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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004

{COM(2023) 217 final} - {SEC(2023) 170 final} - {SWD(2023) 113 final} - {SWD(2023) 115 final}

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Annex 1 ANNEX 1 PROCEDURAL INFORMATION

1.1 1.1 LEAD DG, DECIDE PLANNING/CWP REFERENCES

The 'Revision of the Detergents Regulation' is part of the 2022 Commission Work Programme as one of the REFIT initiatives the Commission is taking under the headline ambition of the "European Green Deal".

The lead DG for this initiative is the DG for Single market, Industry, Entrepreneurship and SMEs (DG GROW). The Directorate in charge is Directorate F – 'Ecosystems I: Chemicals, food, retail'.

The initiative is encoded in Decide Planning with the reference PLAN/2021/10270.

1.2 1.2 ORGANISATION AND TIMING

The inception impact assessment consultation period ran from 21 September to 19 October 2021[1].

The public consultation period ran from 4 March to 25 May 2022[2], and a parallel public consultation on the topic of digital labelling ran from 24 November 2021 – 17 February 2022.

An inter-service steering group was convened and chaired by DG GROW F2. The last meeting of the ISSG on the final draft impact assessment report was held on 13 July 2022. The following Directorates-General participated: SG, LS, JRC, SANTE, JUST and ENV.

1.3 1.3 CONSULTATION OF THE RSB

The Regulatory Scrutiny Board (RSB) was consulted in an upstream meeting on 27 January 2022. This impact assessment was submitted to the RSB on 20 July 2022.

The RSB issued its opinion through written procedure on 16 September 2022 following which this Impact Assessment was revised as follows:

RSB Recommendations	**Revisions introduced**
What to improve	**How the RSB recommendations were taken into account**
The report should clarify the scope of the initiative for refills and microbial detergents. The analysis should better elaborate how serious the problems related to refill sales and microbial products are, and whether facilitation of refill sales is a primary or secondary objective. The	Clarification of the scope for refill sales and microbial cleaning products and on the seriousness of these problems were introduced in section 2.3. of the report.

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13116-Detergents-streamlining-and-updating-the-EU-rules_en

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13116-Detergents-streamlining-and-updating-the-EU-rules/public-consultation_en

report should clarify upfront that the overarching aims of the intervention are safety for citizens and the environment, as well as the level playing field for EU businesses	A paragraph has been added in section 4, clarifying that the overarching aims of the intervention are safety for citizens and the environment, as well as the level playing field for EU businesses.
The report should better explain what success would look like. The analysis should include necessary benchmarks to measure the accomplishment of the objectives. The report should reflect these in the monitoring and evaluation arrangements, the operational objectives and the monitoring indicators.	Section 9 has been revised to better explain what success would look like, in particular for refill sales and microbial cleaning products. A table has been added in Annex 11 of the report 'Monitoring indicators', to include operational objectives, monitoring indicators and related benchmarks to measure the accomplishment of the objectives.
The report should better explain the impacts of each option on SMEs. Given that most of the producers of microbial detergents are SMEs, the report should analyse the impacts on different categories of them, especially microenterprises. The report should better explain why and how the SMEs would 'strongly benefit' from digital labelling.	Where additional data was available, the impacts of the options on SMEs have been better explained in sections 8 and 6 as well as in Annex 10 (SME test). Section 6.2.1. has been revised to explain why and how SMEs would 'strongly benefit' from digital labelling.
The report needs better reasoning behind the 'acceptability' of EUR 200,000 costs for SMEs to fulfil the risk management requirements for microbial products. It should further detail what this cost includes and why it may vary from one company to another. It should better present the evidence to support this assumption and clarify the uncertainty of the calculations	Section 6.2.1. has been revised to provide the underlying evidence of acceptability of the costs from the introduction of risk management requirements for microbial cleaning products and to clarify their varying nature. Annex 4 (section 4.1.2.2.) has been revised to reflect the uncertainty of the above calculations.

1.4 1.4 EVIDENCE, SOURCES AND QUALITY

The evaluation identified the key areas for the revision. It was supported by a study carried out by an external contractor[3].

Two studies were contracted to confirm and update the findings of the evaluation as well as to gather more information on them.

[3] https://ec.europa.eu/docsroom/documents/32561

1) **Detergents revision study**

This study[4] had an overarching scope extending to all issues identified in the evaluation, apart from aspects related to digital labelling and the streamlining of labelling requirements which were examined under the second study (see below).

The Commission's contractor carried out thirty (30) interviews, analysed the data from the public and the targeted consultations, complementing them through desk research. Evidence was also gathered in the Detergents Working Group, and through a stakeholder workshop (see Annex 2 'synopsis report' for details on the consultation activities).

2) **Digital labelling study**

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

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

The parts of this study that were relevant for detergents have been incorporated in this impact assessment.

In addition to the evidence gathered in the above mentioned Detergents revision study, the study on simplification and digitalisation of labelling requirements included additional interviews on the aspects that it covered, two online surveys, a behavioural experiment and a stakeholder workshop (see Annex 8 on digital labelling).

Annex 8 provides detailed descriptions of the methodology used for the collection and analysis of the evidence. Moreover, detailed information regarding the evidence compiled by the external contractor is given in the respective Annexes that address the respective intervention areas.

This impact assessment provides qualitative and quantitative information regarding the positive and negative impacts generated by each Policy Option, reporting the main information on the sectors and economic operators mostly affected by the proposed changed. This qualitative analysis is based on the evidence gathered through interviews and desk research.

Sources have been chosen as reliable as possible. Whenever possible, economic, social and environmental impacts were assessed quantitatively. Whenever quantitative information has been found, EU sources were preferred. When not available, other sources were also considered. Similar data were cross-checked whenever possible. It is acknowledged that some data are estimates; in order to

[4] Draft final report of the Impact Assessment study on the making available and placing on the market of detergents, Europe Economics, The Huggard Group, Milieu (2022).
[5] https://ted.europa.eu/udl?uri=TED:NOTICE:363150-2019:PDF:EN:HTML
[6] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Chemicals-simplification-and-digitalisation-of-labelling-requirements_en

compensate for possible inaccuracies, throughout this document benefits have been estimated in a conservative manner.

Annex 2 ANNEX 2 STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

2.1 2.1 BACKGROUND AND LITERATURE

We used a wide range of existing studies as a source of the evidence to the different pieces of analysis (these are indicated in footnotes throughout the report).

Of particular relevance have been the following:

- 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 (the "Evaluation").
- Support to the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation). RPA and Mayer-Brown (2018). ("Support study to the Evaluation").
- Minutes of the 2019 meeting of the detergent working group experts.

2.2 2.2 SCOPING INTERVIEWS

This impact assessment has involved a range of stakeholder interviews. The main objectives of our contact were to engage with relevant stakeholder groups in order to:

- Secure support for future consultation (help in distributing surveys).
- Identify additional literature or data sources to add to our desk research.
- Inform our initial analysis of the problem definition and policy options.
- Identify key stakeholders for the subsequent targeted consultation phase.

The contractor contacted the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E), the European Bureau of Consumers Unions (BEUC), the International Hydrographic Organization (IHO), the European Environmental Bureau (EEB) and the European Committee of Organic Surfactants and their Intermediates (CESIO), and could secure interviews with A.I.S.E., CESIO and IHO. BEUC declined due to limited resources and other priorities. The contractor did not receive a response from EEB.

A.I.S.E., CESIO and IHO showed interest in the project and responded positively to be contacted in the future. A.I.S.E. confirmed the issues under the scope of the study and provided an additional issue to be investigated. A.I.S.E. have contributed in further interviews in order to provide clarity on some of the issues and data substantiating these. IHO provided a reference of a study undertaken by UBA[7] and have provided their view on the use of phosphate and other phosphorus compounds in industrial and institutional detergents. In the interview, the importance of phosphates in reducing water hardness of water so that detergents can work more effectively, and also as anti-corrosives, was stressed.

[7] https://www.umweltbundesamt.de/publikationen/relevanz-der-gewerblichen-textil-geschirrreinigung

2.3 2.3 RESPONSES TO THE CONSULTATION (INCEPTION IMPACT ASSESSMENT)

The Commission published a preliminary Inception Impact Assessment to inform citizens and stakeholders about the Commission's plans to revise Regulation (EC) 648/2004 on Detergents. This followed an open consultation for stakeholders to provide feedback on the intended initiative and to participate effectively in future consultation activities.[8]

During the consultation period (21 September 2021 - 19 October 2021) citizens and stakeholders were invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

At the time of closure, there were 15 responses received**:** 10 from the industry, 4 national authorities and 1 anonymous. The different issues identified in the responses have been reviewed and used to provide evidence in different parts of the study.

2.4 2.4 CONSULTATION AND INTERVIEWS

The contractor consulted 29 organisations. Some of these were contacted more than once, reaching a total of 41 person/contacts.

- 7 national authorities (5 of which provided a written response);
- 5 industry associations (2 of which, national industry associations);
- 12 EU firms;
- 4 consumer associations;
- 1 environmental association;
- 1 academic expert.

Stakeholders have shown limited willingness to participate in our consultation. This has been despite multiple different attempts to contact stakeholders. Some 21 authorities did not respond to a request sent by EU officials. A further 27 different other organisations did not return our emails after being contacted.

2.5 2.5 EXPERT GROUP MEETING ON DETERGENTS

On 15 December 2021, the contractor presented the ongoing research to the meeting of the Detergents Working Group.[9] The presentation covered the list of identified problems and some of the preliminary findings. Stakeholders at the meeting appeared to have no objections to the approach and methodology being used, and to broadly accept our preliminary conclusions. Many of the stakeholders agreed to

[8] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13116-Detergents-streamlining-and-updating-the-EU-rules_en

[9] The recordings and presentation slides of the workshop are now available on https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/4ac11664-22af-4818-96bd-42114b7cab31?p=1&n=10&sort=modified_DESC

submit any further views by email. The audience seemed very receptive to be contacted in the future as part of our consultation.

2.6 2.6 RESPONSES TO THE CONSULTATION (INCEPTION IMPACT ASSESSMENT)

The Commission published a preliminary Inception Impact Assessment to inform citizens and stakeholders about the revision of the Detergents Regulation. All interested parties were invited to provide feedback on the intended initiative and to participate effectively in future consultation activities[10].

The consultation period ran between 21 September 2021 - 19 October 2021 and 15 responses were received during this time**:** 10 from the industry, 4 national authorities and 1 anonymous. The different issues identified in the responses have been reviewed and used to provide evidence in different parts of the study.

Among the 15 replies provided to this consultation, only a couple of key themes emerge, indicating a high level of agreement on these issues among the respondents. The main concern of participating stakeholders is the lack of coherence with other pieces of legislation, notably the CLP Regulation[11], the REACH Regulation[12], and the BPR Regulation[13]. It is mentioned by all four national authorities and a majority of industry respondents that there are overlaps and inconsistencies with these regulations. The Danish authority added the lack of harmonisation with the Cosmetics Products Regulation[14]. Some industry stakeholders further noted that there are overlaps and duplications specific to labelling requirements with the CLP and BPR Regulations.

Finally, two industry respondents remark that labelling requires both simplification and digitalisation, which could go hand in hand by using digital solutions for labelling.

2.6.1 2.6.1 Public Consultation

The Public Consultation (PC) was launched on 02 March 2022, and remained open until 25 May 2022, for a total of 12 weeks. Overall, **126 replies were recorded to the PC, coming from 21 EU Member States and 5 non-EU countries**.

The questionnaire for the PC included a total of 29 questions, which entailed an introductory section with general questions about the respondent's profile. The remaining questions were thematic questions on the topic at hand. The number of respondents varies across the different questions, as not all of the questions were mandatory and the fact that some questions allowed multiple choice answers.

[10] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13116-Detergents-streamlining-and-updating-the-EU-rules_en

[11] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

[12] 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.

[13] 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 Text with EEA relevance.

[14] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

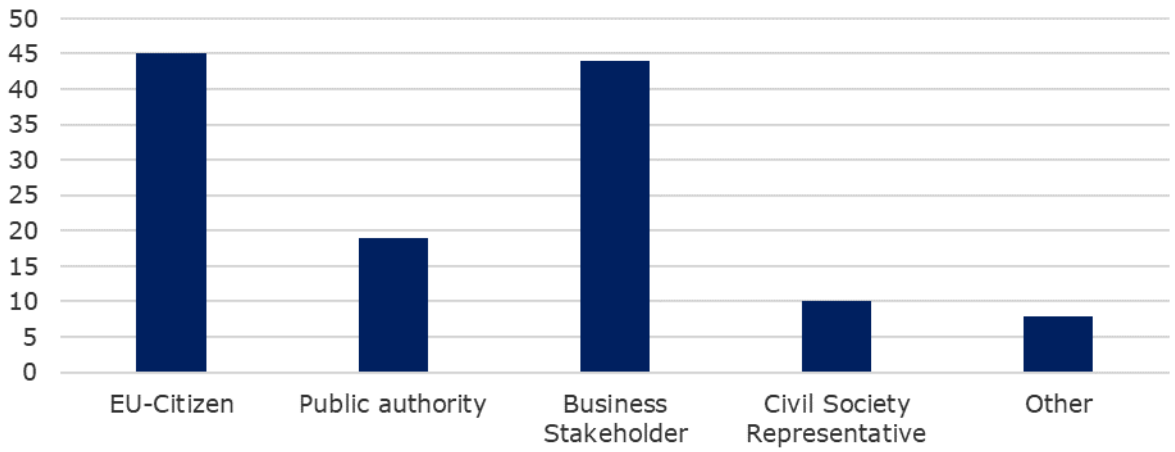
Furthermore, participants had the opportunity to upload additional contributions to the PC, which was done by 9 stakeholders (see 1.8. below).

2.6.1.1 2.6.1.1 General Section

All of the 126 responses to the PC were valid. **A majority – 81 – of replies came from respondents answering on behalf of their business, authority, or organisation**, while 45 participants replied in their role as EU Citizens. To be more precise, the breakdown of respondents was as follows: 45 EU Citizens; 22 Companies / Business Organisations; 22 Business Associations; 19 Public Authorities; 5 NGOs; 3 Consumer Organisations; 2 Environmental Organisations; 8 'Other'.

To ease analysis, the stakeholders were grouped in 5 categories, where appropriate and relevant for the analysis, namely: EU-Citizen (EU-C);[15] Public Authority (PA); Business Stakeholder (BS)[16]; Civil Society Representative (CS)[17]; and Other (O).

Type of Respondents



Respondents covered 21 EU Member States and 5 non-EU countries. The most active country in this Public Consultation was Finland with 32 respondents, followed by Germany with 20 replies. A double-digit of participants was also recorded for Belgium (11), while the remaining answers were spread out across the other Member States. From non-EU countries 7 respondents participated in the PC, which came from Japan, Norway, Switzerland, the United Kingdom, and the United States.

Country of Respondents

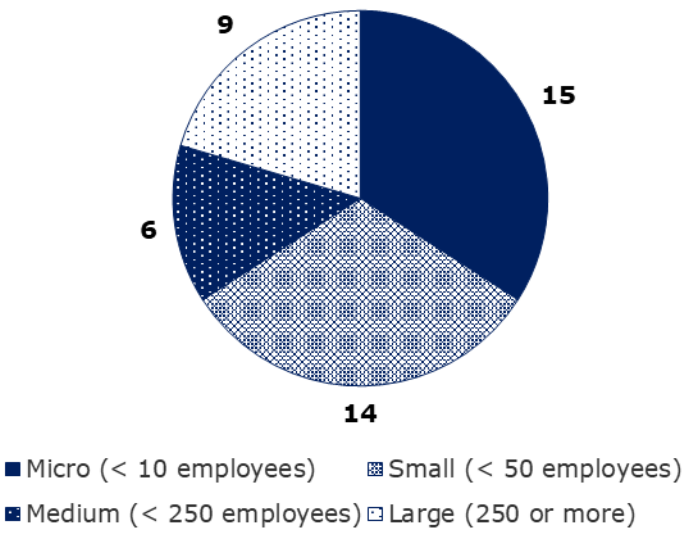
Geographical origin of respondent	Number of respondents	Geographical origin of respondent	Number of respondents
Finland	32	Latvia	2
Germany	20	Portugal	2
Belgium	11	Romania	2
France	7	Croatia	1
Italy	7	Greece	1

[15] No citizen from third countries participated to the PC.
[16] Combining the following sub-groups: (i) Company / Business organisation; and (ii) Business association.
[17] Combining the following sub-groups: (i) NGO; (ii) Consumer organisation; and (iii) Environmental organisation.

Denmark	5	Lithuania	1
Sweden	5	Luxembourg	1
Austria	4	Slovakia	1
Czechia	4	Non-EU countries	7
Spain	4	**Total**	**126**
Ireland	3		
Netherlands	3		
Poland	3		

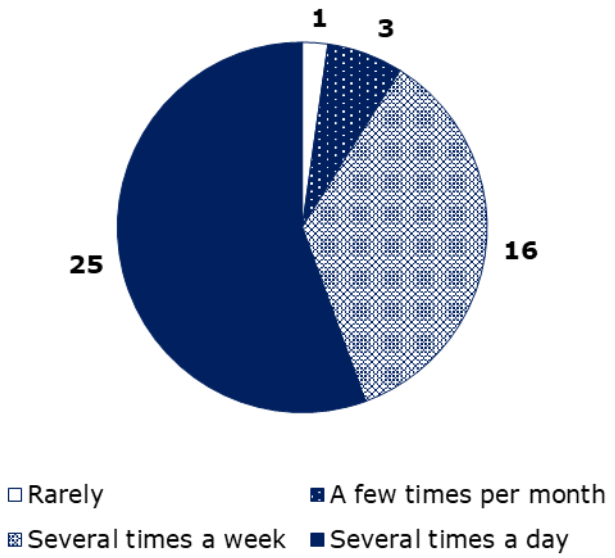
Among business stakeholders that responded to the PC, **a majority represented micro or small organisations with less than 50 employees**. These two sizes combined for 29 of the business responses, with the remaining replies being split between medium (6 respondents) and large (9 respondents) enterprises, whereby large ones slightly outweighed medium ones.

Size of Business / Organisation representation



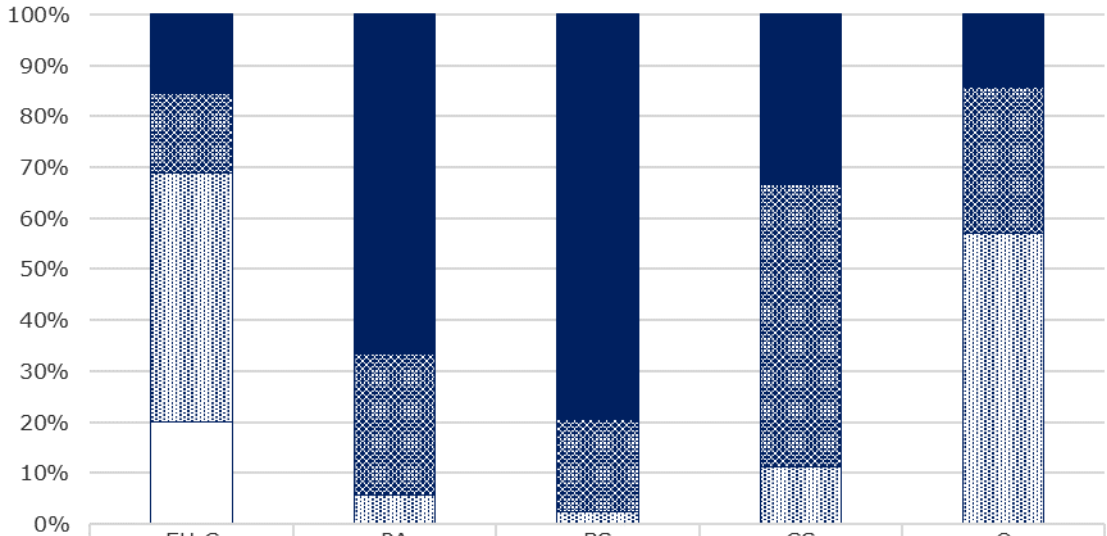
EU citizens were also asked about their age, gender, and the regularity of their detergent use at the beginning of the questionnaire. Among those respondents, a majority of 27 identified itself as female, while 17 registered to be male. With regards to how regularly they use detergents, **a majority (over 50%) stated to use detergents several times a day**. Only a very low number respondents said that their detergent use is limited to a few times per month or occurs rarely.

Q3: How often do you use detergents?



The familiarity of respondents with the Detergents Regulations was quite diverse across the different stakeholder groups. **While among Public Authorities and Business Stakeholders a vast majority was very familiar with the Regulation, the majority of EU citizens is at best slightly familiar with it**. Among the latter, roughly one third stated to be either fairly or very familiar with the Detergents Regulation. The respondents from the **Civil Society and Others showed an overall high level of familiarity with the Regulation.**

Q4: How familiar are you with the Detergents Regulation?

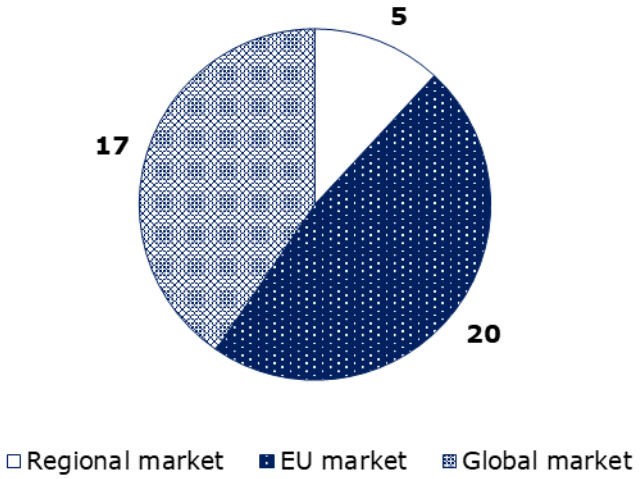


	EU-C	PA	BS	CS	O
Very familiar	7	12	35	3	1
Fairly familiar	7	5	8	5	2
Slightly familiar	22	1	1	1	4
Not familiar at all	9	0	0	0	0

PI : EU citizens ; PA: Public Authorities; BS: Business Stakeholders; CS & O: Civil Society and Others.

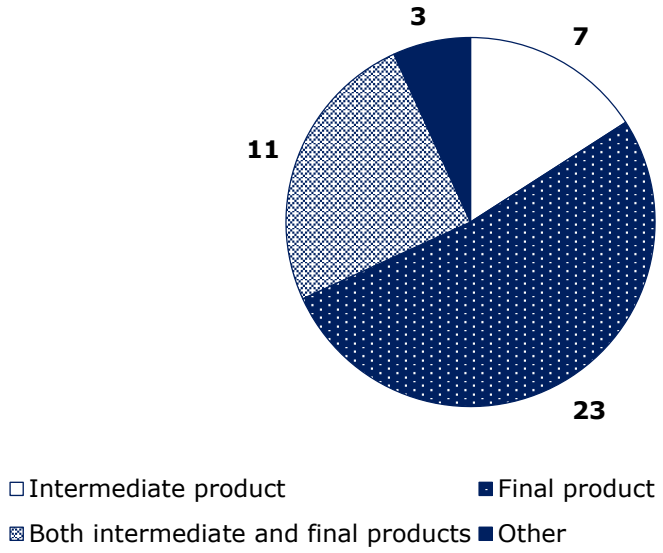
To conclude the general section, a couple of questions were asked to business stakeholders about the characteristics of their operations. At first, stakeholders were asked to indicate the market(s) they are active on.

Q5: Please indicate the market(s) you are active on



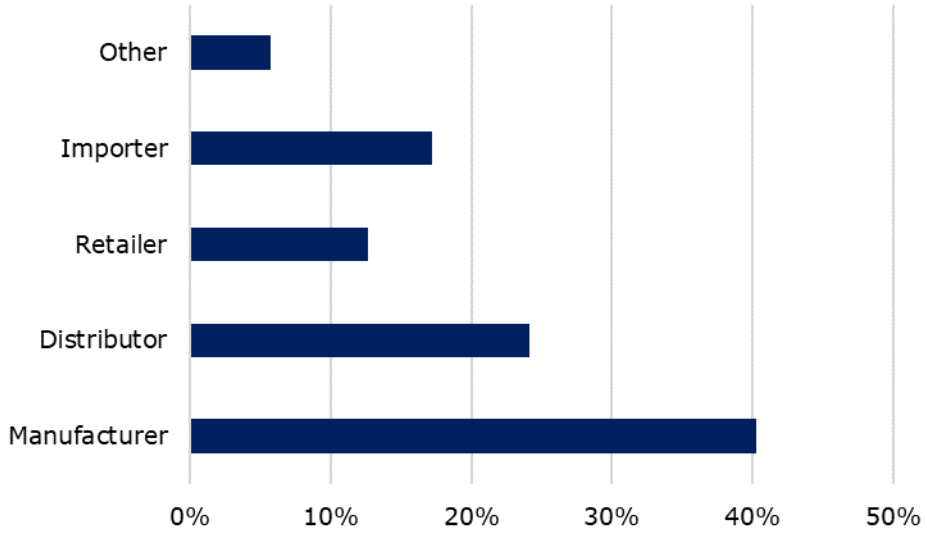
Business stakeholders were then asked about the products that they produce.

Q6: Please specify the type of product your organisation produces or represents



The last question of the introductory section then investigated the position of the responding business stakeholders in the supply chain.

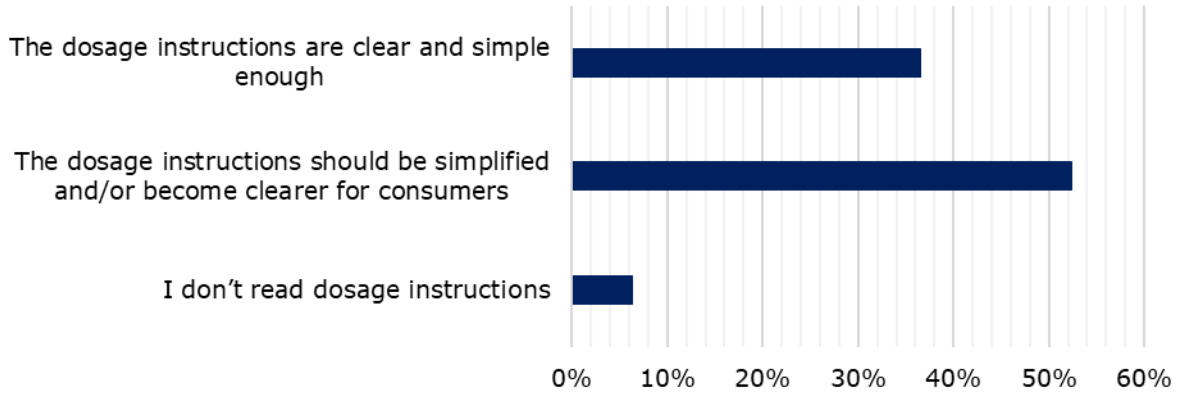
Q7: Please specify where in the supply chain you operate



2.6.1.2 2.6.1.2 Dosage instructions

In the first thematic section of the PC participants were asked to provide their views on dosage instructions. **More than half of the responding stakeholders said that dosage instructions should be simplified and/or become clearer for consumers**, which made this statement the most popular one among the proposed ones. Yet, over one-third of respondents also responded that the dosage instructions are clear and simple enough. Interestingly, this statement was the most selected one among EU citizens. The third statement, namely that they do not read dosage instructions, was chosen by less than 10% of respondents.

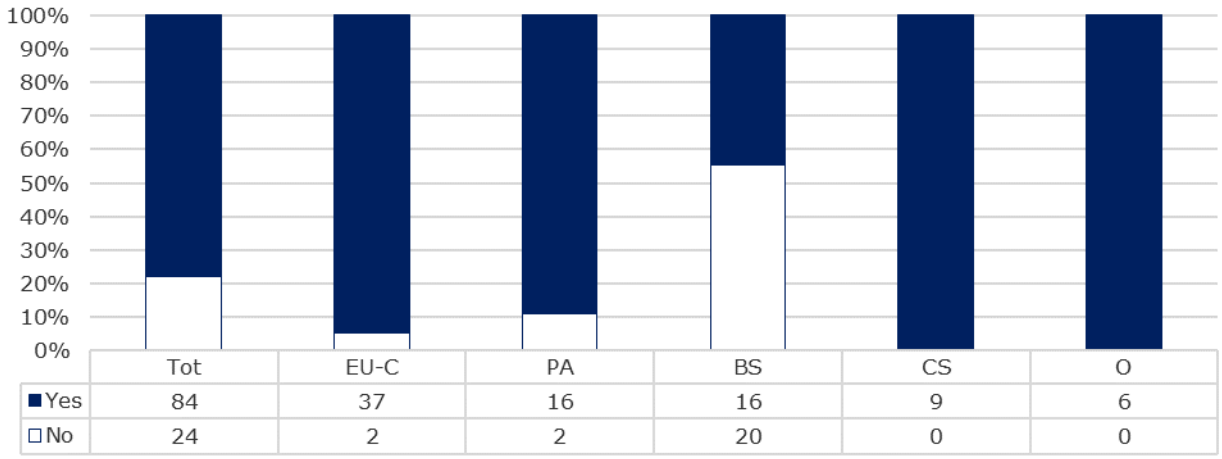
Q8: Please state which of the following statements better represents your views on the above-mentioned dosage instructions for consumer laundry and dishwasher detergents:



2.6.1.3 2.6.1.3 Refill sale of detergents

As regards refill sales, the vast majority of respondents from public authorities, the civil society and other organisations **was in favour of amending the Detergents Regulation in order to accommodate the new practice of refill sale of detergents**. Business stakeholders were the only ones that disagreed by a majority to such an amendment. Considering the size of participating businesses only, it could be seen that **large companies disagreed at a higher rate, while medium, small, and micro in fact agreed with an amendment on this matter.**

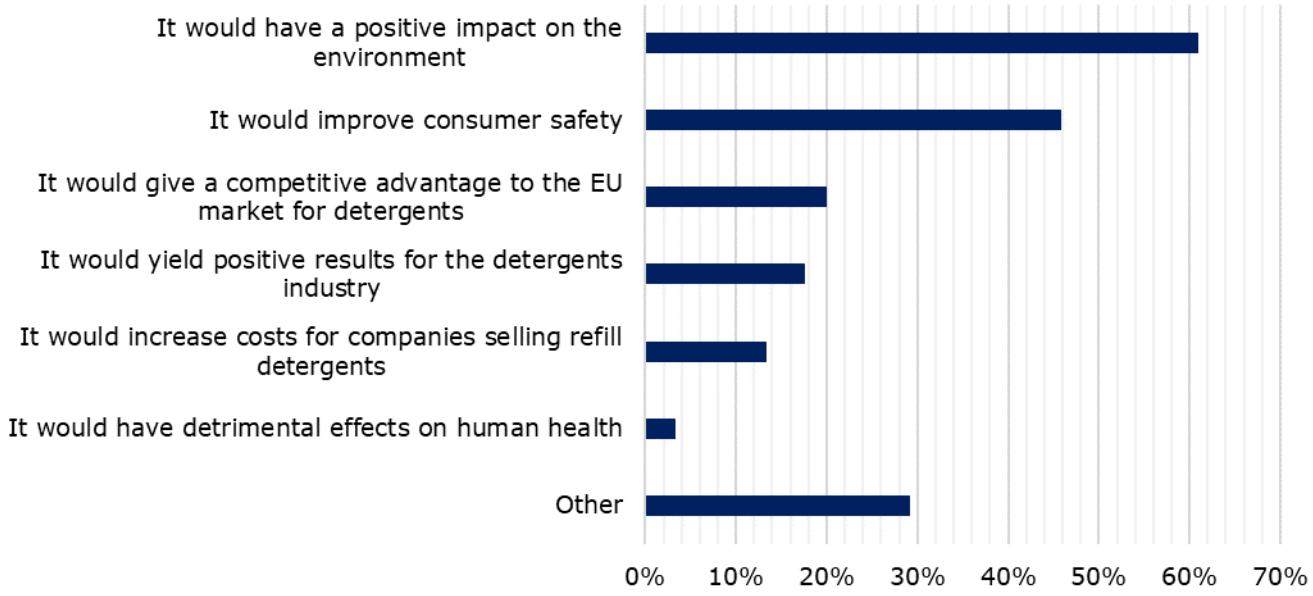
Q9: Should the Detergents Regulation be amended in order to accommodate the new practice of refill sale of detergents?



EU-C: EU-Citizen; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other

The main impact expected by stakeholders from setting rules for the refill sale of detergents is a positive one on the environment. The **second most noted impact was improved consumer safety** (40% of respondents).

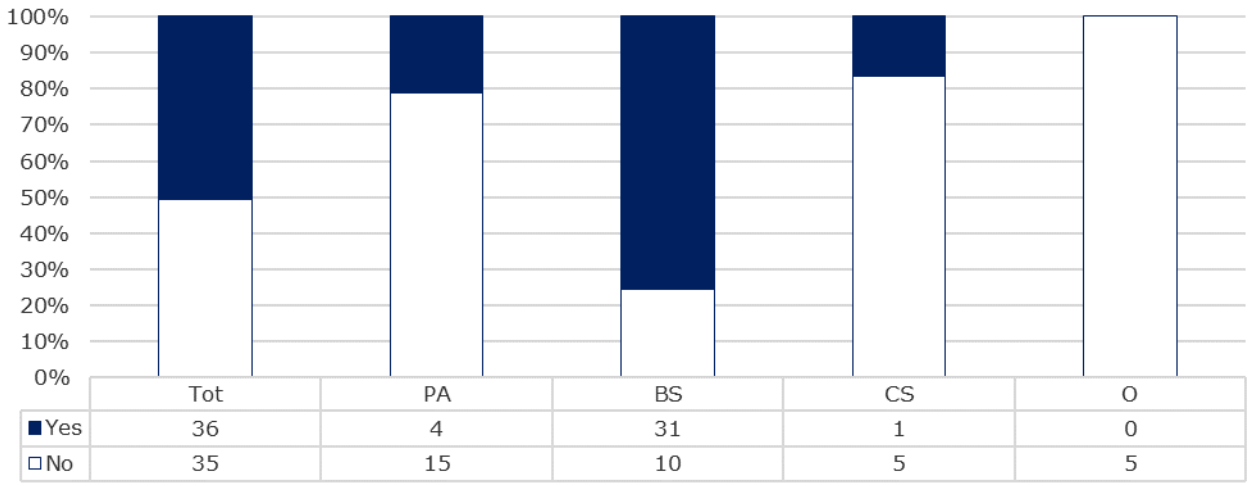
Q10 What would be the impacts of setting rules for the refill sale of detergents?



2.6.1.4 2.6.1.4 Ambiguous definitions

The question whether it is always clear if a product is a detergent or not within the meaning of the Detergents Regulation splits respondents in half almost precisely 50/50. This question was not open to EU citizens, but the remaining groups of stakeholders show greatly varying tendencies. While business stakeholders believe by over two-thirds that it is always clear, public authorities see the exact opposite also by over two-thirds. Respondents from the civil society and other organisations believe even more strongly that this is not always clear.

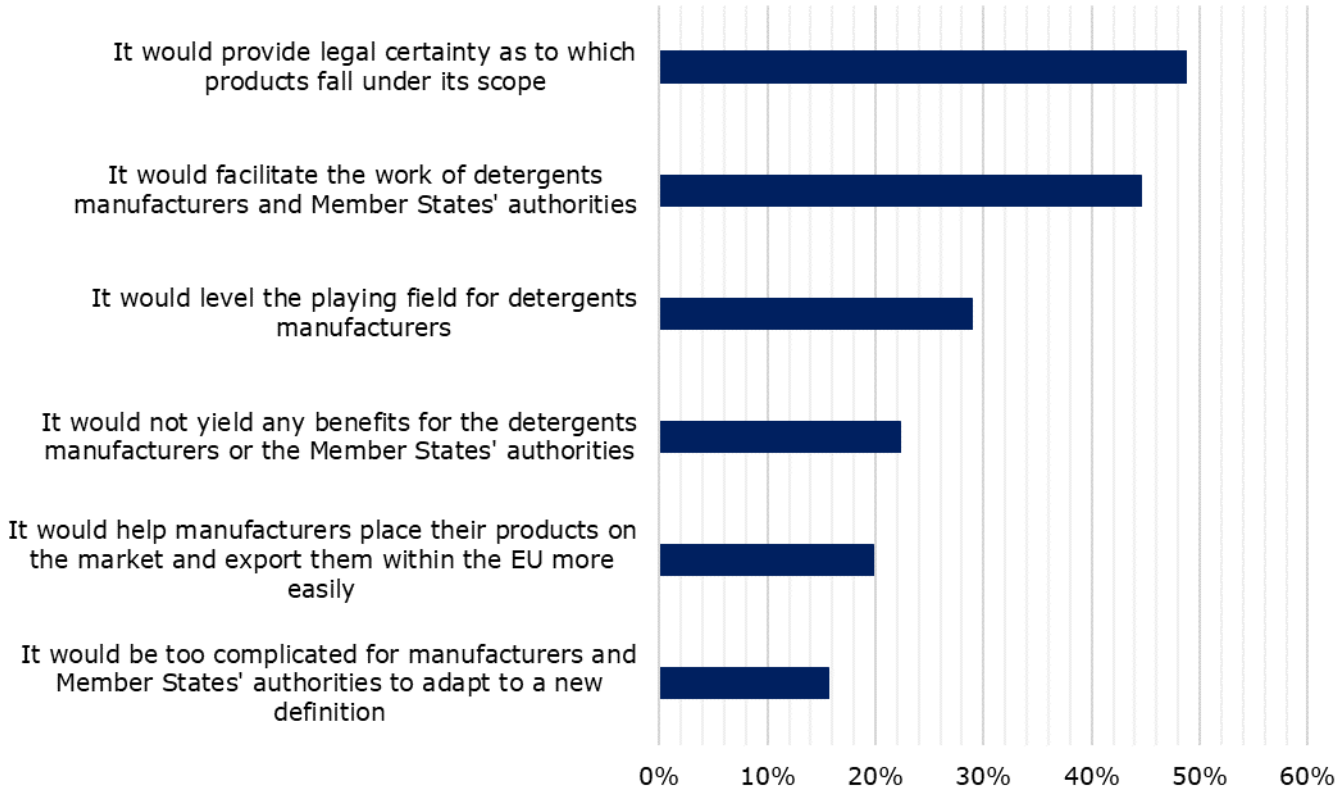
Q11: In your view, is it always clear if a product is a detergent or not within the meaning of the Detergents Regulation?



PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other

Several impacts were then put forward to the stakeholders for the case that the currently provided definitions will be clarified. **Two impacts were mentioned more often than others by respondents, namely that a clarification of currently provided definitions under the Detergents Regulation would provide legal certainty as to which products fall under its scope, and would facilitate the work of detergents manufacturers and Member States' authorities**. These two impacts were mentioned by between 40 and 50% of participating stakeholders. More than one-fourth also noted that it would level the playing field for detergents manufacturers. More than one-fifth still said that it would not yield any benefits for the detergents manufacturers or the Member States' authorities. The remaining two impacts were considered likely by 15-20% of stakeholders.

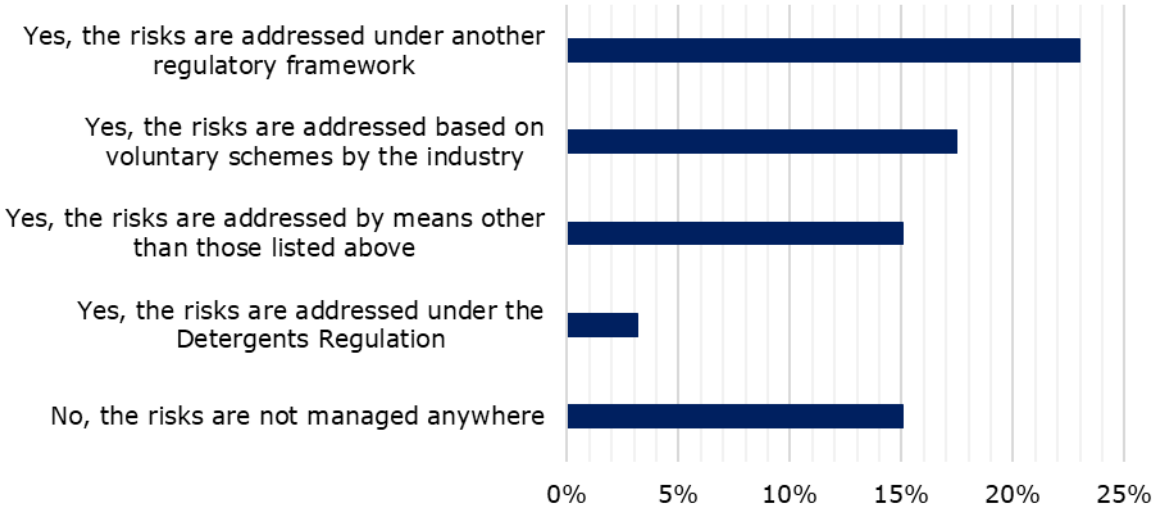
Q12 What would be the impacts of clarifying the definitions currently provided under the Detergents Regulation?



2.6.1.5 2.6.1.5 Microbial cleaning products

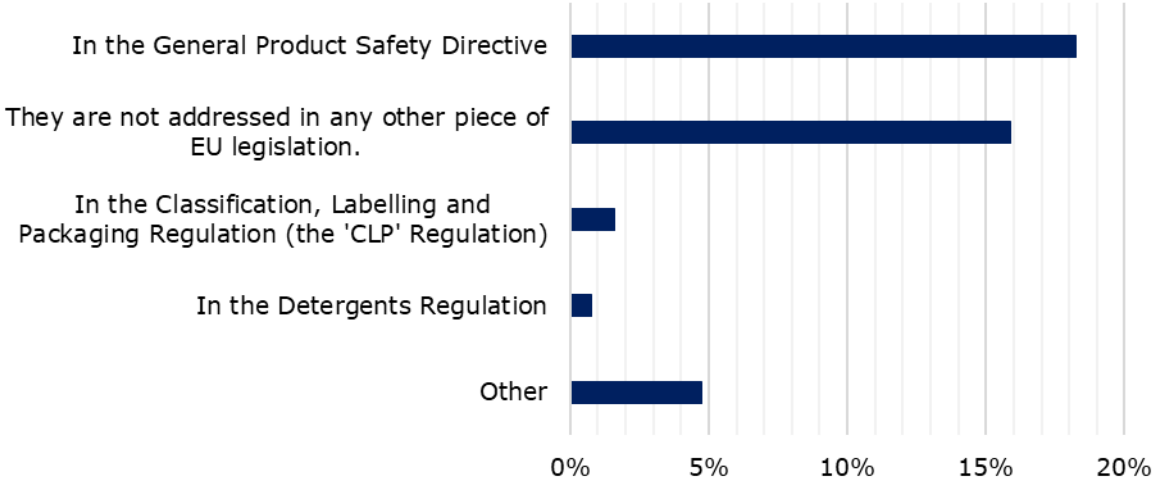
The next thematic questions posed to the responding stakeholders concerned microbial cleaning products. In a first response only a limited number of participants provided replies, but **most of those that did provide a reply said that microbial risks related to microbial cleaning products are addressed under another regulatory framework**. The second most chosen statement was that the risks are addressed based on voluntary schemes by the industry, followed by those who said that the risks are not managed anywhere. The lowest response rate was recorded for the risks being addressed under the Detergents Regulation.

Q13: In your understanding, are any microbial risks related to microbial cleaning products addressed?



A high level of uncertainty could be recorded concerning the regulation of microorganisms that are not biocidal active substances as defined in the Biocidal Products Regulation. **Although the most ticked response was that they are regulated under the General Product Safety Directive, the second-most mentioned reply was that they are not addressed in any other piece of EU legislation**.

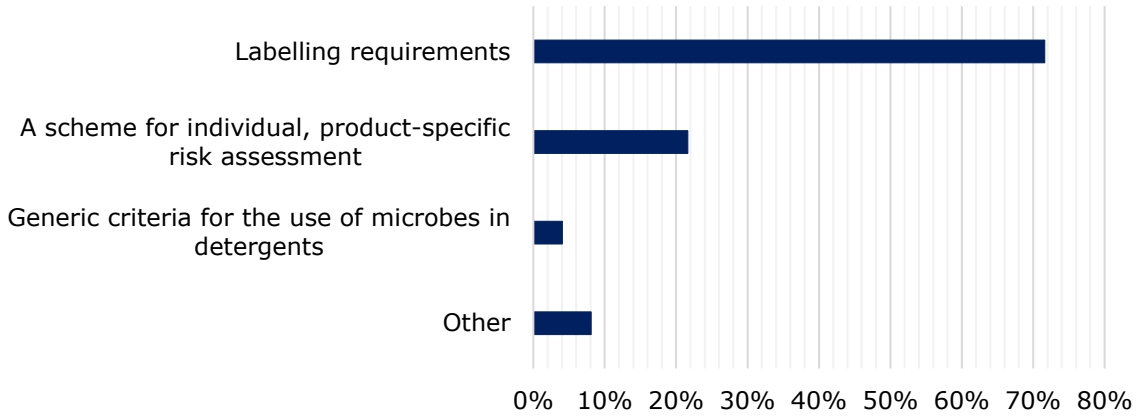
Q14: In case that the microorganisms are not biocidal active substances under the Biocidal Products Regulation, are any risks related to their use in detergents addressed in any of the following pieces of EU legislation?



When asked about necessary risk management measures, **the highest concentration of replies was found for labelling requirements as a measure to introduce in the Detergents Regulation in order to ensure the safe use of microbes in detergents**. This measure was supported by over 40% of all participants to the PC. The introduction of generic criteria for the use of microbes in detergents as a risk management measure was the least supported by stakeholders. However, the more stringent option of

introducing a scheme for individual, product-specific risk assessment measures was supported by 16 out of 53 respondents.

Q15: In case you think that further risk management measures are necessary to introduce in the Detergents Regulation in order to ensure the safe use of microbes in detergents, what sort of measures would you suggest?



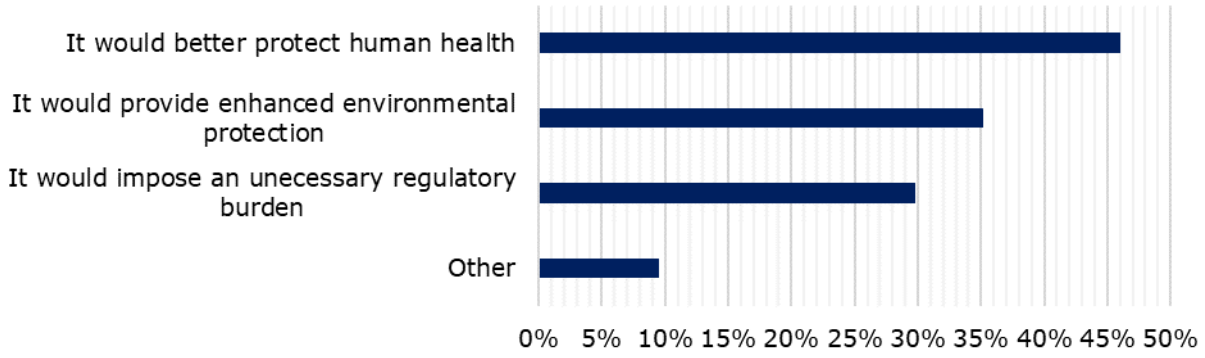
Mentions per respondent group (multiple choice):

	Labelling Requirements	Generic criteria for the use of microbes in detergents	A scheme for individual, product-specific risk assessment	Other
PA	14	0	6	1
BS	31	0	8	3
CS	6	2	1	2
O	2	1	1	0
Total	**53**	**3**	**16**	**6**

*Note: EU-Citizens – no responses; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other. Total of **63** respondents answered this question (excluding 11 that answered exclusively 'I don't know/Cannot answer'). Total respondents per group (excluding 'I don't know/Cannot answer'): PA: **16** respondents; BS: **38** respondents; CS: **7** respondents; O: **2** respondents.*

The impacts from introducing risk measures for microbial cleaning products are viewed differently across stakeholder groups. **Across all respondents, the most expected impact of introducing risk management measures for microbial cleaning products in the Detergents Regulation was better protection of human health**.

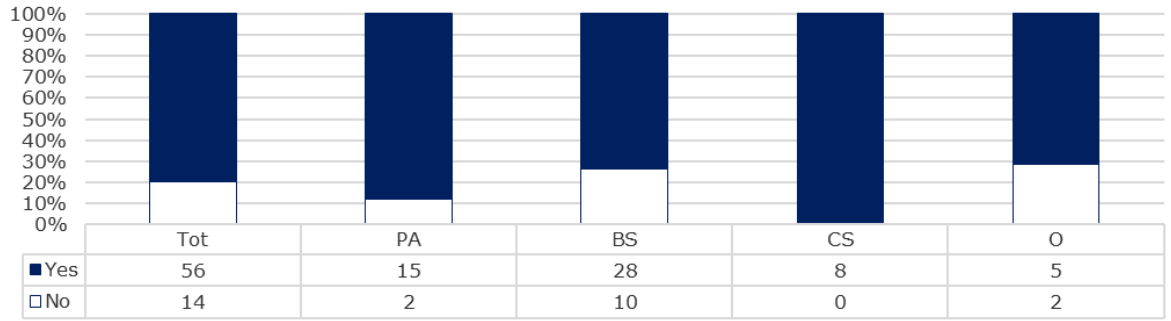
Q16: What would be the impacts of introducing risk management measures for microbial cleaning products in the Detergents Regulation?



2.6.1.6 2.6.1.6 Information to poison centres and ingredient data sheets

In this thematic section, questions evolved around information to be shared with poison centres and ingredient data sheets. **Over two-thirds of all stakeholders agreed that the ingredient data sheet for non-hazardous detergents should be maintained under the Detergents Regulation**. The responses were largely similar across the different respondent groups, with only business stakeholders having a slightly lower agreement rate than the other participants.

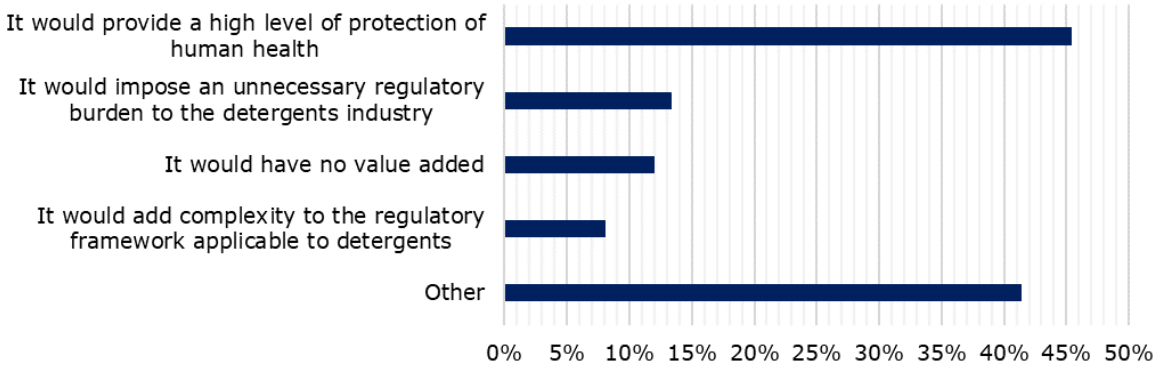
Q18: In your view, should the ingredient data sheet for non-hazardous detergents be maintained under the Detergents Regulation?



EU-Citizens – no responses; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other

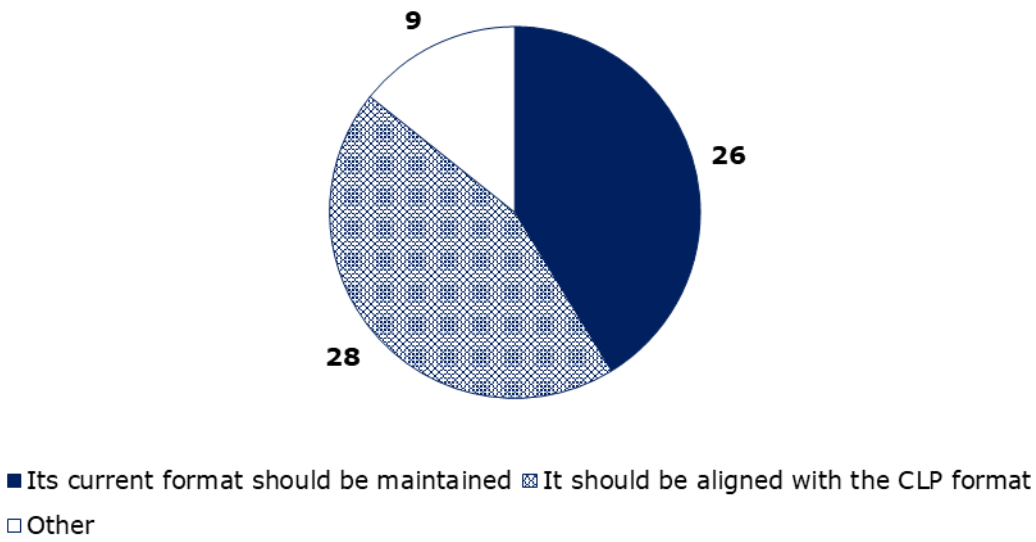
The replies to impacts of maintaining the data sheet were consistent with the responses received on the need to maintaining it. **Over one-fourth of all participants said that maintaining the ingredient data sheet for non-hazardous detergents would provide a high level of protection of human health**. In line with the overall disagreement of removing the data sheet, the three more critical impacts were selected by less than 10% of all respondents to the PC.

Q19: What would be the impacts of maintaining the ingredient data sheet for non-hazardous detergents under the Detergents Regulation?



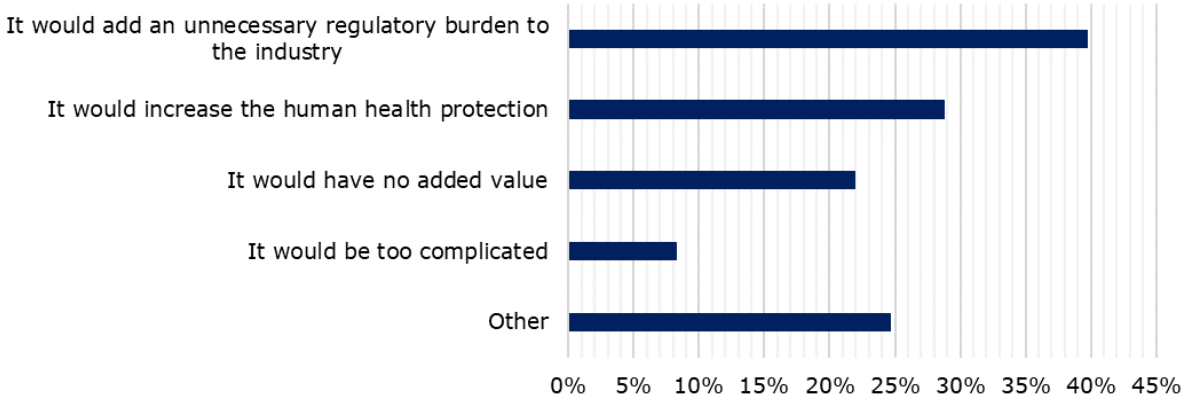
There was a split in terms of the format to be used for the ingredient data sheet for non-hazardous detergents (should this be maintained). **Out of 63 stakeholders providing a response, the majority was almost exactly split between maintaining the current format and aligning it with the CLP format**, with the latter having a very narrow advantage among respondents. In addition to those two options, some respondents also selected that another format should be found.

Q20: If the ingredient data sheet for non-hazardous detergents is maintained, should it be aligned with the format for providing information to poison centres under the CLP Regulation or should its current format be maintained?



Concerning the impacts of aligning the data sheets, **the impact expected by the most stakeholders was that aligning the ingredient data sheet for non-hazardous detergents with the CLP Regulation would result in an added unnecessary regulatory burden to the industry**. This possible impact was chosen by over one-fifth of respondents. An unnecessary regulatory burden was particularly a concern for business stakeholders. Over 15% of all participants expected, on the other hand, that it would increase the human health protection.

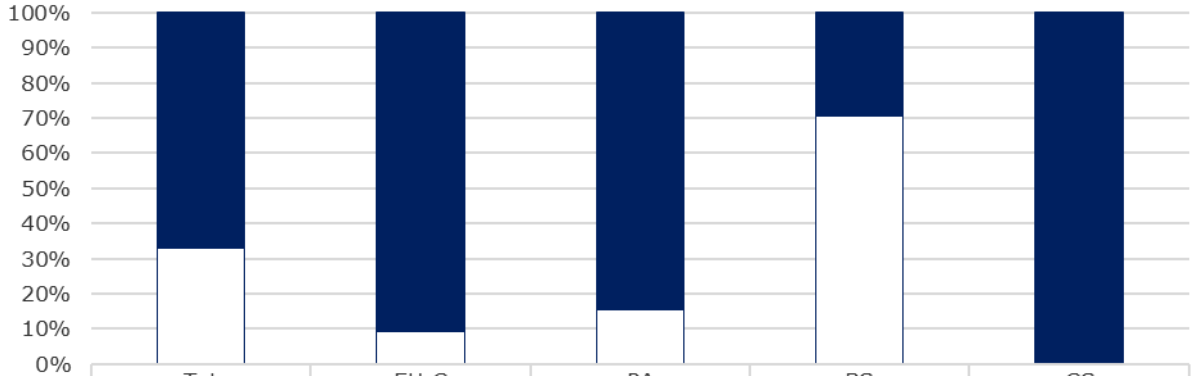
Q21: What would be the impacts of aligning the ingredient data sheet for non-hazardous detergents with the format for providing information to poison centres under the CLP Regulation?



2.6.1.7 2.6.1.7 Phosphorus limitations and biodegradability of non-surfactant organic ingredients

Over two-thirds of respondents agreed that biodegradability requirements for non-surfactant organic ingredients should in fact be added in the Detergents Regulation. Across EU citizens, public authorities, and civil society and other stakeholders the agreement was particularly strong. Business stakeholders, on the other hand, disagreed quite strongly with the introduction of biodegradability requirements for non-surfactant organic ingredients to the Detergents Regulation.

Q22: Do you consider that biodegradability requirements for non-surfactant organic ingredients should be introduced in the Detergents Regulation?



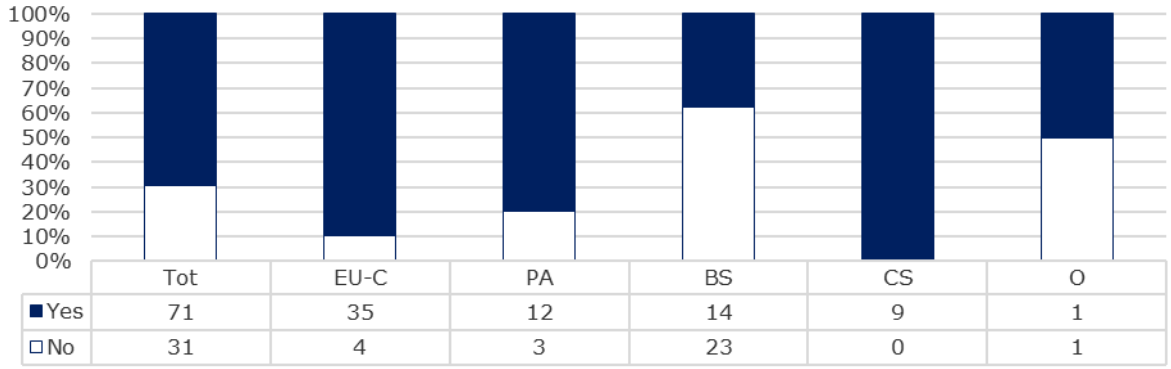
	Tot	EU-C	PA	BS	CS
Yes	71	39	11	12	9
No	35	4	2	29	0

EU-C: EU-Citizen; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other – no responses

Sharing their view on phosphorus limitations, **a majority across all participant groups except for business stakeholders thought that the phosphorus limitations should be expanded to professional detergents**. While the agreement rate in total was over two-thirds, a majority of business stakeholders

disagreed with such an expansion. EU citizens and civil society respondents agreed very strongly with phosphorus limitations being expanded to professional detergents.

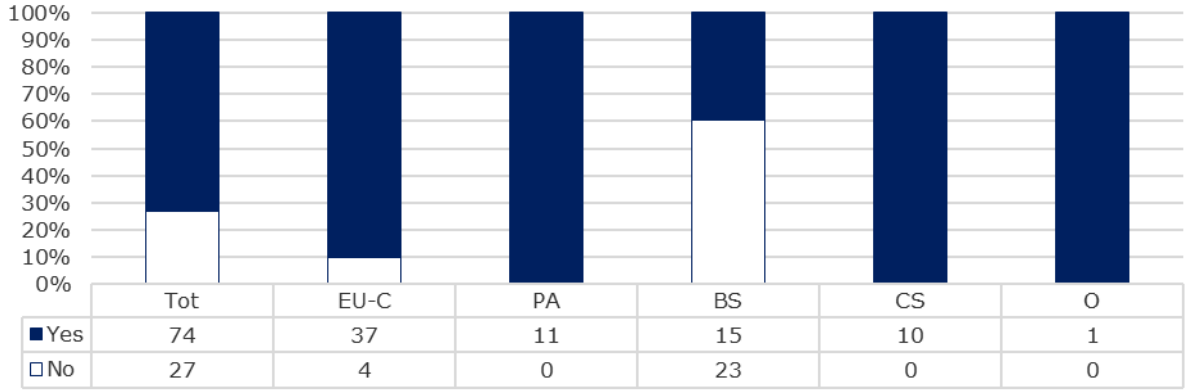
Q23: In your view, should the phosphorus limitations be expanded to professional detergents? *PI: EU citizens; PA: Public Authorities; BS: Business Stakeholders; CS & O: Civil Society and Others.*



EU-C: EU-Citizen; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other

As regards the expansion of phosphorus limitations to consumer dishwashing detergents **more than two-thirds of respondents from** public authorities and civil society and other participants **were in favour while the majority of industry stakeholders were against**.

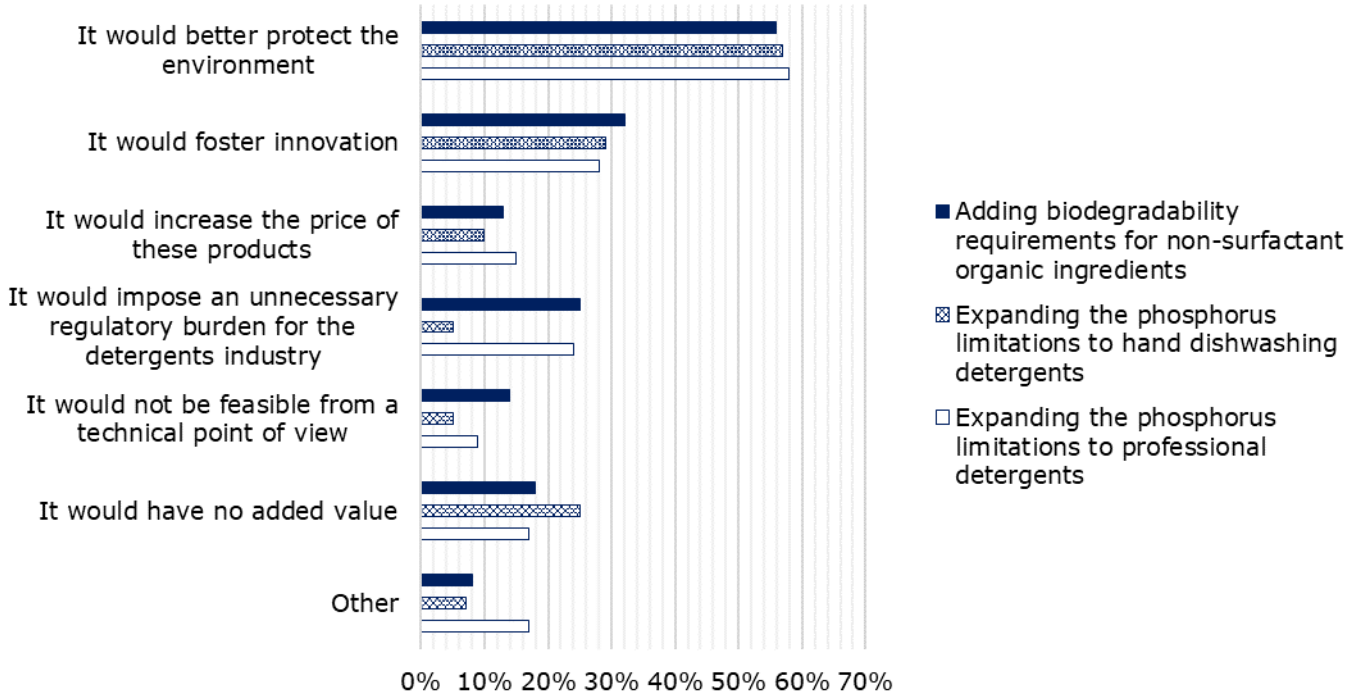
Q24: In your view, should the phosphorus limitations be expanded to consumer hand dishwashing detergents?



EU-C: EU-Citizen; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other

The three possible options presented above were then assessed on their impacts by the stakeholders. **For all three options, the impact considered most likely by respondents was that the environment would be better protected**. Around one-fourth of the respondents also noted specifically that adding biodegradability requirements for non-surfactant organic ingredients, and expanding the phosphorus limitations to professional detergents would impose an unnecessary regulatory burden to detergent industry.

Q25: In your view, what would be the impacts of (multiple answers possible):

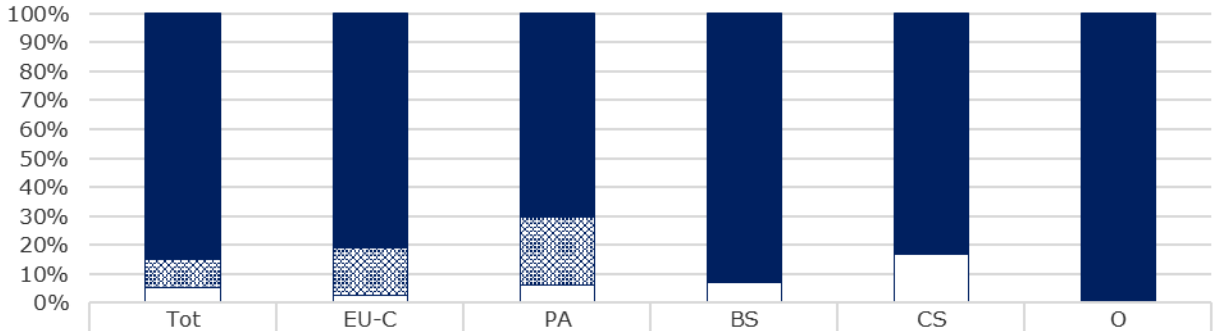


2.6.1.8 2.6.1.8 Overlaps in the labelling of ingredients

The **vast majority of respondents across all groups agreed that overlapping labelling requirements should be streamlined to allow that the relevant substance is labelled only once in accordance with the stricter applicable rules**.

Q26: When labelling requirements according to several pieces of legislation including the Detergents Regulation (i.e. the CLP Regulation or the Biocidal Products Regulation) are

overlapping, do you think that these should be streamlined to allow that the relevant substance is labelled only once in accordance with the stricter applicable rules?

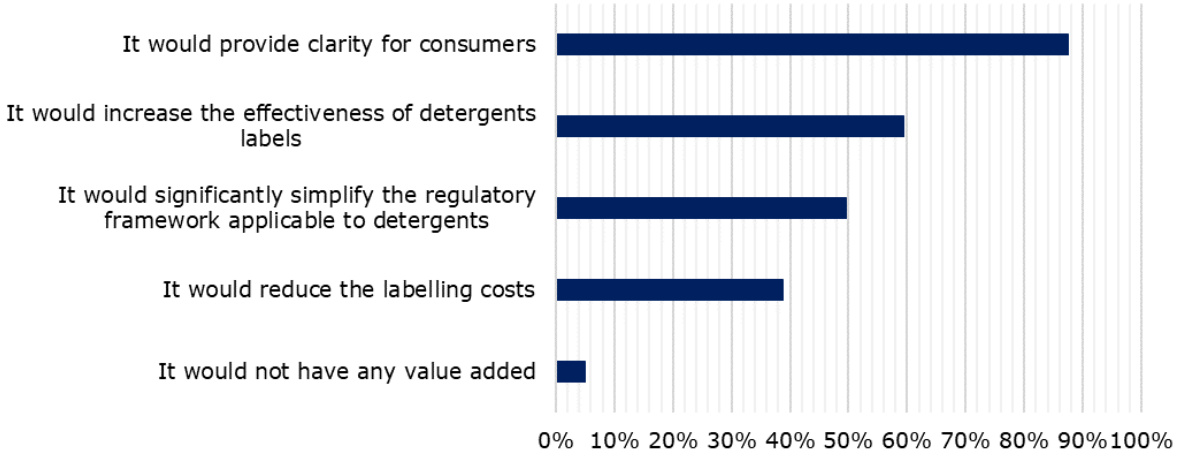


	Tot	EU-C	PA	BS	CS	O
Yes	97	34	12	40	5	6
No	11	7	4	0	0	0
Other	6	1	1	3	1	0

EU-C: EU-Citizen; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other

Concerning the impact of streamlining the labelling requirements for detergents, five impacts were proposed to stakeholders, of which **two were mentioned by more than half of participants, namely that it would provide clarity for consumers and that it would increase the effectiveness of detergent labels**. Close to 50% of respondents also believed that streamlining the labelling requirements would significantly simplify the regulatory framework applicable to detergents. A reduction of labelling costs was noted as an impact by more than one-third still.

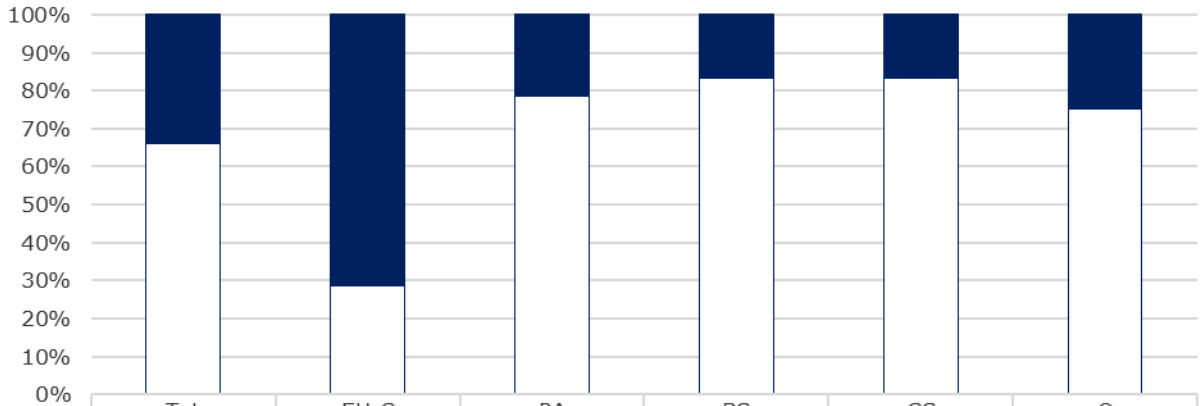
Q27: What would be the impacts of streamlining the labelling requirements for detergents?



2.6.1.9 2.6.1.9 Legislative Instrument

Around two-thirds of respondents replied that the Detergents Regulation should not be repealed. Public authorities, business stakeholders, and civil society and other respondents strongly disagree with a repeal of the Detergents Regulation while this answer found some support from EU citizens.

Q28: In your view, should the Detergents Regulation be repealed, and the material content be included in horizontal pieces of chemicals legislation (i.e. mainly the REACH and CLP Regulations), in order to simplify the regulatory framework for chemicals?



	Tot	EU-C	PA	BS	CS	O
Yes	32	20	3	7	1	1
No	62	8	11	35	5	3

EU-C: EU-Citizen; PA: Public Authority; BS: Business Stakeholder; CS: Civil Society Representative; O: Other.

2.6.2 2.6.2 Additional Contributions to Public Consultation

In addition to their responses to the Public Consultation questionnaire, 9 stakeholders used the opportunity to provide additional contributions, in which they provided either further details on specific questions or additional comments on the overall topic. Some overarching themes can be identified from the contributions.

A first recurrent theme that emerges from the additional contributions is the lack of coherence within the wider regulatory framework applicable to detergents. One aspect raised by a few stakeholders is the duplication of labelling requirements between the Detergents and the CLP Regulation, which should be eliminated. Two contributions remarked that the issue of re-fill sales, on the other hand, has a wider context and should be addressed in the CLP Regulation and not create duplication.

Some contributions also reviewed other aspects of the labelling of detergents, namely their preference to reduce information on the physical labels and support of increased digitalisation of certain labelling information. On the other side, there were contributions urging for additional and/or clearer labelling. For example, it was mentioned that fragrances and preservatives should be obligatory on physical labels because they can cause allergic reactions. Another response stated that nano particles and micro-plastics should be specifically mentioned on labels in view of their environmental impact.

With regard to microbial cleaning products, stakeholders raised a range of issues from lack of scientific information about the risk over appropriate documentation of microbes up to the necessary elements of a risk assessment, such as hazard identification, exposure assessment, or risk characterization. One response dealt specifically with the microbes in microbial detergents and outlined their views on topics

such as genetically-modified-microbes, the microbial count in a product, antibiotic susceptibility of micro-organisms, or the shelf-life of microbial detergents. Another reply explained that microorganisms should be seen as effective alternatives to traditional active substances and hence, regulatory barriers should not be too high.

A handful of more specific matters were expressed by individual contributions such as: (i) the Regulation should consider Gender explicitly, as women buy and use detergents at a higher rate and as particularly pregnant women are at risk to harm; (ii) the Regulation should more clearly integrate the principle of the high protection of human health and the environment; (iii) an Annex concerning safety requirements for microbial-based cleaning products should be added; (iv) concerning re-fill sales, attention should be paid to additional risks to human health due to exposure from refill stations and unclear or lack of safety information for re-filled products; (v) poison centres might want to avoid having several different channels for their information, so ingredient information also for non-hazardous products may be desirable.

For detailed information on the consultation activities undertaken under the digital labelling study, please see Annex 8.

2.7 2.7 STAKEHOLDER WORKSHOP

On 12 May 2022, a stakeholder workshop was organised. Members of the Detergents Working Group and all interested parties were invited to participate and express their views on the preliminary findings of the ongoing Impact Assessment supporting study and the proposed policy options. In particular, the contractor tested and validated his findings with the workshop participants. All the problems, assumptions, estimates, policy options and impacts were clearly described, and responses were encouraged to be provided (either orally or via email) by stakeholders. Workshop participants across all groups agreed with the problem definition and analysis. The proposed policy options and the preliminary assessment of their impacts were welcomed by workshop participants and no opposing views were expressed.

Annex 3 ANNEX 3 WHO IS AFFECTED AND HOW?

3.1 3.1 PRACTICAL IMPLICATIONS OF THE INITIATIVE

The table below details how stakeholders are affected under the preferred option (PO1b+PO2b):

Stakeholders	
Businesses	The preferred policy package is expected to bring benefits in terms of burden reduction and cost savings for the detergents industry. No administrative costs are expected while annual costs savings would be generated as a result of the elimination of superfluous (duplicated) information requirements (€7 million from ingredient data sheets for hazardous detergents) and the facilitation of refill sales (not quantified but cost savings under the baseline are estimated at €3.3 million due to reduced disposal of plastic waste). Some additional administrative costs savings due to the voluntary digitalisation of labels that cannot be quantified may also exist. In particular, by reducing the frequency of disposing of and redesigning physical labels, there could be some ongoing costs savings for enterprises as digital labels are easier and less costly to update than physical labels. This relates to relabelling due to product reformulations (e.g. to increase its effectiveness), changes in the supply chain (e.g. constituent mixture obtained from different supplier) or due to regulatory changes. Minor additional costs (mostly to SMEs) within the range of €200,000 per company per year are expected from the introduction of safety requirements for microbial cleaning products. These would not negatively impact the manufacturers (mostly SMEs), who reported that these costs are within the acceptable range. Minor costs may also be incurred from adapting the existing websites to provide product information online due to (voluntary) digital labelling. Setting a legal framework (also in terms of the 'principles for digital labelling' – see Annex 8) for digital labelling will help achieve a level playing field and create certainty for economic operators, while at the same time avoiding divergent non-harmonised digital labelling schemes (e.g. at Member State level or at the initiative of industry). The introduction of (voluntary) digital labelling brings the following additional benefits for detergents manufacturers: - Better management of fast changing label information; - More space on the physical labels to include additional information; - Possibility to create economies of scale in the sense that the physical label space could allow for more languages, meaning that costs are saved in terms of distribution of sales, and the full potential of the internal market for detergents would be realised. Setting harmonised criteria and clarifying requirements for more environmentally friendly products (microbial cleaning products) and sustainable new practices (refill sales), will facilitate the green transition while ensuring that innovation is not hampered. Given that these market segments are currently dominated by

	SMEs, this will further increase their access and integration into value chains and the market overall.
End Users	The introduction of (voluntary) digital labelling will on one hand provide additional ease of use and improved awareness as the essential information remaining on the physical label becomes clearer and on the other yield additional benefits for vulnerable and visually impaired users. For those without access to digital information of detergents, the 'principles for digital labelling' would mean that alternative ways of providing information would be necessary. The introduction of safety requirements for microbial cleaning products will increase the level of protection of human health and will allow users to make informed choices for their health and the environment. The clarification of the rules on refill sales will ensure that consumers receive the relevant safety and use information, which is crucial e.g. in case of an accident or to ensure proper product use. The ingredient data sheets for non-hazardous detergents is maintained to ensure that end users are further protected.
Public authorities	In terms of direct impacts of PO1b and PO2b on public authorities, despite the positive aspects related to the ease of managing and compiling online data, the preferred policy package could result in a slight increase of enforcement costs due to the expected growth of the refill sales of detergents. Legal clarity and certainty for microbial cleaning products and refill sales as well as the simplification and streamlining of the labelling requirements would facilitate the enforcement activities of market surveillance authorities. The introduction of optional digital labelling would generate a benefit for monitoring activities of market surveillance authorities as it could render the enforcement of existing rules on maintenance of website more effective and help reduce reported issues of non-compliance. Setting up a legal framework for digital labelling (in terms of the 'digital labelling principles') would also be beneficial for public authorities, as the information online will be easy to navigate and searchable (i.e. useful for those looking for specific information).

3.2 3.2 SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
	Direct benefits	
Reduced administrative burden for manufacturers of detergents due to elimination of duplications, digital labelling and	€7 million - abolishment of ingredient data sheets for hazardous detergents Savings due to elimination of duplications in the labelling requirements and digital labelling - non quantifiable.	The introduction of digital labelling is on a voluntary basis and manufacturers of detergents are already required to maintain a website with a full ingredient list.

abolishment of ingredient data sheets	Digital labels are easier to update and less costly compared to physical labels. Moving certain information to the digital labels allows for less relabelling.	
Users enjoying greater ease of use and increased awareness of key information (e.g. ingredients, safety information).	Non-monetary benefit	Evidence from the consultations highlights that increased awareness about product information on labels and more informed decision-making is likely to reduce risks to health and safety. Public authorities also benefit from simplified labels and digital labels render enforcement easier (information online will be easy to navigate and searchable).
Improved functioning of the internal market	Non-monetary benefit	Legal clarity and certainty for microbial cleaning products and refill sales. Harmonised requirements for microbial cleaning products and facilitation of refill sales also through (optional) digital labelling.
Reduced risks to health and safety of users	Non-monetary benefit	Improved label readability would lead to increased consumer safety. Consumers receive complete information on refilled detergents and are allowed to make informed choices for their health and the environment. Ingredient data sheet for non-hazardous detergents is maintained.
Optimised protection of the environment	Non-monetary benefit	Simplified dosage instructions and detailed information on e-labels ensures proper use and prevents overdosing. Consumers receive information on use of refilled detergents and microbial cleaning products.
Indirect benefits		

Reduced disposal of plastic waste (refill sales)	Impact not quantified; the baseline savings estimated at €3.3 million	The facilitation of refill sales would lead to a reduction of disposed plastic waste and consequent cost savings. These savings could increase based on the expected growth of refill sales.
Potential reduction in the disposal of unused labels due to digital labelling	Not quantifiable	Digital labels are easier to update and less costly compared to physical labels. Moving certain information to the digital labels allows for less relabelling.
Administrative cost savings related to the 'one in, one out' approach*		
Annual direct administrative savings - abolishment of ingredient data sheets for hazardous detergents	€7 million	
Potential additional administrative costs savings due to voluntary digitalisation of labels	Not quantifiable	The benefits would stem from the digitalisation of some information compared with the current physical-only labelling requirements. Given the voluntary nature of the preferred option, no costs would be imposed on businesses. Businesses would only provide digital labelling if they perceive the potential to enjoy reduced costs (or if they perceived sufficient other business benefits to justify any cost increase). Cost savings would arise through reducing the frequency of disposing of and redesigning physical labels. There would also be economies of scale in that more languages could fit on physical labels. All types of firms (SMEs and large enterprises) would be able to benefit from digitalisation.

II. Overview of costs – Preferred option							
		Citizens/Consumers		**Businesses**		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Action (a)	Direct adjustment costs	Not relevant	Not relevant	€400,000 Total familiarisation costs (€25.7/h, 4 man hours per company)	€200.000* (tests for microbial cleaning products)	Not relevant	Not relevant
	Direct administrative costs	Not relevant	Not relevant	voluntary digital labelling - minor costs for updating websites	Not relevant	Not relevant	Not relevant
	Direct regulatory fees and charges	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	Direct enforcement costs	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Possible slight increase of enforcement costs – not quantifiable
	Indirect costs	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	Not relevant	Not relevant	Not relevant	Not relevant		

	Indirect adjustment costs	Not relevant	Not relevant	Not relevant	Not relevant		
	Administrative costs (for offsetting)	Not relevant	Not relevant	Not relevant	Not relevant		

* It should be noted that this an upper bound estimate, taking into account the highest number of batches reported by stakeholders during the interviews. The costs related to proving the lack of antibiotic resistance can range from €0 (in cases where the relevant data is already available in EUCAST[18]) to €335 per strain of microorganism used (in cases where this needs to be carried out by the manufacturer). Additional one-off adjustment costs may also arise from the test requirements for placing on the market microbial cleaning products in a spray format. Given that the test methods for proving that microbial cleaning products are safe for respiratory exposure would need to be determined later on, it was not possible to quantify these costs. However, based on stakeholder reports this entails a one-off cost of approx. €5,000 per strain or blend of strains used per company.

3.3 3.3 RELEVANT SUSTAINABLE DEVELOPMENT GOALS

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG #3 Good health and well-being	Digital labelling could improve the communication of safety and use information (including use instructions) on detergents, by providing the information in a clearer and more understandable manner to end users and notably consumers. Allowing more sustainable products and practices under the Regulation; introducing safety requirements for microbial cleaning products; ensuring that consumers receive the necessary information on refill detergents; and maintaining the ingredient data sheet for non-hazardous detergents will provide a higher level of protection of human health and the environment.	Specific Target 3.9 'By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination'
SDG #9 Industry, innovation and infrastructure	Setting up a framework for digital labelling and improving the management of otherwise overloaded labels will allow the detergents industry to transition to increased digital	Specific Target 9.4 'By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use

[18] European Committee on Antimicrobial Susceptibility Testing

	practises and future proof the Regulation. Alternatives to conventional chemical products i.e. microbial cleaning products will be covered by the Regulation, allowing for more innovation while also ensuring their safety through harmonised requirements.	efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities'
SDG #12 Ensure sustainable consumption and production patterns	The communication of safety and use information on detergents will be improved so that consumers and professional users are allowed not only to better protect themselves but also to make informed choices for the environment. Refill detergents will be facilitated through harmonised requirements and (voluntary) digital labelling resulting in a reduction of disposed plastic waste and less disposal of unused label stock. In the long term, the digitalisation of labels could also lead to less re-labelling with further advantages for the environment.	Specific Target 12.4 'By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimise their adverse impacts on human health and the environment'

Annex 4 ANNEX 4 ANALYTICAL METHODS

4.1 4.1 ANALYTICAL METHODS (EXCEPT DIGITAL LABELLING)

This chapter provides the analytical methods used in preparing the impact assessment, and describes the risks and uncertainties associated with our quantitative estimates.

4.1.1 4.1.1 Modelling of impacts

The estimates presented do not derive from a single-overarching model, but from simple algebraic operations, all of which are presented in form of tables from where the calculations can be easily derived.

In the policy option involving a change in the labels of microbials (Option 1A and 1B), the contractor used a step-wise process which estimates the costs of the regulation as a process derived from five steps: familiarisation with the regulation; collection of necessary information; re-design of labels; printing and packing. The approach has been previously used in EU impact assessments related to labelling of food stuff[19], so this was considered to be a robust methodological method. The calculations all assume that the change will be implemented allowing stakeholders a transition period of 18 months and hence most of the costs of any labelling changes would be subsumed in the usual labelling activities of manufacturers (taking place normally every year).

In the policy options related to the costs of datasheets (Option 2A and Option 2B), the contractor has undertaken calculations starting from an estimated amount of products re-formulated each year. The method to arrive at this number follows the method used in the supporting study to the evaluation[20], which derives the re-formulated products from estimates of the total products in a market and the amount of re-formulations in each year. Most of the parameters used are difficult to obtain (since no data exist at such level of disaggregation). The contractor bases its estimates on parameters from the supporting study to the evaluation[21] and refinements based on expert views from the industry. The estimates derived might have a degree of uncertainly, but the assessment recognises that because the estimated costs relate to some minor tasks (filling a datasheet is small compared with the other inputs involved in the production of a detergent) these costs will always be small in magnitude, and this is irrespective of potential other values of parameters used in this exercise (*e.g.* the actual hours used to fill a datasheet, the number of detergent products, or the splits used for hazardous/ non-hazardous detergents used in our simulation).

[19] SEC(2008) 94 COMMISSION STAFF WORKING DOCUMENT accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the provision of food information to consumers IMPACT ASSESSMENT REPORT ON NUTRITION LABELLING ISSUES. SEC(2008) 92 COMMISSION STAFF WORKING DOCUMENT accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the provision of food information to consumers IMPACT ASSESSMENT REPORT ON GENERAL FOOD LABELLING ISSUES.

[20] RPA et al. (2018) Support to the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation), see https://ec.europa.eu/docsroom/documents/32561

[21] Idem.

For the purposes of simulation of impacts of measures related to refill sales of detergents, we have assumed that when operationalised, this option will correct for the problems mentioned by stakeholders and associated with this practice. Our impacts are therefore calculated using assumptions on the evolution of the practice of this type of sales. There are no precise estimates around the size of the refill market, but for the purposes of our simulations we have assumed these can achieve a 1% of the market (the figure comes from an upper bound provided by respondents in our interviews). However, according to other sources[22], refill detergents account for a little over 2% of the overall detergents' market, and chemicals placed on the EU market for self-refill are mostly detergents and home care products[23]. These account for about 179,000 t/year and are estimated to concern a range of 8.95 million to 89.5 million individual sales per year. By 2040 it is expected that this practice will increase up to over 265,000 t/year accounting for about 13.25 million to 132.5 million individual sales per year for self-refill chemicals.

For the policy option for regulating microbials (Option 1B), the evolution of this market is still uncertain to be able to conclude on how many new products will be launched in the coming years. Given expressed during the interviews. that this is currently a niche market cost estimations have been based on stakeholders' views as

4.1.2 4.1.2 Assumptions and limitations

The main limitation of the analysis is in relation to the lack of appropriate data or parameters to estimate some of the impacts. Although the detergents sector is quite well documented (in statistical agencies, but also through the industry association A.I.S.E.) the policies and analysis required for this impact assessment cover very narrow areas for which sufficiently disaggregated data does not exist. Furthermore, in many cases the parameters required are not only not being recorded but are, in many cases, unknown. This is for example in relation to the quantification of refill practices or use of detergents with microbials which are, at present, very new and unknown to a majority of stakeholders (including national authorities and organisations). For these parameters the contractor relied on the views of the industry. In such situations the team has assessed internally the magnitude and validity of such parameters relying on the experience of our experts. We have also made sure that the parameters used and estimates obtained would make economic sense in terms of reflecting what would be expected from economic theory. The results are provided with such estimates but we are clear in the text about the robustness or limitations of such numbers (providing the source where the parameter is derived from).

The options envisaged are likely to have impacts on a broad range of players in this market. Not least, many of the options are envisaged to improve the functioning of the internal market, or the safety of the EU citizens and the environment. Estimating these impacts in such areas is a difficult exercise. The contractor recognised this but provided also the expected impacts qualitatively. Again, the precision of such impacts is affected by a large degree of uncertainly but what is important is to gauge the magnitude. Hence views which are likely to affect all consumers in the internal market can be expected to be very large, but those affecting only a subset of these (for example consumers buying microbial detergents or using refill sales) can be already expected to be more limited.

[22] RPA Europe (2022). Technical and Scientific Support to the Commission's Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP); not yet published.
[23] It should be noted that while the refill chemicals' market is dominated by detergents the category of 'home care products' is wider than detergents.

4.1.2.1 4.1.2.1 Main sources of data and validation

This Impact Assessment is based on evidence provided in the Evaluation and two supporting studies. The interviews and responses received during the consultation activities have all been used as a source for the identification of problems and also for obtaining estimates of unknown parameters. In cases where discrepancies in the data were found or there was lack of clarity in some of the answers these were further investigated with follow-up emails and calls with the respondents.

The contractor sought to test and validate our findings in the Detergents Working Group and the Stakeholder Workshop (15 December 2021 and 12 May 2022). All the assumptions, estimates and impacts were clearly described, and responses were encouraged to be provided (orally or via email) from stakeholders. Some suggestions were made during the meetings that we have reflected on. Stakeholders across all groups were largely in agreement both with the problem definition and the proposed policy options.

4.1.2.2 4.1.2.2 Uncertainty

As ever, with estimates of future costs and benefits, there is uncertainty about the final numbers. The uncertainty can sometimes be considerable. For this part, it has been difficult to collect data from stakeholders on the likely impacts of different policy measures. This reflects in part the limited engagement from stakeholders which might already be interpreted as a sign that the parties do not anticipate the problems and policy measures being considered as likely to have a major impact on them. This would favour modest estimates for costs and benefits, at least at the level of the individual firm or national authority. A second impediment to providing the information was that parties themselves do not appear to hold directly relevant data nor be aware of other available data sources.

The biggest uncertainties derive from the market of microbial cleaning products. No data is available on the market share of these products or the division between consumer and professional microbial cleaning products. It was also not possible to establish how many of these products are also biocides within the meaning of the Biocidal Products Regulation or how many are EU Eco-labelled. Finally, the costs calculations from the introduction of risk management requirements for these products have been based on stakeholders' reports during the interviews.

4.1.2.3 4.1.2.3 Quality

The estimates have been reviewed by different members of the team of the contractor and validated in the Detergents Working Group and the Stakeholder Workshop (see above). The best quality assurance is also provided by the transparency of the calculations which means that these are easily traceable (footnotes to tables explain the different steps for replicating these).

4.1.2.4 4.1.2.4 Baseline

The baseline is taken as the situation of the market and industry at present, without any of the policy options being implemented. Where relevant, the contractor included (a) new policy developments in other areas (such as the ongoing revision of the CLP Regulation) and (b) initiatives in the industry. The baseline has different implications for the different options analysed.

- In the case of labelling of microbial cleaning products the baseline assumes a slight growth of the market in the future.

- The evolution of refill sales is based on current market tends and the expected growth of re-fill detergents, for which the projected growth is positive and around 2% per year, leading to a steady and moderately growing sector[24].

- When analysing the impacts of abolish ingredient data sheet duplications (Option 2A and 2B), we have assumed that under the baseline, the reformulations to be taken each year will be similar to those observed at the present time.

4.2 4.2 LIMITATIONS ENCOUNTERED AND MITIGATION MEASURES FOR DIGITAL LABELLING

4.2.1 4.2.1 Limited availability of updated, EU-level, comparable quantitative data

Although, during the targeted stakeholder consultation, businesses identified specific benefits of transferring 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.). In addition, 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. To counter these issues, the study team triangulated the findings collected from the stakeholder consultation with the quantifiable estimates from the previously conducted[25] and the ongoing studies[26].

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 Full Time Equivalents (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[27], and the voluntary nature of the Policy Options.

The analysis of social impacts on workers and 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), and workers (i.e. trade unions) is not complete due to the lack of responses from such stakeholders to the survey on the policy options. Nonetheless,

[24] Idem.
[25] European Commission (2019). 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
[26] European Commission (2022). Impact assessment study on the making available and placing on the market of detergents (859/PP/GRO/IMA/20/1131/11439).
RPA Europe (2022). Technical and Scientific Support to the Commission's Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP).
[27] 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.

data triangulation and the use of other data sources (i.e. open public consultations, interviews, and behavioural experiment) countered this problem to an extent.

Likewise, the assessment of the environmental impacts lacked the input from the environmental organisations and their opinion regarding the use of digital labels to counter the waste related to the disposal of labels. 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 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 addition, since the quantification of benefits was not feasible, a qualitative approach was chosen instead when assessing the benefits under each Policy Option.

4.2.2 4.2.2 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 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. In regards to the impact on the working conditions under each Policy Option, the study relied on the responses from the industry stakeholders and lacked the input from the worker organisations (i.e. trade unions). In terms of the assessment of the environmental impacts, the study would have benefited from higher participation from the stakeholders in the environmental sector (i.e. environmentalist NGOs).

To counter this issue, other sources of data (i.e. open public consultations, 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.

4.3 4.3 DETAILED COST CALCULATIONS

4.3.1 4.3.1 Costs for compiling ingredient data sheets

Compiling and submitting a data sheet is a typical information obligation; the costs associated are thus administrative costs. As data sheets are provided only for regulatory purposes, all costs are to be considered administrative burdens.

The administrative burdens of such duplications can be calculated using an estimated amount of products re-formulated each year and the cost to produce or update a datasheet. This depends on the total products in a market and the amount of re-formulations in each year. The supporting study to the evaluation[28] estimated the amount of detergents on the market at 31,500 to 51,500, for each of the consumer and I&I market segment. This yields an average of 41,500 consumer and 41,500 professional products i.e. 83,000 detergents overall. However, this figure is based on 2016 data and apart from including the UK which was part of the EU at the time, it also includes the EEA countries. Therefore, in order to calculate the amount of products in the EU-27, we have used as a proxy the total EU population in 2016 minus the population of UK and the EEA countries.

According to Eurostat[29], the total EU population in 2016 was 510.1 million. The population of the UK was 65.3412 million and that of the three EEA countries (i.e. Norway, Iceland and Lichtenstein) was 5.5841 million[30]. The average of 83,000 detergents on the market in 2016 corresponded to 515,684,100 people (EU-27 + UK +EEA). The EU-27 population at the time was 444,758,800. Based on this, the total number of detergents in the EU is estimated at 71,584[31] i.e. 35,795 consumer and 35,795 professional (I&I) detergents respectively[32].

During the interviews industry stakeholders indicated that most detergents belong to the hazardous category, and we assume that the split between hazardous and non-hazardous is 80%-20%, in each of these two market segments[33]. This means that there are 30,426 hazardous and 5,369 non-hazardous detergents in each of the consumer and professional market segments i.e. 60,852 hazardous and 10,738 non-hazardous detergents overall in the EU market.

The total number of detergents being re-formulated every year depends on the life cycle of detergents and the frequency of re-formulation. Based on the findings of the targeted consultation, 80% of consumer products are reformulated every 2 years while the remaining 20% are reformulated every 5 years. In the I&I sector 50% of detergents are reformulated every year and the other 50% every 2.5

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[28]

[29] https://ec.europa.eu/eurostat/documents/2995521/7553787/3-08072016-AP-EN.pdf/c4374d2a-622f-4770-a287-10a09b3001b6#:~:text=at%201%20January%202016%E2%80%A6,-%E2%80%A6&text=On%201%20January%202016%2C%20the,million%20on%201%20January%202015.

[30] Iceland: 332,500; Norway: 5,214,000;Lichtenstein: 37,600

[31] This number is an estimate of products in the EU based on 2016 data. The supporting study to the evaluation estimated the amount of products in the EU+EEA in 2016 at an average of 83,000. The population of the EU-27 + UK +EEA in 2016 was used as a proxy to estimate the amount of products in the EU (for details see Annex 4).

[32] 83,000 * 444,758,800 / 515,684,100

[33] The exact number of hazardous detergents in the EU market is unknown. Industry sources have indicated that around 15% to 20% of total formulations would be non-hazardous mixtures (this would cover fabric conditioners, diluted spray and other diluted products).

years[34]. This indicates that 34,685 hazardous detergents and 6,121 non-hazardous detergents overall (i.e. both consumer and professional) are being reformulated each year. Table 1 below provides a detailed analysis of how these numbers were derived.

Table 1 number of products reformulated each year in the EU

	Hazardous		**Non-hazardous**	
	Consumer	**I&I**	**Consumer**	**I&I**
No of detergents products in the EU	30,426	30,426	5,369	5,369
Frequency reformulation	2 years (80%) 5 years (20%)	1 years (50%) 2.5 years (50%)	2 years (80%) 5 years (20%)	1 years (50%) 2.5 years (50%)
Products re-formulated / year*	13,387	21,298	2,363	3,758
Total	**34,685**		**6,121**	

* Calculated using total detergent products and frequency of reformulation.

(0.8 * 30,426) / 2 + (0.2 * 30,426) / 5 = 13,387

(0.5 * 30,426) / 1 + (0.5 * 30,426) / 2.5 = 21,298

(0.8 *5,369) / 2 + (0.2 * 5,369) / 5 = 2,363

(0.5 * 5,369) / 1 + (0.5 * 5,369) / 2.5 = 3,758

The cost per occurrence of producing an ingredient datasheet under the Regulation was previously estimated at €200[35]. The total administrative costs of compiling ingredient data sheets under the Regulation for both hazardous and non-hazardous detergents can be estimated at €8,161,200 per year i.e. €6,937,000 million for hazardous (€200 * 34,685) and €1,224,200 (€200 * 6,121) for non-hazardous detergents.

4.3.2 4.3.2 Costs of adapting the format to the CLP one

The findings of this IA show that maintaining the current format and aligning it with the harmonised format of providing information to poison centres under CLP would be of a similar magnitude. More specifically, the cost per occurrence of producing a datasheet under CLP is estimated at €220 while the costs for producing a data sheet under the Regulation at €200.

[34] In RPA (2018) it was assumed that half of the consumer products were reformulated every 2 years, whereas the other half were reformulated every 5 years (the same figures for I&I were 1 and 2.5 years). We are using an 80-20 split in the consumer's market because we believe this better reflects the actual situation of detergent products (there are very few products at present which can stay more than 5 years without a change in the formulation). Our assessment is based on different messages from the interviews and our own experience.

[35] Whiting R, Gibbard J. 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), 2015. https://ec.europa.eu/docsroom/documents/14006/attachments/1/translations.

As described above, there is a total of 6,121 non-hazardous detergents each year for which an ingredient data sheet would need to be produced. The additional one-off costs to the industry from aligning the format to the CLP one would therefore be €1,346,620 (€220 * 6,121) and are, consequently, considered negligible. These costs would be further mitigated given that a transition period of 18 months would be allowed. Taking into account the €20 difference between compiling an ingredient data sheet in accordance with CLP compared to the same costs under the Regulation (i.e. €220 - €200) and the total number of non-hazardous detergents per year i.e. 6,121 (see above), in the long term the annual incremental costs to the industry from aligning the format to the CLP one would be €122,420.

4.3.3 4.3.3 Costs for microbial cleaning products – testing

Based on reports from manufacturers of microbial cleaning products during the interviews, the test for antibiotic resistance exclusion for "known" microbes has been estimated as negligible (in values that range between €0 and €335 for each strain of "known" microbes). In cases where the assessment has already been performed by the European Committee on Antimicrobial Susceptibility Testing (EUCAST), resistance exclusion can be easily confirmed at no cost (after a simple search by a technician/ officer). In cases where the assessment has not been previously, the costs of undertaking a separate assessment have been estimated between €200 and €335. This includes genome sequencing of the new species and bioinformatics analysis to identify presence of genes of resistance (costs between €150, and €260); it also includes antibiogram and in vitro tests to confirm or mitigate any risk found (costs between €50 and €75).

Based on stakeholders reports during the interviews the costs related to the pathogens exclusion are estimated at €200 per batch of product produced. Based on reports from two out of the four consulted manufacturers of microbial cleaning products during the interviews conducted under the IA supporting study for this initiative, the number of annual batches can vary from 500 - 1000 depending on the size company. Taking the higher number of batches reported i.e.1000 per year as the basis of our calculations, the total additional on-going adjustment costs amount to €200,000 per company per year.

It was not possible to quantify the costs related to the test methods for proving that microbial cleaning products are safe for respiratory exposure since these would need to be determined later on. **A manufacturer of microbial cleaning products** with almost 80% of the company's portfolio sold in a spray format **mentioned during the interviews** as part of the supporting study that these costs would be acceptable. The same manufacturer provided an estimate of a one-off cost of €5000 per strain or blend of strains used in these products based on respiratory exposure tests already conducted by this company.

4.3.4 4.3.4 Cost savings as a result of reduced plastic waste (refill sales)

The market share of refill detergents has been estimated a 1% - 2% of the total market for detergents. Given the uncertainty in the exact market share and following a cautious to calculate potential cost savings from reduced plastic waste as a result of refill sales, the lower bound estimate i.e. 1% is being used as the basis for the calculation. Given that total detergent sales constitute around €20-21 billion, this implies total refill sales are about €0.2 billion. Assuming an average price of EUR 2 for a 500ml bottle of detergent, this would correspond to about 100 million refillable 500ml bottles. An average 500ml plastic bottle weighs around 33g. Hence, 100 million 500ml bottles constitutes 33,000 tonnes of

plastic. The cost of disposal of a tonne of plastic is roughly €100. Therefore the savings from not disposing an additional 33,000 tonnes of plastic due to refill, would be €3.3 million.

Should the Detergents Regulation not keep up with developments in the market, such that eventually new market practices might be curtailed altogether, there would therefore be a risk of losing this €3.3 million if refill was unintentionally driven out. As a minimum, the clarification and facilitation of refill therefore defends this €3.3 million in value.

Annex 5 ANNEX 5 OVERVIEW OF THE DETERGENTS REGULATION AND THE LEGAL CONTEXT OF DIGITAL LABELLING

5.1 5.1 OVERVIEW OF THE REGULATION

5.1.1 5.1.1 Description of the Regulation

The Detergents Regulation establishes rules for 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[36]. The Regulation requires that only surfactants meeting the criterion of ultimate biodegradability be placed on the market either on their own (e.g. as constituent mixtures used for the manufacturing of detergents) or contained in detergents. In addition, detergent labels must contain ingredient and dosage information[37]. This is on the one hand to protect the health of consumers and on the other to avoid over-consumption of detergents thereby reducing the total amount of detergent and surfactant entering the environment.

As a regulation, it is directly applicable in all EU Member States and it's also applicable to the countries of the European Economic Area (i.e. Norway, Iceland and Lichtenstein). Since its entry into force in March 2004, the Detergents Regulation has been amended:

- to introduce an additional biodegradability test method for surfactants poorly soluble in water and more stringent requirements for the labelling of allergenic fragrances[38];
- to be adapted[39] to the CLP Regulation[40];
- to be adapted[41] to the regulatory procedure with scrutiny;
- to introduce a surfactant derogation by amending Annexes V and VI to the Regulation[42]; and
- to introduce restrictions on the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents[43].

[36] Article 1(1) of the Detergents Regulation.
[37] Article 11 and Annex VII to the Detergents Regulation.
[38] Regulation (EC) No 907/2006 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 Annexes III and VII thereto.
[39] 7 Regulation (EC) No 1336/2008 Regulation (EC) No 1336/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation (EC) No 648/2004 in order to adapt it to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
[40] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
[41] Regulation (EC) No 219/2009 Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two.
[42] Commission Regulation (EC) No 551/2009 of 25 June 2009 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes V and VI thereto (surfactant derogation).
[43] Regulation (EU) No 259/2012 Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents.

5.1.2 5.1.2 Evolution and objectives

Setting legal requirements for detergents in the EU dates back to the early 1970s. Detergents were then falling under the scope of a Council Directive[44] that covered many types of detergents (anionic, cationic, non-ionic and ampholytic). This Directive prohibited the marketing of any of these detergents where the average level of biodegradability of the surfactants was less than 90%. It also stipulated that the use of those surfactants with an average level of biodegradability of 90% or more should not be harmful to human or animal health. No other constituents such as phosphates in detergents were covered at the time.

The Directive by itself was largely unenforceable since it did not specify any testing methods. Testing methods for anionic and non-ionic surfactants were outlined in subsequent 7 implementing directives[45]. The latter only dealt with anionic and non-ionic surfactants and required the biodegradability of surfactants to be no less than 80%, the assumption apparently being that if this level were obtained on every test, then the average level of 90% required by the above mentioned Council Directive would also be obtained. Implementing directives in relation to cationic and ampholytic surfactants were never agreed.

- The Detergents Regulation repealed the above mentioned Directives, consolidated and updated their provisions and extended the scope of the pre-existing legislation: Pre-existing EU legislation on detergents only covered two categories of surfactant. The scope of the Detergents Regulation is now covering all types of surfactants.
- While previous legislation only covered the 'primary biodegradability' of surfactants in detergents, the Detergents Regulation imposes a two-tier testing regime on the biodegradability of surfactants in detergents with the main emphasis on "ultimate biodegradability".
- The Regulation introduces for the first time in the EU limitations on the content of phosphates and other phosphorus compounds, in particular in consumer laundry detergents and consumer automatic dishwasher detergents ('CADD').

5.1.3 5.1.3 Overview of the key provisions of the Detergents Regulation and explanation of the intervention logic

The Detergents Regulation provides key provisions and harmonises rules that ensure the free movement of detergents and surfactants for detergents in the internal market while at the same time protecting the environment and human health. To achieve these objectives the Detergents Regulation employs several mechanisms described below:

5.1.3.1 5.1.3.1 Free movement of detergents and surfactants for detergents

The Detergents Regulation ensures the free movement of detergents and surfactants for detergents in the internal market by harmonising the rules and the conditions under which manufacturers can place

[44] Council Directive of 22 November 1973 (73/404/EEC) on the approximation of the laws of the Member States relating to detergents

[45] Directive 73/405/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of anionic surfactants, amended by Directive 82/243/EEC and Directive 82/242/EEC

their products on the market. These rules apply to both consumer detergents (detergents sold to the general public) and to industrial or institutional detergents (detergents sold for professional use).

In particular, the Detergents Regulation harmonises the following rules for detergents and surfactants of detergents:

- limitations on the content of phosphorus and phosphorus compounds in consumer laundry and CADD;
- labelling requirements for detergents;
- specific biodegradability criteria that detergents and surfactants for detergents need to comply with;
- restrictions or bans on surfactants on grounds of biodegradability; and
- the information that manufacturers must hold at the disposal of designated public bodies and medical personnel (ingredient data sheet).

The harmonisation of these rules prevents the fragmentation of the internal market by divergent national rules. The intra-EU trade becomes easier as manufacturers only need to comply with one set of rules, i.e. those of the Detergents Regulation in order to sell their products across the EU.

Member States cannot prohibit or restrict detergents or surfactants for detergents meeting the requirements of the Detergents Regulation from being sold in their territory. Therefore compliant detergents move freely in the EU without any additional obligations for their manufacturers.

5.1.3.2 5.1.3.2 Protection of the environment

One of the main environmental protection requirements of the Detergents Regulation relates to the biodegradability of surfactants and detergents containing surfactants. Surfactants are surface-active agents that help break down the interface between water and oils and/or dirt. They are one of the two main ingredients used in detergents[46].The Detergents Regulation allows only surfactants meeting the criterion of ultimate biodegradability to be placed on the market either on their own (e.g. as constituent mixtures used for the manufacturing of detergents) or contained in detergents. Manufacturers of detergents and surfactants for detergents can demonstrate compliance with these requirements by using one of the biodegradability test methods provided in the Regulation.

Ultimate biodegradability is defined as the level of biodegradation achieved when the surfactant is totally broken down into carbon dioxide (CO2), water and biomass. By contrast, primary biodegradability only results in the loss of the surface-active properties due to the biodegradation of the parent substance (i.e. the surfactant). Primary biodegradability is providing thus less environmental protection compared to when the ultimate biodegradability criteria are met. Surfactants that do not meet the criterion of ultimate biodegradability are in principle not allowed to be placed on the market. However, manufacturers of industrial and institutional detergents may ask for a derogation if certain conditions are met (Articles 4, 5 and 6 of the Detergents Regulation).

[46] The second one is builders. Builders are added to protect and upgrade the efficiency of surfactants.

Limitations on the content of phosphates and other phosphorus compounds in consumer laundry (from 30 June 2013) and consumer automatic dishwasher detergents (from 1 January 2017) is another means by which the Regulation envisages to reduce the environmental impact of detergents. Less phosphorus in detergents means that less phosphorus is released into the environment when detergents are washed down the drain. As phosphorus is known to contribute to a phenomenon called eutrophication (for more information please see Section 4.3.1.2B.), the harmonised limits were introduced in 2012[47] in order to lower the amount of phosphorus used in detergents and thus reduce the damage that phosphates from detergents may have on ecosystems and aquatic environments.

Information on the correct amount of detergent that consumers need to use when undertaking cleaning activities (i.e. dosage information) is required to be included on the label of consumer laundry and consumer automatic dishwasher detergents. Dosage information aims to prevent the potential over-use of detergents by consumers thus reducing the total amount of detergent and surfactant entering the environment.

5.1.3.3 5.1.3.3 Protection of human health

The labelling of detergents falls by default under two pieces of EU legislation: the Detergents Regulation and the CLP Regulation. Substances that are classified as hazardous from either a human health or an environmental endpoint and fulfilling the labelling requirements set in the CLP Regulation need to be included in detergents' labels. In addition to this information, specific labelling requirements for detergents are also included in the Detergents Regulation.

The labelling requirements of the Detergents Regulation serve as a means of protecting human health. This is because labels communicate important use and safety information to consumers, such as the presence of allergenic fragrances in detergents. By providing information on the content of allergenic fragrances on detergents' labels, consumers with allergies or allergic predispositions are allowed to make informed choices and potential reactions related to the use of detergents are therefore reduced.

Another measure for protecting human health is the requirement for manufacturers to provide, upon request, information on the content of detergents to medical personnel and, where available, to designated public bodies responsible for transmitting this information to medical personnel. The latter are thus informed of all the ingredients contained in detergents and are able to provide the necessary treatment in cases of allergic reactions or incidents of poisoning related to detergents.

To ensure that information concerning detergent composition is readily available to the general public the Detergents Regulation also requires manufacturers to provide an ingredient data sheet online. The website where consumers can find this ingredient data sheet should also be indicated on the detergents' labels.

[47] Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0259

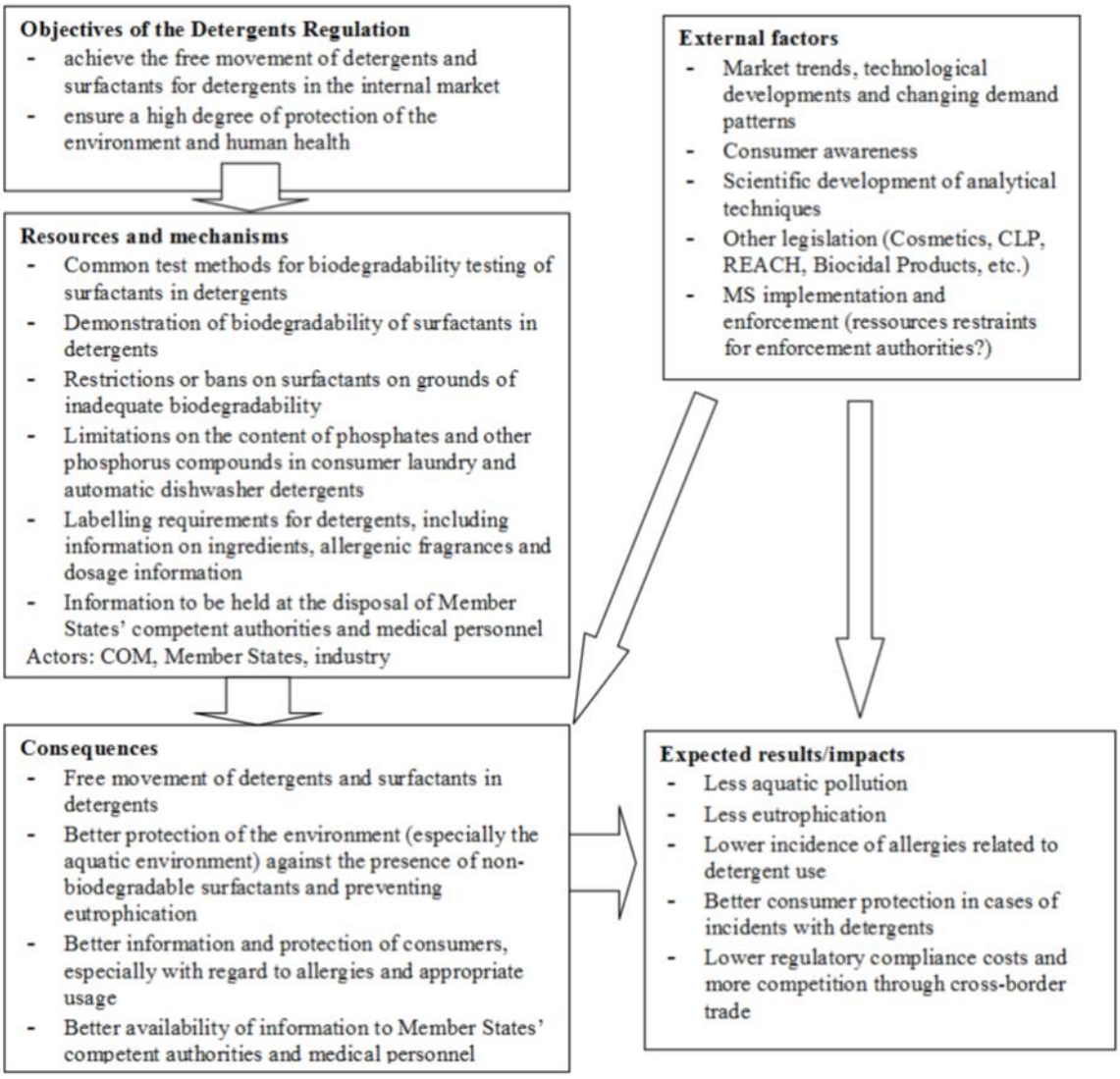
5.1.3.4 5.1.3.4 Obligations of manufacturers and Member States' duties

The Detergents Regulation lays down the specific obligations of manufacturers of detergents and surfactants for detergents. The Regulation also stipulates the measures that Member States shall take in order to enforce the Regulation. In particular:

- Manufacturers must make available to the Member States' competent authorities a technical file on results of the tests described in Annexes II, III and IV to the Detergents Regulation (related to the testing of biodegradability and the complementary risk assessment for surfactants in detergents)
- National authorities may withdraw a compliant detergent product from the market if they consider that it presents a risk to human or animal health or to the environment. They must inform the European Commission and other Member States of their decision (safeguard clause); and
- Member States are required to lay down rules on penalties applicable to infringements of the Regulation and shall take all measures necessary to ensure that they are implemented. These penalties must be effective, proportionate and dissuasive.

Figure 1 below provides the intervention logic diagram for the Detergents Regulation. It summarises the objectives of the Detergents Regulation, the mechanisms, as well as the anticipated consequences and results/impacts.

Figure 1 Intervention logic



5.2 5.2 LEGAL ANALYSIS

This part provides a summary of existing labelling requirements under Classification, Labelling and Packaging Regulation (hereafter 'the CLP') and Detergents Regulations, including labelling examples and the identification of duplications and legislative overlaps between different pieces of EU legislation.[48]

The analysis of the relevant regulation, in conjunction with the exchanges incurred with the Commission, served as a basis to define a "baseline"[49] to be used in the behavioural experiment.

[48] CLP, Detergents Regulation, Cosmetic Products Regulation and Biocidal Products Regulation.

[49] 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.

5.2.1 5.2.1 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))[50]. 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 the 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 are "Hazardous to the aquatic environment" and "Hazardous to the ozone layer" classifications.[51]

The CLP is the primary basis for identifying hazards, and providing hazard classification for EU legislation as well as labelling and other risk and hazard communication measures. The aim of the CLP is that consumers[52], industrial[53] and professional users[54] 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[55] (e.g.,

[50] '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.'

[51] 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.

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

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

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

[55] 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.

fragrance allergens, enzymes, disinfectants, optical 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).[56] 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 the CLP. Where the detergent has a **biocidal function[57] or contains a preservation agent**, the packaging must also contain labelling information as required by the **Biocidal Products Regulation (BPR)[58]**. In addition, the Detergents Regulation makes reference to the Cosmetics Products Regulation (CPR)[59] for the labelling of **allergenic fragrances[60]**.

5.2.1.1 5.2.1.1 Labelling elements under the 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:

a) identification and contact details of the supplier(s);

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

c) the product identifier.

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

- hazard pictograms;
- signal words;
- precautionary statement; and

[56] 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

[57] 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

[58] 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

[59] 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

[60] 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.

- a section for supplemental information:
    - *obligatory:* information which comprise of hazard statements provided for in other parts of the CLP [61] 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 the 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[62]), 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 United Nations Globally Harmonised System (UN GHS) and lays down the use of the hazard statements, precautionary statements, and pictograms. The CLP also includes the use of the two UN GHS signal words "Danger" and "Warning" to indicate the severity of a hazard.

Section 1.2 of Annex I to the 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 2 Minimum dimensions of labels and pictograms under the CLP Regulation[63]

Capacity of the package	Dimensions of the label (in millimetres) for the information required by the 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

[61] 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.
[62] 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.
[63] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.

The CLP requires that the label elements as referred to in Article 17(1) be of such size and spacing as to be easily read[64]. Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background[65].

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[66]. 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[67].

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 (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 the 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[68]. 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 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**

[64] 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.
[65] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.
[66] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021, p.45.
[67] Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008, Version 4.2, March 2021.
68 CLP, Article 18 (3).

preservatives required by Regulation (EC) No 648/2004 on detergents, it is advisable to use the same name[69].

Article 32 of the 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 (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.

Table 3 The CLP Regulation 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 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 the CLP.
Any supplemental information as referred to in Article 25 must be included in the section for	The supplier may choose how to visibly separate this section from the section containing the label elements referred to in Article 17(1)(a)-(g). He

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

CLP requirement (Article 32)	Example of decision left to the discretion of the supplier
supplemental labelling and placed alongside the label elements referred to in Article 17(1)(a)–(g).	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.

5.2.1.2 5.2.1.2 Principles of precedence

5.2.1.2.1 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 (Article 26). As a general rule, the label must include those **pictograms** which indicate **the most severe hazard category of each hazard class**. This would also apply in case a substance has both harmonised[70] and non-harmonised[71] classifications (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 the 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").

5.2.1.2.2 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 (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.

5.2.1.2.3 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,

[70] Harmonised classification applies to substances only.

[71] 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.

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 disposal of the substance or mixture, as well as the disposal of the packaging (Article 28).

i) 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 required and regulated under REACH[72]. 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 the 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 (Article 29(3), Part 5 of Annex II to the CLP).

ii) Small packages where the contents do not exceed 125 ml

Article 29(1) and section 1.5.1 of Annex I to the 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 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 the 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)

[72] 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.

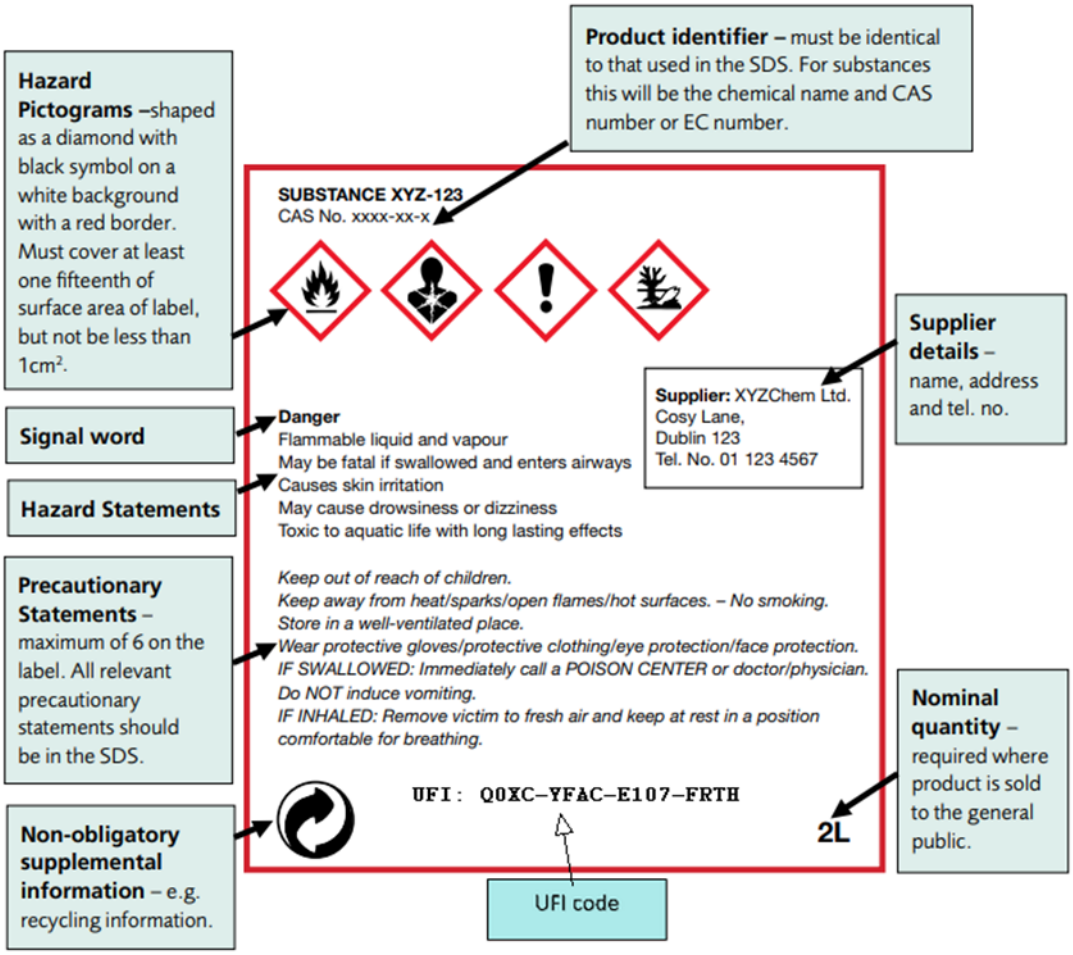
or 1.5.2.1.3 (b); and 3) **the soluble packaging** is contained within outer packaging that fully meets the requirements of Article 17.

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.

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

Figure 2 Example of Hazard Label for Supply[73]

(UFI: Unique Formula Identifier)



[73] 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

5.2.1.3 5.2.1.3 Labelling of Detergents

The labelling of detergents follows three separate regulations: Detergents Regulation 648/2004, the 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 the CLP Regulation and the labelling requirements of Detergents Regulations. The **CLP Regulation** refers to a **label on the packaging**, while **Detergents Regulation** refers to **information** that has to appear **on the packaging**[74]. 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:

- 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[75].

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[76];
    - 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)[77];
    - the indication of instructions for use and special precautions;
    - dosage instructions[78];

[74] 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
[75] For detergents disinfectants and detergents that are also treated articles and which fulfil the labelling requirements of BPR.
[76] Detergents Regulation, Article 11.
[77] 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.
[78] 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.

- website of the manufacturer where the ingredient datasheet is available[79].

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[80]. 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[81]. In addition, there are voluntary icons and tips providing information to consumers how to clean more sustainably saving water, energy, CO_2 and money.[82]

The Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 – March 2021)[83] provides an example of a single language label for a mixture 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 the CLP Regulation and the obligatory supplemental information, in accordance with Detergents Regulation. The supplemental labelling information according to the CLP Regulation 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 Regulation[84]. 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.

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[79] "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

[80] https://www.aise.eu/documents/document/20140129161815-final_draft_aise_safe_use_guidelines_revjan2014.pdf

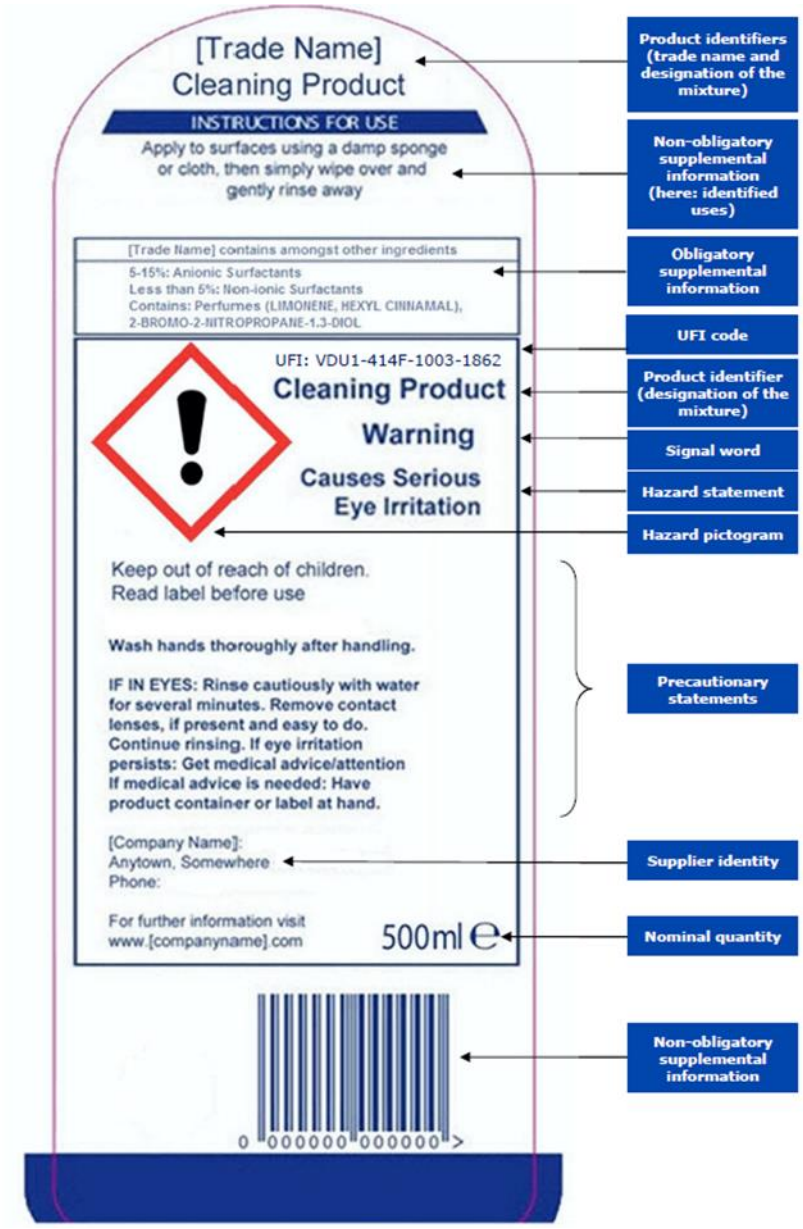
[81] https://www.cleanright.eu/en/safe-use.html#safe-use

[82] Such examples can be found at https://www.cleanright.eu/en/sustainable-use.html

[83] https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf

[84] 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).

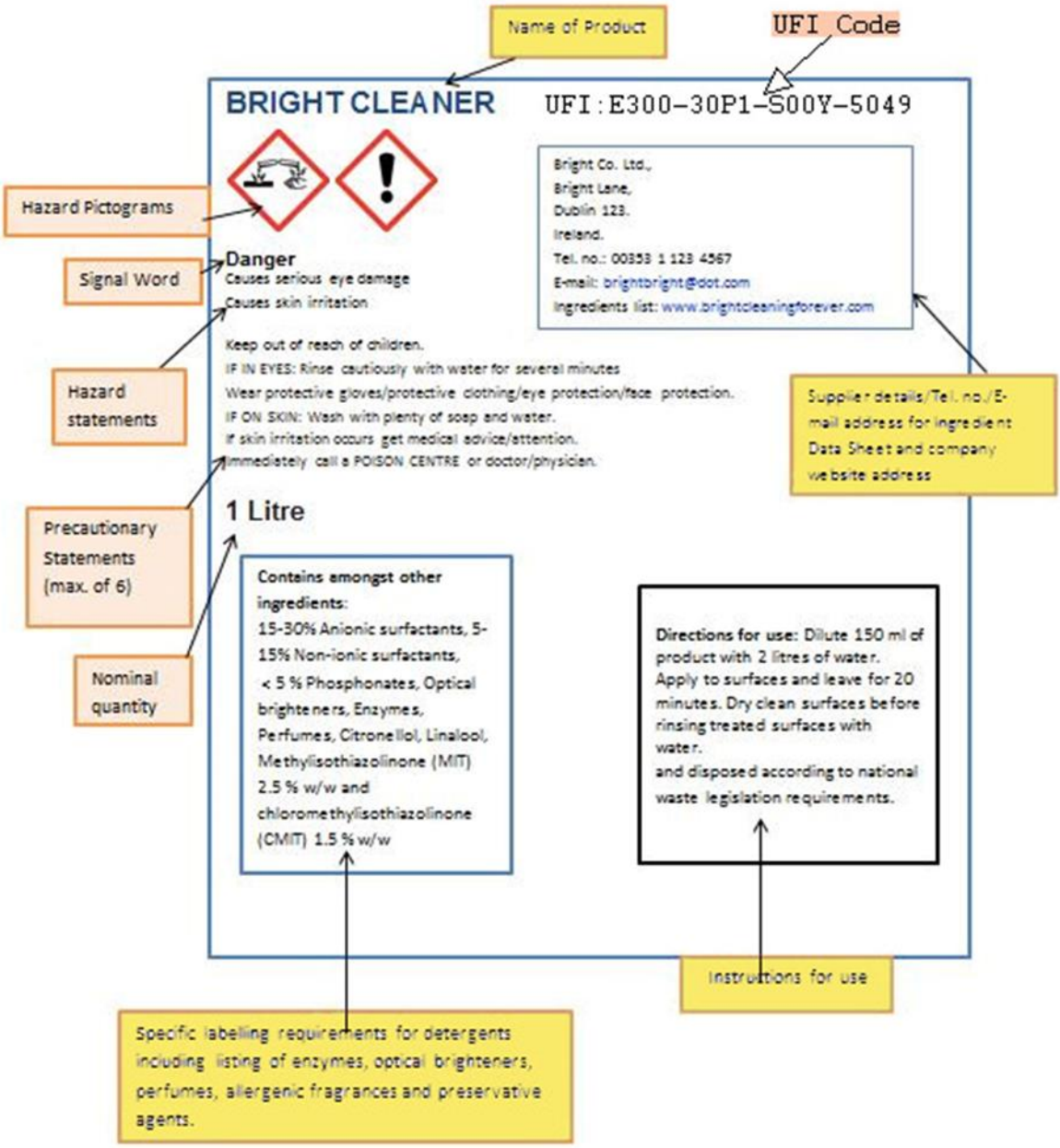
Figure 3 Example of detergent label. Hazard class "Eye Irritation"[85]



The below figure presents an example of the regulatory requirements according to the **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 detergents under the CLP Regulation, while the text in the yellow boxes relates to information requirements under Detergents Regulation.

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

Figure 4 Example of detergent label. Hazard class "Serious eye damage/skin irritation"[86]



5.2.1.4 5.2.1.4 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 preservative[87] (treated articles), both subject to different definitions and different labelling provisions.

[86] https://www.hsa.ie/eng/Your_Industry/Chemicals/Legislation_Enforcement/Detergents/Detergent_Labelling_Packaging_requirements/

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

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[88] (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":

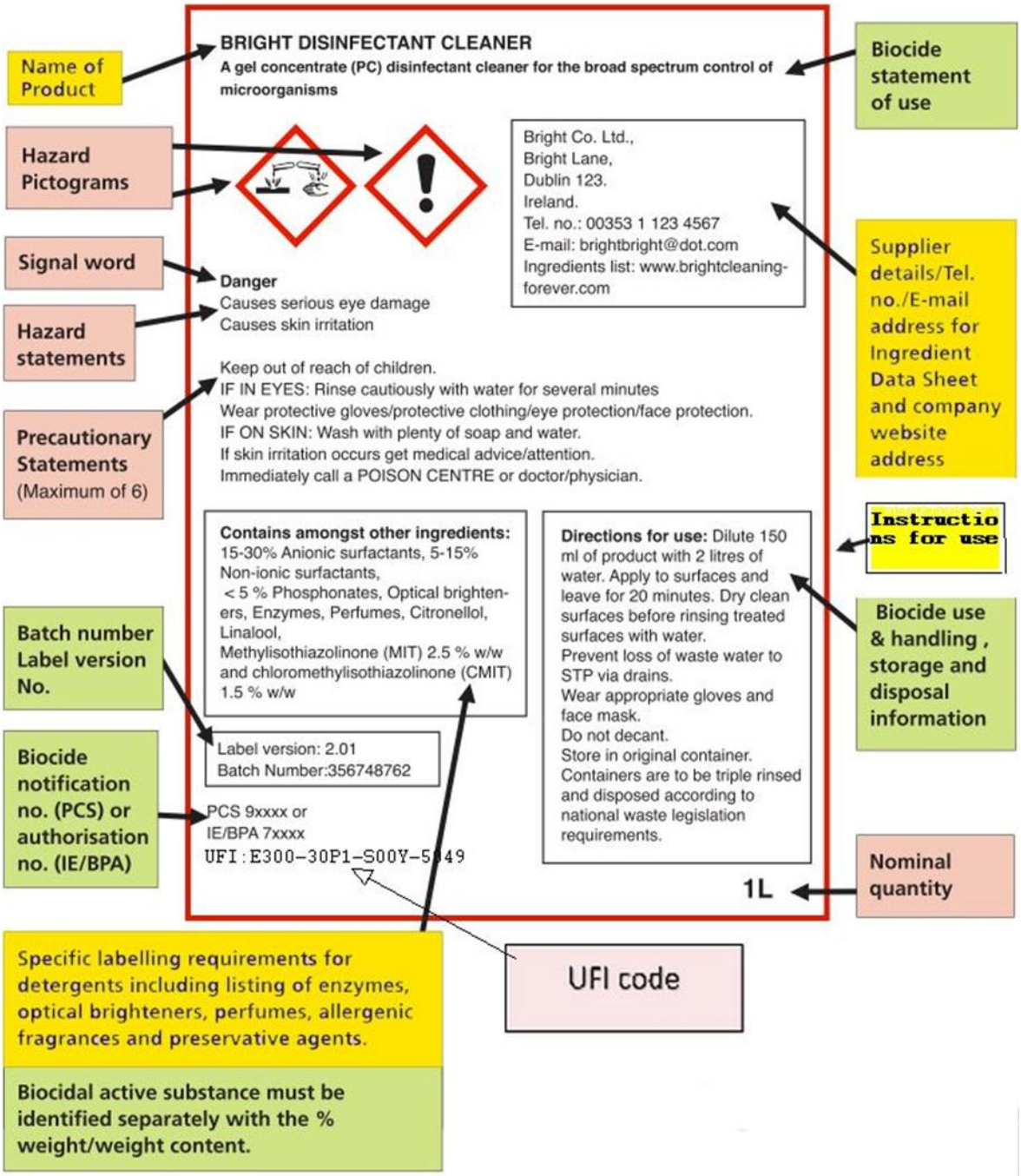
- the name(s) of the biocidal active ingredient(s) and its concentration in the product[89];
- the notification or approval number (e.g., PCS 9xxxx or IE/BPA 7xxxx)[90]. Only notified or approved biocides have such a number;
- the type of product formulation[91];
- what the product is approved for[92];
- the formulation batch number or designation and the expiry date relevant to normal conditions of storage[93];
- details of any restricted users i.e., for general public or professional/industrial use only[94];
- instructions on handling, storage, application, use and disposal of the biocide[95];
- 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[96].

[88] 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.
[89] BPR, Article 69 (2) (a) the identity of every active substance and its concentration in metric units;
[90] BPR, Article 69 (2) (c) the authorisation number allocated to the biocidal product by the competent authority or the Commission;
[91] BPR, Article 69 (2) (e) the type of formulation;
[92] BPR, Article 69 (2) (f) the uses for which the biocidal product is authorised;
[93] BPR, Article 62 (2) (k);
[94] BPR, Article 69 (2) (m) where applicable, the categories of users to which the biocidal product is restricted;
[95] BPR, Article 69 (2) (g), (j).
[96] BPR, Article 69 (2) (l).

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

Figure 5 Example of the information that must be contained on a Detergent package containing a Biocide[97]

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



A laundry liquid detergent formulated with an in-can preservative[98] **having a preserving function[99] in the final product** is an example of a detergent that is also a treated article in accordance with BPR.

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

[99] 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[100], 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 the CLP Regulation, the provisions of BPR Article 58(3) should apply[101]. 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[102]. 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);[103]
- 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 brackets104;
- 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[105].

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

5.2.2 5.2.2 Identified overlaps, duplications, and inconsistencies

The legal analysis shows a difference in the terminology regarding the hazard communication in form of labelling between the CLP Regulation 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 the CLP Regulation 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 Regulation, i.e., they come in addition to CLP requirements. For example, where applicable[106], the section containing the labelling elements dedicated to the CLP Regulation 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 the CLP Regulation (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 regulations complement each other in the sense that both Regulations aim to protect the health of consumers, industrial and professional users [107]. If a substance is regulated or presents a hazard, then there are standard phrases under the CLP Regulation 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[108]. For mixtures (such as detergents, paints, and household chemicals) subject to submission requirements under Article 45 and Annex VIII to the CLP Regulation, 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 Regulation.

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

[107] 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

[108] 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).

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[109] reveals some legislative overlaps between the Detergents Regulation and the CLP Regulation with regard to the labelling of allergenic fragrances. Other overlaps also exist e.g., on the labelling of surfactants[110] and allergenic preservatives when the CLP thresholds are met.

Under the CLP Regulation, 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[111] 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[112] 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")[113].

In parallel, the CLP Regulation requires the inclusion of skin sensitisers[114] (i.e., allergenic substances like preservatives and fragrances) in the list of ingredients that need to figure on the product label when

[109] 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

[110] 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.

[111] 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).

[112] 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

[113] 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.

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

they are present above certain thresholds.[115] These thresholds are different from the thresholds provided in the Detergents Regulation. As most allergenic fragrance ingredients under the Cosmetic Products Regulation are also classified as skin sensitisers under the CLP Regulation this may lead to the labelling of the same substance twice, once following the Detergents Regulation and once following the CLP Regulation.

In addition to the different thresholds for the labelling of allergenic fragrances between the Detergents Regulation and the CLP Regulation 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** Regulation requires that substances are **labelled with either the name and identification number** given in Part 3 of Annex VI to the CLP Regulation[116] 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[117] number together with its IUPAC[118] 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[119].
- 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 Regulation requires that a EUH208 statement[120] 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 6 Example of dual labelling of ingredients.

[115] 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).
[116] Part 3 of Annex VI to the CLP provides a table on the harmonised classification and labelling of hazardous substances.
[117] 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.
[118] 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).
[119] The EC number, i.e., EINECS, ELINCS or NLP, is the official number of the substance within the European Union.
[120] EUH 208 'Contains (name of sensitising substance). May produce an allergic reaction'.

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

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 Regulation 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 Regulation (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 the CLP and Detergents regulations[121].

Figure 7 Typical Detergent Label and a Highlight of the Duplication and Inconsistency

[121] 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.),

CLP INFORMATION

ALLERGENS

(fragrances and preservatives):

- Inconsistencies between CLP and Detergent Regulation lists

DETERGENT REGULATION INFORMATION

SURFACTANTS

- Only ingredients triggering classification (CLP)
- Cited per family and percentage range (Detergent Regulation)

Annex 6 ANNEX 6 ECONOMIC CONTEXT

This section contains an updated analysis of the European detergents market, covering the main figures and trends for consumers and business users. The review of the sector follows the approach of the Evaluation and uses desk research, sourcing most up-to-date data from main available public sources.

The EU27 is the second largest chemical producer in the world (behind China), with sales of €499 billion in 2020 and a global share of 14.4%.[122] Production of chemicals is one of the most important industrial sectors in Europe and accounted for around 7% of the value of manufacturing production in 2018,[123] the fourth largest manufacturing sector by value behind Motor Vehicles (13%), Food Products (12%), and Machinery and Equipment (10%). The detergents industry is an important sub-sector of the European Chemicals industry, accounting for approximately 4.2% of the production value of the total Chemicals sector in 2018.[124]

There is no classification that encompasses manufacture of detergents as per the category defined in DETREG.[125] However, Eurostat contains relevant data for an approximate classification and this corresponds to NACE 20.41 "Manufacture of soap and detergents, cleaning and polishing preparations". This class includes manufacture of substances[126] all of which are included in DETREG, but it also contains glycerol and manufacture of cleaning and polishing products[127] which are out of the scope of DETREG. Given the small share the latter represent in the total category, this is still a relevant code to characterise the market of detergents (it is consistent with the NACE category used in previous studies).

Total production of detergents in Europe can be established at approximately €20-21 billion in 2018,[128] according to Eurostat. The recent evolution shows some growth in the period 2014-2016, but levels have fallen sharply in recent years with production in 2017 and 2018 appearing to be lower than five years ago.

Table 4: Total Production Value: EU-27, 2014-2018[129]

[122] CEFIC 'Facts and Figures 2021' (2022). https://cefic.org/app/uploads/2022/01/Leaflet-FactsFigures_interactif_V02.pdf

[123] Eurostat 2018; based on EU-27, total value of manufacturing production.

[124] Eurostat 2018, based on EU-27

[125] In DETREG, detergents are defined as substances or mixtures containing soaps or other surfactants intended for washing and cleaning processes, in any form (liquid, powder, paste) for household, or institutional or industrial purposes. Detergents also include, for the purposes of the regulation, other products intended for pre-washing, rinsing or bleaching clothes, softeners, cleaning mixtures intended for cleaning of surfaces and "other cleaning and washing mixtures". A product falls within the scope of the Detergents Regulation pursuant to its purpose (cleaning function or not) and not its composition (see Chapter 4 and Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/ 2004 on detergents).

[126] Organic surface-active agents, paper (wadding, felt etc.) coated or covered with soap or detergent, soap, and surface-active preparations (washing powders, dish-washing preparations and textile softeners).

[127] For perfuming or deodorising rooms, artificial waxes and prepared waxes, polishes and creams for leather, for wood for coachwork, glass and metal and scouring pastes and powders.

[128] Eurostat data for 2018 excludes seven countries (Czech Republic, Ireland, Luxembourg, Malta, Netherlands, Slovakia and Slovenia). In 2017, production in these seven countries amounted to circa €1025 million. Therefore an estimated value of total sales for 2018 in EU-27 is circa €21 billion, which represents a 6% increase on sales in 2017.

[129] 2018 is latest Eurostat data as of September 2021. Eurostat data is ex-works value, while AISE is consumption spending purchased through retail.

Year	Million €	% change year on year
2014	22,416	+ 5
2015	22,663	+ 1
2016	23,039	+ 2
2017	19,855	-14
2018	20,089 *	+ 1

Note: * 2018 total excludes Czech Republic, Ireland, Luxembourg, Malta, Netherlands, Slovakia and Slovenia due to lack of availability of data. Source: Eurostat SBS_NA_IND_R2. NACE Rev 2 Code 2041 – Manufacturing of Soaps and Detergents, Cleaning and Polishing Preparations.

Despite some common features, the industry is by no means homogeneous. The main features of this industry are:

- Geographical concentration of production in five countries.
- Large number of enterprises but concentration in production.
- Growing Intra-EU Trade
- Differences in types of surfactants used.
- Two distinct sectors: Household Care and Professional Cleaning and Hygiene.
- Innovation.
- Customer Satisfaction.
- Value Chain and Socio-Economic Impacts.

6.1 6.1 GEOGRAPHICAL CONCENTRATION OF PRODUCTION IN FIVE COUNTRIES

The production of detergents in Europe is concentrated in 5 main producing countries: Germany, Italy, Spain, France, and Poland are the largest producers of detergents, accumulating a total of €17 billion, (around 85% of total European production). However, there are significant differences between the situations in these six countries: Germany is the largest producer, with a 42% share of total production. This is more than twice as large as production in Italy, the next biggest producer.

Table 5: Production Value (€ Million): EU-27, 2018 Top Five Producers

	Production (€ Million)	% share of Production
Germany	8,526	42

Italy	3,082	15
Spain	2,765	14
France	1,337	7
Poland	1,319	7
Other	3,061	15
Total	20,089	100

6.2 6.2 MARKET PLAYERS: LARGE NUMBER OF SMALL ENTERPRISES. PRODUCTION CONCENTRATED IN LARGE ENTERPRISES

The manufacturing of products for the whole market (Care and Professional Cleaning and Hygiene industry) involves around 700 separate facilities throughout Europe.[130]

The vast majority of sites (more than 85%) are operated by SMEs. However, in terms of volume the picture is very different, as output is concentrated into 80-90 large-scale plants, operated by multi-national companies. These are characterised as being large, modern, high productivity, capital-intensive facilities, concentrated in the large-producing countries (Germany, Italy, Spain, France, and Poland) and the Benelux.

Many of these large facilities supply multiple national markets across Europe, increasingly specialising in particular product categories. In contrast, SMEs mostly operate in national markets, supplying national, rather than global brands, and focusing on serving particular market niches (most notably in the Professional Cleaning and Hygiene market).

As many as 3,877 enterprises are involved in activities connected with the manufacture of soaps, detergents, cleaning, or polishes in the Europe, a figure that has seen a significant increase (7%) in 2018. The largest concentrations are in Spain (599 enterprises), France (508), Italy (440), Poland (385), and Germany (384).

The sector contains more enterprises than production facilities as not all enterprises manufacture products themselves: some will be subsidiaries of multinational companies with centralised production, others will be distributors or companies offering technical support, for example.

Table 6: EU-27 Number of Companies in the Sector 2014-2018

	Number of enterprises	**% change year on year**

[130] Figures from AISE 2016 data based on EU-27 plus UK, Norway and Switzerland, see Huggard Consulting Group," The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-economic Analysis" (2016).

2014	3,671	-
2015	3,654	0
2016	3,676	+ 1
2017	3,634	-1
2018	3,877	+ 7

NACE Rev 2 Code 2041 – Manufacturing of Soaps and Detergents, Cleaning and Polishing Preparations. Source: Eurostat SBS_NA_IND_R2 2014-2018.

Eurostat does not provide data broken down by enterprise size for the detergents sector but there are data at a higher level of disaggregation (NACE Rev 2 Code 204 "Manufacturing of Soaps and Detergents, Cleaning and Polishing Preparations, Perfumes and Toilet Preparations"). Taking these as a proxy of the detergents industry, we can gain an insight into the size composition for the sector: in 2018, 7,568 enterprises in the sector were micro-enterprises (less than 10 employees), this is 78% of total enterprises. However, in terms of turnover the picture is very different: large enterprises (more than 250 employees) account for €39 billion of the total €62 billion produced, this is more than 60% of industry turnover.

Table 7: Number of Companies in the Sector and Turnover by Size EU-27

	Number of enterprises	**Turnover (€ Million)**
0-9 employees	7,568	1,827
10-19 employees	793	1,877
20-49 employees	617	3,197
50-249 employees	609	16,255
250 + employees	178	38,507
Total	9,765	61,663

Source: Eurostat SBS_SC_IND_R2 2018. NACE Rev 2 Code 204 "Manufacturing of Soaps and Detergents, Cleaning and Polishing Preparations, Perfumes and Toilet Preparations".

6.3 6.3 GROWING INTRA-EU TRADE

One of the primary goals of the Detergents Regulation is to ensure the free movement of detergents and surfactants (for use in detergents) within the EU Internal Market. To this end, the Detergents Regulation harmonises the rules for placing detergents and surfactants on the market throughout the EU-27.

Levels of intra-EU trade have increased substantially since the Detergents Regulation was introduced in 2005. Looking at intra-EU trade in products that most closely approximate to those covered by the Detergents Regulation, intra-EU trade in both imports and exports have increased by 99% in the period 2005 to 2020. This is the equivalent of just under 5% per annum CAGR.

Table 8: Intra EU Trade (EU-27): Products Relevant to Detergents Regulation (Soap, Cleansing and Polishing Preparations (excluding soap for Personal Use)

Year	**Intra-EU Imports** **Euro Million**	**Intra-EU Exports** **Euro Million**
2002	5,648	5,775
2003	5,957	6,020
2004	5,909	6,018
2005	6,370	6,406
2006	6,983	6,966
2007	7,330	7,460
2008	7,787	7,747
2009	7,506	7,490
2010	8,020	8,083
2011	8,801	8,798
2012	8,782	8,796
2013	9,020	9,067
2014	9,502	9,467
2015	9,813	9,912
2016	10,291	10,394
2017	10,912	10,999
2018	11,645	11,667
2019	12,241	12,309

2020	12,646	12,728

Note: Based on United Nations Standard International Trade Classification (SITC) Code 554 (Soap Cleansing and Polishing Preparations) minus SITC Code 55411 (Soap and organic surface active products for toilet use)[131]. Source: Eurostat DS-018995

Significant levels of growth in intra-EU trade can be seen within the majority of product sub-categories. For example, in the largest sub-group, "Surface active washing and cleaning preparations (nes) for retail sale" (SITC 55422), which accounts for nearly 60% of total intra-EU trade, intra-EU trade has grown by 137% between 2005 and 2020. "Organic Surface Active agents" have grown by 65% over the same period, whilst "Surface active washing and cleaning preparations not for retail sale" have grown by 90%.

Table 9: Intra EU Trade (EU-27): SITC Product Categories Proportion of Intra-EU Trade and Growth in EU-Trade 2005-2020

SITC Code	Description	Intra EU-27 trade in 2020 Exports Euro Million	% of total intra-EU trade in total products approximating to DR	Growth in Intra-EU trade 2005 to 2020
55422	Surface active washing and cleaning preparations for retail sale	7,431	58%	+137%
55421	Organic surface active ingredients, put up for retail sale or not	2,431	19%	+65%
55423	Surface active washing or cleaning preparations (nes) not for retail sale	1,762	14%	+90%
55419	Soap (not elsewhere specified)	374	3%	+94%

[131] Whilst the SITC codes do not exactly match those products covered by the Detergents Regulation, it was accepted in the Evaluation Report that SITC Codes 55415, 55419, 55421, 55422, 55423, 55431, 55432, 55433, 55434 and 55435 were the codes that most closely match the products covered by the Detergents Regulation. It should also be noted that, whilst in theory the international trade balance between EU-27 countries should be zero (i.e. imports should equal exports), it would appear that there are some small discrepancies. According to Eurostat, potential reasons for this could include thresholds, non-response and related adjustments, statistical confidentiality, triangular trade, time lags in the registration of transactions, misclassification of goods, or other methodological differences. (Eurostat, no date).

55415	Soap and organic surface active products in bars etc, not for toilet use	288	2%	+57%
55433	Polishes and similar preparations for coachwork	123	1%	+151%
55435	Polishes, creams and similar preparations for glass or metal	102	1%	+65%
55432	Polishes, creams and similar preparations for maintenance of furniture, floors, and other woodwork	92	1%	+42%
55431	Polishes, creams and similar preparations for footwear and leather	65	1%	-11%
55434	Scouring pastes, powders and other scouring preparations	59	*	+44%
		12,728	100%	+99%

Note: * equals less that 1%. Based on United Nations Standard International Trade Classification (SITC). Source: Eurostat DS-018995

Overall, it would appear that Intra-EU trade has increased significantly since the Detergents Regulation was introduced in 2005. This provides a proxy measure of the extent to which the Detergents Regulation has achieved its objective of ensuring the free movement of detergents and surfactants (for use in detergents) within the Internal Market. It should be noted, however that it is difficult to determine the extent to which such growth can be attributed to the introduction of the Detergents Regulation, and therefore such conclusions should be treated with caution.

6.4 6.4 DIFFERENCES IN TYPES OF SURFACTANTS USED

Detergent manufacturers are “formulators”. They bring together a range of different fragrance and materials technologies to create complex cleaning and maintenance products for households, institutions, and businesses.

An important component in the formulation of any detergent is the surface-active agents (also known as “surfactants”). They help break down the interface between water and oils or dirt. Surfactants decrease the surface tension of water through absorbing the water/ air interface and also by disrupting hydrogen bonds (which cause the relatively high surface tension of water). By doing this, surfactants

enable the cleaning solution to wet a surface (such as clothes or dishes) more quickly, so soil and dirt can be readily loosened and removed. Surfactants also emulsify oily soils and keep them dispersed and suspended so they do not settle back on their surface.[132]

The global market for surfactants is estimated to be in the order of €37 billion.[133] It is forecast to grow significantly by 2027 at around 5% annually. Asia Pacific is the primary driver of this growth due to scale of its customer base, high demand for use in the Household Care sector and increasing development of the personal care market.

Although the global market for surfactants is driven by demand for detergents and cleaning products, surfactants are used widely in other applications as well, including textile and leather, healthcare, vehicle care, food processing, oil and gas, and personal care. Nevertheless, detergents are the main destination of surfactants: it has been estimated that detergents and cleaning account for at least half of global demand for surfactants[134], and that anionic surfactants (used widely in these applications because they are cheap and easy to produce and have excellent cleaning properties), are used in greater volume than any other group.

There are four main types of surfactants, classified on the basis of ionic properties in water. These are: anionic, cationic, non-ionic, and organic. Anionic organic surface-active ingredients are the largest group of surfactants produced in Europe in volume terms, followed by non-ionic organic surface-active ingredients. However, in value terms, non-ionic organic surface-active ingredients are the largest group, followed by anionic organic surface-active ingredients. Production of both anionic and non-ionic surfactants have increased in the Europe over the last five years in volume terms (by close to 20%), but in value terms, production has remained relatively stable.

Table 10: Main Type Surfactants Production: EU-27 2015-2019

	Volume (million Kgs)					**Value (€ million)**				
	2015	**2016**	**2017**	**2018**	**2019**	**2015**	**2016**	**2017**	**2018**	**2019**
An-ionic	1585	1582	1699	1709	1903	1483	1445	1674	1469	1464
Cat-ionic	597	591	579	540	487	610	610	636	615	525
Non-ionic	1296	1268	1346	1535	1530	2131	2087	2183	2450	2087

[132] See European Commission 'Support to the Evaluation of Regulation (EC) No. 648/ 2004 (Detergents Regulation' (Report by RPA/ Mayer Brown, 2018).
[133] Allied Market Research 'Report Preview, Surfactant Market by Type and Application: Global Opportunity Analysis and Industry Forecast' (2020).
[134] Fortune Business Insights 'Surfactants Market Size, Share and COVID-19 Impact Analysis' (2020).

Other	321	346	387	360	413	359	416	463	361	420

Source: Eurostat PRODCOM (NACE Rev 2) and Eurostat COMEXT.

6.5 6.5 HOUSEHOLD CARE AND PROFESSIONAL CLEANING AND HYGIENE SECTORS

Although "detergents" are commonly referred to as if they collectively comprised a single industry, detergents are actually used in (at least) two very distinct markets: the Household Care and the Professional Cleaning and Hygiene sectors.

- The Household Care sector includes households supplied typically through retailers, most prominently supermarkets.
- The Professional Cleaning and Hygiene sector includes public sector institutions, industry, and commercial customers, mostly supplied directly by manufacturers or through distributors. This is a business-to-business market.

In 2020, households and businesses in Europe spent over €41 billion on products produced by the detergents industry. Purchases by households were €32.4 billion (measured at the price paid to retailers by consumers); in the Professional Cleaning and Hygiene sector purchases were €8.8 billion. This shows an uneven share of total consumption with Household Care representing approximately 80% of all purchases and 20% of the value of overall expenditure in the Professional Cleaning and Hygiene sector.

Over the five year period from 2016 to 2020, overall spending rose by €5.6 billion, an increase of over 15%. The value of Professional Cleaning and Hygiene market increased by 24% over that same five-year period, whilst the value of Household Care rose by around 14%. There was a marked increase in overall spending in 2020 due to the COVID-19 pandemic and the increased focus on cleaning and hygiene in both Household Care and Professional Cleaning and Hygiene sectors. This is discussed in more detail below.

Table 11: Consumption of detergent by sectors: Europe (€ billion and %)

	2016	**2017**	**2018**	**2019**	**2020**	**Share % (2020)**
Household Care	28.5	28.6	29.1	30.2	32.4	79%
Professional Cleaning and Hygiene	7.1	7.3	7.6	7.8	8.8	21%
Total	35.6	35.9	36.7	38	41.2	100%

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. Activity and Sustainability Reports 2014 -2015 to 2020-2021.

6.5.1 6.5.1 Household Care

For households and consumers, the Household Care sector meets complex functional and emotional needs for protection from disease and infection, for comfort, appearance and pleasure, for longer-lasting consumer durables, and for freer, less onerous lifestyles. These needs are met, at low cost, by a wide range of products grouped within five major product categories.

- **Laundry Care** – laundry detergents (powders, tabs, liquids, others), fabric softeners, carpet cleaners, and laundry aids.
- **Surface Care** (including toilet care) – multi-purpose, bathroom, oven, kitchen, window/ glass and floor cleaners, de-scalers, drain openers, scouring agents, Household Care antiseptics and wipes, in-cistern devices, in the bowl systems and liquids/ powders, mousses, tablets, and toilet cleaning systems.
- **Dishwashing** – hand and machine dishwashing products and dishwashing additives.
- **Maintenance products** (covering air care, polishes, and home insecticides) – spray/ aerosol air fresheners, gel air fresheners, liquid air fresheners, scented candles, car air fresheners and other air care, shoe, floor, furniture and metal polish, spray/ aerosol insecticides, electric insecticides, coils, baits and other insecticides.
- **Bleaches** – chlorine-based products that are designed for general domestic cleaning purposes – only products that are labelled bleach are included (bleach-based cleaners, primarily marketed as surface or toilet cleaning products are included in the surface care and toilet care product category). This product category also includes chlorine-based laundry bleach (but colour-safe laundry bleach is included in the laundry care product category).

The scale of consumer spending differs significantly between the five Household Care product categories. Laundry care is the largest product category, accounting for 47% of consumer purchases in 2019. Other product categories are smaller in value. Surface care, including toilet care, accounts for 22% of purchases; spending on dishwashing products is nearly 16% of total expenditure; and purchases of maintenance products represents about 13% of spending. Finally, purchases of bleaches accounts for only 2% of total consumer spending on Household Care products.

Table 12: Household Care Products. Consumption Europe 2020 (€ Billion, %)

	€ Billion	**%**
Laundry Care	15.3	47
Surface Care	7.2	22
Dishwashing	5.1	16
Maintenance Products	4.1	13
Bleaches	0.7	2
Total	32.4	100

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. 'Activity and Sustainability Report 2020-2021' (2020), based on Euromonitor.

In the five-year period between 2016 and 2020, consumer expenditure on Household Care products increased by over 12% from €28.8 billion to €32.4 billion. All Household Care markets grew significantly in 2020, in particular surface care, dishwashing and bleaches. This was as a consequence of the COVID-19 pandemic during which people spent an increased amount of time at home, and during which the demand for cleaning products soared. However, it should be noted that this meant 2020 was not a typical year and that the data should be interpreted with care.

Table 13: Household Care Products. Consumption Europe 2016-2020 (€ Billion)

	2016	2017	2018	2019	2020
Laundry Care	13.5	13.5	13.6	14.3	15.3
Surface Care	6.0	6.1	6.4	6.6	7.2
Dishwashing	4.4	4.4	4.5	4.6	5.1
Maintenance Products	3.9	3.9	4.0	4.1	4.1
Bleaches	0.7	0.7	0.6	0.6	0.7
Total	28.5	28.6	29.1	30.2	32.4

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. Activity and Sustainability Reports 2014-2015 to 2020-2021 (2021), based on Euromonitor.

In the Household Care sector, a small number of multi-national companies account for almost 65% of EU sales (retail sales in all product categories). The largest competitors include Procter & Gamble, Unilever, Henkel, Reckitt Benckiser, SC Johnson, and Colgate Palmolive, all competing in most EU markets.[135] Other manufacturers, many SMEs and others who mainly compete nationally, account for nearly 20% of total EU sales. The remainder includes retailers' own label brands.

Within these sectors, there have been some important changes in consumer purchasing behaviour over the last five years. For example, in the Laundry Care market, whilst total sales remained relatively static between 2016-2019, there has been an increase of liquid detergents and detergent tablets, albeit with fluctuations in the period. 2020 has, however, been an exception to this trend, due to the COVID-19 pandemic.

Table 14: Laundry Care. Consumption Europe 2016-2020 (€ Billion)

	2016	2017	2018	2019	2020

[135] The Huggard Consulting Group "The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-Economic Analysis (2016).

Liquid Detergents	4.3	4.3	4.4	4.9	5.0
Powder detergents	2.8	2.6	2.5	2.1	2.7
Detergent Tablets	1.2	2.8	2.8	1.8	2.1
Fabric Conditioners	2.5	2.5	2.5	2.6	2.7
Laundry Aids, Other	2.7	1.3	1.4	2.8	2.8
Total	13.5	13.5	13.6	14.3	15.3

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. Activity and Sustainability Reports 2014-2015 to 2020-2021, based on Euromonitor.

In the Dishwashing market, on the other hand, there has been growth in sales of Automatic Dishwashing products, whilst Hand Dishwashing products have remained relatively static.

Table 15: Dishwashing. Consumption Europe 2016-2020 (€ Billion)

	2016	**2017**	**2018**	**2019**	**2020**
Automatic Dishwashing Products	2.6	2.6	2.7	2.8	3.2
Hand Dishwashing Products	1.8	1.8	1.8	1.8	1.9
Total	4.4	4.4	4.5	4.6	5.1

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. Activity and Sustainability Reports 2014-2015 to 2020-2021, (2021) based on Euromonitor.

Household Care products directly improve the quality of life for every European in a number of ways: they keep clothes, dishes, surfaces, and homes clean, they eliminate bacteria, and they lessen the risk of illness; they enhance the appearance and enjoyment of clothes, surfaces, and homes; improve the durability of investments in household goods; facilitate modern lifestyles (ability to care for clothes and homes in a rapid and efficient manner); and contribute to sustainability by using more ecologically benign substances for delivering cleanliness and hygiene. Over the past two decades, there have been a number of major changes. Key trends include:

- **Low temperature washing** – development of improved materials technologies, along with engagement with customers, has contributed to the extensive use of detergents designed for lower washing temperatures for the majority of wash-loads. Wash temperature reductions help improve significantly the overall sustainability of the laundry process by limiting the consumption of energy, the most important environmental impact.
- **Unit dosing** – unit dose technologies ensure that consumers use the right amount of active ingredients for a single wash. Developed initially for automatic dishwashing, this technology is now extensively used in laundry care. Unit dosing ensures optimal resource use of concentrated

ingredients and contributes to reducing environmental impacts by cutting water consumption, packaging, and transportation.

- **Resource efficiency and packaging** – companies, supported by A.I.S.E., have invested in a series of voluntary initiatives to improve resource efficiency in manufacturing processes and in packaging design.
- **Concentrated formats** – there has been a shift from powders to liquids in both dishwashing and laundry care. The combination of greater compaction with concentrated materials has contributed to a significant reduction in the quantity of detergent used in wash-loads, thereby requiring less packaging, reducing waste, and cutting transport activity;
- **Added value in existing segments** – this has been achieved through a number of different strategies, including cost-of-use reductions; enhanced emotional benefits (particularly feel and smell); increased functionality; and improved convenience and ease of use. In laundry, for example, there has been a shift from visual to sensory. Fresh fragrances and longer lasting smell experiences have become as important as whiteness. In surface cleaners, added value has been created through the introduction of "power cleaners", offering a time efficient, "thorough clean" rather than the traditional time consuming "maintenance clean", for example. In automatic dishwashing, development of multifunctional "3 in 1" and multi-benefit tablets and capsules has delivered additional convenience and ease-of-use for automatic dishwashing, creating added value for customers.
- **New segments** – another focus for innovation investments is the satisfaction of emerging customer needs, thereby creating new market segments. Recent examples include new delivery mechanisms to enhance product life and functionality in the air care market; colour detergents to protect modern garments; additives to remove tough stains; and wipes to improve the convenience and efficacy of surface cleaners.

6.5.2 6.5.2 Professional Cleaning and Hygiene sector

The Professional Cleaning and Hygiene sector supplies businesses and institutions in the public and private sector with a wide range of specialised products, often supported by technical advice, expert services, and equipment, for an extensive range of applications. It serves six groups of customers: healthcare; food and beverage; kitchen and catering; building care; laundry; and technical cleaning in a wide range of industries[136].

- **Healthcare** – hygiene and disinfection of healthcare facilities, hospitals, clinics, operating theatres, cleanrooms, elderly care homes; disinfection of surgical instruments and equipment; hand and skin disinfection.
- **Food and Beverage** – cleaning in place (CIP) chemicals, bottle cleaning, chain lubricants, disinfectants for food industry, combined cleaning and disinfection, caustic/ acid/ neutral surface cleaners, transportation and storage cleaning and hygiene, food contact surface disinfection, employee hygiene, products for agriculture, teat dips, sheep dips, milking equipment hygiene, stable hygiene.
- **Kitchen and Catering** – dishwashing (hand/ machine, liquid/ powder) detergents, additives such as water hardness regulators for dishwashers, glassware cleaners, rinse aids, surface cleaners for equipment, surface disinfectants, employee hand hygiene.

[136] It should be noted that some of these products fall under both the Detergents Regulation and the Biocidal Products Regulation.

- **Building Care** – cleaning and maintenance products, general purpose cleaners, façade cleaning (stone/ wood/ metal/ glass/ graffiti removers), floor care (general, hard surface, carpets/ mats, sealants, strippers, polishes, crystallisers), sanitary cleaners, washroom services, abrasive cleaners, disinfecting cleaners, air conditioner hygiene, surface disinfectants (hospital, sanitary, general, wipes), housekeeping products.
- **Laundry** – on-premises and industrial laundry detergents, fully formulated detergents, powder/ liquid detergents, pre-wash additives, boosters, pH-adjustment, water hardness regulators, bleach additives, disinfectant detergents/ additives for hygienic laundry (hospital, food industry), fabric softeners, starch finishing ironing aid, fragrance rinse.
- **Technical Cleaning** – products for transportation/ car/ aircraft/ railway care, workshop cleaning, spare parts, industrial storage areas, equipment cleaning, metal products cleaning, degreasing, chemical treatment (phosphatising, chromatising etc.), de-laquering, metal surface conversion, metal working aids, and water conditioning/ cooling treatment.

In terms of relative scale, Healthcare is the largest market for Professional Cleaning and Hygiene products (32% of purchases), followed by Food and Beverage (20%), Kitchen and Catering (16%), and Technical Cleaning (15%), Building Care (11%) and Laundry (6%).

Table 16: Professional Cleaning and Hygiene Products. Consumption Europe 2020 (€ Billion, %)

	€ Billion	**%**
Healthcare	2.8	32
Food, Beverage & Agriculture	1.8	20
Kitchen & Catering	1.4	16
Technical Cleaning	1.3	15
Building Care	1.0	11
Laundry	0.5	6
Total	8.8	100

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. 'Activity and Sustainability Report 2020-2021'.(2021)

Overall expenditure by businesses and institutions on Professional Cleaning and Hygiene products rose by approximately 24% in the five-year period between 2016 and 2020. Over the period 2016-2019, growth was largely due to increased expenditure by customers in the Healthcare market. However, in 2020, the COVID-19 pandemic had a significant impact on this market. The industry played an important role in supplying the increased need for cleaning products to help combat the COVID-19 pandemic, and this is reflected in an overall growth rate of nearly 13% in one year. This is particularly the case in strategic sectors such as healthcare. Other sectors such as building care, kitchen and catering and professional laundry all suffered due to business closures of offices, hotels and restaurants.

However, it should be noted that 2020 was not a typical year and that the data should be interpreted with care.

Table 17: Professional Cleaning and Hygiene Products. Consumption Europe 2016-2020 (€ Billion)

	2016	2017	2018	2019	2020
Healthcare	1.7	1.8	1.9	2.1	2.8
Food, Beverage & Agriculture	1.4	1.4	1.5	1.5	1.8
Kitchen & Catering	1.4	1.4	1.5	1.5	1.4
Technical Cleaning	1.2	1.2	1.2	1.1	1.3
Building Care	0.8	0.8	0.8	0.9	1.0
Laundry	0.6	0.7	0.7	0.7	0.5
Total	7.1	7.3	7.6	7.8	8.8

Note: EU-27 plus UK, Switzerland and Norway. Source: A.I.S.E. 'Activity and Sustainability Report 2020-2021' (2021).

In the Professional Cleaning and Hygiene sector, companies supply business and institutional customers with a wide range of cleaning and hygiene products, technical services, processes, equipment and machines, process control systems, and training. Some customers may only require products, whilst other larger and more complex customers purchase bespoke packages that are application-specific (such as building cleaning and maintenance) or sector-specific (such as dairy production).

The market in this segment is characterised by innovative companies that concentrate on developing more focused products, services, and equipment designed to solve specific problems in individual applications or sectors. Larger companies also invest in creating bespoke packages of products, services, technical support, and equipment targeted at particular sectors or applications.

Whilst some of the product innovations developed by companies in the Household Care sector are typically spill over into this market segment, many of the products supplied for business, commercial, and institutional applications are highly specialised. Specific examples include:

- **Laundry products** – formulations, most notably the use of phosphates, differ from consumer laundry product formulations for a number of reasons: different type of 'soil', more difficult stains; more frequent disinfection; higher performance expectations; shorter washing time requirements; and longer lifetime requirement for textiles, particularly in the textile leasing sector.
- **Healthcare** – a number of specialised cleaning products, approved by regulators, for medical devices contain phosphates. Detergents containing phosphates are also used in special washing machines for surgical instruments, thus ensuring a thorough cleaning operation.

- **Kitchen and Catering** – automatic dishwashing products used in the kitchen and catering sector contain phosphates, unlike consumer equivalents, because of the need to meet technical requirements of very short wash time, high temperature, low product dosage, wash water recycling constraints, type of dirt, and frequency of cleaning. Specialised automatic dishwashing products make a significant contribution to ensuring optimal hygiene in this sector.
- **Technical Cleaning** – for special operations, such as the pre-treatment in the automotive manufacturing process, products containing phosphate are needed to prevent corrosion and to ensure complete cleanliness, thereby contributing to the longevity of the vehicle body.

There is a clear division within the structure of the Professional Cleaning and Hygiene market between a small group of global multi-national businesses and a substantial number of national or locally-based SMEs. Diversey, Ecolab, and Procter & Gamble Professional are the largest competitors in the sector, focusing on providing specialist products, often combined with services, extensive technical support, and equipment. They also develop tailored packages of products, services, and equipment targeted at specific complex applications or sectors, such as the meat processing sector or global hotel chains. In contrast, the many hundreds of SMEs participating in the sector tend to focus on local or national markets, frequently supplying specialised products within particular market niches or narrow segments and providing more limited technical support.[137]

Widespread improvements in the quality of life of all Europeans are delivered through the use of Professional Cleaning and Hygiene products, services, and equipment, supplied by the Professional Cleaning and Hygiene sector, in a wide range of industrial, commercial, and institutional contexts. These include protecting Europeans from infectious diseases in a wide range of different industrial, commercial and institutional environments such as offices, schools, and hospitals. Professional Cleaning and Hygiene products also enhance the productivity of a substantial part of Europe's economy, as they enable businesses to use resources (such as labour, capital, energy and raw materials) more efficiently, particularly in sectors such as food and drink processing, pharmaceuticals, hospitality and contract cleaning. These products also help major sectors (such as pharmaceuticals and food and drink) to protect investments in brands by reducing the risk of infection and contamination and thereby protecting the reputation of well-established businesses.

The market structure in this sector has been recently altered, mainly as a result of a progressive increase in investment and innovation. Major trends include:

- **Horizontal (cross-sector) solutions** – certain applications, such as washroom care, floor cleaning, building care, and food preparation, require similar solutions across a whole range of industrial, commercial, and institutional customers. Recent innovations include motorised floor cleaners, improved dispensing equipment and new combinations of equipment, products, and training designed to deliver improved cleaning and asset durability for stone floors.
- **Sector-specific systems solutions** – these meet all of the complex hygiene, cleaning, and maintenance needs of specific industries. This has led to the development of "systems solutions" for sectors such as pharmaceuticals, hospitality, and food and drink. They combine high performing portfolios of specialist products, specialist equipment (such as "Cleaning in Place", foam equipment, and controlled dosing), high levels of technical advice, training and systems

[137] The Huggard Consulting Group 'The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-Economic Analysis' (2016).

management. These packages are tailored to the needs of target sectors and are supported by horizontal building care, personal care, and laundry care products, equipment, and advice.

- **Cleaning in place (CIP) technologies** – these enable specialised detergents to circulate through assembled processing equipment without needing to dismantle it between batches. They protect pipework from internal microbial contamination in hygiene critical sectors, such as pharmaceuticals, and food processing[138].
- **Controlled dosing** – specialist product dispensing equipment has been developed for the laundry, building care, professional kitchen and catering, food and drink processing, agricultural, and healthcare sectors. The dosing equipment ensures that the correct amount is used for each application, ensuring optimal performance, preventing waste and spillage, limiting contact with cleaning products, improving protection of workers, and delivering reduced packaging, materials, and transportation costs. Specialist packages of dosing equipment, targeted products, and technical training are also supplied for specific sectors or horizontal applications.

6.6 6.6 INNOVATION

Since its inception in the second half of the Nineteenth Century the Household Care and Professional Cleaning and Hygiene sector has been characterised by a continuous investment in innovation to improve consumer value, to deliver new and improved consumer benefits, and to improve operating efficiency.

Innovation, primarily in improved functional and emotional product performance, is the most important driver of value-added in the industry. Through continuous, significant, and long-term investment in innovation the industry satisfies the complex hygiene, cleaning, and maintenance needs of Household Care and businesses on a daily basis at reasonable cost.

Significant innovation activity occurs within Europe, a reflection of the historic origins of some of the leading companies, the scale and sophistication of the European market, and the excellence of the European "science base". In 2016, it was estimated that there were more than 15 major innovation centres in Europe owned by companies in the industry.[139]

Moreover, product improvements made in the Household Care sector frequently spill over into the Professional Cleaning and Hygiene sector, where they are combined with service and equipment innovation.

Investment in innovation is a response to three factors:

- Continuing shifts in functional and emotional customer needs, communicated rapidly through everyday purchase patterns and extensive investment in market research;
- Concentrated buyer power of grocery retailers (85% of sales of Household Care products to households), the main form of outlet for Household Care products;

[138] It should be noted that some of these products fall under both the Detergents Regulation and the Biocidal Products Regulation.

[139] The Huggard Consulting Group 'The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-Economic Analysis' (2016).

- Very high levels of competitive intensity amongst manufacturers: the Household Care sector is dominated by 5-6 well-funded and sophisticated multinationals, for example.

There are various measures of the scale of investment in innovation by the Household Care and Professional Cleaning and Hygiene industry.[140] In 2016, it was estimated that using traditional accounting measures, the industry invests 2-3% of its turnover in research and development (alternative approaches, based on estimates of "resources consumed" during the process of creating new and improved products, have suggested that the industry invests 8-10% of turnover in innovation[141]).

6.7 6.7 CUSTOMER SATISFACTION

Evidence from surveys of consumers undertaken by A.I.S.E. suggests that consumers recognise the importance of the industry's products and value the benefits they deliver.

There is, for example, a high degree of salience of the importance of hygiene and cleanliness both at home and in commercial and institutional settings. In 2020, for instance, 89% of respondents believed that cleaning and hygiene helped them to avoid becoming unwell, a level of response undoubtedly influenced by the fear of COVID-19[142].

Respondents in 2017, recognised many of the benefits of Household Care products including: A clean environment is a mark of respect for people and family (83% of respondents); Belongings last longer if cleaned regularly (71%); Household Care products facilitate a convenient and modern lifestyle (61%); Household Care products make lives more enjoyable and satisfying (57%); Household Care products are important for well-being (55%).[143]

Similarly, respondents recognise the benefits of Professional Cleaning and Hygiene products away from the home environment. In 2017, for example, 76% of respondents believed that they worked better in clean offices. There is also recognition of the value of the industry's products in retail and hospitality outlets: the survey revealed that 95% of respondents believe that the attractiveness of a hotel is improved when bed linen and towels are clean, and 94% believe that clean dishes are as important as food quality when deciding upon the attractiveness of a café or restaurant. And the same survey suggested that for more than 79% of respondents they were less inclined to visit a shop if it was dirty.

[140] The Huggard Consulting Group 'The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-Economic Analysis' (2016).
[141] This estimate reflects the way in which innovation occurs in the industry, rather than accounting convention. It recognizes investments in science, new product development, manufacturing, sales and marketing, and investments in advertising and sales promotions. It also takes into account the extensive testing required before a new or improved product is placed on the market, thereby ensuring compliance with extensive regulatory requirements and providing evidence of functional or emotional efficacy for retailers and consumers. Source The Huggard Consulting Group 'The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-Economic Analysis' (2016).
[142] AISE 'Pan-European Consumer Habits Survey 2020' (2020).
[143] AISE 'Consumer Habits Survey 2017' (2018).

6.8 6.8 VALUE CHAIN AND SOCIO-ECONOMIC IMPACTS

The creation, manufacture, supply, and consumption of the industry's products support significant public benefits in Europe through a "value chain" based on different distinct sequential phases of economic activity:

- **Manufacturers** – manufacturers of household care and professional cleaning and hygiene products create wealth and employment through innovation to develop new and improved products, services and equipment; through investment in and utilisation of an extensive network of production and logistics facilities; through expenditure on marketing, advertising, sales promotion, and sales; through the provision, to business customers, of technical support, after-sales service, training, and equipment; and through expenditure on co-ordination and management services.
- **Retailers** – in the final stage of the value chain, end consumers in Europe purchase laundry care, surface care, dishwashing, maintenance, and bleach products manufactured by the Household Care sector. They do this primarily through grocery retailers (85% of purchases by consumer value in 2016), and also through pharmacies, para-pharmacies and drug stores. Purchases in these outlets of household care products generate further jobs and wealth.
- **Supplier** Impacts – manufacturers and retailers within the value chain purchase raw materials, goods and services from other European-based businesses ("bought-in goods and services") to support the creation, production, distribution, and sale of Household Care and Professional Cleaning and Hygiene Products. Purchases of these inputs sustain wealth, jobs, employment costs, and labour taxes in suppliers, generating further economic benefits for Europe.

In 2016, it was estimated that, based on this analysis of its value chain, the Household Care and Professional Cleaning Products industry supported the following socio-economic benefits for Europe[144]:

- Overall gross value added of €24.6 billion;
- More than 360,000 jobs (including approximately 95,000 in manufacturing and 125,000 in retail);
- Employment costs of €11.8 billion, including labour taxes.

During the COVID pandemic, the socio-economic impact of the Household Care and Professional Cleaning and Hygiene Products value chain will have grown as the importance of cleaning and hygiene in general (e.g. hand washing) has been emphasised by governments and public health bodies and recognised by consumers, institutions, and commercial premises alike.

[144] The Huggard Consulting Group "The Household Care and Professional Cleaning and Hygiene Products Industry: A Socio-Economic Analysis (2016).

Annex 7 ANNEX 7 DETAILED PROBLEM ANALYSIS

7.1 7.1 MICROBIAL CLEANING PRODUCTS

Abbreviations

Term or acronym	Meaning or definition
AMR	Antimicrobial resistance
ATTC	American Type Culture Collection
BPR	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
CFU	Colony Forming Units
Detergents Regulation	Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
EFSA	European Food Safety Authority
EUCAST	European Committee on Antimicrobial Susceptibility Testing
GMM	Genetically Modified Microorganism
GPSD	Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
GRAS	Generally Recognized as Safe
IDA	International Depositary Authority
MBCP	Microbial-based cleaning product
OECD	Organisation for Economic Cooperation and Development
QPS	Qualified Presumption of Safety
YOPI	Young, Old, Pregnant and Immune-compromised

Glossary

• **Acquired resistance**: Resistance to a particular antimicrobial agent to which the microorganism was previously susceptible. The change in resistance level is the result of genetic changes in a microorganism due to mutation(s), the acquisition of foreign genetic material, or a combination of both mechanisms.
• **Antimicrobial resistance: AMR** occurs when microbes evolve mechanisms that protect them from the effects of antimicrobials. **Antibiotic resistance** is a subset of AMR that applies specifically to bacteria that become resistant to antibiotics. All classes of microbes can evolve resistance. Resistance in bacteria can arise naturally by genetic mutation, or by one species acquiring resistance from another.
• **Bacterial spores**: Resistant structures used for survival under unfavourable conditions.
• **Genetic modification:** The direct manipulation of an organism's genes using biotechnology.
• **Intrinsic resistance:** Denotes the innate ability of a bacterial species to resist activity of a particular antimicrobial agent through its inherent structural or functional characteristics, which allow tolerance of a particular drug or antimicrobial class.
• **Micro-organism:** A microorganism, or microbe is an organism of microscopic size, which may exist in its single-celled form or as a colony of cells.
• **Opportunistic pathogen**: Denotes a microorganism that does not ordinarily cause disease but that, takes advantage under certain circumstances such as impaired immune responses resulting from other disease or drug treatment, and acts as a pathogen.
• **Pathogen**: A bacterium, virus, or other microorganism that can cause disease/illness.
• **Strain:** It is a genetic variant or subtype of a microorganism (e.g., a virus, bacterium or fungus).
• **Strain identification protocol:** means the method by which microbial strains have been identified by DNA sequencing (full length 1500+1 base pair analysis) and have been named following the naming conventions set in place by the International Code for Nomenclature of Bacteria (ICNB).

7.1.1 7.1.1 Introduction

Over recent years, there has been a novel type of cleaning products containing living microorganisms as active ingredients (subsequently termed 'microbial cleaners'[145] or 'microbial cleaning products') made available on the EU market. The fact that they contain living microorganisms, raises concerns on their potential impact on human health (e.g. possible presence of contamination of unwanted microbes, pathogens) and the environment (e.g. release into the environment of microorganisms in uncontrolled manner).[146]

[145] OECD (2015), "Microbes in cleaning products: Regulatory experience and challenges for risk assessment", in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

[146] 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/attachments/1/translations/en/renditions/native

The aim of this overview is to *i)* define the state-of-art of the products containing microorganisms on the market focusing on the products claiming 'cleaning'[147] actions, *ii)* identify possible risks that may arise from their use, *iii)* discuss their classification into specific pieces of legislation and *iv)* examine current ecolabel schemes that include them in their requirements. The assessment is primarily based on available scientific literature (articles, reports), publications by the European Commission and the Joint Research Centre and reports by various European National Authorities published within the recent years

7.1.2 7.1.2 Microorganisms and their function

Microorganisms are found in almost every habitat present in nature, including hostile environments such as the North and South poles, deserts, geysers, and rocks. They also include all the marine microorganisms of the oceans and deep sea. Some types of microorganisms have adapted to extreme environments and sustained colonies. Microorganisms play critical roles in Earth's biogeochemical cycles as they are responsible for decomposition and nitrogen fixation.

Microorganisms are useful in producing foods, treating waste water, creating biofuels and a wide range of chemicals and enzymes. They are invaluable in research as model organisms. They have been weaponised and sometimes used in warfare and bioterrorism. They are vital to agriculture through their roles in maintaining soil fertility and in decomposing organic matter.[148]

In the detergents industry, the terms 'microbial', 'bacterial', 'biological' and 'probiotic' are generally used to describe cleaning products that utilise **bacteria, or bacterial enzymes**, to facilitate or assist in the cleaning action that the product is trying to fulfil. Microbial cleaning products contain bacteria (either live, or in spore form) and work on the basis that the microorganisms in the product form enzymes that can break down organic matter in a controlled manner. The organic dirt itself is used as 'nutrition' to produce and secrete enzymes.[149]

Research undertaken by the European Commission's Joint Research Centre ("JRC") identified that there are products on the market where manufactures of microbial cleaning products claim **two main modes of action** for the microorganisms included in these products:

- Microorganisms are used to produce enzymes that degrade organic matter. This cleaning action can be extended if spore-forming bacteria are used; and
- beneficial microorganisms colonise surfaces and it is claimed that these are able to out-compete unwanted microorganisms over food sources therefore 'cleaning' the surface.[150]

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[147] Regulation (EU) No 648/2004, Article 2 (3) 'Cleaning' means the process by which an undesirable deposit is dislodged from a substrate or from within a substrate and brought into a state of solution or dispersion.
[148] Microorganism – Wikipedia.

[149] 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/attachments/1/translations/en/renditions/native
[150] Boyano A., Kaps R., Medyna G., Wolf O. (2016): JRC Technical Reports – Revision of six EU Ecolabel Criteria for detergents and cleaning products, Final Technical Report, European Commission. Available at: http://susproc.jrc.ec.europa.eu/detergents/docs/Technical%20background%20report.pdf

Microbial action is also aimed at controlling odour and to support the cleaning action of detergents. Whilst the use of enzymes in detergent formulations is relatively common and is generally understood as bringing environmental benefits (mainly because it allows better and faster removal of matter at lower washing temperatures), what makes this type of microbial solution innovative is the fact that they are using organisms (in the form of microbes or spores),and are not based on the traditional methods containing enzymes (made of protein strings).[151]

More specifically, some microorganisms produce a broad range of extracellular enzymes, including proteases, cellulases, amylases and ureases, which can degrade organic high molecular weight substances in soil. As opposed to cleaners with added enzymes, microbes can further metabolise (some of) these degradation products. Substances creating odour problems such as NH_3 can be metabolised, or the formation of H2S may be avoided by transforming SO_3 into S_2.[152]

Other microbes can directly inhibit the growth of unwanted microbes, for example, by lowering pH which subsequently cause inhospitable conditions for their survival. This second action that some micro-organisms may perform is nevertheless considered direct or even indirect biocidal function of the microorganisms. [153]

Some manufacturers of the MBCPs also claim a long-term effect of the cleaning action because microorganisms will stay on the treated surface (as spores; many formulations contain spore forming bacteria, e.g. Bacillus spp.) and hinder re-colonisation by unwanted microbes. This spore forming property of some of the bacteria allow them to become re-activated again after more soil appear on the treated surface.[154]

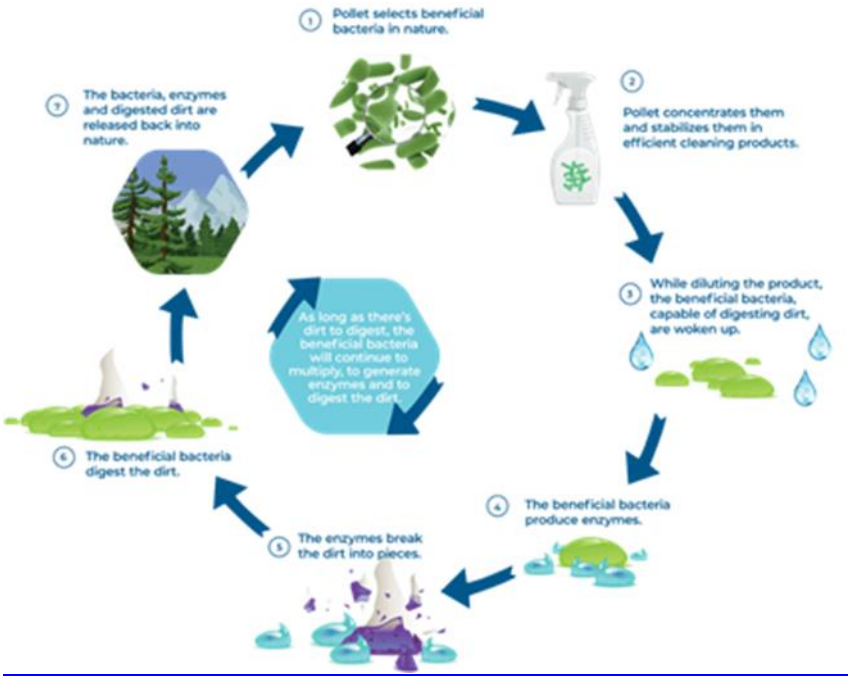
[151] Report by Europe Economics, Milieu Consulting srl and Huggard Consulting Group S.à.r.l., with Economisti Associati srl (Consortium Lead) (2022), Impact assessment study on the making available and placing on the market of detergents (859/PP/GRO/IMA/20/1131/11439) D4 Report

[152] OECD (2015), "Microbes in cleaning products: Regulatory experience and challenges for risk assessment", in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

[153] EUR-Lex - 62018CJ0592 - EN - EUR-Lex (europa.eu).

[154] Boyano A., Kaps R., Medyna G., Wolf O. (2016): JRC Technical Reports – Revision of six EU Ecolabel Criteria for detergents and cleaning products, Final Technical Report, European Commission. Available at: http://susproc.jrc.ec.europa.eu/detergents/docs/Technical%20background%20report.pdf

Figure 8 Lifecycle of microbial cleaning products



7.1.3 7.1.3 Microbial-based cleaning products on the market

The use of microbial cleaners has been described as mainly applied via surface cleaning (in sanitary facilities but also more broadly in buildings with many visitors: public buildings, schools, restaurants, canteens, hotels, production facilities, nursing homes, animal shelters, veterinarian surgeries). Other types of uses include the cleaning carpets and upholstery, cleaning drains, pipes and grease traps, washing of industrial machine parts, or oil spills on masonry.

Microbial cleaners are frequently produced by small and medium sized enterprises (SMEs). Microbial cleaners are used in a very niche part of the market. There are no data on the size of this market regularly collected by any association or authority. The size of this market has been estimated at 25 players. It is important to note that these manufacturers normally do not sell to the end-users, but to distributors who do the main sales, very often under a private label. The number of distributors has been estimated at around 250 by one manufacturer.[155]

Information that is available on the various manufactures' web sites usually show that their produced microbial-based cleaning products possess 'ecological' or 'environmentally-friendly' properties due to the content of probiotic bacteria, sometimes also combined with prebiotics, less or no chemicals in comparison with conventional cleaning products and decreased harmful impact on the environment. However, the composition with attention to the complete identification of microorganisms inside the product is not usually available. Beyond the cleaning action, it is often seen that these products also act

[155] Report by Europe Economics, Milieu Consulting srl and Huggard Consulting Group S.à.r.l., with Economisti Associati srl (Consortium Lead) (2022), Impact assessment study on the making available and placing on the market of detergents (859/PP/GRO/IMA/20/1131/11439) D4 Report

on bad odours and biofilms formed by unwanted microbes and promise the 'healthy' microbiota after use. It is worth noting that there is not always an immediate support for proving the producers' claims, especially when they allege 'safe for human and animal health'.[156] Then, the responsibility lies on the National Market Surveillance Authorities and other responsible bodies to conduct the in-depth checks and ask for such evidence.[157]

7.1.4 7.1.4 Market surveillance reports

There are some market surveillance reports concerning MBCPs conducted by the National Authorities available. One of them found, that on the Dutch market most of the MBCPs found were household cleaners. This report published by National Institute for Public Health and the Environment (The Netherlands) also included some personal care products and animal care products that claimed to contain microorganisms. The experience showed that information on composition of the used microorganisms were limited. As these products were also analysed for composition, it was found that all of the detergents contained one or more Bacillus species, however without knowledge whether in spore form or as living bacteria, or combination. This analysis further confirmed contamination of one of the products by pathogenic species Bacillus cereus. Its presence stems most likely from the production process. This was identified as a serious problem.[158]

The Norwegian report from the Norwegian Scientific Committee for Food and Environment (VKM) summarised currently available literature and add to the most commonly used microorganisms members of the genera *Bifidobacterium*, *Lactobacillus*, *Rhodopseudomonas* and *Sacharomyces*. [159] What persists is the lack of accurate and detailed information on the microbial composition of the MBCPs to the species and strain level.[160]

7.1.5 7.1.5 Microbiological hazards and assessments of risks

Microorganisms in general can be harmless to human health and the environment and many microorganisms have been used for decades and even thousands of years in the processing of food and feed. Other microorganisms are pathogenic or toxic to humans, animals, or plants. In addition, allergenic properties must be considered.[161]

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[156] https://www.chrisal.com, https://en.pollet.eu
[157] Regulation (EU) 2019/1020
[158] L. Razenberg et al., RIVM letter report 2020-0160. Microbial cleaning products: an inventory of products, potential risks and applicable regulatory frameworks, 2020, DOI 10.21945/RIVM-2020-0160
[159] VKM, Elisabeth Henie Madslien, Nana Asare, Øivind Bergh, Erik Joner, Pål Trosvik, Siamak Yazdankhah, Ole Martin Eklo, Kaare Magne Nielsen, Bjørnar Ytrehus, Yngvild Wasteson (2019). Current knowledge of the health and environmental risks of microbialbased cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. VKM report 2019:09, ISBN: 978- 82-8259-325-0, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway
[160] L. Razenberg et al., RIVM letter report 2020-0160. Microbial cleaning products: an inventory of products, potential risks and applicable regulatory frameworks, 2020, DOI 10.21945/RIVM-2020-0160
[161] OECD (2015), "Microbes in cleaning products: Regulatory experience and challenges for risk assessment", in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

Microorganisms have their own biology and response to the environment. It is therefore important to have knowledge about the biological properties of the actual microorganism. Hazards arising are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of microorganisms to persist and multiply in different environments. Moreover, microorganisms consist of a wide range of different organisms, often isolated from the environment, all with their own unique characteristics, behaviours in different environments and modes of action. Micro-organisms may produce a range of different metabolites and toxins (e.g. bacterial toxins or mycotoxins) which may have toxicological significance.[162]

Most of the producers of the MBCPs currently available on the market claim using microorganisms that do not pose any health or environmental concerns. Their assumption is based on the fact, that these microorganisms are used in food and other processing context plus as dietary supplements products. Some of them are generally recognised as safe (GRAS) and/or have a status of the qualified presumption of safety (QPS) which indicates that they have a sufficient track record of safety of use. Also, the species of microorganisms recently found on the market all belong to the Risk Group 1 microorganisms as referred to in the EU Directive 2000/54/EC for occupational safety and health. Besides some producers claim passing various OECD tests to prove additional aspects of safety.

7.1.5.1 7.1.5.1 Taxonomic identification

Taxonomy is the science of classification of organisms. Bacterial taxonomy consists of three separate, but interrelated areas: classification, nomenclature, and identification. Classification is the arrangement of organisms into groups (taxa) based on similarities or relationships. Nomenclature is the assignment of names to the taxonomic groups according to international rules.[163] Identification is the practical use of classification scheme to determine the identity of an isolate as a member of an established taxon or as a member of a previously unidentified species.[164]

Table 1 Taxonomic ranks - an example[165]

Formal rank	Example
Domain	Bacteria
Phylum	Proteobacteria
Class	Alphaproteobacteria
Order	Legionellae
Family	Legionellae
Genus	Legionella
Species	Legionella pneumophila
Subspecies	Legionella pneumophila subsp. pneumophila

[162] Guidance on the Biocidal Products Regulation: Volume V - Guidance on active micro-organisms and biocidal products, European Chemical Agency (2017), Available at: 4d028d38-6d3c-4f2d-80f7-3aa2118ca49a (europa.eu)
[163] International Code of Nomenclature of Bacteria [Sneath, 1992]
[164] Brenner, D.J., Staley, J.T., Krieg, N.R. (2001). Classification of Procaryotic Organisms and the Concept of Bacterial Speciation. In: Boone, D.R., Castenholz, R.W., Garrity, G.M. (eds) Bergey's Manual® of Systematic Bacteriology. Springer, New York, NY. https://doi.org/10.1007/978-0-387-21609-6_4
[165] Brenner, D.J., Staley, J.T., Krieg, N.R. (2001). Classification of Procaryotic Organisms and the Concept of Bacterial Speciation. In: Boone, D.R., Castenholz, R.W., Garrity, G.M. (eds) Bergey's Manual® of Systematic Bacteriology. Springer, New York, NY. https://doi.org/10.1007/978-0-387-21609-6_4

The taxonomic identification of every microorganism is a key element in any risk assessment. The classification in the risk group scheme, the assessment of potential hazardous properties and the existence of relevant experience in safe handling (history of safe use) based on scientific literature and regulatory documents is based on a reliable identification on the species (and frequently on the strain level). It is widely acknowledged that taxonomic identification can lead to erroneous results if not based on proper methods. This is important, as sometimes even taxonomically closely related species or strains can differ considerably in their hazardous properties. For instance, some strains within the same Bacillus species (including some species used in cleaners) can produce enterotoxins whereas other strains are not capable of doing so. The Guidance document for taxonomic identification of bacteria is available for risk assessment purposes published by the OECD.[166]

The qualified presumption of safety (QPS)

The qualified presumption of safety (QPS) is based on reasonable evidence. If an assessment concludes that a group of microorganisms does not raise safety concerns, the group is granted 'QPS status'. No microorganism belonging to that group needs to undergo a full safety assessment. Once the European Food Safety Agency (EFSA) grants a microorganism QPS status, it is included in the list of QPS status recommended biological agents for safety risk assessments or 'QPS list'. A list of all notifications received by EFSA since 2007 in the context of technical dossiers submitted by applicants and considered for possible inclusion in the QPS list is also available. A QPS assessment is done when EFSA receives an application for market authorisation of a regulated product that requires a safety assessment. To be granted QPS status, a microorganism must meet the following criteria:

- Its taxonomic identity must be well defined.
- The available body of knowledge must be sufficient to establish its safety.
- The lack of pathogenic properties must be established and substantiated.
- Its intended use must be clearly described.

Microorganisms that are not well defined, for which some safety concerns are identified or for which it is not possible to conclude whether they pose a safety concern to humans, animals or the environment are not considered suitable for QPS status and must undergo a full safety assessment.

EFSA also carries out an extensive literature search every six months to ensure that the list is up to date. If new information that might change the QPS status of a microorganism is discovered, this is published in a BIOHAZ Panel statement. The statements also include the evaluation of microbiological agents notified to EFSA within each six-month period to be assessed for use in food or feed additives, food enzymes, flavourings, novel foods or pesticides.[167]

7.1.5.2 7.1.5.2 Risk Group 1 micro-organisms

The EU Directive 2000/54/EC has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work. It sets minimum requirements for the protection of workers from risks related to

[166] OECD (2015), "Microbes in cleaning products: Regulatory experience and challenges for risk assessment", in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

[167] Qualified presumption of safety (QPS) | EFSA (europa.eu)

biological agents. Annex III of this Directive lists biological agents of groups numbered 2, 3 and 4 that are known to infect humans. Article (2) of the Directive states information that biological agents belonging to the group 1 are unlikely to cause human disease. The use of microbes classified in risk group 2 or higher requires notification to the national competent authorities and preventive measures by the employers. Employers are obliged to assess the risk including the classification of the microorganisms into one of the four groups of the biological agents.

It should be noted that classification of microorganisms into risk groups may be subject to national regulations. These national regulations should implement the microorganism range and classification from Directive 2000/54/EC, although some variations may occur and should be taken into consideration prior to international marketing of the active substance. Examples for national regulations are German and Swiss guidelines on classification of microorganisms into risk groups.[168]

7.1.5.3 7.1.5.3 Health and environmental risk

Bacteria use regulatory networks that allow them to adapt to almost every environmental niche on earth. A network of interactions among diverse types of molecules including DNA, RNA, proteins and metabolites, is utilised by the bacteria to achieve regulation of gene expression. In bacteria, the principal function of regulatory networks is to control the response to environmental changes, for example nutritional status and environmental stress. A complex organization of networks permits the microorganism to coordinate and integrate multiple environmental signals.[169] This may result among others in carrying and possible transmitting of the antimicrobial resistance genes. Furthermore, the endospores of bacteria are highly resistant to the extreme conditions and thus may survive for a long period of time in the environment upon release.

The assessment of environmental or health risk upon release of the MBCPs requires taxonomic classification to the species or strain level of the microorganism(s), as well as information about relevant release and exposure scenarios. Additionally, information on vulnerable groups (YOPI) must be taken into consideration. Possible risks include **spread of pathogens** (not only human, but also plant and animal**), transmission and spread of antimicrobial resistance genes**, **production of toxins and allergenic properties**. Non-toxigenic and non-pathogenic members of the mostly identified micro-organisms used in MBCPs of genera *Bacillus*, *Bifidobacterium*, *Lactobacilllus*, *Rhodospeudomonas* and *Saccharomyces* are generally regarded harmless to humans and animals (Risk Group)[170]. However, at the moment there is scarcity of complete information on the formulation of MBCPs, as well as there is a clear **data gap on the potential health consequences of MBCPs for humans, animals and plants, and effects on the environment, in both the short and the long term.**

7.1.6 7.1.6 Quality assurance of production

As described above, accurate taxonomic identification of the intentionally added microorganism(s) into the MBCPs is a crucial aspect of the quality assurance when production takes place (usually via fermentation). However, any fermentation process can lead to a development of the unwanted microorganisms in addition to the desired ones. These unwanted microbes may interfere with the

[168] BAuA - Biological Agents - Classification of Biological Agents in Risk Groups - Federal Institute for Occupational Safety an Health
[169] Filloux, A. A.; et al. Bacterial Regulatory Networks. , 1st ed.; Caister Academic Press, 2012; pp xiv–354
[170] Directive 2000/54/EC

intended cleaning effect, possess toxin producing properties or be pathogens themselves. The operators are therefore required to establish and control their quality assurance systems via different process controls such as contamination and concentration (total viable counts) checks. Beyond the possible problems with contamination, the stability during the whole shelf life of the MBCP has to assured. In other words, the producers must secure that the concentrations of the micr-organisms inside the product remain without significant variations and the intended function is then achieved. This requirement has also an influence on the fact that the possibility of unwanted microbes to cause a spoilage of the product is lowered, meaning that sufficient concentration of the desired and microorganisms will hardly let the development of different ones. What is also raising awareness here are the opportunistic pathogens. These may have no effect on healthy individuals, but vulnerable group of people may develop some symptoms or diseases. The vulnerable group covers young, old, pregnant, and immuno-supressed individuals (YOPI).[171] Furthermore, food contaminant species were found during the market surveillance of the Dutch market mentioned above. Bacillus cereus can cause two different types of foodborne illness, the emetic and the diarrheic syndrome. These are usually self-limiting even though there can be severe intoxications leading to hospitalizations and including fatalities.[172]

Producers of MBCPs should be able to provide documentation that on one hand prove the claims they are using when marketing the products and on the other hand that these products meet certain quality standards. It is very important that consumers receive products with high level of safety of use and including relevant information on these products for them to make informed decisions. It is also important that the manufacturers provide specific information on composition, precautions and instruction on usage labelled on the products.

To summarize, the most relevant aspects of the quality control are as follows:

- **Composition of the product**: Accurate identification of the micro-organisms composed in a product, their concentration expressed as log Colony Forming Units (CFU), the state of the microbial cells (viable or spores) and information on methods proving these.
- **Shelf life:** Storage conditions including factors like temperature, humidity, exposure to sunlight, etc. together with the expected shelf life of the product also with information when it may change after the product is firstly opened (e.g. period after opening), where appropriate.
- **Intended use and dosage:** The areas of usage and application instruction for safety use alongside the correct dosage amounts. The batch registering for each product.
- **Safety precautions and disposal:** Statement of any precaution that should be taken during usage plus recommended practices for disposing after usage or after expiration.[173]

[171] OECD (2015), "Microbes in cleaning products: Regulatory experience and challenges for risk assessment", in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

[172] Messelhäußer, U., Ehling-Schulz, M. Bacillus cereus—a Multifaceted Opportunistic Pathogen. Curr Clin Micro Rpt 5, 120–125 (2018). https://doi.org/10.1007/s40588-018-0095-9

[173] VKM, Elisabeth Henie Madslien, Nana Asare, Øivind Bergh, Erik Joner, Pål Trosvik, Siamak Yazdankhah, Ole Martin Eklo, Kaare Magne Nielsen, Bjørnar Ytrehus, Yngvild Wasteson (2019). Current knowledge of the health and environmental risks of microbialbased cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. VKM report 2019:09, ISBN: 978- 82-8259-325-0, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway

7.1.7 7.1.7 Aerosol products

While MBCPs in spray dispensers are also found on the market, the exposure scenarios to the aerosol formation are discussed. First issue is the repeated application of such sprays onto various surfaces like carpets and upholstery which lead to the accumulation of the spores of the micro-organisms resulting in dust-containing spores. Then, daily use of so treated products has to be considered while assessing the risks. This chronic exposure includes not only the direct users but also all the other people and animals present in the same room.[174]

Secondly, the direct respiratory exposure during spraying is of unknown short and long-term effect. The hazard can be caused to some extent by microbial enzymes and/or other components of microbial cells and spores. Due to the lack of agreed tests of the respiratory sensitation for microorganisms, this remains a gap of knowledge.[175]

7.1.8 7.1.8 Scopes of related regulations

7.1.8.1 7.1.8.1 The Detergents Regulation

Current definitions of the Detergents Regulation do not take into consideration the means of cleaning performed by the microorganisms, nor the definition of substances themselves. Apart from the that, another aspect that could be considered relates to the definition of "detergent" under the Detergents Regulation which does not address directly the case of products with an effect based on the action of bacteria (either live or in spore form) but only refers to “substances” and “mixtures”. As a result it could be argued that microorganisms contained in detergents do not fulfil the definition of "substances" and cannot therefore be considered as falling under the scope of the Regulation. Therefore, for MBCPs to fulfil entirely the definitions for purpose of this Regulation some of them would need to be modified.[176]

Under this Regulation there is neither risk management employed to facilitate incorporation of MBCPs which can have impact on consumers’ health and the environment. Furthermore, there is no obligation of labelling products containing intentionally added microorganisms. Yet, some of the producers insist on having complied with the requirements of the Detergents Regulation. Clarity is needed for the manufacturers of MBCPs so they are able to affix CE mark in order to move freely on the internal market. This clarification is also needed for the Member States National Authorities, so the rules are uniformly implemented.[177]

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[174] OECD (2015), “Microbes in cleaning products: Regulatory experience and challenges for risk assessment”, in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

[175] OECD (2015), “Microbes in cleaning products: Regulatory experience and challenges for risk assessment”, in Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings, OECD Publishing, Paris. DOI: https://doi.org/10.1787/9789264213562-14-en

[176] 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/attachments/1/translations/en/renditions/native

[177] 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/attachments/1/translations/en/renditions/native

7.1.8.2 7.1.8.2 REACH

Microorganisms do not fall within the scope of REACH. According to the ECHA guidance on registration, microorganisms do not fall within the scope of the definition of a substance under REACH and are therefore outside its scope.[178] REACH applies to substances defined as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".[179]

7.1.8.3 7.1.8.3 The General Product Safety Directive (GPSD)

The General Product Safety Directive would apply to detergents using micro-organisms as it covers products placed on the market intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and whether new, used or reconditioned (according to the GPSD, businesses must only place products which are safe on the market; Article 2b requires all of such ingredients to undertake a risk assessment). However, this legislation is very general and does not require producers to carry out a detailed risk assessment of substances and/or micro-organisms in products since this assessment and related authorisation requirements are set in sectoral product-specific legislation.[180]

7.1.8.4 7.1.8.4 The Biocidal Product Regulation (BPR)

Some micro-organisms might fall within the rules of BPR. There is a clear indication in definition of an active substance within the scope of the BPR linking to micro-organisms. The BPR applies to micro-organisms that have an action on or against harmful organisms. If micro-organisms fall within the definition of an active substance under the BPR, they will be subject to an approval procedure led by ECHA before being authorised in a biocidal product at Member State level. This approval procedure requires manufacturers to provide an application with relevant information on these micro-organisms (e.g., risk assessment on health and the environment).[181] Micro-organisms used in detergents would be considered as active substances falling under the BPR only if they have an action against "harmful organisms". In such case, detergents using such micro-organisms would also be qualified as biocidal products falling under the BPR.

Due to the ability of micro-organisms to proliferate, there is a clear difference between chemicals and micro-organisms used as biocidal products. The active micro-organism in the biocidal product should

[178] Report by Europe Economics, Milieu Consulting srl and Huggard Consulting Group S.à.r.l., with Economisti Associati srl (Consortium Lead) (2022), Impact assessment study on the making available and placing on the market of detergents (859/PP/GRO/IMA/20/1131/11439) D4 Report
[179] Regulation 1907/2006/EC, Article (3)
[180] Report by Europe Economics, Milieu Consulting srl and Huggard Consulting Group S.à.r.l., with Economisti Associati srl (Consortium Lead) (2022), Impact assessment study on the making available and placing on the market of detergents (859/PP/GRO/IMA/20/1131/11439) D4 Report
[181] Regulation 528/2012/EC

ideally function as a cell factory, working directly on the spot where the target organism is harmful. Thus, understanding the mode of action is a crucial step in the assessment process.[182]

The scope of the BPR which considers products biocidal products if they have an action against "harmful organisms" has been additionally clarified in two decisions from the Court of Justice of the European Union (CJEU).

In Court Case 'Darie-arrest' (CJEU, 2019)[183] the product concerned was a 'probiotic cleaning product' containing Bacillus ferment. And, although there was a lack of biocidal claim and that it simply consumed all the organic waste on which micro-organisms feed, the Court judged, that products without direct effect on the harmful organisms for which they are intended but with effects on the creation or maintenance of the habitat of the harmful organisms, are to be classified as biocides.

In Court Case 'Söll-arrest' (CJEU, 2012)[184] the active substance was not directly destroying or deterring algae, bit it was still judged to be a biocidal product, as it interfered by inhibiting harmful organisms.

For brief illustration what the required information for microorganisms functioning as biocides are, below there is an example of one currently approved biocidal product based on *Bacillus species.* Following information is quoted from the online available safety assessment of biocides, shortened to gain some overview on information and risk assessments it provides.

Bacillus amyloliquefaciens strain ISB06

Product-type 03 (Veterinary hygiene)

Description

Bacillus amyloliquefaciens strain ISB06 is the biologically active ingredient of the product Cobiotex 112 Biofilm+. It has been isolated from an agricultural environment and is a wild-type, hence it has not been modified genetically or in any other way. Cells are gram-positive, mobile medium rods with rounded edges and subterminal spores.

B. amyloliquefaciens has a long and safe history in the production of alpha-amylase for starch liquefaction and detergents. The species is regarded as non-pathogenic and granted QPS status by EFSA.

Activity

The biocidal activity of B. amyloliquefaciens ISB06 may rely on antagonizing bacteria including potential livestock pathogens via growth inhibition. Inhibition by ISB06 affects species of the genera Enterococcus, Listeria, Staphylococcus, Escherichia, Pasteurella, Salmonella and Yersinia and potentially others. Pseudomonas and Acinetobacter species have also been tested but have not been impaired in growth. Hence, B. amyloliquefaciens ISB06 displays specific rather than broad biocidal activity against microorganisms. In dedicated assays it could be shown that ISB06 has no inhibitive or otherwise adverse effects on plants, animals and human cell lines.

[182] Guidance on the Biocidal Products Regulation: Volume V - Guidance on active micro-organisms and biocidal products, European Chemical Agency (2017), Available at: 4d028d38-6d3c-4f2d-80f7-3aa2118ca49a (europa.eu)
[183] EUR-Lex - 62018CJ0592 - EN - EUR-Lex (europa.eu)
[184] EUR-Lex - 62010CJ0420 - EN - EUR-Lex (europa.eu)

The mechanism of the biocidal activity of ISB06 is not fully clarified to date. The biocidal effect may be dependent on several factors including competition with the target microorganisms by nutritive competition and by competitive exclusion. Competitive exclusion may be triggered by the synthesis of antibiotic compounds.

Identification

Genetic stability of ISB06 has been demonstrated by analysis of physiological markers and by PFGE across independent production batches. ISB06 is resistant to ampicillin which is typical for strains of Bacillus amyloliquefaciens.

Inactivation

Spore preparations of ISB06 can be inactivated with heat (98 °C on wet material) and UV radiation on wet material. Also chemical treatment with potassium peroxymonosulfate (CAS 10361-76-9) based sanitizers is effective at 75 °C. Dry spores are resistant to heat and UV radiation. Other sanitizers have been tested and shown to be ineffective in spore inactivation at room temperature and at increased temperatures.

Pathogen distinguishing

Bacillus amyloliquefaciens ISB06 is distantly related to the toxin-producing food-spoilage bacterium Bacillus cereus as well as to the pathogen Bacillus anthracis, the causative agent of anthrax. During identity investigation ISB06 could be firmly distinguished from these Bacillus species on basis of physiological and molecular traits.

Usage

biocidal product is designed to control potentially harmful bacteria in livestock buildings and equipment of animal rearing facilities, e.g. for poultry and pig. The product is intended to complement but not to substitute chemical disinfection measures as a prophylactic treatment. The biocidal product is applied by spraying on abiotic surfaces.

The active substance is intended to be used by professionals only in control and repression of potentially harmful bacteria in livestock buildings and on breeding equipment under Product Type 3. The biocidal product is applied by spraying on abiotic surfaces 24 to 48 hours after steps of cleaning-disinfection in order to avoid remanent effects of disinfectants.

The product is applied in order to colonise the disinfected surfaces and to form a so called "positive biofilm" which leads and/or reduces the potential colonisation of the abiotic surface by other commensal micro-organisms (in particular pathogen strains) and thus reduces the microbial pressure in the local environment. Therefore, the product has a prophylactic action but not a disinfecting one.

Human health

Professional spraying and misting application in livestock buildings is considered to be acceptable for human health. Due to the potential sensitizing effect and expected dermal and inhalation exposure the use of PPE is recommended.

Environment

Compared to the natural abundance of 102-105cfu per g of soil the number of cells and spores introduced into soil following product application can be considered negligible. It is therefore assumed that application of the product and subsequent environmental exposure is unlikely to cause increased abundance of ISB06 in the environment. The environmental risk assessment indicates that for the scenario investigated, the application of Bacillus amyloliquefaciens strain ISB 06 would not result in unacceptable risks for environment. However, this assessment only covers the indoor use of the biocidal product. This includes the assumption that mixing and

application of the product is only done indoors by professionals and on impermeable ground to avoid unintentional direct release into the environment.[185]

7.1.8.5 7.1.8.5 The ecolabel schemes

There are various existing ecolabel schemes already taking into consideration the presence of microorganisms in some of the detergent products while also setting out specific requirements for such MBCPs, their criteria and product types concerned.

The Revision of European Ecolabel Criteria for six product (2016)[186] found groups following ecolabelling schemes to contain criteria related to microorganisms: Nordic Swan (Nordic countries), Green Seal (USA), Good Environmental Choice (Australia), Ecologo (Canada).

Nordic Swan consider MBCPs within the general criteria for cleaning products but specify that only professional sanitary cleaning products are allowed. The other schemes define specific product groups, with tailored criteria, that are limited to products containing microorganisms (and enzymes, in Green Seal's case). The areas covered by the different schemes are all centred on the safety of the microorganisms, efficacy and specific labelling requirements

In 2016, this Revision proposed the addition of the sub-criterion (h) for microorganisms under the EU Ecolabel with specific requirements for them as the Detergents Regulation is closely linked with the EU Ecolabel product groups and it did not directly address the issue of ingredients such as microorganisms in detergent products. In response, the Commission Decision (EU) 2017/1217 established the EU Ecolabel criteria for hard surface cleaning products (HSC) which afterwards were incorporated into the EU Ecolabel user manual.[187]

Hereby the current criteria for sub-criterion (h): Microorganisms used under EU Ecolabel are quoted as whole:

Micro-organisms (only for HSC for professional use)

(i) Identification: all intentionally added micro-organisms shall have an American Type Culture Collection (ATCC) number, belong to a collection of an International Depository Authority (IDA) or have had their DNA identified in accordance with a "Strain identification protocol" (using 16S ribosomal DNA sequencing or an equivalent method).

(ii) Safety: all intentionally added micro-organisms shall belong to both of the following:

− Risk Group I as defined by Directive 2000/54/EC – biological agents at work;

− The Qualified Presumption of Safety (QPS) list issued by the European Food Safety Authority (EFSA).

[185] https://echa.europa.eu/documents/10162/38929c7c-25bb-4dfa-ab7d-c421a90969ca
[186] Boyano A., Kaps R., Medyna G., Wolf O. (2016): JRC Technical Reports – Revision of six EU Ecolabel Criteria for detergents and cleaning products, Final Technical Report, European Commission. Available at: http://susproc.jrc.ec.europa.eu/detergents/docs/Technical%20background%20report.pdf
[187] User's Manual (europa.eu)

(iii) Absence of contaminants: pathogenic micro-organisms, as defined below, shall not be in any of the strains included in the finished product when screened using the indicated test methods or equivalent:

− E. Coli, test method ISO 16649-3:2005;

− Streptococcus (Enterococcus), test method ISO 21528-1:2004;

− Staphylococcus aureus, test method ISO 6888-1;

− Bacillus cereus, test method ISO 7932:2004 or ISO 21871;

− Salmonella, test method ISO6579:2002 or ISO 19250.

(iv) All intentionally added micro-organisms shall not be genetically modified micro-organisms (GMMs).

(v) Antibiotic susceptibility: all intentionally added micro-organisms shall be, with the exception of intrinsic resistance, susceptible to each of the five major antibiotic classes (aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones) in accordance with the EUCAST disk diffusion method or equivalent.

(vi) Microbial count: products in their in-use form shall have a standard plate count equal to or greater than 1x105 colony-forming units (CFU) per ml in accordance with ISO 4833-1:2014.

(vii) Shelf life: the minimum shelf life of the product shall not be lower than 24 months and the microbial count shall not decrease by more than 10 % every 12 months in accordance with ISO 4833-1:2014.

(viii) Fitness for use: the product shall fulfil all the requirements set out in Criterion Fitness for Use and all claims made by the manufacturer on the actions of the micro-organisms contained in the product shall be documented through third-party testing.

(ix) Claims: it is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

(x) User information: the product label shall include the following information:

− that the product contains micro-organisms;

− that the product shall not be used with a spray trigger mechanism;

− that the product should not be used on surfaces in contact with food;

− an indication of the shelf life of the product.

Assessment and verification:

The applicant shall provide:

(i) The name (to the strain) and identification of all micro-organisms contained in the product with ATCC or IDA numbers or documentation on DNA identification.

(ii) Documentation demonstrating that all micro-organisms belong to Risk Group I and the QPS list.

(iii) Test documentation demonstrating that the pathogenic micro-organisms are not present in the product.

(iv) Documentation demonstrating that all micro-organisms are not GMMs.

(v) Test documentation demonstrating that all micro-organisms are, with the exception of intrinsic resistance, susceptible to each of the five major antibiotic classes indicated.

(vi) Test documentation of CFU per ml of in-use solution (for undiluted products, the dilution ratio recommended for 'normal' cleaning shall be used).
(vii) Test documentation of CFU per ml of in-use solution every 12 months for a product stored until the end of its shelf life.
(viii) Test results from a third-party laboratory demonstrating the claimed actions of the micro-organisms and artwork of the packaging or a copy of the product's label highlighting any claims made on the actions of the micro-organisms.(ix) and (x) artwork of the packaging or a copy of the product's label.[188]

With regard to the sub-criterion microorganism **that applies to the HSC product group**, Nordic Swan places additional requirements in comparison to the EU Ecolabel. For instance, product information provided to the user, whether by means of labels/information sheet or other marketing material, shall specify that the product **should not be used in places where immunocompromised people are present.**

As for the antibiotic susceptibility, the **EU ecolabel introduces the exception of intrinsic resistance** of the microorganism to the antibiotic. The same exception is not included in the Nordic Swan requirements.

Finally, the Nordic Swan requires evidence that products containing microorganisms shall display superior performance as compared with the criterion set on fitness for use and that they can degrade proteins, starch and fat.

For HSC, In the Nordic Swan scheme, microbial based products are to be compared for their cleaning power to an equivalent product without microorganisms. In the case of EU Ecolabel, no specific test is stated.

It has to be stressed, that products for non-professional use containing microorganisms that have been deliberately added by manufacturer are excluded from the scope of the category of HSC.[189]

7.1.9 7.1.9 Conclusions

Over recent years, there has been a novel type of cleaning products containing microorganisms (viable or in a form of spores) as active ingredients made available on the EU market, often called as microbial-based cleaning products. The fact that they contain living microorganisms, raises concerns on their potential impact on human health and the environment, even though the current manufactures claim their ‘ecological' properties due to the content of probiotic (‘healthy’) bacteria and/or using of less chemicals (‘environmentally friendly’).

These microbial-based cleaning products facilitate two main modes of action:

[188] EU Ecolabel for detergents and cleaning products, Version 1.2, October 2018
[189] Boyano A., Kaps R., Medyna G., Wolf O. (2016): JRC Technical Reports – Revision of six EU Ecolabel Criteria for detergents and cleaning products, Final Technical Report, European Commission. Available at: http://susproc.jrc.ec.europa.eu/detergents/docs/Technical%20background%20report.pdf

- Microorganisms are used to produce enzymes that degrade organic matter. This cleaning action can be extended if spore-forming bacteria are used; and
- beneficial microorganisms colonise surfaces and it is claimed that these are able to out-compete unwanted microorganisms over food sources therefore 'cleaning' the surface.

The use of microbial cleaners has been described as mainly applied via surface cleaning. Other types of uses include the cleaning carpets and upholstery, cleaning drains, pipes and grease traps, washing of industrial machine parts, or oil spills on masonry. The current size of the market with microbial cleaners is considered niche but with a potential to grow.

There are few microbiological hazards that may pose health and/or environmental risk under various exposure scenarios. The main risks are spread of pathogens, transmission and spread of antimicrobial resistance genes, production of toxins and allergic properties. The data gap remains on the potential health consequences of microbial cleaners for humans, animals and plants and effect on the environment, in both the short and long term. Furthermore, the quality assurance of the production of microbial based cleaning products is highly important to deliver a safe and stable product to all the customers.

The certainty should be established for these products, under which legislative scope they fall, as there is not a consensus among the National Authorities and stakeholders which framework apply. It is certain that microorganisms as such and by the definitions are not covered by REACH and thus neither by CLP. The General Safety Products Directive applies but does not set any specific requirements for these products. The Biocidal Regulation is applicable when the microorganism(s) act against harmful organisms, then the full-fledged risk assessment of the active substance is conducted. The Detergents Regulation is the most appropriate for these products to comply with from the view of some stakeholders and manufacturers due to their intended use and effect. On the other hand, this claim may also be based on the intention to circumvent the costly procedure required by the Biocidal Regulation. However, the definitions set herein do not reflect all the aspects of the currently available microbial based cleaning products on the market. Furthermore, the identified microbiological hazards are not taken into consideration and thus the Detergents Regulation lacks any risk management to deal with microbial cleaners. In contrast, the EU Ecolabel scheme sets specific requirements for the hard surface cleaners containing microorganisms intended for professional use since 2017.

7.2 7.2 HARMFUL INGREDIENTS POTENTIALLY INCLUDED IN DETERGENTS

7.2.1 7.2.1 Biodegradability for non-surfactant organic ingredients

In its 2009 report to the European Parliament and the Council[190] which quotes the study conducted for the Commission in 2006 and the related opinions of the Commission's Scientific Committee[191], the Commission concluded that it is not considered appropriate to propose legislation to impose a requirement of ultimate biodegradability on the non-surfactant organic ingredients. This report

[190] Report from the Commission to the European Parliament and the Council Pursuant to Article 16 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, concerning the biodegradation of main non-surfactant organic detergent ingredients: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009DC0208.

[191] Held in June 2007 and November 2008 which were also discussed with delegates from Member States and industry associations in a number of meetings of the Commission Detergents Working Group.

considers that no risk to the environment has been identified for any of the non-surfactant organic detergent ingredients. It however stresses that risk cannot be excluded for a few of those substances, as information on them is incomplete, the amount of additional data needed for a complete risk assessment is relatively small. It adds that many of the non-surfactant organic ingredients for which data is complete are not ultimately biodegradable but are neither toxic to human health nor to the environment.

Since the publication of this report the REACH Regulation has been in force for around 13 years generating information on chemical substances placed on the market and adopting control measures. The table below summarises how REACH applies to non-surfactant organic ingredients considered of possible concern under the 2006 Commission study led by RPA (Table 16). None of these substances led to control measures under REACH (restrictions/procedures of authorisation). Note that all these ingredients are registered under REACH with the exception of polycarboxylates which are polymers and are therefore exempted[192].

Table 18 REACH and non-surfactants

Main non-surfactant organic ingredients with potential concern according to 2006 RPA study	**Coverage under REACH Regulation according to REACH database**
EDTA and EDTA tetrasodium salt	Substance registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum. No control measures under REACH (i.e. restrictions/ authorisation procedure)[193]
Nitrilotriacetic Acid	Substance registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum. No control measures under REACH (i.e., restrictions/ authorisation procedure)[194]
Phosphonates	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum. No control measures under REACH (i.e., restrictions/ authorisation procedure)[195]
Polycarboxylates (polymers)	All polymers are exempt from registration and evaluation under REACH.

[192] Article 2(9) of REACH: the provisions of Titles II and VI shall not apply to polymers.
[193] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.522.
[194] https://echa.europa.eu/substance-information/-/substanceinfo/100.004.869.
[195] https://echa.europa.eu/substance-information/-/substanceinfo/100.033.682.

	A manufacturer or importer of a polymer must however submit a registration to ECHA for the **monomer** substance (s) or any other substance (s), that have not already been registered by an actor up the supply chain, if both the following conditions are met: • The polymer consists of 2 % weight by weight (w/w) or more of such monomer Substance (s) or other substance(s) in the form of monomeric units and chemically bound substance(s); • The total quantity of such monomer substance(s) or other substance(s) makes up to 1 tonne or more per year. However, polymers are not exempt from the REACH control measures (i.e. restrictions and authorisation procedure)

In case there are concerns about the use of substances in detergents, REACH control measures, can be triggered (e.g. restriction under REACH to limit or ban the manufacture, placing on the market or use of a substance) through a thorough procedure assessing whether these substances pose an unacceptable risk to human health or the environment or not.[196]

To conclude, if these ingredients independently of their biodegradability entail a risk to human health and the environment, REACH assessment procedures and control measures would apply. While polymers are only registered under REACH via their monomers, several actions are currently ongoing that will address this issue. In particular, two initiatives are currently ongoing to address microplastics pollution, namely:

- The Commission is preparing a restriction under REACH for microplastics intentionally added to products[197]. This restriction will also be applicable to detergents.
- The Commission is also examining the unintentional release of microplastics in the environment. A first examination[198] initially identified three main sources of microplastics pollution namely tyres, pellets and textiles. However, in the course of the analysis three new

[196] Note that for the non-surfactant organic ingredients that raised some concerns in the 2006 RPA study (i.e. polycarboxylates, phsphonates, EDTA and its salts, triethanolamine, FWA-5 and paraffins) no restriction procedures have been triggered. And seocifically as regards polycarboxylate polymers, studies suggest that such polymers used in detergent entail limited risks for the environment, see 'Environmental risk assessment of polycarboxylate polymers used in cleaning products in the United States': https://www.sciencedirect.com/science/article/pii/S0045653520314351.

[197] https://echa.europa.eu/hot-topics/microplastics. The Commission's proposal is based on the restriction dossier prepared by the European Chemicals Agency.

[198] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12823-Microplastics-pollution-measures-to-reduce-its-impact-on-the-environment_en

sources were included in the scope of the ongoing impact assessment, among which are also detergents laundry and dishwasher capsules[199].

Finally it should also be noted that voluntary industry initiatives envisaging the full biodegradability of all ingredients used in detergents are ongoing. Unilever, one of the biggest manufacturers in the EU, has embarked on a mission to make all its products formulations 100% biodegradable by 2030[200]. The company also claims that most of the ingredients currently used – approximately 90% by volume – in its products portfolio already biodegrade quickly and completely. However, while proven to be safe for the environment, some ingredients take longer – months – to break down. Even though several challenges appear in replacing a certain ingredient, the company is determined to make the green transition by combining full biodegradability of its products with a shift to 100% renewable carbon. Given that current trends towards sustainability *i.e.* the consumer demand for more sustainable and energy efficient products and the regulatory developments under the Green Deal, and taking into account the above mentioned ongoing developments in the market, it is likely that other companies will also follow with similar initiatives in the near future in order to be able to keep up and make the green transition.

7.2.2 7.2.2 Phosphorus limitations

In 2012 harmonised rules on the content of phosphates and other phosphorus compounds in detergents for household laundry and automatic dishwashing machines were introduced in the Detergents Regulation. The rules however do not apply to hand dishwashing detergents or industrial and institutional detergents. We next explore the possibility of expanding the phosphorus limitations to these products wherever relevant and feasible.

The use of phosphates in detergents has been long recognised as a useful way to combat water hardness and contribute to efficient cleaning: its use, in conjunction with surfactants, allows efficient removal and prevention of encrustation on fibres and an overall enhancement of the washing process. However, at the same time, phosphates from detergents can cause certain adverse effects in the aquatic environment. When in water, they act as nutrients which, in excess, can cause a phenomenon called eutrophication: an accelerated growth of algae and higher forms of plant life which produces an undesirable disturbance to the balance of organisms.[201] Although it is recognised that alternative water-softening ingredients are available, these have traditionally been perceived as inefficient solutions in comparison to phosphates, as they require more demanding inputs and cleaning tasks.

DETREG was amended in 2012 and introduced a limit for the total phosphorus/ phosphate content but only for consumer laundry and dishwashing detergents for use in a domestic machine. It excluded industrial or institutional detergent products from these limitations because it was believed that suitable

[199] The other two additional sources are geotextiles and paints.
[200] https://www.unilever.com/news/news-search/2021/how-we-are-working-to-make-our-product-formulations-biodegradable/
[201] Impact Assessment. COM(2010) 597 final, SEC(2010) 1278 final.

technically and economically feasible alternatives to the use of phosphates in those detergents were not yet available.[202] The restrictions do not apply to hand dishwashing detergents either.

A recent study by UBA[203] (2021) describes the strengths of phosphates and phosphonates when used in industrial and institutional (I&I) detergents. This includes their function as a water dispersant, bleaching medium and disinfectant stabilizer, washing booster, and as a water hardness stabilizer. As a result, when used in I&I detergents, phosphates and phosphonates allow a higher dirt-carrying capacity and ability to reduce metals that interfere with the bleaching and disinfectant capability, all of which makes them more efficient cleaning agents. The features of phosphonate have been stressed by UBA[204] in a whole range of applications for dishwashing[205] and textile washing (hospital and hotel linens, nursing and nursing home linen, and work clothes from food processing companies[206]).

The IHO reported that phosphorus and phosphates have great advantages as a multifunctional raw material in I&I detergents for processing heavily soiled workwear. This is because phosphorus and phosphate provide:

- Protection of textiles;
- Savings of resources by avoiding: textile incrustation, and deposition of Ca/Mg compounds on the components of the machine;
- Dispersion of pigments, fats and oils on heavily soiled clothing from the workwear sector (achieving an increased primary washing effect, compared to conventional techniques);
- Prevention of redeposition on the washed textile thus significantly improving brilliance of blue workwear (hence improving quality and reducing post-washing whilst also improving conservation of resources).

A.I.S.E. has reported on the very particular requirements of detergents in the I&I sector, especially in comparison to the needs for consumers[207]:

- In laundry, the type of soil is different (e.g. hospital textiles and industry textiles), disinfection is more often required (and more critical), and shorter washing times are needed (typically 15-30 minutes). Hence, efficient cleaning can be achieved (around 1/3 of the water used in private appliances), all of which allows a longer lifetime for textiles (a critical feature needed in the

[202] Recital 4 of the 2012 amendment considered that it was "currently not appropriate to extend limitations on the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents to industrial and institutional detergents at the level of the Union because suitable technically and economically feasible alternatives to the use of phosphates in those detergents are not yet available" (Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents).
[203] The German Environment Agency (Umweltbundesamt – UBA).
https://www.umweltbundesamt.de/publikationen/relevanz-der-gewerblichen-textil-geschirrreinigung.
[204] The German Environment Agency (Umweltbundesamt – UBA).
https://www.umweltbundesamt.de/publikationen/relevanz-der-gewerblichen-textil-geschirrreinigung.
[205] Phosphates are important in dishwashing as a greater concentration of dirt can be dispersed, resulting in large savings in water, energy and detergents.
[206] For example, the UBA states that hospital linens or hotel towels must have the water hardness stabilized in order for it to be cleaned most effectively through water softening. Along with this, through the current washing processes, Phosphate may be necessary in the current processes in laundry to achieve the desired cleaning performance.
[207] A.I.S.E. "Position on the Use of Phosphates in Detergents for I&I use". Unpublished document.

professional cleaning sector, for example). In addition, the role of phosphates in the I&I sector is different, as it is used as an anti-redeposition agent, a performance booster and as remover of difficult stains.

- In automatic dishwashing, phosphate is essential in those appliances that have an optimised ingredient use, and to meet technical requirements dictated by: very short wash time (typically 2 minutes), high temperature wash, low product dosage, type of dirt and frequency of cleaning. For example, in the hotel-restaurant-catering sector where optimal hygiene is paramount, phosphate is a key contributor to flawless cleaning; in the health sector, the cleaning of certain surgical instruments can only be achieved with phosphate-based detergents.
- For special cleaning applications (for example pre-treatment in the automotive manufacturing process chain), products containing phosphate are needed to prevent corrosion and to ensure perfect cleanliness (essential for the longevity of the vehicle body, for example).

National authorities corroborated the views on the lack of alternative substances in the I&I sector. Three of the authorities consulted believed that "there are no viable options for substitution" of phosphates in detergents for the I&I sector. This is because of the hygiene and performance requirements in the I&I which can only currently be met efficiently using detergents with phosphorus compounds. They also commented that without the phosphorus compounds, more water and energy would be used to achieve the same results. One final advantage noted is the "non-corrosive effect" of phosphorus on machinery which can aid in the longevity of a machine's lifespan. As a result, one national authority believed that limiting the use of phosphates or using alternatives to phosphates in detergents in the I&I sector could have "negative socio-economic impacts".

The prime concern over the use of phosphate in detergents is related to their discharge into wastewaters, which contributes to the environmental problem of eutrophication.[208]

The size of phosphorus and phosphates discharged into the environment by the I&I sector is in practice small, as much of the residual waters in the professional sector is either connected to sewage treatment plants (where the phosphorus and phosphates concentration is substantially reduced) or undergoes recycling or pre-treatment (with phosphorus removal prior to discharge to the sewer system). This is recognised in the Commission's 2010 Impact Assessment[209]. See also UBA (2021)[210] and A.I.S.E. and IHO (2021)[211].

The amount of phosphorus and phosphates contained in hand dishwashing detergents is negligible or close to zero (this has been asserted by stakeholders responding to our interviews).

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[208] There are no known adverse effects on human health associated with the use of phosphates, nor for the soil or air medium (due to their composition, phosphates do not invade the atmosphere).

[209] COMMISSION STAFF WORKING DOCUMENT Accompanying document to the Proposal for a REGULATION (EU) No 259/…2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorous compounds in household laundry detergents, IMPACT ASSESSMENT SEC/2010/1277 final - COD 2010/0298.

[210] The German Environment Agency (Umweltbundesamt – UBA).
https://www.umweltbundesamt.de/publikationen/relevanz-der-gewerblichen-textil-geschirrreinigung.

[211] AISE news. PAPER BY UMWELTBUNDESAMT ON THE RELEVANCE OF PROFESSIONAL LAUNDRY AND MACHINE DISHWASHING ON THE ENTRY OF PHOSPHATE AND OTHER PHOSPHORUS COMPOUNDS (P) INTO WASTEWATER. October 2021.

The main cause for intervention in this context is linked to the availability (or not) of alternatives to phosphates and other phosphorus. This is because of the lack of suitable technically and economically feasible alternatives.

In the I&I sector, recent research undertaken by UBA[212] has established that, at present, there are no available alternatives to phosphates and other phosphorus compounds to be used in detergents. The alternatives all imply higher requirements (in terms of energy use, water and time) which make them unsuitable for use in the I&I industry. Along with this, machine procedures and attributes may also need to be altered in order to achieve the full potential if alternatives are to be used (this includes making the washers larger in order to allow for more water, higher heating capacities, and longer wash cycles).

Following a request for information, the IHO informed us that there have been no new developments or innovation in phosphorus/ phosphate substitutes since 2012. Alternative substitutes have been available on the market for almost 20 years but are not equally efficient nor economically viable alternatives for professional laundries.[213] This is because concentrations have to be used and significantly higher post-washing is needed (resulting in increased use of water, energy and detergent). In addition, such alternative ingredients also increase the costs of treating wastewater in municipal wastewater works.

The IHO also reported on current national efforts to further expand phosphorus recovery from wastewater, sewage sludge and sewage sludge, which opens, according to the IHO, new possibilities for elimination and potential recycling of phosphorus from German wastewater treatment plants. This might open a more efficient way to achieve phosphorus reduction for residual waters connected to water-treatment plants.

Relevant stakeholders are the producers and users of I&I detergents and hand dishwashing detergents.

In conclusion, in 2012 I&I detergent products were exempt from the limit introduced for total phosphorus/ phosphate content because of a lack of suitable technically and economically feasible alternatives to the use of phosphates in those detergents. Our research has concluded that substitutes are not yet available for such products, so the previous conclusion can still be maintained: the limit for the total phosphorus/ phosphate should still exclude I&I detergents, due to the lack of suitable substitutes in this sector.

As regards consumer hand dishwashing detergents, based on reports from industry stakeholders during the interviews for this Impact Assessment, there is no need to incorporate phosphorus in the formulation.

As explained for other applications of the sector, Phosphorus and its derivatives are a very expensive ingredient and they are already avoided or substituted with alternatives, where possible. The main function of P-compounds is to reduce the hardness of water (concentration of Potassium and Calcium) and to ensure a better performance of washing. This application is fundamental in I&I applications to increase performance and reduce energy consumption and time. It does not, however, produce any advantage in the handwashing, as hand-rubbing replaces any action of the P-compound. For this reason and due to the cost, the number of consumer hand dishwashing products including P, if any, is very low.

[212] The German Environment Agency (Umweltbundesamt – UBA).
https://www.umweltbundesamt.de/publikationen/relevanz-der-gewerblichen-textil-geschirrreinigung.
[213] Based on MGDA-Na3, GLDA-Na4 or IDS-Na4.

The industry also claimed that this type of products is not included in the scope of the study on P emissions carried out by Umwelt Bundesamt (the German Environment Agency) on overall P emissions in wastewater from detergents. To consider the impact of this sector on emissions to wastewater, the study only considers automatic dishwashing, disregarding the hand dishwashing. To me, this constitutes additional evidence of the negligible portion of the hand-dishwashing detergent sector.

7.2.3 7.2.3 No requirements for cat. 2 CMRs and EDs

The issue stems from concerns reported in the Evaluation (by one consumer organisation and two NGOs) that claimed that some Category 2 CMR substances are permitted for use in detergents. The Evaluation made it clear that Category 1 CMRs are strongly regulated by REACH, but that it is "unclear whether Category 2 CMRs are actually used in detergents sold to the general public".

Bearing this in mind, the Evaluation concluded that, based on the precautionary principle, and considering that detergents are products widely used by the general public further investigation on the regulation of Category 2 CMRs in detergents for consumer use (especially those that come in contact with human skin) could be considered.

According to the CLP Regulation, Category 2 CMR are substances which:

- Are suspected human carcinogens on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B, based on strength of evidence together with additional considerations. Such evidence may be derived either from limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans. The classification in Category 2 is based on:
    - positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:
        - somatic cell mutagenicity tests in vivo, in mammals; or
        - other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays.
- Are suspected human reproductive toxicant when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, and where the evidence is not sufficiently convincing to place the substance in Category 1. If deficiencies in the study make the quality of evidence less convincing, Category 2 could be the more appropriate classification. Such effects shall have been observed in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects.

Annex XVII to REACH (the restriction list, entries 28, 29 and 30) restricts the use of CMR Category 1A and 1B substances for supplies to the general public such as detergents and requires additional

labelling for products intended for professional users. There is, however, no similar requirement for Category 2 CMRs under REACH. Despite the lack of a general restriction for cat.2 CMRs under REACH, manufacturers are required to register such substances for specific uses e.g. for use in detergents.

As regards the treatment of these substances under other sectoral EU chemicals legislation, the Cosmetic Products Regulation[214] and the Toy Safety Directive[215] include specific provisions introducing a general prohibition of use for cat. 2 CMRs, subject to derogations[216].

It should, however, be noted that unlike detergents cosmetics are not covered by REACH from a human health perspective. As a result, it is necessary that specific provisions are introduced for the use of these substances in the sectoral legislation *i.e.* the Cosmetic Products Regulation. As regards toys, even though these are covered by REACH, they are used by vulnerable groups *i.e.* children. Given that the exposure levels from using toys could also be higher e.g. due to the inherent tendency that children have of putting toys in their mouths from a very small age, the need to deviate from the horizontal rules is justifiable.

In accordance with the Chemicals Strategy a targeted revision of REACH is being prepared to address a number of issues that have been identified[217]. The most relevant aspect in relation to the revision of the Regulation is the possibility of reforming the restriction process under REACH for certain hazardous substances. Options include extending the generic risk approach to products marketed for professional use; operationalising the concept of essential use in restrictions, including the criteria for granting derogations; and extending the generic risk approach (GRA) to restrictions to most harmful substances. Substances currently considered to be included in the definition of 'most harmful substance' to which the GRA would be extended include: endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs. Any amendments to the REACH Regulation as a result of the ongoing revision, will also apply to detergents. Though the analysis is still in progress, this definition of 'most harmful substance' as detailed above does not include category 2 carcinogenic mutagenic and reprotoxic substances (cat. 2 CMRs). The use of cat. 2 CMRs in detergents is already covered by the horizontal rules applicable to all consumer products under REACH and no evidence has been found under this Impact Assessment (either through the desk research or stakeholders' reports) to substantiate that we need to deviate from these horizontal rules.

[214] Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products.

[215] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

[216] According to Article 15 of the Cosmetic Regulation, the use in cosmetic products of substances classified as CMR substances, of Category 2 under the CLP Regulation is prohibited. However, a substance classified in Category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products. Annex II to the Toy Safety Directive prohibits the use of CMR 1A, 1B or 2 in toys, in components of toys or in micro-structurally distinct parts of toys. Certain derogations exist when (a) the concentration of the substance/mixture is below the classification limit (b) the substance/mixture is inaccessible to children in any form, including inhalation, when the toy is used (c) a decision has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A (no exposure/no suitable alternative/and no REACH restriction).

[217] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en