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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

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[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.

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[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.

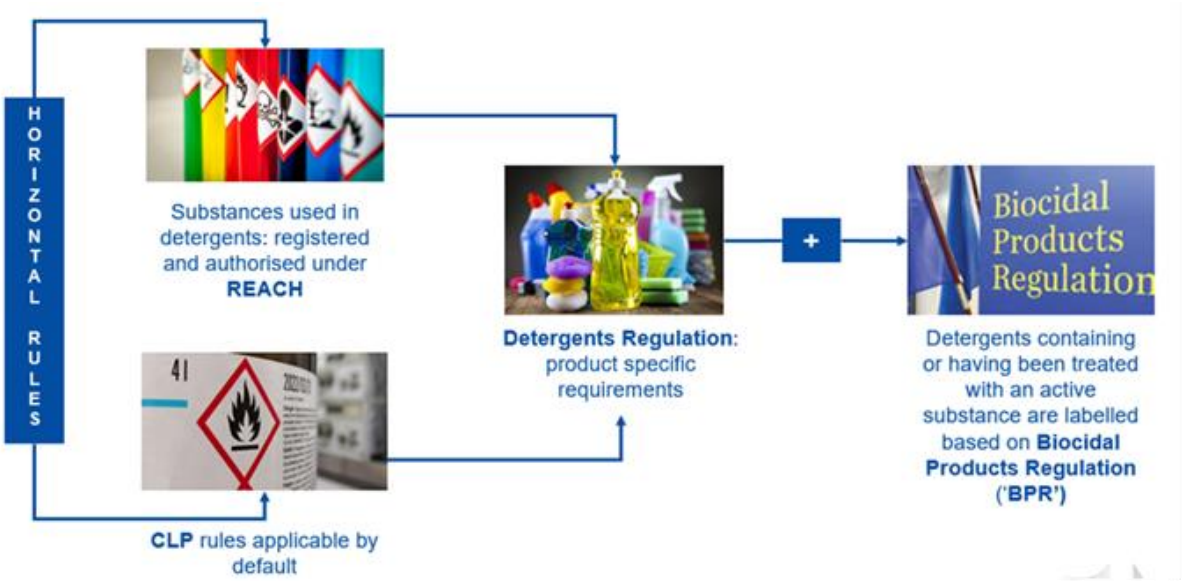

Figure 1 - Overview of the EU Regulatory framework for detergents

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.

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[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).

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[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

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[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

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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].

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[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].

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[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.

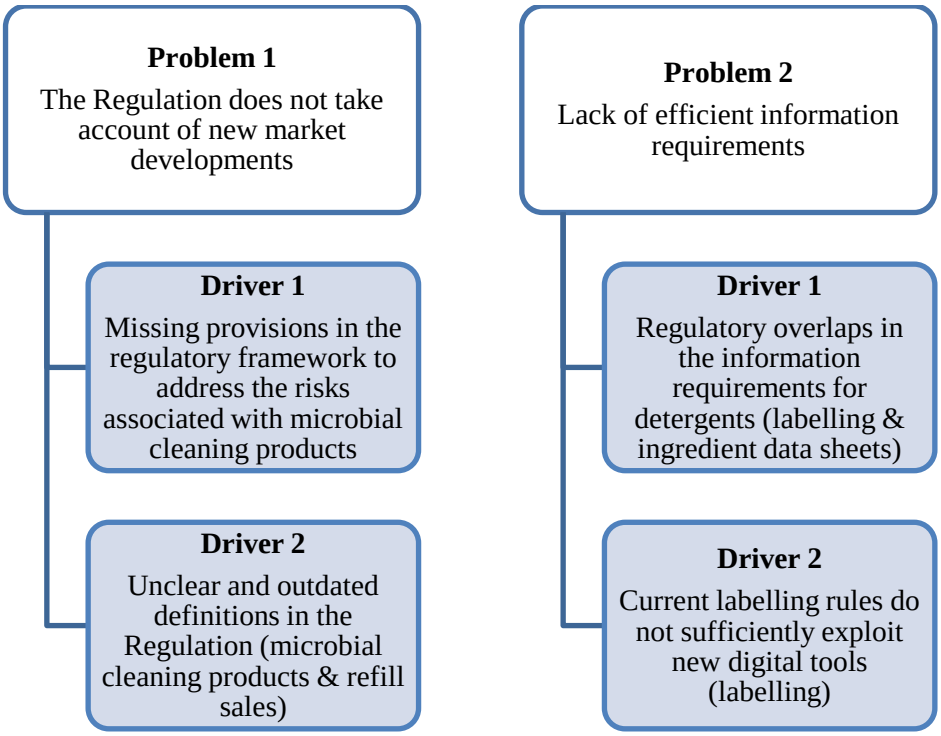
Apart from the above described issues, some other overlaps and inconsistencies in the information requirements for detergents were also identified in the evaluation[78]. Given that the measures to address these are a clarification and/or simplification of the current rules, their impacts have not been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

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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.

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[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.

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[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.

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[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:

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[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]

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[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.

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[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

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[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.

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[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].

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[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.

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[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.