EUROPEAN
COMMISSION

Brussels, 28.4.2023
SWD(2023) 114 final

PART 1/3

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}

Table of contents

Glossary

Term or acronym	Meaning or definition
Biocidal	Any product or substance intended to destroy, control or prevent the effects of harmful organisms, or in any other way control harmful organisms, by any means other than physical or mechanical action.
Biodegradability	A process that results in the breakdown of organic matter by microorganisms, such as bacteria and fungi.
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
CADD	Consumer Automatic Dishwasher Detergent
Chemicals Strategy	Chemicals Strategy for Sustainability [COM(2020)667 of 14 October 2020]
CLP	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
Combination effect	Sometimes referred to as 'cumulative' or 'mixture effect' includes the (eco)toxicological effect on an organism arising from exposure to a chemical mixture. Type and strength of the effect will vary depending on the composition of the mixture and the level of exposure.
DPP	Digital Product Passport
EEA	European Economic Area
EFSA	European Food Safety Authority
Endocrine System	This is a messenger system comprising feedback loops of the hormones released by internal glands of an organism directly into the circulatory system, regulating distant target organs.
ESPR	Proposal for a Ecodesign for Sustainable Products Regulation [COM(2022) 142 of 30 March 2022]
Evaluation	Evaluation of the Regulation [SWD(2019) 298 of 10 July 2019]
FPR	Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products ('Fertilising Products Regulation')
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GPSD	General Product Safety Directive GPSD (Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety)

IA	Impact Assessment
IIA	Inception impact Assessment
Metabolite	An intermediate or end product of metabolism.
Most Harmful Chemicals	This group of chemicals includes substances that are carcinogenic, mutagenic, or toxic to reproduction (CMRs), persistent and bioaccumulative, as well as endocrine-disrupting chemicals (EDCs). This group will also include substances that affect the immune, neurological, or respiratory system, chemicals toxic to a specific organ, persistent, mobile, and toxic (PMT), as well as very persistent, very mobile (vPvM) substances.
NLF	New Legislative Framework [Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93, and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC]
Pathogen	A bacterium, virus, or other microorganism that can cause disease/illness.
PO	Policy Option
Probiotic	Live microorganisms which when administered in adequate amounts confer a health benefit on the host.
QPS	Qualified Presumption of Safety
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals
Regulation	Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
SDS	Safety Data Sheet
Unknown microorganisms	Microorganisms for which no safety assessment has been performed by any scientific body and for which no harmonised risk assessment criteria exist.

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Political Context

Detergents hold a central role in our everyday lives. They help deliver health and hygiene in almost all areas of human activity from households and schools to gyms, offices, hospitals, hotels and restaurants. Detergents are, however, chemicals with intrinsic properties that have the potential to pose risks to human health and the environment. The Detergents Regulation[1] ('the Regulation') lays down the rules that detergents need to comply with in order to be placed and move freely on the EU market. These are essentially rules that ensure the safe use of detergents (labelling and other information requirements) and the high environmental performance of detergents and surfactants[2] for detergents (biodegradability requirements and phosphorus limitations).

The evaluation of the Regulation[3] identified a number of weaknesses that have emerged since the adoption of the Regulation in 2004. The chemicals Fitness Check[4] highlighted the complexity of the EU regulatory framework for chemicals and attributed it to the large number of product and sector specific pieces of legislation with embedded links with each other. It also pointed out that there is room for simplification in the communication of information of overcrowded labels to product users and found that the use of innovative tools for communicating product information is currently not being taken advantage of.

The Chemicals Strategy for Sustainability ('Chemicals Strategy') adopted in October 2020 as part of the European Green Deal commits to further increase the protection of consumers using detergents with regard first to the risks from the most harmful chemicals, *e.g.* those that are prone to cause cancers, genetic defects or affect the reproductive or the endocrine system, and second to the possible combination effects of chemicals. Although the hazards and risks related to detergents are already being assessed and managed under the REACH[5] and CLP[6] Regulations, these do not currently extend to certain substances of particular concern such as endocrine disruptors, or take into account mixture assessment factor(s) for the chemical safety assessment of substances.

The updated Industrial Strategy adopted in May 2021[7] further emphasises the importance of accelerating the green and digital transitions of the EU industry, supported by *i.a.* a coherent

---

[1] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents

[2] Surfactants are surface-active agents that help break down the interface between water and oils and/or dirt. They are one of the main ingredients used in detergents.

[3] Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, SWD(2019)298

[4] Fitness Check of the most relevant chemicals legislation (excluding REACH) SWD(2019)199

[5] 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

[6] 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

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery; COM(2021) 350 final

and stable regulatory framework. The Commission Work Program for 2022[8] lists the revision of the Regulation as a REFIT initiative.

Given the links to the European Green Deal, in particular, the better protection of citizens and the environment; boosting innovation for safe and sustainable chemicals; and the green and digital transition of the EU industry, the objectives of this initiative (see section 4) also contribute to the achievement of the United Nations Sustainable Development Goals (SDGs). Three of these are directly relevant for this initiative: SDG #9 'Industry, innovation and infrastructure', SDG #3 'Good health and well-being', and SDG #12 'Ensure sustainable consumption and production patterns' (see Annex 3, Part 3 for more details).

1.2. Legal and Economic Context

1.2.1. Description of the Regulation

The Regulation harmonises the rules for the placing on the market of detergents and surfactants for detergents. The rules apply to both products for consumer and professional use[9].

In particular, the Regulation aims at ensuring the free movement of detergents and surfactants for detergents in the internal market while, at the same time, providing a high level of protection of human health and the environment. To do this **the Regulation harmonises the following rules for detergents and surfactants for detergents**:

- limitations on the content of phosphorus and phosphorus compounds in consumer laundry and consumer automatic dishwasher detergents ('CADD');
- labelling requirements;
- specific biodegradability criteria;
- 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 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. Ultimate biodegradability is defined as the level of biodegradation achieved when the surfactant is totally broken down into carbon dioxide (CO_2), water and biomass. 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.

In 2012, **harmonised limits on the content of phosphates and other phosphorus compounds** were introduced in the Regulation to reduce the damage that phosphates from detergents may have on ecosystems and aquatic environments given the contribution of

[8] https://ec.europa.eu/info/publications/2022-commission-work-programme-key-documents_en

[9] Also called industrial and institutional detergents, meaning a detergent used outside of the domestic sphere carried out by specialised personnel using specific products e.g. in hospitals, hotels, industrial settlements.

phosphorus to eutrophication[10]. These limitations apply only to two types of products, namely to consumer laundry and consumer automatic dishwasher detergents.

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.

The **labelling requirements** of the Regulation serve as a means of protecting human health. This is because labels communicate important use and safety information to users, such as the presence of skin or respiratory sensitisers (allergenic fragrances, preservatives, enzymes) in detergents. By providing information on the content of these substances on detergents' labels, users 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, an **ingredient data sheet** *i.e.* 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 (consumers) the Detergents Regulation also requires manufacturers to provide **an ingredient data sheet on a dedicated website**[11]**.** This website must also be indicated on the detergents' labels.

1.2.2. Interplay with the EU regulatory framework for chemicals

The Regulation is one of the older pieces of EU legislation on chemicals. Since its adoption in 2004, the EU has established a **comprehensive and solid regulatory framework for chemicals** comprising both horizontal and sectoral pieces of legislation that often have embedded links with each other. The EU regulatory framework for chemicals is spearheaded by two horizontal Regulations, namely REACH and CLP.

REACH establishes procedures for collecting and assessing information on the properties, hazards and uses of substances. Companies cannot manufacture or place a substance on the market in quantities equal or above one tonne per year, unless it is registered. Based on registration dossiers that companies compile, the European Chemicals Agency ('ECHA') and national authorities assess whether the risks of chemical substances can be managed. If not, authorities may either ban the use of such hazardous substances and make them subject to a prior authorisation, or restrict their use. REACH applies to all chemical substances i.e. not only to those used in industrial processes but also in our day-to-day lives, such as detergents. This means that **substances used in detergents need to be registered under REACH** in order to be allowed for use in detergents.

---

[10] Eutrophication is the process by which an entire body of water, or parts of it, becomes progressively enriched with minerals and nutrients, particularly nitrogen and phosphorus. This leads to algae bloom, which can threaten marine life due to reduction of oxygen (and/or production of toxic substances) in the water.

[11] This is a simplified version of the above mentioned data sheet that does not disclose the concentrations in which ingredients are included in the detergent, thus protecting detergents manufacturers.

CLP is the core piece of Union legislation for the hazard assessment of chemicals incorporating the classification criteria and labelling rules agreed at United Nations (UN) level, the so-called Globally Harmonised System of Classification and Labelling of Chemicals ('GHS'). The Regulation requires companies to appropriately classify, label and package their substances and mixtures before placing them on the market. It aims to protect workers, consumers and the environment by labelling that reflects a particular chemical's possible hazards. It also addresses the notification of classifications, the establishment of a list of harmonised classifications and the creation of a classification and labelling inventory.

Detergents need to comply with the requirements of CLP Regulation in order to be lawfully placed on the market. As a result, the **labelling of detergents falls by default under two pieces of legislation** *i.e.* the Regulation and CLP Regulation. In practice, this means that when substances are classified as hazardous based on human health or environmental information, necessitating communication of this classification in the form of labelling according to CLP Regulation, this needs to be included in detergents labels. In addition to this information, specific labelling requirements for detergents are laid down in the Regulation and also need to be included in detergents labels.

On top of these rules, some detergents may also be subject to the **Biocidal Products Regulation**[12] ('BPR') if they have a biocidal function or contain a preservative. The BPR lays down the rules for the placing of biocidal products on the EU market and sets requirements for the placing on the market of products treated with, or intentionally incorporating, one or more biocidal products ('treated articles'). In particular, BPR requires that all biocidal products obtain an authorisation before they can be placed on the market, and that the active substances contained in them must be previously approved[13]. Products can only incorporate or be treated with biocidal products containing active substances approved in the EU. BPR also lays down labelling requirements for products falling under its scope.

Detergents that have an antibacterial function (*i.e.* detergents that are also disinfectants) or contain a preservative ('treated articles') are, therefore, required **to comply with the provisions of both the Regulation and BPR.** In practice, this means that the biocidal active substances used in detergents need to have been previously approved in accordance with BPR and that the detergents containing them or are treated with them **need to be labelled in accordance with both** the Regulation and the BPR.

[12] 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

[13] There are, however, certain exceptions to this principle. For example, biocidal products containing active substances in the Review Programme can be made available on the market and used (subject to national laws) pending the final decision on the approval of the active substance (and up to 3 years after). Products containing new active substances that are still under assessment may also be allowed on the market where a provisional authorisation is granted.

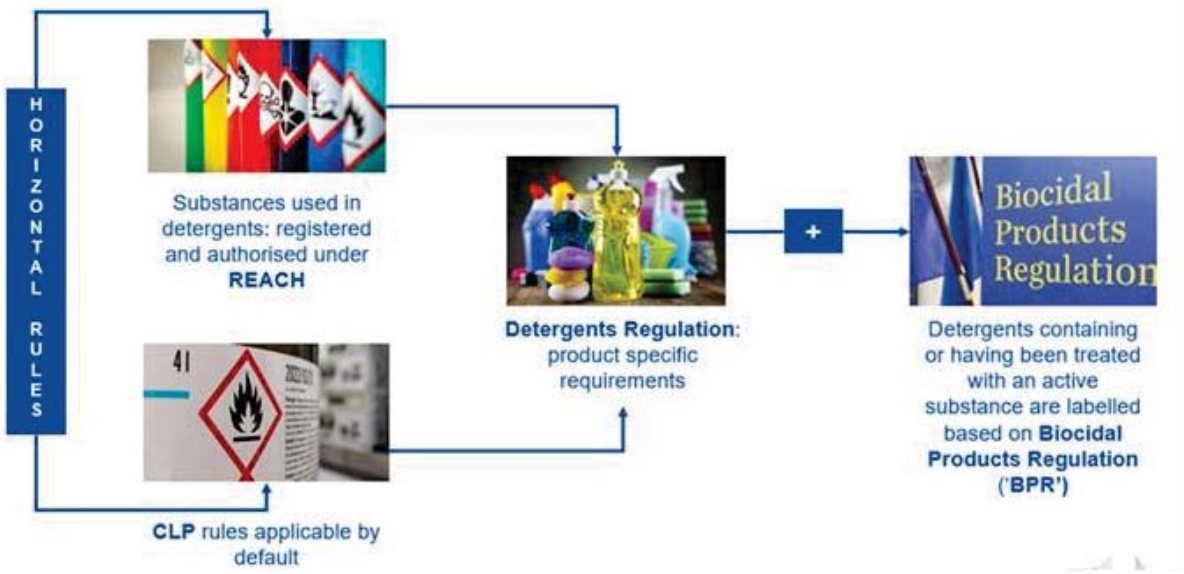


Figure 1 - Overview of the EU Regulatory framework for detergents

1.2.3. Interplay with other initiatives

The Sustainable product policy & eco-design: The proposal for a Regulation on Ecodesign for Sustainable Products ('ESPR')[14] proposes to extend the existing Ecodesign framework in two ways: first, to cover the broadest possible range of products, going beyond energy-related products (*e.g.* textiles, furniture and high impact intermediary products such as steel, cement and chemicals); and second, to broaden the scope of the requirements with which products are to comply. Products to be covered will be prioritised on the basis of a working plan[15]. The proposed regulation sets a framework that will enable product-level rules to be laid down *in a second stage*, through delegated acts, product by product or for groups of products if appropriate. This builds on the approach proven successful under the current Ecodesign Directive.

Further, the ESPR proposal foresees the provision of **product information via digital tools** in the form of Digital Product Passports ('DPP') for all regulated products. In particular, the DPP will gather data on a product and its value chain. This Passport foresees the mandatory adoption of digital ways of communicating product information for the products to be covered by the ESPR based on the above described process (see also section 5.1.3.1 below).

[14] Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting eco-design requirements for sustainable products and repealing Directive 2009/125/EC of 30 March 2022, COM(2022) 142 final.

[15] A public consultation on the products to be selected for the first Ecodesign for Sustainable Products Regulation working plan will be launched by the end of 2022. A preliminary assessment by the Commission has identified that product categories such as textiles, furniture, mattresses, tyres, detergents, paints, lubricants, as well as intermediate products like iron, steel and aluminium, have high environmental impact and potential for improvement, and may thus be suitable candidates for the first workplan.

While detergents have already been identified as potentially suitable candidates for this initiative[16], it should be noted that the development of new requirements under the ESPR will be underpinned by thorough preparatory processes, including inclusive stakeholder consultation and impact assessment, also as regards affordability for consumers, impacts on competitiveness and administrative burden. Any new requirements under the ESPR would only be complementary to those already laid down in the Regulation and no overlaps between these two Regulations are expected to occur.

Microplastics pollution – measures to reduce its impact on the environment: Two initiatives are currently ongoing to address microplastics pollution, namely:

- The Commission is preparing a restriction under REACH for microplastics intentionally added to products[17]. This restriction will also be applicable to detergents.
- The Commission is also examining the unintentional release of microplastics in the environment. A first examination[18] initially identified three main sources of microplastics pollution namely tyres, pellets and textiles. However, in the course of the analysis three new sources were included in the scope of the ongoing impact assessment, among which are also detergents laundry and dishwasher capsules[19].

While this Impact Assessment does not address any issues related to microplastics in detergents, depending on the outcome of the parallel Impact Assessment on the unintentional release of microplastics in the environment, measures could be introduced in the revised Regulation to address it.

Proposal for a General Product Safety Regulation: The Commission presented on 30 June 2021[20] a proposal to revise the General Product Safety Directive[21] with the objectives of protecting consumers when shopping online, including on online marketplaces, and from dangerous products coming from the EU and outside. It also aims at preserving a safety net for all non-food dangerous products and risks not covered in other EU legislations. It will also make product recalls more effective to avoid that dangerous products remain in consumer's hands. The future General Product Safety Regulation, as the current Directive, will continue to address only aspects which may not be specifically covered by the Detergents Regulation. For example, the specific provisions on recalls and online marketplaces are expected to apply to all consumer products including detergents.

A **revision of the CLP[22] and the REACH[23] Regulations** is currently ongoing. For details and interlinks with this initiative please see sections 5.1.3.2 and 5.1.3.3 below.

---

[16] Questions and Answers: sustainable products initiative, https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2014

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

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

[19] The other two additional sources are geotextiles and paints.

[20] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0346

[21] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4.

[22] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en

For packaging and refill sales, the **revision of the EU legislation on packaging and packaging waste**[24] is also considered in this impact assessment. Three elements are particularly relevant here. The first is that packaging should be marked with a label containing information on its material composition in order to facilitate consumer sorting. The proposal specifies that reusable packaging will bear a QR code or other type of data carrier giving access to the relevant information facilitating its re-use. The second is the principle that packaging will have to be designed to minimise its volume and weight while maintaining its ability to perform the packaging functions. And the third is that economic operators who offer products for purchase through refill will have to provide certain information to end-users and to ensure the compliance of refill stations with the requirements laid down in the proposal.

This initiative follows the general trend of **digitalisation of the labels** or documents accompanying other products (construction products[14], medical devices[15] or wines) or the ongoing work towards this objective (batteries[16], fertilising products, cosmetics, hazardous chemicals and the labelling of alcoholic beverages[17]).

1.2.4. The detergents market[25]

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[26] (see Annex 6). The total market value of the European detergents industry in 2020 was EUR 41.2 billion[27]. The manufacturing of products for the whole market that includes both consumer and professional products involves around 700 separate facilities throughout Europe[28]. The vast majority of sites (more than 85%) are operated by SMEs. In terms of volume, the output is concentrated 80-90 large-scale plants located in the large producing countries (Germany, Italy, Spain, France, and Poland) and the Benelux, and operated by multi-national companies[29]. Many of these large facilities supply multiple national markets across Europe, while SMEs mostly operate in national markets, supplying national, rather than global brands, and focusing on serving particular market niches (notably in the professional sector).

---

[23] 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

[24] EUR-Lex - 52022PC0677 - EN - EUR-Lex (europa.eu)

[25] For a detailed description of the market, see Annex 6.

[26] Eurostat 2018, based on EU-27

[27] Includes EU 27, UK, CH and NO, A.I.S.E. Activity and Sustainability report 2020 – 2021 available here: https://www.aise.eu/library/publications.aspx

[28] 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).

[29] 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)

Figure 2 – Overview of consumer and professional detergents

In terms of total consumption, household products represent approximately 80% of all purchases with the professional sector accounting for the remaining 20%. An increase in total expenditure was observed in 2020 due to the COVID-19 pandemic that placed the focus on the importance of cleanliness and hygiene.

2. PROBLEM DEFINITION

2.1. What are the problems?

The evaluation found that, while the Regulation is working well and its objectives are still relevant, there are also several shortcomings and areas for further improvement. In particular, a number of overlaps and/or inconsistencies with other pieces of EU chemicals legislation such as the REACH, CLP and Biocidal Products Regulations that are also applicable to detergents were identified. These overlaps often lead to duplications in the labelling requirements that in turn result in unclear information to consumers, thus reducing the effectiveness of the legislation in conveying essential safety and use information. The evaluation further found that the Regulation had not kept pace with several market developments and trends. Finally, it was unclear whether the Regulation was protective enough with regard to certain potentially harmful substances used in detergents[30]. **Though independent, the issues highlighted by the evaluation have been grouped into two problems given that they are often underpinned by the same drivers and have similar consequences.**

1. *Problem 1: The Regulation does not take account of new market developments*

i. Microbial cleaning products

In recent years, the industry has developed novel cleaning products that contain living microorganisms as active ingredients. Microbial cleaning products usually contain bacteria (either live, or in spore form) and work on the basis of microorganisms in the product which

[30] The findings of this Impact Assessment did not substantiate the existence of this problem. The relevant measures have, therefore, been discarded and explained in detail in section 5.3.6 below.

produce enzymes that can break down organic matter. The organic dirt itself is used as 'nutrition' to produce and secrete these enzymes (degrading action)[31]. Other microbial cleaners work on the basis of a colonising action, namely beneficial microorganisms colonise surfaces and it is claimed that these are able to out-compete unwanted microorganisms either by using up the nutrients in the surfaces, or by directly inhibiting the medium where such unwanted microbes inhabit (for example, by changing the pH/acidity of the medium)[32]. The 'cleaning' function of these products may be achieved in two ways: either solely on the basis of the action of microorganisms or in combination with the surfactants included in them. Microbial cleaning products that are currently on the market may contain either 'known' or 'unknown' species of microorganisms. The former are presumed safe based on reasonable evidence[33] while for the latter no prior assessment exists nor harmonised criteria against which this should be performed are in place.

Microbial detergents are mainly used for surface cleaning[34] in sanitary facilities but also more broadly in buildings with a lot of visitors such as public buildings, schools, restaurants, canteens, hotels, production facilities, nursing homes, animal shelters, veterinarian surgeries. Other types of uses include the cleaning of carpets and upholstery, cleaning drains, pipes and grease traps, washing of industrial machine parts, or oil spills on masonry.

Microbial detergents are frequently produced by small and medium sized enterprises (SMEs) and 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. Based on stakeholder reports, its size can be estimated at 25 manufacturers[35]. However, these manufacturers do not usually sell to end-users, but rather to distributors who then place the products on the market, very often under a private label. The number of distributors is estimated at around 250. Anecdotal data from a previous study[36] suggest that the market of these products has grown significantly in recent years.

The fact that microbial cleaning products contain living microorganisms, raises several concerns to the scientific community and public authorities on their **potential impact on human health and the environment**[37]. Microbiological hazards affecting human health may arise from *e.g.* the possible presence of unwanted microbes and/or pathogens[38], their

---

[31] 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

[32] See Spök and Klade, chapter 10 in 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.

[33] For example belonging to the European Food Safety Authority's Qualified presumption of conformity (QPS) list.

[34] Spök and Klade, chapter in 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.

[35] 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)

[36] https://ec.europa.eu/environment/ecolabel/documents/JRC104463_detergents_without%20watermark.pdf

[37] 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

[38] These effects may be either symptomatic or asymptomatic. Asymptomatically infected persons have no symptoms, but they can spread a microbiological hazard among a population. Symptomatic effects may be local

sensitisation properties[39] or due to the potential for frequent, high and direct exposure to microorganisms[40]. This exposure can result in an infection and related illness and is difficult to quantify as microorganisms may vary in their count and composition during the production, storage and use phases. Vulnerable groups are at a higher risk of developing adverse effects after exposure[41]. Microorganisms may also cause intoxication as some species produce toxins or harmful metabolites, which are able under certain condition to damage host tissues and disable the immune system. The production of these toxins can occur not only in the product itself, but also after uncontrolled disposal to the environment. Finally, some of these microorganisms may carry antimicrobial resistance genes that are mobile and can be transmitted among species, thus rendering them potentially hazardous[42].

As regards their environmental impact, concerns arise from the release into the environment of microorganisms that do not originate from such environments[43]. After being used, some microbial cleaning products will be washed down the drain and thus enter the sewage system. If microbial cleaning agents survive the industrial or domestic waste water treatment, they will enter the environment (surface water) where they can possibly multiply and spread if the conditions so permit. The level of environmental exposure will depend on the frequency of use, on the concentration of the microorganism in the cleaning product, and on the survival and multiplication capacities of microorganisms in untreated and treated waste water.

Stakeholders have expressed contradictory views in terms of the potential impact that these products could have on human health and the environment. The manufacturers of microbial cleaning products consider that the risks of these products are "minimal", as "the production of microbial detergents involves specially selected non-pathogenic microorganisms" (some of the ones used are from widely acknowledged national microbial strain collections, or isolated from natural environments by the producers of microbial detergents), or as the products result from "strains of probiotics which are very close or even identical to those used in food"[44]. Nevertheless, the lack of knowledge on classification of the microorganisms as well as information about relevant release and exposure scenarios of these products bring uncertainty to authorities about their "hazardous properties" or "dangers and risks" (as well as tests needed to monitor them)[45]. There are also concerns about inclusion of potential pathogens

---

or systemic. Local effects of exposure to a microorganism may include irritation and sensitisation; potential systemic effects may include infections and intoxications.

[39] The hazard can be caused to some extent by microbial enzymes and/or other components of microbial cells and spores.

[40] 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

[41] Vulnerable groups cover young, old, pregnant and immuno-supressed individuals.

[42] 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 microbial based 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

[43] Development and use of microbial-based cleaning products (MBCPs): Current issues and knowledge gaps (2017), George Arvanitakis, Robin Temmerman, Armin Spök

[44] Interviews with manufacturers of microbial products, 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)

[45] Interviews with public authorities, Idem.

and proper quality assurance in the manufacturing process (eliminating any potential contamination).

For several stakeholders, it is **unclear whether microbial cleaning products fall under the scope of the Regulation or not and under which conditions**[46]. On one hand, many detergents manufacturers are of the view that all types of microbial cleaning products *i.e.* both those acting solely on the basis of microorganisms and those that have a combined action with the surfactant(s), fulfil the definitions of detergent and cleaning of the Regulation and therefore fall under its scope. Yet, most of these manufacturers are not producing any microbial cleaning products but only conventional/other types of detergents. On the other hand, national authorities and other stakeholders do not share this view, and consider either that only microbial detergents with a combined action of microbes and the surfactant could be regarded as falling under the scope[47] or that these products do not fall under the scope at all[48]. This lack of clarity and different interpretations **impacts the level playing field as it potentially excludes some products from the scope of the Detergents Regulation**. It also affects the uniform implementation and enforcement of the Regulation across the EU. Although an attempt has been made at clarifying the question of the scope in guidance[49], the regulatory failure remains, since apparently not everyone agrees with or applies the guidance, and since according to the same guidance not all microbial cleaning products fall within the scope of the Regulation but only those that have a combined action of surfactants and microbes.

Further, while microorganisms can be very promising alternatives to chemical substances in cleaning products, both in terms of performance and in terms of impacts on the environment, they may also harm human health or the environment, or both (see Annex 7 'detailed problem analysis'). Because these innovative products have emerged on the market after the adoption of the Regulation in 2004, those **risks are not covered by the Regulation.** There are no requirements to document, characterise or manage the risks, or to inform users about the presence of microorganisms in the products via the label or otherwise.

There are also no rules in other EU legislation comprehensively providing for documentation or risk management of microorganisms in detergents, as developed below:

- Contrary to substances, micro-organisms are not registered under REACH, as they are outside of its scope[50].

---

[46] SWD(2019)298 p. 26

[47] Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, Version September, available at: http://ec.europa.eu/DocsRoom/documents/19522/attachments/1/translations/en/renditions/native

[48] One authority stated during the interviews as part of the Impact Assessment supporting study, that some microbial cleaners could potentially be considered as biocides, and would then be regulated under the BPR. Another authority also implied the same thing by mentioning that when such products are biocidal products they are covered by such regulation. According to a detergents manufacturer, some manufacturers of microbial cleaning products could define their products only as detergents in an attempt to circumvent the burdensome risk assessment process for biocidal products under BPR.

[49] Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, Version September, available at: http://ec.europa.eu/DocsRoom/documents/19522/attachments/1/translations/en/renditions/native

[50] ECHA Guidance on registration, version 4.0 August 2021 available at: https://echa.europa.eu/documents/10162/2324906/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2?t=1629205524601.

- Similarly, hazard identification, hazard classification or labelling of microorganisms does not take place under the CLP Regulation.
- The BPR applies to micro-organisms[51] that have an action on or against harmful organisms if they are included in a biocidal product. They are subject to an approval procedure for active substances, based on a detailed assessment to the risks for health and the environment. Some microbial cleaning products may contain microorganisms that are also active substances approved under BPR, or even themselves constitute biocidal products authorised under BPR. However, other microbial cleaning products may contain micro-organisms that are not assessed under BPR, or may – even if the micro-organisms are approved under BPR – not as such constitute biocidal products and therefore not have undergone the full risk assessment underpinning a BPR product authorisation.
- The General Product Safety Directive ('GPSD')[52] applies to a very wide portfolio of products, including microbial cleaning products for consumer use. However, this legislation is very general, and does not require producers to carry out a risk assessment of substances and/or micro-organisms of the kind provided for by *e.g.* REACH or BPR.
- Finally the EU Ecolabel Regulation[53] covers microbial cleaning products used as hard surface cleaners (HSC) for professional use only (see Annex 7). However, the EU Ecolabel is a voluntary scheme that manufacturers of these products may choose to comply with. While it is unclear how many microbial cleaning products already being placed on the market are Eco-labelled, it is clear that no consumer products are.

This was also confirmed by stakeholders during the targeted consultations for this initiative as well as in the evaluation[54] where the existence of a regulatory framework governing the safety of these products was also questioned by several stakeholders. During the interviews, respondents from public authorities mentioned that these products are "not regulated by the current legislation", there is "absence of rules for these products", there is "lack of legal framework", or it is "not clear which type of legislation would apply". During the Public Consultation, stakeholders expressed different views related to the management of risks from microbial cleaning products. In response to the more general question on stakeholders' perception as to whether any of these risks are addressed, the majority of industry respondents stated that the risks are either addressed under another regulatory framework (23 out of 75) or based on voluntary schemes by the industry (21 out of 75). However, 11 out of 17 public authorities that replied to this question stated that the risks are not managed anywhere[55].

---

[51] BPR defines micro-organisms as: "any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths".

[52] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

[53] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel

[54] SWD(2019)298 p. 26

[55] The rest of the public authorities either stated that the risks are managed under another regulatory framework (3), or in voluntary schemes by the industry (1) or by other means (1) or under the Detergents Regulation (2).

When asked more precisely about risks addressed under existing pieces of EU legislation, 20 out of 75 stakeholders from the industry (10), public authorities (8) and civil society[56] (2), reported that if the microorganisms do not fall under the scope of BPR, the risks related to them are not addressed in any other piece of EU legislation. However, it should be noted that a large number of respondents (23 out of 75)[57] to the same question reported that the risks are addressed under the GPSD.

Based on the above, it is clear that **the absence of a regulatory framework governing the risks** associated with these microorganisms would have potential detrimental impacts to human health and the environment. While some of the products are authorised as biocidal products under BPR, and thus have their risks controlled through the robust risk assessment procedure foreseen by that Regulation, others do not have any such authorisation and are, therefore, placed on the market without any requirements to ensure their safety. As explained above, the fact that the GPSD applies to these products does not provide the same guarantees of safety as general chemicals legislation does for substances and mixtures, as GPSD only includes a general obligation for manufacturers of consumer products to place safe products on the market.

ii. Refill sales of detergents

The evaluation identified the refill sale of detergents as an innovation area with which the Regulation has not kept pace[58]. There currently exist different types of refill sale in the EU. Some of them include a service whereby customers fill up their own bottles from a larger container (self-refill). In other cases, refill distribution machines are in place which recognise specific receptacles and which allow the refill only if the correct receptacle is used. These receptacles are either pre-labelled or a label (sticker) is printed at the end of the refilling process.

Refill sales have many advantages. A large part of the waste caused by detergents is their plastic packaging, either the plastic bottles that liquid detergent comes in or the plastic bags or boxes which pods or powdered detergent come in. Refill sales can reduce the quantities of packaging and reduce the plastic waste caused by it. Yet, the first type of refill sales *i.e.* the self-refill does not really fit in the Regulation.

The main issue with the refill sale of detergents is that the labelling requirements of the Regulation were designed based on the assumption that detergents are either sold in separate bottles labelled by their manufacturer or in other types of packaging with a label already affixed on them again by their manufacturer. They are, therefore, not adapted to the case of refill sales where consumers bring their own bottle and refill it in store from a larger container. The main consequence of this is **an issue of non-compliance with the current labelling rules** given that these bottles that are filled from the larger container are either not labelled at all, or bear the wrong label from the bottle that the consumer brought from

[56] Civil society includes: consumer organisations, environmental organisations and NGOs

[57] 19 industry stakeholders and 4 public authorities. It should also be noted that 23 out of 75 respondents answer that they do not know and therefore cannot answer this question and that few respondents (3) mentioned that the risks are addressed either in the CLP (2) or the Detergents Regulation (1).

[58] SWD(2019)298 p. 27

home[59]. Since labels are the primary means for communicating hazard and safety information as well as use instructions to consumers, some argue that refill sales could constitute a risk for human health especially in case *e.g.* of an accident.

Furthermore, because of the definition of "manufacturer" provided in the Regulation, which includes any person changing the label of detergents including *e.g.* the retailer, the evaluation found that doubts occur as to who is the manufacturer responsible for labelling – the manufacturer of the detergent supplied in the large container, or the retailer selling the refill detergent without the original label of the large container[60]. This could result in **the wrong person assuming the responsibility for placing the detergent on the market**.

Interested parties have different views as to whether this practice is allowed under the Detergents Regulation and how the relevant provisions apply to it, in particular with regard to labelling and the responsibility of the person changing the label. Several stakeholders and Member States doubt their legality[61], imposing limitations to the refill sales of detergents or even banning them due to safety considerations[62]. This lack of clarity affects the well-functioning of the internal market, and **no level playing field can be guaranteed for manufacturers that opt for this sustainable practice**. Public authorities that participated in the consultation on the Inception Impact Assessment ('IIA') [63] for this initiative called for clear rules on refill sales and pointed out the need to address the issues related with them especially in view of the benefits that this practice offers[64].

Consulted industry stakeholders expressed some additional concerns, such as the potential use of unsuitable or dirty containers, possible practical difficulties where a product needs to be recalled, potential contaminations during the refilling process, or risks when refilling stations are placed within the reach of children[65].

Data on the precise scale of refill sales of detergents across the EU is unavailable. During the interviews, industry stakeholders were unable to give an estimate of the market share of the refill sales of detergents, but all agreed that refill products currently would have a share lower than 1%. Many also indicated that these practices are not currently being undertaken in

[59] The CLP Impact Assessment, has estimated the current non-compliance rate of refill detergents with the CLP requirements is 50%: Impact Assessment report accompanying the proposal for a Regulation of the European Parliament and of the Council amending the CLP Regulation p. 284; not yet published.
[60] SWD(2019)298 p. 28
[61] In the past, Tukes the Finnish Safety and Chemicals Agency expressed some doubts about the legality of the refillable detergents practice with regard to the labelling requirements set in the Detergents Regulation. According to them, the refill sale of bulk detergents is not allowed, regardless of whether they are classified as hazardous or not.
[62] The refill sale of detergents is banned in Greece in accordance with national legislation concerning the "rules for product trafficking and marketing", see Comments from Greece on re-fill sale of detergents, available here: https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp; Limitations and bans on the refill sale of detergents under certain conditions have also been observed in France, see https://www.anses.fr/en/system/files/BIORISK2021SA0051.pdf p. 28-30, p. 38
[63] DK, IE, SK *i.e.* 3 out of 4 participating public authorities, the fourth being NO.
[64] Refill practices have large environmental benefits due to the reuse of packaging and the related reduction of resources needed to produce new packaging as well as the consequent reduction in packaging waste.
[65] 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)

supermarkets, which automatically confers them a small volume (compared with the detergents sold therein)[66].

However, according to other sources[67], 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[68]. 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.

2. Problem 2: Lack of efficient information requirements for detergents

i. Ingredient data sheets and poison centres information

The Regulation requires that detailed information on the composition of detergents be provided to medical professionals, upon request, via the "ingredient data sheet", and also allows Member States to request that such a datasheet is made available to a public body in charge of providing this information to medical personnel ('poison centres'). This requirement **applies to both hazardous and non-hazardous detergents** based on their CLP classification.

The ingredient data sheet under the Regulation serves a similar purpose as the harmonised information that is provided to poison centres under the recently added Annex VIII to the CLP Regulation. The latter **applies only to hazardous detergents** and requires that producers and importers of hazardous detergents provide uniform information on the product composition to poison centres in all Member States.

The evaluation, therefore, found that there is **a duplication in these information requirements** which poses an unnecessary burden to detergents manufacturers. The total administrative costs of compiling ingredient data sheets under the Regulation for both hazardous and non-hazardous detergents have been estimated at €8.2 million per year[69]. It was, therefore, concluded that when the newly introduced rules under CLP would start applying in 2020, the ingredient data sheet under the Regulation should be abolished to prevent a duplication with CLP that would lead to an unnecessary administrative burden for the industry.

In response to this conclusion from the evaluation, several Member States authorities expressed concerns within the Detergents Working Group as regards the abolishment of the ingredient data sheet for non-hazardous detergents[70]. While the CLP Regulation, which is the

---

[66] A simple comparison of the numbers and space used by refill stations at present, in comparison with the large number of supermarkets and retail outlets, all of which allow for large selling spaces, and extensive number of shelfs dedicated to detergents, would seem to indicate that the market size of the refill-sales market is small or very small.

[67] 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.

[68] It should be noted that while the refill chemicals' market is dominated by detergents the category of 'home care products' is wider than detergents.

[69] €7 million for hazardous and €1.2 million for non-hazardous detergents (see section 6.3.1. below and Annex 4 for details)

[70] Minutes of the Detergents Working Group, 2018: https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=9110&fromExpertGroups=true

main piece of legislation dealing with communicating chemical hazard information, does not include similar requirements for non-hazardous mixtures, these authorities claimed that the abolishment of the ingredient data sheet for non-hazardous detergents under the Regulation would result in lowering the current level of protection of human health since a mixture that is not classified as hazardous under CLP, could still contain hazardous substances[71].

As a result, the added value of maintaining the ingredient data sheet for non-hazardous detergents under the Regulation, needs to be explored. Further, if this data sheet were to be maintained, it would also need to be clarified under which format, namely: its current format under the Regulation or in accordance with the harmonised format required under Annex VIII to CLP for the provision of information to poison centres.

ii. Overlaps in the labelling requirements

The evaluation identified legislative overlaps between the Regulation and the CLP Regulation, which often lead to the labelling of the same substance twice or thrice on the same label and sometimes under completely different names. The multiple labelling of ingredients stems from the regulatory failure that the Regulation and CLP often require the labelling of the same substance. The main issue relates to the labelling of the so-called sensitising substances (*e.g.* allergenic fragrances, preservatives, enzymes). Apart from being mentioned multiple times on detergents labels, these sensitising substances are also often listed under different names. This is because the Regulation requires economic operators to label them either in accordance with the International Nomenclature of Cosmetic Ingredients ("INCI names")[72] or the class of constituent (enzymes), whereas the CLP Regulation requires other identifiers[73] for the same substances to be used on the label. There are also different thresholds between the Regulation and CLP, and sometimes an additional requirement under the latter to include a EUH208 statement[74], which adds to the regulatory complexity and therefore increases the administrative burden for detergents manufacturers. Similar issues are observed, to a lesser extent, with other ingredients, such as surfactants.

Given that labels are the primary means by which the Regulation aims to achieve its objective of protecting human health, this results in a sub-optimal communication of safety and use information to consumers. This information can on one hand be crucial in case of an incident and on the other allow consumers to make informed choices. Apart from causing confusion to consumers, this also creates an unnecessary regulatory burden for the detergents industry.

The evaluation further found that detergents labels are overloaded with information. This makes labels hard to read and it is not easy for consumers to detect the information that they

---

[71] The classification of a mixture (*e.g.* a detergent) as hazardous under CLP is based on several criteria set in the legal text. It is possible that while substances contained in the mixture are classified as hazardous under CLP, the mixture as a whole is not because it does not fulfil the classification criteria.

[72] This is the case for allergenic fragrances and preservatives.

[73] CLP requires that substances are labelled with either the name and identification number given in Part 3 of Annex VI to the CLP 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 number together with its IUPAC 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.

[74] EUH208 is a hazard statement that must be included in the label when a mixture though not classified as sensitising under CLP it still contains sensitising substances. It reads as follows: 'Contains (name of sensitising substance). May produce an allergic reaction'

are looking for, which could be crucial in case for example of an allergic reaction or a poisoning incident. This was confirmed by the findings of the chemicals Fitness Check[75] which concluded that labels can become overloaded with *e.g.* too much text, and too long and not meaningful chemical names to non-professional users, that make it difficult for downstream users and consumers to focus on the essential hazard information, thus reducing the effectiveness of hazard communication.

Since the entry into force of the Regulation in 2004, digitalisation has led to the development of new labelling technologies that are not adequately captured by the scope of the current regulatory framework, falling behind the megatrend "Accelerating technological change and hyperconnectivity" [76]. Based on this, the evaluation and the chemicals Fitness check concluded that the Regulation does not exploit the opportunities offered by digital tools, while their use could be beneficial for consumers and the detergents industry as it would help improve the communication of information to the former, while at the same time alleviating the regulatory burden and compliance costs for the latter[77]. In particular, no mention is made in the Regulation of the possibility to use digital labelling solutions to improve the communication of use and safety information to consumers (see Annex 8 on digital labelling). During the consultation, both for the evaluation and the chemicals Fitness Check, industry stakeholders suggested that a potential way of addressing the above mentioned overlaps in the labelling requirements is the use of digital tools (*e.g.* QR codes) that are now available and which could help reduce the amount of information presented on product labels.

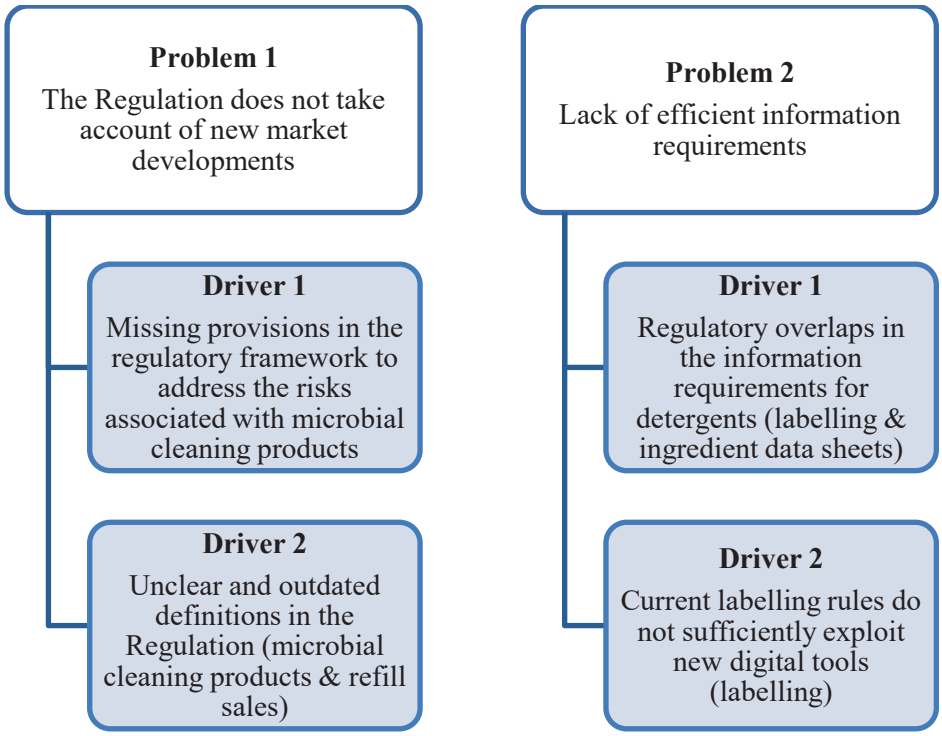
Apart from the above described issues, some other overlaps and inconsistencies in the information requirements for detergents were also identified in the evaluation[78]. Given that the measures to address these are a clarification and/or simplification of the current rules, their impacts have not been assessed and are included in Annex 9 to this report on simplification measures.

2.2. What are the problem drivers?

The problem drivers were explained above together with the problems. They are all considered to be regulatory failures. A summary of problems and their drivers can be found in Figure 3 below:

[75] SWD(2019)199 p. 53, 109, 244
[76] See https://knowledge4policy.ec.europa.eu/foresight/megatrends-engagement-tools_en
[77] SWD(2019)298 p. 51
[78] Idem.

Figure 3 Problems and drivers



2.3. How likely is the problem to persist?

Without any policy intervention (soft or hard law measures), the problems will continue or worsen, as will the social, economic and environmental consequences. Further, the problems can be expected to grow, especially in light of current sustainability trends and the forthcoming developments in the EU regulatory framework for chemicals under the Chemicals Strategy (CLP and REACH revision - see section 1.2) that will introduce new requirements, adding further complexity to an already complicated framework.

Microbial cleaning products contain living microorganisms. These have their own biology and response to the environment. Due to the ability of microorganisms to proliferate, there is a clear difference between conventional and microbial detergents. Therefore, the arising hazards 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 and to produce a range of different metabolites and toxins of potential toxicological significance**.** Recognising these hazards[79], the Biocidal Products Regulation has put in place a strict authorisation procedure for microorganisms that are also biocidal active substances. Yet, similar safeguards do not exist for microorganisms used in detergents and microbial detergents can be placed on the market with any type of microbe contained in them and no safety requirements to comply with. Microbial cleaning products are currently a niche market comprising a total of 25 manufacturers. However, as opposed to refill sales, the size of the

[79] ECHA Guidance on the Biocidal Products Regulation, Volume V, Guidance on Active Micro-organisms and Biocidal Products: https://www.echa.europa.eu/documents/10162/2324906/biocides_guidance_micro_organisms_en.pdf/4d028d38-6d3c-4f2d-80f7-3aa2118ca49a

market is of less relevance/significance in this case in view of the inherent risks that microorganisms carry and the identified regulatory gap to manage these. Without the proposed intervention, microbial cleaning products will continue to be placed on the market with no safety requirements to comply with and with no clarity as to whether they are included under the scope of the Regulation or not. Due to the very divergent views of most interested parties on the matter, the well-functioning of the single market will continue to be hampered and the protection of human health and the environment will be jeopardised.

On refill sales, parallel actions taken within the context of the CLP revision are likely to correct some aspects of this problem (for details see section 5.1). However, the specific issues related to the definitions and labelling of refills ensuing from the Regulation will continue. As explained in section 2.1(1) (ii) above, there is currently a lack of clarity as to whether refill sales are covered by the Detergents Regulation. As a result, the single market for refilled detergents is fragmented due to the different practices and divergent rules put in place in some Member States. For the same reason, the sale of refilled detergents is also characterised by a high level of non-compliance with the labelling rules in place. The CLP Impact Assessment[80] has estimated that the current non-compliance rate of refilled detergents with the CLP labelling requirements is at 50%. While we were not able to gather concrete data on the level of non-compliance with the labelling requirements of the Detergents Regulation, we can safely assume that this is the same or very similar to that of the CLP Regulation since in most cases consumers bring their own bottle to (re)fill in store from a larger container and this bottle either bears the wrong or no label at all.

The available market data indicates that refill sales is still a niche market accounting for a maximum of 2% of the overall market for detergents[81]. However, this market also presents the biggest potential for growth in the near future. The refill sale sector is, in general, an area with strong predicted growth over the next 10 years. Specifically for refilled detergents, the projected growth is positive and around 2% per year, leading to a steady and moderately growing sector (see section 2.1. (1)(ii) and 5.1.1). Therefore, without the proposed intervention different national rules will continue regulating or prohibiting refill sales and manufacturers will remain hesitant to invest further in their development. Furthermore, one can also reasonably assume that the ambiguity about the possible application of the Regulation and notably its labelling rules on this type of sales will remain, and that the applicable requirements will differ increasingly across Member States. Moreover, the opportunities offered by digitalisation will remain unexploited.

Finally, the regulatory overlaps in the information requirements for detergents will be maintained continuing to cause increased unnecessary costs for the detergents industry and negatively affecting the communication of safety and use information to users. Opportunities to update, simplify and future proof the legislation through the introduction of digital labelling will be missed. As a result, the regulation will continue to be outdated and unable to keep up with an increasingly digitalised framework, especially in view of the ongoing

---

80 Impact Assessment report accompanying the proposal for a Regulation of the European Parliament and of the Council amending the CLP Regulation p. 284; not yet published.

81 The detergents and home care products placed on the EU market for self-refill 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 (see section 2.1. (1)(ii) of the Impact Assessment).

initiatives on digitalisation of chemicals labels under the CLP and Fertilising Products Regulation ('FPR').

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The Regulation harmonises the rules for the placing on the market of detergents and surfactants for detergents. The Regulation is based on Article 114 Treaty on the Functioning of the European Union (TFEU) the objective of which is the establishment and functioning of the internal market by approximating national rules. Any revision of the Regulation would build on the current objectives of free movement of detergents and creating a level playing field for companies in the internal market, while ensuring a high level of protection of human health and environment, and would thus have the same legal basis.

3.2. Subsidiarity: Necessity of EU action

During the consultation activities for the detergents evaluation[82], there was widespread consensus among all interested stakeholders that the issues addressed by the Regulation continue to require action at the EU level. This is because, the issues related to detergents, both in terms of protection of human health and the environment, have an EU-wide dimension. This is for example the case of the biodegradability requirements for surfactants to protect the environment or the communication of ingredient information to consumers to protect human health. The same applies to the identified problems that do not present any national or sub-national specificities but rather have an EU-wide impact (*e.g.* refill sales, microbial cleaning products, lack of understanding and awareness of chemicals labels by consumers) and cannot, therefore, be addressed at national level in order to ensure the well-functioning of the internal market and an equal level of human health and environmental protection across the EU.

Further, since the Regulation fully harmonises the matters it explicitly covers, Member States are not allowed to make changes to the scope, concepts and definitions or other requirements of the Detergents Regulation: these must therefore be made at EU level. In the absence of a uniform set of rules applicable to detergents, manufacturers would be faced with 27 different sets of rules, leading to different levels of protection for consumers and professional users, market barriers and distorted competition among market operators from different Member States.

Finally, the abolition of some superfluous information obligations imposed by the Regulation can only be achieved through an amendment of the Regulation.

3.3. Subsidiarity: Added value of EU action

The detergents evaluation concluded that the added value of having harmonisation rules for the making available and placing on the market of detergents was uncontested[83]. Indeed, the Detergents Regulation resulted in levelling the playing field for detergents' manufacturers, making it easier for companies to trade cross border and delivering positive results for human health and the environment.

---

[82] Evaluation of the Detergents Regulation, SWD(2019)298 p. 64
[83] Idem.

Regulatory action at EU level would ensure a regulatory context that allows innovation for new types of products, new marketing techniques and new labelling technologies across the single market while providing the same level of protection of human health and the environment across the EU. It would bring the legislation up to date by including innovative products and sustainable new practices in the scope of the Regulation; reduce the regulatory burden for detergents manufacturers through simplified and streamlined (information) requirements; and adapt the legislation to the digital age through the introduction of digital labelling. Regulatory action of this sort would: (i) help further develop the single market; (ii) provide legal certainty and a level playing field for the industry; and (iii) ensure an optimised protection of human health and the environment.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

The **primary and overarching objective of this initiative** is to level the playing field across the Single Market and to optimise the protection of human health and the environment. However, depending on the nature and specific concern to be addressed for each problem, the main primary objective may vary between free movement and optimised protection (see section 4.1. below) or secondary objectives may also be sought.

For example, refill sales offer large environmental benefits due to the reuse of packaging and the related reduction of resources needed to produce new packaging as well as the consequent reduction in packaging waste. While the available data indicate that this sector amounts to a maximum of 2% of the overall market for detergents, it also presents the biggest potential for growth in the near future, with some sources estimating this growth at 2% annually (see section 2.1(1)(ii) and 5.1.1.). In view of the advantages that this practice offers and the projected growth of the sector, the main primary objective for refill sales is to ensure a level playing field in the Single Market and **as a secondary goal** is also sought *i.e.* to facilitate this type of sales by providing the necessary regulatory enablers that would allow its easier uptake by detergents manufacturers.

As opposed to refill sales of detergents, the main primary objective for microbial cleaning products is to ensure their safety and having more microbial cleaning products on the market is not an objective per se of this initiative.

4.1. General objectives

There are two general policy objectives to be pursued when revising the Regulation to address the problems outlined above. These general objectives are in line with the current objectives of the Regulation and can be described as follows:

1) Continue to ensure the well-functioning of the single market, the free movement of detergents and surfactants for detergents and the undistorted competition between market operators; and
2) Continue to ensure a high level of protection of human health and the environment.

4.2. Specific objectives

This initiative pursues the following specific objectives (SO):

- **SO1:** Clear and updated rules that level the playing field and allow for innovative products and sustainable new practices

The aim under SO1 is to ensure that not only traditional products are covered by the Regulation, but that innovative products and sustainable new practices, in particular

microbial cleaning products and refill sales, are also included in its scope. Updating and clarifying the definitions of the Regulation will facilitate the take up of new products and practices in the future, and will help reduce uncertainties in the implementation of the Regulation (see also Annex 9 on simplification measures). The introduction of digital labelling will update and adapt the regulatory framework to the digital age by allowing the use of digital tools to communicate product information in line with the megatrend "Accelerating technological change and hyperconnectivity". The clear and harmonised requirements will level the playing field for detergents manufacturers and ensure a healthy competition in the detergents market.

- **SO2:** Optimised protection of human health and the environment

The improved communication of safety and use information aims at increasing consumer understanding of labels which in turn leads to a higher awareness of the potential risks associated with the use of detergents and of the special precautions or use instructions to be followed. Addressing emerging risks from new products and ensuring that sustainable new practices are included in the scope of the Regulation and are properly regulated aims at further increasing the level of protection of human health and the environment.

- **SO3:** Burden reduction for detergents manufacturers

A simplification of the labelling requirements under the Regulation would be beneficial for the industry, notably in terms of reducing the administrative burden that businesses incur to comply with the current rules. The elimination of duplicated information requirements related to emergency health response would further reduce costs and regulatory burden for detergents manufacturers.

- **SO4:** Improved consumer understanding and awareness of labels

The fourth specific objective is to address the current overlaps in the labelling requirements for detergents in order to on one hand reduce the information load of the current labels and thus improve their readability and on the other to improve the consumer's understanding and awareness of labels through clear and simplified information.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

The baseline – "policy option 0" – consists in no additional EU action, meaning no change to the current Regulation. This would lead to the continuation of the shortcomings identified in the evaluation, and the problems and consequences described in Section 2. The following elements are being considered under the dynamic baseline:

5.1.1. Market trends

Based on the past trends, the production of detergents in the EU in the medium-term is likely to remain similar to the current levels. Consumption is expected to continue growing, albeit at a slower pace (*e.g.* 2 to 3% per year) compared to the peak in sales following the outbreak of the COVID-19 pandemic[84] (see also Annex 6 on economic context).

[84] 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)

Further, certain niche products or practices are expected to increase. This is very likely the case for refill sales, whose diffusion is expected to grow considering both, the evolving consumer preferences for sustainable solutions, as well as the ongoing policy developments under the Green Deal.

A recent study by Eunomia has made a first high-level attempt at assessing market trends of packaging-free shops, and reported a central estimate for the EU total turnover from bulk good sales in 2030 of approximately €1.2 billion, and a 'best case scenario' of over €3.5 billion[85]. The study acknowledged that if radical shifts in the economy or consumer behaviour are also considered, the projections made on the future scale of the bulk and refill sale sector could be even greater. Based on these findings, the re-fill sale sector is an area with strong predicted growth over the next 10 years. The number of re-fill chemicals accompanied without correct labelling and packaging and the level of non-compliance by economic operators are only likely to increase if no action is taken[86]. Specifically for re-fill detergents, the projected growth is positive and around 2% per year, leading to a steady and moderately growing sector[87].

Similarly, the market of microbial cleaning products is expected to grow in the medium-term, thus multiplying the uncertainties faced by public authorities and economic operators alike. No other regulatory developments are currently ongoing to address the issues related to the risks stemming from the use of living microorganisms in these products. The lack of appropriate or specific norms for microbial cleaning products and refill sales may also lead to the emergence of national rules and practices, which may fragment the Single Market[88].

5.1.2. Digitalisation trend

Technological uptake is relevant for the analysis of a regulatory intervention that would entail the use of electronic labels on chemical products.

According to the latest Eurostat data[89], the percentage of individuals using the internet increased considerably in the last 10 years, going from 74% of the EU27 population in 2012 to 90% in 2021. This technology update has seen a strong increase also amongst older groups of citizens. The percentage of individuals in the age group between 55 and 64 years that use the internet increased by 34% between 2012 and 2021, and the percentage of individuals in the age group between 65 and 74 years doubled (from 28% in 2011 to 61% in 2021)[90]. According to this trend, it is expected that in the next 10 to 20 years nearly the whole EU27 population will use the internet regularly. Further, digital inclusion is an EU-wide effort to ensure that everybody can contribute to and benefit from the digital world. The EU is

[85] 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.
[86] Impact Assessment report accompanying the proposal for a Regulation of the European Parliament and of the Council amending the CLP Regulation p. 113; not yet published.
[87] Idem.
[88] 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).
[89] Eurostat data on internet use of individual, see: https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=isoc_ci_ifp_iu&lang=en
[90] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published

fostering digital inclusion through several policy areas, including digital skills and social inclusion.

Another aspect of technological uptake that is relevant for the baseline is the percentage of the EU27 population that uses a smartphone. This is particularly relevant if the proposed electronic labels would require the use of these devices to scan and access data provided online.

According to the latest available data, the percentage of the EU27 population that accessed the internet with a mobile phone was 71%, though there were lower shares for older groups of citizens (*i.e.* 45% in the age group 55-74 years old). There has been a steady increase in this statistic over the last 10 years, conditioned to a large extent by the availability on the market of mobile devices with internet capabilities[91].

Digitalisation of businesses is a critical aspect for the uptake of electronic labels by enterprises. As for consumers, the trends described here are related to the Commission's Megatrends Hub[92] namely "Accelerating technological change and hyperconnectivity".

Statistics show a small but steady increase of the share of companies that have a website. Data from 2021 shows that 78%[93] of businesses use websites to provide information about their products or services, and their prices. This share increases to 94% amongst manufacturers of chemical products[94]. This is a good indicator for the potential readiness of businesses for the uptake of electronic labels.

5.1.3. Parallel regulatory developments

5.1.3.1. Ecodesign for Sustainable Products Regulation and Digital Product Passport (see also section 1.2.3 above)

The proposal on Ecodesign for Sustainable Products Regulation (ESPR) sets out the framework for a Digital Product Passport (DPP)[95]. According to this proposal, the DPP will include new mandatory information relevant to product sustainability (such as recyclability or energy efficiency) and regulatory compliance information about the product (technical file, declaration of conformity). In addition, an inventory of all materials and raw materials used in a product, and a full list of chemical contents may be required. This could make it easier to facilitate tracking along the supply chain, for instance, for substances of concern.

The detailed requirements will be determined on a product-by-product basis in a subsequent step. Consequently, product-specific requirements are not yet determined for detergents. However, as detergents are currently included on the 'priority' list currently under development by the Joint Research Centre[96], the DPP is considered in the dynamic baseline scenario.

---

[91] Idem.
[92] See https://knowledge4policy.ec.europa.eu/foresight/megatrends-engagement-tools_en
[93] Digital economy and society statistics, Enterprises with a website [isoc_ciweb]
[94] Digital economy and society statistics, Enterprises with a website [isoc_ciweb], Manufacture of chemicals and chemical products (10 or more employees and self-employed persons).
[95] Proposal for Ecodesign for Sustainable Products Regulation; https://ec.europa.eu/environment/publications/proposal-ecodesign-sustainable-products-regulation_en
[96] Questions and Answers: sustainable products initiative, https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2014

Therefore synergies between the DPP and digital labelling under the Regulation have been considered as regards how the information is to be provided. Thus, even though the type of information to be provided is different, it is important to ensure that when information is provided digitally concerning a product, it ends up being coherent and in one place.

5.1.3.2. CLP revision

The ongoing revision of the CLP regulation[97] is particularly important in three aspects, namely the refill sale of chemicals, the introduction of new hazard classes for endocrine disruptors and the introduction of digital labelling.

In the context of the revision, the introduction of new hazard classes in particular for endocrine disruptors is being considered[98]. These newly introduced hazard classes will also be applicable to detergents.

As regards digital labelling, we assume that the European Parliament and the Council will accept digital labelling as part of the proposal on the revision of the CLP Regulation, and that certain information requested under CLP Regulation for detergents containing hazardous substances will be provided digitally. The precise timing of entry into force and the labelling information considered are unknown.

The CLP revision will also address issues related to the refill sales of chemicals, including detergents. Measures that are currently considered to achieve this are *e.g.* clarifications that refill chemicals would need to comply with the CLP labelling requirements, and restrictions to sell in a refill format chemicals in certain hazard classes. These measures will be of a horizontal nature and will, therefore, not be able to address the specific issues related to the definitions and the labelling of detergents that have emerged under the Regulation (see section 2ii above). As a result, complementary provisions under the Regulation are necessary to address this issue in its entirety and further facilitate the refill sale of detergents. No overlaps are expected given the complementary nature of the provisions.

5.1.3.3. REACH revision

While a Commission proposal is still not available, the ongoing revision of the REACH Regulation[99] is particularly important as regards the extension of the generic approach to risk management (GRA) for consumer and professional uses to the most harmful substances such as endocrine disruptors (EDs). Though the analysis is still in progress, category 2 carcinogenic mutagenic and reprotoxic substances (cat. 2 CMRs) are not expected to be included in the extended scope of GRA under REACH. As in the case of the CLP revision, any amendments to the REACH Regulation as a result of the ongoing revision, will also apply to detergents and are likely to address any issues that ensue from the use of the most harmful substances in them. No overlaps between this initiative and the revision of REACH are expected given that assessment and management of the risks related to substances or mixtures used in detergents already takes place under the REACH Regulation and no similar requirements are included in the Regulation or planned by this initiative.

---

[97] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en

[98] As regards endocrine disruptors it should also be noted that the extension of the generic approach to risk management under REACH will also cover these substances (see section 5.1.3.3 below).

[99] 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

On top of the above, a **general trend of digitalisation of the labels** or documents accompanying products is observed. Rules are under preparation for fertilising products[100] and cosmetics[101].

5.2. Description of the policy options

Two policy options were identified to address problem 1 and another two for problem 2. In order to address all problems that the initiative aims to tackle, option 1a or 1b (addressing problem 1 related to new market developments not being accounted for) would have to be combined with option 2a or 2b (addressing problem 2 related to lack of efficient information requirements). The options have been constructed to address the identified problems as a whole.

A transition period of 18 months is being considered under all options.

Table 1 below presents an overview of the intervention logic, highlighting the link between identified problems and drivers and suggested specific objectives and policy options.

Table 1 Intervention logic- Overview of the policy options and their link to identified problems and drivers

Problems	Drivers	Specific Objectives	Policy Options
New market developments not being accounted for	Missing provisions in the regulatory framework to address the risks associated with microbial cleaning products Unclear and outdated definitions in the Regulation	SO1 - Clear, updated and future proof rules that level the playing field and allow for innovative products and sustainable new sales methods SO2 - Optimised protection of human health and the environment	PO1a – **Facilitate** the refill sales and introduce **minimum information requirements** for microbial cleaning products PO1b - **Facilitate + digitise** the refill sales and introduce **risk management requirements** for microbial cleaning products
Lack of efficient information requirements for detergents	Regulatory overlaps in the information requirements for detergents Current labelling rules do not sufficiently exploit new digital tools	SO2 - Optimised protection of human health and the environment SO3 - Burden reduction for detergents manufacturers SO4 - Improved consumer understanding and awareness of labels	PO2a - **Complete abolishment** of ingredient data sheet + streamlining and simplifying the labelling requirements through the introduction of digital labelling PO2b – Abolishment **only of duplicated** ingredient data sheet + streaming and simplifying the labelling requirements through the introduction of digital labelling

5.2.1. Policy options to take into account new market developments

5.2.1.1. Option 1a – Facilitate the refill sales and introduce minimum information requirements for microbial cleaning products

Microbial cleaning products: Under PO1a microbial cleaning products for both consumer and professional use would be brought under the scope of the Regulation and minimum

[100] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Chemicals-simplification-and-digitalisation-of-labelling-requirements_en

[101] EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision) (europa.eu)

information requirements for these products would be introduced. This means that manufacturers of microbial detergents would need to provide information on the labels about the presence of microbes in the detergent. Under PO1a, all microbial cleaning products currently on the market *i.e.* both those that contain known and unknown species of microbes would be included in the scope of the Regulation. The safety of the products containing these microorganisms would continue to be governed by the general prescription of the GPSD to place only safe products on the market (see section 2.1 above).

Refill sale of detergents: The revised Regulation would introduce requirements to clarify and facilitate the refill sale of detergents. This means that refill sales of detergents would be allowed across the EU based on harmonised requirements. A definition of refill sales would be introduced in the Regulation to provide legal certainty. Manufacturers that decide to place their products on the market in a refill format would be free to choose by which means to provide the labelling information required under the Regulation (*e.g.* print-out of the label, sticker, pre-labelled bottle). The different responsibilities of the manufacturer of the refill detergents and the retailers would also be clarified: the manufacturer would be solely responsible for placing the product on the market. (S)he would also be responsible for providing the print out of the label or the sticker with the labelling information while the retailer would be responsible for handing out this printed label to the consumer or for affixing the sticker on the refilled bottle.

5.2.1.2. Option 1b – Facilitation and voluntary digitalisation of refill sales and introduction of risk management requirements for microbial cleaning products

Microbial cleaning products: Under PO1b, microbial cleaning products for both consumer and professional use would be brought under the scope of the Regulation. Risk management requirements would be introduced that microbial cleaning products would need to comply with in order to be lawfully placed on the EU market. These include **generic criteria** similar to the ones found in existing eco-labelling schemes[102], labelling requirements, certain restrictions on the use of microbes and a review clause.

In particular, manufacturers of microbial cleaning products would need to hold at the disposal of market surveillance authorities a technical dossier with the following information: 1) evidence that the microorganisms used in the detergent belong to both the European Food Safety Authority's ('EFSA') Qualified Presumption of Safety ('QPS') list[103] and to Risk Group 1 of Directive 2000/54/EC[104]; and 2) taxonomic identification of the microorganisms to the strain level and the microbial count. Similarly to PO1a, **labelling requirements** would also be introduced to inform product users about the presence of microbes in the detergent. Manufacturers of microbial cleaning products choosing to place their products on the market in a spray format would need to demonstrate that these are safe for use even for vulnerable groups, through the use of suitable test methods. Several **restrictions** similar to those existing under current eco-labelling schemes would, further, be introduced for microbial cleaning products. These include the following:

---

[102] E.g. EU Ecolabel and the Nordic Swan. For more information see Annex 7.

[103] The 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.

[104] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)

1. Only detergents containing 'known' microorganisms *i.e.* those belonging to both the above mentioned categories (*i.e.* QPS list+ Risk group 1) would be allowed to be placed on the market.
2. No pathogenic microorganisms may be found in any of the strains included in the finished product.
3. No genetically modified microorganisms (GMMs) may be intentionally added in detergents.
4. All intentionally added microorganisms must not demonstrate an antibiotic resistance to each of the five major antibiotic classes[105].

Recognising the data gaps on microorganisms and their potential effects on human health and the environment, PO1b foresees the introduction of a **review clause** in the revised Regulation. Currently, microbial cleaning products placed on the market may contain both known and unknown species of microorganisms. A lack of data exists on the properties and potential hazards related to these unknown species as well as a lack of harmonised risk assessment requirements to conclude on their safety. In addition, current eco-labelling schemes only allow microbial cleaning products for professional use that comply with their requirements to bear the Eco-label. However, microbial cleaning products for consumer use are already being placed on the EU market with no safety requirements to comply with. This policy option, therefore, suggests that based on a report from a scientific body acting on a mandate from the Commission, the latter will examine in depth the issues related to microorganisms contained in products; reassess the fitness of the above described requirements; and, if needed, present a proposal to the European Parliament and the Council amending them. Until the results of the above mentioned report have been delivered, and in line with the precautionary principle, microbial cleaning products containing unknown species of microorganisms would not be allowed to be placed on the market for either professional or consumer use. However, in order not to hamper innovation, these unknown microorganisms would be allowed to be placed on the market solely for R&D purposes but may not be sold to end users. Finally, microbial cleaning products for consumer use would be included in the scope of the Detergents Regulation so that they would at least comply with minimum safety requirements (as described above) until the results of the above mentioned report have been delivered and thoroughly assessed.

Refill sale of detergents: On top of facilitating the refill sale of detergents, as described under PO1a above, this option also proposes the introduction of digital labelling to further ease the uptake of this sustainable practice. In particular, detergents manufacturers using this sales method may further choose to provide the specific labelling information required under the Regulation only digitally, *e.g.* through a sticker with a barcode or a QR code. Dosage instructions for laundry and automatic dishwasher detergents would always need to be provided in a physical format[106].

[105] Aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones in accordance with the EUCAST disk diffusion method or equivalent.
[106] A simplified dosage grid as described in section 5.2.2.1 below for laundry detergents would also be allowed.

5.2.2. Policy options to address the lack of efficient information requirements for detergents

5.2.2.1. Option 2a - Abolishment of ingredient data sheet for both hazardous and non-hazardous detergents + streamline and simplify the labelling requirements and introduce digital labelling

Ingredient data sheet: Under option 2a the ingredient data sheet would be abolished for both hazardous and non-hazardous detergents.

Labelling requirements: Regarding labelling of ingredients and the identified overlaps with the CLP Regulation, this option suggests to streamline the labelling requirements and to introduce the possibility of digital labelling. The streamlining could be achieved through one of the ways described in the sub-options, namely: either by requiring the labelling of ingredients only once, based on the stricter rules. This means that either the requirements of the detergents Regulation or the CLP Regulation will be applicable (sub-option 1); or by removing the duplicated provisions from the Detergents Regulation (sub-option 2).

By opting for **digital labelling,** manufacturers would also benefit from the possibility to provide certain information only through the digital label. This includes the moving of certain ingredients and other labelling information to the digital label, as well as the simplification of the dosage instructions for laundry detergents. A simplified dosage grid would, thus, be left on pack to allow end-users to follow basic instructions when doing their laundry whereas detailed dosage information indicating for instance different degrees of water hardness or soil, would be accessible through the digital tool. The selection of the information that could be moved to a digital label under PO2a has been done with caution, so as not to compromise on safety, and takes into account which categories of information are considered most essential by each category of users (for details see Annex 8).

Under PO2a, the introduction of digital labelling would be underpinned by some fundamental principles in order to protect end-users and to ensure the accessibility, availability and quality of digital information (see Annex 8 for details). These principles should support creating a level playing field for the industry. They would safeguard the otherwise adverse impacts digital labelling could have on vulnerable segments of societies and those impacted by the digital divide. Such principles could further assist in enforcing the labelling rules. To maximise efforts of consistency in terms of 'how' digital labelling could be allowed, these principles are also introduced under the Impact Assessments which include digital labelling for CLP and Fertilising Products.

Manufacturers could only put digital labels on their products when these mandatory principles are followed. For more information on these digital principles see Annex 8.

Simplification measures: The revised Regulation would in all options clarify the identified ambiguous definitions and other identified overlaps and inconsistencies in the information requirements for detergents, namely: the labelling of professional detergents through Safety Data Sheets ('SDS'), the labelling of carry-over preservatives in detergents and the labelling of disinfectants (see Annex 9 for details).

5.2.2.2. Option 2b – Abolishment of ingredient data sheet for hazardous detergents + streamline and simplify the labelling requirements and introduce digital labelling

Ingredient data sheet: Under option 2b only the duplicated requirement to provide an ingredient data sheet for hazardous detergents would be abolished, while the ingredient data sheet for non-hazardous detergents would be maintained.

Labelling requirements: same as in PO2a above.

Simplification measures: same as in PO2a above.

Table 2 Summary of proposed interventions on the ingredient data sheet under PO2a and PO2b

	Baseline	PO2a	PO2b
Hazardous	CLP & Detergents Regulation	CLP	CLP
Non-Hazardous	Detergents Regulation	Abolished	Detergents Regulation

5.3. Options discarded at an early stage

5.3.1. Options on the instrument

Repeal of the Regulation and incorporation of its material content in other (horizontal) pieces of EU chemicals legislation such as REACH and CLP: This option was considered in view of the findings of the chemicals Fitness Check[107] that highlighted the complexity of the EU regulatory framework for chemicals and attributed it to the large number of product- and sector-specific pieces of legislation with embedded links with each other. It aimed at simplifying the regulatory framework for detergents by reducing the number of pieces of legislation applicable to them. However, during the consultation activities for this Impact Assessment, there was no support across any stakeholder group to repeal the Regulation. In particular, out of the 15 responses to the consultation on the IIA, no stakeholder supported that the Regulation should be repealed. The same applies to the Public Consultation where 62 out of 94 respondents[108] supported that the Regulation should be maintained. Apart from lack of stakeholder support, repealing the Regulation would also not be appropriate in line with the new market developments in the sector (see section 2.1) and the need for requirements to address them.

5.3.2. Digitalisation of detergents labels

Digital labelling as full alternative to physical label/mandatory digital labelling: these options were discarded because of the expected significant costs that they would entail for businesses – SMEs in particular[109] – and for the difficulties of access for groups of EU citizens due to lack of access to digital tools, lack of digital skills and/or lack of internet connection. Those options were also not widely supported by stakeholders, as found in the digital labelling study on CLP and Detergents[110], and particularly national authorities, as they were seen to go against the objective of the labelling requirements under the Regulation,

[107] SWD(2019)199

[108] It should be noted that the majority of responses supporting the repeal came from EU citizens (20 out of 28) while public authorities, business stakeholders, civil society (*i.e.* NGOs, consumer and environmental organisations) and other respondents strongly disagreed with the repeal of the Regulation.

[109] SME United emphasised that mandatory digitalisation should not be put forward, since all companies do not have "sufficient options and experience in adding or using digital information" and therefore the choice should be available to provide certain information either digitally or on the packaging.

[110] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published

namely to communicate product information and use instructions to guarantee consumers' safety when using detergents.

Centralised database for providing information digitally: During the consultation activities, public authorities expressed a general preference for this solution, albeit not seeing negatively the possibility for manufacturers to provide this information through their own website. Stakeholders from the industry, on the other hand, would rather have an electronic label directly linked to their own website in order to have greater control about the information provided. Having a centralised database was, however, discarded as a measure given the various disadvantages that it presented. First, detergents manufacturers are already required under the Regulation to maintain their own website with product information. Therefore, there already exists a suitable platform to host the labelling information to be provided digitally which manufacturers own and manage by themselves. Further, a centralised database would force companies to adopt a certain digital solution, the structure of which would be managed externally. This would not allow the legislation to stay technologically neutral in order to allow innovation and the uptake of future technologies, and its establishment would be time consuming and costly. Comparatively, the IA of the batteries proposal found that "the cost of a centralised database could be in the region of EUR 5.6 million plus EUR 1.3 million for maintenance" in the 2021-2030 period[111]. It was, therefore, concluded that the benefits of this measure would likely not outweigh the costs and shortcomings related to its implementation. It should also be noted that this approach is consistent with that followed under other digital labelling initiatives for chemicals *i.e.* the CLP and Fertilising Products Regulation IA.

5.3.3. Guidance only

Microbial cleaning products: despite the existing guidance on whether microbial cleaning products fall under the scope of the Detergents Regulation, confusion and different interpretations among stakeholders still exist. Further guidance would, therefore, not offer the necessary legal certainty. In addition, guidance would not be able to address the safety concerns related to microbial cleaning products or the risks associated with their use (see section 2.1 and Annex 7).

Refill sales: The fact that the Regulation does not specifically refer to the practice of refill sales, nor includes specific requirements applicable to it, has hampered the well-functioning of the internal market since no level playing field can be guaranteed for manufacturers that opt for this sustainable practice (see section 2.1.ii). Due to the substantive nature of the issues related to the concept of refill sales, it would not be possible to resolve them only through guidance while ensuring legal certainty and a harmonised approach across the EU.

5.3.4. Updating the dosage instructions for laundry detergents

The evaluation found that the dosage instructions for laundry detergents were out of date. This is because these instructions are expressed in relation to the capacity of washing

[111] Commission Staff Working Document - Impact Assessment Report - Accompanying the document - Proposal for a
Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive
2006/66/EC and amending Regulation (EU) 2019/1020, COM(2020)798, SWD(2020)334, Part 3/3, see pg. 290

machines which have increased over time[112]. A policy measure was, therefore, considered to update the dosage instructions in order to take account of these developments. However, it was found that while the capacity of washing machine loads has increased, the consumer wash loads haven't[113]. As a result, the existing dosage instructions better reflect the consumer habits and should therefore not be updated. This measure was also not supported by the majority of stakeholders, particularly the industry, who stated during the interviews that the "current dosage instructions are still relevant and should not be re-designed", and who also reported that a change in the standard washing machine load would have significant implications affecting the comparability of different types of laundry detergents by consumers (see Annex 7)[114].

5.3.5. Expansion of the scope of the Detergents Regulation to air fresheners[115]

During the consultation for the evaluation stakeholders reported that the scope of the Regulation should be expanded to cover air fresheners that, though not detergents, are somewhat related to cleaning. An overwhelming majority of interviewed industry stakeholders (9 out of 10) and all interviewed public authorities were against the expansion of the scope to non-cleaning products. Only one company and 2 out of 5 consumer associations participating in the interviews were in favour of including these products under the scope since they contain similar ingredients to detergents. The industry has established a voluntary programme to manage problems surrounding the use of air fresheners[116]. This programme focuses on good safety and communication practices such as responsible design and manufacturing, standards to measure emissions from combustible air fresheners, clear information to consumers and use instructions on labels. Finally, several aspects of these products are already being regulated under CLP and the GPSD.

5.3.6. Harmful ingredients potentially used in detergents

During the consultation for the evaluation and the IIA for this initiative, stakeholders reported on the lack of requirements for certain potentially harmful ingredients used in detergents. These relate to the lack of requirements for category 2 Carcinogenic Mutagenic and Reprotoxic substances (CMR) and endocrine disruptors (EDs), the lack of phosphorus limitations for professional detergents and consumer hand-dishwashing detergents and the lack of biodegradability requirements for non-surfactant organic ingredients[117]. While the evaluation did not gather sufficient data to conclude on the existence of a problem for the first two reported issues, based on the principle of precaution it was concluded that further investigation was warranted. During the Public Consultation, 71 out of 106 respondents[118]

---

[112] Currently the Detergents Regulation sets the 'standard washing machine load' as 4.5 kg dry fabric for heavy-duty detergents and 2.5 kg dry fabric for light-duty detergents, while the standard washing machine loads have now increased to 6-8 kg.

[113] 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).

[114] Idem.

[115] It should also be noted that

[116] Product Stewardship Programme on Indoor Air Emissions from Air Fresheners: https://www.aise.eu/our-activities/product-stewardship-programmes/air-fresheners/aise-product-stewardship-programme-on-indoor-air-emissions-from-air-fresheners-2016.aspx

[117] Only the reports on the lack of biodegradability requirements for non-surfactant organic ingredients were mentioned again as part of the feedback received on the IIA.

[118] EU citizens (39 out of 43), public authorities (11 out of 13), industry (12 out of 41) and civil society (9 out of 9).

stated that biodegradability requirements for non-surfactant organic ingredients should be introduced in the Regulation. The majority of these stakeholders are EU citizens (39 out of 43) and public authorities (11 out of 13), while the majority of industry stakeholders responding to this question (29 out of 41) were against the introduction of such requirements. Similarly, the majority of stakeholders from all groups except the industry were in favour of expanding the phosphorus limitations to professional (I&I) detergents (71 out of 102) and consumer hand-dishwashing detergents (74 out of 101). Once more, the majority of positive replies came from EU citizens (35 out of 39 and 37 out of 41 responses respectively) and public authorities (12 out of 15 and 11 out of 11 responses respectively). However, during this Impact Assessment no evidence was found to substantiate the existence of a problem for the following reasons: 1) these issues are already being partly or wholly dealt with under REACH and no evidence substantiating the need to deviate from the horizontal rules was found (cat. 2 CMRs, biodegradability of non-surfactant organic ingredients – see Annex 7); 2) regulatory actions or voluntary industry initiatives[119] are ongoing that will address them (biodegradability of non-surfactant organic ingredients ((polymers[120])), cat. 2 CMRs and EDs[121]); and 3) lack of economically and technically feasible alternatives (phosphorus limitations). For more information see Annex 7.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

The following assessment provides a qualitative analysis of the impacts generated by each policy option, based on the evidence gathered from multiple sources. Whenever possible, it also provides a quantitative analysis of benefits and costs relating to the main economic and social impacts. The cost/benefit analysis, however, is not fully comprehensive due to significant data gaps and limitations. The quantification of costs and benefits is based on a number of assumptions coming from stakeholder feedback and expert knowledge of the contractor. The aim of this assessment is to provide ranges of the magnitude of potential impacts generated by each policy option, rather than exact monetisation. Taking into account that this initiative involves a revision of the Regulation, some familiarisation costs would result under all options and which would, to a certain extent, affect the whole industry. These have been estimated at around €400,000 (four man hours; €25.7/h for 3,877 affected companies overall[122]). See annex 4 for details concerning methods and limitations.

No significant impacts on fundamental rights are expected under this initiative. Wherever (optional) digital labelling has been considered, this will be underpinned by some fundamental principles that have been particularly designed to safeguard those not able to access digital information and to ensure the accessibility, availability and quality of digital information. The introduction of (optional) digital labelling could yield additional benefits for vulnerable and visually impaired users (for details see Annex 8 on digital labelling).

[119] Voluntary industry initiatives envisaging the full biodegradability of all ingredients used in detergents by 2030 are currently ongoing; see https://www.unilever.com/news/news-search/2021/how-we-are-working-to-make-our-product-formulations-biodegradable/

[120] Ongoing initiatives to tackle microplastics pollution. See section 1.2.3 above.

[121] Revision of the CLP and REACH Regulations. For details see section 1.2.3 above.

[122] Eurostat does not contain granular data on the number of companies in the detergents sector as the relevant category i.e. NACE 20.41 "Manufacture of soap and detergents, cleaning and polishing preparations"is wider than the products falling under the scope of the Detergents Regulation. The supporting sudy has estimated the number of companies in the detergents sector in the EU at 3,877 (for details see Annex 6).

This initiative further respects the principle of 'doing no significant harm' and is in line with the digital by default principle especially under options 1b, 2a and 2b, where the introduction of (optional) digital labelling is being considered.

6.1. Policy option 1a – Facilitate the refill sales and introduce minimum requirements for microbial cleaning products

6.1.1. Economic Impacts

Microbial cleaning products: Under PO1a, microbial cleaning products would be brought under the scope of the Regulation by adapting the current definitions and including specific provisions to address them. PO1a is therefore expected to provide **legal clarity and certainty** for economic operators and competent authorities compared to the baseline.

This option also entails a change in the labelling requirements to inform users about the presence of microorganisms in the detergent. **No or negligible additional administrative costs for businesses are expected under PO1a**, and to a larger extent to those, mostly SMEs, manufacturing and placing on the market microbial cleaning products. This is based on the following:

a) No costs of collection of necessary information are expected, as the manufacturer will already know the microbes contained in the detergent.
b) During the targeted consultation, manufacturers of microbial cleaning products reported that first, they already provide labelling information for marketing and commercial reasons and second, that they tend to change these labels at least once a year ('label cycle'). Given that a transition period greater than 12 months would be granted, the change in the label will be performed as part of the changes naturally envisaged by firms, and hence at no extra costs. Based on this, no costs of re-designing are expected under PO1a either.
c) It is also unlikely that the new requirements will imply a change in the size of the label as they only involve a minor change compared to the baseline. There will not be additional consequences in the production process. The printing of the new labels is likely to imply very minimal costs for the industry. For these reasons, the impacts of the new labels on printing and packaging are also expected to be zero.

Currently all manufacturers of microbial detergents are SMEs. This measure is **not expected to have excessive or disproportionate impacts on these SMEs** as the costs incurred are very low and do not involve any high fixed costs which would affect them compared to larger companies. During the interviews, two SME microbial companies[123] indicated a positive reaction to this measure[124].

No significant impact is expected on sectoral competitiveness. However, the increased legal certainty as a result of PO1a, the harmonised information requirements as well as the current trends towards more sustainable products could increase the demand for and uptake of microbial products in the future.

PO1a could have minor benefits in terms of innovation given that microbial cleaning products will be brought under the harmonisation scope and will, consequently, move freely

[123] 2 out of 4 manufacturers of microbial cleaning products that participated in the interviews.
[124] 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).

in the internal market and considering that this option allows the inclusion of both 'known' and 'unknown' microbes in the detergent, albeit with no safety requirements to comply with.

No or negligible additional costs for public authorities are expected under PO1a given that the controls on microbial cleaning products will be performed as part of their usual surveillance activities.

Refill sales: PO1a is overall expected to provide **legal clarity and certainty** for economic operators and competent authorities compared to the baseline under which divergent views have arisen between stakeholders, both on the legality of this practice and as regards the requirements applicable to them. As explained in section 5.1.3.2 above, measures on refill sale of chemicals under the revised CLP will also be applicable to detergents but due to their horizontal nature they will not be able to address the specific issues related to the definitions and labelling resulting from the Regulation.

In particular, under PO1a it will be clarified that manufacturers of detergents that choose to sell their products in a refill format need to comply with the labelling requirements of the Regulation by providing *e.g.* a print-out or sticker of the label. No costs of collection of necessary information or re-designing of labels are expected given that manufacturers of refill detergents should already be complying with the labelling requirements. Costs of packaging the detergent with the new label are not relevant under this sales method. Therefore, **no additional costs for businesses are expected under this option**, especially given that any costs for detergents manufacturers would already be incurred within the context of the parallel developments for the refill sale of chemicals under the CLP Regulation (see 5.1.3.2 above)[125]. In addition, any additional costs would only be borne by manufacturers who are already selling refill detergents and that are not yet complying with the current rules and would be further mitigated since a transition period greater than 12 months is allowed, given that the average label cycle for detergents manufacturers is two years[126]. It should also be noted that manufacturers who are currently not selling their products in refill format (but in separate bottles) are already incurring these costs and should they wish to opt for this sales method it would rather result in cost savings due to the reduction of packaging than in any additional costs[127].

The majority of respondents (84 out of 108) to the public consultation were **in favour of introducing specific rules for refill sales in the Regulation**. It should be noted that these responses mostly came from SMEs, NGOs, environmental and consumer organisations, while business organisations and larger companies did not believe that there is a need to amend the Regulation to accommodate the refill sales of detergents[128].

In terms of sectoral competitiveness, PO1a would support the development of the refill distribution channels which could attract **new entrants (most likely SMEs) into this market**. In addition, given that most manufacturers of refill detergents are SMEs, clarifying the rules and providing legal certainty will be beneficial for them.

---

[125] According to the CLP IA, the facilitation of refill sales would entail an annualised one-off cost for businesses between €23,320 and €40,670.

[126] The average label cycle is one year for microbial detergents and two years for all the others.

[127] See also the SME test in Annex 3.

[128] 20 out of 36 industry stakeholders responding to this question, stated that the Regulation should not be amended to accommodate the refill sale of detergents. This could be explained by the fact that currently the majority of refill manufacturers is SMEs.

The **functioning of the internal market would also be improved** by preventing diverging national rules from emerging. By ensuring that a single regulatory framework is applicable, the emergence of economies of scale for manufacturers and distributors of detergents, as well as for their suppliers (*e.g.* suppliers of containers, e-labels) would also be fostered.

Despite the fact that PO1a is a clarification of the existing requirements and how these should be applied to refill sales, PO1a could entail a **slight increase in enforcement costs for public authorities**[129], taking into account that ongoing enforcement activities are not expected to be high due to the lack of clarity in the existing framework and the expected growth of the refill sales of detergents.

6.1.2. Environmental and health impacts

Microbial cleaning products: No significant health or environmental benefits are expected under PO1a, given that it would not introduce any safety requirements for microbial cleaning products to comply with. The mandatory and harmonised labelling requirements would allow end users to make informed choices and, therefore, better protect themselves in case of previous sensitisation or vulnerability. However, during the interviews under the impact assessment supporting study manufacturers of microbial cleaning products reported that they already provide this information on the label for marketing and commercial reasons. Based on this, users' awareness is not expected to change significantly compared to the baseline. It should, however, be noted that **some detrimental effects for human health and the environment could arise** especially from the use of 'unknown' microbes in detergents which, under PO1a, would also be allowed to be placed on the market with no safety requirements to comply with apart from the general prescription under the GPSD (see section 2.1. above). During the Public consultation, 34 out 74 stakeholders across all groups supported that introducing risk management requirements[130] for microbial cleaning products in the Regulation would better protect human health and 26 out of 74 stakeholders across all groups stated that it would provide enhanced environmental protection[131].

Refill sales: The impact of the clarification of the provisions for refill sales under PO1a would be **positive on public health effects,** as consumers would have complete information and could make informed choices for their health and the environment. Refill practices have **large environmental benefits** for the reuse of packaging and related reduction of resources needed to produce new packaging as well as the consequent reduction in packaging waste. While these could not be quantified, the annual cost **savings from disposing plastic waste** under the baseline are estimated at €3.3 million[132]. These savings are likely to increase in line with the growth of refill sales of detergents in the future. The restrictions of refill sales of detergents displaying hazardous properties (*e.g.* corrosivity) under the revised CLP

[129] The CLP IA has estimated these costs at €25,000 per year per enforcement project in the EU (while it is not expected that a specific enforcement project on refill chemicals would occur every year).
[130] Labelling is also a risk management measure given that it provides information to end users about potential risks associated with a product. In the Public Consultation, introducing labelling requirements was one of the risk management measures that stakeholder were asked to express their views on.
[131] It should be noted that 21 out of 36 industry stakeholders responding to this question reported that it would impose an unnecessary regulatory burden.
[132] The market share of refill detergents has been estimated between 1% - 2% (see section 2.1ii). Taking into account the lower bound estimate *i.e.* 1% of the total value of detergents sales this means savings of around 100 million refillable bottles, each weighing around 33 g. and considering that the cost of disposal of one tonne of plastic is roughly €100. See Annex 4 for details.

Regulation, will already limit exposure of consumers and reduce the likelihood of damage to the environment. During the public consultation, the majority of stakeholders across all groups reported that accommodating the practice of refill sales under the Regulation would have a positive impact on consumer safety and the environment (73 and 55 out 113 respondents respectively)[133].

6.1.3. Social impacts

Microbial cleaning products: The mandatory and harmonised labelling requirements would allow end users to make informed choices and use the product correctly. Since this is a niche market, the **social impacts** under PO1a are, however, **expected to be small**.

Refill sales: The clarification that manufacturers need to provide proper labelling information on refillable containers would fill an existing information gap. This would thus ensure that consumers receive the necessary use and safety information, yielding an **overall positive impact for society**. The legal certainty would remove an existing barrier to a more widespread adoption of this practice, which in turn could lead to more consumers having access to refill detergents in their local store. Respondents to the public consultation across all stakeholder groups agreed that accommodating the refill sales of detergents under the Regulation would also have a positive impact on consumer safety (55 out 113 respondents)[134].

A slightly positive impact on employment is expected under PO1a given that the clear rules and level playing field are likely to attract new entrants into the refill sales market.

6.2. Policy option 1b - Facilitation + digitalisation of refill sales and introduction of risk management requirements for microbial cleaning products

6.2.1. Economic Impacts

Microbial cleaning products: PO1b would have **the same impacts as PO1a in terms of introducing labelling requirements** for microbial cleaning products. PO1b would, however, result in **additional on-going costs** as a result of the introduction of risk management requirements for microbial cleaning products. These costs are expected to stem from the requirement to provide evidence on the lack of pathogens in the final product and the lack of antibiotic resistance of the microorganisms used in the detergents. Based on stakeholder reports during the interviews the costs related to the pathogens exclusion are estimated at **€200 per batch of product produced**[135]. Given that the number of batches is estimated at

[133] It should be noted that this was a multiple choice question. These were the two most popular answers followed by competitive advantage to EU market (24), positive results for industry (21), increase cost for refill manufacturers (16) and detrimental effects to human health (4).
[134] It should be noted that this was a multiple choice question and improved consumer safety was the second most popular answer after improved environmental protection (73 out of 113 respondents).
[135] This is the average of the costs reported from two out of the four consulted manufacturers of microbial cleaning products during the interviews conducted under the IA supporting study for this initiative *i.e.* 150

1000 per year[136], the total additional **on-going adjustment costs amount to €200.000 per company per year**[137].

Manufacturers of microbial cleaning products reported during the interviews that the costs related to proving the lack of antibiotic resistance per strain of microorganism used can range from €0 (in cases where the relevant data is already available in EUCAST[138]) to €335 (in cases where this needs to be carried out by the manufacturer)[139]. It should be noted that 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[140]. 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. For details see Annex 4.

It should, however, be noted that the costs of EUR 200,000 is an upper bound estimate, calculated on the basis of the average costs for testing and the highest number of batches[141] reported by manufacturers of microbial cleaning products during the interviews. It is, therefore, highly likely that the overall costs under this option will vary significantly depending on: a) the size of the company; b) the number of products in the company's portfolio or batches produced per year; c) whether the tests are conducted in house or outsourced to a laboratory; and d) the extent that the companies are already complying with all or some of these requirements. For example, companies whose products already bear the EU-Ecolabel, having a more limited product portfolio or producing less batches would incur no or minor additional costs.

Most of the companies working with microbial cleaning products are currently SMEs[142]. They would, therefore, have to bear the above mentioned costs as a result of the newly introduced requirements in the revised Regulation.

4 out of 25 overall manufacturers of microbial cleaning products participated in the targeted consultation for this initiative. Two of them were large companies with 6500 and 2100 employees respectively and two were small enterprises with less than 50 and 20-25 employees respectively**.** All four interviewed manufacturers expressed their support for explicitly covering microbial cleaning products under the Detergents Regulation and

---

[136] 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.

[137] This is an upper bound estimate, taking into account the highest number of batches (1000) reported by stakeholders during the interviews. According to other manufacturers the annual number of batches would not exceed 500.

[138] European Committee on Antimicrobial Susceptibility Testing.

[139] See Annex 4 for details.

[140] 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.

[141] While the basis of the calculations is the highest number of batches reported by manufacturers (i.e. 1000), it should be noted that other manufacturers of microbial cleaning products reported a maximum number of 500 batches per year. This means that even in the unlikely scenario where these manufacturers would have to incur all the above costs, these would already be cut in half.

[142] Draft final report of the Impact Assessment study on the making available and placing on the market of detergents, 2022, Europe Economics, The Huggard Group, Milieu

mentioned that **they view the costs as being within the acceptable range of costs for these new products**[143]. In addition, the detailed cost implications were discussed extensively with both of the two small interviewed manufacturers and there was consensus between them that the costs are within the acceptable range.

The introduction of generic criteria for the use of microbes in detergents was not strongly supported by the respondents to the Public Consultation for this initiative. In particular, only 3 out of 74 respondents across all stakeholder groups were in favour of introducing such criteria in the Regulation while 21 out of 36 industry stakeholders reported that introducing requirements for microbial cleaning products under the Regulation would impose an unnecessary regulatory burden[144]. Despite the little support for the introduction of generic criteria for the use of microbes in detergents, the more stringent option of introducing a scheme for individual, product-specific risk assessment measures was supported by 16 out of 53 total respondents to this question[145].

Positive impacts on the functioning of the internal market are also expected under PO1b due to the clear and harmonised framework that would be provided for these products. Given the size of this market, the **overall impact is expected to be small but likely to grow over time**, slightly improving the sectoral competitiveness and, thus, providing a benefit to SMEs, which currently represent most of the economic actors in this market.

PO1b is **not expected to bring any negative impacts in terms of innovation**. The option allows the inclusion of new strains of microbes as well as 'unknown' microbes, albeit only for R&D purpose and not for sale to end users. While it is not possible to know if and how many unknown microbes that are safe for use in detergents would be developed in the future, the incentives to additional research ensure that PO1b would not have a negative impact on innovation.

No or negligible impacts would be incurred by public authorities given that controls on microbial cleaning products would be undertaken as part of existing enforcement activities.

Refill sales: PO1b would have **the same impacts in terms of facilitating the refill sales of detergents as PO1a above**. However, PO1b further proposes the introduction of optional digital labelling as a means of further encouraging the uptake of this sustainable practice and reducing administrative burden for SMEs.

Overall, based on the findings from the online survey under the digital labelling study, public authorities had a slightly positive opinion on introducing digital labelling for refill detergents under PO1b. Similarly, industry stakeholders also expressed a positive opinion on this option (83% assessed PO1b positively[146]).

Allowing digital labelling for refill detergents on a voluntary basis, under PO1b, would lead to **overall positive economic impacts**. First, it would entail reduced burden for companies in

[143] See also the SME test in Annex 3.
[144] This concerns the introduction of requirements in general *i.e.* both under PO1a and PO1b.
[145] 6 out of 14 public authorities respoding tot his question, 8 out of 31 industry stakeholders, 1 out of 6 representatives of the civil society and 1 out of 2 'other'.
[146] It should be noted that this positive opinion/percentage includes the proposed interventions on digitalisation of refill chemicals under the CLP Regulation. Stakeholders showed a preference on the introduction of digital labelling under the latter compared to those proposed under the Regulation. This can, however, be easily explained due to the wider scope of the CLP Regulation that covers all refill chemicals and not only detergents.

the refill sector that are already complying with the current physical labelling obligations. At the moment, there is a lack of control over proper labelling (no or incorrect labels), which can diminish the level of protection for human health and the environment[147]. PO1b is, therefore, expected to have a positive impact with regard to increasing compliance by allowing manufacturers to provide information about their product only online.

Similarly to PO1a above, **no additional costs are expected under this option**. This is because under PO1b manufacturers may choose to provide all mandatory labelling information apart from dosage instructions, where relevant, through the digital label only. Only minor additional costs are expected from the introduction of optional digital labelling for refill detergents given the voluntary nature of the measure and the fact that detergents manufacturers are already required under the Regulation to develop and maintain a website with a full ingredient list *i.e.* all labelling information is already available online. These minor costs would mostly result from any adaptations required to the website *e.g.* if the manufacturer chooses to provide only simplified dosage information on pack and detailed information online[148].

Overall, the benefits of the introduction of digital labelling are expected to be even higher in the case of refilled detergents given that refill sales provide the opportunity to fully exploit the advantages brought by digitalisation. This is because, as opposed to pre-packaged detergents where only certain information would be allowed to be moved to the digital label, **in the case of refilled detergents it will be possible to go fully digitally.** In practice this means that the labelling information required under the Detergents Regulation would not need to be provided through any sort of physical label (*e.g.* in the form of a printout or a sticker) but a sticker with a digital tool of the manufacturer's choice (*e.g.* a QR code) that allows end users to access this information through a digital label would be sufficient to fulfil the labelling requirements of the Regulation.

This will offer great flexibility and burden reduction to manufacturers of refilled detergents as digital labels are easier to comply with and less costly to update than physical labels. Given that most companies in the refill sector are SMEs, these **would strongly benefit from the reduced administrative burden**. This would potentially also incentivise others to opt for this type of sales, thus **increasing the competitiveness of the sector** by attracting new entrants (most likely SMEs) into this market[149] which in turn will further facilitate the refill sales of detergents, allowing to reap the benefits of this practice especially the reduction in the production of packaging and the related packaging waste.

Digitising the refill sale of detergents would also have **a positive impact on public authorities** as enforcing and monitoring digital labelling is considered to be less costly compared to current enforcement costs[150]. The Policy Options survey found that one-third (30%, 3 out of 10) of consulted public authorities reported that the introduction of optional digital labelling would generate a high benefit[151] for monitoring activities of market

[147] SWD(2019)298

[148] The current provision in the Regulation requires that only a full ingredient list is provide on the manufacturer's website. Given that under PO1b manufacturers may choose to also provide detailed dosage instructions, where relevant online, minor adaptations to the website will be required.

[149] See also the SME test in Annex 10.

[150] For detergents, this means not only the physical label but also the manufacturers' website.

[151] Please note that 4 out of 10 answered that 'low' or 'very low' benefits would be generated and 3 out of 10 answered that no benefits would be generated.

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 with these rules. In general, due to existing non-compliance in the refill sector, the incentive for the refill manufacturers to comply with the Regulation is also welcomed by the public authorities.

6.2.2. Health and environmental impacts

Microbial cleaning products: Under PO1b, **impacts on human health are expected to be positive** compared to the baseline given that microbial cleaning products would need to comply with safety requirements before being placed on the market. In addition, by restricting the types of microorganisms only to 'known' and presumed safe species of microbes, the risk that consumers are exposed to unsafe microbes is significantly reduced. The introduction of labelling requirements would have the same positive impact as under PO1a above. **No significant impacts are expected for the environment**, however, instructions on use and disposal of microbial cleaning products could result in a **higher protection compared to the baseline**. During the Public consultation, 34 out 74 stakeholders across all groups supported that introducing risk management requirements for microbial cleaning products in the Regulation would better protect human health and 26 out of 74 stakeholders across all groups stated that it would provide enhanced environmental protection[152].

Refill sales: In addition to the environmental benefits described under PO1a above, this option would offer **additional environmental benefits** in terms of avoiding the waste of label stock as a result of reformulations or regulatory changes, given that this information would only be provided online. Stakeholders estimating a positive effect on the environment also argued that an additional benefit could be that detailed information on the disposal, re-use, and the recyclability of the products that is currently not possible to have on the physical label, due to lack of available space, could be provided through the digital label[153]. Having this information on digital labels would potentially increase consumer awareness on the dispersion of harmful substances in the natural environment, thus, **further benefiting the environment**. Under PO1b, dosage instructions would remain on-pack to ensure proper use and prevent negative impacts to the environment from overdosing.

As regards impacts on human health, it should be noted that the possibility to provide all labelling information under the Regulation through the digital label only is **not expected to have any negative impacts on human health** even for those end-users that may not have immediate access to the internet or a smart device. This is because, the CLP information, which is primarily responsible for communicating hazard information to end users, would still remain on the pack and would allow product users to make informed choices and protect themselves even in case of an accident[154]. The latter would remain the same even under the proposed changes to the CLP Regulation on refill sales of chemicals, where this information would still need to be provided *e.g.* through a print-out of the label or a sticker.

---

[152] It should be noted that 21 out of 36 industry stakeholders responding to this question reported that introducing requirements for microbial cleaning products in general in the Regulation (*i.e.* either under PO1a or PO1b) would impose an unnecessary regulatory burden.

[153] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published

[154] This takes into account the fact that hazard pictograms, poison centres information and the UFI according to which poison centres identify the product and access all relevant information would still be provided on pack by virtue of CLP.

6.2.3. *Social impacts*

Microbial cleaning products: PO1b would overall yield a **positive impact for the society** as it would close the current regulatory gap on microbial cleaning products by introducing safety and information requirements that will help end users be better protected in case of an incident and would also allow them to make more informed choices.

Refill sales: Industry representatives (68%, 19 out of 28) believe that this policy option would have **a positive impact on general consumer safety** as it would fill a current information gap (since this information is not currently provided on physical labels for these products)[155].

Based on the findings from the online survey on the Policy Options, the majority of industry stakeholders (61%, 17 out of 28) and 40% (4 out of 10) of stakeholders from public authorities think that PO1b would also have **a positive impact on visually impaired consumers** because communication on digital labels can transfer all the relevant information online in an easily readable way compared to the physical labels[156].

A slightly positive impact on employment is expected under PO1b given that the clear rules and harmonised requirements for refill sales and microbial cleaning products respectively may attract new entrants on the market.

6.3. **Policy Option 2a -** Complete abolishment of ingredient data sheet + streamlining and simplifying the labelling requirements and introduction of digital labelling

6.3.1. *Economic Impacts*

Labelling requirements: PO2a (streamlining and simplifying the labelling requirements and introduction of digital labelling) entails a change in the labelling requirements for detergents. Stakeholders across all groups had a positive or very positive view of the intervention foreseen under PO2a[157]. Despite this positive view, the majority (10 out of 13) of consulted industry stakeholders reported that the costs or benefits of removing regulatory overlaps would generate **no to very low impact on enterprises**. In terms of costs, and according to the views of the same stakeholders, streamlining the labelling requirements of the Regulation would generate **no (6 out of 13) or low costs (3 out of 13)** for companies[158]. These costs are associated with the one-off cost for the disposal of non-compliant labels (as a result of the new requirements), which would be mitigated given that a transitional period of 18 months would be allowed.

Regarding the assessment of the two sub-options to address the overlaps in the labelling requirements, public authorities and consumer organisations responding to the Policy Options survey for the digital labelling study had no particular preference on either of them. Industry representatives participating in the same survey expressed a slight preference for sub-option 2b arguing that this sub-option would be more straightforward for the industry to apply[159].

---

[155] Survey on the policy options under the digital labelling study: VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published
[156] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published
[157] Idem.
[158] Idem.
[159] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published

However, during the public consultation for this initiative, the vast majority of stakeholders (97 out of 114) across all stakeholder groups, including industry representatives (40 out of 43 respondents), stated that they would be in favour of streamlining the labelling requirements so that ingredients are labelled only once in accordance with the stricter rules.

PO2a further foresees the possibility for manufacturers to provide some mandatory information on a digital label *i.e.* detailed dosage instructions and some categories of ingredients (see annex 8). In terms of the scope of the information to be provided only digitally, this has been chosen with caution in order to ensure that all safety and use related information remains on the physical label. It should also be noted that hazard and safety information will also remain on pack in accordance with the CLP labelling requirements.

The majority of stakeholders responding to the same survey (15 out of 17 of industry representatives, and 8 out of 11 of public authorities) assessed this policy option positively. This positive assessment reflects the feedback collected during the interviews for the digital labelling study where stakeholders emphasized that dosage instructions are considered most useful by all types of stakeholders to ensure appropriate use of the product, and could be simplified compared to how they are presented now. Finally, during the public consultation for this initiative, 66 out of 113 stakeholders across all stakeholder groups supported that dosage instructions should be simplified and/or become clearer for consumers[160].

As already mentioned in section 2 above, the digitalisation of labelling information under PO2a would be underpinned by some fundamental principles in order to protect end-users and to ensure the accessibility, availability and quality of digital information (see Annex 8 for details). Within the context of the digital labelling study, economic operators, national authorities, professional and non-professional users as well as other stakeholders such as NGOs were consulted on these principles, and feedback confirmed wide support for all of the principles[161].

As regards the introduction of digital labelling, this measure is of voluntary nature. PO2a would, therefore, **not impose any additional costs on businesses** across the EU, as these could avoid incurring additional costs simply by continuing their current method of providing all label information on the physical label only. Detergents manufacturers are already required under the Regulation to provide and update a full ingredient list online, through their own website. In addition, 74% of the consulted industry stakeholders (98 out of 132) in the public consultation on digital labelling indicated that they already provide product information via IT solutions or digital tools and that companies are already providing information about their products online, making these business as usual costs.

Under PO2a, two **types of costs** can be identified namely:

1) Costs related to providing and updating product information specific to PO2a online;
2) Cost of changing physical labels to include QR codes on the product.

---

[160] 24 EU citizens, 8 public authorities, 29 industry stakeholders and 2 representatives of civil society and 3other. It should be noted that the majority of stakeholders from the public authorities (10) and the civil society (6) stated that the dosage instructions are simple enough. It should be noted that this was a multiple choice question.

[161] Majority of stakeholders responding to the 'policy options' survey 'strongly agreed' or 'agreed' with all 10 principles.

Based on the above, **only minor costs related to providing and updating product information online** are expected for the detergents industry. Costs related to the inclusion of the QR code in the physical label and the re-design of the physical label due the simplification of the on-pack labelling requirements would be negligible. These costs are, therefore, not calculated, especially considering that manufacturers are already required to re-design their physical labels[162] and that the average label cycle for detergents manufacturers is 2 years[163]. In fact, simplifying requirements on physical labels and allowing to remove some of the information of the products from the physical to digital labels would only bring benefits to the manufacturers in this regard.

It should be noted that some costs may additionally be incurred by manufacturers opting for digital labelling, associated with the application of digital labelling principle 8 (*e.g.* in terms of printing a leaflet with label information – for details see Annex 8 on digital labelling). Although such costs could not be quantified, they are expected to be marginal, given that product information would only be supplied to small portions of the target markets (and otherwise the label information could be provided on the physical label, incurring the baseline costs).

Addressing the identified legal overlaps and duplications would have a positive impact for detergents manufacturers that would be relieved from the obligation to mention the same substance more than once on their product's label. In the long term, industry stakeholders also see the possibility of less re-labelling for detergents if duplicated requirements are removed and ingredients are labelled only in accordance with CLP under both sub-options. The overall annual costs of disposal of unused labels for companies in response to the streamlined labelling requirements (*e.g.* disposal of ready labels that cannot be used, potential re-labelling of products, adaptation/design of new labels) should remain very similar to the baseline with a slight chance of cost decrease. It is difficult to estimate how much the cost related to the disposal of labels due to regulatory changes would decrease under this option but it is clear that in addition to ongoing digitalisation efforts (including under the DPP), PO2a would further contribute to reducing this cost.

As with the large detergent manufacturers, SMEs would equally benefit from the simplifications of the labelling requirements under PO2a. In fact, more than half of the consulted stakeholders in the public consultation for this initiative reported that streamlining the labelling requirements would significantly simplify the regulatory framework (60 out of 116)[164] and reduce labelling costs (47 out of 116)[165]. As regards the introduction of digital labelling, the findings of the digital labelling study indicate that although SMEs are also expected to benefit from digital labelling overall, their short term cost savings are likely to be slightly less. Compared to large companies, the public consultation found SMEs to be less likely to provide information about their products online, but not by significant amounts. Based on the results from the public consultation, 70% of the SMEs[166] compared to 79% of

[162] 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 so ingredients are different) or due to regulatory changes.
[163] The average label cycle of microbial cleaning products is 1 year while for all other detergents 2 years.
[164] Out of which 32 were industry representatives, 16 EU citizens, 9 public authorities, 2 representatives of civil society and 1 'other'. Multiple choice question.
[165] Out of which 29 were industry representatives, 12 EU citizens, 3 public authorities, 2 representatives of civil society and 1 'other'. Multiple choice question.
[166] Multiple selection question. 58 out of 83 total selections.

the large companies[167] already provide information about their products digitally. This illustrates that benefits as a result of the introduction of digital labelling would be very likely for SMEs.

In terms of sectorial competitiveness, introducing digital labelling and simplifying the physical label, could help retailers or wholesalers to overcome the obstacles they sometimes face because of territorial supply constraints[168]. An increased share of information provided only on electronic labels would allow for more space on physical labels for multiple languages. This would allow for more cost-effective product distribution across EU markets and less re-labelling due to linguistic differences between the EU Member States. Therefore, measures to promote digital labelling and simplify labelling under PO2a would have, overall, a positive impact on sectoral competitiveness in the EU, both for detergents manufacturers.

The majority of all the consulted stakeholders (10 out of 12 including industry stakeholders and public authorities) estimate that the provisions of PO2a would not generate costs – or would generate very low costs – for public authorities. On the other hand, nearly half (5 out of 12) of consulted public authorities reported that PO2a would generate a high benefit[169] thanks to the simplification and streamlining of the regulatory framework. One-third (30%, 3 out of 10) of consulted public authorities responding to the Policy Options survey reported that 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 with these rules. Representatives from public authorities further argued that changes under PO2a related to the introduction of digital labelling would not require extra surveillance or enforcement activities.

Ingredient data sheets: PO2a also foresees the complete abolishment of the ingredient data sheet in view of the similar requirements introduced under CLP (see section 2 above).

The total administrative costs of compiling ingredient data sheets under the Regulation for both hazardous and non-hazardous detergents can be estimated at €8.2 million per year[170]. This was calculated based on the following:

- The total number of detergents in the EU is estimated at 71,590[171] *i.e.* 35,795 consumer and 35,795 professional (I&I) detergents respectively[172]. See Annex 4 for detailed calculations.
- During the interviews industry stakeholders indicated that most detergents belong to the hazardous category, and we assume that the split between hazardous and non-

[167] Multiple selection question. 59 out of 75 total selections.
[168] European Commission (2020). Study on territorial supply constraints in the EU retail sector. Available at: https://ec.europa.eu/growth/news/half-eu-fast-moving-consumer-goods-sellers-experience-supply-constraints-based-their-location-2020-11-19_en
[169] This was the most popular answer given, equal with the answer option that PO2a would generate low benefits (also 5 of 12).
[170] €7 million for hazardous and 1.2 million for non-hazardous detergents
[171] 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).
[172] The supporting study to the evaluation estimated the split between the amount of consumer and professional products on the market to be 50-50.

hazardous is 80%-20%, in each of these two market segments[173]. 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 years. 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. See Annex 4 for detailed calculations.
- The cost per occurrence of producing an ingredient datasheet under the Regulation was previously estimated at €200[174].

Under PO2a, the requirements on ingredient data sheets are eliminated for both hazardous and non-hazardous detergents. This amounts to an annual administrative burden reduction of 8.2 € million across the EU *i.e.* €7 million for hazardous and €1.2 million for non-hazardous detergents (as all of these would be eliminated).

Despite the fact that cost savings under this option are low to moderate, **SMEs would particularly benefit,** since the costs for compiling data sheets are fixed, irrespective of the turnover generated by the product and company.

Eliminating duplications and simplifying data sheets **might also bring savings, albeit small,** in the administrative costs of authorities that manage them. The cost savings could be of a similar magnitude or smaller to the ones estimated for manufacturers.

No impacts on the competitiveness of the sector are expected under PO2a.

6.3.2. Environmental and health impacts

Labelling requirements: The majority of public authorities (60%, 6 out of 10) reported during the policy options survey under the digital labelling study that addressing the inconsistencies, overlaps and duplications on the physical label would bring **a positive impact to the awareness of consumers on the effects of dispersion of harmful substances in the natural environment.** Compared to the baseline, PO2a could have a **slightly higher positive impact to the environment** in terms of decreasing re-labelling of products due to inconsistencies, overlaps and duplications (notably with the CLP Regulation) and the related disposal of unused labels. Environmental benefits could also be brought by the simplification of the on-pack dosage instructions. Increased consumer understanding of dosage instructions would lead to correct dosing which is crucial in terms of preventing product overuse and thus reducing the amount of detergent that could end up in the environment.

---

[173] 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).

[174] 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.

The simplification of labels and the additional digital labelling would lead to **increased understanding of chemical labels** and **improved effectiveness of the communication of safety and use information** with regard to end-users. The more comprehensive communication could reduce adverse effects on consumer health, in particular in case of an accident (as label information relevant in case of an accident becomes easier to find). During the Public Consultation for this initiative, the vast majority of respondents (106 out of 116) across all stakeholder groups indicated that streamlining the labelling requirements would provide clarity for consumers and that it would increase the effectiveness of detergents labels (72 out of 116)[175].

The physical label as it is today will remain mandatory to a large extent. As the overarching principle that guides the selection of what information could be moved to an online label is to ensure that it does not lower the level of safety and therefore decrease consumer protection or information, as well as the application of the digital principles[176] there will **be no negative impact for population groups without or with limited access to digital tools or the internet.** At the same time, digital labels could have **significant positive impacts for vulnerable groups like those with visual or other impairments** (*e.g.* through the aid of read-out-loud digital labels). Digital labels would also allow to integrate additional language versions for those users that are not sufficiently fluent with the official languages of the Member State concerned.

However, the way of eliminating the identified overlaps between the Regulation and CLP has different impacts in terms of protection of human health under the proposed sub-options. In particular under the second sub-option (removal of duplicated requirements from the Regulation) the thresholds for labelling some sensitising ingredients would be higher, given that the Regulation is on several instances imposing stricter thresholds than those of the CLP Regulation. This points to a potential concern that consumers might receive less information about the presence of these ingredients in detergents and thus a lowering of the current level of protection of human health.

Ingredient data sheets: No environmental impacts are expected under PO2.

In terms of human health, the impacts should be distinguished between those for hazardous and non-hazardous detergents. As regards hazardous detergents the **level of protection will remain very similar compared to the baseline.** Currently, the information provided to poison centres under CLP is much more extensive and elaborate than that provided in the ingredient data sheets under the detergents Regulation. The duplicated requirements have, therefore, no added value in terms of protection of human health. On the other hand, the abolishment of the ingredient data sheet for non-hazardous detergents **could result in negative impacts on human health** given that medical personnel would not be able to receive the necessary information in case of emergency (accident or poisoning) under either the Regulation or CLP. This is especially because even though the detergent as a mixture of

[175] It should be noted that this was a multiple choice question. Other supported replies across all stakeholder groups included that streamlining the labelling requirements would significantly simplify the regulatory framework (60 out of 116) and reduce labelling cists (47 out of 116).

[176] For example through the application of digital principle 8: Economic operators who opt for the digital label shall ensure that appropriate alternative ways of providing information are available to end-users in case of lack of digital tools or skills, or in the absence of network access, both before buying the product and after having bought the product.

substances may not classified as hazardous under CLP, it could still contain hazardous substances.

During the interviews under the supporting study for this initiative, stakeholders cautioned against the potential risks of eliminating the ingredient data sheet for non-hazardous detergents. The responses to the public consultation also show a wide agreement amongst stakeholders across all stakeholder groups (56 out of 70 responses) towards maintaining the relevant requirement under the Regulation as this would provide a higher level of protection of human health (34 out of 75 respondents)[177].

6.3.3. Social Impacts

Labelling requirements: From a social point of view, reduced information on the label has been carefully chosen based on what different users find essential on a detergent's label. PO2a does not remove any type of safety information (considered the most important information on a label), with the aim to foremost protect those users who may not have access to digital information. Hazard communication on detergents labels is primarily being undertaken under CLP, so PO2a would not impact the current level of protection of human health.

Half of the respondents from public authorities (five out of ten) and 62% of stakeholders from industry (13 out of 21) would also agree with having some of the ingredients on a digital label only. The idea of allowing manufacturer information (*e.g.* telephone, address) only on digital labels finds less support, with only a 36% approval rate (4 out of 11) from public authorities and a neutral opinion (50%, 9 out of 18) among industry[178].

Secondly, the information that remains on the physical label was found to be the most essential, and by removing duplications and reducing the amount of other label information provided on the physical label, such information could become clearer. In terms of understandability of detergents labels, PO2a makes it easier to distinguish between essential and less relevant information, and identify the information needed at various points in time by different users. Thirdly, the digital principles were developed to safeguard those not able to access digital information, in case the moved label information holds importance or significance to those consulting the label.

According to the policy options survey, public authorities and industry representatives agreed that addressing inconsistencies, overlaps and duplications on the physical label under PO2a would have an overall positive impact on consumers' awareness. More specifically, label readability would be strongly improved according to a large majority of public authorities (92%, 11 out of 12) and of industry representatives (85%, 22 out of 26).

Overall, industry stakeholders expect a slightly positive or neutral impact of PO2a on working conditions. Around 83% (10 out of 12) of the consulted stakeholders from public authorities and 42% of the industry stakeholders[179] (10 out of 24) think that addressing the

[177] It should be noted that this was a multiple choice question, in which providing a high level of protection to human health was the most popular answer followed by 'other' (31 out of 75 respondents), and impose an unnecessary burden to the industry (10 put of 75 respondents).
[178] VVA (2022) Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling; not yet published
[179] Based on the findings from the survey on the policy options under the digital labelling study (see Annex 2 and 8).

inconsistencies, overlaps and duplications on the physical label would have a positive impact on professional users in terms of label readability, and overall safety of products dedicated to professional and industrial users.

Ingredient data sheets: no social impacts are expected under PO2a apart from those on consumer's health described above.

6.4. Policy Option 2b – Abolishment of the duplicated ingredient data sheet + streamlining and simplifying the labelling requirements through the introduction of digital labelling

6.4.1. Economic Impacts

Labelling requirements: same as PO2a above.

Ingredient data sheet: During the public consultation for this initiative, the majority of stakeholders across all stakeholder groups (56 out of 70) agreed that the ingredient data sheet for non-hazardous detergents should be maintained. This includes 15 out of 17 public authorities, 28 out of 38 industry stakeholders, 8 out of 8 representatives from the civil society[180].

Under PO2b administrative cost savings will ensue from the abolishment of the ingredient data sheet for hazardous detergents. These are estimated at €7 million (see section 6.3.1 above).

Responses to the public consultation were split in terms of the format under which the ingredient data sheet should be maintained. Out of a total of 63 stakeholders, the responses were almost split in half between maintaining the current format and aligning it with the CLP one, with the latter having a very narrow advantage among respondents (28 versus 26 out of 76 responses). The majority of respondents from public authorities and civil society were in favour of adapting it to the CLP format while the majority of industry stakeholders preferred the current one[181].

In terms of costs, 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. The additional one-off costs to the industry from aligning the format to the CLP one would be €1.35 million[182] and are, therefore, considered negligible. These costs would be further mitigated given that a transition period of 18 months would be allowed. In the long term, the annual incremental costs to the industry would be €122,420[183].

Nevertheless, during the public consultation for this initiative the majority of respondents (29 out of 73) indicated that aligning the format to the CLP one would impose an unnecessary

[180] And 5 out of 7 'others'.
[181] 4 out of 7 'others' also preferred the alignment to the CLP format.
[182] Considering that the total number of non-hazardous detergents that needs to be reformulated every year is estimated at 6,121 (see section 6.3.1 above) and that the cost of producing a data sheet is €220 under CLP.
[183] Taking into account the total number of non-hazardous detergents (consumer and I&I) that need to be reformulated every year in the EU and the €20 difference between compiling an ingredient data sheet in accordance with CLP compared to the same costs under the Regulation (*i.e.* €220 under CLP and€ €200 under the Regulation).

burden to the industry and 16 out of 73 respondents stated that it would have no added value. The majority of these responses comes from industry representatives (23 and 9 respectively) and public authorities (4 and 5 respectively)[184].

6.4.2. Environmental and human health impacts

Labelling requirements: same as PO2a above.

Ingredient data sheet: No environmental impacts are expected under PO2b. However, the maintenance of the ingredient data sheets for non-hazardous detergents under the Regulation would provide **an equally high or a slightly higher level of human health protection** compared to the baseline in case that the more elaborate CLP format would be provided. The majority of respondents to the public consultation across all stakeholder groups (34 out of 71) sustained that maintaining the ingredient data sheet for non-hazardous detergents would provide a high level of protection of human health[185]. In addition, 21 out 73 stakeholders coming mostly from the civil society[186] reported that aligning the format to the CLP one would increase the human health protection. However, as already reported above industry stakeholders and public authorities disagreed with this view and stated that it would have no added value.

6.4.3. Social Impacts

Labelling requirements: same as PO2a above.

Ingredient data sheets: No social impacts are expected under PO2b.

7. HOW DO THE OPTIONS COMPARE?

Based on the multi-criteria analysis (see Table 2 below) PO1b is superior to PO1a. While both options provide legal clarity and certainty and improve the functioning of the internal market, PO1a is more effective in achieving the first specific objective (SO1) given its potential minor positive impact on innovation. However, PO1b allows for a much higher protection of human health and the environment (SO2) because of the safety requirements that would be introduced for microbial cleaning products. In terms of efficiency, despite the fact that no or negligible costs and the same cost savings are expected under both options, PO1a scores a little better in terms of costs compared to PO1b. Coherence with parallel developments on the refill sales of chemicals under the CLP and the digitalisation of chemicals labels is ensured under both options.

[184] 18 out of 73 mentioned 'other' but did not specify what that was.
[185] It should be noted that 31 out of 71 responses stated that maintaining it would have 'other' impacts but did not clarify what would those be.
[186] NGOs, consumer and environmental organisations.

Table 3 Comparison of options under PO1- effectiveness in meeting objectives, efficiency, coherence

	Effectiveness in meeting objectives		Efficiency	Coherence
	SO1 / Clear and updated rules that level the playing field and allow for innovative products and sustainable new practices	**SO2 / Optimised protection of human health and the environment**		
Option 1a	+++ Legal clarity and certainty for microbial cleaning products and refill sales Improved functioning of the internal market as a result of clear rules Potential minor positive impact on innovation especially for unknown microbes as these would not need to comply with any requirements	+ Positive impacts on human health from refill sales: consumers receive complete information and are allowed to make informed choices for their health and the environment Large environmental benefits due to reuse of packaging and consequent reduction in packaging waste Potential negative impacts on human health and the environment: no safety requirements for microbial cleaning products	++ No or negligible additional costs for the industry Cost savings refills: from reduced plastic waste	+/- The intervention considered under PO1a is coherent with horizontal rules on refill sales of chemicals under CLP It is also coherent with the parallel initiatives on digitalisation of chemicals labels such as CLP and FPR will be ensured
Option 1b	++ Legal clarity and certainty for microbial cleaning products and refill sales Functioning of the internal market is further improved due to harmonised framework for risk management of microbial cleaning products and the further facilitation of refill sales through the introduction of (optional) digital labelling No negative impact on innovation: unknown microbes allowed for R&D	+++ Positive impacts on human health from refill sales: consumers receive complete information and are allowed to make informed choices for their health and the environment Large environmental benefits due to reuse of packaging and consequent reduction in packaging waste Increased protection of human health as a result of safety requirements for microbial cleaning products	+ Higher additional costs for the industry compared to PO1a but still negligible Increased cost savings refills: from reduced plastic waste and potential less re-labelling due to (optional) digitalisation	+/- The intervention considered under PO1a is coherent with horizontal rules on refill sales of chemicals under CLP It is also coherent with the parallel initiatives on digitalisation of chemicals labels such as CLP and FPR will be ensured

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ highly positive impact; - minor negative impact; -- negative impact; --- significant negative impact.

Comparison of PO2a and PO2b shows these are quite close in terms of performance along their different dimensions. On one hand, by eliminating data sheets for both hazardous and non-hazardous substances, PO2a provides for greater regulatory cost savings and for more harmonisation of the legal framework in the Single Market (scores worse in terms of SO3). On the other hand, PO2b maintains data sheets for non-hazardous detergents, thus providing a higher level of protection of human health (scores better for SO2).

As regards the sub-options for streamlining and simplifying the labelling requirements under both PO2a and PO2b, the second sub-option *i.e.* the elimination of all duplicated requirements from the Regulation, was slightly preferred by industry stakeholders who claimed that this sub-option would be more straightforward for the industry to apply. However, given that under the first sub-option the elimination of the duplicated requirement

would be based on the least protective rules, and considering that on many instances the Regulation imposes stricter thresholds for the labelling of certain substances than CLP, the first sub-option would provide a higher level of protection of human health and is therefore superior to the second one.

In terms of efficiency PO2a scores slightly higher than PO2b given that the complete elimination of the ingredient data sheet would result in further burden reduction for the detergents industry, albeit small. The introduction of digital labelling under both options would lead to cost savings considering that updating digital labels is less costly than physical ones and the consequent reduction of disposing unused label stock. Both options have highly positive impacts on improving coherence within the regulatory framework applicable to detergents given that they result in the elimination of duplicated requirements either on labels or in the information related to emergency health response.

Table 4 Comparison of options under PO2- effectiveness in meeting objectives, efficiency, coherence

	Effectiveness in meeting objectives			**Efficiency**	**Coherence**
	SO2 - Optimised protection of human health and the environment	**SO3 - Burden reduction for detergents manufacturers**	**SO4 - Improved consumer understanding and awareness of labels**		
Abolish data sheets (hazardous and non-hazardous)	+/-	++	+/-	++	+++
Streamline labelling and digitalisation	+	++	++	+	+++
Sub option a	-	++	++	+/-	+++
Sub option b	++	++	++	+	+++
Total Option 2a	**+ Minor positive impact**	**++ Positive impact**	**++ Positive Impact**	**++ Positive Impact**	**+++ Highly positive impact**
Abolish data sheets (hazardous)	+	+	+/-	+	+++
Streamline labelling and digitalisation	+	++	++	+	+++
Sub option a	-	++	++	+/-	+++
Sub option b	++	++	++	+	+++
Total Option 2b	**++ Positive impact**	**+ Minor Positive Impact**	**++ Positive Impact**	**+ Minor Positive Impact**	**+++ Highly Positive Impact**

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ highly positive impact; - minor negative impact; -- negative impact; --- significant negative impact.

In terms of key impacts PO1b scores higher compared to PO1a for social and health and environmental impacts but lower in terms of economic impacts, given that it may have less positive impacts in terms of innovation. Similarly PO2b scores higher for social and health and environmental impacts compared to PO2a, but lower in terms of economic impacts given

that it results in less burden reduction. Table 5 and Table 6 below provide a comparison of the options in terms of their key impacts.

Table 5 Comparison of options - key impacts PO1

	Economic Impacts	Health and environmental impacts	Social impacts
Total Option 1a	++ Positive economic impact on the market and potential higher benefits in terms of innovation	+ Positive impacts on human health and the environment due to refill sales but potential negative impacts due to lack of safety requirements for microbials	++ Positive impacts for society as a result of the facilitation of sustainable practices and of enabling consumers to make informed choices
Total Option 1b	+ Positive economic impact on the market due to digitalisation and no negative impacts on innovation but slightly higher costs (albeit still negligible)	+++ Increased human health and environmental protection due to safety requirements for microbials	+++ Significant positive impact on the society due to increased user safety and potential benefits for visually impaired users (digital labelling)

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ highly positive impact; - minor negative impact; -- negative impact; --- significant negative impact.

Table 6 Comparison of options - key impacts PO2

	Economic Impacts	Health and environmental impacts	Social impacts
Total Option 2a	++ Positive impacts due to increased burden reduction and elimination of duplicated requirements	+ Positive impacts but potentially less protection given the elimination of requirements for non-hazardous detergents	++ Positive impacts in terms of increased awareness, readability and understandability of detergents labels
Total Option 2b	+ Slightly lower positive impacts, due to elimination of less requirements	++ Positive impacts and increased protection of human health	++ Positive impacts in terms of increased awareness, readability and understandability of detergents labels

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ highly positive impact; - minor negative impact; -- negative impact; --- significant negative impact.

Stakeholders' support varied depending on the group that they belonged to for the interventions proposed under PO1a and PO1b. More convergent views are observed on the proposed interventions under PO2a and PO2b. An overview of stakeholders' support can be found in Table 7 below.

Table 7 Comparison of options – stakeholders' support

	Industry	Public authorities	Civil society
Option 1a	+ Manufacturers of microbial cleaning products supported the intervention but part of the overall industry viewed it as imposing an unnecessary burden while recognising the benefits it could offer. Overall support for refill sales measures	++ Strong support for both the introduction of specific rules on refill sales and minimum information requirements for microbial cleaning products	+ Strong support for the introduction of specific rules on refill sales but less support for minimum information requirements for microbial cleaning products
Option 1b	++ Stronger support due to digitalisation of refill sales. Manufacturers of microbial cleaning products viewed costs within the acceptable ranges	+ Slightly positive opinion on digitalisation of refill sales and positive opinion on risk management requirements for microbial cleaning products	+/- Some support for microbial cleaning products; strong support for refill sales and no specific views on their digitalisation
Option 2a	++ Strong support for proposed labelling intervention and less support for abolishing the ingredient data sheet for non-hazardous detergents	++ Strong support for proposed labelling intervention and less support for abolishing the ingredient data sheet for non-hazardous detergents	++ Strong support for proposed labelling intervention and less support for abolishing the ingredient data sheet for non-hazardous detergents
Option 2b	+++ Strong support for proposed labelling intervention and for maintaining the ingredient data sheet for non-hazardous detergents	+++ Strong support for proposed labelling intervention and for maintaining the ingredient data sheet for non-hazardous detergents	+++ Strong support for proposed labelling intervention and for maintaining the ingredient data sheet for non-hazardous detergents

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ highly positive impact; - minor negative impact; -- negative impact; --- significant negative impact.

8. PREFERRED OPTION

Based on the comparative assessment presented above, the preferred combination of policy options consists of PO1b and PO2b. These options scored better overall in comparison to their alternatives across a range of criteria (positive economic, social, environmental and health impacts, effectiveness, efficiency and coherence). In particular, PO1b and PO2b are expected to bring benefits in terms of burden reduction and cost savings for the industry, as well as improved readability of detergents labels. They are also expected to reduce the burdens for economic operators in terms of the extensive and overlapping labelling requirements under the wider EU regulatory framework applicable to detergents, notably through eliminating all duplications in the information requirements and by offering flexibility in providing some label information through a digital label. There would also be economies of scale in the sense that the physical label space could allow for more languages, meaning 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 sustainable products (microbial cleaning products) and 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, thus contributing to the achievement of SDG #9 'Industry, innovation and infrastructure'.

The combination of PO1b and PO2b further ensures a high level of protection of human health, of safety, and of the environment and contributes to the achievement of SDG #3 'Good health and well-being' and SDG #12 'Ensure sustainable consumption and production patterns'. In particular, the introduction of risk management measures for microbial cleaning products will ensure that microbes used in detergents are safe both from a human health and environmental perspective and will allow end users to make informed choices and better protect themselves in case of prior sensitisation or vulnerability. Targeted and simplified use instructions on the label will further allow product users to correctly use these products, thus providing an optimised environmental protection. Furthermore, the introduction of specific requirements for refill sales will ensure that consumers receive all relevant safety and use information when buying refilled detergents and will promote a sustainable practice that has significant environmental benefits in terms of packaging waste. Allowing some of the labelling information to be provided only digitally would further reduce waste ensuing from disposal of unused label stock.

Streamlining and simplifying the labelling requirements will increase readability and comprehensibility of detergents labels, allowing end users to find the relevant information more easily and quickly, which is crucial *e.g.* in case of an accident. Sub-option 1 of PO2a, according to which ingredients are labelled only once based on the stricter applicable rules is preferred as it will offer a higher level of protection of human health. Moreover, the introduction of optional digital labelling will on one hand provide additional ease of use and 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. The digital principles, which will apply when the manufacturers of detergents decide to label digitally, will further safeguard the high level of protection of human health. Finally, the maintenance of the ingredient data sheet for non-hazardous detergents under the Regulation will ensure that the level of protection remains very high.

Under the preferred option, the functioning of the Single Market benefits from the introduction of harmonised norms for microbial cleaning products and refill sales, which would prevent the emergence of diverging national rules. The preferred option will entail no or negligible costs for companies and large cost savings. The largest impact – in the form of cost savings – results from the abolition of ingredient data sheet for hazardous detergents, with an annual estimated saving of €7 million per year. The current format of the ingredient data sheet will be maintained to avoid unnecessary additional costs and complexity for the industry, especially SMEs.

Additional annual small burdens due to the risk management requirements for microbial cleaning products are expected for SMEs, in the area of €200.000 per company. It should, however, be noted that this is an upper bound estimate, and calculated on the basis of the average costs for testing and the highest number of batches reported by manufacturers (see section 6.2.1). It is also highly likely that this number will vary depending on several factors (e.g. company or portfolio size; current level of compliance etc.) but will not, in any event, negatively impact the manufacturers (mostly SMEs), who reported during the interviews that

these costs are within the acceptable range. For companies currently working on "known microbes" the costs of introducing new requirements is expected to be negligible as many of the proposed requirements are already being fulfilled or can be met at negligible cost. These firms will, therefore, be able to work and expand their production at no cost.

The preferred option complies with the proportionality principle. It does not exceed what it is needed to achieve the objectives sought. The elimination of regulatory overlaps will ensure a greater coherence with the wider EU regulatory framework applicable to detergents. The facilitation of refill sales is in line with overarching EU initiatives aiming at reducing the environmental impact and with SDG #12 'Ensure sustainable consumption and production patterns'. The introduction of (optional) digital labelling both for refill detergents and overall is consistent with the transition to the digital era and with parallel digitalisation initiatives in the chemicals area such as CLP, the Fertilising Products Regulation and DPP. As experience and confidence is gained in digital labelling, it could be possible to increase the amount of information available digitally in the future, which may further increase the simplification potential for industry.

8.1. REFIT (simplification and improved efficiency)

One of the main objectives of this initiative is to simplify the rules that are applicable to detergents and reduce regulatory burden for detergents manufacturers. Simplifying and streamlining the labelling requirements would on one hand reduce the regulatory burden for manufacturers as it will be easier for them to comply with the rules. On the other hand, the overall annual costs of unused label disposal for companies in response to the streamlined labelling requirements present a slight chance of cost decrease compared to the baseline. While it has not been possible to quantify this decrease it is clear that the additional digitalisation efforts, would further contribute to reducing this cost. 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. Further, the abolishment of the ingredient data sheet for hazardous detergents would generate cost savings of €7 million per year. Finally, the facilitation of refill sales under the revised Regulated is also estimated to generate annual cost savings for the detergents industry due to reduced disposal of plastic waste. While it was not possible to quantify these costs savings, under the baseline these are estimated at €3.3 million. In total, the preferred option is estimated to generate annual cost savings of more than €10 million for the detergents industry per year.

8.2. [Application of the 'one in, one out' approach]

The estimated adjustment and administrative costs and savings for the preferred option elements were presented in section 6 above. The following table provides a summary of the administrative costs and savings under the preferred option that would be subject to the "one-in, one-out" approach. There could be some additional administrative costs savings due to the voluntary digitalisation and streamlining and simplifying of labels but those cannot be quantified. There are no administrative costs for citizens.

Table 7 Overview of administrative costs and savings under the preferred PO

Estimated costs		Estimated savings	
Annual direct administrative costs	€0	Annual direct administrative savings - abolishment of ingredient data sheets for hazardous detergents	€7 million
Total	€0	Total	€7 million
Grand total	**€7 million**		

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The sale of refilled detergents is currently characterised by a high level of non-compliance with the labelling rules in place. This leads to consumers not receiving the necessary safety and use information that is commonly provided on detergents labels. Further, the single market of refilled detergents is fragmented by divergent rules or limitations that are put in place in some Member States. Success in the case of refill sales of detergents would, therefore, mean that the clear rules and explicit coverage of this type of sales by the Regulation amount to lower non-compliance rates, properly informed consumers and a well-functioning internal market for refilled detergents that is not disrupted by divergent national rules.

As regards microbial cleaning products, the main issue relates to the management of risks associated with the use of living and potentially unknown/unsafe microorganisms in the detergent. Hence, in the case of microbial cleaning products success would mean that the revised rules ensure that no unsafe microbial cleaning products are being placed on the EU market. Provided that the required research has been carried out and that the necessary safeguards are in place, success for microbial cleaning products could also mean that a variety of more sustainable alternatives to conventional detergents will also available on the EU market in the future. The increased legal certainty as a result of clear rules for microbial cleaning products is also likely to encourage innovation in the long term and translate into a wider uptake of these products by detergents manufacturers.

In terms of labelling, success would translate into: 1) a simpler framework for companies, especially SMEs, to comply with; 2) reduced labelling costs for businesses; 3) labels that are more easily read and understood by consumers; and 4) a high uptake of digital labelling that further reduces costs for businesses and increases ease of use and understandability of labels for consumers, including vulnerable and visually impaired consumers. Finally, success in the case of the ingredient data sheet for hazardous detergents means reduced costs and simplification for businesses without any detrimental effects for end-users.

The Commission will monitor the implementation and application of the revised provisions of the Regulation. A Commission Expert Group with all relevant stakeholders and Member States will analyse the implementation of the revised Regulation in all Member States. The Commission will pay specific attention to microbial cleaning products, refill sales and digital labelling, based on the assumption that they constitute novelties that are still quite rare in the single market at the moment of adoption of the proposal by the co-legislator. The Commission will seek more detailed information from industry on the availability and market share of microbial cleaning products and refill sales, and on the use of digital labelling. In addition, the Commission will demand market surveillance authorities to launch specific surveillance activities on microbial cleaning products, refill sales and digital labelling, in

accordance with the Market Surveillance Regulation (EU) 2019/1020 and possibly partly financed by the Single Market Programme or its successor. The relevant findings on digital labelling will be cross-checked with other digital labelling findings in other product areas (*e.g.* cosmetics, fertilising products, CLP).

The Commission will conduct an evaluation after 5 years from the entry into application of the revised Regulation. This evaluation will also assess the fitness of the newly introduced requirements for microbial cleaning products. Based on a report from a scientific body acting on a mandate from the Commission, the latter will examine in depth the issues related to microorganisms contained in products and, if needed, present a proposal to the European Parliament and the Council amending them.

A number of indicators monitoring the impacts of the preferred option have also been identified. These are presented in Annex 11.

EUROPEAN
COMMISSION

Brussels, 28.4.2023
SWD(2023) 114 final

PART 2/3

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}

Contents

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.

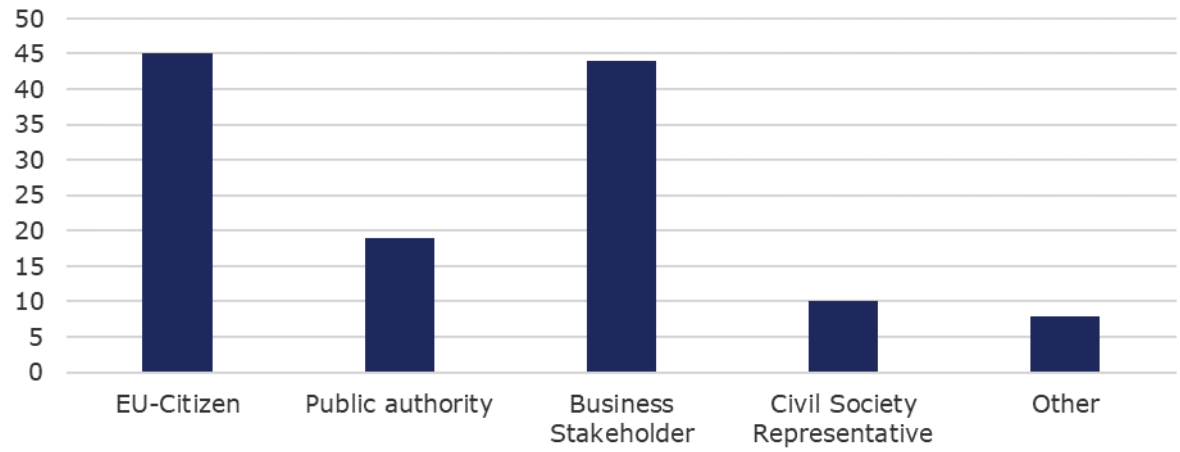
Furthermore, participants had the opportunity to upload additional contributions to the PC, which was done by 9 stakeholders (see 1.8. below).

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

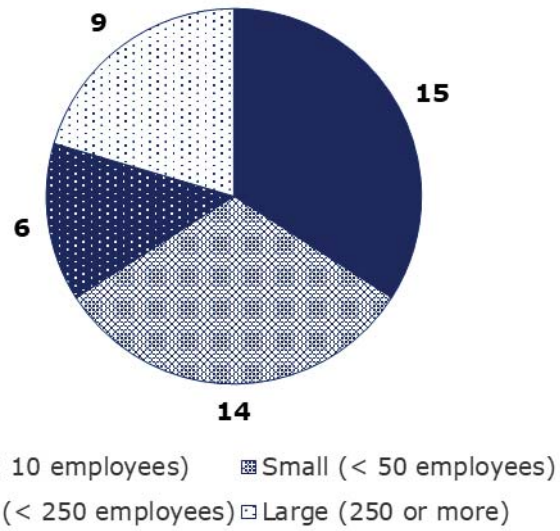
Geographical origin of respondent	Number of respondents	Geographical origin of respondent	Number of respondents
Finland	32	Latvia	2
Germany	20	Portugal	2
Belgium	11	Romania	2
France	7	Croatia	1
Italy	7	Greece	1

[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		

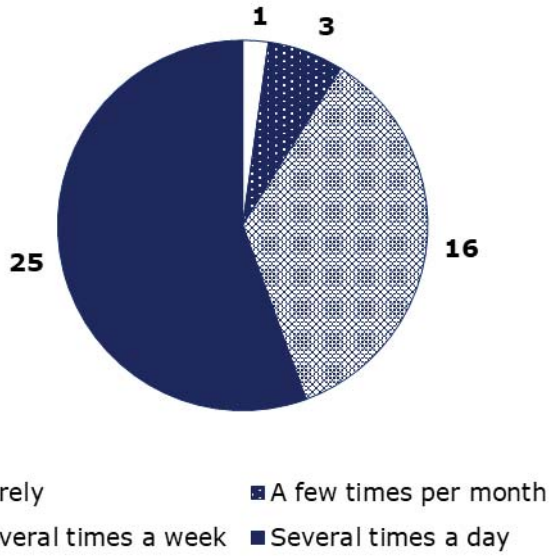
Among business stakeholders that responded to the PC, **a majority represented micro or small organisations with less than 50 employees**. These two sizes combined for 29 of the business responses, with the remaining replies being split between medium (6 respondents) and large (9 respondents) enterprises,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

Size of Business / Organisation representation



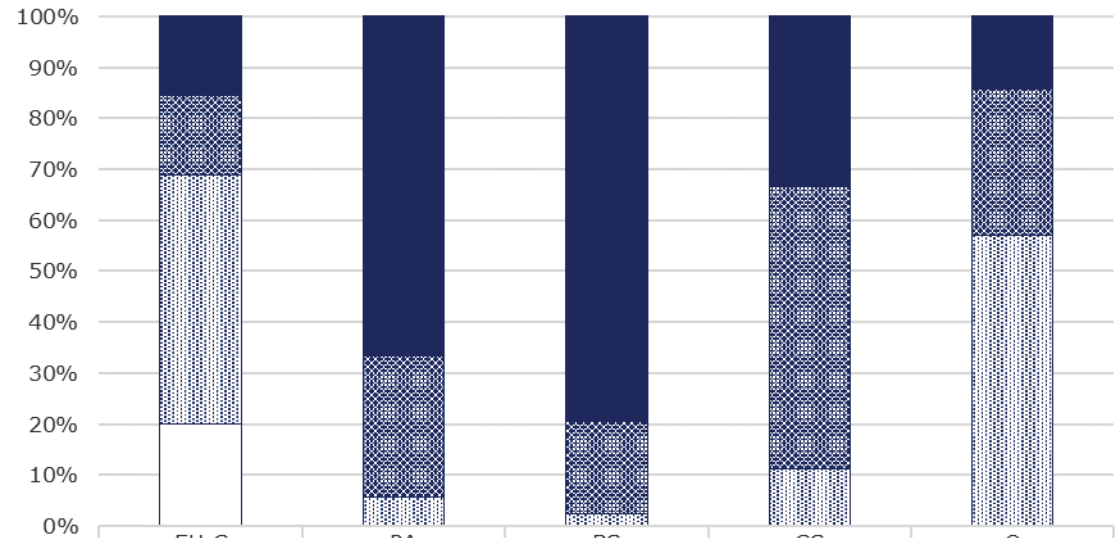
EU citizens were also asked about their age, gender, and the regularity of their detergent use at the beginning of the questionnaire. Among those respondents, a majority of 27 identified itself as female, while 17 registered to be male. With regards to how regularly they use detergents, **a majority (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?

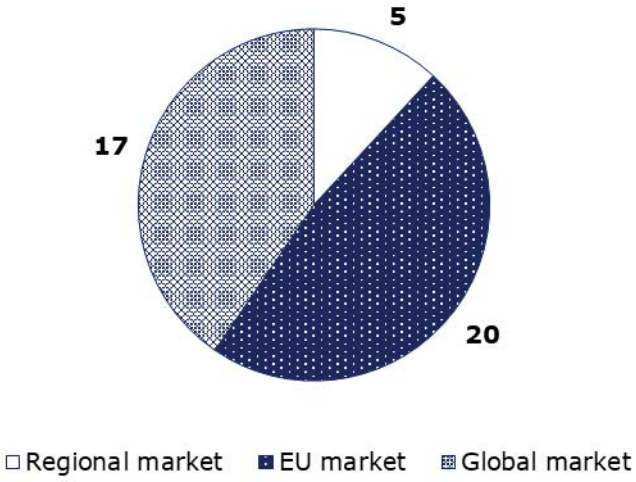


	EU-C	PA	BS	CS	O
Very familiar	7	12	35	3	1
Fairly familiar	7	5	8	5	2
Slightly familiar	22	1	1	1	4
Not familiar at all	9	0	0	0	0

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

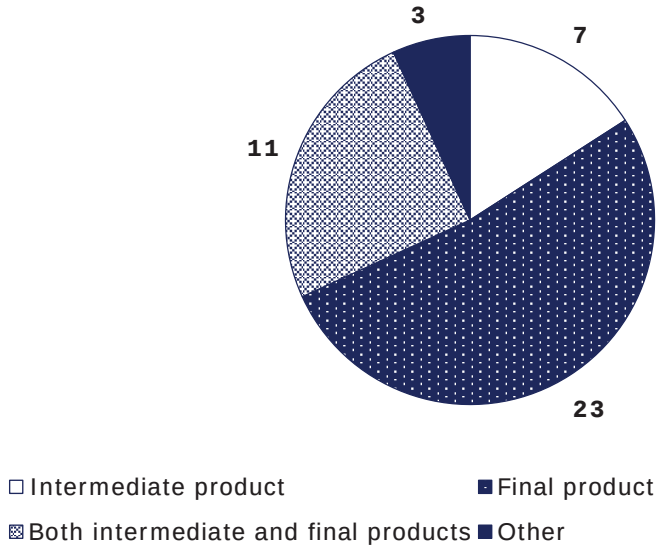
To conclude the general section, a couple of questions were asked to business stakeholders about the characteristics of their operations. At first, stakeholders were asked to indicate the market(s) they are active on.

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



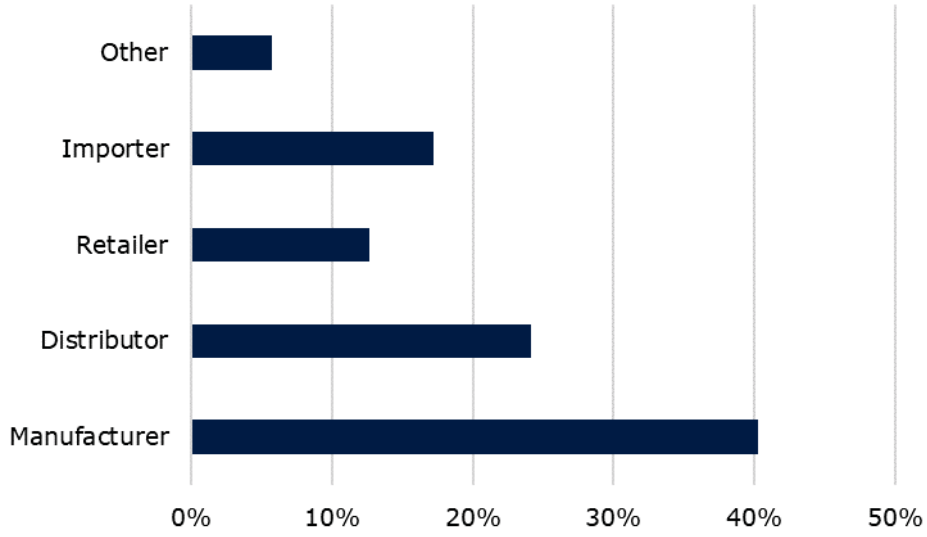
Business stakeholders were then asked about the products that they produce.

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.

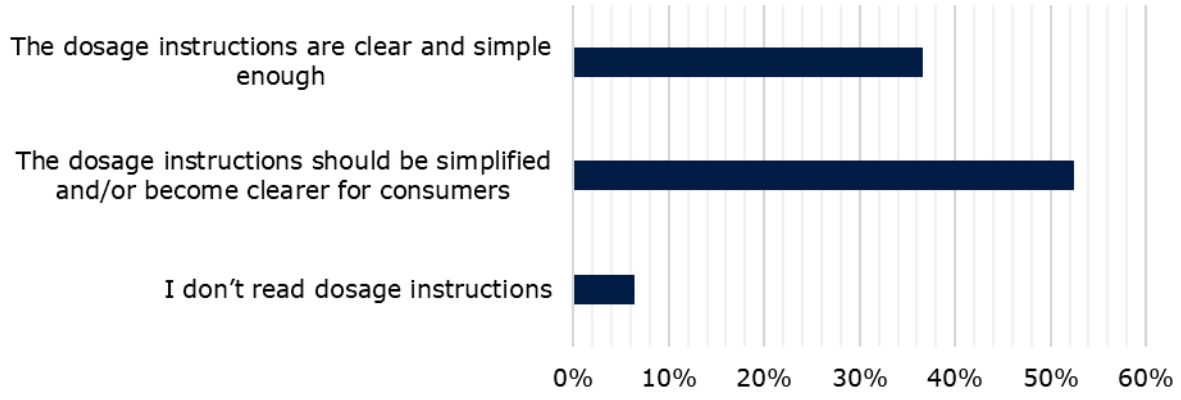
Q7: Please specify where in the supply chain you operate



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.

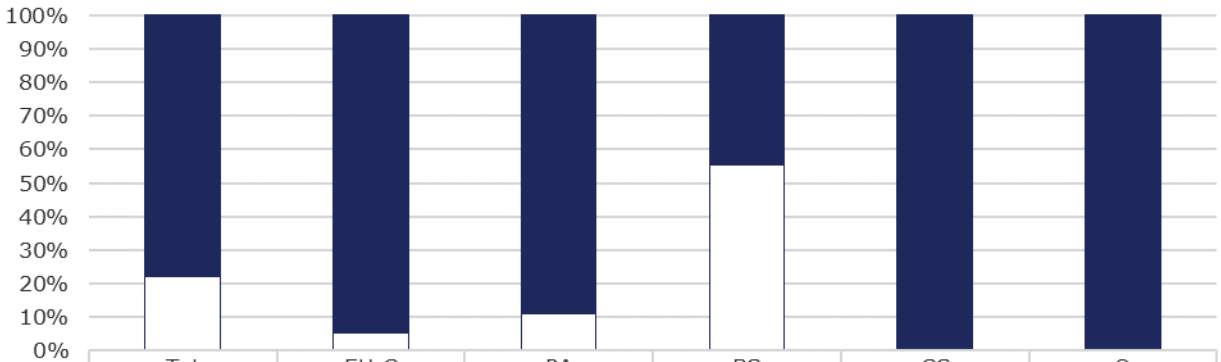
Q8: Please state which of the following statements better represents your views on the above-mentioned dosage instructions for consumer laundry and dishwasher detergents:



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?

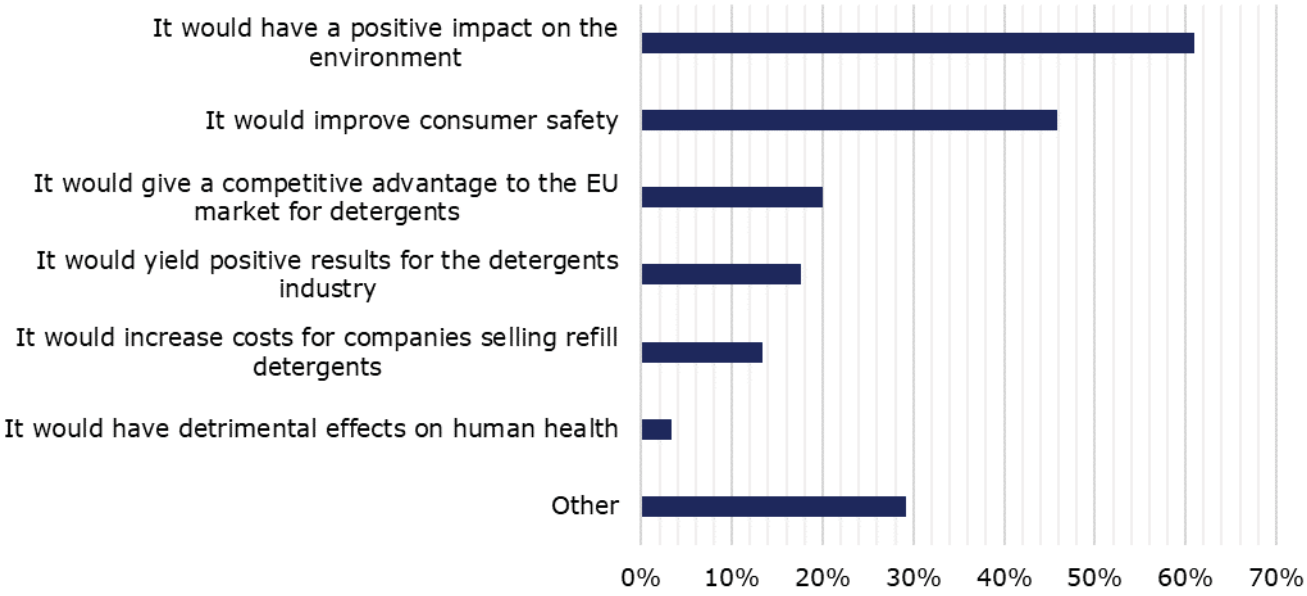


	Tot	EU-C	PA	BS	CS	O
Yes	84	37	16	16	9	6
No	24	2	2	20	0	0

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).

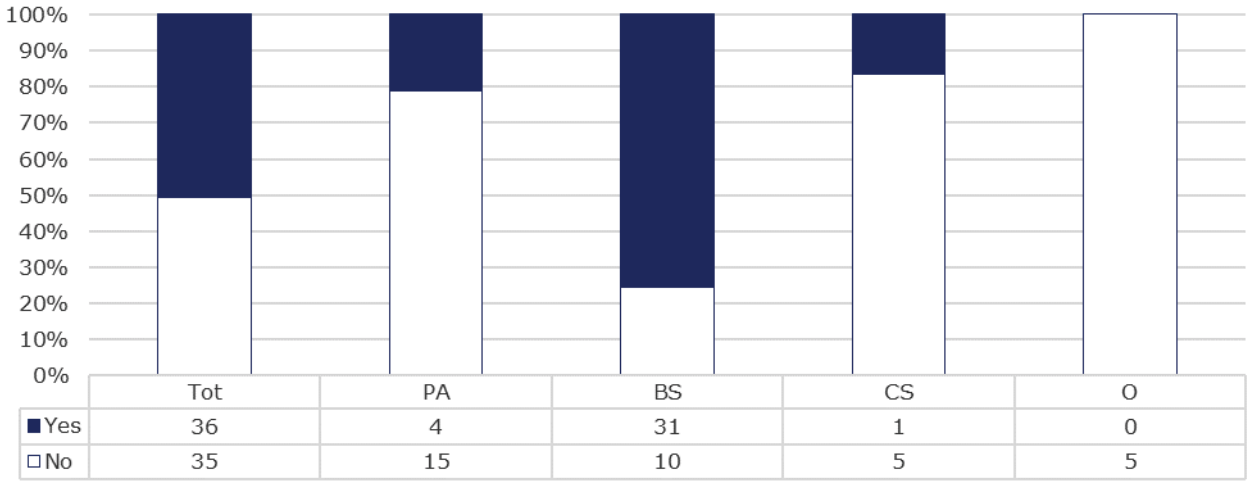
Q10 What would be the impacts of setting rules for the refill sale of detergents?



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?

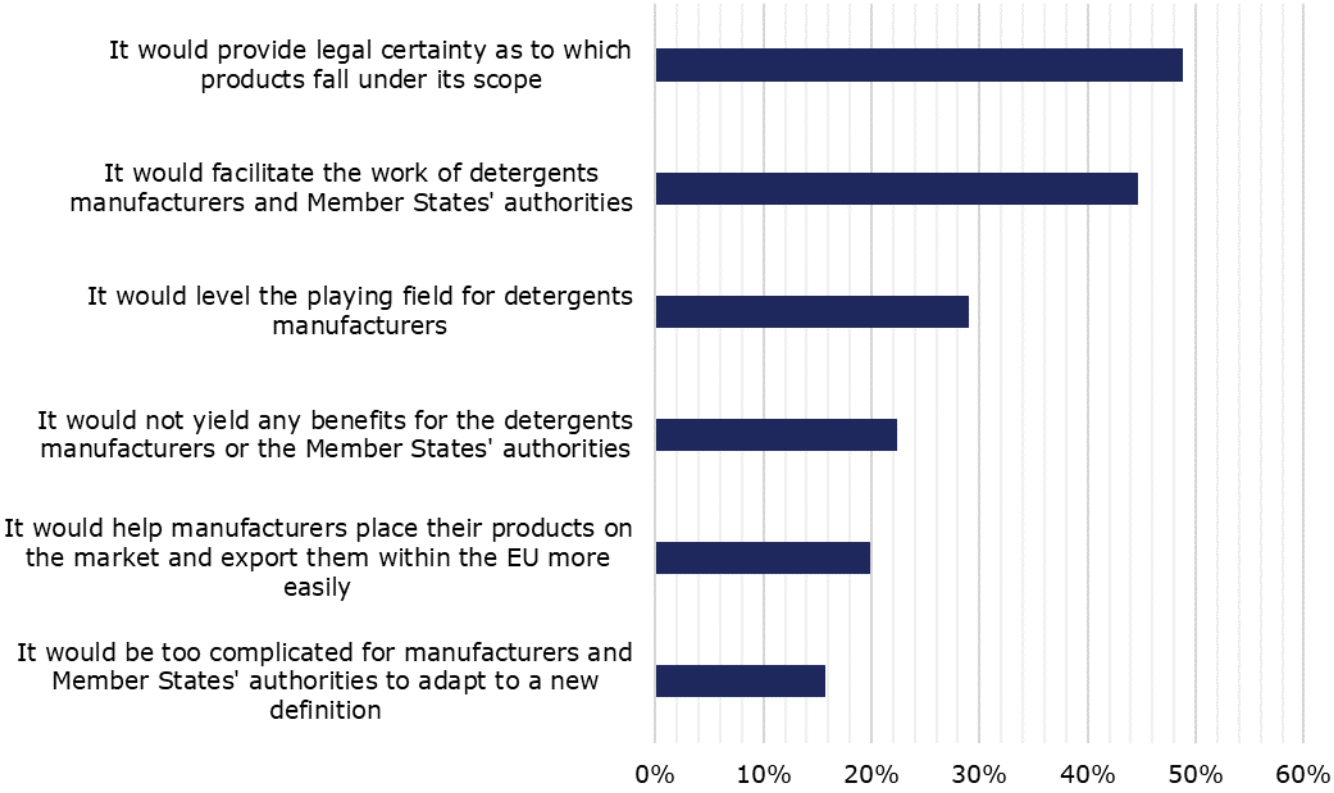


	Tot	PA	BS	CS	O
Yes	36	4	31	1	0
No	35	15	10	5	5

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.

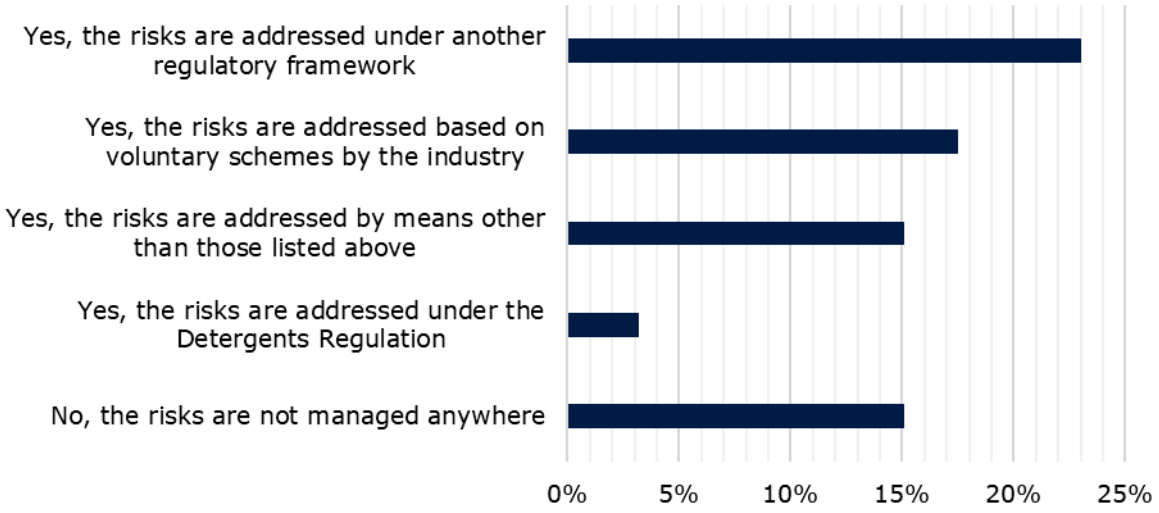
Q12 What would be the impacts of clarifying the definitions currently provided under the Detergents Regulation?



2.6.1.5 2.6.1.5 Microbial cleaning products

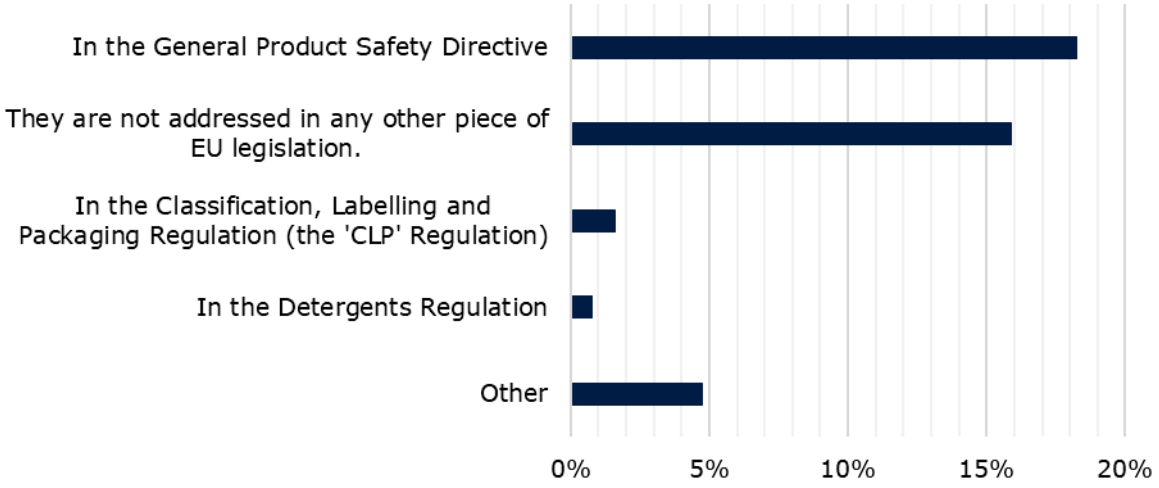
The next thematic questions posed to the responding stakeholders concerned microbial cleaning products. In a first response only a limited number of participants provided replies, but **most of those that did provide a reply said that microbial risks related to microbial cleaning products are addressed 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**.

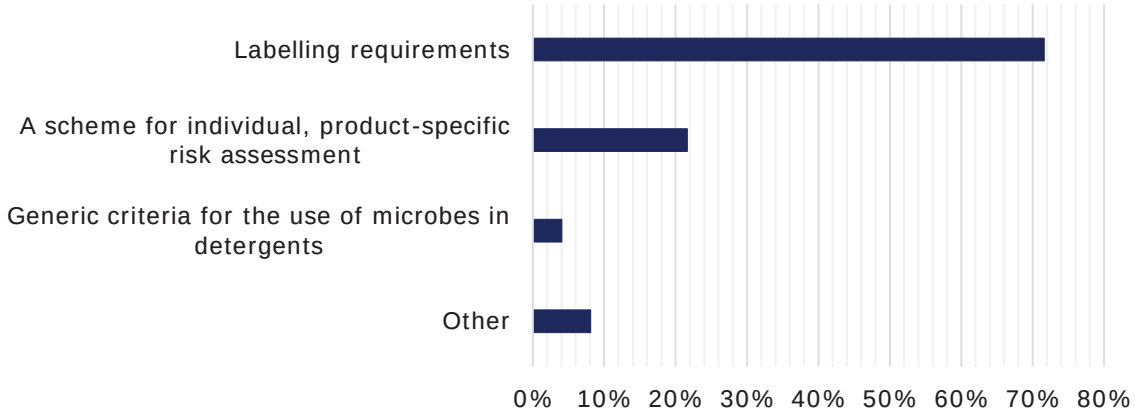
Q14: In case that the microorganisms are not biocidal active substances under the Biocidal Products Regulation, are any risks related to their use in detergents addressed in any of the following pieces of EU legislation?



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?



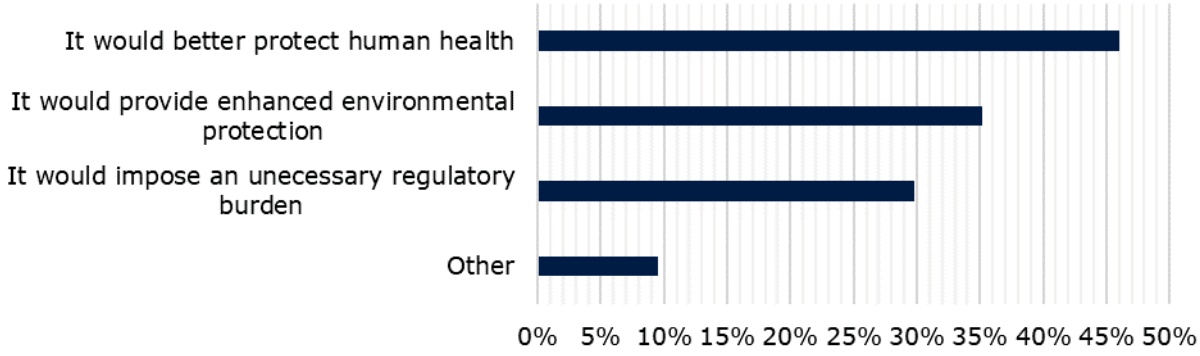
Mentions per respondent group (multiple choice):

	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**.

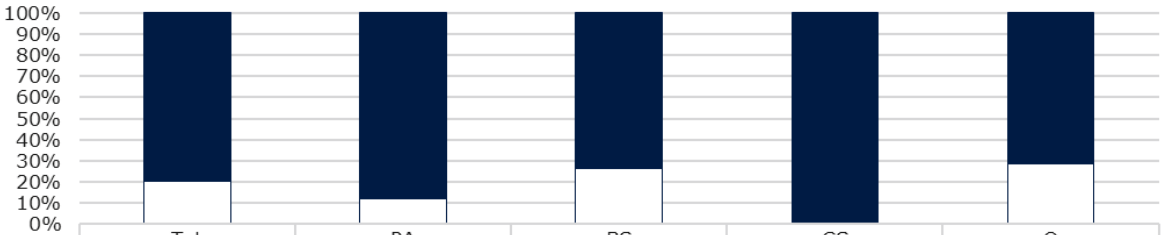
Q16: What would be the impacts of introducing risk management measures for microbial cleaning products in the Detergents Regulation?



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?

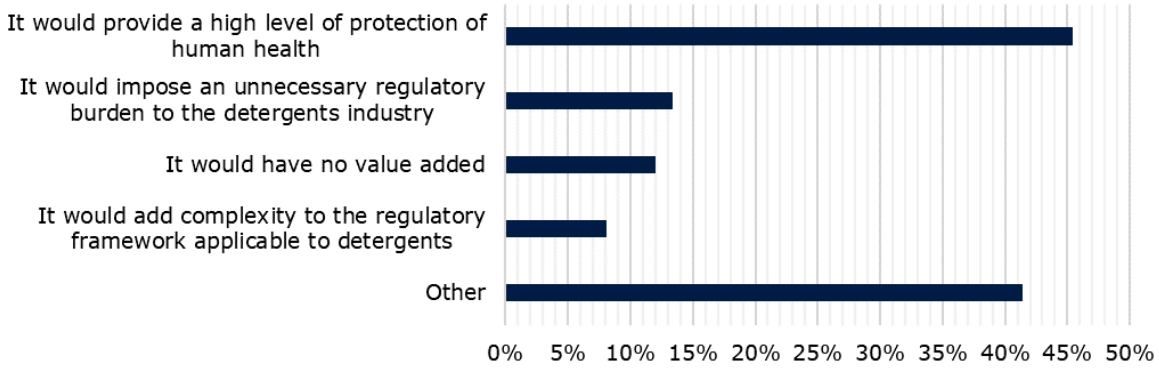


	Tot	PA	BS	CS	O
Yes	56	15	28	8	5
No	14	2	10	0	2

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

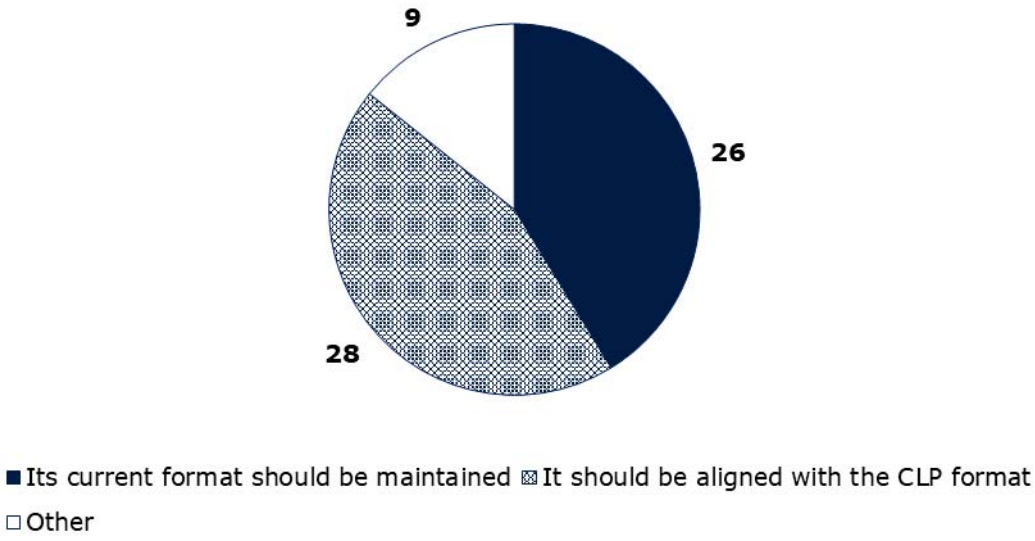
The replies to impacts of maintaining the data sheet were consistent with the responses received on the need to maintaining it. **Over one-fourth of all participants said that maintaining the ingredient data sheet for non-hazardous detergents would provide a high level of protection of human health**. 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?



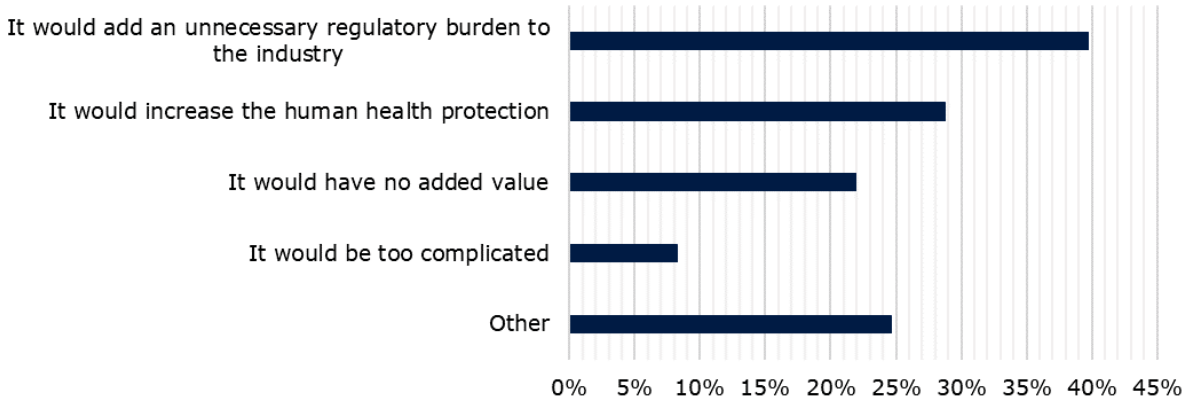
There was a split in terms of the format to be used for the ingredient data sheet for non-hazardous detergents (should this be maintained). **Out of 63 stakeholders providing a response, the majority was almost exactly split between maintaining the current format and aligning it with the CLP format**, 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.

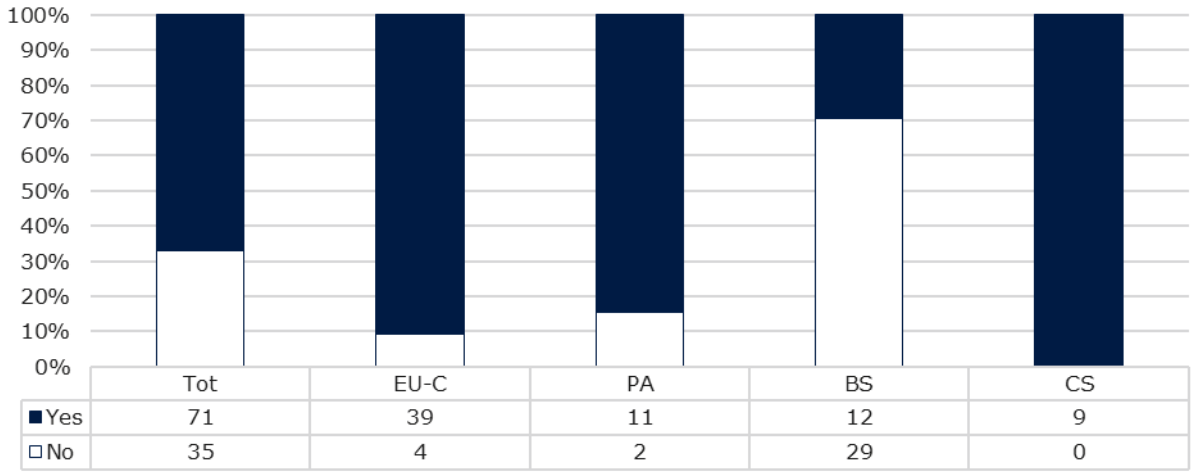
Q21: What would be the impacts of aligning the ingredient data sheet for non-hazardous detergents with the format for providing information to poison centres under the CLP Regulation?



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?



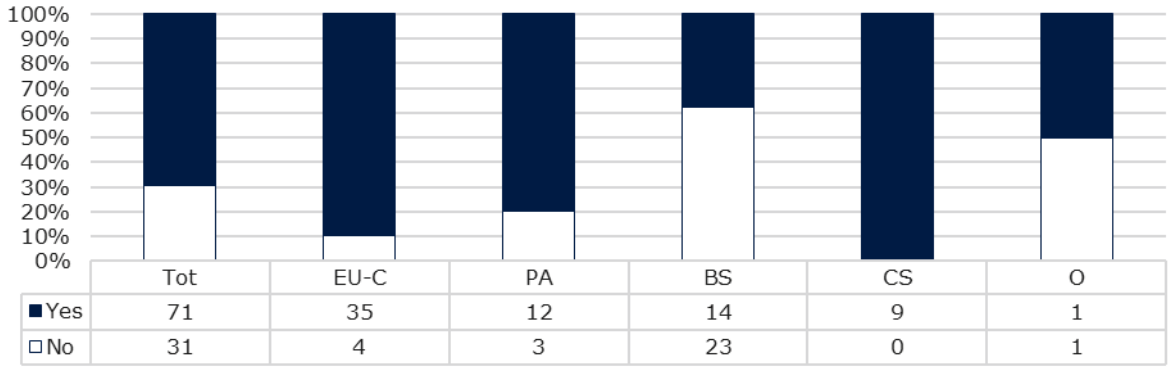
	Tot	EU-C	PA	BS	CS
Yes	71	39	11	12	9
No	35	4	2	29	0

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.*

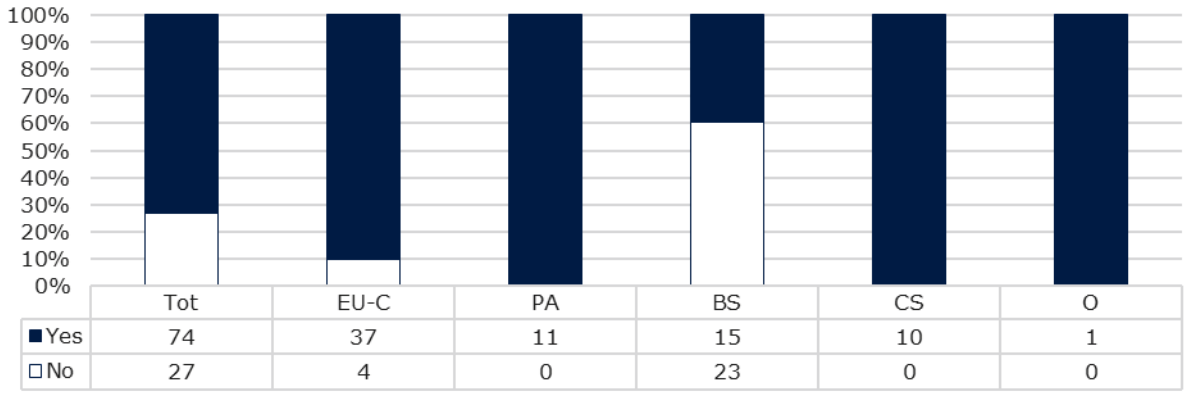


	Tot	EU-C	PA	BS	CS	O
Yes	71	35	12	14	9	1
No	31	4	3	23	0	1

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?

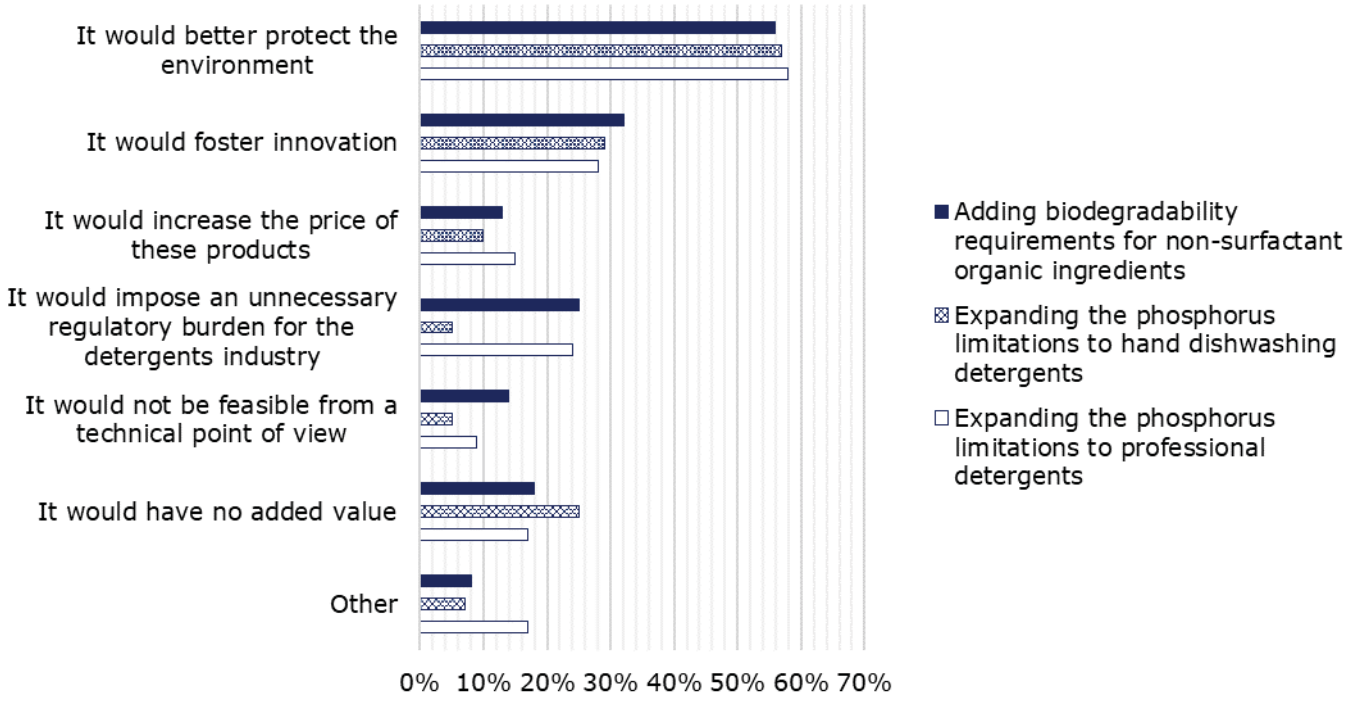


	Tot	EU-C	PA	BS	CS	O
Yes	74	37	11	15	10	1
No	27	4	0	23	0	0

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):

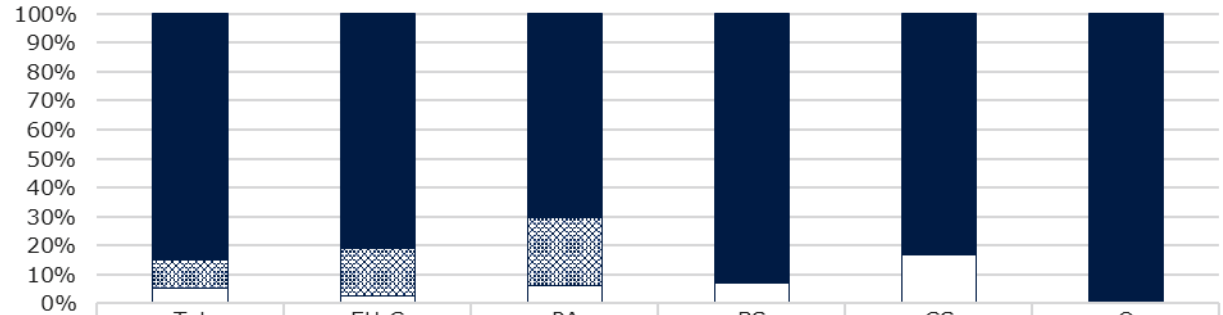


2.6.1.8 2.6.1.8 Overlaps in the labelling of ingredients

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?

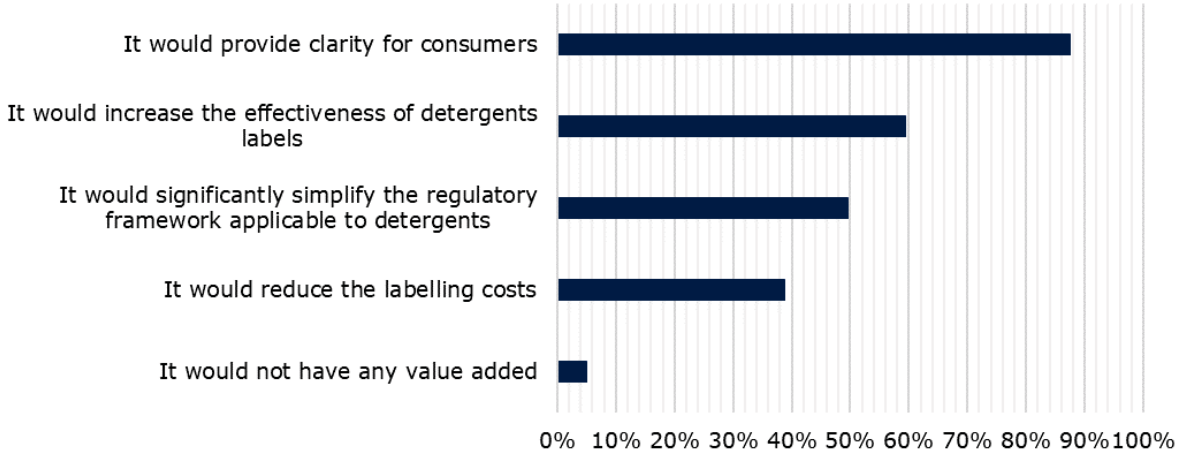


	Tot	EU-C	PA	BS	CS	O
Yes	97	34	12	40	5	6
No	11	7	4	0	0	0
Other	6	1	1	3	1	0

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.

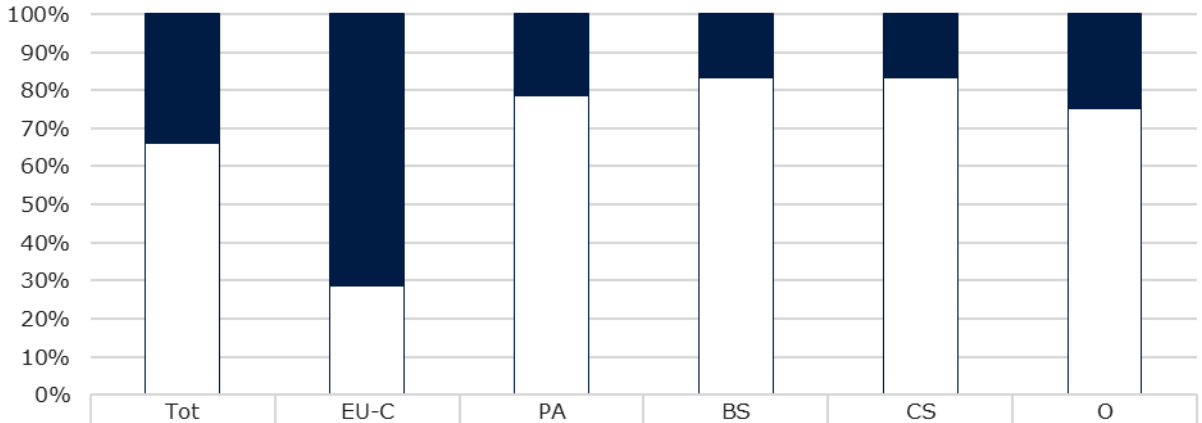
Q27: What would be the impacts of streamlining the labelling requirements for detergents?



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

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

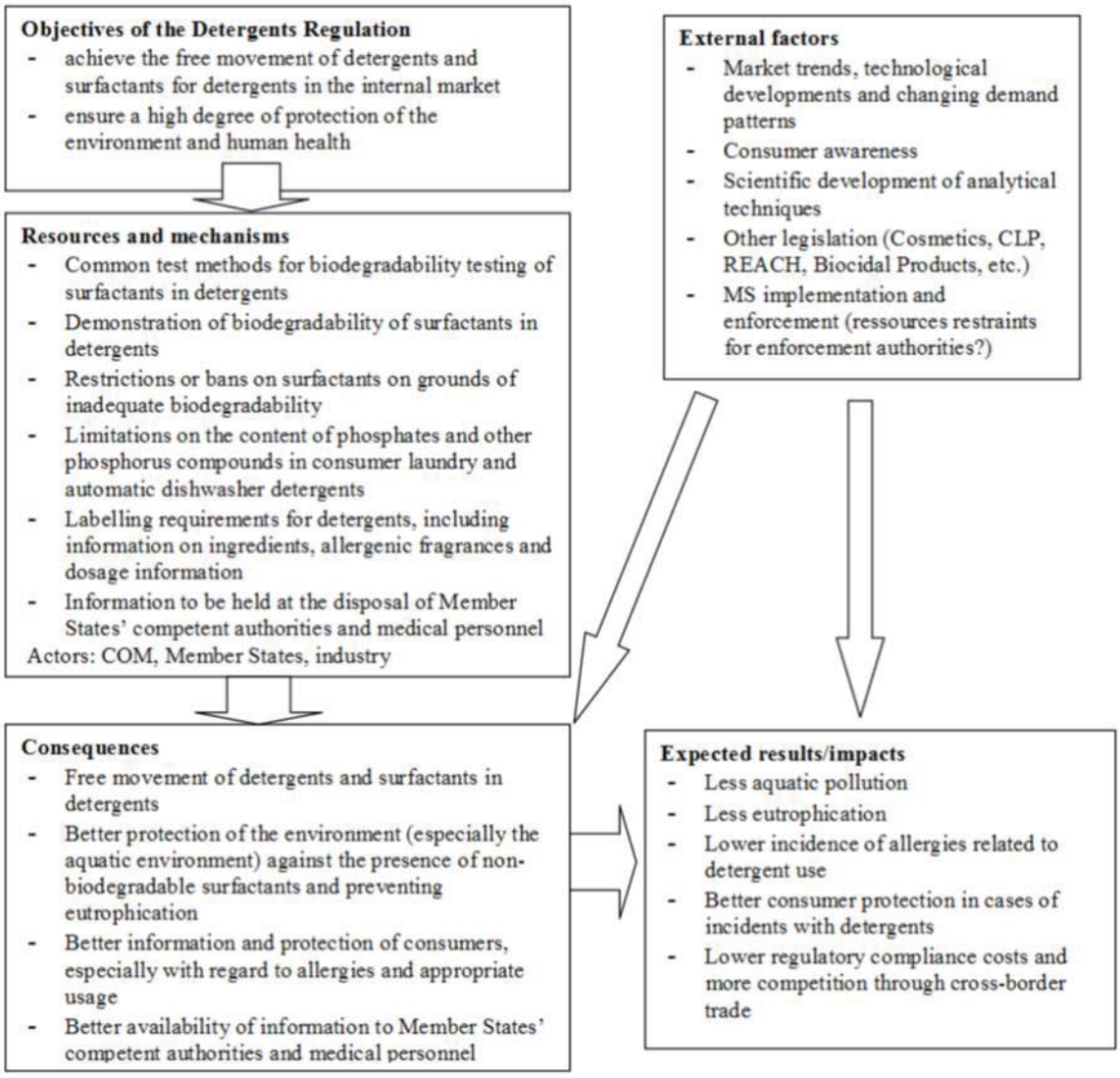
5.1.3.4 5.1.3.4 Obligations of manufacturers and Member States' duties

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.

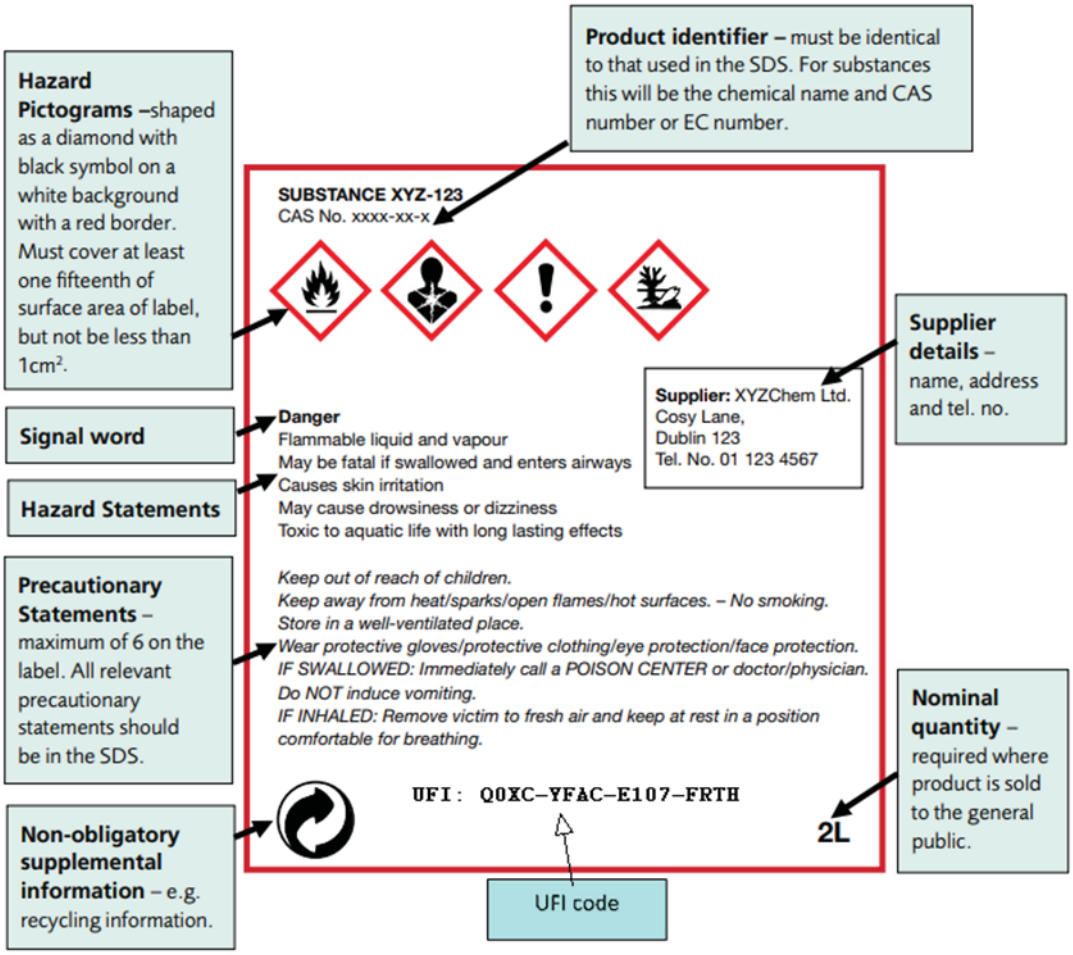
or 1.5.2.1.3 (b); and 3) **the soluble packaging** is contained within outer packaging that fully meets the requirements of Article 17.

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.

---

[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

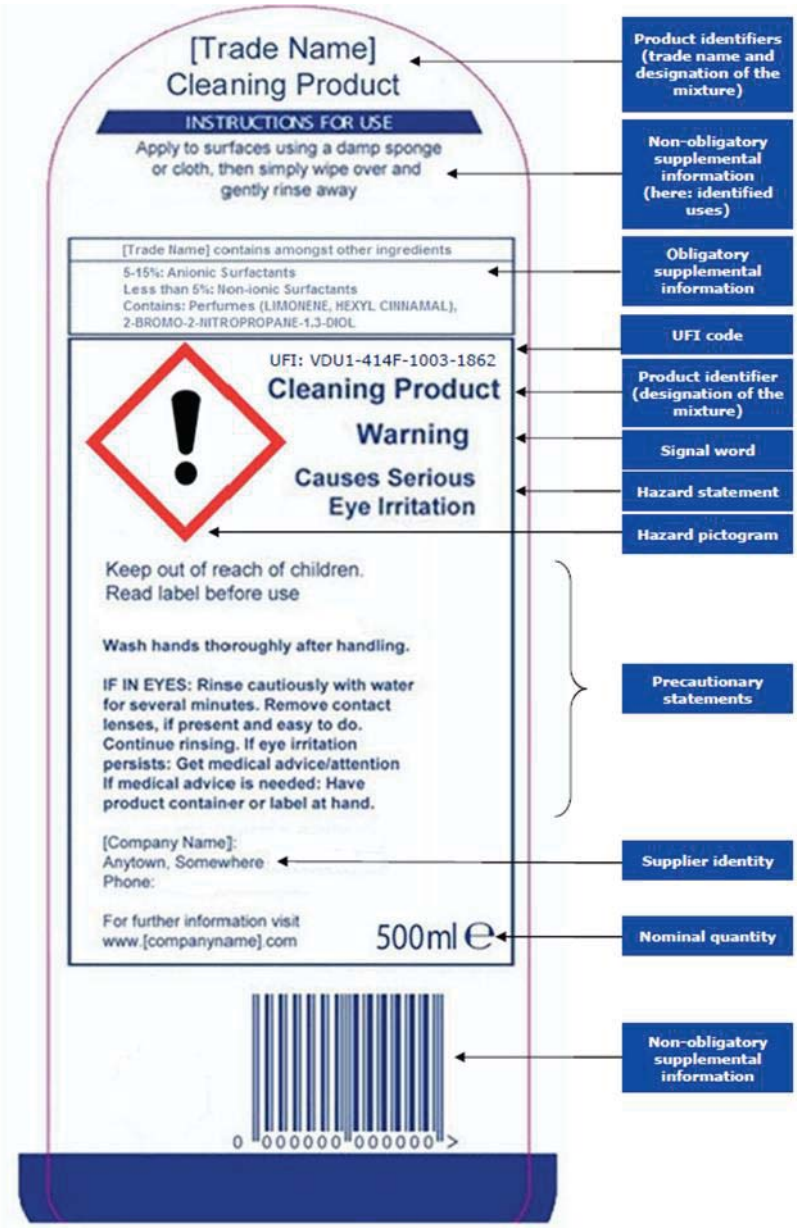
[81] https://www.cleanright.eu/en/safe-use.html#safe-use

[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).

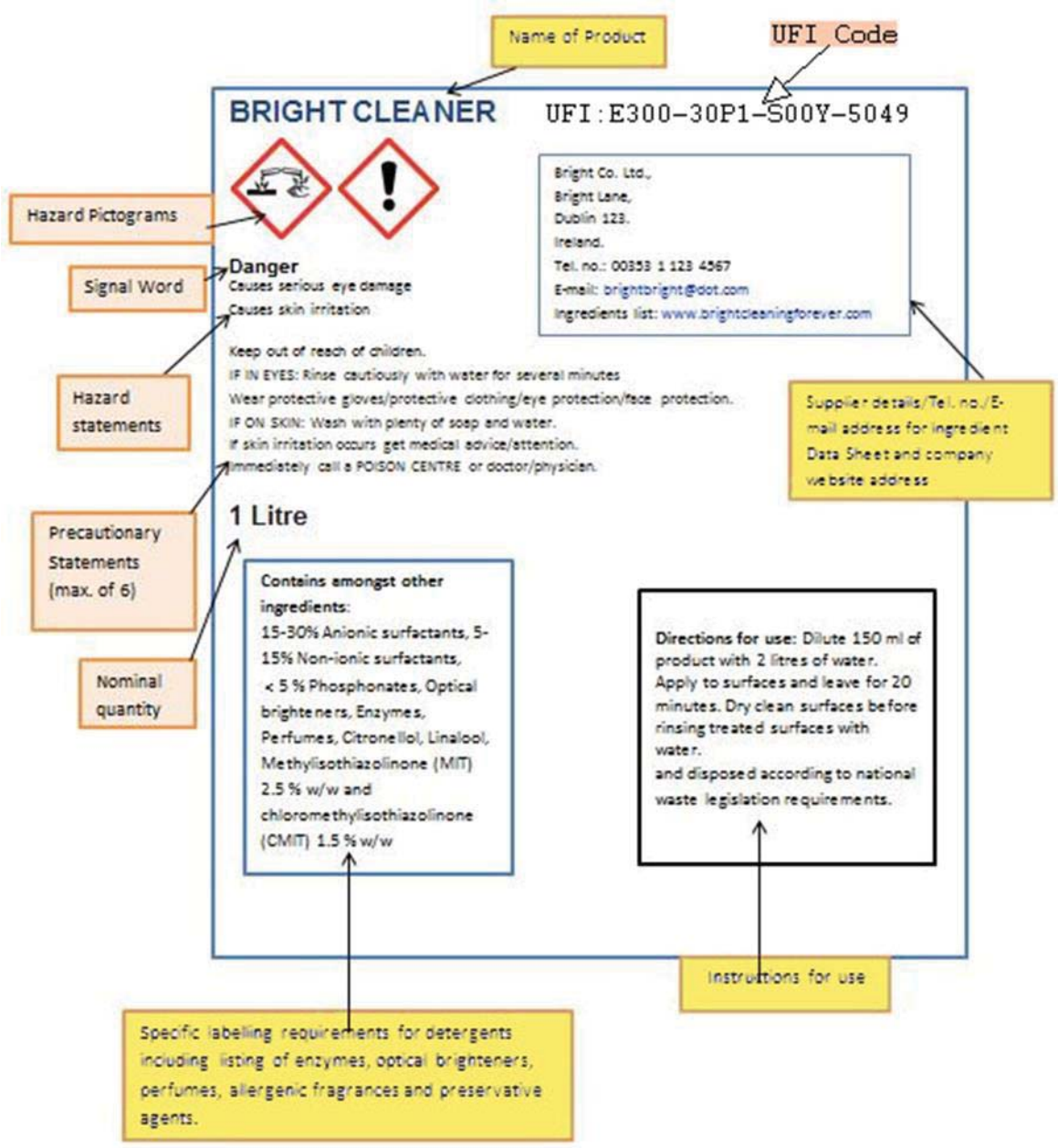
Figure 3 Example of detergent label. Hazard class "Eye Irritation"[85]



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":

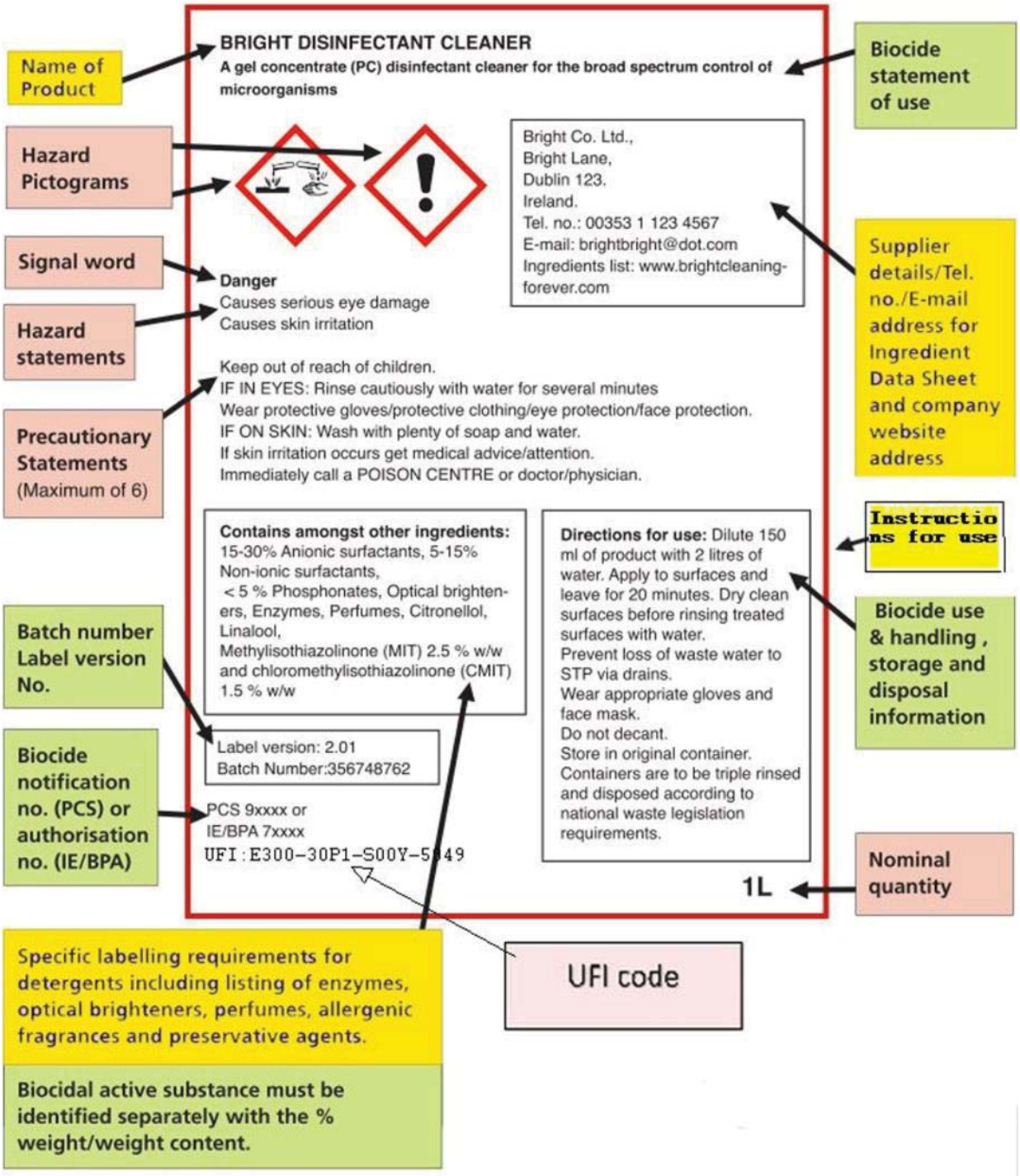
- the name(s) of the biocidal active ingredient(s) and its concentration in the product[89];
- the notification or approval number (e.g., PCS 9xxxx or IE/BPA 7xxxx)[90]. Only notified or approved biocides have such a number;
- the type of product formulation[91];
- what the product is approved for[92];
- 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.

---

[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:

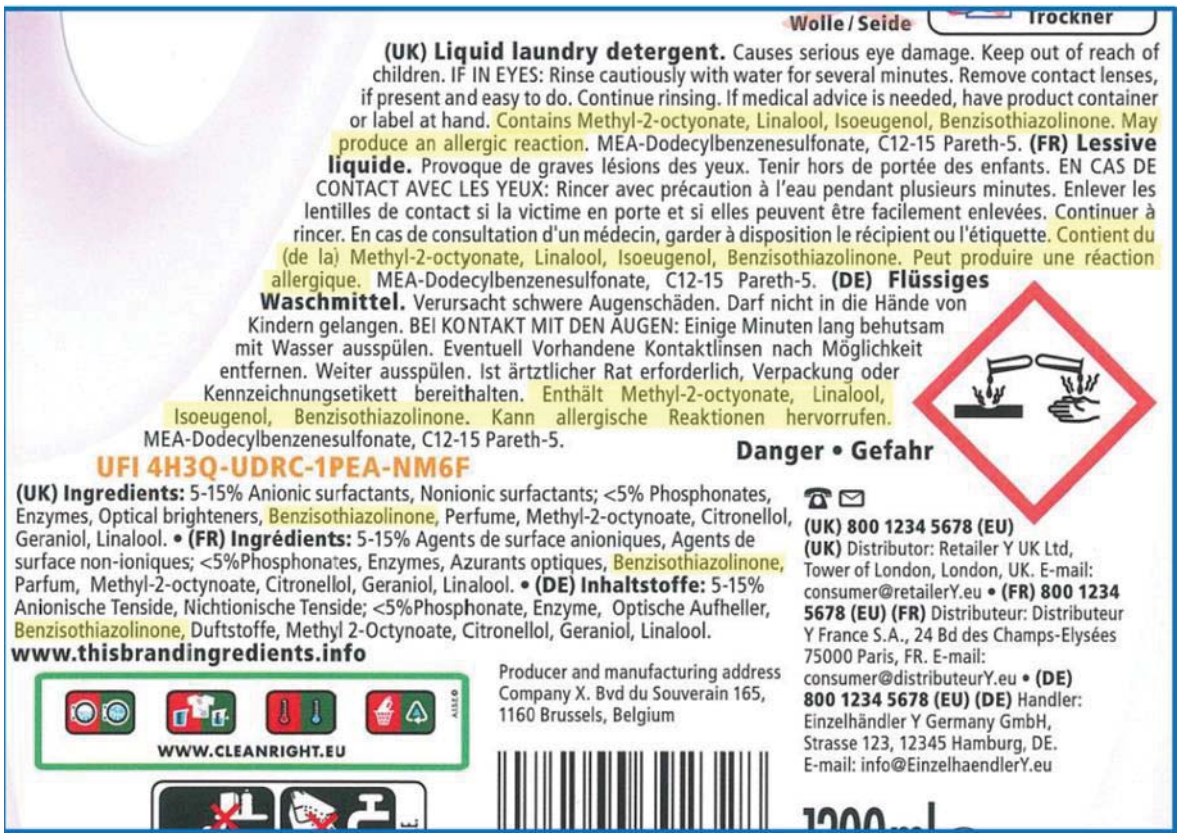
- **The product identifier of the substance**, i.e., the name (and identification number) under which the allergenic fragrance is to be labelled, **is different** under these two Regulations: as the **Detergents Regulation refers to the Cosmetic Products Regulation** for the labelling of allergenic fragrances, 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.),

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]

---

[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]

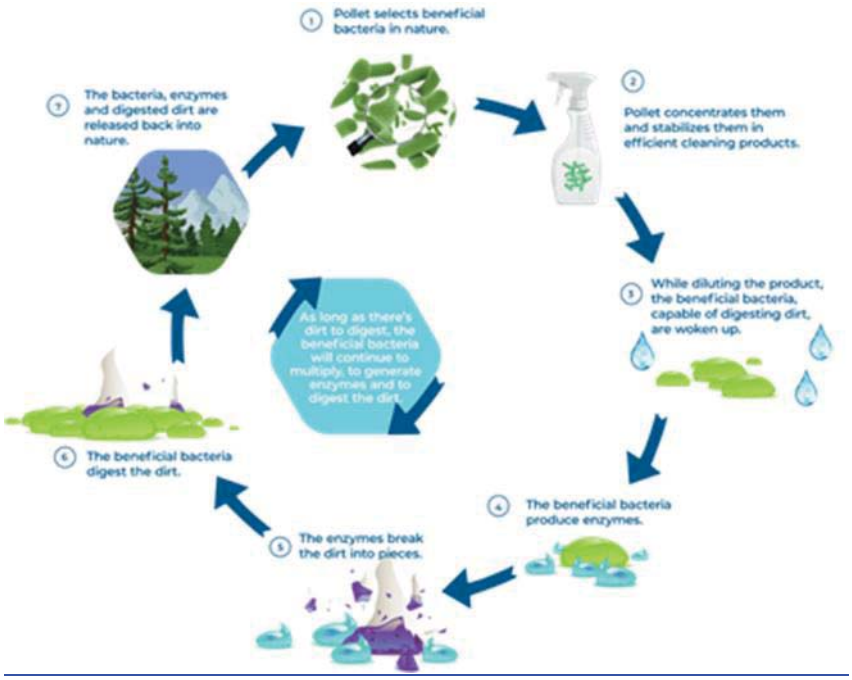
[151] Report by Europe Economics, Milieu Consulting srl and Huggard Consulting Group S.à.r.l., with Economisti Associati srl (Consortium Lead) (2022), Impact assessment study on the making available and placing on the market of detergents (859/PP/GRO/IMA/20/1131/11439) D4 Report

[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]

---

[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]

---

[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).

---

[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

EUROPEAN
COMMISSION

Brussels, 28.4.2023
SWD(2023) 114 final

PART 3/3

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}

Contents

Annex 8 ANNEX 8 DIGITAL LABELLING

8.1 8.1 DIGITAL PRINCIPLES

Digital labelling should at least comply with the following general requirements:

1. The obligation for the digital label to include the **full set of labelling information** (i.e. there should not be a split of information between the physical and digital label), to ensure that the information provided is meaningful;

2. The obligation to **provide all digital data in one place**, separately from other commercial information (e.g. the mandatory information shall not be displayed together with other information intended for sales or marketing purposes). Coherence should also be sought with other digital provision of information on products (e.g. under the Digital Products Passport);

3. The **format of the data provided digitally must be appropriate** (e.g. rules on font size, the content of the digital label must be searchable);

4. The **protection of personal data** (e.g. prohibition of collecting and tracking user data or using that information for commercial purposes) in accordance with Regulation (EU) 2016/679;[1]

5. **Accessibility of the data** both in terms of ease of access (e.g. "two-click" maximum rule to access the information), and in terms of accessibility for users (e.g. also for users with disabilities). Access to the digital label must be free and without a need for prior registration or a password, or prior download of applications. Access limitations for certain user groups (e.g. geo-blocking in accordance with Regulation (EU) 2018/302[2]) are not allowed;

6. Instead of prescribing a particular technology, a set of **minimum technical requirements** are to be defined and complied with, in order **to ensure technological neutrality of the IT solutions used**. The IT solution must be easily readable via widely used digital technologies (e.g. a QR code scanner/ reader). It must be ensured that the data can be accessed, navigated and read on, and is compatible with, all major operating systems and browsers. Information must also be available for old browser version and operating systems;

7. The information must be provided in a **language which is easily understood by end-users,** as determined by the Member State in which the product is marketed. Additional

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0679-20160504

[2] Regulation (EU) 2018/302 of the European Parliament and of the Council of 28 February 2018 on addressing unjustified geo-blocking and other forms of discrimination based on customers' nationality, place of residence or place of establishment within the internal market and amending Regulations (EC) No 2006/2004 and (EU) 2017/2394 and Directive 2009/22/EC: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32018R0302

languages are permitted; users must have the possibility to select their language of choice, regardless of their physical location.

8. Economic operators who opt for the digital label shall ensure that appropriate alternative ways of providing information are available to end-users in case of **lack of digital tools or skills, or in the absence of network access**, both before buying the product and after having bought the product.

9. Where the detergent is supplied in a package, **the IT solution (e.g. QR code) must be printed or placed physically on a label** which is affixed to that package. Where the package is too small to contain IT solutions or the product is sold in bulk, the IT solution shall be provided in a separate leaflet accompanying that package/product.

10. The **data contained under the digital label must remain accessible** for 10 years after they sold the last detergent or surfactant. The data present on the digital label must remain available even after an insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created the digital label.

8.2 8.2 CONSULTATION ACTIVITIES – SIMPLIFICATION AND DIGITALISATION OF CHEMICALS LABELS

8.2.1 8.2.1 Introduction & Consultation strategy

Data collection has been performed using the following tools: legal review, desk research, interviews (scoping interviews and stakeholder interviews), online surveys and behavioural experiments. The results of the public consultation run by the European Commission have also been integrated in the analysis.

Stakeholder consultation activities were conducted at different stages of the study:

- Interviews (April-December 2021): to collect information related to the current understanding of chemical labels, the usefulness of information provided to users, the assessment of labelling requirements and needs of users, as well as the existing digital solutions available for e-labelling.
- Behavioural experiment (September-October 2021): to investigate consumers' understanding of chemical and detergents labels, the importance of different label elements as well as their interpretation with respect to safe use.
- Inception Impact Assessment
- Public Consultation (November 2021-February 2022): It must be noted that only the findings of this consultation related to the CLP Regulation (e.g. chemical products in general) are presented in this synopsis report.
- Online surveys (Two online surveys are conducted for the purpose of this study: a survey for industrial and professional users and a survey for the assessment and comparison of policy options.

Regarding the country coverage, the consultation covered the EU-27, except for the behavioural experiment which has been conducted in four EU Member States (Germany, France, Romania and Greece).

8.2.2 8.2.2 Consultation activities and tools

8.2.2.1 8.2.2.1 Interviews

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

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

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

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

- Perceived current understanding of chemical labels by different categories of users;
- The usefulness and relevance of information provided currently on chemical labels;
- The assessment of labelling requirements and needs of users;
- The analysis of existing IT solutions available for e-labelling;
- Identification of information that should remain on the physical label and suggestions of information to put on an e-label for chemical products.

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

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

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

8.2.2.2 8.2.2.2 Behavioural experiment

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

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

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

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

8.2.2.3 8.2.2.3 Public Consultation - Simplification and digitalisation of labels on chemicals

This consultation, run by the European Commission, aims to gather experiences and opinions from various stakeholders (consumers, professional and non-professional product users, industry, civil society organisations, national authorities and any other interested stakeholders) on a possible introduction of digital labelling of many daily used products such as glues, laundry and dishwashing detergents and fertilising products, under the Regulation on Classification, Labelling and Packaging of substances and mixtures (‘ the CLP Regulation’), the Detergents Regulation and the Fertilising Products Regulation.

The findings presented in this synopsis report and integrated in the report represent an analysis of the responses collected on 17 February, with 205 respondents.

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

8.2.2.4 8.2.2.4 Online survey on policy options

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

The answers have been divided by stakeholder category: 1414 member state authorities, 6767 industry representatives (industry associations, businesses).

8.2.2.5 8.2.2.5 Online survey for professionals and industry users

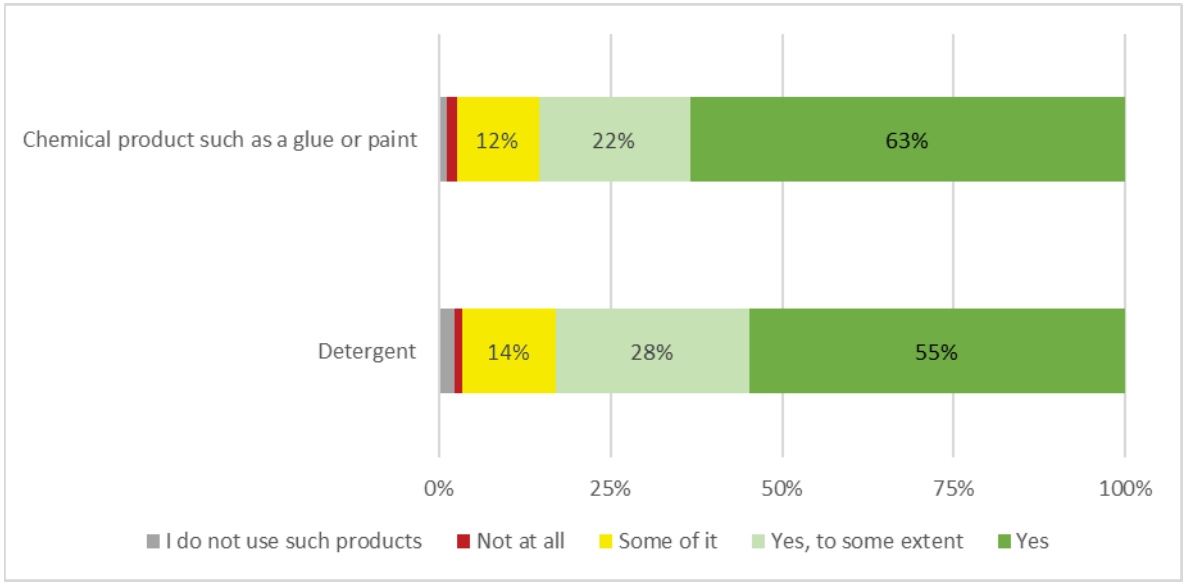
The aim of the survey was to collect information from the stakeholders representing professionals and the industry on the importance of having certain pieces of information[3] on the packaging of the specific chemical products[4] as well as the easiness to understand the information concerning these elements in these products.

In total, 50 stakeholders participated to this survey: 11 Member States authorities, 10 industry associations, 28 enterprises, and 1 consumer organisation.

8.2.3 8.2.3 Detailed findings of the Public Consultation

The analysis of the answers provided to the public consultation show that, when asked if they usually understand the information provided on the label of a chemical product, over two-thirds of stakeholders answered "Yes" or "Yes to some extent" (115/141 of stakeholders representing the private sector, and 38/53 of stakeholders representing consumers), showing a relative good understanding of the current chemical labels. The OPC also focussed on products falling under the Detergents Regulation. To the question regarding the understandability of the labels on detergent products, a large majority of stakeholders replied positively (97/129 of stakeholders representing the private sector and 36/50 stakeholders representing consumers).

Figure 9: Do you usually understand the information provided on the label of a:



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

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

Source: Open public consultation for the Impact Assessment Study on the simplification of the labelling requirements for chemicals and the use of e-labelling

More specifically, the understanding of information on chemical labels can be broken down into different categories of information.

Regarding the chemical products, first of all, the majority of stakeholders from both categories estimate that the information on chemical label properly inform them about:

- the dangers or risks of the product (89/141 stakeholders representing the private sector and 39/53 of stakeholders representing consumers answered "yes" or "yes to some extent");
- safe use of the product (81/141 stakeholders representing the private sector and 34/53 of stakeholders representing consumers answered "yes" or "yes to some extent");
- incentives to take preventive measures (75/141 stakeholders representing the private sector and 29/53 of stakeholders representing consumers).

However, a majority of stakeholders answered either 'not always' or 'not at all' to whether information on chemical labels help them select less hazardous products (70/141 stakeholders representing the private sector and 42/53 stakeholders representing consumers), and to whether it would prevent them from using the product (81/141 stakeholders representing the private sector and 40/53 stakeholders representing consumers), suggesting room for improvements in the communication of these information.

To the question of whether they are currently accessing any product information via IT solutions or digital tools, the majority of stakeholders across all stakeholder groups gave a positive answer (90/141 of stakeholders representing the private sector, and 30/53 of stakeholders representing consumers), showing an apparent readiness and interest of respondents to e-labelling of chemical products.

This conclusion can be moderated by the answers provided to the following question, when ask how they would evaluate if some information was removed from on-pack label and could be obtained via digital tools, views are mixed among stakeholder groups. On one hand, over two-thirds of stakeholders representing the industry (98/141) evaluate it either 'very positively' or 'moderately positively'. On the other hand, views are mixed among stakeholders representing consumers, with 24 consumers answering either 'very positively' or 'moderately positively', 25 consumers answering either 'moderately negatively' or 'very negatively' and 3 consumers answering 'neither positively nor negatively'. These findings can indicate the need to pay specific attention to which information are removed from on-pack label and accessible via digital tools in order to not lower consumer protection.

To this regard, respondents were asked to evaluate to what extent different kind of information could be removed from the on-pack label of a chemical product and be transferred to a digital IT solutions.

On one hand, some categories of information were assessed as necessary to remain on pack, such as:

- pictograms showing the risk of the product (45/69 stakeholders representing the private sector, and 29/40 stakeholders representing consumers);
- hazard statements or signal words (43/69 of stakeholders representing the private sector and 25/42 stakeholders representing consumers);
- identification code for poison centers (43/69 stakeholders representing the private sector and 22/42 of stakeholders representing consumers).

On the other hand, mixed views were given concerning precautionary statements on how to store, dispose, prevent accidents etc., the majority of stakeholders representing the private sector indicated the need to keep basic information on pack and provide more detailed online (35/69), which was agreed by a third of stakeholders representing consumers (17/42), while 13/42 of stakeholders representing consumers expressed the need to keep it on pack, agreed by 18/69 of stakeholders from the private sector.

Finally, the majority of stakeholders from both categories provided that information on the name of chemicals causing the hazard could be moved online, either fully (19/67 stakeholders representing the private sector, and 16/42 stakeholders representing consumers) or with a combination of basic information being kept on pack and more details provided online (31/67 stakeholders representing the private sector, and 11/42 stakeholders representing consumers).

Overall, respondents believe that the most effective method to increase the communication of information on labels of chemicals is by simplifying the text on labels, having less information on the on-pack label and instead of providing full details via digital labels, and by using more pictograms or graphic symbols instead of text. In addition, answers given by consumer representatives show that reducing the number of additional languages on labels would be most effective to improve the communication of information.

The majority of the respondents (124 out of 174) have currently accessed product information via IT solutions or digital tools. More specifically, around 78% of respondents from the industry answered positively to this question , and 62% of respondents representing consumers.

The majority of the respondents look for product information online (for any product) daily or weekly . Only two respondents look for product information online (for any product) once a year or less. This finding can be mitigated when looking specifically at answers given by respondents representing consumers. Indeed, about a third of those look for product information online only a few times a year.

The most popular choices for the products to use to access the labelling information via IT solutions were smartphones, laptops, tablets, and desktop computers . The analysis of answers given by consumer representatives also found the same most popular choices within this stakeholder group. Regarding touch-end technologies, close to two-thirds of the respondents would prefer to use QR codes and website address to access the information online, while around 13% of the respondents do not have a preference for the digital solution as long as it would work with their preferred device. The analysis of answers given by consumer representatives also found the same most popular digital solutions within this stakeholder group.

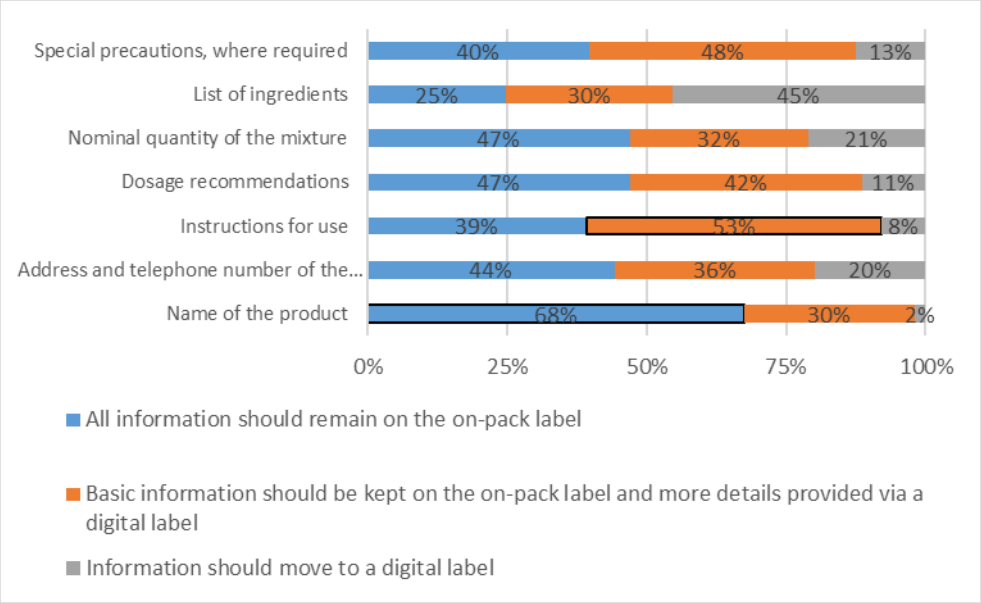
It must however be noted that the majority of the stakeholders also assessed that the biggest challenges of presenting some label information via digital labels would be the difficulty to

access information (e.g. poor internet connection, lack of electricity), the potential differences between the information displayed on the on-pack label and via digital labels (e.g. due to updates, inconsistencies), and, and creating inequalities for certain population groups.

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

In regards to the other parts of the information, the respondents had different views on what kind of information should remain on the on-pack label, should be kept on the on-pack label and more details provided via a digital label, or transferred to a digital label completely. For none of the items there was a majority to move all information to a digital label though for the list of ingredients this group was particular large. The full overview of the responses to this question is provided in Figure 10**: To what extent do you think that the following pieces of information could be removed from the on-pack label of a detergent and transferred to a digital label?**

Figure 10: To what extent do you think that the following pieces of information could be removed from the on-pack label of a detergent and transferred to a digital label?

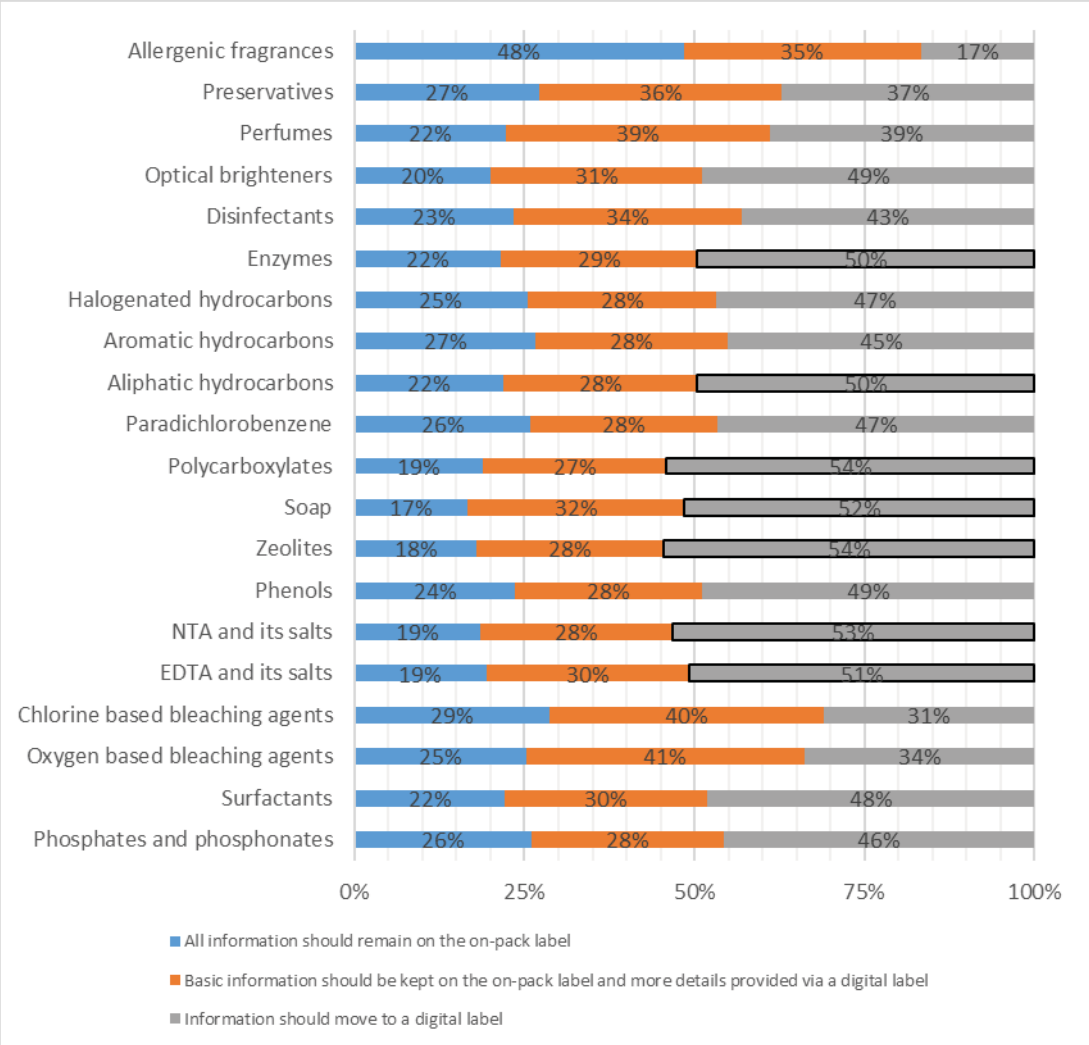


This finding needs to be mitigated by the answers given specifically by consumer representatives only, less inclined to move information online. Indeed, within this stakeholder group, the majority of respondents indicated that all information should remain on pack for the following categories of information: name of the product, instructions for use , dosage recommendations , nominal quantity of mixtures , and special precautions . Finally, consumer representatives had different views on whether to keep on pack, provide basic information on pack and more details digitally, or completely move to a digital label the following information: address and telephone number of the manufacturer and list of ingredients.

Around half of the stakeholders believe that the information from the on-pack label of a detergent should be moved to the digital label for the following ingredients: enzymes; Aliphatic hydrocarbons; Polycarboxylates; soap; Zeolites ; NTA and its salts; EDTA and its salts .

In regard to the other ingredients, the respondents had different views on what kind of information should remain on the on-pack label, should be kept on the on-pack label and more details provided via a digital label, or transferred to a digital label completely. The full overview of the responses to this question is provided in Figure 11**: To what extent could the following ingredients be removed from the on-pack label of a detergent and transferred to a digital label?**

Figure 11: To what extent could the following ingredients be removed from the on-pack label of a detergent and transferred to a digital label?



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

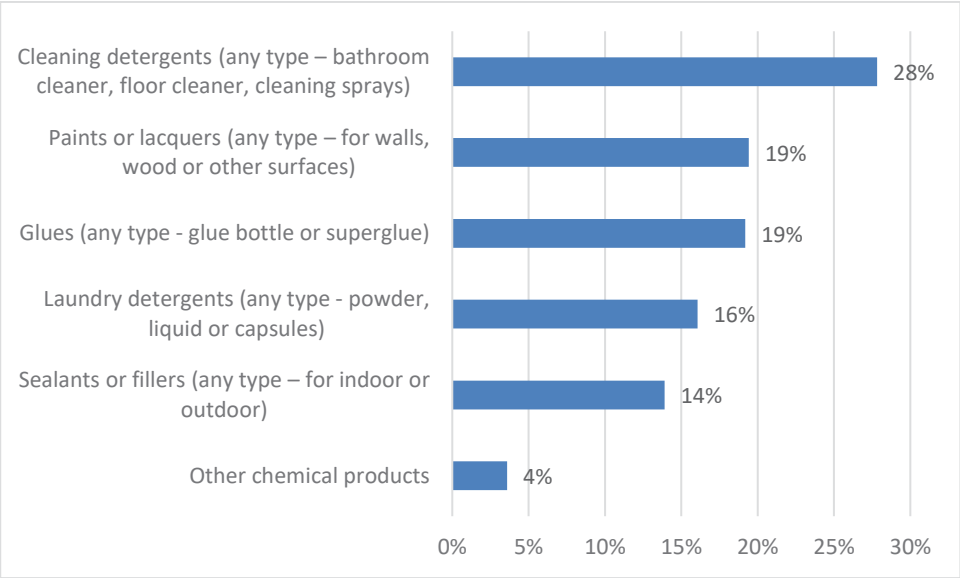
8.2.4 8.2.4 Online survey for professionals and industry users

In total, the survey has collected responses from 206 stakeholders from four countries (France, Germany, Greece, and Romania) and three sectors (construction, hotels & restaurants, and manufacturing). More than half of the survey respondents[5] were from micro & small companies (less than 49 employees), around one-quarter[6] were from medium size companies (between 50 and 249 employees), and the remaining respondents[7] represented large companies (more than 250 employees).

80% of the respondents (164 out of 206) have answered that the companies they represent are involved in preparing the definitions of the usage guidelines of chemical products used by workers. In addition, around one third of the respondents (136 out of 204) mentioned that have received training on chemical products or substances, e.g. on hazards or precautions of safely using these products.

When asked to indicate the three most-used products at work, respondents have identified cleaning detergents[8] as the most often used products at work followed by paints or lacquers[9], and glues[10].

Figure 12: Could you please indicate the 3 mostly used products at work? (multiple choices question)

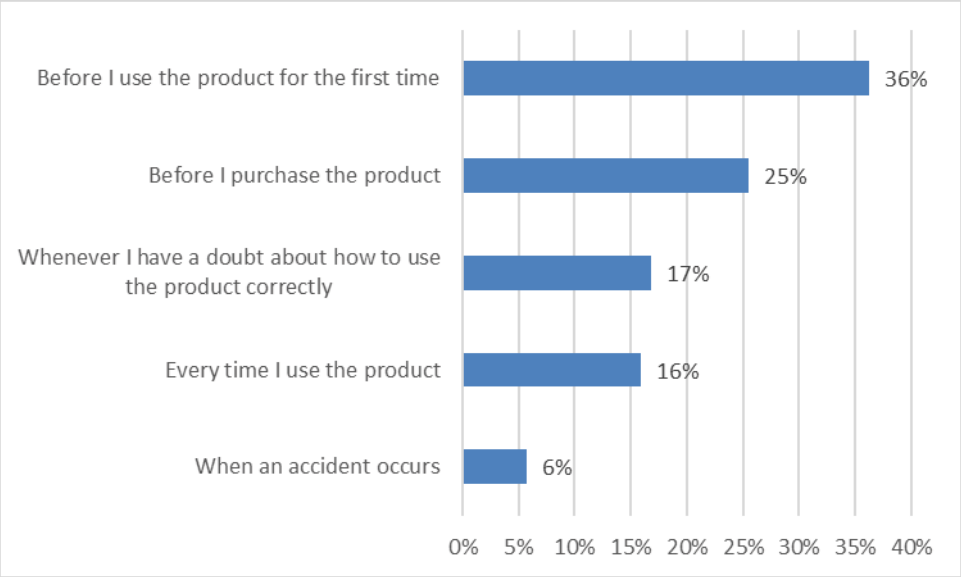


When asked to identify the time when do they usually read the safety information on a label of a chemical product, the majority of the respondents answered that they typically read the safety

[5] 114 out of 206.
[6] 54 out of 206.
[7] 36 out of 206.
[8] 116 out of 417 total choices.
[9] 81 out of 417 total choices.
[10] 80 out of 417 total choices.

information on a label either before they use the product for the first time[11] or before they purchase the product[12].

Figure 13: When do you usually read the safety information on a label of a chemical product? (multiple choices question)



In terms of rating the importance of certain pieces of information concerning the packaging of the afore mentioned products, the respondents have rated the signal words[13] (i.e., "Warning" or "Danger") and instructions for use[14] as the most important elements of information on the package of the product, whilst marketing information[15] seems to be of the least importance to the respondents. According to the results from the survey, in general, having all the pieces of information seems to be most essential to laundry detergents[16], while having all of the pieces of information on the package present in the glues[17] seem to be the least essential overall. More detailed results concerning the importance of having certain pieces of information in the different categories of chemical products is available in Table 19: **In general, on the packaging of the chemical products mentioned below how important do you rate having the following pieces of information?** .

[11] 121 out of 334 total choices.
[12] 85 out of 334 total choices.
[13] Across the five products, respondents have rated the importance of this piece of information as "Absolutely Essential" or "Very Important" 350 out of 400 times.
[14] Across the five products, respondents have rated the importance of this piece of information as "Absolutely Essential" or "Very Important" 349 out of 401 times.
[15] Across the five products, respondents have rated the importance of this piece of information as "Absolutely Essential" or "Very Important" 175 out of 397 times.
[16] Across the 14 pieces of information, respondents have rated the importance of the pieces of information to this product as "Absolutely Essential" or "Very Important" 761 out of 934 times.
[17] Across the 14 pieces of information, respondents have rated the importance of the pieces of information to this product as "Absolutely Essential" or "Very Important" 795 out of 1085 times.

Table 19: In general, on the packaging of the chemical products mentioned below how important do you rate having the following pieces of information? [18]

Piece of information	Laundry detergent	Cleaning detergent	Glue	Paint	Sealant or filler	Average
Signal word, i.e., "Warning" or "Danger"	93%	90%	86%	85%	82%	87%
Instructions for use	93%	89%	80%	86%	88%	87%
Dosage recommendations	87%	86%	86%	86%	82%	86%
Hazard pictogram	90%	83%	83%	79%	75%	82%
Statements on the products hazards for human health environment and physical hazards	88%	85%	78%	75%	81%	81%
List of ingredients contained in the product, such as allergens, preservatives or enzymes	90%	82%	78%	75%	81%	81%
Statements on how to prevent and minimise adverse effects when accidentally exposed	88%	84%	77%	81%	74%	81%
Quantity	79%	78%	76%	83%	81%	79%
Statements on the precautions to be taken on the use, storage and disposal of the product	85%	80%	78%	79%	74%	79%
Name of the product	80%	76%	75%	81%	81%	79%
Information relevant in case of intoxication e.g. poison centre telephone number, UFI-code etc.	84%	80%	76%	77%	75%	78%
Address and telephone number of the supplier	64%	76%	63%	72%	72%	69%

[18] % of survey respondents who have rated the following piece of information as "Absolutely Essential" or "Very Important".

Piece of information	Laundry detergent	Cleaning detergent	Glue	Paint	Sealant or filler	Average
Weblink to receive full ingredients list	75%	74%	62%	55%	70%	67%
Marketing information	47%	41%	37%	44%	56%	45%
Total	81%	79%	74%	76%	77%	77%

Concerning the easiness to read the afore mentioned pieces of information in these products, respondents to the survey think that name of the product[19] is usually the most easy to understand piece of information of the product, while marketing information[20] seems to be the most difficult piece to understand. According to the respondents, the products that are most easy to understand concerning the information on the package are laundry detergents[21], while the most difficult to understand are glues[22]. More detailed results concerning the easiness to understand certain pieces of information in the different categories of chemical products is available in Table 20: **From your experience with labels of the products mentioned below, how easy to understand do you find each piece of information typically included on the packaging?** .

Table 20: From your experience with labels of the products mentioned below, how easy to understand do you find each piece of information typically included on the packaging? [23]

	Laundry detergent	Cleaning detergent	Glues	Paints	Sealants or fillers	Average
Name of the product	94%	90%	92%	89%	88%	91%
Quantity	91%	85%	82%	80%	88%	85%
Instructions for use	87%	81%	83%	83%	86%	84%

[19] Across the five products, respondents have rated the easiness to understand of this piece of information as "Very easy to understand" or "Rather easy to understand" 361 out of 399 times.
[20] Across the five products, respondents have rated the easiness to understand of this piece of information as "Very easy to understand" or "Rather easy to understand" 233 out of 388 times.
[21] Across the 14 pieces of information, respondents have rated the importance of the pieces of information to this product as Very easy to understand" or "Rather easy to understand" 729 out of 926 times.
[22] Across the 14 pieces of information, respondents have rated the importance of the pieces of information to this product as Very easy to understand" or "Rather easy to understand" 793 out of 1107 times.
[23] % of survey respondents who have rated the following piece of information as "Very easy to understand" or "Rather easy to understand".

	Laundry detergent	Cleaning detergent	Glues	Paints	Sealants or fillers	Average
Signal word, i.e., “Warning” or “Danger”	87%	82%	81%	80%	79%	82%
Dosage recommendations	85%	78%	75%	78%	75%	78%
Address and telephone number of the supplier	83%	82%	66%	74%	70%	75%
Statements on the products hazards for human health environment and physical hazards	79%	76%	71%	74%	74%	75%
Hazard pictogram	85%	72%	70%	71%	72%	74%
Statements on the precautions to be taken on the use, storage and disposal of the product	75%	70%	73%	79%	67%	73%
Information relevant in case of intoxication e.g. poison centre telephone number, UFI-code etc.	73%	70%	69%	64%	74%	70%
Statements on how to prevent and minimise adverse effects when accidentally exposed	76%	68%	62%	75%	67%	69%
Weblink to receive full ingredients list	69%	70%	62%	67%	71%	68%
List of ingredients contained in the product, such as allergens, preservatives or enzymes	60%	64%	61%	73%	72%	66%
Marketing information	59%	64%	56%	59%	61%	60%
Total	79%	75%	72%	75%	74%	74%

Regarding the respondents' opinion on the possibility of use of an online electronic label for chemical products, the majority of the respondents[24] view this possibility positively or very positively.

Moreover, the majority of the respondents think that moving all of the pieces of information currently available on physical labels to the online electronic labels would not impact detriment to workers' safety, with address and telephone number of the supplier[25], and marketing information[26] gaining the highest, and information relevant in case of intoxication e.g. poison centre telephone number, UFI-code etc., and dosage recommendations gaining the lowest support by the respondents[27].

Figure 14: In case of use of an online electronic label of the chemical products that your company uses, in your opinion which piece of information currently on physical labels could be moved without detriment to workers' safety?

[24] 147 out of 206 respondents have selected options "Positively" or "Very positively".
[25] 168 out of 204 respondents have selected option "Yes".
[26] 157 out of 195 respondents have selected option "Yes".
[27] Option "Yes" have been selected 123 out of 199 times for both pieces of information.

8.2.5 8.2.5 Online survey on policy options

In total, the survey has collected responses from 81 stakeholders from 22 countries[28]. Because of the significant differences in the number of responses collected from different type of stakeholders, the answers have been divided by stakeholder category: 14 respondents belonged

[28] Public authorities: 1 respondent each from Austria, Cyprus, Denmark, Finland, Norway, Poland, Portugal, Romania, Slovakia; 2 respondents from Slovakia; 3 respondents from Lithuania.
Industry: 1 participant each from Bulgaria, Croatia, Czech Republic, Finland, Lithuania, Slovakia, Switzerland; 2 participants from the Netherlands, 3 participants each from France and the United Kingdom, 5 participants from United States, 9 participants from Belgium, 10 participants from Spain, and 28 participants from Germany.

to member state authorities, and 67 were industry representatives (industry associations, businesses).

8.2.5.1 8.2.5.1 Overall assessment of the Policy Options

Stakeholders were asked to rate their overall preference for the Policy Options of this study (for the description of the Policy Options, please see chapter 5). A rating of -5 is considered as least favourable, 0 as neutral, and +5 as most favourable. The analysis described in detail in the paragraphs below consists of the median rates given to the Policy Option by stakeholders.

Public authority stakeholders generally preferred Policy Options 1, 2, and 3 with no preference on proposed interventions either on the CLP or Detergents regulations considering Policy Options 1 and 2, and preference towards the proposed interventions on Detergents regarding Policy Option 3. Out of all the Policy Options considered, public authority stakeholders had the most negative opinion about Policy Option 4.

On the other hand, stakeholders from industry expressed their preference towards Policy Option 4 with a preference for proposed interventions on the Detergents Regulation. In addition, Policy Options 3 and 5 also received a positive feedback with a preference for the proposed interventions on the Detergents Regulation under Policy Option 3 and a slight preference for the proposed interventions on the CLP Regulation under Policy Option 5.

Table 21: Stakeholders' opinion on the Policy Options[29]

Type of stakeholder	Policy Option 0	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	Overall: 2.5	Overall: 4 CLP: 4 Detergents 4	Overall: 4 Sub-option 2(a): 4 Sub-option 2(b): 4	Overall: 4 CLP: 3 Detergents 4	Overall: -2 CLP: -1 Detergents 2	Overall: 2 CLP: 1 Detergents 1
Industry	Overall: -1	Overall: -3.5	Overall: 1.5	Overall: 3	Overall: 5	Overall: 3

[29] Public authorities: 12 respondents for Policy Option 0, 10 respondents for Policy Option 1 overall, and 9 each for CLP and Detergents, 11 respondents for Policy Option 2 overall and Sub-option 2(a), and 12 for Sub-option 2(b), 11 respondents for all the options under Policy Option 3, 11 respondents for Policy Option 4 overall, and 9 for CLP and Detergents, 11 respondents for Policy Option 4 overall, and 10 for CLP and Detergents, 11 respondents for Policy Option 4 overall, and 10 for CLP and Detergents.
Industry: 54 respondents for Policy Option 0, 38 respondents for Policy Option 1 overall, and 33 each for CLP and Detergents, 26 respondents for Policy Option 2 overall, 23 for Sub-option 2(a), and 21 for Sub-option 2(b), 38 respondents for Policy Option 3 overall, and 33 for CLP and Detergence, 31 respondents for Policy Option 4 overall, and 29 for CLP and Detergents, 30 respondents for Policy Option 4 overall, and 28 for CLP and Detergents, 30 respondents for Policy Option 4 overall, and 28 for CLP and Detergents.

Type of stakeholder	Policy Option 0	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
		CLP: -3 Detergents: -3	CLP: 3 Detergents 4	CLP: 2 Detergents 3	CLP: 4 Detergents 5	CLP: 3 Detergents 2.5

8.2.5.2 8.2.5.2 Impact on the awareness of consumers about safe use of products and label readability

Stakeholders were asked to rate the impact of the Policy Options from very negative (-2) to very positive (+2)[30]. The analysis described in detail in the paragraphs below consists of the median rates given to the Policy Option by the stakeholders.

Concerning the impact of the policy options on the awareness of consumers about safe use of products and label readability, public authorities had an overall positive opinion about Policy Options 1, 2, and 3 (besides neutral opinion the impact from the proposed interventions on Detergents Regulation). Public authorities had an overall negative opinion concerning Policy Options 4 and 5.

Industry stakeholders had an overall positive opinion about each Policy Options with the exception of Policy Option 1, which would have no impact on consumer safety. The proposed interventions under Policy Option 3 on the Detergents Regulation received the highest support from industry stakeholders as its impact on consumer safety was estimated as very positive.

Table 22: Impact on consumer safety and label readability[31]

Type of stakeholder	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	Overall: Slightly positive	Overall: Slightly positive	Overall: Slightly positive	Overall: Slightly negative	Overall: Slightly negative
			CLP: Slightly positive		
			Detergents: Neutral		

[30] -2 =very negative, -1 = slightly negative, 0 = neutral, +1 = slightly positive, +2 = very positive.
[31] Public authorities: 11 respondents for Policy Option 1, 12 respondents for Policy Option, 11 respondents for all the options under Policy Option 3, 11 respondents for Policy Option 4, 11 respondents for Policy Option 5.
Industry: 41 respondents for Policy Option 1, 26 respondents for Policy Option 2, 36 respondents for Policy Option 3 overall, and 33 for CLP and Detergence, 29 respondents for Policy Option, 28 respondents for Policy Option 5.

Type of stakeholder	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Industry	Overall: Neutral	Overall: Slightly positive	Overall: Slightly positive	Overall: Slightly positive	Overall: Slightly positive
			CLP: Slightly positive		
			Detergents: Very positive		

8.2.5.3 8.2.5.3 Impact on the well-being of consumers with impairments

In terms of the impact of the Policy Options on the well-being of consumers with the impairments, public authorities considered Policy Option 1 as the most positive for consumers who are impaired. In particular, Policy Option 1 was considered to have a very positive impact on consumer who have cognitive/learning impairments. On the other hand, public authorities estimate an overall neutral or negative impact from the other Policy Options with the exception of Policy Option 4 and its impact on visually impaired consumers.

Industry stakeholders considered Policy Options 3 and 4 as most positive for impaired consumers. In particular, industry stakeholders estimated a very positive impact under Policy Option 4 for visually impaired consumers. On the other hand, industry stakeholders estimate an overall neutral or negative impact from the rest of the Policy Options with an exception of the positive impact on visually impaired consumers under Policy Options 1 and 5. In addition, none of the options were estimated to have an overall positive impact on consumers with mobility or physical impairments.

Table 23: Impact on the well-being of consumers with impairments[32]

[32] Public authorities: **Policy Option 0**, Vision n=3 out of 12; Colour blind – 3 out of 11, Cognitive/Learning – 4 out of 11, Mobility/Physical 2 out of 11. **Policy Option 1**, Vision n=6 out of 11; Colour blind – 8 out of 13, Cognitive/Learning – 7 out of 11, Mobility/Physical 7 out of 11, **Policy Option 3**, Vision n=7 out of 11; Colour blind – 4 out of 11, Cognitive/Learning – 3 out of 11, Mobility/Physical 4 out of 13, **Policy Option 4**, Vision n=5 out of 11; Colour blind – 2 out of 11, Cognitive/Learning – 2 out of 11, Mobility/Physical 3 out of 11, **Policy Option 5**, Vision n=5 out of 11; Colour blind – 3 out of 11, Cognitive/Learning – 3 out of 11, Mobility/Physical 3 out of 11.
Industry: **Policy Option 0**, Vision n=6 out of 47; Colour blind – 6 out of 49, Cognitive/Learning – 6 out of 48, Mobility/Physical 5 out of 47. **Policy Option 1**, Vision n=21 out of 40; Colour blind – 12 out of 42, Cognitive/Learning – 13 out of 39, Mobility/Physical 9 out of 39, **Policy Option 3**, Vision n=20 out of 31; Colour blind – 18 out of 32, Cognitive/Learning – 16 out of 31, Mobility/Physical 8 out of 30, **Policy Option 4**, Vision n=24 out of 31; Colour blind – 15 out of 30, Cognitive/Learning – 16 out of 30, Mobility/Physical 6 out of 28, **Policy Option 5**, Vision n=17 out of 28; Colour blind – 10 out of 27, Cognitive/Learning – 9 out of 28, Mobility/Physical 7 out of 28.

Type of stakeholder	Type of impairment	Policy Option 0	Policy Option 1	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	**Vision:**	25%	55%	64%	45%	45%
	Colour blind:	27%	62%	36%	18%	27%
	Cognitive/Learning	36%	70%	27%	18%	27%
	Mobility/Physical	18%	64%	31%	27%	27%
Industry	**Vision:**	13%	53%	65%	77%	61%
	Colour blind:	12%	29%	56%	50%	37%
	Cognitive/Learning	13%	33%	52%	53%	32%
	Mobility/Physical	11%	23%	27%	21%	25%

8.2.5.4 8.2.5.4 Impact on the awareness of consumers about the effects of dispersion of harmful substances in the natural environment

Stakeholders were asked to rate the impact of the Policy Options from very negative (-2) to very positive (+2)[33]. The results described in detail in the paragraphs below consist of the median ratings given to the Policy Option by the stakeholders.

Public authorities consider Policy Options 0, 1, and 2 as having an overall positive impact on consumer awareness about the effects of dispersion of harmful substances in the natural environment. Policy Options 4 and 5 are estimated to have a negative impact and Policy Option 3 is considered to have no impact in this area.

Industry stakeholders consider Policy Options 3 and 4 as having an overall positive impact on consumer awareness about the effects of dispersion of harmful substances in the natural environment, while the remaining Policy Options are estimated to have no impact in this area.

Table 24: Impact on the awareness of consumers on the effects of dispersion of harmful substances in the natural environment[34]

[33] -2 =very negative, -1 = slightly negative, 0 = neutral, +1 = slightly positive, +2 = very positive.

[34] Comparison of median results. Stakeholders were asked to rate the coherence from very negative (-2) to very positive (+2)
Public authorities. 12 respondents, in total, under Policy Option 0, 12 respondents, in total, under Policy Option 1, 12 respondents, in total, under Policy Option 2, 13 respondents, in total, under Policy Option 3, 11 respondents, in total, under Policy Option 4, 11 respondents, in total, under Policy Option 5.

Type of stakeholder	Policy Option 0	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	Slightly positive	Slightly positive	Slightly positive	Neutral	Slightly negative	Slightly negative
Industry	Neutral	Neutral	Neutral	Slightly positive	Slightly positive	Neutral

8.2.5.5 8.2.5.5 Coherence with the digitalisation trends of the market

Stakeholders were asked to rate each Policy Option in term of its coherence with the digitalisation trends in the market. A rating of 0 is considered as the least coherent, 5 as neutral, and 10 as most coherent. The results described in detail in the paragraphs below consist of the median ratings given to the Policy Option by the stakeholders.

Public authorities considered Policy Option 1 as the most coherent with the digitalisation trends in the market. Policy Options 3, 4 and 5 also received overall positive feedback, while Policy Option 2 was estimated to have no impact on coherence with digitalisation trends in the market.

Industry stakeholders considered Policy Option 4 as most coherent with digitalisation. Policy Options 3 and 5 also received overall positive feedback, while Policy Options 1 and 2 were estimated to have negative impact on the coherence with the digitalisation trend.

Table 25: Coherence with the digitalisation of the market[35]

Type of stakeholder	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	8	5	6.5	7	7.5
Industry	2	1	7	9	7

Industry. 51 respondents, in total, under Policy Option 0, 41 respondents, in total, under Policy Option 1, 19 respondents, in total, under Policy Option 2, 35 respondents, in total, under Policy Option 3, 28 respondents, in total, under Policy Option 4, 27 respondents, in total, under Policy Option 5.

[35] Public authorities. 12 respondents, in total, under Policy Option 1, 12 respondents, in total, under Policy Option 2, 12 respondents, in total, under Policy Option 3, 11 respondents, in total, under Policy Option 4, 12 respondents, in total, under Policy Option 5.

Industry. 44 respondents, in total, under Policy Option 1, 29 respondents, in total, under Policy Option 2, 35 respondents, in total, under Policy Option 3, 25 respondents, in total, under Policy Option 4, 27 respondents, in total, under Policy Option 5.

8.2.5.6 8.2.5.6 Impact on the competitive position of EU firms with respect to non-EU competitors

Stakeholders were asked to rate the impact of the Policy Options from very negative (-2) to very positive (+2)[36]. The results described in detail in the paragraphs below consist of the median ratings given to the Policy Option by the stakeholders.

Public authorities consider Policy Option 3 as having an overall positive impact with regards to the competitive position of EU firms with respect to non-EU competitors. Policy Option 5 is estimated to have a negative impact and Policy Options 2 and 4 are considered to have no impact in this area.

Industry stakeholders estimate that none of the Policy Options would have any impact on the competitive position of EU firms with respect to non-EU competitors.

Table 26: Impact to competitive position of EU firms with respect to non-EU competitors[37]

Type of stakeholder	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	Neutral	Slightly positive	Neutral	Slightly negative
Industry	Neutral	Neutral	Neutral	Neutral

8.2.5.7 8.2.5.7 Impact on SMEs

Stakeholders were asked to rate the impact of the Policy Options from very negative (-2) to very positive (+2). The results described in detail in the paragraphs below consist of the median ratings given to the Policy Option by the stakeholders.

Public authorities consider Policy Options 3, 4 and 5 as having an overall positive impact on addressing disproportionate costs for SMEs in comparison to larger enterprises, while Policy Option 2 is considered to have no impact on SMEs in this regard.

Industry stakeholders consider Policy Option 4 as having an overall positive impact on addressing disproportionate costs for SMEs in comparison to larger enterprises, while Policy Options 2, 3 and 5 are considered to have no impact on SMEs in this regard.

[36] -2 =very negative, -1 = slightly negative, 0 = neutral, +1 = slightly positive, +2 = very positive.
[37] Public authorities. 3 respondents each under Policy Options 2, 3, and 4, 1 respondents under Policy Option 5. Note: responses "I don't know" were not taken into consideration under the analysis here.
Industry. 26 respondents, in total , under Policy Option 2, 16 respondents, in total, under Policy Option 3, 11 respondents, in total, under Policy Option 4, 18 respondents, in total, under Policy Option 5. Note: responses "I don't know" were not taken into consideration under the analysis here.

Table 27: Impact on SMEs[38]

Type of stakeholder	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	Neutral	Slightly positive	Slightly positive	Slightly positive
Industry	Neutral	Neutral	Slightly positive	Neutral

In terms of the stakeholder perception on the costs-benefits ratio[39] under each Policy Option, public authorities consider Policy Option 2 as the most cost-effective Policy Option, while Policy Option 3 is estimated to be neutral in this regards, and Policy Options 4 and 5 appear to bring considerably more costs than benefits regarding the activities of the market surveillance authorities.

On the other hand, industry stakeholders estimate high benefits and low costs under Policy Options 4 and 5, while for Policy Option 3, industry stakeholders estimate that the costs under this option will slightly outweigh the benefits.

Table 28: Stakeholders' perception on the cost-benefits ratio under the Policy Options[40]

[38] Public authorities: 6 respondents, in total , under Policy Option 2, 4 respondents, in total, under Policy Option 3, 4 respondents, in total, under Policy Option 4, 5 respondents, in total, under Policy Option 5. Note: responses "I don't know" were not taken into consideration under the analysis here.
Industry. 13 respondents, in total , under Policy Option 2, 16 respondents, in total, under Policy Option 3, 11 respondents, in total, under Policy Option 4, 11 respondents, in total, under Policy Option 5. Note: responses "I don't know" were not taken into consideration under the analysis here.

[39] Ratio of stakeholders who've indicated that cost and benefits under the Policy Option are high or very high. If the ratio is negative it means stakeholders estimate higher costs than benefits under the option.

[40] Public authorities: **Under Policy Option 2**, 2 out of 12 stakeholders estimate high or very high costs, 5 out of 12 stakeholders estimate high or very high benefits**. Under Policy Option 3**, 3 out of 10 stakeholders estimate high or very high costs, 3 out of 10 stakeholders estimate high or very high benefits. **Under Policy Option 4**, 3 out of 11 stakeholders estimate high or very high costs, 1 out of 11 stakeholders estimate high or very high benefits. **Under Policy Option 5**, 3 out of 12 stakeholders estimate high or very high costs, 1 out of 12 stakeholders estimate high or very high benefits.
Industry: **Under Policy Option 3**, overall, 17 out of 26 stakeholders estimate high or very high costs, 19 out of 32 stakeholders estimate high or very high benefits. Under CLP, 17 out of 26 stakeholders estimate high or very high costs, 19 out of 32 stakeholders estimate high or very high benefits. Under Detergents Regulation, 8 out of 23 stakeholders estimate high or very high costs, 8 out of 25 stakeholders estimate high or very high benefits. **Under Policy Option 4**, overall, 16 out of 24 stakeholders estimate high or very high costs, 21 out of 26 stakeholders estimate high or very high benefits. Under CLP,16 out of 24 stakeholders estimate high or very high costs, 21 out of 26 stakeholders estimate high or very high benefits. Under Detergents Regulation, 8 out of 20 stakeholders estimate high or very high costs, 10 out of 21 stakeholders estimate high or very high benefits. **Under Policy Option 5**, overall, 9 out of 20 stakeholders estimate high or very high costs, 18 out of 23 stakeholders estimate high or very high benefits. Under CLP,9 out of 21 stakeholders estimate high or very high costs, 18 out of 23 stakeholders estimate high or very high benefits. Under Detergents Regulation, 5 out of 18 stakeholders estimate high or very high costs, 7 out of 18 stakeholders estimate high or very high benefits.

Type of stakeholder	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4	Policy Option 5
Public authorities	Undefined	Overall: 27%	Overall: 0%	Overall: -14%	Overall: -16%
Industry	Undefined	Undefined	Overall: -7% CLP: -7% Detergent: -3%	Overall: 14% CLP: 14% Detergent: 7%	Overall: 34% CLP: 35% Detergent: 11%

8.3 8.3 BEHAVIOURAL EXPERIMENT FOR DIGITAL LABELLING – METHODOLOGY AND RESULTS

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

8.3.1 8.3.1 Research Questions

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

1. What is the level of understanding of chemical and detergents labels?
2. What is the **importance of different elements** contained in labels? Which information is considered essential?
3. How do consumers interpret labels with respect to hazards and safe use?
4. Does label **simplification and the introduction of digital tools** positively or negatively affect consumers' understanding and perceptions?
5. Do consumers prefer information to remain on the physical label or to be communicated via digital tools?

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

8.3.2 8.3.2 Methodology

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

Table 29: General Structure of the Behavioural Experiment

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

In order to answer the research questions a **randomised controlled trial-design** was implemented that systematically varied types of labelling-treatments (see section 8.3.3.2). In addition, a supporting consumer survey was designed in order to collect further insights on non-behavioural variables. Furthermore, the experiment was **incentivised** (see section 8.3.5).

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

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

8.3.3 8.3.3 Overview of Modules

The experiment consisted of **five subsequent modules** that are displayed in the table below. Each participant went through the same sequence of modules and completed several tasks on

label understanding, interpretation as well as preferences regarding labelling elements and their communication channels.

Table 30: Overview of Modules in Behavioural Experiment

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

8.3.3.1 8.3.3.1 Products

At the heart of the experiment stand **two products** containing chemical substances that fall either exclusively under the CLP Regulation or under both the CLP and the Detergents regulations[41]. The two products were carefully selected so that they cover products consumers

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

are familiar with and frequently handle in their personal life. A further requirement for product selection was that products differ in their degree of potential harmfulness, i.e. with respect to their physical, health-related as well as environmental hazards. Following desk research on representative product types available on consumer markets, the choice fell on a **laundry detergent** and a **glue**.

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

8.3.3.2 8.3.3.2 Treatments

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

8.3.3.2.1 Status Quo Label

The first label was the **Status Quo Label** which comprises labelling requirements from current legislation. It contained all informational elements necessary, i.e. dosage information, ingredients, UFI-code, GHS-pictogram, signal words as well as hazard and precautionary statements. Figure 15 displays the Status Quo Label for the laundry detergent and Figure 16 displays the variant for the glue.

Figure 15: Status Quo Label – Laundry Detergent

Figure 16: Status Quo Label – Glue

8.3.3.2.2 Simplified Label with QR Code

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

In the case of the **laundry detergent,** the simplification consisted of reducing the dosage table, i.e. instead of the full dosage table including separate rows for different degrees of water hardness, the Simplified Label only contained one row for medium water hardness. Furthermore, the list of ingredients was removed from the package label. The reduced / removed information was made available via a website which could be accessed via a QR Code added to the packaging. Hence, the full dosage table for different degrees of water hardness and the list of ingredients was available on the website. Furthermore, the label was amended by further pictograms that were taken from A.I.S.E. (International Association for Soaps, Detergents and Maintenance Products).[42] The GHS-pictogram, signal word and hazard and precautionary statements remained on the label in accordance with current legislation. Figure 17 displays the label for the laundry detergent as well as the website to be opened when scanning the QR code.[43]

Figure 17: Simplified Label with QR Code – Laundry Detergent

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

[43] Please note that scanning the QR-code was mimicked in the experimental design by a pop-up to be opened in the browser. More information on this aspect may be found in section 1.2.3.2.

In a similar way, the simplified label of the **glue** was designed. Information on the ingredients was removed from the package and moved to a website to be accessed via a QR code. Additionally, A.I.S.E. icons were added to the packaging while information on hazards and precautions, pictograms and signal word remained in accordance with current regulation (status quo). Figure 18 displays the Simplified Label for the glue as well as the website on ingredients.

Figure 18: Simplified Label with QR Code – Glue

8.3.3.2.3 No Label Baseline

Lastly, one of the tested treatments displayed only the front packaging of the two products. Hence, it is referred to as the **No Label Baseline**. It was introduced as a methodological control in order to robustly test whether labelling information in the other two treatments indeed informs consumers' understanding. Participants in the No Label Baseline answered the same set of questions as in the other treatments but without consulting the labels, i.e. responses were based on the **experience consumers have with the products**. Figure 19 and Figure 20 display the image for the laundry detergent and glue.

Figure 19: No Label Baseline – Laundry Detergent

Figure 20: No Label Baseline – Glue

8.3.4 8.3.4 Randomisation, Variables and Tasks

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

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

- Objective understanding of labels
- Ability to identify a less harmful product given label information
- Perception of labels
- Anticipated behaviour given label information
- Rating of importance of label elements as well as understandability and ease to find information

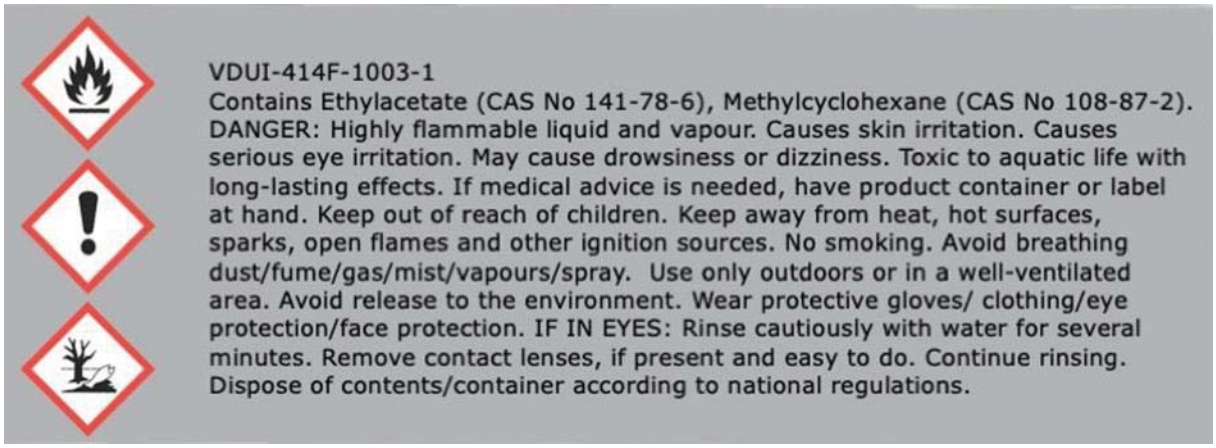
The exact framing of questions and tasks was provided with the scripting document. For all label-related questions participants saw the image of the product on the left side of the screen. The question text was displayed on the right side of the screen. Furthermore, in some of the treatments, participants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

8.3.4.1 8.3.4.1 Behavioural Variables when Consulting Labels

In testing consumers' understanding and appreciation of labels, an important aspect is **whether** they **indeed consult the label**. In reality, consumers have a physical packaging in front of them and whenever they need information contained in the label, they take the packaging and read the relevant labelling section. Ideally, the experiment would allow tracking whether the participant actually looked at the label at display – which for example could be done by implementing eye-tracking during the tasks. As eye-tracking was not in scope of the underlying study, the experiment design included a technical featured that mimicked "zooming" on (looking at) the label. This **zooming-function** allowed participants to hover with their mouse cursor over the label image in order to open a pop-up of the enlarged label. While the whole packaging was by default displayed in small size, i.e. relevant information on hazards and precautions was in very small font, the zoomed-label was of readable size. Figure 21 and Figure 22 display zooming (pop-up) for the Status Quo Label for the laundry detergent as well as the glue.

Figure 21: Zooming on Status Quo Label – Laundry Detergent

Figure 22: Zooming on Status Quo Label – Glue



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

As introduced above, one treatment was a simplified label that also introduced a digital element, i.e. a QR code to a website containing further information (see section 8.3.3.2.2). In reality consumers would open a QR code by using their smartphone. As this actual scanning of a QR code was not feasible in the experimental environment, the experiment introduced an **open-website-function**. By hovering over a link displayed at the bottom of the screen a pop-up of the website opened on screen. Again, the opening behaviour was tracked for all relevant questions.

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

8.3.4.2 8.3.4.2 Comparative Choice Task

As indicated above, the aim of the experiment was also to measure consumers' **ability to identify a potentially less harmful product** by reading and understanding labelling information. Therefore, the experiment included a comparative choice task where participants were presented with two variants of the product, i.e. the product "original" and its "twin". The product twins were constructed in parallel to their original versions and differed only with respect to the potential hazards for human health and the environment.[44] For the laundry detergent the product original was less harmful than its twin, while for the glue the original was more harmful than the twin.

Within the task, participants saw both the original and the twin next to each other on screen and had to **select the potentially less harmful variant**. The alignment to either right or left was

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

fully randomised. Furthermore, participants repeated the task for both the laundry detergent as well as the glue (order was randomised as well).

Each participant remained within the treatment they were assigned to at the beginning of the study, i.e. when assigned to the Status Quo Label, the participant also answered the comparative choice task on the Status Quo Label. Additionally, the comparative choice task included the zooming-feature for the Status Quo and Simplified Label as described above. In order to enlarge labelling details, participants were able to hover over both of the label images of the original and twin and a pop-up opened. Figure 23–Figure 28 display the original and twin product for the laundry detergent and glue in the Status Quo Label, Simplified Label and No Label Baseline treatment.

Figure 23: Comparative Choice Task for Status Quo Label – Laundry Detergent

Figure 24: Comparative Choice Task for Status Quo Label – Glue

Figure 25: Comparative Choice Task for Simplified Label – Laundry Detergent

Figure 26: Comparative Choice Task for Simplified Label – Glue

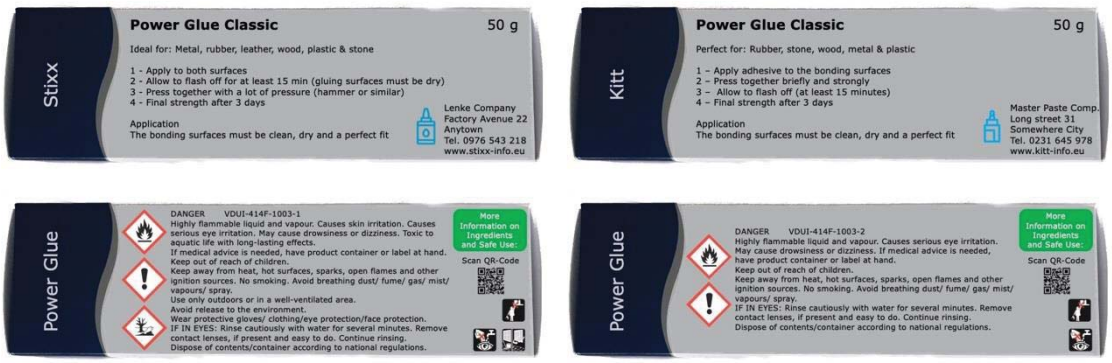
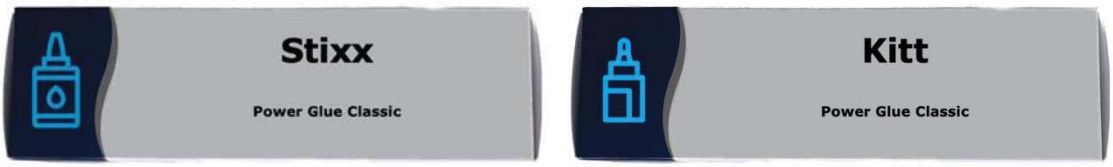


Figure 27: Comparative Choice Task for No Label Baseline – Laundry Detergent

Figure 28: Comparative Choice Task for Simplified Label – Glue



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

8.3.4.3 8.3.4.3 Further Variables

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

8.3.5 8.3.5 Incentives

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

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

8.3.6 8.3.6 Overview on the Data Set

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

8.3.6.1 8.3.6.1 Sample description

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

Table 31: Sample Description

	DE (N=1,000)	FR (N=1,001)	RO (N=1,000)	EL[45] (N=1,002)
Age mean (s.d.)	50.26 (16.53)	49.53 (16.94)	47.98 (16.11)	46.05 (14.89)
Gender (male / female / other-diverse)	49.3% / 50.7% / 0%	48.2% / 51.8% / 0.1%	48.4% / 51.6% / 0%	49.0% / 50.6% / 0.4%
Education[46] (low / Medium / high)	19% / 53% / 28%	9% / 55% / 36%	20% / 57% / 22%	8% / 46% / 46%
Income[47] (low / medium / high)	34.0% / 31.6% / 34.0%	34.0% / 35.5% / 30.6%	43.1% / 50.6% / 6.2%	31.0% / 40.6% / 28.4%

8.3.6.2 8.3.6.2 Treatment assignment

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

Table 32: Treatment Assignment

	Laundry Detergent	Glue

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

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

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

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

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

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

To answer the first research question on consumers' understanding, the experiment included several questions which are presented in the following. All results are based on a **comparison** of the **Status Quo Label and** the **No Label Baseline** in order to confirm whether current legislation indeed enhances consumers' understanding.[48]

8.3.6.2.1.1 Objective Understanding of Product Hazards

Based on the desk research performed to design the two products, **different hazards apply** to the laundry detergent and glue. These include, for example: "Causes serious eye irritation" (H319) or "Toxic to aquatic life with long lasting effects" (H411).[49] The question was presented as a set of correct as well as incorrect hazard statements and participants were asked to identify the correct ones (additional payment for correct answer).

Figure 29 displays the percentage of participants that correctly answered the question on product hazards by product.[50] For the **Status Quo Label** of the laundry detergent **54%** of the participants answered the question on hazards **correctly** while **only 8%** in the **No Label Baseline** were successful. The difference between the two conditions is highly significant ($p<0.001$)[51].

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

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

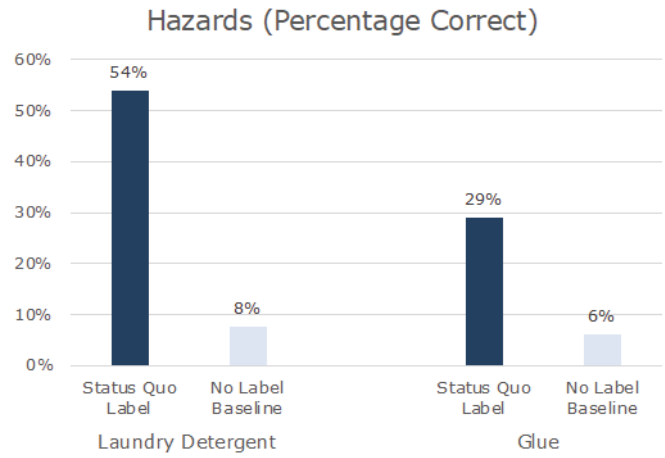
[49] Please note that the hazards differed by product. As described in the methodological section the laundry detergent was designed to be less harmful, while the glue included more hazards. The actual statements are representative for products to be found in supermarkets, drugstores and DIY-stores.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

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

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

product itself was constructed in a way to be more harmful, i.e. more hazard statements apply to the product.

Figure 29: Objective Understanding of Product Hazards by Treatment



Notes: The question was: "Please select all statements that are true about the product displayed on the left:" (Status Quo Label) and "Thinking about a [laundry detergent / glue], please select all statements that are usually true about such a product:" (No Label Baseline).

Number of observations: N=1,333 (LD), N=1,335 (G)

Source: ConPolicy analysis of the experiment and survey data.

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

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

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

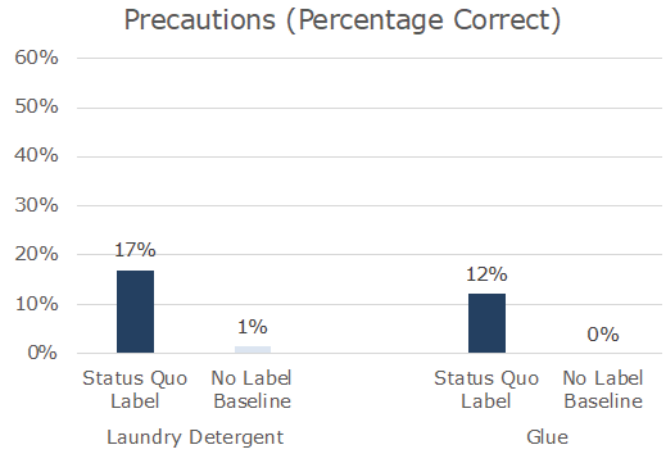
to consult labelling information in the experiment and **when they did,** they also **performed significantly better** than when they did not actively read the label.

8.3.6.2.1.2 Objective Understanding of Precautionary Measures

Similarly, **different precautionary statements apply** to the two products. These included for example: "Keep out of reach of children" (P102) or "IF IN EYES: Rinse cautiously with water for several minutes" (P305+P351).[52] Again, the question was presented as a set of correct as well as incorrect precautionary statements and participants were asked to identify the correct ones (additional payment for correct answer).

Figure 30 displays the percentage of participants that correctly answered the question on product precautions by product. It can be seen that the Status Quo Label again performs better than the No Label Baseline. For both products the difference is highly significant ($p<0.001$). For the **laundry detergent 17%** in the **Status Quo Label** treatment and **1%** in the **No Label Baseline** answered correctly. For the **glue 12%** in the **Status Quo Label** treatment and **0%** in the **No Label Baseline** answered correctly.

Figure 30: Objective Understanding of Precautions by Treatment



Notes: The question was: "From your reading of the label, when using this product would you: (Select all that apply)" (Status Quo Label) and "When using a [laundry detergent / glue] would you: (Select all that apply)" (No Label Baseline).

Number of observations: N=1,333 (LD), N=1,335 (G)

Source: ConPolicy analysis of the experiment and survey data.

When looking at **zooming behaviour, 63%** of the participants in the **Status Quo Label** of the **laundry detergent** took a closer look at the label. Of those who zoomed on the label 26% answered the question correctly while those who did not zoom only answered the question on precautions correctly in 1% of the cases (difference highly significant, $p<0.001$). The same pattern may be observed for the Status Quo Label of the **glue** where **66%** of the participants took a closer look at the label. Of those who zoomed 18% answered the question correctly,

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

while those who did not zoom only answered the question correctly in 2% of the cases (difference highly significant, p<0.001).

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

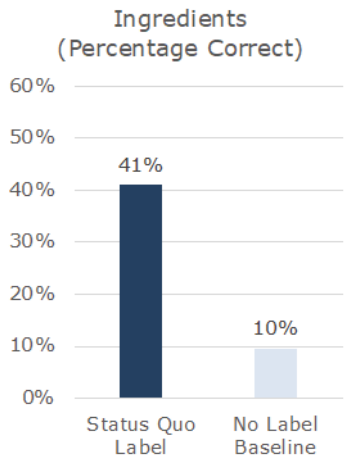
In summary, objective understanding of the precautions applicable to chemical products follows the same pattern as for hazards. **Receiving labelling information** as defined by current regulation (Status Quo Label) **resulted in significantly better performance than answering on experience** (No Label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

8.3.6.2.1.3 Objective Understanding of Ingredients

Lastly, a question on the **ingredients** was presented. It was only asked of participants that were assigned to the laundry detergent. Again, the question was presented as a set of correct, e.g. "enzymes" or "perfumes", and incorrect answer items and participants were asked to select the correct ones (additional payment for correct answer).[53]

Figure 31 displays the percentage of participants that correctly answered the question on product ingredients for the laundry detergent. It can be seen that **41%** in the **Status Quo Label** treatment answered the question on ingredients correctly, while the share was **only 10%** in the **No Label Baseline**. The difference between groups is statistically highly significant (p<0.001).

Figure 31: Objective Understanding of Product Ingredients by Treatment



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

Notes: The question was: "From your reading of the label, which ingredients are contained in this product? (Select all that apply)" (Status Quo Label) and "From you experience with laundry detergents which ingredients are usually contained in such a product? (Select all that apply)" (No Label Baseline).

Number of observations: N=1,333

Source: ConPolicy analysis of the experiment and survey data.

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

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

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

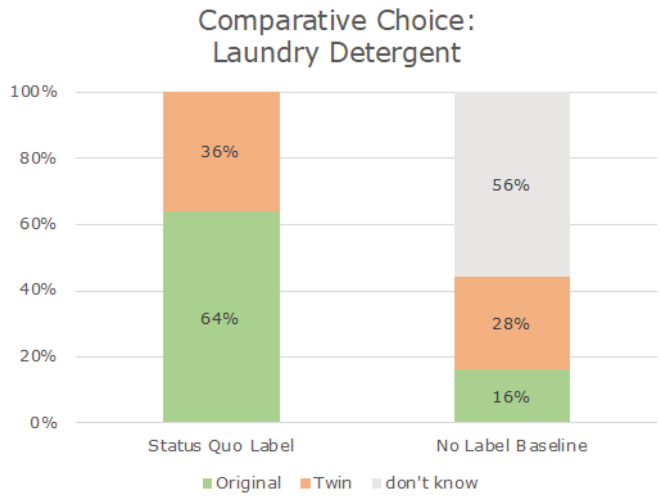
8.3.6.2.1.4 Ability to Identify a Less Harmful Product

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

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

Figure 32 displays the percentage of participants correctly identifying the original product to be less harmful than its twin. As can be seen **64%** in the **Status Quo** treatment answered the question **correctly**. In the No Label Baseline performance was significantly worse because participants were asked to answer the question based on their experience without any further information. Since the **No Label Baseline** only included the front packaging without any information on hazards (pictogram, statements), the majority of participants (**56%**) selected that they don't know the answer or would **need more information** to make the choice. 16% chose the correct product and 28% chose the wrong product. Again, the difference between the treatments is statistically highly significant ($p<0.001$).

Figure 32: Comparative Choice Task Laundry Detergent by Treatment



Notes: The question was: "Please take a look at the two laundry detergents. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.

Number of observations: N=1,340 (Status Quo Label), N=1,328 (No Label Baseline)

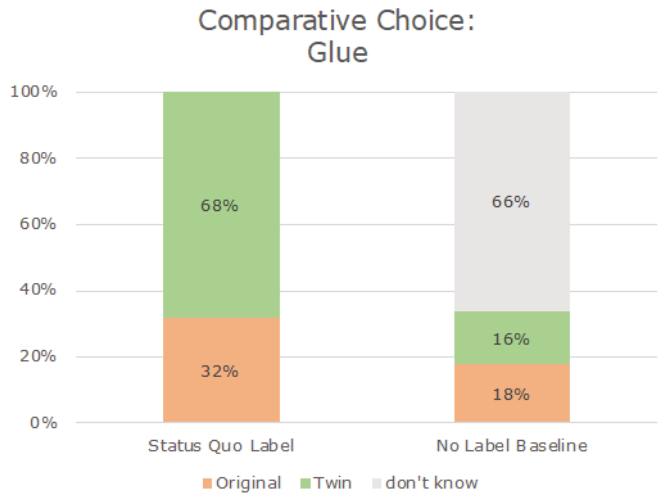
Source: ConPolicy analysis of the experiment and survey data.

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

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

Figure 33 displays the percentage of participants correctly identifying the twin product to be less harmful than the original. Again, the same pattern may be observed. In the **Status Quo Label** treatment, the majority of **68%** selected the **correct** product. In the **No Label Baseline** the majority of **66%** indicated that they did not know the answer and **needed more information** for making their choice. The share of choosing the correct product was 16% and the share of choosing the incorrect product was 18%. Again, the difference between the two treatments is statistically highly significant (p<0.001).

Figure 33: Comparative Choice Task Glue by Treatment



Notes: The question was: "Please take a look at the two glues. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.

Number of observations: N=1,340 (Status Quo Label), N=1,328 (No Label Baseline)

Source: ConPolicy analysis of the experiment and survey data.

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

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

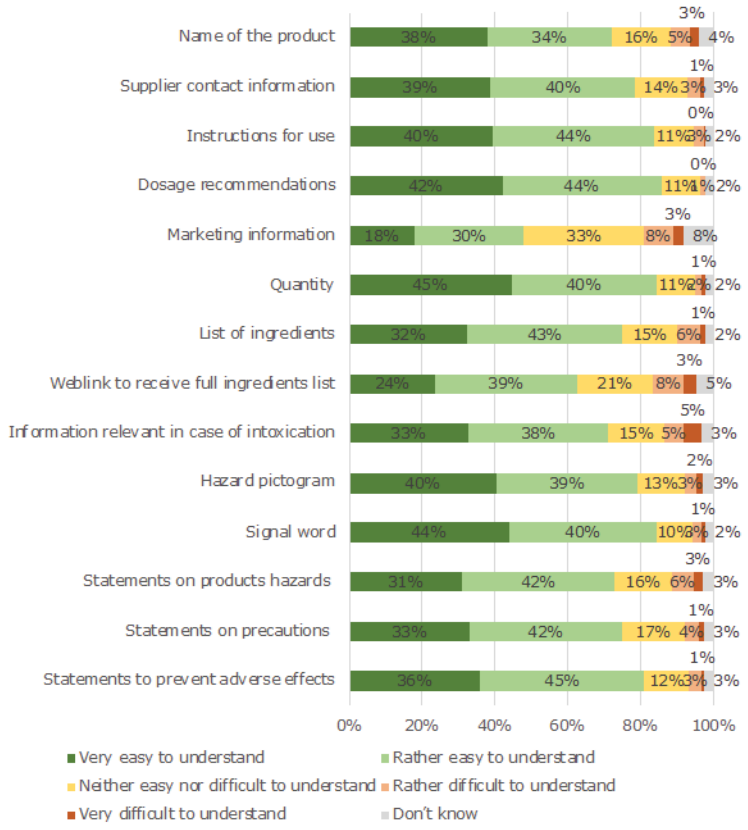
Lastly, it must be noted that results only provide information on consumers' objective understanding and not whether labelling information also causes consumers to purchase the less harmful product. Furthermore, results also cannot demonstrate whether better objective understanding also causes consumers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

8.3.6.2.1.5 Rating of Understandability of Relevant Label Elements

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

Figure 34 displays the subjective understandability of the Status Quo Label for the laundry detergent. All **aspects related to the CLP Regulation** performed well and were perceived as at least rather **understandable** by the vast majority of participants (above 70%). The only aspect that stands out to be different is marketing information. Here only 48% of the participants rated information as understandable.

Figure 34: Rating of Understandability of Label Elements (Status Quo Label, Laundry Detergent)



Notes: The question was: "Still looking at this label, how easy to understand do you find each piece of information?".

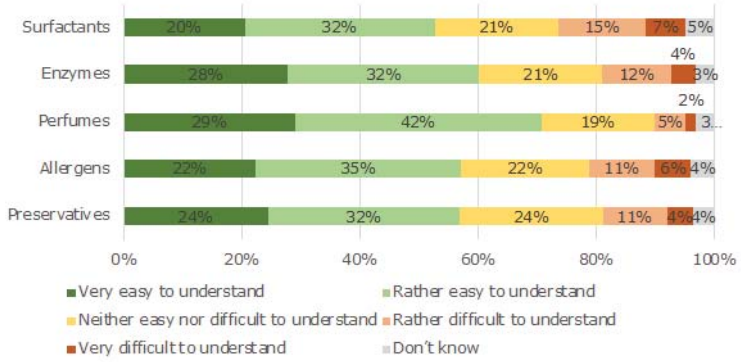
Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

Figure 35 displays the subjective understandability of ingredients information of the Status Quo Label for the laundry detergent. Compared to the previous results on CLP-related labelling

elements the rating was lower. Nevertheless, the **majority** of the participants indicated that **specific ingredient information** was **(rather) easy to understand**.

Figure 35: Rating of Understandability of Label Elements on Ingredients (Status Quo Label, Laundry Detergent)



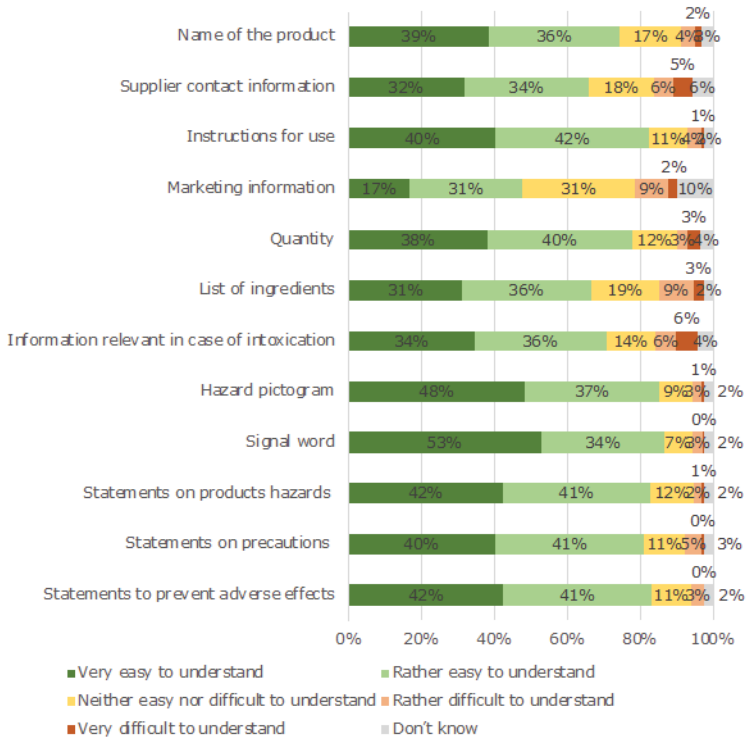
Notes: The question was: "Still looking at this label, how easy to understand do you find the specific information on the ingredients contained in the product?".

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

Lastly, Figure 36 displays the subjective understandability of the Status Quo Label for the glue. Again, the ratings of **CLP-related information** are good with a **majority** of over 70% indicating that information was very or rather **easy to understand**. The only aspect that stands out is marketing information which received a lower understandability rating (48%).

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



Notes: The question was: "Still looking at this label, how easy to understand do you find each piece of information?".

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

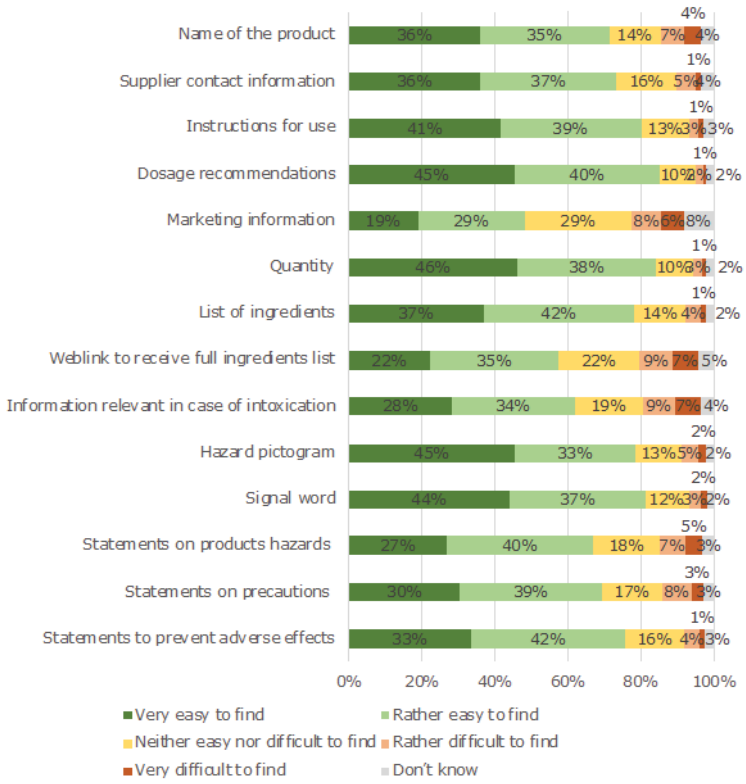
In conclusion, the data shows that overall **consumers perceived relevant labelling elements as (rather) understandable**. Nevertheless, it must be emphasised that this result is based on an individual and subjective self-assessment. When looking at the objective understanding of safe use information contained on labels performance was rather poor (see sections 8.3.6.2.1.1, 8.3.6.2.1.2 and 8.3.6.2.1.3).

8.3.6.2.1.6 Rating of Ease to Find Relevant Label Elements

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

Figure 37 displays the rating of the **ease to find label elements** for the Status Quo Label of the laundry detergent. **Over 60%** of the participants indicated that **CLP-related information** was very or rather **easy to find**. Additionally, dosage recommendations provided as a table on the label were perceived as very or rather easy to find by 85% of the participants. On the other hand, marketing information was perceived as easy to find by only 48% of the participants.

Figure 37: Rating of Ease to Find Label Elements (Status Quo Label, Laundry Detergent)



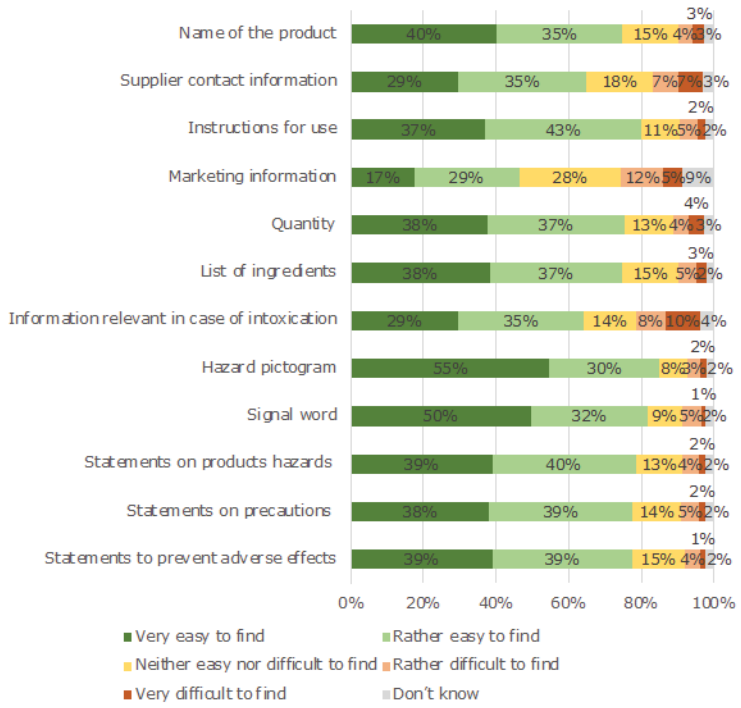
Notes: The question was: "Still looking at this label, how easy is it to find each piece of information?".

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

Figure 38 displays the rating of the ease to find label elements for the Status Quo Label of the glue. Again, all **CLP-related elements** were very or rather **easy to find** (above 60%) while marketing information stands out with a lower rating (36%).

Figure 38: Rating of Ease to Find Label Elements (Status Quo Label, Glue)



Notes: The question was: "Still looking at this label, how easy is it to find each piece of information?".

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

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

8.3.6.2.1.7 Conclusion

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

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

One other aspect that makes the experimental set-up different is the time spent on the label, or at least, the time spent on answering questions on objective understanding. Data reveals that participants take rather sufficient time to answer questions and there also exists a positive correlation between time spent on the question and performance. On the one hand, this is a positive result as it confirms that consulting a label supports consumers' understanding. On the other hand, spending that much time on a label of a chemical substance or detergent is rather uncommon (e.g. in shopping situations labels are not consulted this thoroughly and in the case of an accident induced stress could also lower consultation times).

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

8.3.6.3 8.3.6.3 RQ 2: What is the importance of different elements contained in labels? Which information is considered essential?

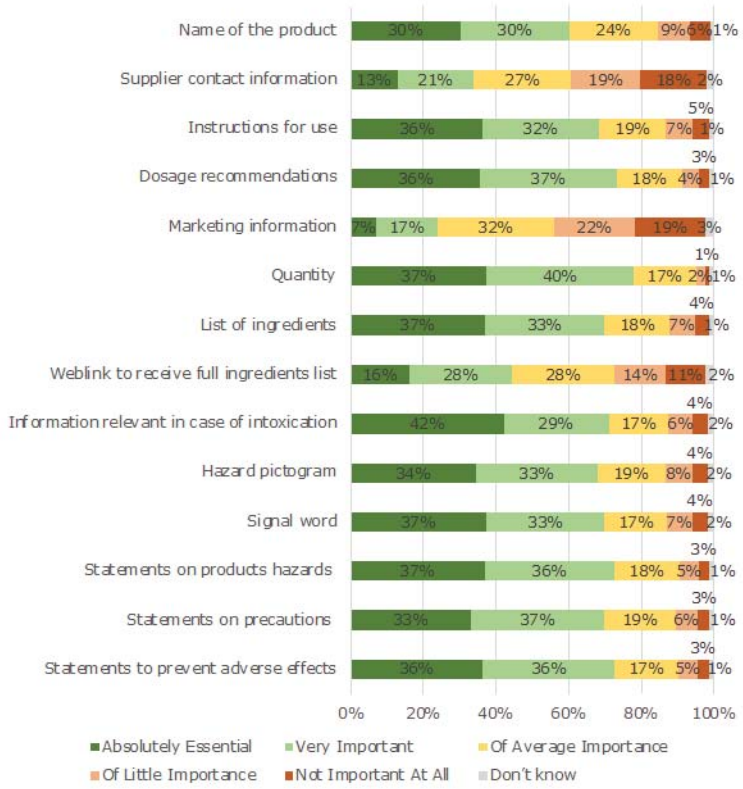
In order to answer the second research question on consumers' perceived importance of label elements, the experiment contained two questions which are presented in the following sections. The first question was asked at the beginning of the experiment before the participants saw the label images on screen,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

8.3.6.3.1 Rating of Importance of Label Elements Without Seeing a Label

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

Figure 39 displays the rating of the importance of label elements for the laundry detergent. **CLP- and Detergent relevant information** such as the hazard pictogram, signal word, statements on hazards and precautions and dosage instructions were rated as either **absolutely essential or very important by more than 70%** of the participants. The weblink to receive the full ingredient list received a share of 44% and supplier contact information of 34%. The lowest rating was assigned to marketing information with only 24% who indicated the information to be absolutely essential or very important.

Figure 39: Rating of Importance of Label Elements Without Label (Status Quo Label, Laundry Detergent)



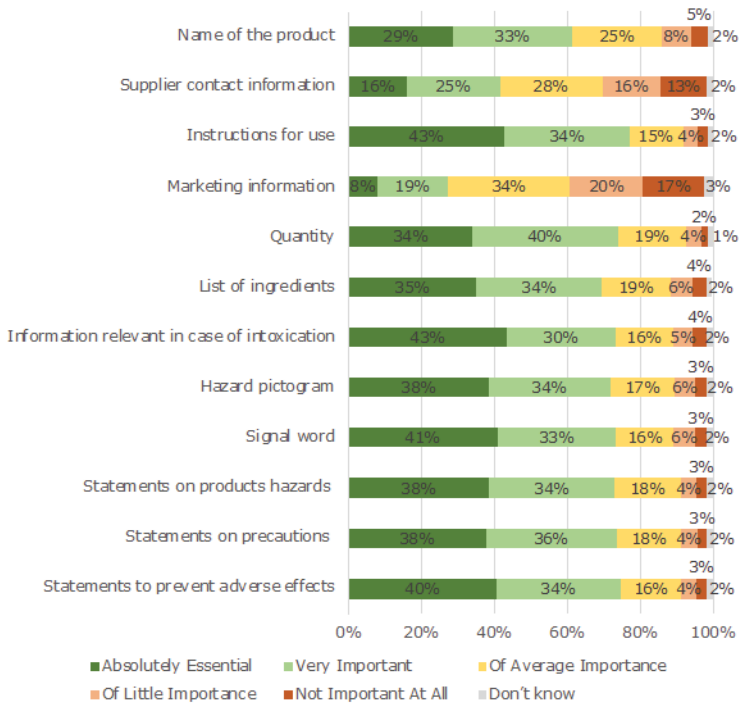
Notes: The question was: "Please think about your last purchase or use of a laundry detergent: In general, on the packaging of a laundry detergent how important do you rate having the following pieces of information?"

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

Figure 40 displays the rating of the importance of label elements for the glue. Again, the same patterns may be observed. **CLP-relevant information received high ratings** of **above 70%** (absolutely essential or very important). Supplier contact information received a lower rating of 31% and the lowest importance was again attached to marketing information were 17% of the participants rated the information to be absolutely essential or very important.

Figure 40: Rating of Importance of Label Elements Without Label (Status Quo Label, Glue)



Notes: The question was: "Please think about your last purchase or use of a glue: In general, on the packaging of a glue how important do you rate having the following pieces of information?"

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

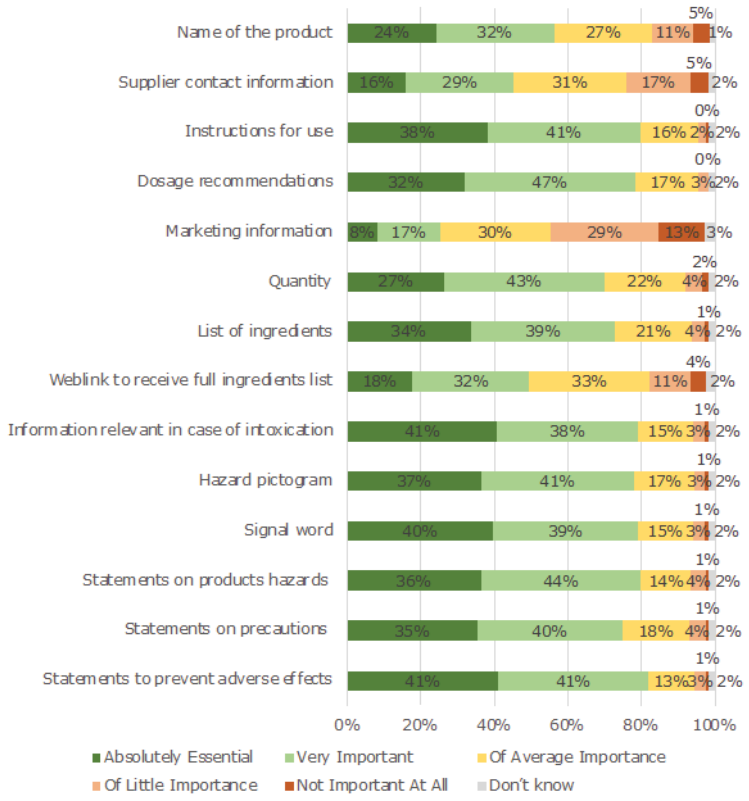
Overall, the **appreciation of different CLP- and Detergent-relevant label elements was high**. Even without seeing a label at display, consumers indicated that information on hazards and precautions are highly important.

8.3.6.3.2 Rating of Importance of Label Elements When Seeing a Label

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

Figure 41 displays the rating of the **importance of label elements** for the Status Quo Label of the laundry detergent. The patterns are in accordance with the previous results. It can be found that **CLP- and Detergent relevant elements received ratings well above 70%**. The weblink to receive the full ingredients list was rated absolutely essential or very important by 50% of the participants and supplier contact information by 45%. The lowest rating again may be found for marketing information. Only 25% of the participants rated this type of information as absolutely essential or very important.

Figure 41: Rating of Importance of Label Elements With Label (Status Quo Label, Laundry Detergent)



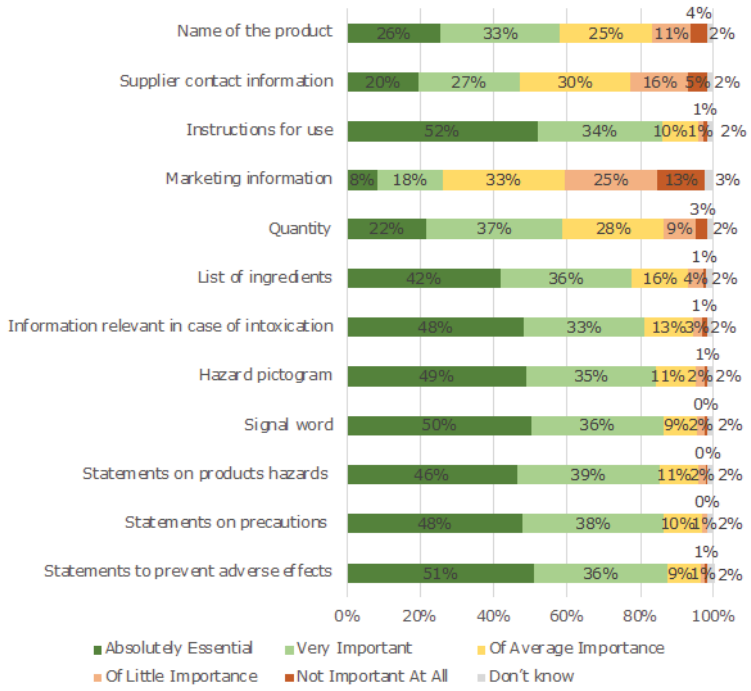
Notes: The question was: "Looking at this label, how important do you rate having the following pieces of information?".

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

Figure 42 displays the rating of the importance of label elements for the Status Quo Label of the glue. Again, the results are in accordance with the previous results. While **CLP-relevant information** such as hazard and precautionary statements or the pictogram received **shares of above 80%** (absolutely essential or very important), marketing information was rated less relevant. Only 26% of the participants indicated that it is absolutely essential or very important.

Figure 42: Rating of Importance of Label Elements With Label (Status Quo Label, Glue)



Notes: The question was: "Looking at this label, how important do you rate having the following pieces of information?"

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

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

8.3.6.3.3 Conclusion

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

8.3.6.4 8.3.6.4 RQ 3: How do consumers interpret labels with respect to hazards and safe use instructions?

The third research question regards the interpretation of labels given provided information. Therefore, several questions were included in the experiment. The first set of questions

focussed on the products' **risk perception** while the second investigated **behaviour induced by the labels**.

8.3.6.4.1 Risk Perception Induced by Label

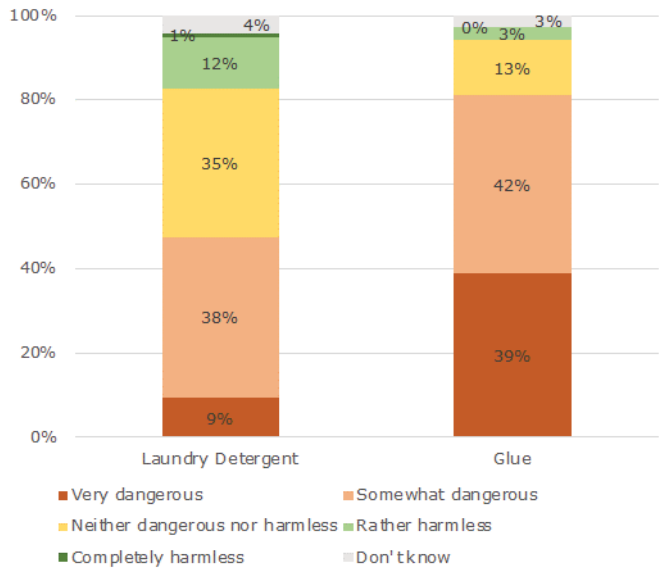
The experiment design included two different **products** that **differed in their degree of potential harmfulness**. Among other aspects, the labels at display differed in the amount of GHS-pictograms presented (one versus three), the signal word ("warning" versus "danger") as well as the amount and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

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

8.3.6.4.2 Risk Perception of Use

The question on **general risk perception of use** was elicited on a 5-point-Likert-scale ranging from "very dangerous" to "completely harmless". Figure 43 shows the results by product type. It can be seen that the glue indeed was rated as more dangerous than the laundry detergent. For the **glue 39%** of the participants indicated the product to be very **dangerous** while the share for the **laundry detergent** is **only 9%**. The difference in danger ratings between the two products is highly statistically significant ($p<0.001$).

Figure 43: Risk Perception of Use by Product (Status Quo Label)



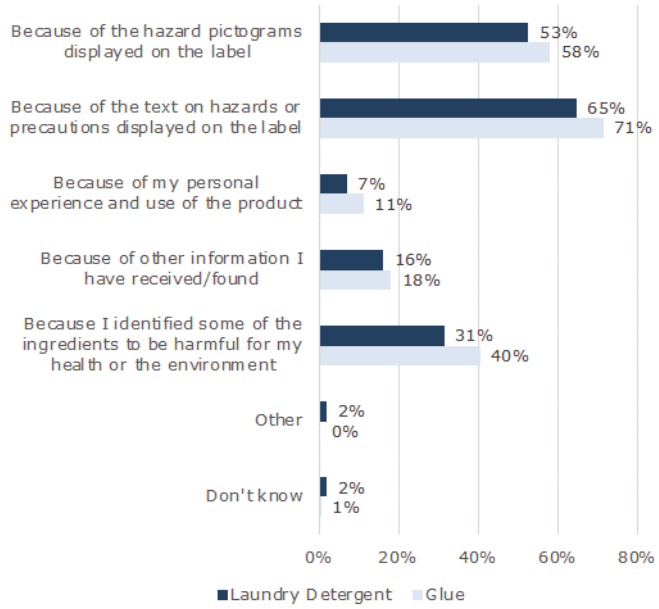
Notes: The question was: "In general, how dangerous do you rate using this product?"

Number of observations: N=670 (LD), N=670 (G)

Source: ConPolicy analysis of the experiment and survey data.

Subsequently, participants rating product use as very or somewhat dangerous were asked to indicate their **reasons for** their **danger perception**. Figure 44 displays the replies by product. It can be seen that for both products the **hazard and precautionary statements** on the label were the **most relevant** reason for rating the product as dangerous (69% for both product types). Similarly, the **hazard pictograms** were rated as **relevant information** for indicating the products to be dangerous (56% for both product types). The ingredients contained in the product were a reason for 37% of the participants, while only 17% and 10% named other information and personal experience.

Figure 44: Reasons for Risk Perception by Product (Status Quo Label)



Notes: The question was: "You indicated that you rate using this product as somewhat or very dangerous. Why?" (multiple answers)

Number of observations: N=313 (LD), N=543 (G)

Source: ConPolicy analysis of the experiment and survey data.

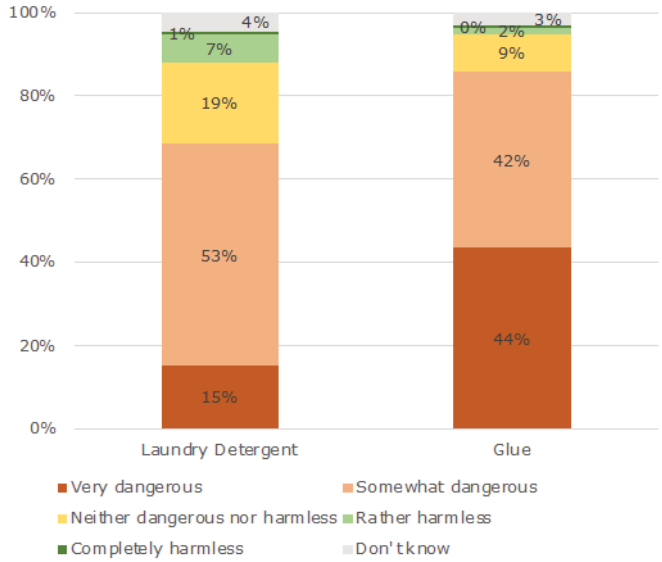
Hence, the results show that **under current regulation** (Status Quo Label) consumers were indeed **able to interpret** the provided information **correctly** and attached more risk to an objectively riskier product. The result confirms findings from the comparative choice task (see section on the first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

8.3.6.4.3 Risk Perception of Wrong Application

The question on general risk perception of wrong application was elicited on a 5-point-Likert-scale ranging from "very dangerous" to "completely harmless". Figure 45 shows the results by

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

Figure 45: Risk Perception of Wrong Application by Product (Status Quo Label)



Notes: The question was: "In general, how dangerous do you rate the wrong application of this product, e.g. when an accident occurs?"

Number of observations: N=670 (LD), N=670 (G)

Source: ConPolicy analysis of the experiment and survey data.

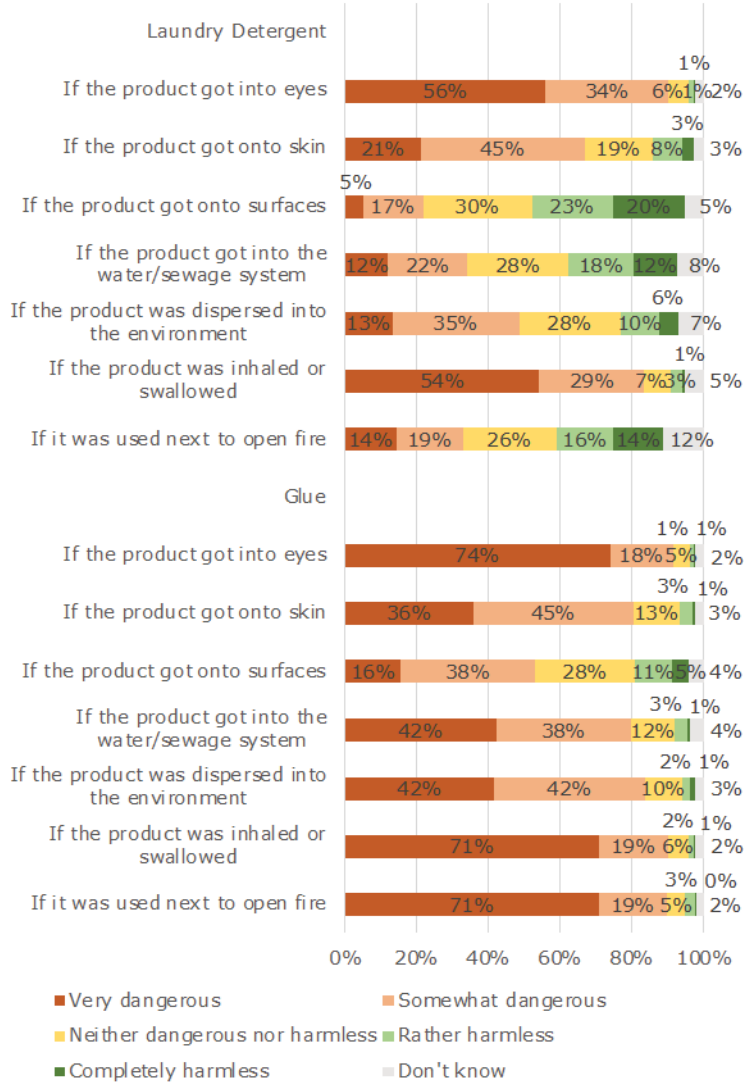
Hence, it can be concluded that labelling information induces the **correct perception** of **application dangers** as well.

8.3.6.4.4 Risk Perception of Different Hazards

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

Figure 46 displays the results by hazard category and product. For all categories the glue was on average rated as more dangerous ($p<0.001$). Furthermore, the rating of product getting into eyes was comparatively large for both product types. This is **in accordance with the actual information displayed on the labels**, i.e. a specific hazard statement is included on the packaging. Dispersing the product into the water systems or the environments was rated more threatening for the glue. Again, this is in accordance with the information contained on the specific labels, i.e. specific hazard statement as well as a GHS pictogram included on the packaging. The same applies to the products being used next to fire, where the glue received a higher rating than the laundry detergent. Similarly, a reason for this difference might be the actual hazard statements and GHS pictogram included on the packaging (the glue was constructed to be flammable while the laundry detergent was not).

Figure 46: Risk Perception of Different Hazards by Product (Status Quo Label)



Notes: The question was: "From your reading of the label, please rate how dangerous each of the following would be:"

Number of observations: N=670 (LD), N=670 (G)

Source: ConPolicy analysis of the experiment and survey data.

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

8.3.6.4.5 Behaviour Induced by Label Information

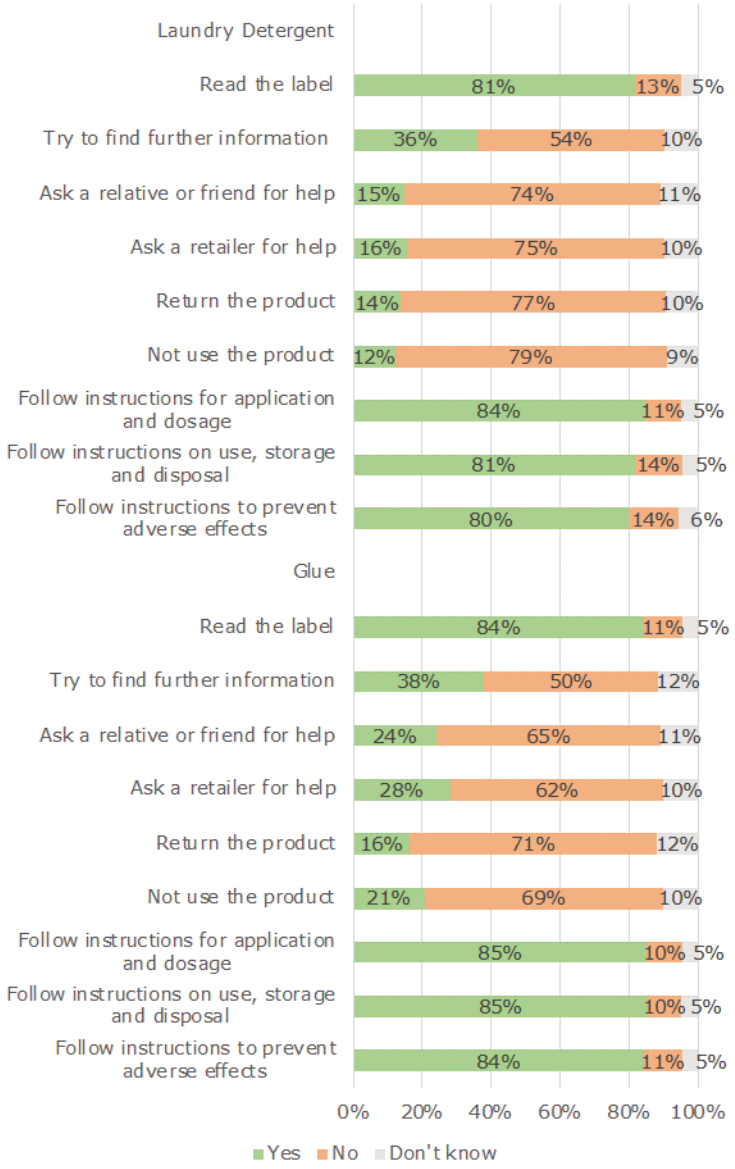
The second set of questions focussed on the behaviours induced by label information. It included questions on the **motivation to read and follow instructions**, **behaviour in case of an accident** as well as on **dosage behaviour**.

It must be noted that objectively there are no wrong answers for these questions. Nevertheless, from a policy perspective reading the information on package is relevant to avoid adverse effects or dose the product correctly, whereas the need to ask other people for help or consulting external sources would be less desirable. Similarly, bringing the packaging to a doctor or applying first aid measures in the case of an accident could be interpreted as positive, while the need to additionally consult a search engine would indicate that information on the packaging is not sufficient.

8.3.6.4.6 Motivation to Read and Follow Instructions

Results regarding consumers' motivation to read and follow instructions may be found in Figure 47. The results show that over **80%** of the participants (regardless of product) would indeed **read the label** and **follow the relevant instructions** on dosage, use and precautions. Trying to find **further information** only applies to **37%** of the participants and asking for **further help** either from relatives or friends or the retailer is **only** applicable to **19% and 22%** respectively.

Figure 47: Motivation to Read and Follow Instructions by Product (Status Quo Label)



Notes: The question was: "Does this label motivate you to:"

Number of observations: N=670 (LD), N=670 (G)

Source: ConPolicy analysis of the experiment and survey data.

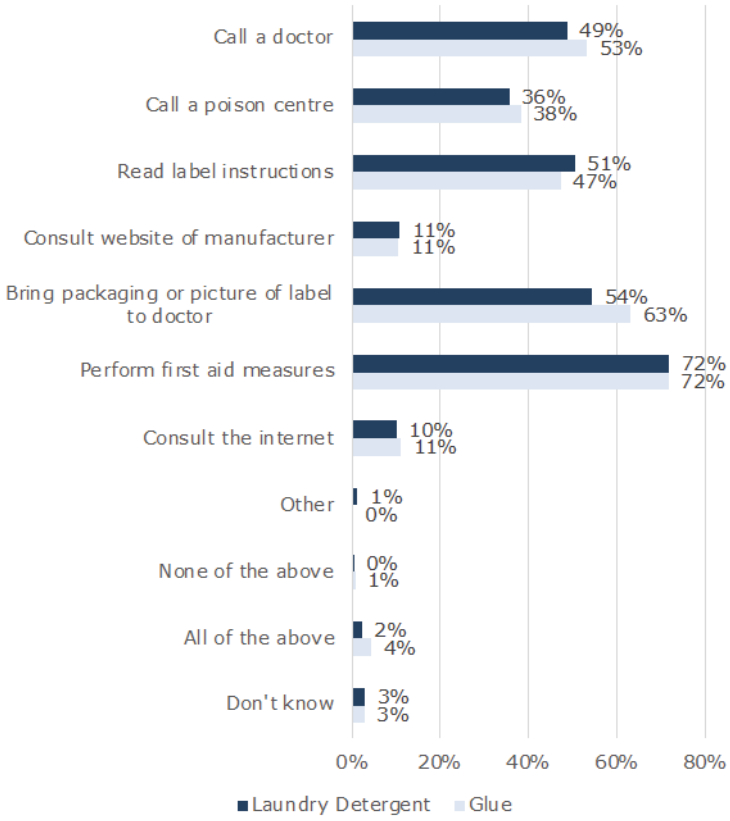
In conclusion, results show that consumers are **motivated to apply appropriate steps** related to labelling information. Especially **reading the label** and **following instructions** appears to be relevant whereas there is no indication that provided information was insufficient and consumers would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

8.3.6.4.7 Behaviour in Case of an Accident

Results regarding consumers' behaviour in case of an accident are displayed in Figure 48. The results show that consumers indeed would be **willing to take appropriate actions**. The majority indicated performing first aid measure, bringing the packaging to the doctor and

calling a doctor. In contrast, **only 11%** indicated that they would **need to consult further sources**, i.e. via a search engine or the website of the manufacturer.

Figure 48: Behaviour in Case of an Accident by Product (Status Quo Label)



Notes: The question was: "Imagine an accident occurs while using this product. This could be that you or a member of your household swallows the product or the product splashes into someone's eyes. What would you do? (Select all that apply)"

Number of observations: N=670 (LD), N=670 (G)

Source: ConPolicy analysis of the experiment and survey data.

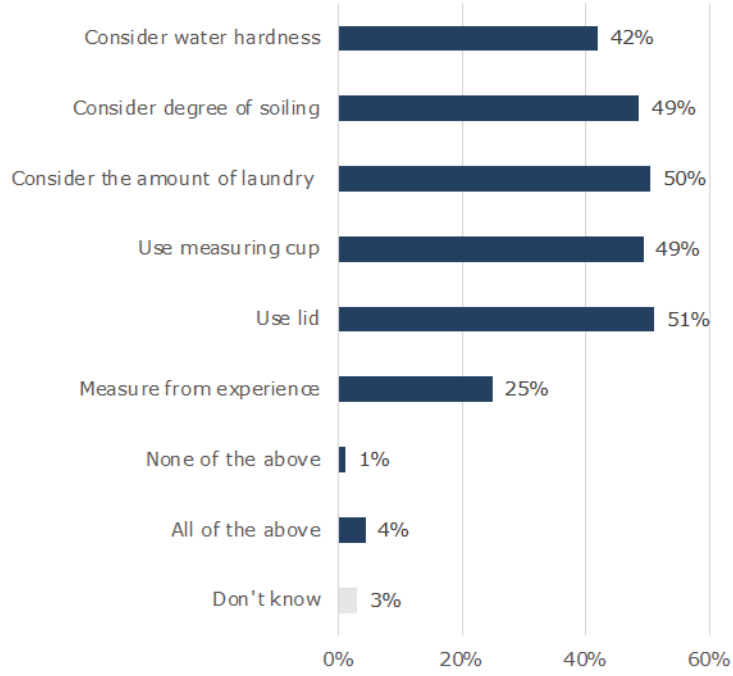
The results confirm previous findings and show that consumers would **take the appropriate measures** in case of an accidents. Furthermore, they **did not** indicate a **need** for **further information** by consulting additional resources.

8.3.6.4.8 Dosage Behaviour

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

Figure 49 displays the results on dosage behaviour for the laundry detergent.[54] Results show that indeed **relevant measures** were claimed to be **taken by at least 40%**, whereas only **25%** of the participants would **rely on their personal experience** of using such a product. Lastly, **only 1%** of the participants indicated to take **none of the presented actions**.

Figure 49: Dosage Behaviour for Laundry Detergent (Status Quo Label)



Notes: The question was: "Imagine you would like to use this product. Which aspects do you consider and which tools would you use when dosing the product? (Select all that apply)"

Number of observations: N=670

Source: ConPolicy analysis of the experiment and survey data.

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

8.3.6.4.9 Conclusion

Taken the results on the third research question together **consumers are (subjectively) able to interpret chemical labels under the current legislation/regulations**. They draw appropriate conclusions from the given information at display, i.e. the questions on risk ratings uniformly show that consumers attach more risk to an objectively riskier product. Furthermore, they are able to interpret specific label elements on hazards and process them correctly. In addition, the results show that CLP-relevant label elements are the ones consumers base their perception on, i.e. the GHS pictogram as well as hazard and precautionary statements. In the light of the second

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

research question on the importance of labelling elements, results are confirmative. Hence, consumers not only rate CLP elements as important but also base their risk perception on them.

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

8.3.6.5 8.3.6.5 RQ 4: Does label simplification and the introduction of digital tools positively or negatively affect consumers' understanding and perceptions?

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

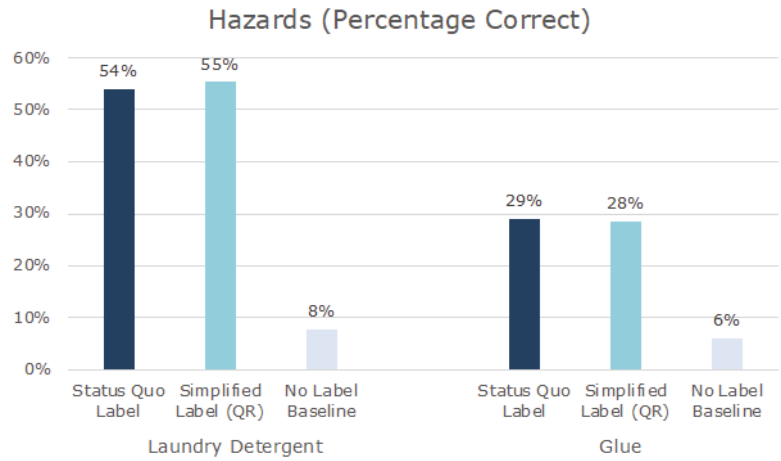
8.3.6.5.1 Objective Understanding

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

Figure 50 displays the results for product hazards. **55%** of the participants in the **Simplified Label** treatment of the **laundry detergent** were able to **correctly** answer the question on hazards. The share of correct answers in the Status Quo treatment was 54% and in the No Label Baseline 8%. When comparing performance by treatment the difference between the Simplified Label and No Label Baseline is highly statistically significant ($p<0.001$). Performance between the Simplified and Status Quo Label on the other hand is not ($p=0.61$).

The same pattern may be observed for the **glue**. In the **Simplified Label** treatment **28%** of the participants answered the question **correctly**, in the Status Quo Label treatment the share was 29% and for the No Label Baseline it was only 6%. Again, the difference between the Simplified and Status Quo Label is not significant ($p=0.79$) while it is highly significant for the Simplified Label and the No Label Baseline ($p<0.001$).

Figure 50: Objective Understanding of Product Hazards by Treatment



Notes: The question was: "Please select all statements that are true about the product displayed on the left:" (Status Quo Label & Simplified Label (QR)) and "Thinking about a [laundry detergent / glue], please select all statements that are usually true about such a product:" (No Label Baseline).

Number of observations: N=2,001 (LD), N=2,002 (G)

Source: ConPolicy analysis of the experiment and survey data.

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

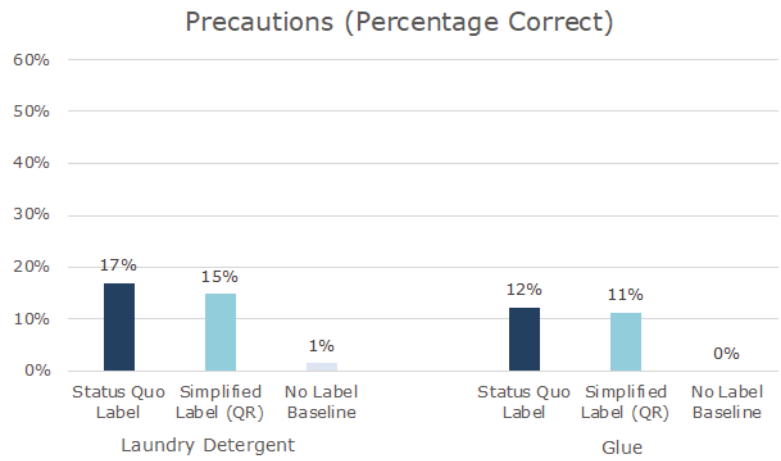
Overall, participants in the Simplified Label treatment of the laundry detergent spent on average 78 seconds to answer the question on hazards. For those assigned to the glue the average was 89 seconds. Furthermore, the data reveals that there exists a positive and significant correlation between time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

Figure 51 displays the results for precautionary statements that apply to the products. As can be seen on the left (**laundry detergent**), the share of participants who **correctly** answer the question in the **Simplified Label** treatment was **15%**. For the Status Quo Label it was 17% and for the No Label Baseline 1%. The difference between the Simplified Label and the No Label Baseline is highly statistically significant ($p<0.001$), while it is not when comparing the Simplified and the Status Quo Label ($p=0.31$).

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

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

Figure 51: Objective Understanding of Precautions by Treatment



Notes: The question was: "From your reading of the label, when using this product would you: (Select all that apply)" (Status Quo Label & Simplified Label (QR)) and "When using a [laundry detergent / glue] would you: (Select all that apply)" (No Label Baseline).

Number of observations: N=2,001 (LD), N=2,002 (G)

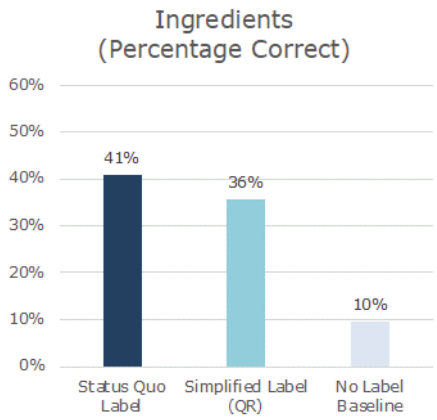
Source: ConPolicy analysis of the experiment and survey data.

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

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

Lastly, Figure 52 displays the results for ingredients contained in the laundry detergent. Participants in the **Simplified Label** treatment answered the question **correctly** in **36%** of the cases. The share of correct answers in the Status Quo Label treatment was 41% and in the No Label Baseline it was 10%. Performance in the Simplified Label treatment was significantly better than in the No Label Baseline (p<0.001). Similarly, performance in the Status Quo Label treatment was weakly, significantly better than in the Simplified Label treatment (p=0.05). Nevertheless, the effect size of the performance is negligible (Cohen's d = 0.11).

Figure 52: Objective Understanding of Product Ingredients by Treatment



Notes: The question was: "From your reading of the label, which ingredients are contained in this product? (Select all that apply)" (Status Quo Label & Simplified Label (QR)) and "From you experience with laundry detergents which ingredients are usually contained in such a product? (Select all that apply)" (No Label Baseline).

Number of observations: N=2,001

Source: ConPolicy analysis of the experiment and survey data.

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

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

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

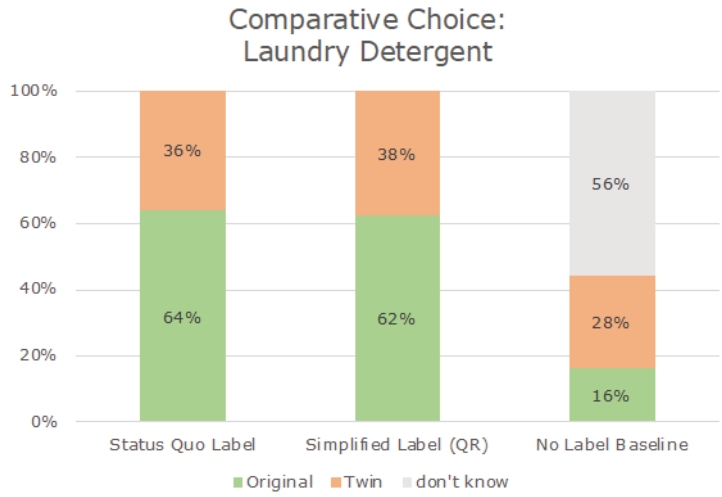
consulted the label their **understanding was** also **better** than when they did not consult the label.

8.3.6.5.2 Ability to Identify a Potentially Hazardous Product

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

As described previously for the **laundry detergent,** the original product was less harmful than its twin. Figure 53 displays the results by treatment. It can be observed that the majority of the participants (**62%**) in the **Simplified Label** treatment were able to **correctly** identify the less harmful product. The share among participants in the Status Quo Label was 64% and in the No Label Baseline it was 16%. When comparing the treatments with respect to correct answers, it can be found that the distribution of the Simplified Label and the No Label Baseline is highly statistically different ($p<0.001$). The difference between the Simplified Label and Status Quo Label, on the other hand, is not statistically significant ($p=0.46$).

Figure 53: Comparative Choice Task Laundry Detergent by Treatment



Notes: The question was: "Please take a look at the two laundry detergents. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.

Number of observations: N=4,003

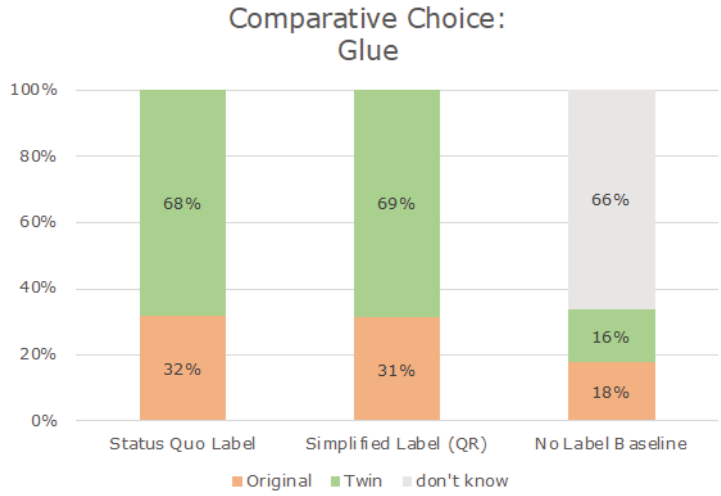
Source: ConPolicy analysis of the experiment and survey data.

Furthermore, the data from the comparative choice task shows that **72%** of the participants **zoomed** in **on both labels** displayed on screen. **21% consulted one** of the two labels and **8% did not zoom**. Among those who zoomed in on both labels 66% were able to correctly identify the less harmful product. The share among those who only consulted one of the two labels was

55% and among those who zoomed in on none it was 47% (difference highly statistically significant, p<0.001).

The comparative choice task for the **glue** was designed such that the original product was more harmful than its twin. Hence, correctly interpreting labelling information would lead participants to choose the twin product. Figure 54 displays the results by treatment. Again, the majority of participants (**69%**) in the **Simplified Label** treatment were able to make the **correct** choice. The share for the Status Quo Label is 68% and for the No Label Baseline it is 16%. When comparing the distribution of correct answers by treatment it can be found that the Simplified Label treatment and the No Label Baseline are highly statistically different (p<0.001). The difference between the Simplified Label and the Status Quo Label, on the other hand, is not significant (p=0.77).

Figure 54: Comparative Choice Task Glue by Treatment



Notes: The question was: "Please take a look at the two glues. Taking into consideration the information available here, which product is less harmful, i.e. less hazardous for human health or the environment?". "Don't know"-category only available for No Label Baseline.

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

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

In conclusion, the results from the comparative choice task confirm the findings from the previous question on objective understanding. The **Simplified Label performs significantly better than** the **No Label Baseline**, i.e. having label information allows consumers to make the correct choice. Similarly, the **Simplified Label and** the **Status Quo Label perform**

equally well. Lastly, **consumers were willing to consult** the label to gather relevant information and zooming in on the label partially helped consumers to make a better choice.

8.3.6.5.3 Rating of understandability and ease to find

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

The question on **understandability** was rated on a scale from "very easy to understand" (1) to "very difficult to understand" (5). The average rating over both products and all information elements was 2.00 for the **Simplified Label** which corresponds with **"rather easy to understand"**. The average rating of the Status Quo Label was slightly better with 1.94 which also corresponds with "rather easy to understand". Although the difference between the Simplified and Status Quo Label is weakly statistically significant ($p=0.04$) the absolute difference is rather negligible.

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

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

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

8.3.6.5.4 Conclusion

In conclusion, the results on the fourth research question show that the **Simplified Label with QR code performs significantly better than** the **No Label Baseline**. Hence, providing this

type of labelling information can inform consumers with respect to relevant measures on safe use. Additionally, the **Simplified Label performs equally well as** the **Status Quo Label**, with the **exception of ingredients information** where the Status Quo Label performs slightly better.

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

Lastly, **both labels** are also **subjectively rated very positive**, i.e. with respect to subjective understanding and ease to find relevant labelling elements. The Status Quo Label under current regulation is rated slightly better than the Simplified Label. Nevertheless, the difference is not great and hence, both labels should be interpreted as equally good.

8.3.6.6 8.3.6.6 RQ 5: Do consumers prefer information to remain on the physical label or to be communicated via digital tools?

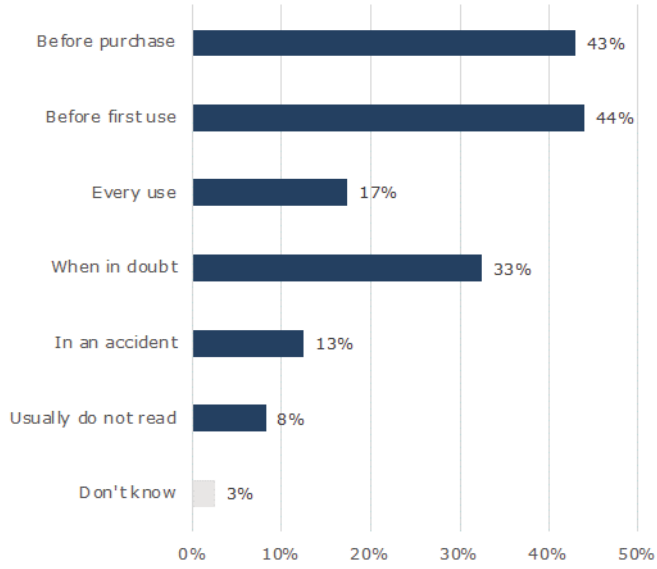
The fifth research question focusses on consumers' preferences regarding the ways to communicate CLP- and Detergents-relevant information. As the previous section demonstrated, both the Status Quo Label under current regulation and the Simplified Label with a QR code performed equally well with respect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

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

8.3.6.6.1 Reading Behaviour

As a first step, participants were asked about their reading behaviour of chemical labels, i.e. the point in time when they would usually read safety information. Figure 55 displays the results. The most frequent answers with **44% and 43%** respectively indicated reading the **label before first use or before purchase**. 33% said to read it when in doubt and 17% every use. 13% indicated to read it in case of an accident and only 8% said not to read the label.

Figure 55: Reading Behaviour of Labels



Notes: The question was: "When do you usually read the safety information on a label of a chemical product such as a laundry detergent or glue? (Select all that apply)"

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

Hence, the point in time when consumers usually consult labelling information is either **at purchase** (before buying the product) **or before using the product** at home. Hence, the means of communicating relevant information on safe use, ingredients and dosage should be tailored to these situations. The share of consulting the label in case of an accident was comparatively low which might be because not too many consumers "usually" experience accidents with chemical products. When looking at the results from the third research question, it can be seen that consulting the label in case of an accident is indeed a relevant measure to prevent adverse effects.

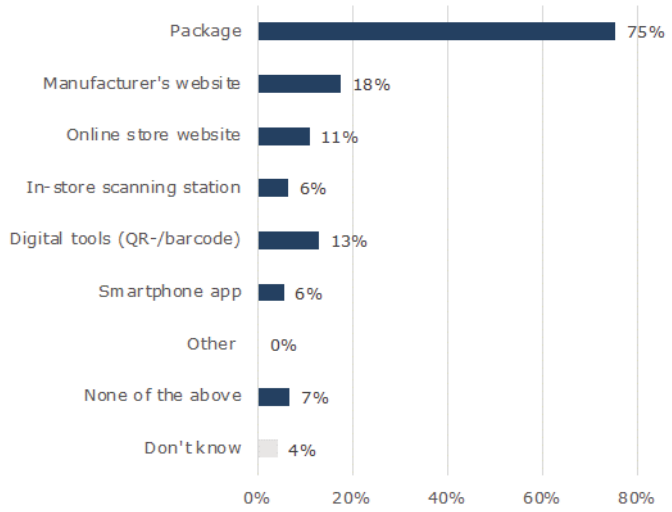
8.3.6.6.2 Information Channels

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

Figure 56 displays the results by information channel. The **vast majority** of participants **(75%)** indicated that they would **consult** labelling information **via the physical packaging.** All other means were less popular. 18% chose the manufacturer's website, 13% digital tools such as QR- or barcodes, 11% an online store website and 6% an in-store scanning station or smartphone app. The percentage of consumers who are willing to **consult at least one digital tool** is **35%**.[55]

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

Figure 56: Willingness to Consult Labelling Information via different Information Channels



Notes: The question was: "When purchasing or using a chemical product such as a laundry detergent or glue, would you actively consult use instructions, information on hazards or precautions via any of the following means: (Select all that apply)"

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

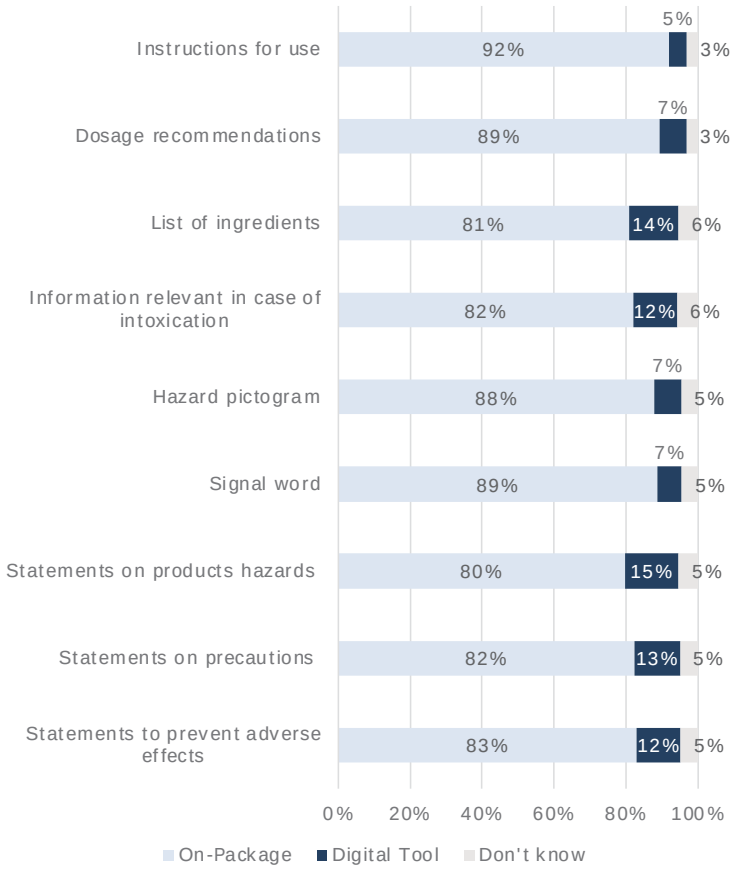
In conclusion, the results are a first indication that physical labelling is the preferred option. The vast **majority** indicated to be willing to consult information **via** the **packaging** of the product. Nevertheless, it must also be noted that **approx. one third** of the consumers are **at least willing to consider digital means**.

8.3.6.6.3 Preference for Communicating Label Elements (analogue versus digital)

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

Figure 57 shows that for all types of labelling elements the **majority of over 80% prefers physical labelling over digital tools**.

Figure 57: Preference for Communicating Label Elements (analogue versus digital)



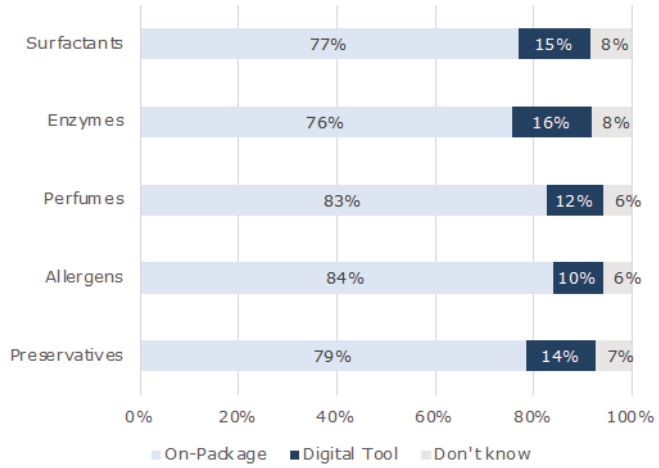
Notes: The question was: "Thinking of a product label for a chemical product such as a laundry detergent or glue, how would you like to receive the following product information: You can either choose to have it on the package label or to access it through / by using a digital tool such as websites,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

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

Furthermore, the question was repeated for ingredients contained in detergent products. Participants again were asked to choose among physical or digital labelling for a list of specific laundry detergent ingredients. Again, the results confirm previous findings (see Figure 58). For all different types of specific ingredients potentially contained in detergents, **approx. 80% preferred the physical label over digital means**.

Figure 58: Preference for Communicating Ingredient Information (analogue versus digital)



Notes: The question was: "Thinking of a product label for a laundry detergent in specific, how would you like to receive the information on certain / some of the ingredients contained in the product:"

Number of observations: N=4,003

Source: ConPolicy analysis of the experiment and survey data.

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

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

8.3.6.6.4 Conclusion

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

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

Nevertheless, the results demonstrate that when consumers would need to decide between either physical labelling on the packaging or digital tools, their preferences are clear. The

majority prefers physical over digital labelling when it comes to relevant CLP- and Detergents-information. A potential explanation could be consumers' age and their digital readiness. Nevertheless, the analysis only indicates the effects to be small.

Annex 9 ANNEX 9 SIMPLIFICATION MEASURES

9.1 9.1 LABELLING OF PROFESSIONAL DETERGENTS THROUGH SAFETY DATA SHEETS ('SDS')

9.1.1 9.1.1 The problem

The evaluation found that an inconsistency exists between the requirements for compiling a SDS under REACH and the labelling requirements of the Regulation for industrial and institutional detergents that can be provided in a SDS as an alternative to the on-pack label. 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 Regulation. The guidance[56] has clarified that the criteria for listing ingredients according with the Regulation differ in three important aspects from the corresponding criteria for Section 3 of the safety data sheet as detailed in Annex II to REACH:

- The specification of ingredients according to the Regulation is not dependent on whether these ingredients are hazardous or non-hazardous. In this sense the Regulation only provides a list of selected substances to be specified, whereas REACH requires that only hazardous substances or substances with specific characteristics are listed in the safety data sheet;
- For the listing of hazardous substances in the safety data sheet REACH refers to the concentration thresholds set in the CLP Regulation. These concentration thresholds are different from those provided for the listing of ingredients under the Detergents Regulation; and
- The format of listing substances under the two Regulations can sometimes differ: the safety data sheet requires the listing of individual hazardous substances while for certain ingredients[57] the Detergents Regulation requires the listing of classes of substances.

As a result, a single ingredient list cannot be expected to successfully meet the requirements of both pieces of legislation. However, according to the guidance, both lists (i.e. the list of substances to be listed in Section 3 of the safety data sheet according to REACH, and the list of detergent ingredients according to the labelling requirements of the Detergents Regulation) can be displayed under Section 3 of the safety data sheet, as long as they are clearly distinguished from each other by means of suitable (sub) headings indicating to which piece of legislation they apply.

Despite the existing guidance, stakeholders sustained that these inconsistencies could result in lack of clarity for workers and create an unnecessary burden on micro and small-sized manufacturers dealing with multiple pieces of legislation with different requirements.

During the consultation for this Impact Assessment, stakeholders did not identify this as a significant issue. While several manufacturers confirmed the existence of the above described inconsistency, they did not classify this a 'major issue' for the industry. Similar views were

[56] European Commission (2018): Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, available at: http://ec.europa.eu/DocsRoom/documents/19522/attachments/1/translations/en/renditions/native

[57] Enzymes, disinfectants, optical brighteners and perfumes (Annex VII A to the Detergents Regulation).

also expressed by national authorities. Although the need for clarification was requested in a few cases, all respondents agreed this could be done with guidelines and not as a change to the Regulation. The only exception is one authority that suggested the simplification of Section 3 of Annex II to REACH.

9.1.2 9.1.2 The policy option

This policy option suggests that a provision will be included in the revised Regulation to explicitly refer to a suitable section of the SDS in which the specific labelling information for professional detergents should be included so that this information is clearer to professional users. This option is a simplification of the implementation of the existing requirements which will impose no additional costs to the industry but which will provide a clarification to professional users and will facilitate manufacturers when compiling the SDS for professional detergents. The intervention is linked with the second specific objective (SO2) i.e. to provide an optimised protection of human health and the environment.

9.2 9.2 CARRY-OVER PRESERVATIVES

9.2.1 9.2.1 The problem

The evaluation identified an issue related to the labelling of preservatives in detergents. The Regulation requires that, if added, preservatives shall be listed irrespective of their concentration on detergents labels. This provision of the Regulation has been subject to different interpretations and poses certain issues with regards to the labelling of what is often referred to as 'carry-over preservatives'. Carry-over preservatives are preservatives that are not added in the detergent as such by the detergent manufacturer, but are present in a mixture which the detergent manufacturer incorporates in the detergent (constituent mixture). Traces of the preservative that was included in the constituent mixture can be therefore found in the final product (i.e. the detergent) in small concentrations.

Companies, industry associations and Member State authorities noted that it is not clear how carry-over preservatives should be dealt with within the context of the Regulation and if the above mentioned provision is applicable to them as well. This lack of clarity results in differences in the implementation and enforcement of this provision of the Regulation alike.

For example, one consumer organisation noted during the consultation for the evaluation that carry-over preservatives are not always listed on the label and that only preservatives that preserve the final product are. An industry association highlighted the example of a company that had declared the use of a substance (a carry-over preservative) in a detergent on the product label even though it was included in the detergent at a concentration below the limit of detection. The company had received an official complaint by the authorities who indicated that the substance had been incorrectly labelled (because the authorities were unable to detect it). Another industry stakeholder indicated that the ability to test for substances used in products has increased over recent years and that the most important consideration is that substances used in detergents are below the levels deemed to cause any adverse impacts.

9.2.2 9.2.2 The policy option

In the revised Regulation, it will be clarified that carry-over preservatives will need to be listed on detergents labels unless these do not present an adverse effect even for sensitised persons or they are technically unavoidable. This policy option contributes to the achievement of the second specific objective (SO2 - optimised protection of human health and the environment).

9.3 9.3 AMBIGUOUS DEFINITIONS

9.3.1 9.3.1 The problem

During the consultation for the evaluation stakeholders reported that some of the definitions provided in Article 2 of DETREG are unclear or open to interpretation. The definitions that were identified as posing a particular issue in this regard are the following:

- Detergent (Article 2(1));
- Cleaning mixture (Article 2(1));
- Other cleaning and washing mixtures (Article 2(1)); and
- Cleaning (Article (2(3)).

These stakeholders claimed that this results in lack of clarity as to whether some of the products available on the market fall under the scope of the Regulation or not. During the Public Consultation for this initiative responses were split almost precisely in half (50/50) as to whether it is always clear if a product fall under the scope of the regulation or not. While business stakeholders believe by over two-thirds (31 out of 41) that it is always clear, public authorities see the exact opposite and more than two-thirds of them (15 out of 19) believe that it is not always clear if a product is a detergent or not within the meaning of the Regulation. Respondents from the civil society and other organisations believe even more strongly that this is not always clear (5 out of 6 responses and 5 out of 5 respectively).

9.3.2 9.3.2 The policy option

The definitions that have been identified as unclear or open to interpretation will be clarified based on existing guidelines. The definitions will in any case need to be revised to accommodate new products (microbial cleaning products) and clarify sustainable new practices (refill sales). During the Public Consultation for this initiative, the majority of respondents mentioned that clarifying the definitions would provide legal certainty, facilitate the work of manufacturers and Member States authorities and level the playing field for detergents manufacturers[58]. Clarifying the definitions will also contribute to the achievement of SO1 as it could facilitate the take up of new products and practices in the future, and will help reduce uncertainties in the implementation of the Regulation.

[58] 27 out of 121 respondents stated that it would not yield any benefits for detergents manufacturers or Member State authorities. It should be noted that this was a multiple choice question.

9.4 9.4 LABELLING OF DISINFECTANTS

9.4.1 9.4.1 The problem

Detergents that have an antibacterial function or contain a preservation agent are required to comply with the provisions of both the Detergents Regulation and the Biocidal Products Regulation. The rules apply to both laundry and dishwasher detergents as well as other detergent types, covering detergents for consumer, professional and industrial use.

Under the Detergents Regulation, surfactants that are also active substances within the meaning of the Biocidal Products Regulation and that are used as disinfectants are exempt from the biodegradability criteria of the Detergents Regulation provided that they are either approved active substances or authorised constituents of biocidal products under the Biocidal Products Regulation[59]. These surfactants and the detergents that contain them do, however, need to comply with the labelling provisions of the Detergents Regulation.

During the consultation, several stakeholders noted that there is an overlap between the Detergents Regulation and the Biocidal Products Regulation in the sense that detergents that are also used as disinfectants would need to comply with the labelling provisions of both. As the labelling requirements for these ingredients differ between the two Regulations, this often leads to duplicate labelling i.e. the same substance being labelled twice, once following the provisions of the Detergents Regulation and once those of the Biocidal Products Regulation.

9.4.2 9.4.2 The policy option

The duplicated requirement to label disinfectants will be removed from the Detergents Regulation. This policy option will further increase the readability of detergents labels and reduce burden for detergents manufacturers, thus contributing to SO3 and SO4 of this initiative.

9.5 9.5 NLF ALIGNEMENT

9.5.1 9.5.1 The problem

Decision 968/2008[60] lays down a common framework for the marketing of products in the Union by establishing a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products as well as a reference text for existing legislation. Its main objective is to improve market surveillance and clarify and strengthen the conformity assessment procedures through which products can be CE marked and move freely in the internal market.

The Regulation dating from 2004 is not aligned with the New Legislative Framework ('NLF') that the above Decision has established. As a result the Regulation is first not aligned with other Union product legislation and secondly not able to fully take advantage of the opportunities that this framework offers.

[59] Article 3 of the Detergents Regulation.
[60] Decision No 768/2008/EC of the European parliament and of the council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

9.5.2 9.5.2 The policy option

This option suggests to align the Regulation with the NLF. While this option was not strongly supported by industry stakeholders who indicated in their responses to the IIA their preference for maintaining status quo, an alignment with the NLF is, nevertheless, considered appropriate and necessary in order to, on one hand, facilitate the work of economic operators that would have the same obligations as under all sectoral Union legislation already aligned to NLF and, on the other, to facilitate the work of market surveillance authorities.

As part of this alignment a digital product passport for detergents and surfactants will be introduced in the revised Regulation. This product passport should replace the EU declaration of conformity under Directive 2009/48/EC and include the elements necessary to assess the compliance of the detergent or surfactant with the applicable requirements and test methods. Through the data carrier, market surveillance authorities, economic operators and consumers should have immediate access to compliance or other information on the detergent or surfactant.

SME TEST

The initiative is considered as relevant for SMEs.

Step 1/4: Identification of affected businesses

Main affected businesses are manufacturers of detergents. Manufacturers encompass a wide range of players in the industry, covering small, medium and large enterprises that manufacture and sell an extensive and diverse range of products. Eurostat does not contain granular data on sizes of companies in the detergents sector as the relevant category is wider than the products falling under the scope of the Detergents Regulation[61]. However, using this category as a proxy for the detergents industry, we can gain an insight into the size composition for the sector. In general, SMEs are estimated to represent more than 92% of the overall companies in the detergents sector, generating about 11% of its turnover. In 2018, 7,568 enterprises in the sector were microenterprises (less than 10 employees) amounting to a total of 78% of the total number of companies, while small and medium enterprises represented about 8% and 6% respectively (see also Annex 6) [62].

Distributors and retailers of detergents and professional users (professional cleaning and hygiene sectors) are also affected.

Two types of policy options have been assessed and these affect differently the SMEs:

- Currently refill sales and microbial cleaning products are being actively undertaken mostly by SMEs in the EU, and this makes option 1b (facilitate the refill sales and introduce new requirements for microbial cleaning products) one which mainly impacts SMEs.
- Option 2b (abolishment of duplicated ingredient data sheet and streamline and simplify labelling requirements via the introduction of digital labelling), uniformly affects the sector overall, and hence also SMEs.

Key question: **To what extent is the initiative relevant for SMEs?** (not relevant, relevant, highly relevant)

This initiative is considered relevant for SMEs, as these constitute the main players in the manufacturing of microbial detergents and in refill sales. The initiative was considered as relevant for SMEs by the SME Filter.

Step 2/4: Consultation of SME Stakeholders

Acknowledging the importance of SMEs in the sector, several efforts were made to reach out to as many SMEs as possible and gather their views on the proposed intervention. The responses and concerns of SMEs as expressed during the consultation activities for this impact assessment have been duly considered and accounted for.

[61] The relevant category is NACE 20.41 "Manufacture of soap and detergents, cleaning and polishing preparations". This includes some products that are included in Detergents Regulation, but also contains glycerol and manufacture of polishing products, perfumes and toilet preparations which are largely out of its scope.

[62] 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).

In particular, consultation with SMEs representatives has taken place through the following (for details see synopsis report in Annex 2):

The Commission published an Inception Impact Assessment[63] to inform citizens and stakeholders about the Commission's plans to revise the Detergents Regulation. During the consultation period (21 September 2021 - 19 October 2021) all interested 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, including a response from SME United, which is the main EU business federations grouping SME trade associations.

A Public Consultation (PC) was launched on 02 March 2022, and remained open until 25 May 2022, for a total of 12 weeks[64]. In total, 126 replies were recorded to the PC, coming from 21 EU Member States and 5 non-EU countries. Of those: 21 replies were from SMEs: 6 from micro (<10 employees), 11 from small (< 50 employees), and 4 from medium (< 250 employees). SME United also contributed to the PC. In an attempt to maximise SME participation and feedback on this initiative, the link to the PC and the questionnaire for the targeted consultation were also disseminated to SMEs through the SME Envoy Network.

Finally, several targeted interviews were undertaken. These included nine SMEs, as well as SME United. The responses and concerns of SMEs have been taken into account in the assessment. In cases where there were doubts, questions were followed up with additional interviews and email exchanges. During these interviews, no specific issues were raised by SMEs and where costs were identified, these were considered acceptable by them.

Step 3/4: Assessment of the impact on SMEs

When conducting the SME test, we have established that adding labelling requirements under policy option 1 (a and b) to inform consumers about the presence of microbes in detergents could be done at negligible costs for manufacturers and distributors. In addition, for those SME companies currently working on “known microbes” the costs of introducing new requirements on those products under policy option 1b will be negligible, as most of the microbes are already part of both the QPS list and Risk Group 1 (tests of exclusion of pathogens and antibiotic resistance are already being undertaken or can be done at negligible cost). Those firms will be able to work and expand their production at no cost. The policy option allows working in new strains for R&D purposes, but given the uncertain state of scientific evidence about possible harms from those new microbes, it also foresees that these can be placed on the market after a report has been produced by a scientific body based on a mandate stemming from the introduction of a review clause in the revised Regulation. Because at the moment most manufacturers are working with known microbes, this is expected to have little impact on SMEs. It is clear that as a result of the option, trade across the EU of microbial products would become easier, as a harmonised framework would be provided for such products, making intra-EU trade less costly also for small operators. However, the overall impact will be small, as the market for these products is currently very small (although it may grow over time). In any case, positive impacts would benefit mostly

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

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

SMEs, which represent most of the economic actors in this market. The intervention on refill sales under policy option 1 will modify labelling requirements for those sales, thus affecting administrative burdens borne by companies along the value chain (manufacturers and distributors). At the same time, the proposed changes would allow companies to use e-labelling as well as other forms of labels, including stickers and printouts of labels, which would reduce administrative burdens for manufacturers. In summary, we have concluded that this option would support the development of the refill distribution channels which could benefit existing players, including small ones, as well as attract new entrants (most likely SMEs) into this market. Intervention would be done in a way that does not result in additional burdens but rather provides clarity and legal certainty for manufacturers and retailers of refill detergents, all of which will benefit refill distributors that mostly consist of SMEs. In any case, by harmonising rules for refill sales, this option would prevent any emerging national diverging regulations for this new sales method. Therefore, it would avoid that barriers to trade emerge within the EU.

The net impact of abolishing duplicated ingredient data sheets and of streamlining and simplifying labelling requirements via the introduction of digital labelling under policy option 2b will result in cost savings for the industry, including SMEs. The burden savings achieved under this option are low to moderate, and hence unlikely to generate major market impacts. However, they would particularly benefit SMEs, since the burdens for compiling data sheets is a fixed cost, irrespective of the turnover / sales generated by the product and company. Under this option the functioning of the Single Market will also be improved because of a more even level-playing field, the elimination of current discrepancies among Member States in the application and enforcement of the existing information requirements. Finally, a more widespread use of e-labels would reduce burdens due to redesign, since online information is less costly to amend. However, the positive impact would be less significant for SMEs than for larger companies. This is largely because SMEs are more likely to lack the IT skills necessary to transition to digital labelling, as well have more limited resources to invest in digitalisation. The switch to digital labelling would generate certain administrative burdens, both one-off and ongoing, for setting up an online information repository, but it will not be disproportionate, as these would only be incurred on a voluntary basis. Given the SMEs' lower human and financial resources, targeted support for smaller players to promote digitalisation in this area could be considered.

Overall, the proposed policy interventions favour SMEs and when costs are incurred, these do not overburden SMEs in comparison to bigger enterprises. In particular, additional very small burdens are expected due to the risk management requirements for microbial cleaning products, in the area of €200.000[65]. However, the abolishment of the ingredient data sheet for hazardous detergents would generate cost savings of €7 million per year. The facilitation of refill sales under the revised Regulated is expected to generate further annual cost savings due to reduced disposal of plastic waste. While these could not be quantified, the relevant cost savings under the baseline are within the range of €3.3 million. Even though these cost

[65] This **is an upper bound estimate, calculated on the basis of the average costs for testing and the highest number of batches reported by manufacturers** (see section 6.2.1). It is therefore highly likely that this number will vary depending on: a) the size of the company; b) the number of products in the company's portfolio or batches produced per year; c) whether the tests are conducted in house or outsourced to a laboratory; and d) the extent that the companies are already complying with all or some of these requirements. For example, companies whose products already bear the EU-Ecolabel, having a more limited product portfolio or producing less batches would incur no or minor additional costs.

savings are for the whole detergents industry given that SMEs represent more than 95% of the companies in the sector and that most companies producing refill detergents are SMES, the latter would particularly benefit from these cost savings under the preferred option. Finally, it should be noted that some additional administrative costs savings due to voluntary digitalisation of labels that cannot be quantified could also exist.

Step 4/4: Minimising negative impacts on SMEs

Some measures have been considered to mitigate the impacts on SMEs. These are:

- Allowing a transition period greater than a year (*i.e.* 18 months) for updating labels of detergents.
- Allowing unknown microbes to be used for R&D purposes.
- Allowing unknown microbes to be placed on the market, introduction of a review clause for new ('unknown') microbes (following the report from a scientific body).
- Allowing exclusive digital labelling for refill detergents.

Annex 10 ANNEX 10 MONITORING INDICATORS

Table 33 Overview of indicators for monitoring the impacts of the preferred option

Specific objective	Operational objective	Indicator	Unit of measurement	Baseline (benchmarks for comparison)	Data Source
SO1: Clear and updated rules that level the playing field and allow for innovative products and sustainable new practices	Increased legal certainty and reduced fragmentation of the Single Market	Perceived increased legal certainty and reduced legal fragmentation	% increase of stakeholders declaring legal uncertainty	Stakeholders reported both during the consultation for the Evaluation and this Impact Assessment legal uncertainty and a lack of level playing field both for refill sales and microbial cleaning products	Study/ consultation__of stakeholders /
	Incentivise growth of refill sales	Growth of the refill sales of detergents	% growth of sales	1-2% of the overall detergents market	Study/ consultation__of stakeholders
	Increased compliance with labelling by the refill sector	Rate of compliance with the provision of labelling by the refill sector	% increase of compliance rate	50% non-compliance*	Consultation of market surveillance authorities within the Detergents Working Group/ Market surveillance findings in the internet-supported

					information and communication system for the pan-European market surveillance (ICSMS)
		Uptake of digital labelling within the sector (including for refill sales)	% of uptake of digital labelling	Baseline data not available given that these are newly introduced requirements-benchmarks to be established during the evaluation	Study/ consultation of stakeholders /
		Rate of compliance with the provision of labelling information online	% increase of compliance with the requirement to maintain a website with a full ingredient list	40% of non-compliance with the website rules (either providing the address on the label or the full list of ingredients on the website)	Study/ consultation of stakeholders / consultation of market surveillance authorities within the Detergents Working Group / Safety Gate notifications (e.g. RAPEX)
SO2: Optimised protection of human health and the environment	Increased safety from the introduction of safety requirements for microbial cleaning products	Perceived safety from the introduction of safety requirements for microbial cleaning products	% of compliance of microbial cleaning products with the new requirements Number of RAPEX notifications	Baseline data not available given that these are newly introduced requirements-benchmarks to be	Study/ desk research / consultation of market surveillance authorities within the Detergents Working Group / Safety Gate

			for microbial cleaning products	established during the evaluation 0 –no RAPEX notification concerning microbial products until 2021	notifications (e.g. RAPEX)
	Increased safety from the introduction of clarified rules for refill sales	Perceived safety from the introduction of clarified rules for refill sales	Number of RAPEX notifications for refilled detergents Consumers perception of safety of refilled detergents	0 –no RAPEX notification concerning refilled sales of detergents Baseline data not available given that this type of sale was previously not explicitly covered by the Regulation - benchmarks to be established during the evaluation	Study/ desk research / consultation of market surveillance authorities within the Detergents Working Group / Safety Gate notifications (e.g. RAPEX)
SO3: Burden reduction for detergents	Reduction of relabelling costs due to simplification and	Reduced re-labelling costs	% of reduction of re-labelling costs and potential changes in the	Stakeholders highlighted high labelling costs for	Study/desk research/consultation of stakeholders

manufacturers	digitalisation of labels		labelling cycle	detergents during the consultations both under this IA and the Evaluation - benchmarks to be established during the evaluation	
	Reduction of plastic waste and unused label stock	Increased reduction of plastic waste and unused label stock	% of reduction of plastic waste and unused label stock	Estimated monetary value of unused label stock under baseline - 3.3. million annually	Study/desk research/consultation of stakeholders
SO4: Improved consumer understanding and awareness of labels	Reduction of accidents, or poisoning incidents with detergents	Increased reduction of accidents, or poisoning incidents with detergents	% of poisoning incidents with detergents	benchmarks to be established during the evaluation	Study/desk research/ consultation of poisoning centres
	Ease of readability and understandability of labels	Consumer perception of simplified labels	Increased ease of readability and understandability of labels compared to the baseline	Consumers do not understand current labels that are overloaded with information and include duplications Consumers do not	Study/desk research/consultation of stakeholders

				easily locate the relevant information on detergents labels	
	Use of digital labelling by consumers and level of awareness and understanding of labelling information	Number of consumers using the digital label and impacts on awareness and understanding	Wide use of digital labelling by consumers and increased level of awareness and understanding of labelling information	benchmarks to be established during the evaluation	Study/desk research/consultation of stakeholders

* Rate of non-compliance of refill detergents with the CLP requirements and assumed the same with the similar requirements under the Detergents Regulation since in most cases consumers bring their own bottle to (re)fill in store from a larger container and this bottle either bears the wrong or no label at all (see section 3 of the report).

Annex 11 ANNEX 11 CONCLUSIONS OF THE DETERGENTS EVALUATION AND THE CHEMICALS FITNESS CHECK

11.1 11.1 DETERGENTS EVALUATION

11.1.1 11.1.1 Relevance

The findings of this evaluation indicate that the objectives of the Detergents Regulation (i.e. to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health) are still relevant considering the evolution of societal needs and technological developments. The new limits introduced in 2012 on the phosphorus content of consumer laundry detergents and consumer automatic dishwasher detergents, for example, were seen as a positive adaptation to changing needs.

A key issue that was identified is that the concepts and definitions used in the Detergents Regulation may not always be in line and coherent with the meaning they have gained over time and in practice. This results in lack of clarity on whether certain products available on the market fall under the scope of the Regulation or not (e.g. microbial cleaning products).

There are some areas where the Regulation has not kept pace with technical and other developments. For example, the labelling requirements of the Regulation are not well adapted to the recently developed practice of the refill sale of detergents and the dosing instructions might need to be adapted to the current size of standard washing machine loads.

11.1.2 11.1.2 Coherence

The provisions of the Detergents Regulation were found to be internally coherent with no major gaps or inconsistencies existing among them.

Some gaps were identified between the Detergents Regulation, the Cosmetic Products Regulation and the Biocidal Products Regulation. These gaps relate to the lack of specific provisions to restrict or ban the use of category 2 Carcinogenic Mutagenic and Reprotoxic substances ('CMRs') in detergents and the lack of specific labelling requirements for nanomaterial ingredients in the Detergents Regulation. While no evidence exists about the use of category 2 CMRs in detergents, it is however true that these substances are treated differently under the Detergents Regulation and the Cosmetic Products Regulation even though detergents and cosmetics are similar formulations to a large extent and certain detergents are comparable to rinse-off cosmetics in the sense that they come in contact with the human skin. No impacts have been reported from this inconsistency neither from the detergents industry's point of view nor from a consumer perspective.

A similar gap exists with regards to nanomaterial ingredients in detergents. While for both biocides and cosmetics specific labelling requirements are in place under the respective Regulations, no such requirements exist under the Detergents Regulation. It should, however, be noted that substances in nanoform that trigger a classification under the CLP Regulation would be labelled on detergents following the labelling requirements of the CLP Regulation.

The only difference with the requirements for cosmetic and biocidal products would be that in this case the word ‘nano’ would not be added next to the substance contained in the detergent in a nanoform. While it is understandable that such a reference would improve the communication of information to consumers, the extent to which this information would be useful to them needs to be further explored.

Some overlaps and inconsistencies were identified between the Detergents Regulation and other pieces of EU chemicals legislation, i.e. the REACH Regulation, the CLP Regulation, the recently added Annex VIII to the CLP Regulation harmonising the information relating to emergency health response and the Biocidal Products Regulation. These overlaps often result in duplications in the labelling of substances/ingredients on detergents' labels. The principal areas of overlap/inconsistency are as follows:

- **The Detergents Regulation and the REACH Regulation:**
    - An overlap between the ingredient data sheet under the Detergents Regulation and the safety data sheet under REACH was identified. The findings of this evaluation do not allow however to conclude with certainty what exactly the impact of this overlap is and whether it would be possible to rely on only one of these data sheets to achieve the purposes of both.
    - Inconsistencies were found between the requirements for compiling a safety data sheet under REACH and the labelling requirements of the Detergents Regulation for industrial and institutional detergents that can be provided in this safety data sheet (as an alternative to on-pack label). These inconsistencies could result in lack of clarity for workers and create an unnecessary burden on micro and small-sized manufacturers dealing with multiple pieces of legislation with differing requirements.

- **The Detergents Regulation and the CLP Regulation:** Legislative overlaps were identified between the Detergents Regulation and the CLP Regulation, notably with regard to the labelling of allergenic fragrance ingredients. As the labelling of detergents falls by default under these two pieces of EU legislation, this overlap may lead to the labelling of the same substance twice or thrice on the same label and most of the time under completely different names. This contributes to the overload of detergents labels, which on one hand can be detrimental to consumer understanding and on the other creates an unnecessary regulatory burden for the detergents industry.

- **The Detergents Regulation and Annex VIII to the CLP Regulation:** The ingredient data sheet under the **Detergents** Regulation serves a similar purpose as the harmonised information that will need to be provided to poison centres under the recently added Annex VIII to the CLP. When the CLP requirements start applying, the abolishment of the ingredient data sheet related provisions under the Detergents Regulation should be considered in order to avoid duplication and reduce administrative burden for detergents' manufacturers.

- **The Detergents Regulation and the Biocidal Products Regulation:** An overlap exists between the Detergents Regulation and Biocidal Products Regulation in the sense that detergents that are also disinfectants are subject to the labelling requirements of both Regulations which however often differ from one another. This overlap creates a duplication in the labelling requirements that contributes to the overload of detergents labels

and can be detrimental to the communication of use and safety information to consumers and an unnecessary regulatory burden for the detergents industry. A potential inconsistency also exists between these two Regulations with regards to the labelling requirements for what are often referred to as 'carry-over preservatives'. The relevant provision of the Detergents Regulation is currently subject to different interpretations by manufacturers and Member State authorities alike. Discussions on the correct implementation of this provision of the Detergents Regulation are already being held between the Member States' competent authorities and the European Commission in the Working Group on detergents.

The above-mentioned duplications and overlaps in the labelling requirements for detergents result in unclear information to consumers. As a result, consumers may not easily understand the information provided on the label with negative impacts on the protection of their health and the environment. Duplications in the labelling requirements also create an unnecessary burden for the detergents industry. Therefore, this issue needs to be addressed with priority.

11.1.3 11.1.3 Effectiveness

The Detergents Regulation has helped to harmonise the rules in place in different Member States, thus making it easier for companies to trade cross-border. The harmonised rules for placing detergents and surfactants for detergents in the internal market have levelled the playing field for detergents manufacturers. Data from Eurostat, supported by more concrete and recent data from the detergents industry show a steady growth of both the detergents market and the detergents industry since the entry into force of the Detergents Regulation.

The biodegradability requirements for surfactants provide a high degree of protection of the environment. Moreover, the restrictions on the phosphorus content for consumer laundry and consumer automatic dishwasher detergents have been largely effective in reducing the amount of phosphorus/phosphate used in these products. The impact of the harmonised limits is more noticeable in the case of consumer automatic dishwasher detergents where only four Member States had restrictions in place before the intervention at EU level. Due to several limitations it has not, however, been possible to quantify the exact contribution of these limits in reducing eutrophication.

Dosing instructions are generally perceived as an effective means of reducing the over consumption of detergents. However, part of the dosing information that is currently required under the Detergents Regulation is out of date (e.g. size of standard washing machine loads). This factor combined with the fact that consumers may not read, understand or correctly follow these instructions, reduces the effectiveness of the Regulation to protect the environment. Updating and simplifying the dosing instructions of the Detergents Regulation should therefore be considered.

A key issue that has arisen is a duplication in the labelling requirements for detergents that fall within the scope of multiple pieces of EU legislation (i.e. the Detergents Regulation, the CLP Regulation and the Biocidal Products Regulation). Detergents labels can become overloaded with information e.g. too much text, too long and not meaningful chemical names to non-professional users that make it difficult for consumers and downstream users to focus on the essential hazard and safety information and use instructions. Too much information provided on detergents labels may be detrimental to consumer understanding and reduces the

effectiveness of the Regulation in terms of protecting human health. It also creates an unnecessary regulatory burden for industry.

This issue could be addressed with the use of innovative communication methods and digital tools (e.g. Q-R codes) which are now available and already used on some detergents available on the EU market. This way, some of the ingredient information currently indicated on detergents labels would be provided online, and linked to the product using a Q-R code. Several aspects related to the use of digital tools, such as data safety issues, access to an internet enabled portable device (e.g. mobile phone, tablet computer, etc.) and assessment of the type of information that could be provided through these tools need however to be further examined.

Member States have put in place a variety of sanctions for infringements of the Detergents Regulation. Based on the available information these sanctions were found in theory to be dissuasive, effective and proportionate. However, due to lack of sufficient data, it has not been possible to conclude with certainty whether the enforcement activities of Member States are able to ensure the appropriate enforcement of the Detergents Regulation. Based on the perception of stakeholders the enforcement of the Detergents Regulation is at least "somewhat effective". In this respect, the introduction of reporting obligations for Member States under the Detergents Regulation could improve the availability of data, thus allowing us to better assess its enforcement.

11.1.4 11.1.4 Efficiency

The total cost to the detergents industry from the Detergents Regulation has been estimated at EUR 764 million to EUR 1.8 billion (2004-2016). Compared to the annual turnover of the detergents industry these costs appear to be proportionate (the costs are less than 0.5% of the annual turnover). The largest costs are estimated to have arisen as a result of the need to use different raw materials in place of phosphorus, from having to provide ingredient data sheets to poison centres and from the research and development necessary for reformulation in order to meet the phosphorus limitations for consumer laundry and consumer automatic dishwasher detergents ('CADD'). No quantification of costs incurred by other actors than industry authorities was carried out. No quantified cost figures were available regarding enforcement costs borne by public authorities.

In terms of benefits, the Detergents Regulation and its amendments are generally perceived by different groups of stakeholders as providing an enhanced level of protection to human health as well as improved information on product ingredients for consumers. There was general agreement among stakeholders that the Detergents Regulation has helped to level the playing field for manufacturers of detergents and surfactants within the EU. This is also supported by Eurostat and industry data that show a steady growth of both the detergents market and the detergents industry since the entry into force of the Detergents Regulation. The Regulation has also had a positive impact on the environment. This was achieved through the improved biodegradability of surfactants and the reduced amount of phosphorus/phosphate used in consumer laundry and consumer automatic dishwasher detergents. Industry stakeholders also considered that the Detergents Regulation has had a positive impact in terms of innovation. Finally, most industry stakeholders were of the opinion that the Regulation has improved the corporate image of the sector.

It is difficult to attribute any quantified benefits associated with reduced eutrophication to the Detergents Regulation via the introduction of limits of phosphorus content in detergent products.

As no quantified estimates of benefits were available, the answer to the question whether costs of implementing the Detergents Regulation are justified takes into account stakeholder views expressed during the different consultation activities carried out for the purposes of this evaluation. These views suggest that costs involved in implementing the Detergents Regulation are justified.

11.1.5 11.1.5 EU added value

The harmonisation of rules for making available and placing on the market of detergents has levelled the playing field for detergents' manufacturers and ensured to a large extent the free movement of detergents in the internal market. The Regulation's delivered added value on the protection of human health is also substantive as consumers have now access to the full list of ingredients contained in detergents and can therefore make more informed choices and better protect themselves. The Regulation also had a positive impact on the environment through improved biodegradability rules that require surfactants to be totally broken down into water, carbon dioxide and biomass. These harmonised rules for the biodegradability of surfactants are often regarded internationally as the "golden standard", potentially conferring a competitive advantage to detergents manufactured in the EU. In addition, the phosphorus limits, especially the limits for consumer automatic dishwasher detergents (‘CADD’), were seen as having raised the bar in many countries, where similar limits were not already in force. For these reasons, there was widespread consensus among all stakeholders that the issues addressed by the Detergents Regulation continue to require action at the EU level.

11.2 11.2 BACKGROUND AND RELEVANT CONCLUSIONS OF THE CHEMICALS FITNESS CHECK

The Commission undertook the Fitness Check in 2015[66]. Unlike most evaluations carried out under the European Commission's Regulatory Fitness and Performance programme (REFIT)[67], this Fitness Check was not an evaluation of just one or two pieces of legislation. It assessed over 40 pieces of legislation[68] that cover a great part of the EU chemicals *acquis*. It focused on the chemical hazard and risk assessment and risk management requirements, procedures and processes within the legislation. The legislation within the scope of this Fitness Check regulates both the chemical sector as well as related downstream industries that use chemicals and thus covers the full lifecycle of products manufactured both in Europe and abroad. The REACH Regulation[69], the pharmaceutical and food additives legislation were excluded from the scope

[66] Roadmap is available here http://ec.europa.eu/smart regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf

[67] COM(2012) 746 final

[68] See Annex 4 of the Commission's Staff Working Document on the Fitness Check of the most relevant chemicals legislation (excluding REACH) as well as related aspect of legislation applied to downstream industries: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530884012&uri=SWD:2019:199:FIN

[69] Except its Annex XIII laying out identification criteria for persistent, bioaccumulative, toxic and very persistent and very bioaccumulative substances. Under the REACH Regulation, there is a legal obligation to review the legislation every five years. Findings of the second REACH evaluation are presented in the ‘Commission General Report on the operation of REACH and review of certain elements’ (COM(2018) 116 final) and its accompanying

of this Fitness Check[70]. The assessment provided a first comprehensive presentation of how various pieces of the EU chemicals legislation all fit together and addressed a number of stakeholder concerns expressed during the consultation activities. Its main findings are presented in a Report[71].

The EU chemicals legislation is composed of two horizontally applicable pieces of legislation (CLP and REACH) and around 100 sectoral or product specific pieces of legislation that contain one or more provisions on chemicals and that in some cases have embedded links with each other as well as with the CLP and/or the REACH Regulations[72]. The findings of the Fitness Check showed that different stakeholders, in particular SMEs, struggle with understanding the functioning of the EU chemicals legislation and their legal obligations thus affecting their capacity to comply with it. Cutting the red tape and reducing administrative burden could reduce regulatory compliance costs, increase compliance rates thus also increasing the protection of citizens and the environment. It requires however the simplification of the current regulatory complexity.

The Fitness Check provides a comprehensive assessment regarding the performance of the EU chemicals legislation in light of its objectives of protecting human health and the environment, ensuring the efficient functioning of the single market and enhancing competitiveness and innovation. The following findings of the Fitness check are also highly relevant for detergents:

1. There is room for simplification in the communication of hazard and safety information to consumers and for improvement in terms of its effectiveness and efficiency; and
2. The use of innovative digital tools for the communication of such information is currently suboptimal.

Staff Working Documents (SWD(2018) 58 final). This second evaluation builds on the findings of its first evaluation in 2013 and focused on its developments and achievements since then.

[70] The fact that hazard and risk assessment under the pharmaceuticals and food additives legislation is based on different considerations and underpinning mechanisms explains their exclusion of the scope of this Fitness Check. For example, under the Medicinal Products for Human Use Directive (2001/83/EC) the primary objective is to safeguard public health i.e. treat or prevent disease in human beings, restore, correct or modify physiological functions or make a medical diagnosis.

[71] Report: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN; and Commission Staff Working Document: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530884012&uri=SWD:2019:199:FIN

[72] Please refer to Annex I for the list of 40+ the most relevant pieces of EU chemicals legislation that were in the scope of the recently adopted fitness check (COM(2019) 264); other pieces of legislation are listed in Annex I to the study entitled "Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps" available here https://ec.europa.