RESTRICTIONS) Online products (substances, mixtures, artcles) - average			**49%**			
Online products (substances, mixtures, artcles) from EU marketplace			98%	REACH restrictions	ECHA Ref 8 report	2023
Online products (substances, mixtures, artcles) from NON-EU marketplace			84%	REACH restrictions	ECHA Ref 8 report	2024
Online Articles from marketplace			45%	Non compliance with restriction	ECHA Ref 8 report	2020
Online Arictles from Webshop			18%	Non compliance with restriction	ECHA Ref 8 report	2020
Online products (substances, mixtures, artcles)			54%	Noncompliant with CLP Article 48 (2)	REF-8 (2020)* as reported in ECHA Ref 8 report	2020
Online products (substances, mixtures, artcles)	1,314	1,083	82%	Noncompliant with CLP Article 48 (2)	e-commerce project[3] (2017)* as reported in ECHA Ref 8 report	2016
Online products (substances, mixtures, artcles)	2,752	2,065	75%	non-compliant with CLP (Article 48(1) and (2))	ECHA Ref 8 report	2020
Online products (substances, mixtures,	2,752	1,321	48%	No hazard informtion CLP (Article 48(1) and (2))	ECHA Ref 8 report	2020

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Table 184: Collated information on online product non-compliance					
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
artcles)						
Online hazardous mixture	1,335	92	7%	Information provided was not complete (e.g. missing hazard statements, H-codes only instead of full hazard statements)	ECHA Ref 8 report	2020
Online hazardous mixture	1,335	626	47%	No hazard information provided	ECHA Ref 8 report	2020
Online hazardous mixture	1,335	718	54%	No or incomplete hazard information	ECHA Ref 8 report	2020
Online hazardous mixture	1,083	902	83%	No information provided on hazard statements and/or supplementary hazard statements	ECHA Final report on the Forum Pilot Project on CLP focusing on control of internet sales (2017)	2017
Online hazardous mixture	1,083	55	5%	The information on the hazard statements provided is not complete (e.g. H-codes instead of phrases)	ECHA Final report on the Forum Pilot Project on CLP focusing on control of internet sales (2017)	2017
Online hazardous mixture	1,083	98	9%	The text of the hazard statements is not in the official language of relevant MSs which are addressed with the Article 48(2) advertisement	ECHA Final report on the Forum Pilot Project on CLP focusing on control of internet sales (2017)	2017
Online hazardous mixture	1,083	172	16%	Other non-compliance	ECHA Final report on the Forum Pilot Project on CLP focusing on control of internet sales (2017)	2017
CLP INORMATION Online products (substances,			**70%**			

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
mixtures, articles) - average						
Online products (substances, mixtures, artcles) from EU marketplace			73%	CLP	ECHA Ref 8 report	2027
Online products (substances, mixtures, artcles) from NON-EU marketplace			100%	CLP	ECHA Ref 8 report	2028
Online products (substances, mixtures, artcles)	956	49	5%	REACH SDS (Article 31)	ECHA Ref 8 report	2020
Online products (substances, mixtures, artcles) from EU marketplace			16%	READ SDS	ECHA Ref 8 report	2025
Online products (substances, mixtures, artcles) from NON-EU marketplace			0%	READ SDS	ECHA Ref 8 report	2026
Online products (substances, mixtures, artcles)			42%	Non- compliant with BPR Articles 17 and 89	REF-8 (2020)* as reported in ECHA Ref 8 report	2020
Online products (substances, mixtures, artcles)			7%	Non- compliant with BPR Articles 17 and 89	REF-6[2] (2018)* as reported in ECHA Ref 8 report	2018
Online products	1,153	891	77%	Non compliant with BPR	ECHA Ref 8 report	2020

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
(substances, mixtures, artcles)						
Online products (substances, mixtures, artcles) from EU marketplace			89%	BPR	ECHA Ref 8 report	2029
Online products (substances, mixtures, artcles) from NON-EU marketplace			100%	BPR	ECHA Ref 8 report	2030
Online products (substances, mixtures, artcles) from marketplace			95%	Non compliant with BPR, REACH or CLP	ECHA Ref 8 report	2021
Online products (substances, mixtures, artcles) from webshop			65%	Non compliant with BPR, REACH or CLP	ECHA Ref 8 report	2022
Non-compliance with other (non-chemical related) requirements						
Online Toys			58%	Non-compliant only	DGCCRF (Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes) 2020 survey	2020
Online Toys			23%	Non-compliant and dangerous (suffocation, strangulation and small parts)	DGCCRF (Direction générale de la Concurrence, de la	2020

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
					Consommation et de la Répression des fraudes) 2020 survey	
Online Toys	193	55	28%	Containing small parts	June 2020 Toy industry survey	2020
Online Toys	193	36	19%	Packaging thickness	June 2020 Toy industry survey	2020
Online Toys	193	24	12%	Shape and size	June 2020 Toy industry survey	2020
Online Toys	193	10	5%	Access to stuffing material	June 2020 Toy industry survey	2020
Online Toys	193	10	5%	Sharp points	June 2020 Toy industry survey	2020
Online Toys	193	7	4%	Small ball release	June 2020 Toy industry survey	2020
Online Toys	193	6	3%	Long cords	June 2020 Toy industry survey	2020
Online Toys	193	5	3%	Suction cups	June 2020 Toy industry survey	2020
Online Toys	193	5	3%	Short circuit	June 2020 Toy industry survey	2020
Online Toys	193	8	4%	Other reason	June 2020 Toy industry survey	2020
Online Toys for <3 year olds	21	19	90%	Any aspect	BEUC report	2021
Online Toys for <3 year olds	21	12	57%	Small parts	BEUC report	2021

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
Online Toys for <3 year olds	21	4	19%	Choking hazard	BEUC report	2021
Online Toys for <3 year olds	21	2	10%	Strangulation hazard	BEUC report	2021
Online Toys for <3 year olds	21	1	5%	Accessible stuffing	BEUC report	2021
Online Toys for <3 year olds	21	2	10%	Packaging issues	BEUC report	2021
Online Toys for <3 year olds	21	1	5%	Battery accessible	BEUC report	2021
Online Toys for <3 year olds	21	2	10%	Suffocation hazard	BEUC report	2021
Online Teething toys	8	6	75%	Small parts broke off in tests	BEUC report	2021
Online Smoke detectors	9	4	44%	Non-compliant only	DGCCRF (Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes) 2020 survey	2020
Online Smoke detectors	9	5	56%	Non-compliant and dangerous	DGCCRF (Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes) 2020 survey	2020
Online Smoke detectors	4	4	100%	Detection	BEUC report	2021

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
Online Carbon monoxide alarms	7	7	100%	Detection and/or safety	BEUC report	2021
Online Power banks	12	7	58%	Electrical/fire safety	BEUC report	2021
Online USB travel adapters	12	11	92%	Electrical/fire safety	BEUC report	2021
Online USB chargers	12	8	67%	Electrical/fire safety	BEUC report	2021
Online Christmas tree lights	13	12	92%	Electrical/fire safety	BEUC report	2021
Online Jewellery			38%	Non-compliant and dangerous	DGCCRF (Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes) 2020 survey	2020
Online Chilrens clothing	16	14	88%	Safety requirements	BEUC report	2021
Online Electrical products			87%	Electrical safety	DGCCRF (Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes) 2020 survey	2020
Online Motorcycle helmets for children	3	2	67%	Safety standards	BEUC report	2021
Online consumer products 2018-19	274	157	57%	No manufacturer	General Product Safety Directive IA_SWD2021	2019

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Table 184: Collated information on online product non-compliance						
Product	**Reference number/ Number tested/assessed**	**Non-compliant**	**Non-compliant (%)**	**Requirement/reason**	**Source**	**Year**
Online consumer products 2018-19	274	100	36%	No brand	General Product Safety Directive IA_SWD2021	2019
Online consumer products 2018-19	274	80	29%	No type/model	General Product Safety Directive IA_SWD2021	2019
Online consumer products 2018-19	274	138	50%	No batch number/barcode	General Product Safety Directive IA_SWD2021	2019
Online consumer products 2018-19	274	35	13%	None of the four	General Product Safety Directive IA_SWD2021	2019
NOT online consumer products 2018-19	3,590	1,280	36%	No manufacturer	General Product Safety Directive IA_SWD2021	2019
NOT online consumer products 2018-19	3,590	700	19%	No brand	General Product Safety Directive IA_SWD2021	2019
NOT online consumer products 2018-19	3,590	451	13%	No type/model	General Product Safety Directive IA_SWD2021	2019
NOT online consumer products 2018-19	3,590	667	19%	No batch number/barcode	General Product Safety Directive IA_SWD2021	2019
NOT online consumer products 2018-19	3,590	17	0.5%	None of the four	General Product Safety Directive IA_SWD2021	2019

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It is important to note that almost all of the surveillance information provided in Table 184: relates to products sold online generally and does not distinguish between points of origin in the EU versus outside the EU. Some of the information data relates to specific products or product types and some of the information is more general, relating to 'online products' consisting of substances, mixtures or articles. Average values for percentage non-compliance with REACH Restrictions and CLP for different products/types of product have also been provided in Table 184: and these are summarised in Table 185.

*Table 185: Average of surveillance data values for products (from **Table 184**: overleaf)*

	CLP non-compliance	**REACH non-compliance (Restrictions)**
COSMETICS - average	No data/not applicable	37.3%
TOYS AND CHILDCARE ITEMS - average	No data/not applicable	20.4%
ELECTRICAL PRODUCTS - average	No data/not applicable	44.0%
JEWELERY - average	No data/not applicable	27.3%
LEATHER AND TEXTILES - average	No data/not applicable	2.6%
Online products (substances, mixtures, articles)	69.7%	49.4%

When reflecting on the averages derived from the surveillance data (Table 184: and Table 185), it is worth noting that the approaches adopted in the surveillance are biased towards specific products where the likelihood of non-compliance (or the risk) is likely to be highest. As such, surveillance and enforcement does not adopt a representative sampling approach of, for example, 'toys' but, rather, focuses on certain types (such as 'soft plastic toys') where non-compliance is most likely to be found and/or the risk/exposure of the consumer/end user is highest. Regardless of this, these non-compliance statistics provide the only basis from which to begin to attribute levels of non-compliance to the various categories of products sold online.

Table 186 provides average non-compliance data from the surveillance reports (from Table 184: and Table 185) mapped onto the most relevant product categories listed in in the Eurostat e-commerce data. As can be seen from the table, there are no relevant surveillance data that would apply to the categories 'Furniture, home accessories or gardening products' and 'Bicycles, mopeds, cars, or other vehicles or their spare parts'. What values are available from the surveillance data are high for the reasons outlined above (i.e. sampling approaches biased to high non-compliance risk products).

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Table 186: Mapping of average surveillance data onto EUROSTAT e-commerce product categories			
EUROSTAT e-commerce data category	**Category from surveillance data**	**Relevant average non-compliance value from surveillance data**	
		CLP	**REACH (RESTRICTION)**
Clothes (including sport clothing), shoes or accessories	LEATHER AND TEXTILES - average	No data/not applicable	3%
Children toys or childcare items	TOYS AND CHILDCARE ITEMS - average	No data/not applicable	20%
Furniture, home accessories or gardening products	No comparable category in surveillance data	No data	No data
Computers, tablets, mobile phones or accessories	ELECTRICAL PRODUCTS - average	No data/not applicable	44%
Consumer electronics or household appliances	ELECTRICAL PRODUCTS - average	No data/not applicable	44%
Cosmetics, beauty or wellness products	COSMETICS - average	No data/not applicable	37%
Cleaning products or personal hygiene products	Online products (substances, mixtures, articles) from EU marketplace	70%	49%
Bicycles, mopeds, cars, or other vehicles or their spare parts	No comparable category in surveillance data	No data	No data

Expanding on and being informed by the values from surveillance reports, Table 187: provides three baseline scenarios (Lower, Central and Upper) for percentage non-compliance of online products sourced from sellers within the EU with CLP and REACH requirements.

There is some evidence and some suspicion that products purchased directly from outside the EU have higher levels of non-compliance than products purchased from within the EU. Regarding CLP, the information from the Ref 8 report suggested 73% non-compliance from products sourced from sellers within the EU compared with 100% non-compliance for outside the EU. Thus, for CLP this would suggest levels of compliance are 1.37 times higher than those within the EU (100/73).

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Table 187: Mapping of average surveillance data onto Eurostat e-commerce product categories			
EUROSTAT e-commerce data category	**Category from surveillance data**	**CLP**	**REACH (RESTRICTION)**
Clothes (including sport clothing), shoes or accessories	LEATHER AND TEXTILES - average	No data/not applicable	3%
	Lower scenario	-	2%
	Central scenario	-	3%
	Upper scenario	-	5%
Children toys or childcare items	TOYS AND CHILDCARE ITEMS - average	No data/not applicable	20%
	Lower scenario	-	3%
	Central scenario	-	5%
	Upper scenario	-	10%
Furniture, home accessories or gardening products	No comparable category in surveillance data	No data	No data
	Lower scenario	-	1%
	Central scenario	-	2%
	Upper scenario	-	3%
Computers, tablets, mobile phones or accessories	ELECTRICAL PRODUCTS - average	No data/not applicable	44%
	Lower scenario	-	5%
	Central scenario	-	8%
	Upper scenario	-	10%
Consumer electronics or household appliances	ELECTRICAL PRODUCTS - average	No data/not applicable	44%
	Lower scenario	-	5%
	Central scenario	-	8%
	Upper scenario	-	10%
Cosmetics, beauty or wellness products	COSMETICS - average	No data/not applicable	37%
	Lower scenario	-	3%
	Central scenario	-	5%
	Upper scenario	-	8%
Cleaning products or personal hygiene products	Online products (substances, mixtures, articles) from EU marketplace	70%	49%
	Lower scenario	10%	2%
	Central scenario	15%	5%
	Upper scenario	30%	10%
Bicycles, mopeds, cars, or other vehicles or their spare parts	No comparable category in surveillance data	No data	No data
	Lower scenario	-	1%
	Central scenario	-	2%
	Upper scenario	-	3%

For REACH compliance the available evidence is conflicting. One of the data points in Table 184: from the Ref 8 report suggests 98% non-compliance for 'online products' sourced from sellers within the EU compared with 84% non-compliance for outside the

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EU. In contrast, the only other data point (for lead in solder, also from the Ref 8 report) suggests 40% non-compliance for the EU compared with 60% non-compliance for outside the EU (i.e. 1.5x).

Considering thee values, lower, central and higher scenario assumptions for increased levels of non-compliance with CLP and REACH are applied in the analysis. The multipliers applied are provided in Table 188 and the resulting percentage non-compliance in the scenarios by application of these to the scenarios in Table 187 are provided in Table 189.

Table 188: Non-compliance of products sources from sellers outside the EU relative to sellers within (multipliers)

	CLP	**REACH (RESTRICTION)**
Lower scenario	1.37	1.37
Central scenario	1.5	1.5
Upper scenario	2	2

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Table 189: Resulting scenarios for levels of non-compliance of online products for the assessment					
		Within EU		**Outside EU**	
		CLP	**REACH (RESTRICTION)**	**CLP**	**REACH (RESTRICTION)**
Clothes (including sport clothing), shoes or accessories	Lower scenario	-	2%	-	3%
	Central scenario	-	3%	-	5%
	Upper scenario	-	5%	-	10%
Children toys or childcare items	Lower scenario	-	3%	-	4%
	Central scenario	-	5%	-	8%
	Upper scenario	-	10%	-	20%
Furniture, home accessories or gardening products	Lower scenario	-	1%	-	1%
	Central scenario	-	2%	-	3%
	Upper scenario	-	3%	-	6%
Computers, tablets, mobile phones or accessories	Lower scenario	-	5%	-	7%
	Central scenario	-	8%	-	12%
	Upper scenario	-	10%	-	20%
Consumer electronics or household appliances	Lower scenario	-	5%	-	7%
	Central scenario	-	8%	-	12%
	Upper scenario	-	10%	-	20%
Cosmetics, beauty or wellness products	Lower scenario	-	3%	-	4%
	Central scenario	-	5%	-	8%
	Upper scenario	-	8%	-	16%
Cleaning products or personal hygiene products	Lower scenario	10%	2%	14%	3%
	Central scenario	15%	5%	23%	8%
	Upper scenario	30%	10%	60%	20%
Bicycles, mopeds, cars, or other vehicles or their spare parts	Lower scenario	-	1%	-	1%
	Central scenario	-	2%	-	3%
	Upper scenario	-	3%	-	6%

Resulting numbers of non-compliant online products

The resulting total numbers of online products purchased and the number of CLP and REACH non-compliant products for 2021 and 2022 and all of the three scenarios are provided in Table 190. A breakdown of these numbers by product type for the year 2021 is provided for the central scenario in Table 191.

Table 190: Total number of online products purchased and number of CLP and REACH non-compliant products purchased (millions of products) under each scenario

Location of seller	Year	Total purchases (million)	Total number of consumers (million)	CLP non-compliant (millions)	REACH Restriction non-compliant (million)
Lower scenario					
Within EU	2020	1,545.9	248.3	11.5	41.7
Outside EU	2020	386.5	62.6	3.9	14.3
Within EU	2021	1,609.2	251.0	11.1	42.5
Outside EU	2021	470.4	69.5	4.4	17.0
Central scenario					
Within EU	2020	1,545.9	248.3	17.2	69.6
Outside EU	2020	386.5	62.6	6.4	26.1
Within EU	2021	1,609.2	251.0	16.6	70.8
Outside EU	2021	470.4	69.5	7.3	31.0
Upper scenario					
Within EU	2020	1,545.9	248.3	34.4	106.9
Outside EU	2020	386.5	62.6	17.2	53.5
Within EU	2021	1,609.2	251.0	33.3	110.0
Outside EU	2021	470.4	69.5	19.5	64.3

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Table 191: Breakdown of the online products purchased in 2021 for the Central Scenario			
	Total purchases (million)	**CLP non-compliant (millions)**	**REACH Restriction non-compliant (million)**
Within EU - 2021			
Clothes (including sport clothing), shoes or accessories	527.2	0.0	15.8
Children toys or childcare items	152.6	0.0	7.6
Furniture, home accessories or gardening products	222.0	0.0	4.4
Computers, tablets, mobile phones or accessories	180.3	0.0	14.4
Consumer electronics or household appliances	138.7	0.0	11.1
Cosmetics, beauty or wellness products	208.1	0.0	10.4
Cleaning products or personal hygiene products	111.0	16.6	5.5
Bicycles, mopeds, cars, or other vehicles or their spare parts	69.4	0.0	1.4
Total (million)	**1,609.2**	**16.6**	**70.8**
Total number of consumers (million)	**251.0**		
Average purchases per consumer per year	6.4		
Outside EU - 2021			
Clothes (including sport clothing), shoes or accessories	154.1		6.9
Children toys or childcare items	44.6	0.0	3.3
Furniture, home accessories or gardening products	64.9	0.0	1.9
Computers, tablets, mobile phones or accessories	52.7	0.0	6.3
Consumer electronics or household appliances	40.6	0.0	4.9
Cosmetics, beauty or wellness products	60.8	0.0	4.6
Cleaning products or personal hygiene products	32.4	7.3	2.4
Bicycles, mopeds, cars, or other vehicles or their spare parts	20.3	0.0	0.6
Total (million)	**470.4**	**7.3**	**31.0**
Total number of consumers (million)	**69.5**		
Average purchases per consumer per year	6.8		

Interpretation and conclusions on the situation in 2021

The discussion in the following text focusses on the estimates for 2021 under the central scenario. Here, the estimates in Table 190 and Table 191 would suggest the following:

- With respect to REACH restriction non-compliant items from sellers within the EU:

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In 2021 there were some 251 million consumers in the EU who purchased goods online from sellers within the EU.
From sellers within the EU, these consumers purchased 1 609.2 million items from categories of goods for which REACH restrictions are relevant for some of the goods. This equates to an average of 6.4 products for each of the 251 million consumers.
70.8 million of the 1 609.2 million items purchased by these consumers from sellers within the EU were not compliant with REACH restrictions.
This equates to an absolute maximum number of 70.8 million consumers purchasing REACH non-compliant items from EU sellers (assuming one non-compliant item per consumer) and an absolute minimum of 11 million consumers purchasing REACH non-compliant items from EU sellers (assuming that all 6.4 items on average purchased by these 11 million consumers are REACH non-compliant products).
The average of these two estimates of consumers (70.8 million and 11 million) would suggest 40.9 million consumers purchase an average of 1.7 REACH non-compliant items per year from sellers within the EU. This is equivalent to the following conclusion:
In 2021 40.9 million consumers purchased one REACH non-compliant item from sellers within the EU and a further 14.9 million consumers purchased two REACH non-compliant products from sellers within the EU – making a total of 70.8 million REACH non-compliant items purchased from sellers within the EU.

- With respect to REACH restriction 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 470.4 million items from categories of goods for which REACH restrictions are relevant for some of the goods.
  31 million of the 470.4 million items purchased by these consumers from sellers outside the EU were not compliant with REACH restrictions.
  Following the same logic as above, in 2021, 17.8 million consumers purchased one REACH non-compliant item from sellers outside the EU and a further 6.6 million consumers purchased two REACH non-compliant products from sellers outside the EU – making a total of 31 million REACH non-compliant items purchased from sellers outside the EU.

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

  - In 2021 there were some 251 million consumers in the EU who 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.
  - 16.6 million of the 111 million items purchased by these consumers from sellers within the EU were not compliant with CLP requirements.
  - Following the same logic as before, 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.
  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 Table 192 for all three scenarios (lower, central and upper).

Table 192: 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

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Annex 16 – Information Gaps for Poison Centres

CONTEXT

Appointed bodies responsible for receiving information relating to emergency health response, colloquially known as "**poison centres**", can provide only sub-optimal emergency health response because they do (possibly) not have all available information on mixtures in case of (i) cross-border distribution and/or (ii) re-branding/re-labelling.

This matter does not originate from the CSS or the Fitness Check. By implementing Annex VIII to CLP regarding harmonised information to poison centres[213], it was observed and discussed that certain relevant information is lacking and/or that there is ambiguity on how to correctly implement Annex VIII.

PROBLEM

What is/are the problems?

Available information to poison centres in case of cross-border distribution and re-branding/re-labelling

Article 45 of the CLP Regulation provides the obligation for downstream users and importers to submit relevant information for emergency health response – but not for distributors or any other type of supplier – in those Member States where they place mixtures on the market. This legal structure, which excludes some actors in the supply chain, could bring information loss for poison centres in the following cases:

Cross-border distribution: A distributor purchases a product in one Member State and places it on the market in another one. In the original Member State information to the national poison centre would have been submitted by the duty holder further up in the supply chain. However, as it is not sufficiently clear from the current CLP text whether distributers have the obligation to notify, no information would be available in the receiving Member State.

Re-branding/re-labelling: The original supplier or a downstream supplier places the mixture on the market in the same Member State but they just re-brand or re-label it (without changing the composition or packaging). In such case, the mixture could only be identified via the UFI and not via the brand name/label whereas the latter would be the most obvious reference for consumers in case of an emergency. Explaining and looking for the UFI on the label in a stressful situation may cost valuable time and is only possible if the packaging is actually at hand.

Poison Centres across the European Union answer over half a million calls for support per year, and approximately half of the cases are related to accidental exposures involving children.[214] Information loss for poison centres means having incomplete emergency health response databases at national level, which results in not being able to or provide incorrect/incomplete responses, leading to patients' overtreatment or sending them to the hospital/first aid.

[213] Commission Delegated Regulations 2020/1676, 2020/1677, OJ L 379, p. 1 and 3.
[214] https://ec.europa.eu/growth/sectors/chemicals/poison-centres_en

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Following a Commission's interpretation proposed in ECHA guidance, distributors and any other types of supplier) are already bound to submit relevant information for medical response in those cases where poison centres would otherwise be pre-empted from carrying out their tasks by virtue of Article 4(10) providing for a general obligation to comply with the CLP Regulation. Based on that interpretation certain distributors may notify already (by following Art. 4(10)), hence reducing the scale of the problem from significant to relatively significant.

Available information to poison centres on substances

Article 45 of the CLP Regulation does not provide for the obligation to submit information on substances to appointed bodies (poison centres). Information to provide emergency health response could be needed for substances too since not having that information leads to the same consequences as outlined above.

Based on the consultations carried out, not submitting information on substances is actually not a problem because poison centres retrieve data on substances from other sources (e.g. data is available through the registered substance database, the classification and labelling inventory, the product label), and cases where substances are the origin of a poisoning incident are significantly less frequent. *E.g.*, the German poison centre indicated that between 2-4% of its 200 daily calls are estimated to be related to substances, whereas data from the German Federal Institute for Risk Assessment (BfR), who are collecting information on around 8 000 poisoning incidents at workplaces each year, found that in 2020, for 23% of cases it was documented that a substance was the causative agent. For this relatively high figure of 23%, additional factors which might alleviate any concerns should be taken into account. In workplace situations typically more information on response is available from the safety data sheet (SDS), hence there is less need of information on substances. Also, the 23% figure refers to all incidents and not only those where a poison centre was needed. Belgium reported that 350 out of 13,000 calls relate to substances and that for those cases poison centres do not have difficulties to identify the substances. During the consultation of the expert group CARACAL, experts of the competent authorities raised the issue that data additionally submitted data on substances would overload their systems, which might already contain substance-related information and make relevant information more difficult to retrieve.

What are the problem drivers?

Hazard communication across the supply chain is insufficient, therefore, many downstream suppliers who do not have all available information on hazardous mixtures are not able to notify the full set of information to poison centres (regulatory failure).

Article 45 and Annex VIII of the CLP Regulation do not specifically cater for the cases of information loss mentioned above, whereas the obligation under Article 4(10) is very generic. ECHA guidance provides clarification to the generic obligation under Article 4(10) to comply with CLP and for distributors to submit in certain cases. However, ECHA guidance is not legally binding and thus distributors might not consider the obligations under Article 4(10), read in combination with ECHA's guidance, binding. Therefore, due to some ambiguity in the legislation, outcomes are sub-optimal. Either mixture distributors might be aware of the applicable provisions but do not consider them stringent/clear enough to comply with, or they might not even be aware of them (results in insufficient supply chain communication). Legal clarity is needed for distributors to comply with the applicable rules and to assure that all distributors obey to the same obligations in order to create a level-playing field in the EU.

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How likely is the problem to persist?

The problem is likely to persist since distributors will continue placing on the market mixtures with a cross-border dimension and/or re-branding/re-labelling them. Data from Eurostat[215] shows that in 2020 intra-EU sales of chemicals accounted for EUR 496 billion in 2020 (up from EUR 207 billion in 2002), which made up 17% of all intra-EU sales. Without EU intervention, the scale of the problem may increase over time, mainly driven by the growing trend in intra-EU sales. This applies in particular to countries with a high number of EU borders as well as to small countries where cross-border distribution happens or where chemicals are re-labelled to comply with the language requirements.

What is to be achieved - objectives

General objectives

The overall objective of improving submissions to poison centres is the protection of human health as well as ensuring a good functioning of the internal market by enabling a level-playing field for the supply of chemical mixtures in the EU.

Specific objectives

The CLP revision should improve legal clarity and compliance of the requirements related to poison centre notifications by distributers and other supplier types.

To effectively and efficiently protect consumers, national poison centres (or appointed bodies) need the best available information on chemicals placed on the market to which users could be exposed and for which adequate and swift emergency health response is needed. This objective is in line with SDG 3 good health and well-being.

Legislation should be drafted in a clear, simple and accurate manner to improve its efficiency allowing duty holders to properly comply with it. This objective is in line with SDG 16 peace, justice and strong institutions.

Poison centres should not be overwhelmed with unnecessary or duplicated information. Hence, the need to only cater for those cases where information is currently not available (no need for double-notifications if importers or downstream users already notified the same mixture under the same brand/label in the same Member State). Also, there is no need to submit information on substances if poison centres already have sufficient access to such information.

WHAT ARE THE AVAILABLE POLICY OPTIONS?

What is the baseline from which options are assessed?

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), 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

[215] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Intra-EU_trade_in_goods_-_main_features#Intra-EU_trade_in_goods_by_main_product_groups

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.

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 the figures presented in the table below (almost 7.7 million notifications).

Table 193: Summary of population of EU Member States and notifications received by PCNs

Member State	Population (2021)	Number of Poison Centre submissions in 2021
Germany	83,155,031	583,493
France	67,439,599	478,053
Italy	59,257,566	604,775
Spain	47,394,223	414,199
Poland	37,840,001	444,448
Romania	19,186,201	244,333
Netherlands	17,475,415	316,837
Belgium	11,566,041	214,877
Czech Republic	10,701,777	268,901
Greece	10,682,547	251,609
Portugal	10,298,252	446,018
Sweden	10,379,295	250,240
Hungary	9,730,772	142,749
Austria	8,932,664	332,514
Bulgaria	6,916,548	221,832
Denmark	5,840,045	245,333
Finland	5,533,793	188,175
Slovakia	5,459,781	222,649
Ireland	5,006,907	218,503
Croatia	4,036,355	240,974
Lithuania	2,795,680	251,670
Slovenia	2,108,977	219,211
Latvia	1,893,223	223,510
Estonia	1,330,068	205,451
Cyprus	896,005	153,681
Luxembourg	634,730	116,029
Malta	516,100	199,217

Source: ECHA (2022) and Eurostat (2021).
See: https://ec.europa.eu/eurostat/databrowser/view/tps00001/default/table?lang=en

Number of distributors and distributed 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.

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To estimate the number of distributors in the EU, data from Eurostat was used on the number of enterprises in the G46.12 (Agents involved in the sale of fuels, ores, metals and industrial chemicals) and G46.75 (Wholesale of chemical products) codes. This gave an estimate of 41,300 distributors.

To calculate the number of products placed on the market by each distributor, data on the number of PCNs received during 2021 (1,444,290) was combined with data on the number of manufacturers (28,168) and distributors (41,337) in the EU-27. Dividing the number of PCNs with the combined number of manufacturers and distributors results in a figure of approximately 20 products per company. This estimate assumes that all distributors are complying with their requirements under Article 45. To provide an estimate where there is zero compliance from distributors, the number of PCNs (1,444,290) was divided by the number of manufacturers (28,168) to give an estimate of approximately 50 products per company. If it is assumed the average portfolio size of distributors is similar to the rest of the chemical industry, this gives an approximate estimate of 825,000 – 2,100,000 products placed on the EU market by distributors each year (41,337 x (20 – 50) = 825,000 – 2,100,000).

The following limitations are recognised with this approach:

- The number of PCNs submitted in 2021 only reflects notifications submitted due to new products being brought to market or changes to existing products. It does not provide an estimate of the total number of products each company currently places on the market. It, therefore, underestimates the number of products per company. However, historical data on PCNs submissions from ECHA is not available.

- ECHA data does not provide the number of notifiers responsible for the notification received, so broad assumptions have had to be made.

Number of distributors and distributed products traded intra-EU-27

To estimate the number of distributors purchasing chemical products from one Member State and selling them in another, the following methodology was applied. For distributors, data for the number of companies involved in imports and/or exports was not available at the NACE Rev. 2 four-digit level – that is, for sectors G46.12 and G46.75. Their number was estimated using available data in the following way:

1. The EU-27 total number of enterprises in each of the two distributing sectors related to chemicals products (46.12 and 46.75) and in their 3-digit parent sector (46.1 and 46.7) was taken from the Survey of Business Statistics (SBS_NA_DT_R2), and the percentages of each of the 4-digit sectors over their respective 3-digit sector was computed.

Table 194: Number of enterprises

NACE	Number of enterprises	Percentage of parent NACE
G46.7	239,260	100%
G46.1	547,112	100%
G46.75	26,455	11%
G46.12	16,559	3%

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2. The number of enterprises involved in intra-EU-27 "imports"[216] and the number of enterprises involved in intra-EU-27 "exports" at the three-digit level was taken from EXT_TEC09. That data covers only 15 EU-27 countries[217], so it was rescaled using the percentages that these countries represent for the overall number of companies in those two sectors (59% in sector 46.1 and 68% in sector 46.7). The largest number of companies between importing and exporting companies was chosen under the assumption that there will be a large and unknown overlap between companies doing imports and exports. However, the final number of companies will likely be underestimated, if there are companies that only do imports and companies that only do exports.

Table 195: Number of enterprises importing

NACE	**Number of enterprises importing intra-EU**	
	EU-15	***EU-27***
G46.7	57,150	84,083
G46.1	47,017	80,206

3. The percentage of enterprises involved in intra-EU-27 imports and in exports was estimated by applying the percentage of total number of enterprises in the 4-digit level sectors over the 3-digit parent sectors to the estimated number of companies involved in imports and in exports at the 3-digit level sectors (see step 1).

Table 196: Number of enterprises importing intra-EU

NACE	**Number of enterprises importing intra-EU-27 in parent NACE**	**Percentage of parent NACE**	**Number of enterprises importing intra-EU-27**
G46.75	84,083 (G46.7)	11%	9,297
G46.12	80,206 (G46.1)	3%	2,428
Total	**164,289 (G46.7 + G46.1)**	**-**	**11,725**

In total 11,725 distributors were estimates to trade chemicals products intra-EU-27, which is 27% of the total number of distributors. 2019 data was used for this estimate, as 2020 data was incomplete. Applying this percentage to the number of distributors in 2020 (see Table 196) gives a figure of 11,160.

To calculate the number of intra-EU-27 traded products placed on the market, the estimate of 20 – 50 products per company calculated earlier was applied to the estimate of 11,160 distributors that import products intra-EU-27. Multiplying this data together gives an approximate total of 220,000 – 560,000 products that are sold intra-EU.

Number of re-branders/re-labellers and re-labelled/re-branded products

[216] Imports should be read as cross-border sales. Reference to import/export in this context is only made to clarify the movement of goods entering and exiting another Member State.
[217] The 15 countries covered are Belgium, Czechia, Germany (until 1990 former territory of the FRG), Spain, France, Latvia, Lithuania, Luxembourg, Netherlands, Austria, Poland, Portugal, Romania, Slovenia and Slovakia.

The information gap surrounding re-labellers and re-branders is due to mixtures being purchased from suppliers and placed on the market in the same Member State as that in which it was purchased, but with a different label or branding. Re-branders and re-labellers are a type of distributor, so the starting point for estimating the number of re-branders and re-labellers was estimated the number of distributors operating in a single Member State.

Data from Cefic (2021) shows that 15% of the production value of chemical sales were home sales (occurred in one Member State only). Applying this percentage to the number of distributors in the EU-27 (41,337) gives a figure of 6,200 home sale distributors. Multiple this by the average number of product per company (20 – 50) gives a total of 130,000 – 310,000, however only a proportion of these products will have been re-branded or re-labelled. The exact proportion is unknown, but an estimate of 25% is considered realistic, which would equate to 32,500 – 77,500.

Cost of non-Europe

As outlined below in heading 4.1, 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[218] 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).

Conclusion

To summarise, estimates 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.

Description of the policy measures

To solve the problem of having sub-optimal emergency health response for poison centres due to insufficient information provided, the following measures were identified:

#21: Include in Article 45 an obligation for distributers and other types of suppliers (including re-branders/re-labellers) to submit a notification in cases where no notification was submitted yet by another actor in the supply chain to the relevant poison centre in the Member State where the product will be placed on the market.

This regulatory measure is particular relevant in cases of:

- Cross-border distribution: A distributor purchases a product in one Member State and places it on the market in another one. No information would be available in the latter Member State.

- Re-branding/re-labelling: The original supplier or a downstream supplier place the mixture on the market in the same Member State but they re-brand or re-label

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

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it[219]. Then the mixture could only be identified via the UFI and not via the brand name/label.

Including this obligation means that distributers and other suppliers need to make sure that notifications exist already for the Member States in which they place their mixtures on the market. This requires good supply chain communication with the upstream supplier(s) who have detailed information about mixture compositions. Notification by the upstream supplier (manufacturer, downstream user, importer) for all Member States where their distributors place on the market is recommended, since then distributors may simply refer to that notification. Instead, if no supply chain communication takes place and if the distributor does not have access to the full composition information, it may opt to, or, if the notification does not exist yet, has to notify the information contained in the safety data sheet, which is less detailed. That way poison centres have less granular information available.

This measure would cater for preventing both cases of information loss without obliging each distributor to notify. A good supply chain communication is needed but can only be recommended, otherwise poison centres end-up with having the least granular information available (SDS information).

#19: Include in Article 45 a default obligation for distributers and other types of suppliers to submit a notification, regardless whether poison centres already have the relevant information.

Equally as for the previous measure, without a good supply chain communication poison centres would end-up with having the least granular information available (SDS information) as well as all distributors having the burden to notify.

#20: Introduce a new definition of re-brander/re-labeller in CLP under Article 2 and include these actors in Article 45(3)

Currently CLP actor definitions are consistent with REACH and both legislations do not contain the definition of re-brander. REACH guidance provides that a re-brander is an "actor who affixes his own brand to a product that somebody else has manufactured" and specifies that those actors fall under the definition of distributors[220].

This measure would misalign the actor definitions under REACH and CLP and hence be incompatible with the overall principles that REACH and CLP should be as much as possible aligned due to their closed interlinks[221]. It would solve the problem of re-branding/re-labelling but not of cross-border distribution (which concerns all distributors). So it would bring about inconsistencies with REACH and provide only one solution to two problems.

[219] If they changed the composition or packaging in addition to re-branding/re-labelling, they would be downstream users and needed to notify in any event.

[220] See ECHA guidance for downstream users, table 8: Identification of roles – roles other than downstream user or manufacturer/importer.

[221] See Recital (12) of CLP stating that "The terms and definitions used in this Regulation should be consistent with those set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (13), with those set out in the rules governing transport and with the definitions specified at UN level in the GHS, in order to ensure maximum consistency in the application of chemicals legislation within the Community in the context of global trade".

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

Currently Article 45 sets forth that each Member State is responsible for the data notified to their national appointed bodies only and the emergency response in their territory. With this new measure, no distinction would be made as to which Member State notifications should be sent and which Member State is ultimately responsible to keep the data confidential. Member States would have to renounce on their national submission systems and all notifications would run via ECHA to the Member States (who could not collect national submission fees anymore). ECHA would become the data owner and maintain responsibility for its confidentiality.

This measure was discarded given that both Member States and industry stakeholders did not support it for the following reasons:

Disproportionate impact on existing databases and national notification systems, in particular strong concerns that this would be very disruptive for a relatively recently introduced system that works overall for relatively little added value

Strong concerns that language needs could be an issue;

The measure would not solve the issue of re-branding/re-labelling.

SCREENING OF POLICY MEASURES – WHAT ARE THE IMPACTS OF THE POLICY MEASURES?

In order to quantitatively assess the impacts of the different policy measures, estimations were carried out which might have their limitations or bring about some levels of uncertainty.

The kind of economic, social and environmental impacts of measures #21, #19, #20 are the same, albeit with different magnitudes (see comparison).

Economic impacts

All policy measures would have moderately negative impacts on the administrative burden on businesses and public authorities, and potentially high negative impacts on the operating costs and the conduct of business. All policy measures are likely to have a positive market impact in levelling the playing field across the EU.

Administrative burden on business

Administrative burden on business depends on how well supply chain communication works. Distributors who get the UFI from their upstream supplier bear much less costs than distributors who start a notification from scratch. Costs per notification can amount to 70 EUR for those suppliers carrying over the UFI code or communicating well with their upstream supplier (lower bandwidth)[222]. Starting notifications from scratch is much more costly. The Commission's *Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC)*

[222] Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation), DocsRoom - European Commission (europa.eu), p. 61. The cost of an SDS submission under the national system amounts to 70EUR , which can be taken as a reference value for a notification knowing the UFI.

No 1272/2008 (CLP Regulation)[223], estimated that an average notification cost of a harmonised notifications should be €220 (upper bandwidth).

One-off and annualised costs

Estimates show that approximately 11,725 distributors supply chemicals intra-EU-27 of the total number of chemicals distributors (approx. 41,337). Based on estimations, distributors have a product portfolio between 20-50 mixtures[224].

By not calculating twice cross-border distributors and re-branders/re-labellers, estimates of the latter regarded only re-labellers/re-branders operating in their Member State. Data from Cefic (2021) shows that 15% of the production value of chemical sales were home sales (occurred in one Member State only). Applying this percentage to the number of distributors in the EU-27 (41,337) gives a figure of 6,200 home sale distributors. Multiple this by the average number of product per company (20 – 50) gives a total of 130,000 – 310,000, however only a proportion of these products will have been re-branded or re-labelled. The exact proportion is unknown, but an estimate of 25% is considered realistic, which would equate to 32,500 – 77,500 re-branders/re-labellers who have to notify.

Based on a reality assumption of the current and evolving baseline, 50% of distributors will already comply with Article 4(10) of CLP, hence, they notify in cases where poison centres' access to information would jeopardise their activities (relevant for all measures #21, #20, #21). Therefore, the following table contains two columns (figures with no and a 50% compliance rate).

[223] Ibid.

[224] To calculate the number of products placed on the market by each distributor, data on the number of PCNs received during 2021 (1,444,290) was combined with data on the number of manufacturers (28,168) and distributors (41,337) in the EU-27. Dividing the number of PCNs with the combined number of manufacturers and distributors results in a figure of approximately 20 products per company. This estimate assumes that all distributors are complying with their requirements under Article 45. To provide an estimate where there is zero compliance from distributors, the number of PCNs (1,444,290) was divided by the number of manufacturers (28,168) to give an estimate of approximately 50 products per company.

Table 197: One-off and annualised cost					
	Submissions	**Cost (in million EUR) – compliance rate of 50%***	**Annualised**	**Cost (in million EUR) – no compliance rate****	**Annualised**
#21	252,500 – 637,500 (no compliance rate)	8.9 – 22.3 (lower bandwidth) 27.8 – 70.2 (upper bandwidth)	0.6 – 1.5 (lower bandwidth) 1.9 – 4.7 (upper bandwidth)	17.7 – 44.6 (lower bandwidth) 55.5 – 140.3 (upper bandwidth)	1.2 – 3.0 (lower bandwidth) 3.8 – 9.4 (upper bandwidth)
#19	826,740 – 2,066,850 (no compliance rate)	28.9 – 72.3 (lower bandwidth) 90.9 – 227.4 (upper bandwidth)	1.9 – 4.9 (lower bandwidth) 6.1 – 15.3 (upper bandwidth)	57.9 – 144.7 (lower bandwidth) 181.7 – 454.7 (upper bandwidth)	3.8 – 9.8 (lower bandwidth) 12.2 – 30.6 (upper bandwidth)
#20	32,500 – 77,500 (no compliance rate)	1.1 – 2.7 – lower bandwidth 3.6 – 8.5 – upper bandwidth	0.07 – 0.18 (lower bandwidth) 0.2 – 0.6 (upper bandwidth	2.3 – 5.4 – (lower bandwidth) 7.2 – 17.1 – (upper bandwidth)	0.14 – 0.36 (lower bandwidth) 0.5 – 1.1 (upper bandwidth)
**Cost calculated for lower bandwidth: 70 EUR per submission; **Costs for upper bandwidth: 220 EUR per submission*					

Recurrent costs

The 2018 Evaluation of the Detergents Regulation estimates that half of all consumer detergent products are reformulated every two years, while the other half are reformulated every five years. If we take this as representative of all products, this equates to 35% of products being reformulated each year. The Evaluation also estimates that the product label is updated 60% to 70% of the time when consumer detergent products are reformulated. This implies that in the remaining 30 - 40% of cases, changes are not significant enough to trigger relabelling or submitting updated notifications to poison centres. Taking the midpoint (65%) and applying this to the 35% of products reformulated each year, equates to approximately 23% of products which would require new PCNs each year. Therefore, this table presents recurrent costs as 23% of the one-off costs.

Table 198: Recurrent costs					
	Submissions	**Cost (in million EUR) – compliance rate of 50%**	**Annualised[225]**	**Cost (in million EUR) – no compliance rate**	**Annualised[226]**
#21	58,075 – 146,625 (no compliance rate)	2.0 – 5.1 (lower bandwidth) 6.4 – 16.1 (upper bandwidth)	2.7 – 6.9 (lower bandwidth) 8.6 – 21.6 (upper bandwidth	4.1 – 10.3 (lower bandwidth) 12.8 – 32.3 (upper bandwidth)	5.4 – 13.8 (lower bandwidth) 17.2 – 43.2 (upper bandwidth)
#19	190,150 – 475,375 (no compliance rate)	6.7 – 16.6 (lower bandwidth) 20.9 – 52.3 (upper bandwidth)	9.0 – 22.3 (lower bandwidth) 28.0 – 70.3 (upper bandwidth)	13.3 – 33.3 (lower bandwidth) 41.8 – 104.6 (upper bandwidth)	18.0 – 44.6 (lower bandwidth) 56.0 – 140.6 (upper bandwidth)
#20	7,475 – 17,825 (no compliance rate)	0.3 – 0.7 – lower bandwidth 0.8 – 2.2 – upper bandwidth	0.4 – 0.9 – lower bandwidth 1.1 – 3.0 – upper bandwidth	0.5 – 1.2 – lower bandwidth 1.6 – 3.9 – upper bandwidth	0.8 – 2.0 – lower bandwidth 2.2 – 6.0 – upper bandwidth

Operational costs to Member States

These relate to the increase in annual running costs of poison centres (IT systems etc.) and more staff needs to review the notifications. This is alleviated by ECHA providing a centralised dispatch mechanism and searchable database to which Member States is gained access for free (they would just have to adapt their national IT systems to receive the data).

Concerning the **burden for SMEs**, the overall cost can be expected to be less than that of large enterprises given that SMEs do not distribute cross-border. However, they might re-brand/re-label and those costs may be greater in relative terms to their income from the sale of these products.

Social impacts

Regarding the social impacts, no quantitative estimates were possible to make due to lack of data.

[225] Annualised costs are the same as the recurring costs because we apply a 4% discount rate, but we assume a 4% inflation figure.
[226] Annualised costs are the same as the recurring costs because we apply a 4% discount rate, but we assume a 4% inflation figure.

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From a qualitative point of view, clarifying the scope of obligations under Art. 45 will lead to better and more timely medical advice being given, thus reducing the number of severity of cases of ill health, and instances where overtreatment is given.

It has been estimated through contact with the EU Poison Centres that on average these services receive and treat 600,000 calls per year (almost 1,700 calls per day, mostly related to child exposure) and the number of fatalities related to chemical exposure is more than 400 per year[227]. Further breakdown of these calls to identify trends within specific products groups as well as the volume and nature of more serious incidents is also covered as part of the work of these centres. For example, an indicative breakdown of call volume by severity includes[228]:

Germany - Poisoning cases related to chemicals exposure from one of the German Poison Centres were 11,470 in 2013 and they had 120 severe symptoms and 6 fatalities (this centre represents ~ 16% of Germany). Scaling this up assuming full proportionality and representativeness results in around 70,000 calls, 750 cases with severe symptoms and around 40 fatalities for the whole of Germany.

Italy - The Milan Poison Centre reported 16,000 cases in 2009 including 6 fatalities. By extrapolation, this suggests there could be approximately 21,000 cases for the whole of Italy and 8 fatalities (the Milan Poison Centre covers around 75% of the country).

France – The Nancy Poison Centre reported that for France as a whole the French Poison Centres attended to 85,000 call per annum. There were also around 300 fatalities per annum as a result of exposure to hazardous chemicals.

The Netherlands received 43,334 calls in 2013, of which 2,882 (or 12%) concerned chemical products.

Spain - In 2014 the Spanish PC (INTCF) received about 71,000 calls for actual exposure (other consultations are excluded; e.g. preventive measures). Accidental exposure to chemicals: accounted for about 29,000 calls.

Quantitatively, the Fitness Check provides average economic costs for society of €16,618 (€967 for hospitalisation + €15,651 for severe eye impairment) for a severe incident and €70.50 – €306 (example for a day of respiratory symptoms) for a minor incident.

Economic analysis undertaken by the National Chemical Emergency Centre (NCEC) in the UK provide some justification for the estimate provided in the Fitness Check. The analysis found that each emergency call brought health benefits of approximately €8,100 based on avoidance of fatal and non-fatal injury, incidents of ill-health, and savings in hospital visits, ambulance call-outs, and doctor consultations. As well as the benefits from avoiding cases of injury and ill-health, there is the reduction in the time spent by emergency services, delays to road users from emergency services, and avoided productivity losses to businesses. 2019-2020 data from the NCEC estimates a benefit of around €1,075 saving per emergency call for time spent by emergency services, a €3,175 saving in time lost by road users per call, and a €530 saving in health costs to businesses per call. These additional benefits equalled €4,780, meaning the total benefits per

[227] Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation), DocsRoom - European Commission (europa.eu)
[228] Ibid.

emergency call are €12,880. All estimates were converted to Euros and adjusted to 2021 prices[229].

Environmental impacts

No negative or positive environmental impacts are expected from the policy measures since Article 45 does not target environmental hazards.

A summary of the costs and benefits of each of the three policy options is provided below:

Summary of cost and benefits of policy options #19, #20, and #21			
	Policy measure #19	**Policy measure #20**	**Policy measure #21**
Costs - businesses			
Total one-off costs over a 20-year period	€28,900,000 – €227,400,000 (mid-estimate: €128,150,000)	€1,100,000 – €8,500,000 (mid-estimate: €4,800,000)	€8,900,000 – €70,200,000 (mid-estimate: €39,550,000)
Recurring costs every 1 year	€6,700,000 – €52,300,000 (mid-estimate: €29,500,000)	€300,000 – €2,200,000 (mid-estimate: €1,250,000)	€2,000,000 – €16,100,000 (mid-estimate: €9,050,000)
Total recurring costs over a 20-year period	€127,300,000 – €993,700,000 (mid-estimate: €560,500,000)	€5,700,000 – €41,800,000 (mid-estimate: €23,750,000)	€38,000,000 – €305,900,000 (mid-estimate: €171,950,000)
PV of one-off costs (20 years; 3%)	€38,850,679 – €305,697,038 (mid-estimate: €172,273,859)	€1,478,746 – €11,426,670 (mid-estimate: €6,452,708)	€11,964,396 – €94,370,853 (mid-estimate: €53,167,625)
PV of one-off costs (20 years; 3%) (annualised)	€1,942,534 – €15,284,852 (mid-estimate: €8,613,693)	€73,937 – €571,334 (mid-estimate: €322,635)	€598,220 – €4,718,543 (mid-estimate: €2,658,381)
PV of recurring costs (20 years; 3%)	€171,131,192 – €1,335,844,973 (mid-estimate: €753,488,082)	€7,662,591 – €56,192,332 (mid-estimate: €31,927,461)	€51,083,938 – €411,225,699 (mid-estimate: €231,154,818)
Total PV – costs - businesses	€209,981,871 – €1,641,542,011 (mid-estimate: €925,761-941)	€9,141,336 – €67,619,002 (mid-estimate: €38,380,169)	€63,048,334 – €505,596,553 (mid-estimate: €284,322,443)
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%)			

[229] 24/7 chemical helpline - NCEC (the-ncec.com)

Total PV – costs – public authorities			
Total PV cost of policy option #19	**€209,981,871 – €1,641,542,011 (mid-estimate: €925,761-941)**	**€9,141,336 – €67,619,002 (mid-estimate: €38,380,169)**	**€63,048,334 – €505,596,553 (mid-estimate: €284,322,443)**
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)	-€209,981,871 – -€1,641,542,011 (mid-estimate: -€925,761-941)	-€9,141,336 – -€67,619,002 (mid-estimate: -38,380,169)	-€63,048,334 – -€505,596,553 (mid-estimate: -€284,322,443)

A summary of the present value (3% discount) costs and benefits of each policy measure are presented below.

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #19 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs			
Direct administrative costs	€209,981,871 – €1,641,542,011 (mid-estimate: €925,761-941)		
Direct regulatory fees and charges			
Indirect costs			
Benefits			
Description	**Businesses**	**Administrations**	**Society**
Direct benefits			

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #20 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs			
Direct administrative costs	€9,141,336 – €67,619,002 (mid-estimate: €38,380,169)		
Direct regulatory fees and charges			
Indirect costs			
Benefits			

Description	Businesses		Administrations		Society	
Direct benefits						
Indirect benefits						

Summary of costs and benefits (PV; 20 years; 3%) of policy measure #21 by type			
Costs			
	Businesses	**Administrations**	**Society**
Direct adjustment costs			
Direct administrative costs	€63,048,334 – €505,596,553 (mid-estimate: €284,322,443)		
Direct regulatory fees and charges			
Indirect costs			
Benefits			
Description	**Businesses**	**Administrations**	**Society**
Direct benefits			
Indirect benefits			

Summary of impacts

Table 199: Summary of impacts

	Economic impact						Env	Social	PO
	Business			Administration					
	One-off	Recurrent	Total annualised	One-off	Recurrent	Total annualised			
#21 Provide obligation for distributors to notify in case of information loss (cross-border distribution or re-branding/re-labelling).	Weakly negative	Weakly negative	Weakly negative	Weakly negative	Weakly negative	Weakly negative	No / limited impact	Strongly positive	Y
#19 Include default obligation to submit for suppliers (all distributors) in Article 45	Strongly negative	Weakly negative	Weakly negative	Strongly negative	Strongly negative	Strongly negative	No / limited impact	Strongly positive	N
#20 Introduce new definition of re-brander/re-labeller under Art. 2 and include them in the scope of Article 45	Weakly negative	Weakly negative	Weakly negative	Weakly negative	Weakly negative	Weakly negative	No / limited impact	Weakly positive (no solution for cross-border distributions)	N

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PREFERRED OPTION

Preferred measure

#21 is the preferred measure. #21: This measure would cater for preventing both cases of information loss without obliging each distributor to notify by default. First the distributor would have to check if a notification is required and only then it would have to notify. To carry out such checks, a good supply chain communication with the upstream supplier(s) is paramount for both (i) alleviating the downstream supplier's burden of notification and (ii) providing poison centres the utmost detailed information (as a last resort, they may end-up with the SDS information). #19 has more economic impacts on business and administration than measure #20 and results in the same strongly positive social impact. Measure #20 would have a weakly negative impact on businesses and administration and be better than #21, but worse from a social impact perspective since it does not cater a solution for cross-border distribution. More, it would bring incoherence to the CLP/REACH framework.

REFIT (simplification and improved efficiency)

In order to make the provision of information requirements for poison centres optimal and not merely sub-optimal, no further simplification is possible given that , the entire poison centres format and notification system was already simplified and made workable by adopting the latest version of Annex VIII in 2020[230] via delegated act. However, SM(a) is the best available measure without disrupting the system. The mainly regulatory failure at hand could not be addressed at the time via delegated act. Yet, the overall achievements in terms of simplification and efficiency obtained with the delegated act should be considered when overall comparing the additional economic costs with the health benefits. I.e., the assessment should be cost savings due to harmonisation minus additional costs for distributors compared to overall health benefits. Before introducing harmonised requirements to notify information on emergency health response, the Commission review revealed that multiple submissions needed to be provided, diversity lead to inconsistencies in the information available for poison centres, and a cost and benefit study of the Commission confirmed that the harmonisation would overall lead to significant cost savings (overall, harmonisation could lead to savings of perhaps 900 million EUR per year for companies and the introduction of the UFI could lead to total costs of around 340 million EUR per year with total net savings of 550 million EUR per year, cost of "non-Europe"). Although the introduction of the new measure for distributors and other types of suppliers will lead to additional costs, the impact assessment demonstrated that those will not outweigh the overall savings and benefits of the system and make it even more coherent and complete.

[230] Commission Regulation 1676/2020 and 1677/2020, OJ L379/1 and /3.

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