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COMMISSION STAFF WORKING DOCUMENT

EVALUATION

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

{SWD(2019) 299 final}

Glossary.....	4
Introduction.....	5
1 Background to the intervention.....	5
1.1 Description of the initiative.....	5
1.1.1 Evolution and objectives.....	6
1.1.2 Overview of the key provisions of the Detergents Regulation and explanation of the intervention logic.....	7
1.2 An overview of the EU detergents industry.....	10
1.2.1 Detergents industry.....	10
1.2.2 Production of detergents and surfactants for detergents in the EU.....	12
1.2.3 Consumption of detergents and surfactants in the EU.....	13
1.3 Baseline.....	14
2 State of play.....	15
2.1 Member States' implementation and enforcement activities.....	15
2.2 Level of compliance with the Detergents Regulation.....	19
3 Methodology.....	20
3.1 Evidence, data collection and stakeholder consultation activities.....	20
3.1.1 Supporting study.....	20
3.1.2 Stakeholder consultation activities.....	21
3.2 Limitations and robustness of findings.....	22
4 Analysis and answers to the evaluation questions.....	23
4.1 Relevance.....	23
4.1.1 To what extent are the objectives of the Detergents Regulation still relevant considering the evolution of societal needs and technological developments?.....	23
4.1.2 To what extent are the concepts and definitions used in the Detergents Regulation in line and coherent with the meaning they have gained over time in practice and do they cover all the commonly accepted detergents products available on the market?.....	24
4.1.3 Have there been any technical or other developments since the adoption (and further amendments) of the Regulation that were not foreseen in the Regulation that have impacts on the relevance of the Regulation? Have there been any new problems/issues related to detergents, their use and their impact on the environment and human health that are currently not addressed through the Detergents Regulation?.....	27
4.2 Coherence.....	32
4.2.1 To what extent are the Detergents Regulation provisions internally coherent? Do provisions overlap or contradict, do they co-act as intended?.....	32
4.2.2 To what extent is the Detergents Regulation coherent with other EU legislation? Are there gaps between the Regulation and other pieces of legislation? Do provisions overlap or contradict, do they co-act as intended? What impacts do these overlaps have?.....	33
4.3 Effectiveness.....	43

4.3.1	To what extent does the Detergents Regulation meet its objectives, i.e. establishment of a true internal market for detergents, while ensuring a high degree of protection of the environment and human health?.....	43
4.3.2	Which provisions or parts of the Detergents Regulation have met their objectives (i) most effectively (ii) least effectively, and which parts have not met their objectives.	53
4.3.3	To what extent is the Regulation effectively implemented across EU Member States (e.g. enforcement, use of safeguard procedure)? What are the implementation and enforcement measures that have been put in place? Were they adequate?.....	54
4.4	Efficiency.....	55
4.4.1	Costs and cost drivers.....	55
4.4.2	Benefits.....	61
4.4.3	To what extent are the costs involved in implementing the Detergents Regulation justified given the benefits which have been achieved?	63
4.5	EU value added.....	63
4.5.1	To what extent has the Regulation permitted achievements which could not be reached at Member State level? To what extent is EU level intervention still warranted?	63
4.5.2	To what extent have MS issued national rules on detergents that go beyond the scope of the Detergents Regulation?.....	65
5	Conclusions.....	65
5.1	Relevance.....	65
5.2	Coherence	65
5.3	Effectiveness.....	67
5.4	Efficiency.....	68
5.5	EU added value.....	69
6	Annex 1 Procedural information.....	70
6.1	Lead DGs and internal references	70
6.2	Organisation and timing	70
6.3	Exceptions to the better regulation guidelines.....	70
6.4	Evidence	71
7	Annex 2 Synopsis report: stakeholder consultation activities	72
7.1	General overview.....	72
7.2	Outcome of the consultation activities	73
7.2.1	Public consultation (PC).....	73
7.2.2	SME survey	78
7.2.3	Telephone interviews	78
7.2.4	Targeted email consultation	78
7.2.5	Validation workshop	78
8	Annex 3 Methods and analytical models	82

8.1	The supporting study of the Detergents Regulation	82
8.1.1	General overview of the methodology	82
8.1.2	Methodology used for cost assessment	110
8.2	Other studies used for the purposes of the evaluation of the Detergents Regulation	127
8.2.1	Study on the regulatory fitness of chemicals legislation (excluding REACH), in particular the CLP Regulation and related legislation (1 st FC Study)	127
8.2.2	Cumulative Cost Assessment for the EU Chemical Industry (the CCA1 Study)	134
9	Annex 4 Enforcement of the Detergents Regulation	140
9.1	Sanctions.....	140
9.2	Enforcement of the Detergents Regulation	143
10	Annex 5 - Evolution of intra-EU trade between 2002-2015	147

Glossary

AISE	International Association for Soaps Detergents and Maintenance Products
BEUC	Bureau Européen des Unions de Consommateurs/The European Consumer Organisation
BPR	Biocidal Products Regulation
CAS	Chemical Abstracts Service
CADD	Consumer Automatic Dishwasher Detergents
CCA	Cumulative cost assessment
CLEEN	Chemical Legislation European Enforcement Network
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
DPD	Dangerous Preparations Directive
DSD	Dangerous Substances Directive
ECHA	European Chemicals Agency
EEA	European Economic Area
EEN	Enterprise Europe Network
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GPSD	General Product Safety Directive
INCI	International Nomenclature of Cosmetic Ingredients
JRC	Joint Research Centre
MS	Member State(s)
NGO	Non-Governmental Organisation
PC	Public Consultation
PBTs	Persistent, Bioaccumulative and Toxic substances
RAPEX	Rapid Alert System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
SCCS	Scientific Committee on Consumer Safety
SDS	Safety Data Sheet(s)
SITC	Standard International Trade Classification
SME	Small and Medium Sized Enterprise(s)
SVHC	Substance of Very High Concern
vPvBs	Very Persistent and Very Bioaccumulative substances

Introduction

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. They have contributed to the improvement of human health and life expectancy, and to our societal comfort and wellbeing. The European detergents industry is characterised by steady growth and contributes significantly to the EU industrial competitiveness and job-creating. Detergents are, however, chemicals with intrinsic properties that have the potential to pose risks to human health and the environment.

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents¹ ('The Detergents 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 degree of protection of the environment and of human health. To do so, the Regulation lays down specific rules to ensure the safe use of detergents by consumers (labelling requirements) as well as the high environmental performance of detergents and surfactants (biodegradability requirements and phosphorus limitations).

The Detergents Regulation has not undergone an evaluation since its entry into application in October 2005. In line with the Better Regulation Guidelines an *ex post* evaluation of the Regulation is therefore considered necessary.

The European Commission has decided to undertake this evaluation to examine which elements of the Detergents Regulation work well and what needs to be improved, in terms of both meeting policy objectives and reducing regulatory burden. An in-depth assessment of the overall operation of the Regulation in the EU and the European Economic Area (EEA) between 2005-2018 was undertaken in this respect.

In particular, the objective of this evaluation is to assess the relevance, coherence, effectiveness, efficiency and EU value added of the Detergents Regulation².

The findings of this evaluation will serve to improve the Regulation's implementation and contribute to ensuring a correct functioning of the EU chemicals legislation³ in general.

1 Background to the intervention

1.1 Description of the initiative

The Detergents Regulation establishes rules for the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health⁴. The Regulation requires that only surfactants meeting the criterion of ultimate biodegradability be placed on the market either on their own (e.g. as constituent mixtures used for the manufacturing of detergents) or contained in detergents. In addition, detergent labels must contain ingredient and dosage

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1551786823575&uri=CELEX:02004R0648-20150601>

² The five evaluation criteria of the Better Regulation Guidelines.

³ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses <http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF>

⁴ Article 1(1) of the Detergents Regulation.

information⁵. This is on the one hand to protect the health of consumers and on the other to avoid over-consumption of detergents thereby reducing the total amount of detergent and surfactant entering the environment.

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

- to introduce an additional biodegradability test method for surfactants poorly soluble in water and more stringent requirements for the labelling of allergenic fragrances⁶;
- to be adapted⁷ to the CLP Regulation⁸;
- to be adapted⁹ to the regulatory procedure with scrutiny;
- to introduce a surfactant derogation by amending Annexes V and VI to the Regulation¹⁰; and
- to introduce restrictions on the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents¹¹.

1.1.1 Evolution and objectives

Setting legal requirements for detergents in the EU dates back to the early 1970s. Detergents were then falling under the scope of a Council Directive¹² that covered many types of detergents (anionic, cationic, non-ionic and ampholytic). This Directive prohibited the marketing of any of these detergents where the average level of biodegradability of the surfactants was less than 90%. It also stipulated that the use of those surfactants with an average level of biodegradability of 90% or more should not be harmful to human or animal health. No other constituents such as phosphates in detergents were covered at the time.

The Directive by itself was largely unenforceable since it did not specify any testing methods. Testing methods for anionic and non-ionic surfactants were outlined in subsequent

⁵ Article 11 and Annex VII to the Detergents Regulation.

⁶ Regulation (EC) No 907/2006 Commission Regulation (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes III and VII thereto.

⁷ Regulation (EC) No 1336/2008 Regulation (EC) No 1336/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation (EC) No 648/2004 in order to adapt it to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

⁹ Regulation (EC) No 219/2009 Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two.

¹⁰ Commission Regulation (EC) No 551/2009 of 25 June 2009 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes V and VI thereto (surfactant derogation).

¹¹ Regulation (EU) No 259/2012 Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents.

¹² Council Directive of 22 November 1973 (73/404/EEC) on the approximation of the laws of the Member States relating to detergents

implementing directives¹³. The latter only dealt with anionic and non-ionic surfactants and required the biodegradability of surfactants to be no less than 80%, the assumption apparently being that if this level were obtained on every test, then the average level of 90% required by the above mentioned Council Directive would also be obtained. Implementing directives in relation to cationic and ampholytic surfactants were never agreed.

The Detergents Regulation repealed the above mentioned Directives, consolidated and updated their provisions and extended the scope of the pre-existing legislation:

- Pre-existing EU legislation on detergents only covered two categories of surfactant. The scope of the Detergents Regulation is now covering all types of surfactants.
- While previous legislation only covered the ‘primary biodegradability’ of surfactants in detergents, the Detergents Regulation imposes a two-tier testing regime on the biodegradability of surfactants in detergents with the main emphasis on “ultimate biodegradability”.
- The Regulation introduces for the first time in the EU limitations on the content of phosphates and other phosphorus compounds, in particular in consumer laundry detergents and consumer automatic dishwasher detergents (‘CADD’).

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

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

i. Free movement of detergents and surfactants for detergents

The Detergents Regulation ensures the free movement of detergents and surfactants for detergents in the internal market by harmonising the rules and the conditions under which manufacturers can place their products on the market. These rules apply to both consumer detergents (detergents sold to the general public) and to industrial or institutional detergents (detergents sold for professional use).

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

- limitations on the content of phosphorus and phosphorus compounds in consumer laundry and CADD;
- labelling requirements for detergents;
- specific biodegradability criteria that detergents and surfactants for detergents need to comply with;
- restrictions or bans on surfactants on grounds of biodegradability; and

¹³ Directive 73/405/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of anionic surfactants, amended by Directive 82/243/EEC and Directive 82/242/EEC

- the information that manufacturers must hold at the disposal of designated public bodies and medical personnel (ingredient data sheet).

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

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

ii. Protection of the environment

One of the main environmental protection requirements of the Detergents Regulation relates to the biodegradability of surfactants and detergents containing surfactants. Surfactants are surface-active agents that help break down the interface between water and oils and/or dirt. They are one of the two main ingredients used in detergents¹⁴. The Detergents Regulation allows only surfactants meeting the criterion of ultimate biodegradability to be placed on the market either on their own (e.g. as constituent mixtures used for the manufacturing of detergents) or contained in detergents. Manufacturers of detergents and surfactants for detergents can demonstrate compliance with these requirements by using one of the biodegradability test methods provided in the Regulation.

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

Limitations on the content of phosphates and other phosphorus compounds in consumer laundry (from 30 June 2013) and consumer automatic dishwasher detergents (from 1 January 2017) is another means by which the Regulation envisages to reduce the environmental impact of detergents. Less phosphorus in detergents means that less phosphorus is released into the environment when detergents are washed down the drain. As phosphorus is known to contribute to a phenomenon called eutrophication (for more information please see Section 4.3.1.2B.), the harmonised limits were introduced in 2012¹⁵ in order to lower the amount of phosphorus used in detergents and thus reduce the damage that phosphates from detergents may have on ecosystems and aquatic environments.

¹⁴ The second one is builders. Builders are added to protect and upgrade the efficiency of surfactants.

¹⁵ Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0259>

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.

iii. Protection of human health

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

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

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

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

iv. Obligations of manufacturers and Member States' duties

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

- Manufacturers must make available to the Member States' competent authorities a technical file on results of the tests described in Annexes II, III and IV to the Detergents Regulation (related to the testing of biodegradability and the complementary risk assessment for surfactants in detergents)
- National authorities may withdraw a compliant detergent product from the market if they consider that it presents a risk to human or animal health or to the environment. They must inform the European Commission and other Member States of their decision (safeguard clause); and

- Member States are required to lay down rules on penalties applicable to infringements of the Regulation and shall take all measures necessary to ensure that they are implemented. These penalties must be effective, proportionate and dissuasive.

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

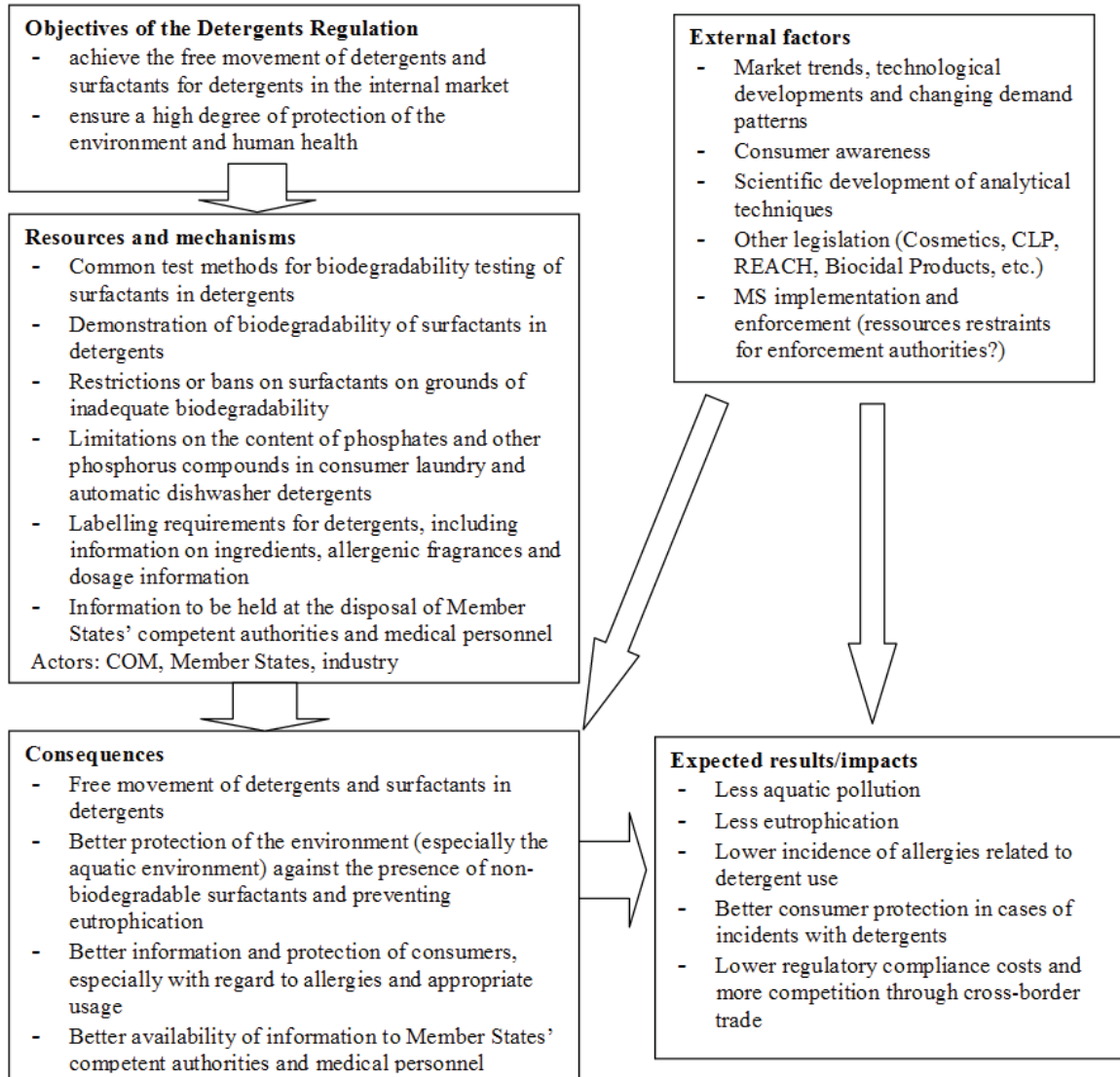


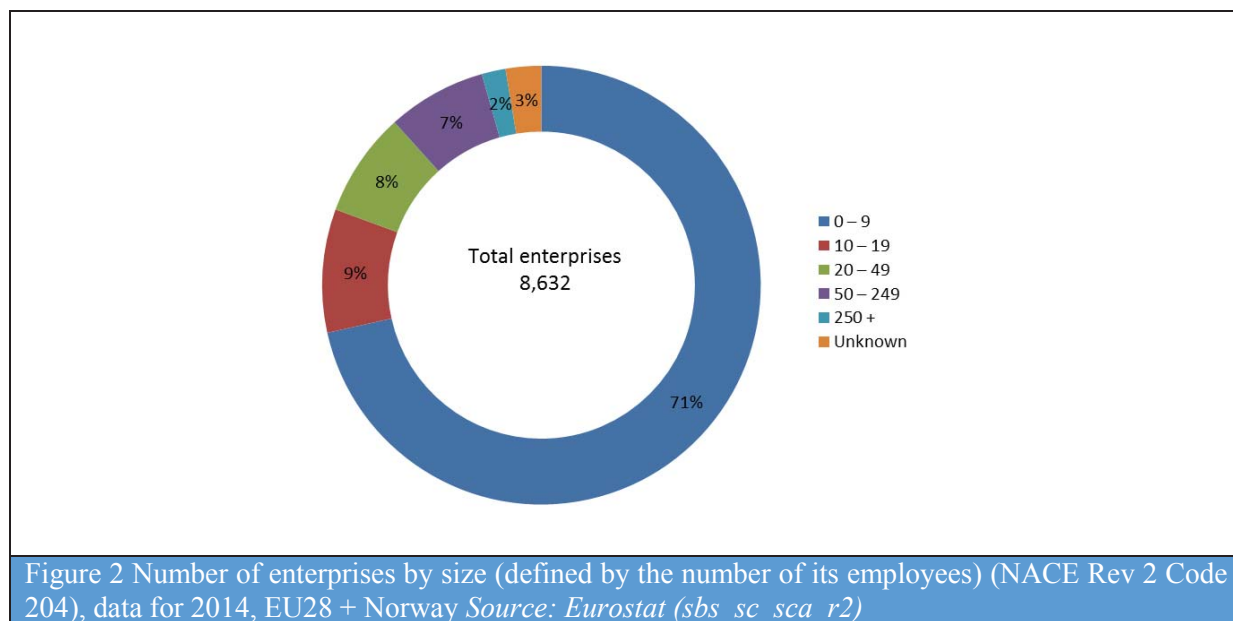
Figure 1 Intervention logic for the Detergents Regulation

1.2 An overview of the EU detergents industry

1.2.1 Detergents industry

The detergents industry is one of the main subsectors of the EU chemicals industry, which is the fifth largest in the EU, accounting for 7% of the EU's industrial production. The sector manufacturing soap and detergents, cleaning and polishing preparations, perfumes and toilet

preparations (NACE 204)¹⁶ was dominated in 2014 by micro-enterprises with less than 10 employees, with 71% of firms falling into this category (see Figure 2 below for a breakdown of enterprises by size). 47% of enterprises falling within this category manufacture soap and detergents, cleaning and polishing preparations¹⁷. According to Eurostat, the number of enterprises in the EU28 manufacturing soap and detergents, cleaning and polishing preparations was 4040 in 2016. Despite not being the main producer of detergent products, Spain is home to the largest number of enterprises (575) followed by France (465) and Italy (439).



According to data from the International Association for Soaps, Detergents and Maintenance Products ('AISE')¹⁸, the manufacturing activity within the household care and professional cleaning and hygiene products industry involves around 700 separate facilities throughout the EU, Norway and Switzerland, more than 85% of which are operated by SMEs. Output is, however, concentrated in 80-90 large-scale plants operated by multi-national companies. These large sites are concentrated in Germany, the UK, France, Italy, Spain, the Benelux countries and Poland¹⁹. In the professional cleaning and hygiene sector, SMEs mostly operate in national markets or focus on serving particular niches²⁰.

The detergents sector is characterised by a history of innovation, particularly in the laundry detergents' sub-sector. The sector has kept pace with the technological advances that have been made in washing machines and washing technologies. Novel packaging and modes of

¹⁶ The Eurostat data is presented in product codes. NACE 204 is, along with NACE 2041, the most relevant code for detergents. It should however be noted that both these categories are much broader than the range of products falling under the scope of the Detergents Regulation but are used as a useful proxy in the absence of better data.

¹⁷ Product code NACE 2041, corresponding more closely to the Regulation's definition of "detergent".

¹⁸ AISE (2018): Activity & Sustainability Report 2017-18 – Cleanliness & Hygiene, Regulatory Affairs, Sustainable Development, available at: <https://www.aise.eu/newsroom/aise-news/aise-publishes-activity-sustainability-report-2017-18.aspx>

¹⁹ The Huggard Consulting Group (2016): The household care and professional cleaning and hygiene products industry, A socio-economic analysis, available at: https://www.aise.eu/documents/document/20160628174212-aise_sea_final_report_jan2016.pdf

²⁰ Idem.

delivery have been developed, such as detergent capsules/pods, and the formulation of detergent products has also changed. Concern about the environmental impact of detergent use has been an important driver of innovation in the detergents industry. This innovation aimed at developing products containing ingredients that are not harmful to human health or the environment and to practices intended to reduce energy or natural resource consumption.

1.2.2 Production of detergents and surfactants for detergents in the EU

Based on the available data from Eurostat and supported by data presented in the AISE Activity and Sustainability Reports for 2015-2016²¹ 2016-2017²² and 2017-2018²³, Germany, Spain, Italy, France, the United Kingdom and Poland are the most prominent producers of soaps and detergents, cleaning and polishing preparations (products falling under NACE Code 2041²⁴). For most of the period 2008-2016, Germany has been the top manufacturer of soaps and detergents, cleaning and polishing preparations in terms of production value, having surpassed Italy in 2009.

The total volume of surfactants produced in the EEA between 2003 and 2015 is presented in Figure 3 below. The total production value of surfactants in the EU28 is presented in Figure 4 below. It has been estimated that, in terms of volume, household detergents accounted for more than 50% of the global surfactants market in 2014²⁵. Anionic surfactants are produced and used in greater volume than any other groups due to their ease and low cost of manufacture²⁶. The most widely used surfactant is currently the anionic surfactant linear alkyl benzene sulfonate (LAS), which is estimated to account for nearly 40% of the global anionic surfactants market²⁷.

²¹ AISE (2016): Activity & Sustainability Report 2015-16 – Cleanliness & Hygiene at Home and in Society, available at: http://www.sustainable-cleaning.com/content_attachments/documents/AISE_AR15_16_FINAL.pdf

²² AISE (2017): Activity & Sustainability Report 2016-17 – Cleanliness & Hygiene at Home and in Society, available at: https://www.aise.eu/documents/document/20170616104451-aise_ar16-17_def-150.pdf

²³ AISE (2018): Activity & Sustainability Report 2017-18 – Cleanliness & Hygiene, Regulatory Affairs, Sustainable Development,, available at: <https://www.aise.eu/newsroom/aise-news/aise-publishes-activity-sustainability-report-2017-18.aspx>

²⁴ It should be noted that the product types included within NACE Rev 2 Code 2041 do not exactly correspond to products falling under the scope of the Detergents Regulation. For example, some types of polish would not fall under the scope of the Detergents Regulation, nor would soaps and shampoos intended for personal care (these are covered by the Cosmetic Products Regulation (EU) No 1223/2009).

²⁵ Transparency Market Research (2015): Surfactants (Anionic, Cationic, Non-ionic, Amphoteric, and Others) Market for Household Detergents, Personal Care, Industrial & Institutional Care, Food Processing, Oilfield Chemicals, Textile & Leather and Other Applications – Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2015-2023. Report Preview available at: <http://www.transparencymarketresearch.com/surfactants-market.html>

²⁶ Yangxin YU et al. (2008): Development of surfactants and builders in detergent formulations, Chinese Journal of Chemical Engineering, 16 (4) pp 517-527. Available at: <http://www.chemeng.tsinghua.edu.cn/scholars/yuyx/papers/Yu%20Detergent%20Review1.pdf>

²⁷ Transparency market research (2014): Global industry analysis, size, share, growth, trends and forecast. Abstract available at: <http://www.mrrse.com/sodium-lauryl-sulfate-market>

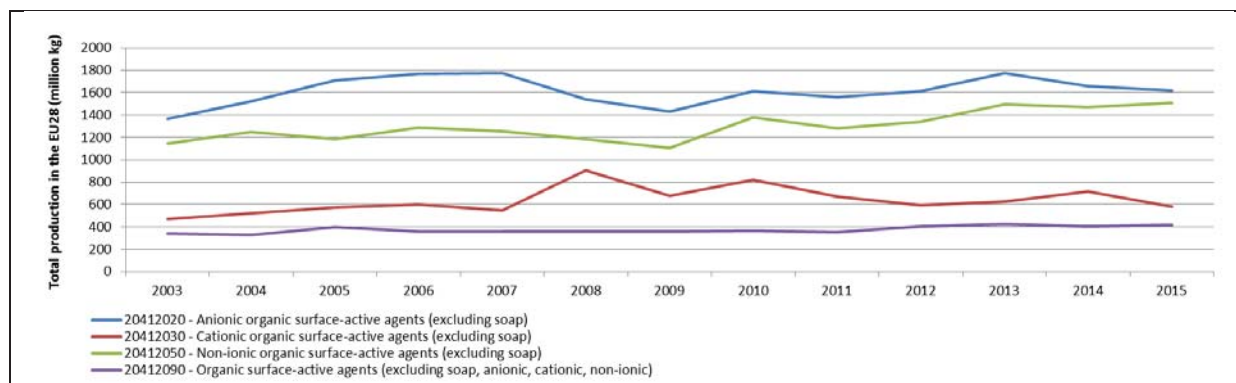


Figure 3 Surfactants - Total production volume in the EEA, million kg

Source :Eurostat (DS-066342) (data were not available for Liechtenstein)

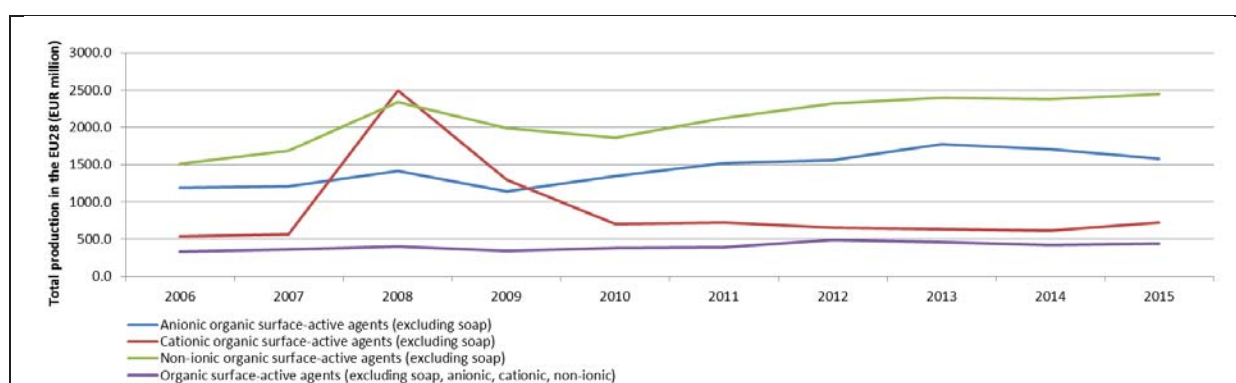


Figure 4 Surfactants - Total production value in the EU28, million EUR

Source: COMEXT. Data not available for Norway, Iceland and Liechtenstein

1.2.3 Consumption of detergents and surfactants in the EU

The detergents sector is one of the chemical sectors where the products are sold directly to consumers (retail) and to professionals (maintenance products). Data for the period 2015-2017 show a steady growth of the detergents industry²⁸.

The total EU market value (EU28 plus Norway and Switzerland) of the detergents industry was estimated at EUR 35.7 billion in 2015 with the household care market accounting for EUR 28.8 billion and the professional cleaning and hygiene sector for EUR 6.9 billion. In 2016, there was a slight decrease in the total EU market value²⁹ (EUR 35.6 billion) with EUR 28.5 billion attributed to the household sector and EUR 7.1 billion to the professional cleaning and hygiene products. However, in 2017, the total EU market value of detergents (EU28 plus Norway and Switzerland) increased again and was estimated at EUR 35.9 billion, with the

²⁸ The data presented in this section are derived from AISE's Activity and Sustainability Reports for 2015-16, 2016-17 and 2017-2018. Eurostat data are presented in product codes, which are wider in scope than the products falling under the scope of the Detergents Regulation. For this reason the AISE data were chosen as more representative of the detergents sector and its sub-sectors.

²⁹ AISE (2016): Activity & Sustainability Report 2015-16 – Cleanliness & Hygiene at Home and in Society, available at: http://www.sustainable-cleaning.com/content_attachments/documents/AISE_AR15_16_FINAL.pdf

household care sector accounting for EUR 28.6 billion and the professional cleaning and hygiene products for EUR 7.3 billion³⁰.

The household care sector is grouped into five main product areas: laundry care, surface care, dishwashing (which includes washing by hand or by means of an automatic dishwasher), maintenance products and bleaches. The value of the laundry care market (e.g. powder detergents, liquid detergents, fabric conditioners, etc.) across Europe (EU28 plus Norway and Switzerland) remained quite steady between 2015-2017 and was estimated at approximately EUR 13.5 billion. All five product group areas have experienced growth in market value over the same time period, with the household care sector experiencing an overall increase of approximately 0.8% every year.

The professional cleaning and hygiene sector supplies detergent products that are used in a wide range of professional applications, which can be grouped as follows: healthcare; food; beverage and agriculture; kitchen and catering; technical cleaning; building care and laundry. The total EU market value (EU28 plus Norway and Switzerland) of this sector has steadily increased from EUR 6.9 billion in 2015 to EUR 7.1 and 7.3 billion in 2016 and 2017 respectively³¹. The healthcare product group area is dominating the professional cleaning and hygiene sector with a market share of approximately 24% between 2015-2017. The market value (EU28 plus Norway and Switzerland) of the healthcare area increased from EUR 1.6 billion in 2015 to EUR 1.7 billion and EUR 1.8 billion in 2016 and 2017 respectively³².

1.3 Baseline

This is the first *ex-post* evaluation of the Detergents Regulation since its entry into force in March 2004, followed by several amendments (the latest being in 2012). The 2012 amendment of the Detergents Regulation³³ introduced limits on the content of phosphorus and phosphorus compounds in consumer laundry and consumer automatic dishwasher detergents. The European Commission's proposal was accompanied by an impact assessment³⁴ covering only these aspects of the Regulation.

The assessment provided in the remainder of this document covers the 2005-2018 time period.

Given that no pre-existing evaluation or impact assessment of the Detergents Regulation exist, it has not been possible to establish one single baseline for this evaluation. The points of reference used for different evaluation criteria are as follows:

The coherence of the Detergents Regulation was assessed both internally i.e. considering the degree to which different provisions of the Regulation complement each other and work together as intended or whether overlaps and inconsistencies between them exist, and in relation to other (related) pieces of EU legislation that are applicable to detergents. These

³⁰ AISE (2018): Activity & Sustainability Report 2017-18 – Cleanliness & Hygiene, Regulatory Affairs, Sustainable Development,, available at: <https://www.aise.eu/newsroom/aise-news/aise-publishes-activity-sustainability-report-2017-18.aspx>

³¹ AISE Activity and Sustainability report for years 2015-2016-2017.

³² Idem.

³³ Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents

³⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52010SC1277&from=EN>

pieces of legislation include the REACH Regulation (e.g. for the registration of substances used in detergents), the CLP Regulation (for aspects relating to the labelling and packaging of detergents) and the Biocidal Products Regulation (for detergents that are also disinfectants or contain a preservation agent). Certain aspects of the Detergents Regulation were also assessed in relation to the Cosmetic Products Regulation, notably the labelling of allergenic fragrances.

The effectiveness of the Regulation to achieve the free movement of detergents and surfactants for detergents in the internal market was assessed by looking at impacts on businesses within the EU illustrated by evolution of intra-EU trade values based on data from Eurostat over the period 2002 - 2015. Data from this period allow us to have an overview of the situation before the Regulation started applying (i.e. before 2005) and for ten years after that. More recent data (2015-2017) from the International Association for Soaps Detergents and Maintenance Products ('AISE') were also used in this respect.

Expected results and impacts as outlined in the impact assessment³⁵ that accompanied the Commission's proposal to introduce limits on the content of phosphorus and phosphorus compounds as well as stakeholder views were used as point of reference to assess the effectiveness of these measures. Data from the International Association for Soaps Detergents and Maintenance Products ('AISE') on the number of consumer laundry and consumer automatic dishwasher detergents that were phosphorus free before the introduction of the 2012 phosphorus limitations were also used to this effect. According to this data, it was estimated that across the EU, about 70% of laundry detergent formulations and 5% of Consumer Automatic Dishwasher Detergents were already phosphorus-free as a result of voluntary actions and national restrictions by 2012. This means that about 30% of laundry detergent formulations and 95% of Consumer Automatic Dishwasher Detergents had to be reformulated as a result of Regulation (EU) No 259/2012.

In order to assess whether and how efficiently the Detergents Regulation works only costs and only those reasonably attributable to the new obligations arising from the Detergents Regulation, i.e. additional/increased costs with respect to the existing situation (i.e. the Detergents Directive), as well as additional costs to the costs that would have emerged in the absence of the intervention (i.e. if the Detergents Directive had not been repealed and replaced by the Detergents Regulation) were assessed.

2 State of play

Unlike a Directive, the Detergents Regulation is directly applicable across the EU, as well in the other countries of the European Economic Area (i.e. Norway, Iceland and Lichtenstein). The Regulation does however require Member States to adopt certain measures for its correct implementation and enforcement. This section describes the state of play of the Detergents Regulation and the factors affecting its implementation and enforcement.

2.1 Member States' implementation and enforcement activities

The Detergents Regulation requires Member States to take the following measures in order to ensure its correct implementation across the EU and the European Economic Area ('EEA'):

³⁵ Idem.

1. the appointment of competent authorities or authorities responsible for communicating and exchanging information on the correct implementation of the Regulation.
2. the notification to the European Commission and other Member States of a list of approved laboratories, competent and authorised to carry out the tests required by the Detergents Regulation.

The lists of both the Member States' competent authorities³⁶ and approved laboratories³⁷ are published on the European Commission's website.

Under the Detergents Regulation Member States are required to introduce "effective, dissuasive and proportionate" sanctions for the purpose of enforcing it. Luxembourg was the only EU Member State that did not initially comply with this obligation under the Detergents Regulation³⁸.

A variety of sanctions have been implemented in different Member States which range from administrative options (such as verbal or written advice) to more stringent penalties such as fines, bans (e.g. forcing products to be withdrawn from the market), and in some cases, even imprisonment.

Examples of sanctions laid down in different Member States can be found below (more details on sanctions implemented in different Member States can be found in Annex 4 to this evaluation):

- In Austria, the relevant sanctions include fines, product withdrawals and bans.
- In Denmark apart from sales bans and enforcement notices, an infringement of the Detergents Regulation may lead to imprisonment for up to 2 years, in cases where: the violation is committed intentionally; in case of gross negligence; if the violation has inflicted injury on humans, animals or the environment; or if financial gain or cost savings have been obtained.
- In Finland, the national enforcement authority may ban the operator from continuing operations or repeating procedures in violation of the provisions or they may order the operator to otherwise fulfil the obligations laid down by law.
- In Ireland, sanctions available to enforcement authorities range from verbal or written advice, to enforcement notices (contravention and prohibition), to criminal prosecution.
- Administrative penalties are provided in the case of violation of the Detergents Regulation in Latvia. Products that do not comply with the requirements of the Regulation can be temporarily banned or withdrawn from the market until they are brought into conformity.
- In Sweden, the most stringent sanction available is a ban, but fines also exist.
- In Norway, the relevant sanctions include the possibility to give verbal and written advice, administrative orders, impose coercive fines and product withdrawals.

³⁶ <http://ec.europa.eu/DocsRoom/documents/14128/attachments/1/translations/>

³⁷ <http://ec.europa.eu/DocsRoom/documents/14127/attachments/1/translations/>

³⁸ Case C-184/08 - Commission of the European Communities v Grand Duchy of Luxembourg. Failure of a Member State to fulfil obligations - Regulation (EC) No 648/2004 - Article 18 - Market for detergents and for surfactants for detergents – Sanctions.

Based on the above presented data the existing sanctions for infringements of the Detergents Regulation are dissuasive, effective and proportionate. As shown in Figure 5 below, about a third of the respondents³⁹ to the public consultation agreed with this finding. This compares to about 15% that did not find the sanctions to be dissuasive, effective and proportionate. During the targeted consultation, most of the market surveillance authorities also indicated that the sanctions in their country are effective, proportionate and dissuasive.

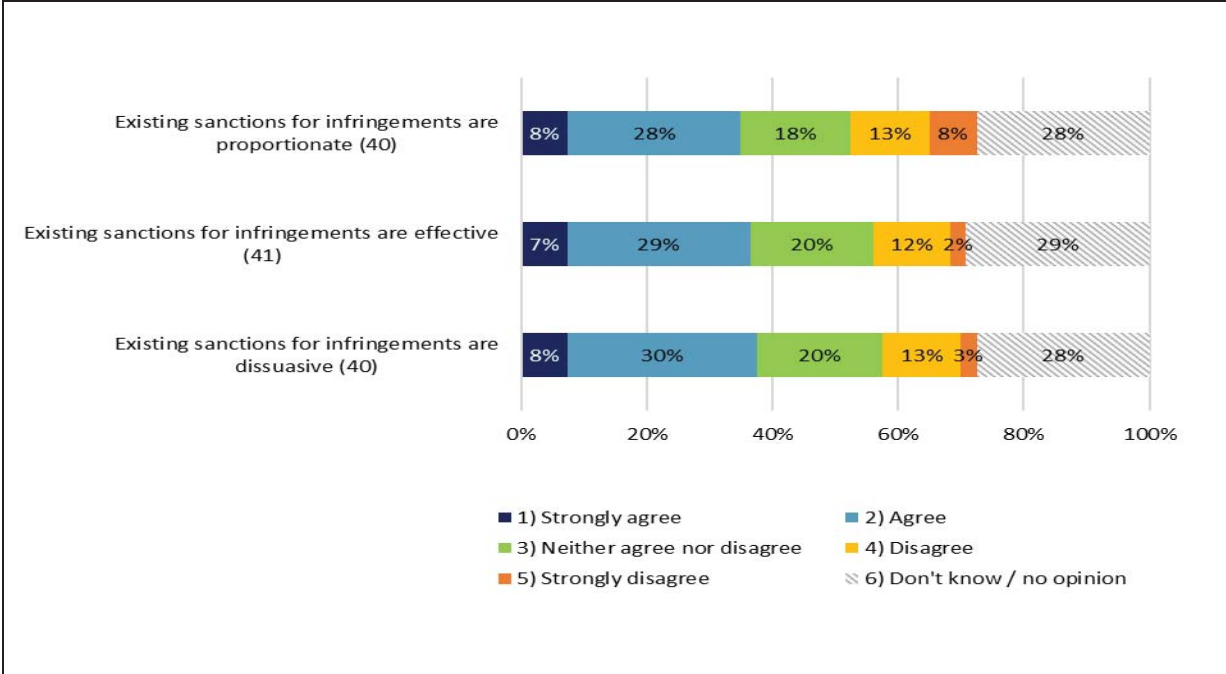


Figure 5 To what extent do you agree that existing sanctions for infringements of the Detergents Regulation are dissuasive, effective and proportionate? Responses to the public consultation – Organisations

In order to enforce the Detergents Regulation, Member States are allowed to introduce control measures. During the consultation, market surveillance authorities confirmed that, in most cases, inspections on detergents under the Detergents Regulation tend to not be carried out in isolation, but are rather coordinated with inspections for other chemicals legislation, such as the CLP Regulation and the REACH Regulation. This is for example the case for Ireland, Austria, Latvia, Denmark and Finland.

Only two Member States reported data separately in relation to the Detergents Regulation as part of official Member States’ reporting on market surveillance activities in the chemicals sector, namely Estonia and Greece. In Estonia, the number of inspections increased from 173 in 2010 to 264 in 2013. Inspections in Greece also increased between the same time (from 272 in 2010 to 375 in 2013) with the highest number of inspections observed in 2011 (438). In

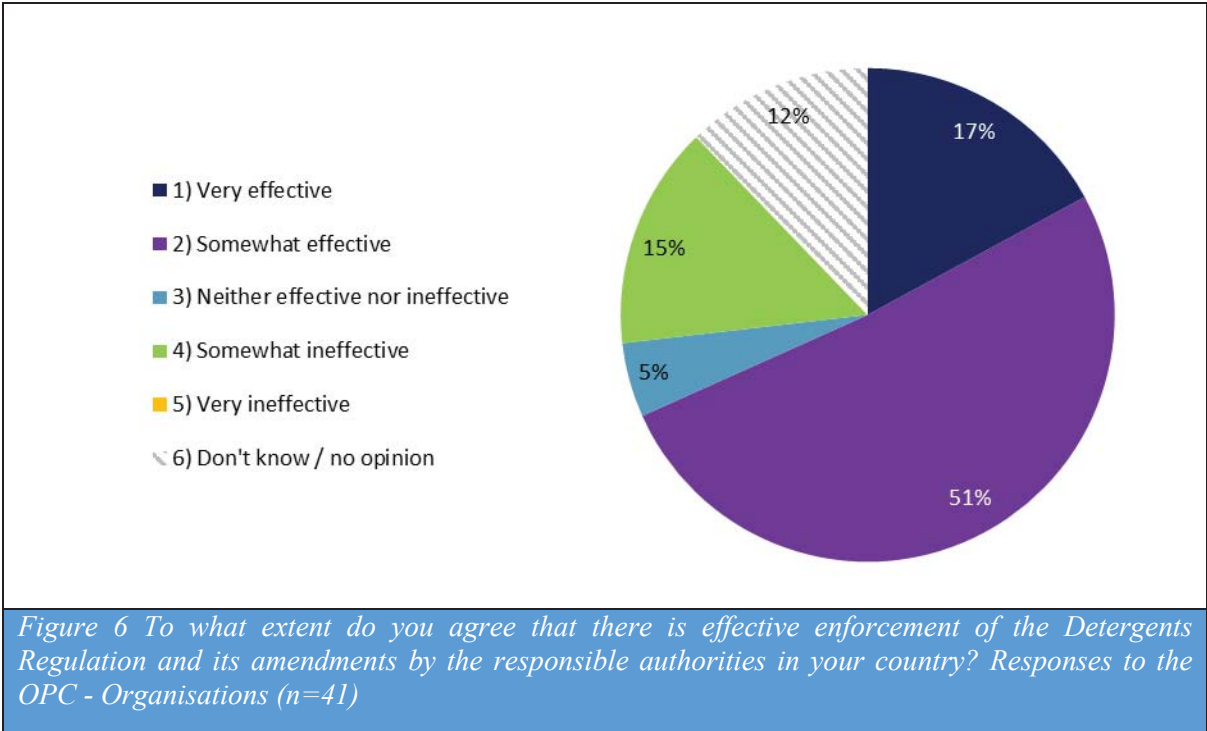
³⁹ Participants include public authorities and bodies responsible for implementing and/or enforcing the Detergents Regulation; companies (large and small); industry associations and sector groups representing companies in the detergents sector; trade unions; environmental and consumer NGOs; and universities and research institutes.

both countries, several instances of non-compliance were found which resulted in the issuing of memos in Estonia and restrictive measures and sanctions in Greece⁴⁰.

In addition to Greece and Estonia, the following countries provided data for the purposes of this evaluation: Ireland, Romania, Austria, Latvia, Denmark, Slovakia, Finland and Norway. Data reported from the competent authorities in these Member States show that different Member States have different approaches to the inspections conducted under the Detergents Regulation. For example, Austria, Romania and Latvia conduct both proactive and reactive inspections while Finland only conducts reactive ones. In some Member States (e.g. Ireland and Romania), the number of inspections appears to be increasing in time, while in others these inspections are in general quite limited (e.g. Norway, Finland, Denmark) (for more information on Member States’ enforcement activities please see Annex 4 to this evaluation).

As these countries account for a relatively small share of the overall detergents market, the above presented data does not allow concluding with certainty whether such activities are sufficient to ensure appropriate enforcement of the Detergents Regulation.

Organisations⁴¹ that participated in the public consultation were asked about the extent to which they agree that there is effective enforcement of the Detergents Regulation and its amendments by the responsible authorities in their country. Their responses indicate that most stakeholders view national enforcement as being at least “somewhat effective” (see Figure 6 below).



⁴⁰ It should nevertheless be noted that both countries are relatively small players in the market for detergents, accounting for less than 2% of all detergents (by value) produced in the EU and cannot, therefore, be taken as representative of the sector overall.

⁴¹ Organisations include public authorities and bodies responsible for implementing and/or enforcing the Detergents Regulation; companies (large and small); industry associations and sector groups representing companies in the detergents sector; trade unions; environmental and consumer NGOs; and universities and research institutes.

2.2 Level of compliance with the Detergents Regulation

Information is scarce regarding the level of compliance of companies with the Detergents Regulation as there is no reporting obligation for Member States.

The Rapid Alert System for dangerous non-food products ('RAPEX-Safety Gate')⁴² enables the quick exchange of information between the national authorities of 31 countries and the European Commission on measures taken on products posing a risk to the health and safety of consumers. RAPEX notifications for detergents can therefore provide an insight on the level of compliance with the Detergents Regulation, without however constituting an indicator of compliance as such.

There were ten non-compliance cases, leading to a risk for consumers, reported to RAPEX in the period 2005 - 2018 (with two of them being for detergents originating from countries outside the EU). In most cases, the reason for the RAPEX notification was a lack of appropriate labelling to ensure that consumers are aware of the hazards associated with the use of the product and the measures to take to ensure safe use. In all these cases apart from two, the non-compliance was related to lack of appropriate labelling according to the CLP Regulation⁴³ (e.g. lack of the relevant CLP pictograms and hazardous statements). In all cases, actions taken by the notifying countries involved a sales ban and withdrawal of the products from the market (including recalls from consumers) or facilitation of a voluntary withdrawal together with a recall from consumers.

The EuroDeter project⁴⁴ was carried out by the Chemicals Legislation European Enforcement Network ('CLEEN'). It focused on the enforcement of the Detergents Regulation during the period 2012-2014. Twelve countries⁴⁵ participated in the project, completing a detailed inspection for 907 products in 319 companies. The findings of the EuroDeter project provide some additional elements of information regarding the level of compliance of companies with the Detergents Regulation:

- There is a high level of compliance with the biodegradability requirements of the Detergents Regulation.
- More than 40% of the inspected products were not including, where applicable, all mandatory allergenic fragrance ingredients on the label or packaging.
- More than 30% of the inspected products failed, where applicable, to "list the preservation agents" contained in the mixture on the label of the detergent.
- Almost 30% of the inspected detergents, for use by the general public, did not provide a website address where consumers can find a full ingredient list of the detergent.

⁴² RAPEX is an effective tool that allows public authorities to rapidly share appropriate risk mitigation measures on consumer goods (toys, textiles, cosmetics, etc.). However, the level of compliance of detergents placed on the EU market cannot be determined based only on information that RAPEX provides.

⁴³ As explained above, the labelling of detergents falls by default under the CLP Regulation and the Detergents Regulation.

⁴⁴ The final report (2014) is available at: <http://www.cleen-europe.eu>

⁴⁵ Belgium (BE), Estonia (EE), Finland (FI), Germany (DE), Ireland (IE), Latvia (LV), Lithuania (LT), Poland (PL), Slovenia (SI), Spain (ES), Sweden (SE) and Switzerland (CH) have participated in the project, completing detailed inspections.

Furthermore, this list of ingredients was not available at the website address mentioned on the label for 46% of the inspected products.⁴⁶

- For 23% of inspected detergent products, the manufacturer's contact details (which would be required by medical personnel seeking the ingredient datasheet) were missing. Furthermore, for 23% of inspected products, an ingredient datasheet was not available at all, while for another 14% of inspected products, the ingredient datasheet was not made available for inspectors. About a quarter (26%) of the ingredient datasheets were not in conformity with the requirements of the Detergents Regulation (for more information on the ingredient data sheet see section 4.2.2.2A below).
- Less than 70% of labels providing dosage information on consumer laundry detergents contained information on standard washing machine loads.

The findings of the EuroDeter project point to several issues of non-compliance with the Detergents Regulation. However, as mentioned above the project only covers a specific time period (2012-2014). In the absence of reporting obligations from Member States or any other comprehensive and more recent data, it is therefore not possible to conclude on the level of compliance with the Regulation and on whether the situation has changed since 2014.

3 Methodology

3.1 Evidence, data collection and stakeholder consultation activities

The evaluation of the Detergents Regulation was assisted by an interservice steering group covering all Commission services concerned by detergents-related aspects (see Annex 1). The evaluation was also supported by a study (see below) that provides useful data and stakeholders' views. Priorities for assessment were established on the basis of the main areas of improvement identified in this study, considering the concerns raised by stakeholders.

3.1.1 Supporting study

In December 2016, the European Commission commissioned a study to support its evaluation of the Detergents Regulation⁴⁷. As mentioned above, the supporting study provides useful data for the assessment of the effectiveness, efficiency, relevance, coherence and EU-added value of the Detergents Regulation and its amendments.

The approach to the study included legal analysis, collection and review of relevant statistical data and literature review⁴⁸. Moreover, the study gathered data and information on the detergents industry in the EU and EEA⁴⁹. This involved analysing the composition of typical detergent products on the market, levels of production and consumption of detergents and surfactants, as well as data on the number of enterprises operating in the sector in the

⁴⁶ Similar issues were identified by KEMI in 2017 during the project 'Check your dishwashing soap for allergenic preservatives'. Results are available at: <http://KemI.taenk.dk/bliv-groennere/check-your-dishwashing-soap-allergenic-preservatives>

⁴⁷ By Risk & Policy Analysts Ltd (RPA) and Mayer Brown LLP. The supporting study is available at: <https://ec.europa.eu/docsroom/documents/32561>

⁴⁸ Including reports from the European Commission and authorities/agencies in the Member States; academic literature and grey literature.

⁴⁹ For more information see annex 1 to the supporting study available here: <https://ec.europa.eu/docsroom/documents/32561>

EU/EEA. Information was also gathered on the main sustainability aspects and on recent trends in the detergents sector.

3.1.2 Stakeholder consultation activities

Consultation activities included a public consultation for organisations⁵⁰ and citizens, a survey designed specifically for SMEs, telephone interviews with relevant organisations and targeted consultation. The consultation reached the majority of relevant stakeholders. Nevertheless, the participation of the water industry would have also been useful in terms of quantifying the benefits resulting from the phosphorus limitations adopted under the Detergents Regulation.

3.1.2.1 Roadmap

A roadmap⁵¹ was published in October 2016 presenting the scope and the key evaluation questions to be addressed, as well as a consultation strategy to ensure stakeholders' engagement in the process (see below and Annex 2). The Roadmap was open to feedback for four weeks.

3.1.2.2 Public consultation

A public consultation was launched on 2 May 2017 and closed on 25 July 2017. Two separate questionnaires were developed for the purposes of the public consultation: one for citizens and one for organisations. Both questionnaires were made available in English, German and French.

The public consultation generated a total of 102 responses. Of these responses 61 online replies belonged to citizens originating from 15 Member States and Switzerland. With regard to the questionnaire for organisations, a total of 41 organisations submitted a response, with most responses coming from detergents industry associations (12 responses) and government or public authorities (12 responses).

3.1.2.3 SME survey

A simplified questionnaire was developed and distributed to SMEs via the Enterprise Europe Network ('EEN'). The SME survey was launched at the beginning of May 2017 and ran until the end of June 2017. It generated a total of 41 responses, split almost equally between micro-enterprises (<9 employees), small enterprises (10 to 49 employees) and medium-sized enterprises (50 to 249 employees).

3.1.2.4 Telephone interviews

In order to examine stakeholders' views in greater depth, a series of targeted interviews were held.

It proved very difficult to engage stakeholders to the degree initially envisaged. Arranging interviews with companies proved particularly problematic and, as a result, the study team decided to redirect its focus towards industry associations and sector groups that were more

⁵⁰ Including public authorities and bodies responsible for implementing and/or enforcing the Detergents Regulation; companies (large and small); industry associations and sector groups representing companies in the detergents sector; trade unions; environmental and consumer NGOs; and universities and research institutes.

⁵¹ http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_305_evaluation_detergents_en.pdf

willing to participate and could represent the views of their member companies. Environmental and consumer NGOs were also very difficult to engage, with several citing a lack of knowledge of the Detergents Regulation as a reason for not wanting to participate.

3.1.2.5 Targeted email consultation

In addition to interviews, complementary data, information and views were gathered via targeted emails. Such tailored emails were sent to a variety of organisations such as market surveillance authorities (e.g. to obtain data on enforcement related to the Detergents Regulation), national poison centres (e.g. to obtain information on detergents' related illnesses/incidents) and regional seas conventions (to obtain data in relation to phosphorous loads in EU water bodies).

3.1.2.6 Validation workshop

To validate the preliminary findings of the supporting study, a one-day workshop was held in Brussels on 13 October 2017. In total 27 participants representing 20 organisations participated at the workshop⁵². A summary of the workshop findings is provided in Annex 2 to this evaluation.

3.2 Limitations and robustness of findings

The main limitations of the supporting study are as follows:

- The data gathered via the SME survey suggest that a sizable proportion of the 'detergent' formulations produced by SMEs may not currently fall within the scope of the Detergents Regulation. It is, nevertheless, unclear whether these data reflect the actual situation on the market as some SMEs may not realise that the Regulation is applicable to their products while the question may have also been misinterpreted/misunderstood.
- Due to the limited participation of stakeholders in the public consultation in some cases, it was impossible to categorise the input received by stakeholder type. Whenever this was not possible, the input received was divided in two categories, i.e. data received from organisations and data received from citizens. The former category is very broad and includes a variety of stakeholders ranging from public bodies responsible for implementing and/or enforcing the Detergents Regulation; companies (large and small) to industry associations and sector groups representing companies in the detergents sector, trade unions, environmental and consumer NGOs, and universities and research institutes.
- The Eurostat data is presented in product codes⁵³. These products codes cover a much broader range of products than those included under the scope of the Detergents Regulation. This means that apart from detergents the same products are also used for the production of other formulations e.g. cosmetics. It is therefore not possible to know the exact quantities corresponding to the production of detergents. For this reason, more concrete and recent data from the International Association for Soaps, Detergents and Maintenance Products ('AISE') were used.

⁵² Members of the Commission's steering group, 7 industry associations, 2 Member States authorities, 5 companies and 2 consumer organisations

⁵³ NACE 204 and 2041 are the most relevant product codes for detergents.

- While stakeholders were an important source of data and information and although throughout the evaluation, care has been taken to cross-check and verify information from different sources, it should be recalled that the consultation is based on a limited sample size and that responses cannot be perceived as being representative overall. Arranging interviews with companies proved especially difficult.
- In terms of costs incurred by the detergents industry as a result of the Detergents Regulation, it has not been possible to calculate the one-off costs associated with changing production processes and the on-going costs associated with testing the biodegradability of surfactants. This introduces considerable uncertainty into cost calculations.
- It was not possible to provide reliable quantified estimates of costs incurred by public authorities or the society in general as a result of the Detergents Regulation. To the extent possible, a qualitative description was provided.
- Providing reliable quantified estimates of benefits resulting from the Detergents Regulation proved challenging and therefore such estimates are not present for neither industry or other economic operators, nor public authorities or society in general.

Where specific obstacles and challenges were encountered, limitations are mentioned and explained in the relevant sections.

Care was taken to accurately report different opinions and findings while also ensuring that the evidence and sources can be traced back. Wherever possible the data gathered were cross-checked and validated against several sources in order to ensure reliability and robustness.

4 Analysis and answers to the evaluation questions

The following sections answer the evaluation questions concerning the five central evaluation criteria of relevance, coherence, effectiveness, efficiency, and EU added value.

Many of the factors that affect one of the abovementioned evaluation criteria were found to be closely linked with one or more of the others. Issues identified in one section are, therefore, sometimes referred to in other sections where they are evaluated in more detail.

4.1 Relevance

4.1.1 To what extent are the objectives of the Detergents Regulation still relevant considering the evolution of societal needs and technological developments?

The overarching objectives of the Detergents Regulation are set out in its Article 1(1), which states that:

‘This Regulation establishes rules designed to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health.’

The main change in societal needs since 2004 is an increased interest towards sustainability⁵⁴. This includes, washing in lower temperatures with equally effective products, recyclable or recycled packaging and more eco-friendly products (e.g. less harm to the environment, smaller dosages with same effectiveness etc.).

The Detergents Regulation has responded to past and current societal needs by giving consumers the opportunity to select among a large variety of products that move freely in the internal market. These products are more sustainable than before (less phosphorus, concentrated products, surfactants that are completely biodegradable etc.) and provide a similarly high level of protection to human health by allowing consumers to have access to all the ingredients contained in them. It is therefore clear that the objectives of the Detergents Regulation continue to be relevant.

This was also supported by the findings of the public consultation. In particular, industry associations (13), public authorities (9), companies (6), consumer organisations (3) and NGOs (4)⁵⁵ that responded to the public consultation either agreed or strongly agreed that the objectives of the Regulation are still relevant while none disagreed. During the interviews, stakeholders also agreed that the objectives of the Detergents Regulation are still relevant, considering the evolution of societal needs and technological developments. For example, in the words of one Member State authority, that provided a written response to the questions in the interview guide:

'We believe that the aims of article 1 of the regulation are still all relevant, especially given the expected population growth. The ingredients used are still largely similar to those when the regulation was introduced.'

4.1.2 To what extent are the concepts and definitions used in the Detergents Regulation in line and coherent with the meaning they have gained over time in practice and do they cover all the commonly accepted detergents products available on the market?

4.1.2.1 Ambiguous definitions

The majority of responses (28 out of 41) to the public consultation from industry associations, companies, consumer associations, NGOs and public authorities indicate that the scope of the Detergents Regulation covers all commonly accepted detergent products available on the market. Interestingly, the majority of the stakeholders that disagreed belonged to public authorities (5 out of 8 negative responses). Opinions were split with regards to whether the concepts and definitions used in the Detergents Regulation are in line with the meaning they have gained over time in practice. While 37% of responses from industry associations, companies, consumer organisations and Member State authorities that participated in the consultation agreed that they are, an equal proportion of the same stakeholders (37%) disagreed.

Furthermore, several public authorities (6), industry associations (5), companies (4) and one NGO stated during the consultation that some of the definitions provided in Article 2 of the

⁵⁴ A.I.S.E. Pan-European Consumer Habits Survey 2017, Perceptions of cleanliness and hygiene – Cleaning habits, sustainability and safety: https://www.aise.eu/documents/document/20180528165059-aise_consumershabitssurvey2017_summary_final.pdf

⁵⁵ Representing in total 35 out of 41 respondents.

Detergents Regulation are unclear and/or open to interpretation. The definitions that were identified as posing a particular issue in this regard are the following:

- Detergent (Article 2(1));
- Cleaning mixture (Article 2(1));
- Other cleaning and washing mixtures (Article 2(1)); and
- Cleaning (Article (2(3))).

This results in lack of clarity on whether some of the products available on the market fall under the scope of the Regulation or not. Products that have been identified as susceptible to cause such problems are the following: 1. *cleaning wipes and scouring pads* impregnated with detergent, 2. *re-usable washing eggs/balls* that contain pellets of detergent, 3. some *related household products* (e.g. waxes, polishes and textile dyes) and 4. certain ‘*do-it-yourself*’ *cleaning products* such as white vinegar.

The guidance⁵⁶ document for the implementation of the Detergents Regulation gathers questions and agreed answers concerning the implementation of the Regulation. The answers to these questions are discussed and agreed upon between the European Commission services and the Member States’ representatives in the Working Group on detergents.

For the first two types of products, the Member States and the European Commission services have agreed in the guidance⁵⁷ for the implementation of the Detergents Regulation that while, in their view, the scouring pads and the eggs/balls themselves fall outside the scope of the Regulation, the detergent formulation that they contain does. It is therefore considered that both of these products fall under the Regulation's scope. As regards the last two types of products the agreed interpretation⁵⁸, that the claimed function (i.e. whether the product has a cleaning function or not) prevails over the composition of the product (i.e. whether it contains a surfactant or not), could be applied. As a result, a cleaning product falls within the scope of the Regulation as soon as it claims to have surface cleaning functions.

4.1.2.2 *Microbial cleaning products*

In recent years, novel cleaning products have been developed that contain living microorganisms as active ingredients. These so called ‘microbial cleaning products’ appear to be growing in popularity⁵⁹. The fact that they contain living microorganisms, raises concerns on their potential impact on human health (e.g. possible presence of unwanted microbes, pathogens and issues related to chronic respiratory exposure to them⁶⁰) and the environment

⁵⁶ 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>

⁵⁷ The Guidance document for the correct interpretation of the Detergents Regulation gathers questions and agreed answers concerning the interpretation of the Regulation. The answers to these questions are discussed and agreed upon between the Commission services and the Member States’ representatives in the Working Group on detergents.

⁵⁸ 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>

⁵⁹ NVZ (2017): Microbiologische reinigingsmiddelen. Available at: https://www.nvz.nl/download_file/view/384/334/

⁶⁰ 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>

(e.g. release into the environment of microorganisms that do not originate from such environments⁶¹).

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

Research undertaken by the European Commission's Joint Research Centre ("JRC")⁶² indicates that manufacturers of microbial cleaning products claim two main modes of action for the microorganisms included in these products:

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

For some organisations, it is not always clear which pieces of legislation govern the safety and marketing of these products (Spök & Klade, 2009)⁶³ and, during the consultation, several stakeholders questioned whether microbial cleaning products fall within the scope of the Detergents Regulation.

The European Commission services and Member States have examined in the past a specific company's request for clarification as to whether a product with a claimed cleaning effect depending on the action of bacteria falls within the scope of the Detergents Regulation. The label of that product claimed that its cleaning action is a result of applying bacteria to feed on the excrement of dust mites. The European Commission services and Member States agreed⁶⁴ that such a product, *though it contains surfactants*, does not seem to have a cleaning action as defined in the Detergents Regulation⁶⁵ and consequently does not fall within the scope of the Detergents Regulation. However, there are other products on the market (like certain drain cleaners) which work through a combined action of surfactants, enzymes and bacteria. As the cleaning process of these products is not based solely on the action of bacteria, they do fall within the scope of the Detergents Regulation.

⁶¹ Development and use of microbial-based cleaning products (MBCPs): Current issues and knowledge gaps (2017), George Arvanitakis, Robin Temmerman, Armin Spök

⁶² 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>

⁶³ Spök A & Klade M (2009): Environmental, health and legal aspects of cleaners containing living microbes as active ingredients, Results and conclusions of a study commissioned by the Austrian Federal Ministry of Agriculture, Forestry, Environments and Water Management, undertaken by IFZ. Available at: www.ifz.at/Media/Dateien/Downloads-IFZ/Publikationen/.../IFZ-EWP-3-2010

⁶⁴ 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>

⁶⁵ Article 2(3) of the Detergents Regulation states that: ‘cleaning means the process by which an undesirable deposit is dislodged from a substrate or from within a substrate and brought into a state of solution or dispersion’.

Apart from the cleaning function of microbial cleaning products another aspect that could be considered relates to the definition of "detergent" under the Detergents Regulation which does not address directly the case of products with an effect based on the action of bacteria (either live or in spore form) but only refers to "substances" and "mixtures". "Substance" means "*chemical elements and their compounds in the natural state or obtained by any production process...*" (Article 2(4)), whereas mixture means "a mixture or solution *composed of two or more substances*" (Article 2(5)). As a result it could be argued that microorganisms contained in detergents do not fulfil the above mentioned definition of "substances" and cannot therefore be considered as falling under the scope of the Regulation.

This lack of clarity impacts manufacturers of microbial cleaning products because even if their products comply with the requirements of the Detergents Regulation, they still cannot affix the CE mark in order for them to move freely on the internal market. This lack of clarity could also lead to different interpretations in different Member States with impacts on the uniform implementation and enforcement of the Regulation. Finally, consumers' health and the environment could also be affected, as risks associated with the use of these products are not assessed under the Detergents Regulation. In order to avoid legal uncertainty it is therefore considered that further clarification is needed on whether these products fall under the scope of the Detergents Regulation or not.

4.1.3 Have there been any technical or other developments since the adoption (and further amendments) of the Regulation that were not foreseen in the Regulation that have impacts on the relevance of the Regulation? Have there been any new problems/issues related to detergents, their use and their impact on the environment and human health that are currently not addressed through the Detergents Regulation?

About one third (34%) of the organisations that participated in the public consultation were aware of new problems/issues related to detergents that are not currently addressed through the Detergents Regulation. On the contrary, only 5% of SMEs that participated in the survey disseminated by the EEN said "yes"; 46% said "no" and 49% said "don't know".

Analysis of the available information from literature and consultation has identified some emerging issues that affect the relevance of the Detergents Regulation, namely:

1. The refill sale of detergents;
2. The use of nanomaterial ingredients in detergent products;
3. The change of washing machine loads and implications for detergent dosing;
4. The emission of microplastics to the environment as a result of detergent use; and
5. The potential for making use of new digital tools (for more information on this see section 4.3.1.3A below).

4.1.3.1 Refill sale of detergents

The refill sale of detergents has been identified as an innovation area with which the Detergents Regulation has not kept pace. There currently exist different types of refill sale in Europe. Some of them include a service whereby customers fill up their own bottles from a larger container. In other cases, refill distribution machines are in place that recognise specific receptacles (with the correct label) and that allow the refill only if the correct receptacle is used.

The main issue of this practice is related to the requirement laid down in the Regulation that certain information must be legible and visible on detergents' labels. It is often the case that this labelling requirement is not fulfilled in the refill sale of detergents as the product is sold in bulk and filled into empty containers that are either not labelled at all, or bear the wrong label since the detergent filled in them is not the same as the one that they previously contained. Provided that labels are the primary means by which the Detergents Regulation communicates information on the content of detergents and their safe use to consumers, this could result in potential issues in terms of protecting human health.

Another potential issue with the refill sales of detergents results from the definition of "manufacturer" provided in the Detergents Regulation⁶⁶. As any person changing the label of detergents is deemed to be a manufacturer under the Detergents Regulation, the refill sale of detergents could lead to a situation where a retailer or (in a more extreme scenario) even a consumer, changing the label of a detergent sold in bulk is deemed to be its manufacturer, and therefore responsible for placing that detergent on the market.

Tukes (2013)⁶⁷, the Finnish Safety and Chemicals Agency, has 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.

On the other hand, AISE's Cleanright panel labels⁶⁸ actively promote the refilling of detergent packaging. During the consultation, AISE explained that the bulk/refill sale of detergents does not introduce any vulnerability in terms of safety and is a practice that has the potential to contribute to sustainability and the circular economy by reducing for example the amount of packaging waste generated.

Other concerns related to this practice and which could pose safety issues for consumers are: the potential use of unsuitable or dirty containers; the case where a product needs to be recalled; the situation where consumers try to clean/wash containers at home; or when refilling stations are placed within the reach of children.

Based on the above, it is therefore considered necessary that further guidance is required in order to clarify whether the refill sale of detergents is allowed under the Detergents Regulation and whether modifications in the legal text are necessary in order to avoid situations where retailers could assume the responsibilities of manufacturers.

⁶⁶ According to its Article 2(10) "manufacturer means the natural or legal person responsible for placing a detergent or a surfactant for a detergent on the market; in particular, a producer, an importer, a packager working for his own account, or any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof, shall be deemed to be a manufacturer. A distributor who does not change the characteristics, labelling or packaging of a detergent, or of a surfactant for a detergent, shall not be deemed to be a manufacturer, except where he acts as an importer".

⁶⁷ Tukes (2013): Letter to the attention of the members of the Detergents Working Group. Available at: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail_groupDetailDoc&id=11241&no=2

⁶⁸ A.I.S.E. and Cefic have created a number of voluntary industry initiatives designed to promote sustainable development and ensure product safety. Cleanright is a service provided to consumers to help them understand the broad range of cleaning and maintenance products available, the benefits each type of product offers, and how to get the best results from them in a safe and environmentally responsible way: <http://uk.cleanright.eu/index.php>

4.1.3.2 *Nanomaterial ingredients*

A recent development in the detergents market is the production of detergents that contain nanomaterial ingredients (e.g. nanosilver, which is used as an antibacterial agent in some detergent products). During the consultation, it was indicated that hard surface cleaners, dishwasher tablets and laundry detergents (powders and liquids) are the most likely to contain nanomaterial ingredients.

Although nanomaterials offer technical and commercial opportunities, they may also pose a risk to the environment and raise health and safety concerns for humans and animals⁶⁹. It has therefore been argued that consumers have a right to know whether the products they buy contain nanomaterials⁷⁰. During the consultation, Member States' authorities and companies were of the opinion that the requirement to label nanomaterials should be dependent on whether they are hazardous or not. It should however be noted that this is in contradiction with the labelling requirements of the Detergents Regulation that do not distinguish between hazardous and non-hazardous materials.

Unlike the Detergents Regulation (which does not include any specific requirements for nanomaterials), both the Biocidal Products Regulation⁷¹ and Cosmetic Products Regulation⁷² provide specific provisions regarding nanomaterials and require the name of each nanomaterial ingredient included in the product to be stated on the label, followed by the word "nano" in brackets.^{73, 74} The EU Ecolabel⁷⁵ also requires that all nanomaterials in detergents are clearly indicated on the product label.

Nanomaterials are also regulated by the REACH Regulation⁷⁶ and the CLP Regulation⁷⁷ because they are covered by the definition of "substance" in both Regulations. Indeed, REACH has recently been amended⁷⁸ to introduce specific clarifications and new provisions in the chemical safety assessment (Annex I) and registration information requirements (Annex

⁶⁹ ECHA (2017): Nanomaterials under Biocidal Products Regulation. Article available at: <https://echa.europa.eu/regulations/nanomaterials-under-bpr>

⁷⁰ Nano&me (2017): Household cleaning products. Article available at: <http://www.nanoandme.org/regulation/household-cleaning-products>

⁷¹ 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.

⁷² Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

⁷³ According to Article 19 (1) of the Cosmetic Products Regulation: "All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets".

⁷⁴ Article 58 of the Biocidal Products Regulation.

⁷⁵ Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel.

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

⁷⁷ 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 .

⁷⁸ Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1551290627031&uri=CELEX:32018R1881>

III and VI-XI) for the registration of nanoform substances and related downstream user obligations (Annex XII). As of 1 January 2020, the amendments will apply both to new and existing registrations. They will significantly clarify the REACH registration requirements with regard to nanomaterials and will address the knowledge gap on which substances registered under REACH are placed on the market as nanomaterials and in which quantities.

Unlike REACH, the CLP Regulation does not contain specific provisions for nanomaterial ingredients. However, like bulk substances, nanomaterials that fulfil the criteria for classification as hazardous under the CLP must be classified and labelled. This applies to both nanomaterials as substances on their own, and to nanomaterials as special forms of a substance. As a result, substances in nanoform triggering a CLP classification would be labelled on detergents following the labelling requirements of the CLP Regulation⁷⁹. The only difference with the requirements for cosmetic and biocidal products would be that in this case the word “nano” would not be added next to the substance contained in the detergent in a nanoform. While it is understandable that such a reference would improve the communication of information to consumers, the extent to which this information would be useful to them needs to be further explored.

4.1.3.3 *Dosing information*

The Detergents Regulation requires manufacturers to include in the label of detergents information on the recommended quantities for use ("dosing information") and/or dosage instructions. This requirement applies to both consumer laundry and consumer automatic dishwasher detergents. As regards the latter, the dosing requirements of the Detergents Regulation do not seem to present an issue. However this is not the case for consumer laundry detergents.

The dosing information for consumer laundry detergents is, under the Detergents Regulation, expressed in relation to the standard washing machine load that is in its turn determined by the EU Ecodesign Regulation⁸⁰. As the size of washing machine loads has changed over time, stakeholders have expressed concerns that the dosing information required under the Detergents Regulation is now out of date.

Indeed, studies have shown that the average washing machine capacity has increased over the last decade⁸¹ but consumers do not use the full capacity of their machine for every wash⁸². As a result, some industry stakeholders noted that the standard washing machine loads (defined by the Regulation as 4.5 kg dry fabric for heavy-duty detergents and 2.5 kg dry fabric for light-duty detergents⁸³) need to be updated to take account of these trends. During the consultation for this evaluation, the JRC noted that the Ecodesign requirements for washing machines are currently being revised and these weight limits may change. In such a case, the

⁷⁹ As explained above the labelling of detergents falls by default under two pieces of EU legislation: the CLP Regulation and the Detergents Regulation.

⁸⁰ Commission Regulation (EU) No 1015/2010 of 10 November 2010 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household washing machines.

⁸¹ Michel A et al (2014): Monitoring the washing machines market in Europe. Available at: http://www.topten.eu/uploads/File/EEDAL15_Anette_Michel_Monitoring_washing_machines_market.pdf

⁸² AISE (2015): Pan-European consumer survey on sustainability and washing habits [Summary of findings, 2014]. Available at: <https://www.aise.eu/our-activities/information-to-end-users/consumer-activities.aspx>

⁸³ Annex VII B to the Detergents Regulation.

alignment of the provisions of the Detergents Regulation with the revised weight limits should therefore be considered.

Finally, it should also be noted that for consumer laundry detergents the Detergents Regulation does not contain any specific provisions regarding pre-dosed detergents such as liquid tablets or pouches. Potential clarifications for these types of products, as is the case of consumer automatic dishwasher detergents ('CADD'), could be considered.

4.1.3.4 *Microplastics*

Tiny pellets of plastic – commonly referred to as microplastics – are reportedly being used in detergents, for example as an abrasive medium, deposition aids for functional ingredients intended to stay on fabrics, in micro-encapsulation of fragrances or as opacifiers. These microplastic particles (in principle items smaller than 5 mm) can be released in the aquatic environment after being washed down the drain or potentially enter the human food chain⁸⁴.

While so far there was very little publicly available information on the extent of microplastics used in detergent products, some studies and reviews have found suspected plastic ingredients in cleaning products in Northern Europe^{85,86}. During the consultation, multiple stakeholders indicated their support for a ban on the use of microplastics in detergents (including Member State authorities, environmental and consumer NGOs).

Pollution of the seas from plastics and microplastics is one of the areas addressed by the Strategy for Plastics⁸⁷, adopted by the European Commission on 16 January 2018. One of the Strategy's actions to reduce microplastic pollution is to start the process to restrict the intentional addition of microplastics to products via the REACH Regulation.

At the request of the European Commission, the European Chemicals Agency (ECHA) has assessed the health and environmental risks posed by intentionally added microplastics used in a variety of sectors, including detergents. ECHA recently published the Annex XV dossier for a restriction of microplastics intentionally added to products⁸⁸. The Risk Assessment and Socio-Economic Analysis Committees of ECHA will assess the restriction dossier in the course of 2019. These Committees will formulate their opinions and send them to the European Commission, expected in spring 2020. If adopted, the restriction will cover the use of microplastics in detergents.

⁸⁴ House of Commons Library (2017): Briefing Paper, Microbeads and microplastics in cosmetic and personal care products. Available at: <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7510>

⁸⁵ Flora & Fauna International (2017): Appendix 3: Summary of microplastic ingredient (MPI) data from UK product database: www.fauna-flora.org/wp-content/uploads/2017/01/FFI-Microbeads-Guidance-Document-January-2017.pdf

⁸⁶ Verschoor et al (2016), as reported by ELUK (2017): Environment Links UK response to Defra, Scottish Government, Welsh Government and Department of Agriculture, Environment and Rural Affairs in Northern Ireland's Consultation: Proposals to ban the use of plastic microbeads in cosmetics and personal care products in the UK and call for evidence on other sources of microplastics entering the marine environment. Available at: <http://www.wcl.org.uk>

⁸⁷ <http://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy.pdf>

⁸⁸ <https://echa.europa.eu/documents/10162/12414bc7-6bb2-17e7-c9ec-652a20fa43fc>

4.2 Coherence

4.2.1 To what extent are the Detergents Regulation provisions internally coherent? Do provisions overlap or contradict, do they co-act as intended?

Views were somewhat contradicting with regards to whether there are gaps, overlaps or inconsistencies/contradictions *within* the Detergents Regulation. On one hand, the majority (23 out of total 41 responses) of industry associations, public bodies, companies (4 large and one small) and NGOs that responded to the public consultation were of the opinion that such gaps, overlaps and inconsistencies *within* the Regulation exist. On the other hand, the stakeholders that participated in the interviews generally indicated the opposite (i.e. that the provisions of the Detergents Regulation are internally coherent and that there are no major overlaps or inconsistencies).

During the public consultation two Member State authorities reported the following inconsistencies:

- an overlap between the requirement for the manufacturer to provide medical personnel with an ingredient data sheet and the additional requirement to publish the list of ingredients online; and
- the fact that when publishing them online the manufacturer must list the ingredients with their INCI names⁸⁹, when no such requirement exists for the detergents label.

As regards the first point, it should be noted that the list of ingredients published on the website is only a subset of the information included in the ingredient data sheet. In particular, while all ingredients need to be present in the online list, their weight percentage ranges and CAS numbers⁹⁰ are not required. This is important because otherwise manufacturers would be making public the full composition of their products. In addition, the ingredient data sheet is only provided to medical personnel upon request whereas the information on the website serves as a means of informing the general public and should be available at all times. This is also why the Detergents Regulation requires manufacturers to indicate the ingredients on the website using their INCI names, which are more easily understandable to consumers. Regulation No 907/2006 introduced this amendment to the original text of the Detergents Regulation for this exact purpose⁹¹. Based on this, it appears that the second reported inconsistency is also unfounded.

Apart from the above reported inconsistencies, no other evidence to support the claims that overlaps, gaps or inconsistencies between the provisions of the Detergents Regulations exist was provided. In the absence of such explanations, the opinion that the Detergents Regulation is internally inconsistent needs to be nuanced and considered with caution. This is also in line

⁸⁹ International Nomenclature Cosmetic ingredient.

⁹⁰ The unique numeric identifiers developed by Chemical Abstracts Service (CAS). CAS numbers are used for CLP classification.

⁹¹ Recital (5) of Regulation No 907/2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes III and VII thereto .

with the views of stakeholders that participated in the interviews that had an overall positive opinion regarding the internal coherence of the Detergents Regulation.

4.2.2 To what extent is the Detergents Regulation coherent with other EU legislation? Are there gaps between the Regulation and other pieces of legislation? Do provisions overlap or contradict, do they co-act as intended? What impacts do these overlaps have?

4.2.2.1 Gaps compared to other pieces of EU legislation

A consumer organisation and two NGOs reported some gaps or inconsistencies between the Detergents Regulation, the Biocidal Products Regulation and the Cosmetic Products Regulation, namely:

1. the lack of specific provisions to restrict or ban the use of category 2⁹² carcinogenic, mutagenic, reprotoxic substances ("CMRs") in the Detergents Regulation;
2. the lack of labelling requirements for nanomaterials in the Detergents Regulation (for more information on this issue, please see Section 4.1.3.2).

Detergents and cosmetics are similar formulations that share many ingredients. In addition, some types of detergents, such as hand dishwashing detergents, are comparable to rinse-off cosmetics in the sense that they come in contact with the human skin. Therefore, consumer organisations supported that the use of category 2 CMRs should be prohibited in detergents as is the case for cosmetics.

As mentioned above, carcinogens of category 1A and 1B are banned in detergents for consumer use under REACH. In addition, even though as a general rule category 2 CMRs are prohibited for use in cosmetics it is also possible to derogate from that rule. Article 15 of the Cosmetic Products Regulation states that category 2 CMRs may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety ('SCCS') and found safe for use.

Few consumers also expressed similar views about substances used in detergents. When asked about this issue one industry association stated that these concerns are not substantiated as for the detergents industry 'CMRs are strongly regulated by REACH, which studies and restricts its utilization for consumer uses'. The same association added that the inclusion of rules on CMRs under the Detergents Regulation would not help improve human health but would only create duplications and overlaps between the Detergents Regulation and the REACH Regulation.

Based on the available data, it is unclear whether category 2 CMRs are actually used in detergents sold to the general public. Further investigation on the regulation of category 2

⁹² Following classification under Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation).

CMRs in detergents for consumer use - especially those that come in contact with human skin could however be considered.

4.2.2.2 Coherence with other pieces of EU legislation

As already explained in section 1.1.2 above, detergents are subject to several pieces of EU legislation. The labelling of detergents is subject to both the Detergents Regulation and the CLP Regulation. Some detergents may also be subject to the Biocidal Products Regulation if they have a biocidal function or contain a preservation agent. In addition, although detergents are not subject to the Cosmetic Products Regulation, the Detergents Regulation refers to that Regulation for the labelling of allergenic fragrances. Other pieces of EU legislation that are applicable to detergents include: the REACH Regulation (e.g. for registration of chemical substances used in detergents), the Market Surveillance Regulation⁹³ (for the controls performed by national authorities on detergents) and the General Product Safety Directive (for any risks that detergents might pose and which are not covered by the specific provisions of the Detergents Regulation).

Organisations that participated in the public consultation were asked whether they are aware of any overlaps, inconsistencies or contradictions between the Detergents Regulation and other pieces of EU legislation. Almost two thirds (64%) of these organisations replied that they “agree” or “strongly agree” that there are overlaps and inconsistencies/contradictions between the Detergents Regulation and other pieces of EU legislation compared to only 12% that said that they “disagree” or “strongly disagree”.

The following issues were reported during the public consultation as potential overlaps and inconsistencies between the Detergents Regulation and other pieces of EU legislation:

A. Overlaps and inconsistencies between the Detergents Regulation and REACH (Regulation (EC) 1907/2006)

I. Ingredient data sheets and Safety Data Sheets

The Detergents Regulation requires that manufacturers placing detergents on the market shall, upon request, make available without delay and free of charge, to any medical personnel, an ingredient data sheet. This is without prejudice to the right of Member States to request that this data sheet is also made available to a designated public body assigned with the task to provide this information to medical personnel.

REACH includes a similar requirement for the suppliers of substances that are hazardous, or persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB), or on a candidate list of substances eventually subject to authorisation, to provide the recipient of that substance with a safety data sheet. For hazardous mixtures the same

⁹³ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

requirement applies. For mixtures not meeting the criteria for classification as hazardous but containing substances with particular characteristics (e.g. that pose human health or environmental hazards, or have PBT/vPvB⁹⁴ properties), such a safety data sheet is only required at the recipient's request. Section 3 of this safety data sheet provides information on the ingredients of the substance or mixture.

During the consultation both for the Fitness Check of the most relevant chemicals legislation (excluding REACH) ('The Fitness Check')⁹⁵ and for this evaluation, stakeholders indicated that it is unclear why there should be this difference and that the safety data sheets produced in accordance with REACH should be sufficient for detergents as well.

Indeed, it appears that a certain overlap between the provisions of the Detergents Regulation and REACH exists. However, some additional factors need to be considered, namely:

- The ingredient data sheet under the Detergents Regulation does not distinguish between hazardous and non-hazardous ingredients while the safety data sheet does: under REACH, the information that needs to be provided in Section 3 of the safety data sheet relates to hazardous substances that are classified for human health and/or environmental endpoints or substances with particular characteristics which are present in the mixture.
- The ingredient data sheet is to be prepared for *all* detergents and to be provided to medical personnel only *upon request*. On the contrary, REACH distinguishes between safety data sheets for hazardous mixtures and non-hazardous mixtures containing at least one substance with particular characteristics. For the former the safety data sheet needs to be provided *by default* and for the latter is only required *upon request*.
- The safety data sheet and the ingredient data sheet serve two different purposes, namely: the ingredient data sheet aims at providing medical personnel with information on the composition of the detergent in case for example of an allergic reaction or an incident of poisoning. In that sense, it is more similar to the requirements of Article 45 of CLP and the recently added Annex VIII to that Regulation (for more information on this, please see section C below). The safety data sheet also aims at enabling users to take the necessary measures for the protection of human health, safety at the workplace and the protection of the environment by providing, among other, the necessary information for the safe use, storage, handling and disposal of the substance or mixture. Its scope is therefore much broader.

Nevertheless, the data gathered for the purposes of this evaluation do not permit to conclude with certainty what exactly the impact of this overlap has been and whether it would be possible to rely on only one of these documents to achieve both the above mentioned

⁹⁴ Persistent bio accumulative and toxic substances and very persistence very bio accumulative substances.

⁹⁵ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses <http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF>

purposes. It appears more appropriate that the ingredient data sheets are replaced by the harmonized information relating to emergency health response under Annex VIII to CLP. It is however necessary that further analysis is conducted in this respect.

II. *Safety data sheet for industrial and institutional detergents*

All detergents (i.e. both those intended for consumer use and those that are intended to be used in the industrial and institutional sector) are subject to CLP labelling⁹⁶. In addition to these requirements, the Detergents Regulation lays down (further) labelling requirements for detergents sold to the general public (i.e. to consumers). Industrial and institutional detergents are exempted from these additional labelling requirements under the Detergents Regulation, if *equivalent information* to the labelling requirements laid down in that Regulation for detergents sold to the general public is provided by means of technical data sheets, safety data sheets or in a similar appropriate manner⁹⁷. So, in practice, the *labelling information* required under the Detergents Regulation for industrial and institutional detergents is often given in the *safety data sheet*, specifically in its Section 3.

An inconsistency between the Detergents Regulation and REACH was reported with regard to the information that needs to be included in the safety data sheet for industrial and institutional detergents.

This inconsistency results from the fact that the safety data sheet is compiled in accordance with the requirements stipulated in REACH, which are different from the labelling requirements of the Detergents Regulation. In the guidance for the correct implementation of the Detergents Regulation⁹⁸, the European Commission services have clarified that, in their view, the criteria for listing ingredients according to the Detergents Regulation differ in three important aspects from the corresponding criteria for Section 3 of the safety data sheet as given in Annex II to REACH:

1. The specification of ingredients according to the Detergents Regulation is not dependent on whether these ingredients are hazardous or non-hazardous. In this sense the Detergents Regulation only provides a list of selected substances to be specified, whereas REACH requires that only hazardous substances or substances with specific characteristics are listed in the safety data sheet;
2. For the listing of hazardous substances in the safety data sheet REACH refers to the concentration thresholds set in the CLP Regulation. These concentration thresholds are different from those provided for the listing of ingredients under the Detergents Regulation; and

⁹⁶ Article 11 (1) and recital (8) of the Detergents Regulation.

⁹⁷ Annex VII A to the Detergents Regulation.

⁹⁸ European Commission (2018): Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, available at: <http://ec.europa.eu/DocsRoom/documents/19522/attachments/1/translations/en/renditions/native>

3. The format of listing substances under the two Regulations can sometimes differ: the safety data sheet requires the listing of individual hazardous substances while for certain ingredients⁹⁹ the Detergents Regulation requires the listing of classes of substances.

As a result, a single ingredient list cannot be expected to successfully meet the requirements of both pieces of legislation. However, according to the Commission services¹⁰⁰, both lists (i.e. the list of substances to be listed in Section 3 of the safety data sheet according to REACH, and the list of detergent ingredients according to the labelling requirements of the Detergents Regulation) can be displayed under Section 3 of the safety data sheet, as long as they are clearly distinguished from each other by means of suitable (sub) headings indicating to which piece of legislation they apply.

Stakeholders sustained that these inconsistencies could result in lack of clarity for workers and that they create unnecessary burden on micro and small-sized manufacturers dealing with multiple pieces of legislation with differing requirements. Potential alignment of the legal requirements could therefore be explored.

B. Overlaps and inconsistencies between the Detergents Regulation and the CLP Regulation

Information received from AISE and other stakeholders during the consultation for the Fitness Check¹⁰¹ suggests that there are legislative overlaps between the Detergents Regulation and the CLP Regulation with regard to the labelling of allergenic fragrances. Similar views were also expressed by stakeholders during the consultation for the present evaluation.

The Detergents Regulation requires economic operators to include allergenic fragrances listed in Annex III to the Cosmetic Products Regulation and which are added to detergents at concentrations exceeding 0.01% by weight on detergents' labels. The labelling of these fragrances shall be done by using the International Nomenclature of Cosmetic Ingredients ("INCI names"). The Scientific Committee on Consumer Safety ('SCCS') assesses the safety of cosmetic ingredients, including allergenic fragrances. On the basis of the SCCS opinions, changes to Annex III to the Cosmetics Regulation concerning labelling requirement for fragrance allergens can be adopted.

In parallel, the CLP Regulation requires the inclusion of skin sensitizers (i.e. allergenic substances) in the list of ingredients that need to figure on the product label when they are

⁹⁹ Enzymes, disinfectants, optical brighteners and perfumes (Annex VII A to the Detergents Regulation).

¹⁰⁰ European Commission (2018): Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, available at: <http://ec.europa.eu/DocsRoom/documents/19522/attachments/1/translations/en/renditions/native>

¹⁰¹ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses <http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF>

present above certain thresholds¹⁰². These thresholds are different from the thresholds provided in the Detergents Regulation. As most allergenic fragrance ingredients under the Cosmetic Products Regulation are also classified as skin sensitizers under the CLP Regulation this may lead to the labelling of the same substance twice, once following the Detergents Regulation and once following the CLP Regulation.

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

1. The product identifier of the substance, i.e. the name (and identification number) under which the allergenic fragrance is to be labelled, is different under these two Regulations: as the Detergents Regulation refers to the Cosmetic Products Regulation for the labelling of allergenic fragrances, the latter are listed on detergents' labels with their INCI name. Contrary to that, the CLP Regulation requires that substances are labelled with either the name and identification number given in Part 3 of Annex VI to the CLP¹⁰³ 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 CAS¹⁰⁴ number together with its IUPAC¹⁰⁵ 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 names¹⁰⁶.
2. For mixtures not classified as sensitising but containing at least one skin sensitizer (e.g. an allergenic fragrance) above a pre-defined concentration threshold, as is commonly the case for detergents, the CLP Regulation requires that a EUH208 statement¹⁰⁷ is included in their label.

Based on the above it appears that one and the same allergenic fragrance contained in a detergent is very likely not only to be indicated twice on the detergent's label but also under completely different names. In addition, if a EUH statement needs to be included, then the same allergenic fragrance is labelled thrice, i.e. twice under the CLP Regulation (product identifier + EUH statement) and once under the Detergents Regulation.

The underlying reason for this effect is not so much an incoherence between the Detergents Regulation and CLP, but between the Cosmetics Regulation and CLP. The effect of this incoherence propagates to detergents through the reference in the Detergents Regulation to the list of allergenic fragrances in the Cosmetic Products Regulation.

¹⁰² Under CLP, skin sensitizers must be indicated on the label if added at concentrations exceeding 1.0% (skin sensitizer Category 1), 0.1% (skin sensitizer Category 1A) and 1.0% (skin sensitizer Category 1B).

¹⁰³ Part 3 of Annex VI to the CLP provides a table on the harmonised classification and labelling of hazardous substances.

¹⁰⁴ CAS Registry Number is a unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature.

¹⁰⁵ The IUPAC nomenclature of organic chemistry is a [systematic](#) method of naming [organic chemical compounds](#) as recommended by the [International Union of Pure and Applied Chemistry](#) (IUPAC).

¹⁰⁶ The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union.

¹⁰⁷ EUH 208 'Contains (name of sensitising substance). May produce an allergic reaction'.

As the list of allergens included in the Cosmetic Products Regulation is currently under consideration by the European Commission, this issue could be further exacerbated in the future. This is because in its opinion¹⁰⁸ the SCCS has recommended that the presence of any of 127 fragrance allergens is indicated on cosmetic product labels. As the Detergents Regulation refers to the Cosmetic Products Regulation for the labelling of fragrance allergens, a potential expansion of the list of fragrance allergens included in the labels of cosmetics (and therefore detergents) would result in more allergens being listed on the pack and potentially more duplications in the labelling requirements.

Given the importance of allergenic fragrances for human health¹⁰⁹ this issue warrants further attention.

Further reported inconsistencies between the Detergents Regulation and CLP were the following:

- 1) Under CLP, ingredients that present a chemical hazard should be included in the product label using the chemical name. On the contrary, under the Detergents Regulation ingredients can be listed under a generic name (e.g. anionic surfactant). It was noted that this can result in the labelling of the same substance twice, using different names.
- 2) The Detergents Regulation (Annex III) requires surfactants to be biodegradable, but detergents may be classified (and must therefore be labelled) as “may be harmful to aquatic environment” under CLP. The supporting study to the Fitness Check¹¹⁰ noted that this may potentially be confusing communication from a consumer perspective¹¹¹.

C. An overlap between the Detergents Regulation and Regulation (EU) No 2017/542 harmonising the information relating to emergency health response by adding an Annex to CLP

As outlined in section A above, the Detergents Regulation requires that detailed information on the composition of detergents be provided to medical professionals, upon request, via the “ingredient data sheet”. The Regulation also states that “this is without prejudice to the right of a Member State to request that such a datasheet is made available to a specific public body to which the Member State has assigned the task of providing this information to medical personnel”.

¹⁰⁸ https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

¹⁰⁹ Allergy is the most common chronic disease in Europe. Today, more than 150 million Europeans suffer from chronic allergic disease, and it is estimated that, by 2040, around 40% of the EU’s population will have an allergic predisposition (EAACI, 2016). As well as impacting individuals’ productivity and quality of life, dealing with allergic reactions imposes a significant cost burden on national health systems (EAACI, 2015).

¹¹⁰ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses <http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF>

¹¹¹ RPA et al. (2017): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation – Annex VI. For the European Commission. Available at: <http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/>

In parallel, CLP creates a framework for the submission (by importers and formulators of hazardous mixtures) of information relevant for formulating preventative and curative measures, in particular in the event of emergency health response to the appointed bodies across the EU (often known as poison centres). This information includes the chemical composition of the mixtures and the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency¹¹². Physicians, professional users and consumers can contact these poison centres to get recommendations for medical treatment in cases of poisoning.

Regulation (EU) No 2017/542 amended CLP by adding Annex VIII on a harmonised format for information relating to emergency health response. The Regulation requires producers and importers of chemical mixtures (such as detergents, paints and household chemicals) to provide i.a. uniform information on the product composition. This means that emergency responders in all EU countries will have the same information available. Poison centres will also be able to identify the exact product and its composition through a new uniform product identifier (UFI). This will lead to a better and more adequate medical response and will reduce unnecessary over-treatment often prescribed to cover all possible scenarios.

During the consultation for this evaluation, several industry associations stated that when Regulation 542/2017 starts applying¹¹³, the provisions of the Detergents Regulation related to the ingredient data sheet should become obsolete and that the Detergents Regulation should, therefore, foresee the gradual abolishment of these provisions.

AISE and other consultees similarly indicated that requiring manufacturers of detergent products to provide a list of ingredients to medical personnel upon request causes an unnecessary administrative burden for the detergents industry and that it would therefore be more logical and efficient for medical personnel to obtain this information from poison centres, which not only have information on product ingredients, but also on the actions that should be taken following a poisoning incident.

Based on the above, it appears that the ingredient data sheet under the Detergents Regulation serves a similar purpose as the harmonised information that will need to be provided to poison centres under the recently added Annex VIII to the CLP. When the CLP requirements start applying, the abolishment of the ingredient data sheet related provisions under the Detergents Regulation should therefore be considered in order to avoid duplication and reduce administrative burden for detergents' manufacturers.

¹¹² ECHA, European Chemicals Agency : <https://echa.europa.eu/>

¹¹³ Regulation 542/2017 establishes different deadlines for submitting information depending on the intended use of the hazardous mixtures at stake. For a hazardous detergent that is intended for consumer use, the information must be submitted by 1 January 2020. Detergents used in professional or industrial settings will need to comply by 2021 and 2024, respectively.

D. Overlaps and inconsistencies between the Detergents Regulation and the Biocidal Products Regulation (Regulation (EU) 528/2012)

Detergents that have an antibacterial function or contain a preservation agent are required to comply with the provisions of both the Detergents Regulation and the Biocidal Products Regulation. The rules apply to both laundry and dishwasher detergents as well as other detergent types, covering detergents for consumer, professional and industrial use.

Under the Detergents Regulation, surfactants that are also active substances within the meaning of the Biocidal Products Regulation and that are used as disinfectants are exempt from the biodegradability criteria of the Detergents Regulation provided that they are either approved active substances or authorised constituents of biocidal products under the Biocidal Products Regulation¹¹⁴. These surfactants and the detergents that contain them do, however, need to comply with the labelling provisions of the Detergents Regulation.

During the consultation, several stakeholders noted that there is an overlap between the Detergents Regulation and the Biocidal Products Regulation in the sense that detergents that are also used as disinfectants would need to comply with the labelling provisions of both. As the labelling requirements for these ingredients differ between the two Regulations, this often leads to duplicate labelling i.e. the same substance being labelled twice, once following the provisions of the Detergents Regulation and once those of the Biocidal Products Regulation.

Many stakeholders also argued that the boundary between the two pieces of EU legislation is not entirely clear. For example, industry associations explained that it can be difficult to identify ingredients as disinfectants and that in some cases, when Member State authorities interpret the legislation, they consider that a product should fall under the scope of the Detergents Regulation while the industry interprets it differently, which leads to disputes between them. It is therefore considered necessary to provide further guidance to clarify the interface between these two pieces of EU legislation and to avoid, to the extent possible, a potential duplication in the labelling requirements for detergents.

Another issue relates to the labelling of preservation agents. The Detergents Regulation requires that, *if added*, preservatives shall be listed irrespective of their concentration on detergents labels. This provision of the Detergents Regulation has been subject to different interpretations and poses certain issues with regards to the labelling of what is often referred to as ‘carry-over preservatives’. Carry-over preservatives are preservatives that are not added in the detergent as such by the detergent manufacturer, but are present in a mixture which the detergent manufacturer incorporates in a detergent (constituent mixture). Traces of the preservative that was included in the constituent mixture can be therefore found in the final product (i.e. the detergent) in small concentrations.

Companies, industry associations and Member State authorities noted that it is not clear how carry-over preservatives should be dealt within the context of the Detergents Regulation and if the above mentioned provision is applicable to them as well. This lack of clarity results in

¹¹⁴ Article 3 of the Detergents Regulation.

differences in the implementation and enforcement of this provision of the Detergents Regulation by manufacturers and Member States' authorities alike.

For example, one consumer organisation noted during the consultation that carry-over preservatives are not always listed on the label and that only preservatives that preserve the final product are. An industry association highlighted the example of a company that had declared the use of a substance (a carry-over preservative) in a detergent on the product label even though it was included in the detergent at a concentration below the limit of detection. The company had received an official complaint by the authorities who indicated that the substance had been incorrectly labelled (because the authorities were unable to detect it). Another industry stakeholder indicated that the ability to test for substances used in products has increased over recent years and that the most important consideration is that substances used in detergents are below the levels deemed to cause any adverse impacts.

In addition to the above, stakeholders also reported that if this labelling requirement of the Detergents Regulation is interpreted as being applicable to carry-over preservatives as well, this would lead to an inconsistency in the treatment of these preservatives between the Detergents Regulation on one hand and the Biocidal Products Regulation¹¹⁵ and the Cosmetic Products Regulation¹¹⁶ on the other.

The correct interpretation of the labelling requirements for preservation agents of the Detergents Regulation was recently brought to the attention of the Working Group on detergents. Following the question of a Member State competent authority the European Commission services launched in December 2018 a written procedure in order for Member States to provide their opinion on the matter. The deadline for providing comments was end of January 2019. Based on the input provided by different Member State competent authorities and the discussion that will be held in the next Detergents Working Group meeting in September 2019, the European Commission services and Member States will agree on a harmonised interpretation of this provision. The agreed interpretation will subsequently be included in the guidance document for implementation of the Detergents Regulation¹¹⁷.

¹¹⁵ Especially the provisions related to treated articles under the Biocidal Products Regulation and the relevant guidance document: CA-Sept13-Doc.5.1.e

¹¹⁶ Article 17 of the Cosmetic Products Regulation entitled 'Traces of prohibited substances' stipulates that: The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.

¹¹⁷ 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>

4.3 Effectiveness

4.3.1 To what extent does the Detergents Regulation meet its objectives, i.e. establishment of a true internal market for detergents, while ensuring a high degree of protection of the environment and human health?

4.3.1.1 Impacts in terms of the internal market

Data from Eurostat can be used to analyse changes in the intra-EU trade of detergents and surfactants between 2002 and 2015¹¹⁸. Taking into consideration the products that are most likely to fall under the scope of the Detergents Regulation, it appears that the intra-EU trade in detergents and surfactants has increased since 2002¹¹⁹, particularly for the following statistical groups:

- Organic surface-active agents, put up for retail sale or not (SITC¹²⁰ code 55421)
- Surface-active washing or cleaning preparations, put up for retail sale (SITC code 55422) or not (SITC code 55423);
- Polishes, creams and similar preparations (except artificial and prepared waxes), for footwear and leather (SITC code 55431) and for glass or metal (SITC code 55435); and
- Polishes and similar preparations (except metal polishes, artificial and prepared waxes), for coachwork (SITC code 55433).

The increase in the intra-EU trade was used as the most practical way to measure change in the level of harmonisation and free movement of detergents and surfactants for detergents. As mentioned above, Eurostat's data clearly point to an increase in the intra-EU trade in detergents and surfactants for detergents. However, it cannot be excluded that other factors and market forces may have also contributed to this effect.

Views expressed during different consultation activities provide additional elements of information:

- During the public consultation, 40% of the respondents including industry associations (12), public authorities (11), companies (5) consumer organisations (2) and a NGO indicated that they "agree" or "strongly agree" that the Detergents Regulation has made cross-border trade of detergents and surfactants for detergents easier within the EU. This strongly supports the view that the Detergents Regulation has made it easier for companies to participate in cross-border trade. The validation workshop confirmed this view.
- During the SME Survey, 53% of SMEs indicated that the Detergents Regulation has levelled the playing field for manufacturers of detergents and surfactants for detergents within the EU and only 6% replied that it hasn't. However, most of the SMEs that participated in the survey regarded that the Detergents Regulation has had no effect on their customer base or sales within the EU.

¹¹⁸ Eurostat (2016): Statistics explained, Intra-EU trade in goods – recent trends, available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Intra-EU_trade_in_goods_-_recent_trends

¹¹⁹ For more information on the intra-EU trade of detergents and surfactants for 2002-2015, please see Annex 6 to this evaluation.

¹²⁰ Standard International Trade Classification (SITC)

- During the interviews, the prevailing view of stakeholders was that the Detergents Regulation has helped to harmonise the rules in place in different Member States and that this has made it easier for companies to trade cross-border.

Read in conjunction with the data received from Eurostat, the above mentioned views provide basis to conclude that the Detergents Regulation has achieved to a large extent its objective of ensuring the free movement of detergents and surfactants for detergents in the internal market.

4.3.1.2 *Protection of the environment*

The results from the public consultation and the SME survey clearly indicate that stakeholders from across all groups (i.e. industry associations, companies, NGOs, a consumer organisation and public authorities) perceive the Regulation as being effective to a large extent in achieving its objective of ensuring a high degree of protection to the environment. The effectiveness of the specific provisions of the Detergents Regulation related to protection of the environment is assessed below:

A. Biodegradability of surfactants

One of the main environmental protection requirements of the Detergents Regulation deals with the concept of biodegradability of surfactants and detergents containing surfactants. As outlined in section 1.1.2 above, the Detergents Regulation stipulates that only surfactants meeting the criterion of “ultimate biodegradability” may be placed on the market.

Ultimate biodegradability is the highest level of environmental protection that can be ensured as the surfactant is totally broken down into carbon dioxide (CO₂), water and biomass. The findings of the EuroDeter project¹²¹ and data reported from controls on detergents performed in different Member States (see sections 2.1 and 2.2 above) suggest there is a high level of compliance with the biodegradability requirements of the Detergents Regulation. The fact that the ultimate biodegradability criteria offer the highest possible level of protection of the environment read in conjunction with the high level of compliance to these criteria suggests that the biodegradability requirements of the Detergents Regulation are largely effective in achieving the Regulation’s aim of protecting the environment.

This is also supported by the findings of the public consultation. Stakeholders from across all groups indicated that extending the scope of the legislation to cover all types of surfactant and changing the focus to ultimate biodegradability were positive steps in terms of protecting the environment. Several industry associations and companies further remarked that the biodegradability requirements have been effective in directing companies towards more environmentally friendly formulations and that the biodegradability requirements of the Detergents Regulation are often seen internationally as the “golden standard” for the biodegradability of surfactants.

Some stakeholders (including MS authorities and environmental NGOs) have indicated that the biodegradability requirements should be extended to other non-surfactants organic ingredients used in detergent products. The possibility to extend the biodegradability requirements to the main non-surfactant organic ingredients in detergent formulations has been thoroughly examined by the Commission both under the Detergents Regulation¹²² and

¹²¹ The final report (2014) is available at: <http://www.cleen-europe.eu>

¹²² Article 16 of the original text of the Detergents Regulation (i.e. as adopted in 2004 before any amendments) included a requirement for the Commission to carry out a review on the biodegradation of main non-surfactant

during the preparatory work for the adoption of the REACH Regulation, when targeted risk assessments on detergent ingredients were carried out. The Commission has concluded in its report to the European parliament and the Council¹²³ that no risk to the environment has been identified for any of the non-surfactant organic detergent ingredients and that it is therefore not considered appropriate to propose legislation to impose a requirement of ultimate biodegradability on the non-surfactant organic ingredients.

B. Phosphorus limitations

In 2012, the Detergents Regulation was amended¹²⁴ with the aim of reducing the damage caused by phosphates from detergents to the environment (and particularly the aquatic ecosystems) through the process of eutrophication.

Eutrophication, causes and environmental impacts

Phosphorus is one of the main limiting factors for biomass production in nature and phosphorus emissions, along with emissions of nitrogen, have been recognised as a major contributor to eutrophication in the aquatic environment. Increasing the phosphorus concentration in water bodies can increase the growth rate and biomass of algae, in the form of slime, mats and blooms, as well as certain rooted aquatic plants and weeds. This can affect a receiving ecosystem in a number of ways, especially with respect to the quality of water and the uses to which that water can be put.¹²⁵ Eutrophication can result in visible algal blooms which cause an increase in the turbidity of water and can create taste and odour problems. During a bloom, algae can also produce noxious toxins that can render water unsafe and cause fish mortality. The Urban Waste Water Treatment¹²⁶ Directive and the Water Framework Directive¹²⁷ establish a legal framework to protect the environment from the adverse effects of urban waste water discharges and discharges from certain industrial sectors, to restore clean water across Europe and ensure its long-term, sustainable use.

organic detergent ingredient and to report to the Council and the Parliament by 8 April 2009: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009DC0208>.

¹²³ Report from the Commission to the European Parliament and the Council Pursuant to Article 16 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, concerning the biodegradation of main non-surfactant organic detergent ingredients: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009DC0208>

¹²⁴ Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0259>

¹²⁵ Bateman I et al (2006): Does the phosphate treatment prevention of eutrophication pass the benefit-cost test? CSERGE Working Paper EDM 06-13. Available at: <https://s3-eu-west-1.amazonaws.com/esrc-files/.../mY3kqLIpuEeVWVXVGuxE9Q.pdf>

¹²⁶ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31991L0271>

¹²⁷ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32000L0060>

Regulation (EU) No 259/2012 introduced harmonised rules on the content of phosphates and other phosphorus compounds in detergents for household laundry and automatic dishwashing machines. It sets a limitation of:

- 0.3 grams of the total phosphorus content per standard dosage in Consumer Automatic Dishwasher Detergents ('CADD'), applicable as of 1 January 2017; and
- 0.5 grams of the total phosphorus content per recommended dosage in laundry detergents, applicable as of 30 June 2013.

The new rules did not, however, specifically provide a limitation on the content of phosphorus in detergents for washing laundry and dishes *by hand*. During the meeting of the Detergents Working Group on 8 November 2012¹²⁸, it was clarified that while hand-washing laundry detergents are covered by this limitation, hand-dishwashing detergents are not.

The discussions held with AISE and other industry associations during the consultation suggest that the market for hand washing detergents is much smaller than for products used in washing machines or dishwashers, and that many companies have voluntarily removed phosphates/phosphorus from hand washing detergents. Nevertheless, according to AISE's Activity & Sustainability reports¹²⁹, hand dishwashing detergents account for a significant market share, *i.e.* 41% of the total household dishwashing detergents market¹³⁰. As no quantified data exist on the number of companies that have actually voluntarily applied a restriction on the content of phosphorous, it is not possible to know whether and how this exemption has affected the Regulation's effectiveness to protect the environment. It should also be noted that the Detergents Regulation does not set any limitations on the content of phosphorus in industrial and institutional detergents even though these products account for approximately 20% of the total market¹³¹ for detergents¹³².

During the literature review and consultation undertaken for this evaluation, repeated attempts were made to identify data that could be used to measure the effectiveness of the new 2012 provisions as well as the effectiveness of the new limits for reducing eutrophication (for example, data on phosphorus concentrations in raw sewage, phosphorus concentrations in EU water bodies and corresponding levels of eutrophication).

AISE has estimated that, across the EU, about 70% of laundry detergent formulations and 5% of Consumer Automatic Dishwasher Detergents were already phosphorus-free as a result of voluntary actions and national restrictions by 2012. This means that about 30% of laundry detergent formulations and 95% of Consumer Automatic Dishwasher Detergents had to be reformulated as a result of Regulation (EU) No 259/2012. AISE has noted that this would be equivalent to a reduction of about 55 000 tonnes of phosphorus per year across the EU.

The majority of respondents to the public consultation agreed that consumer laundry detergents and consumer automatic dishwasher detergents on the market today contain less phosphorus than they did in the past as a direct result of the Detergents Regulation and its amendments. In a similar vein, about one third of SMEs that responded to the survey

¹²⁸ European Commission (2012): Draft Summary Record of the Meeting of the Detergents Working Group – 8th November 2012. Available at: <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1321>

¹²⁹ AISE Activity & Sustainability Reports for 2015-2016-2017

¹³⁰ For more information, see section 1.2.3 above.

¹³¹ EU plus Norway and Switzerland.

¹³² AISE Activity and Sustainability report for 2015-2016-2017.

conducted by EEN stated that they had reformulated products to reduce the total phosphorus/phosphate content as a direct result of the Regulation and its amendments.

It appears thus that the Detergents Regulation has been largely effective in reducing the amount of phosphorus/phosphate used in consumer laundry and consumer automatic dishwasher detergents. For the latter, the impact of the Detergents Regulation is even bigger as only 5% of them had limited phosphorus content before the introduction of the harmonised limits under the Detergents Regulation.

However, as regards to measuring the effectiveness of the Detergents Regulation in reducing the damage caused by phosphates from detergents to the environment (and particularly the aquatic ecosystems) through the process of eutrophication, it proved even more challenging due to a range of factors, namely:

- Firstly, it was not possible to find any data on phosphorus emissions/concentrations that postdate the coming into force of the restrictions (i.e. from 2013 onwards). As noted by one Member State authority during the targeted consultation, the restrictions on phosphorus only came into force relatively recently (2013 for laundry detergents and 2017 for CADD) which means that it may still be too early to be seeing their full effects;
- Secondly, many EU countries already had restrictions on the content of phosphorus in detergents in place before 2012, or were planning similar restrictions. It is therefore unlikely that a noticeable impact on phosphate loadings in these countries can be observed.
- Another challenge is that the contribution of detergents to phosphorus concentrations in river and lakes was relatively small (e.g. compared to agriculture), even before the restrictions were put in place. As noted by one Member State authority, this makes it extremely difficult to detect the signal from detergents and changes in their phosphorus content.
- The amount of phosphorus in sewage effluent is a poor measure of detergent phosphorus loadings, as many treatment works are equipped for ‘tertiary’ treatment, a key requirement under the Urban Waste Water Treatment Directive (Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment)¹³³.
- The impact of phosphorus on eutrophication is not uniform. A small amount of detergent phosphorus in one location could have a devastating effect on a waterbody and its biodiversity, while in another location, a much larger quantity of phosphorus could have a negligible impact;
- Some waterbodies (e.g. the Baltic Sea) receive inflows from non-EU territories that are not party to the Detergents Regulation.

Since the consultations for this evaluation were conducted, the European Commission has assessed the Member States 2nd River Basin Management Plans¹³⁴. Eutrophication is

¹³³ The Urban Waste Water Treatment Directive requires more stringent treatment to remove nitrogen and/or phosphorus from urban waste water from agglomerations above 10 000 population equivalents that discharge into areas that have been designated as sensitive (i.e. in areas that are eutrophic or at risk of eutrophication).

¹³⁴ Fifth Implementation Report: http://ec.europa.eu/environment/water/water-framework/impl_reports.htm

identified as a common cause of failure to meet the good ecological status objective. Agriculture is a major cause. However, some Member States have yet to fully implement the requirements of the Urban Waste Water Treatment Directive, and this failure could be a contributing factor to nutrient (including phosphorus) pollution in some cases.

C. Dosing information

In terms of effectiveness in the protection of the environment, the dosing information requirements in the Detergents Regulation serve as a means of preventing product overuse, thereby reducing the total amount of detergent and surfactant entering the environment.

The Detergents Regulation requires that the packaging of detergents sold to the general public bares information on the recommended dosage, namely:

1. For Consumer Laundry Detergents:
 - The recommended quantities and/or dosage instructions appropriate for standard washing machine loads¹³⁵; and
 - The number of standard washing machine loads for normally soiled fabrics¹³⁶ in the case of heavy-duty detergents and for lightly soiled fabrics in the case of detergents for delicate fabrics.
 - The capacity of any measuring cup provided must also be indicated in millilitres or grams, and markings must be provided to indicate the dose of detergent appropriate for a standard washing machine load for soft, medium and hard water hardness levels.
2. For consumer automatic dishwasher detergents ('CADD'):
 - the standard dosage expressed in grams or ml or number of tablets for the main washing cycle for normally soiled tableware in a fully loaded 12 place settings dishwasher, making provisions, where relevant, for soft, medium, and hard water hardness.

The literature review¹³⁷ and consultation activities undertaken for the purpose of this evaluation indicate that the dosing requirements of the Regulation are in principle an effective means of reducing the over-consumption of detergents. Whether in reality the dosing requirements of the Detergents Regulation have led to a reduced use of detergents by consumers remains unclear as it depends on whether consumers read, understand and correctly follow the dosing instructions. Some elements of answer (even though difficult to interpret) are provided by the answers received to the public consultation questionnaires.

Most citizens that participated in the public consultation indicated that they read, understand and follow the dosing information provided on the detergent packaging. In direct contrast,

¹³⁵ The instructions shall be expressed in millilitres or grams appropriate to a standard washing machine load, for soft, medium and hard water hardness levels and making provision for one or two cycle washing processes.

¹³⁶ The standard washing machine loads are defined as 4.5 kg dry fabric for heavy-duty detergents and 2.5 kg dry fabric for light-duty detergents, in line with the definitions of Commission Decision 1999/476/EC of 10 June 1999 establishing the Ecological Criteria for the award of the Community Eco-label to Laundry Detergents.

¹³⁷ p. 96-99 and 344-353, Support to the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) by Risk & Policy Analysts Ltd (RPA) and Mayer Brown LLP: <https://ec.europa.eu/docsroom/documents/32561>

consumer organisations stated the opposite and suggested that the dosing provisions of the Detergents Regulation need to be revised so that the information is easier for consumers to understand.

There are several reasons why this contradiction in views might have arisen. Beyond the fact that citizens' views expressed during the public consultation are not representative of society overall, it is also possible that consumers do not realise that they are not correctly following the dosing instructions (e.g. they may not realise that they live in a soft water area, what is meant by "lightly soiled" or that the lid does not always serve as a measuring cup).

Indeed, concerns were raised by Member States on how detergent users are interpreting the classification of "lightly soiled" and "normally soiled" used in the Regulation. During the consultation, one Member State authority explained that "lightly soiled" fabrics are actually the normal case, and this is potentially resulting in the excessive use (overdosing) of detergents. Consumer organisations may as well have underestimated the willingness and ability of consumers to understand and follow the dosage information and instructions.

Due to the contradicting views of stakeholders (especially consumer organisations) and citizens it is difficult to conclude with certainty what is the extent to which the dosing provisions of the Detergents Regulation are effective in protecting the environment. While the necessity of such provisions in order to inform consumers on recommended quantities and avoid product overuse is undeniable, it is possible that they need to be simplified in order to become more effective.

4.3.1.3 *Protection of human health*

As explained in section 1.1.2 above, the Detergents Regulation puts in place a number of provisions that aim to ensure the protection of human health. The effectiveness of each of these provisions in ensuring a high level of protection of human health is assessed below.

Stakeholders were asked to indicate the extent to which the Detergents Regulation has been effective in protecting human health. While overall the majority of organisations responding to the public consultation (63%) indicated that the Regulation has been "somewhat" or "very" effective, when split by respondent type, the industry stakeholders had more mixed views. 47% of industry associations and companies considered that the Regulation has been "somewhat" or "very" ineffective. These views are contrasted by those expressed during the SME Survey where 74% of respondents agreed that the Detergents Regulation has helped to protect human health. Moreover, 85% of government or public bodies also indicated that the Regulation has been at least somewhat effective in this regard.

A. Labelling of contents and the potential for making use of new digital tools

The labelling requirements of the Detergents Regulation is the primary means by which the Regulation aims to achieve its objective of ensuring the protection of human health. This is because the information included in detergents labels serves as a means of communicating information on the content of detergents (e.g. fragrance allergens) and use instructions to consumers thus allowing them to make more informed choices.

As already explained in detail in sections 4.2.2.2B and 4.2.2.2D above, the labelling of detergents falls *by default* under two pieces of legislation, i.e. the CLP Regulation and the Detergents Regulation. As a result, detergents labels contain also *by default* two sections i.e. one section dedicated to the CLP labelling requirements and one section for the additional

labelling requirements of the Detergents Regulation. In addition, the overlaps that exist between these two pieces of legislation result in duplications in the labelling of certain substances (e.g. allergenic fragrances). This means that the same substance is labelled twice or sometimes thrice on the same label and most of the time under different names (for more information on this please see section B above). Similar duplications and overlaps exist between the Detergents Regulation and the Biocidal Products Regulation, for detergents that have a biocidal function or contain a preservation agent.

Considering that in addition to all the above, the detergents labels also include:

- the name and trade name of the product;
- the name or trade name or trademark and full address and telephone number of the party responsible for placing the product on the market;
- the address, email address, where available, and telephone number from which the ingredient datasheet can be obtained;
- the indication of instructions for use and special precautions;
- dosage instructions;
- the relevant CLP pictograms; and
- information on poison centres,

it becomes apparent that detergents labels end up overloaded with information. Overloading of labels with information is a factor that may reduce the effectiveness of the Regulation in terms of achieving its objectives in relation to human health. Detergents labels become hard to read and it is not easy for consumers to detect the information that they are looking for, which could be crucial in case for example of an allergic reaction or a poisoning incident.

This is also in line with the findings of the Fitness Check¹³⁸ which concluded that labels can become overloaded with e.g. too much text, 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. Too much text included on labels, especially when this is required to appear in multiple languages, restricts the comprehension of the provided information.

During the consultation for this evaluation, a number of stakeholders also argued that some irrelevant information is being presented to consumers on product labels, and that this distracts them from more pertinent information. For example, one consumer organisation noted that, the surfactant content of the product must be listed on the label in terms of weight percentage ranges¹³⁹. This organisation explained that consumers would not know what to do with this information and that removing this unnecessary information would provide more space on the label for information that is important and of greater value to the consumer (e.g. allergenic fragrances and instructions for use).

¹³⁸ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses <http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF>

¹³⁹ Note that this requirement was originally introduced by Commission Recommendation of 13 September 1989 for the labelling of detergents and cleaning products, which proposed to introduce a more detailed labelling to make it possible for “*products to be used with greater discernment, which will have a direct impact on water quality and on the environment in general*”.

Apart from not being effective, many companies and industry associations indicated that the labelling requirements also pose an unnecessary regulatory burden for the detergents industry¹⁴⁰. During the consultation both for this evaluation and for the Fitness Check¹⁴¹, industry stakeholders suggested that a potential way of addressing these issues is with the use of innovative communication methods (e.g. Q-R codes¹⁴²) which are now available and which could help reduce the amount of information presented on product labels. In this way some of the ingredient information currently indicated on detergents labels would be provided online, and linked to the product using a Q-R code. Stakeholders pointed out that such Q-R codes are already used on some detergents available on the EU market. AISE (and some other stakeholders consulted) also suggested that innovative communication technologies could be used to convey other relevant information, such as sustainable consumption tips.

The use of innovative digital tools could be a win-win situation 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 for the latter. However, there are several factors related to the use of digital tools that need to be further considered. First, the use of digital tools requires an in-depth examination of the information that needs to figure on the labels so that they keep serving their purpose of protecting human health (e.g. allergenic fragrances). This information should be clearly identified and distinguished from other information that is not essential on the label and could therefore be provided via digital means (e.g. weight percentages for certain non-problematic ingredients). Second, the access to an internet-enabled portable device (e.g. mobile phone, tablet computer, etc.) is not always easy and for some parts of the population or age groups it might not be possible at all. Finally, data safety issues related with the use of digital tools should also be examined.

B. Provision of ingredient datasheets to medical personnel and specific public bodies

As previously outlined (sections 4.2.2.2A and 4.2.2.2C), manufacturers of detergents need to provide medical professionals, upon request, with an ingredient datasheet. Unlike detergents labels, where only specific ingredients are listed, ingredient data sheets include a comprehensive list of all the ingredients contained in detergents along with their respective concentrations. This allows medical personnel to provide the suitable treatment in cases of incidents related to detergents such as allergic reactions or poisoning.

As explained in section 2.2 above, a number of compliance issues related to the requirements on ingredient datasheets have been recorded that have a significant impact on the effectiveness of these provisions. Furthermore, as the recently added Annex VIII to the CLP Regulation¹⁴³ that harmonises the information relating to emergency health response starts

¹⁴⁰ A recent assessment of the cumulative costs faced by the EU chemicals industry has found that the detergents sector bears a relatively high administrative burden, compared to other sub-sectors within the EU chemicals industry. During the public consultation for this evaluation, it was noted by AISE and other stakeholders from the detergents industry that labelling requirements are an important component of the administrative burden faced by the detergents industry.

¹⁴¹ 61% of respondents to SME panel consultation agreed or strongly agreed that providing information on chemical hazards to consumers should rely more on novel tools, such as Q-R codes, apps and websites.

¹⁴² i.e. matrix barcodes that are machine-readable and that contain information about the item to which they are attached.

¹⁴³ Commission Regulation (EU) No 2017/542 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an

applying, not only the efficiency but also the need of such a requirement under the Detergents Regulation is questionable. In line with the findings described in section 4.2.2.2C above, it is suggested that once the CLP provisions start applying the abolishment of the ingredient data sheet related provisions under the Detergents Regulation should be considered in order to avoid duplication and reduce regulatory burden for detergents' manufacturers.

C. Publication of ingredient lists online

The Detergents Regulation requires manufacturers of detergents to make available on a website the list of all ingredients contained in their product. The website address from where this list can be obtained needs to be indicated on the label. The online ingredient list serves as a means of informing the general public. This is because the Detergents Regulation requires only specific constituents of detergents to be listed on the labels and only if they are added in specific concentrations in the product¹⁴⁴. This is for example the case for allergenic fragrances which will not be listed on detergents labels unless they are added in concentrations exceeding 0, 01% by weight. The presence of an allergenic fragrance would, however, be indicated in the online ingredient list irrespective of the concentration in which it is found in the product. As a result, a consumer with allergies or allergic predispositions would be able to obtain this information from the online list and thus be better protected.

Citizens that stated that they, or another member of their household, is allergic to substances found in detergents were asked whether they, or anybody in their household, has ever visited the website where the ingredient datasheets can be found. Of the twelve citizens that responded to this question, six indicated that they had visited the website, two said 'no' and three said that they don't know. When asked whether the website was easy to find, and whether the information provided on this website was helpful, half of the respondents(6) indicated "yes".

During the consultation for this evaluation, the following issues were however reported that affect the effectiveness of this provision:

- The EuroDeter project¹⁴⁵ found that almost 30% of the inspected detergents, for use by the general public, did not provide a website address related to the list of ingredients on the label or packaging. Furthermore, the list of ingredients was not available at the website address mentioned on the label for 46% of the inspected products. Compliance checks carried out by the Danish Consumer Council 'THINK Chemicals'¹⁴⁶ similarly found missing ingredient lists (datasheets), lists that were extremely difficult to find and lists that were outdated¹⁴⁷.
- Information received during the consultation similarly confirms that such issues are prevalent. For instance, one consumer organisation noted that some brands provide outdated information in their ingredient lists, and some brands do not communicate the

Annex on harmonised information relating to emergency health response. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0542>

¹⁴⁴ The Regulation also establishes certain exceptions where specific ingredients need to be labelled irrespective of the concentrations in which they added in the product e.g. enzymes, disinfectants etc.

¹⁴⁵ The EuroDeter project covers the time period 2012-2014: <http://www.cleen-europe.eu>

¹⁴⁶ KEMI (2017): Check your dishwashing soap for allergenic preservatives. Available at: <http://KemI.taenk.dk/bliv-groennere/check-your-dishwashing-soap-allergenic-preservatives>

¹⁴⁷ It should be noted that the controls carried out by THINK Chemicals only concerned products that are found in the Danish market.

ingredient lists when required. Another consumer organisation also commented that sometimes the ingredient list is not available online, sometimes it is difficult to find, sometimes it is there but has not been updated (and therefore contains incorrect information) and sometimes it is available and correct.

- During the consultation, two Member States' authorities noted that the website addresses given on detergent packaging does not always link directly to the list of ingredients and that it is not always possible to find the list of ingredients on manufacturers' websites.
- Member States' authorities remarked that the requirement for the information to be easily accessible, is not currently specifically expressed in the Regulation although this is specified in the Commission's guidance on the Regulation¹⁴⁸.

D. Instructions for use and special precautions

The Detergents Regulation requires that, if needed, the detergent's label shall indicate instructions for use and special precautions¹⁴⁹. The Regulation does not provide further guidance on what indications of use or measures should be mentioned and how they could be included in the label, although some industry associations have issued guidance to this effect.

During the consultation, industry associations and companies were predominantly of the view that this aspect of the Detergents Regulation is working well, although a couple stated that further guidance on how to provide such information would be welcomed.

Similar factors to those outlined in section A above regarding the effectiveness of the provisions on labelling may affect the effectiveness of the provisions related to instructions for use and precautionary statements. Information is lacking on whether consumers generally read (at least) the instructions and precautions provided on product labels. If too much, and too complex, information is presented on detergent labels, it might prevent them from doing so. This is reflected in research undertaken by AISE¹⁵⁰ which found that an increasing share of consumers believe that there is too much information provided to them on how to use detergent products safely.

It should however be noted that only 16% of citizens that participated in the public consultation for this evaluation stated "there is too much information" provided on how to use detergent products safely. This compares to 41% that indicated "there is about the right amount of information" and 39% that indicated "there is not enough information.

4.3.2 Which provisions or parts of the Detergents Regulation have met their objectives (i) most effectively (ii) least effectively, and which parts have not met their objectives.

Based on the analysis above (sections 4.3.1.2 and 4.3.1.3), the biodegradability requirements for detergents and surfactants for detergents as well as the limitations on the phosphorus content have met their objectives effectively. In both instances, the Detergents has provided a level of harmonisation that would not have been achievable otherwise (for more information,

¹⁴⁸ 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>

¹⁴⁹ Article 11(3) of the Detergents Regulation.

¹⁵⁰ Vandecasteele B et al. (2014): Washing habits 2014, U&A tracking, Prepared for AISE by InSites Consulting. Research Abstract for RPA, prepared March 2016

see section 4.5.1 below). Despite the effectiveness of the individual provisions, it should, however, be noted that their overall contribution to achieving the objective of the Regulation to protect the environment could not be quantified.

An area where the Detergents Regulation seems not to be fully effective is related to the labelling requirements. Indeed, as previously outlined (see sections 4.2.2 and 4.3.1.3A above), one of the key issues that has arisen from the overlaps between the Detergents Regulation and other pieces of the chemicals legislation is a duplication in the labelling requirements for detergents and the possibility that some unnecessary information figures on detergents labels. This results in labels being overloaded with information, which has a detrimental impact on consumer understanding and, in turn, reduces the effectiveness of the Regulation in terms of ensuring a high degree of protection of human health.

4.3.3 To what extent is the Regulation effectively implemented across EU Member States (e.g. enforcement, use of safeguard procedure)? What are the implementation and enforcement measures that have been put in place? Were they adequate?

As already explained in section 2.1 above, Member States do not have a reporting obligation under the Detergents Regulation. This poses a significant limitation in assessing the effectiveness of the implementation and enforcement measures put in place in different Member States.

From the information presented in previous sections and the views of the detergents industry's stakeholders, we can conclude that Member States have put in place a variety of sanctions (for more information please see section 2.1 above and Annex 4 to this evaluation). The data reported from Member States competent authorities further suggest that the existing sanctions for infringements of the Detergents Regulation are dissuasive, effective and proportionate.

During the supporting study for the Fitness Check, concerns were raised in relation to a lack of consistency in enforcement between Member States, which potentially results in inconsistent implementation of the Detergents Regulation¹⁵¹. It is unclear however if and whether this has had an impact in the effectiveness of the Regulation.

Participants in the public consultation were asked about the extent to which they agree that there is effective enforcement of the Detergents Regulation and its amendments by the responsible authorities in their country. The majority (18) of respondents including industry associations, companies, public authorities and one intergovernmental organisation stated that national enforcement is "somewhat effective" and six indicated that it is "very effective"¹⁵². Only one consumer organisation and one public authority found the enforcement to be somewhat ineffective and three stakeholders (among which an NGO, a public authority and an industry association) stated that they don't know.

¹⁵¹ RPA et al. (2017): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation – Annex VI. For the European Commission. Available at: <http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/>

¹⁵² Three industry associations, one public authority and two others.

4.4 Efficiency

For the purposes of this evaluation were assessed the incremental costs, i.e. additional with respect to the existing situation, as well as additional to the costs that would have emerged in the absence of the intervention.

Quantification has been carried out to the extent possible. Quantified cost estimates for industry are presented below. Other costs incurred by different actors including public authorities were analysed from a qualitative perspective, e.g. no quantified cost elements are presented regarding enforcement costs.

4.4.1 Costs and cost drivers

4.4.1.1 *What are the costs for industry associated with the implementation of the Detergents Regulation? What are the key drivers for those costs?*

The regulatory costs assessed for the purposes of this evaluation cover substantive compliance costs and administrative costs. Detailed calculation methods and assumptions used to assess these costs are provided in Annex 3 Methods and analytical models to this evaluation.

In total, the sector has incurred an estimated cost that ranges between EUR 764 million and EUR 1.8 billion (2004-2016) or approximately EUR 63.7 million to EUR 149 million per year (see below).

According to Eurostat, the annual EU turnover for the industry manufacturing soaps and detergents, cleaning and polishing preparations¹⁵³ was EUR 32.657,2 million in 2016¹⁵⁴. Compared to this, the maximum annual total cost incurred by this industry (i.e. EUR 149 million) as a result of the Detergents Regulation accounts for less than 0.5% of its annual turnover (based on the 2016 industry turnover).

However, as the Eurostat data is presented in product codes and these codes are wider in scope than the products falling under the scope of the Detergents Regulation¹⁵⁵, the above-mentioned figure on annual turnover might not be representative of the detergents industry as such. Indeed, during the public consultation several industry stakeholders including AISE stated that the annual EU turnover of the detergents industry is approx. EUR 17-18 billion. Compared to this potentially more accurate figure, the maximum annual total cost incurred by the detergents industry (i.e. EUR 149 million) as a result of the Detergents Regulation accounts for approximately 0.83% of its annual turnover.

In both cases however the costs are not significant and can be assumed that they are justified. It should nevertheless, be noted that several stakeholders from the detergents industry stated during the consultation that this might not be the case for all companies and that local and national differences should be taken into account in this respect. For example, these costs could be justified for some multinational companies trading in multiple countries but compared to them SMEs trading only at national level might have incurred high net costs.

¹⁵³ NACE code 2041, manufacture of soap and detergents, cleaning and polishing preparations.

¹⁵⁴ Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

¹⁵⁵ For example, pet soaps and some types of polishes that do not have a cleaning function would not fall under the scope of the Detergents Regulation but would be included in this category.

DIRECT COSTS FOR DETERGENTS INDUSTRY	QUANTIFICATION / QUALITATIVE DESCRIPTION
SUBSTANTIVE COMPLIANCE COSTS <i>Costs associated with reformulation to reduce the phosphorus content</i>	
One-off costs	EUR 26 million - EUR 142 million
On-going costs	<u>Consumer laundry detergents</u> : appr. EUR 419 million (June 2013 – January 2018) <u>Consumer automatic dishwasher detergents</u> : EUR 61 million (January 2017 – January 2018)
<i>Costs associated with labelling requirements</i>	
One-off costs	<u>Revision of labels and artwork</u> : EUR 6.3 million - EUR 154.5 million <u>Throwing old label stock away</u> : EUR 3.2 million - EUR 9 million
On-going costs	<u>Updating consumer detergent product labels</u> : EUR 0.8 million EUR 1.5 million per year (the total cost estimated at EUR 9.5 million - EUR 18.5 million)
<i>Costs associated with providing information in ingredient datasheets</i>	
For industrial and institutions detergents	
One-off costs	EUR 3.2 million - EUR 10.3 million
On-going costs	EUR 0.7 million to EUR 2.5 million per year (the total cost estimated at EUR 7.9 million - EUR 30.3 million)
For consumer detergent products	
One-off costs	<u>Providing ingredient datasheets online</u> : EUR 0.9 million - EUR 1.5 million
On-going costs	<u>Updating simplified ingredient datasheets and providing these online</u> : EUR 0.3 million to EUR 0.4 million per annum (the total cost estimated for the period 2006-2016 at EUR 3.3 million - EUR 5.4 million)
<i>Costs of familiarization and keeping up to date with the provisions of the Detergents Regulation</i>	
One-off costs	EUR 7.6 million - EUR 15.7 million
On-going costs	<u>Familiarization with the five amendments</u> : EUR 37.8 million - EUR 78.5 million
<i>Costs of testing biodegradability</i>	EUR 2.4 million - EUR 18.0 million
ADMINISTRATIVE COSTS	
<i>Of compiling ingredient datasheets</i>	
One-off costs	EUR 9.5 million - EUR 25.8 million
On-going costs	<u>Consumer detergent products</u> : EUR 1.7 million - EUR 4.5 million per annum (the total cost estimated at EUR 19.8 million - EUR 54.1 million) <u>Industrial and institutional detergent products</u> : EUR 3.3 million - EUR 9 million per annum (the total cost estimated at EUR 39.7 - EUR 108.1 million)
<i>Of providing information to poison centers</i>	
One-off costs	EUR 11.3 million to EUR 72 million
On-going costs (total)	EUR 71.3 million to EUR 453.8 million
<i>Of providing information to medical personnel</i>	EUR 58 400 - EUR 62 900 per annum (the total cost estimated at EUR 0.7 million - EUR 0.75 million)

Table 1 Overview of costs for the detergents industry

The largest costs are estimated to have arisen as a result of the need to use different raw materials in place of phosphorus, from having to provide ingredient datasheets to poison centres and from the research and development necessary for reformulation i.e. to reduce the

total phosphorus content of consumer laundry detergents and consumer automatic dishwasher detergents (CADD).

During the consultation, industry associations and companies clarified that the costliest elements of the Detergents Regulation for the detergents industry have been the one-off costs associated with the reformulation of products (to reduce the total phosphorus content); keeping information for websites and medical personnel up to date; and the one-off and ongoing costs associated with labelling changes (which may impact SMEs more than larger companies due to the need to dispose of old labels). Detergent manufacturers have also faced on-going costs associated with using different raw materials in place of phosphorus in consumer laundry detergents and consumer automatic dishwasher detergents. Several industry representatives noted that switching to producing phosphorus-free detergents led to a 10% increase (approximately) in raw material costs. Industry stakeholders indicated that these costs have not been passed on to consumers (as higher prices).

A. Substantive compliance costs

Substantive compliance costs can be divided into:

- one-off costs that are borne by industry having to adjust and adapt to the changes in legal rules; and
- recurrent (on-going) costs that are borne on regular basis.

Below are presented costs associated with reduction of phosphorus content, labelling and testing of biodegradability.

I. *Costs associated with reformulation to reduce the phosphorus content*

In 2012, the Detergents Regulation was amended to harmonise rules on limiting the content of phosphates and other phosphorus compounds in detergents for household laundry and dishwashing machines to reduce the damage phosphates that detergents may have on ecosystems and water quality (a phenomenon known as ‘eutrophication’). For consumer laundry detergents, the limitation applies since 30 June 2013. For consumer automatic dishwasher detergents (‘CADD’), the limitation applies since 1 January 2017.

a. One-off costs

The reformulation costs provided by SMEs during the consultation for the purposes of this evaluation are broadly consistent with those of the Commission’s 2010 impact assessment accompanying the proposal for Regulation (EU) No 259/2012¹⁵⁶ that estimated the total one-off (CAPEX) reformulation costs across the EU to be between EUR 26 million and EUR 142 million.

It was however not possible to provide a reliable estimate of the total one-off costs of changing production processes even though in some cases, these may have been significant.

¹⁵⁶ European Commission (2010): Commission Staff Working Document accompanying document to the Proposal for a Regulation (EU) No ... of the European Parliament and of the Council amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in household laundry detergents, SEC(2010) 1277 Final, available at: <http://www.ipex.eu/IPEXL-WEB/dossier/document/SEC20101277FIN.do>

b. On-going costs

Detergent manufacturers have also faced substantive on-going compliance costs associated with using different raw materials in place of phosphorus. During the interviews, companies explained that there is no simple one-for-one alternative to phosphorus and that, to reduce the amount of phosphorus/phosphate used in detergents, multiple ingredients need to change.

Since June 2013 when the new limits for consumer laundry detergents came into force, the detergents industry would have incurred costs of approximately EUR 419 million. The new limits for CADD only came into force on 1 January 2017 and thus CADD manufacturers will have incurred costs of EUR 61 million (approx. January 2017 –January 2018). In total, it is estimated that costs of the order of EUR 479.7 million have been incurred by the detergents industry so far.

II. *Costs associated with labelling requirements*

As outlined above, there are specific labelling provisions in the Detergents Regulation that apply without prejudice to those resulting from the CLP Regulation.

a. One-off costs

Pre-existing legislation on detergents i.e. the Council Directive [73/404/EEC](#) only required the name of the product and name and address of the party responsible for placing the product on the market to be indicated on the label. Unlike the Detergents Regulation, it did not require, for example, the content of the detergent to be labelled, an indication of the dosage to use, or specific languages to be used.

The total one-off cost of labelling changes (covering the revision of labels and artwork) to the detergents industry can be estimated at EUR 6.3 million to EUR 154.5 million. The total one-off cost of throwing label stock away can be estimated at EUR 3.2 million to EUR 9 million. This gives a total one-off cost of producing new labels for consumer detergents of EUR 9.5 million to EUR 163.5 million across the EU/EEA.

Stakeholders noted that the labelling provisions of the Detergents Regulation have been particularly costly for companies and that SMEs may have been disproportionately affected by the changes because they tend to buy-in labels, rather than produce them in-house¹⁵⁷.

SMEs responding to the EEN survey were asked to indicate the one-off costs associated with “changes to labelling including the disposal of old labels”. Responses to this question varied significantly without any clear and plausible explanation. 17% of SMEs indicated that the one-off costs were greater than EUR 20 000. Around one quarter of SMEs that participated in the survey indicated that the average one-off cost per formulation of fulfilling the labelling requirements specific to the Detergents Regulation was less than EUR 250.

¹⁵⁷ Companies that do not produce their own detergent labels may have been required to throw some (non-compliant) stock away when the new rules came into force. During consultation, several companies (both large and small) noted that they incurred costs because labels and packaging had to be thrown away.

b. On-going costs

The total on-going cost of updating consumer detergent product labels can be estimated at EUR 0.8 million to EUR 1.5 million per year. Between 2004 (date of entry into force of the Detergents Regulation) and 2016, the total cost to the detergents industry can be estimated at EUR 9.5 million to EUR 18.5 million.

III. *Costs associated with providing information on the content of industrial and institutional detergents by means of technical data sheets or safety data sheets as an alternative to on-pack label*

As explained in section 4.2.2.2A above, the labelling information required under the Detergents Regulation for industrial and institutional detergents can be provided (Annex VII A) and in practice is often given in a technical or a safety data sheet.

The total one-off cost of providing this labelling information for industrial and institutional detergents in a technical or a safety data sheet is estimated to range between EUR 3.2 million and EUR 10.3 million. The on-going costs for keeping technical datasheets and safety datasheets up-to-date can be estimated at EUR 0.7 million to EUR 2.5 million per year. The overall costs that the detergents industry has incurred can be estimated at EUR 7.9 million to EUR 30.3 million (2004-2016).

IV. *Costs of familiarisation and keeping up to date with the provisions of the Detergents Regulation*

SMEs that participated in the survey conducted by the EEN were asked to estimate the one-off costs associated with understanding the legislative requirements. 14% of SMEs indicated that it costs less than EUR 1 000; 9% indicated that it costs between EUR 1 000 and EUR 2 500; 3% indicated it costs between EUR 2 500 and EUR 5 000; 6% indicated it cost between EUR 5 000 and EUR 10 000, while 11% indicated it cost more than EUR 20 000. Based on these views, one-off cost of familiarisation with the Detergents Regulation (as enacted in 2004) can be estimated at EUR 7.6 million to EUR 15.7 million.

V. *Costs of testing of biodegradability*

The total cost across the industry of testing for each surfactant to ensure it meets the requirements of ultimate biodegradability is estimated between EUR 2.4 million and EUR 18 million. To some extent, however these costs can be considered business as usual costs as the pre-existing EU legislation already required certain surfactants (anionic and non-ionic; which before the Detergents Regulation came into force accounted for about 90% of the total surfactants on the EU market¹⁵⁸) to be tested for their (primary) biodegradability.

B. Administrative costs

Administrative costs are borne by the industry as a result of administrative activities performed to comply with the information obligations included in the legal rules. Administrative burden is the result of regulatory requirements.

¹⁵⁸ Intertek (2012): Understanding & attaining compliance to the EU Detergent Regulation, available at: www.intertek.com/WorkArea/DownloadAsset.aspx?id=48909

I. Administrative costs of compiling ingredient datasheets

Across the industry, the total one-off cost of compiling ingredient datasheets can be estimated at EUR 9.5 million to EUR 25.8 million.

During the interviews, stakeholders clarified that, although the one-off cost of compiling an ingredient datasheet is relatively small, the on-going costs add up because these datasheets need to be updated even for a very small change in the formulation. For consumer detergent products, the total annual cost of keeping ingredient datasheets up-to-date can be calculated at EUR 1.7 million to EUR 4.5 million per annum, or EUR 19.8 million to EUR 54.1 million (2004-2016). For industrial and institutional detergent products, the total annual cost of keeping ingredient datasheets up-to-date can be calculated at EUR 3.3 million to EUR 9 million, or EUR 39.7 to EUR 108.1 for the period 2004-2016.

II. Administrative costs associated with providing ingredient datasheets online

Manufacturers of consumer detergents are required to make available, on a website, a simplified ingredient data sheet (for more information see section 4.3.1.3C). The total one-off cost of providing ingredient datasheets online can be estimated at EUR 0.9 million to EUR 1.5 million. The total on-going cost of updating simplified ingredient datasheets for consumer detergent products and providing these updated datasheets online can be estimated at EUR 0.3 million to EUR 0.4 million per annum, or an estimated total ranging from EUR 3.3 million to EUR 5.4 million for the period 2006-2016.

III. Administrative costs of providing information to poison centres

The total one-off cost of providing ingredient datasheets to poison centres can be estimated at EUR 11.3 million to EUR 72 million.

The on-going costs of providing ingredient datasheets to poison centres can be estimated at EUR 71.3 million to EUR 453.8 million (2004-2016).

IV. Administrative costs of providing information to medical personnel

The total annual cost to the detergents industry can be estimated at EUR 58 400 to EUR 62 900, or EUR 0.7 million to EUR 0.75 million in total for the period 2004-2016.

4.4.1.2 What are the costs for society associated with the implementation of the Detergents Regulation?

During the interviews, industry stakeholders were asked whether any of the costs incurred by industry as a result of the Detergents Regulation had been passed on to consumers in higher prices. In response to this question, most organisations indicated that although the industry faced some costs as a result of the Detergents Regulation, these costs have not been passed on to consumers.

During the consultation, AISE confirmed that companies invested in alternative ingredients in order to comply with the biodegradability requirements and phosphorus restrictions, but that in doing so companies have been able to maintain, if not improve the cleaning performance of their products. Citizens that responded to the public consultation were asked whether they have noticed any changes in the cleaning performance of detergent products over the course

of the last decade. Most citizens (39%) that responded to this question indicated that “the cleaning performance of detergent products has not changed” and that the diversity of products on the market has not changed either.

4.4.2 Benefits

No quantified estimates of benefits resulting from the Detergents Regulation were available. These were assessed and are presented with a qualitative description.

4.4.2.1 What are the benefits for industry associated with the implementation of the Detergents Regulation?

By harmonising the rules for placing detergents and surfactants for detergents on the market, the Detergents Regulation has levelled the playing field between detergents manufacturers and has facilitated the intra-EU trade of detergents. Both the detergents market and the detergents industry have experienced steady growth since the entry into force of the Detergents Regulation (see section 1.2.3). As previously outlined (see section 4.3.1.2A) the Detergents Regulation is often regarded internationally as the "golden standard" for the biodegradability of surfactants. European companies can therefore benefit from perception of quality of detergents manufactured in the EU, which could, potentially, bring important advantages in terms of international trade.

During the interviews, industry associations and companies largely agreed that the Regulation has been a success in terms of levelling the playing field between Member States. Most organisations (76%) that participated in the public consultation were of the view that the Detergents Regulation has helped to level the playing field for manufacturers of detergents and surfactants for detergents in the EU. However, nearly half (42%) of the industry stakeholders (companies and industry associations) that participated in the public consultation disagreed that the Regulation has led to market opportunities. This is twice the number of industry stakeholders that agreed (21%).

According to stakeholders, the Detergents Regulation has had a mixed effect in terms of innovation. On one hand, the detergents industry has noted that new products have been developed in response to the Detergents Regulation, particularly in response to the phosphorus limits introduced for consumer automatic dishwasher detergents ('CADD'). On the other hand, several industry representatives noted that resources had to be used to ensure compliance and that this reduced the total resources available for innovation.

The view of SMEs is particularly important when considering the impacts of the Detergents Regulation in terms of innovation. The survey asked SMEs whether the Detergents Regulation has had any effect on their business in terms of the development of new products.

- 38% of SMEs indicated that the Regulation has led to an increase in the development of new products, while 50% indicated that the Regulation has had no effect.
- During the public consultation, 79% of companies and industry associations indicated that the Detergents Regulation has led to innovation in the detergents sector.
- Nearly half the SMEs that participated in the survey conducted by European Enterprises Network (EEN) indicated that the Detergents Regulation has led to innovation in the detergents section. Only 11% disagreed.

Most companies and industry associations participating in the public consultation (74%) thought that the Regulation has improved the corporate image of the sector. A high proportion of SMEs (48%) indicated the same in the survey conducted by the EEN.

4.4.2.2 What are the economic, social and environmental benefits for society associated with the implementation of the Detergents Regulation?

The Detergents Regulation and its amendments have provided an enhanced level of protection to human health and the environment. The harmonised rules on biodegradability ensure that surfactants are totally broken down to water, carbon dioxide and biomass. Another environmental benefit results from the limitations on the content of phosphorus in consumer laundry and consumer automatic dishwasher detergents. Attributing quantified benefits associated with reduced eutrophication to the Detergents Regulation thanks to reduced phosphorus emissions from detergents has not been possible due inter alia to difficulties in source apportionment of phosphate emissions across the range of human and agricultural sources. However, as less phosphorus in detergents also means less phosphorus entering the environment when detergents are washed down the drain, it can reasonably be assumed that the harmonised limits introduced by the Detergents Regulation have contributed to the overall reduction of eutrophication.

Detergents' labels provide important information on product ingredients for consumers, enabling them to make more informed choices. Consumers with allergies or allergic predispositions are informed about the presence of allergenic fragrances in detergents and potential reactions related to the use of detergents are therefore reduced. Medical personnel is informed of all the ingredients contained in detergents and is able to provide the necessary treatment when required. Finally, the free movement of detergents on the internal market has increased consumer choice allowing consumers to choose from a wide variety of products that are potentially more suitable for their needs.

During the consultation, it was widely agreed that new (greener/more sustainable) detergent products have been developed in response to the Detergents Regulation. It was also agreed that the Regulation has made it easier for companies to trade detergents cross-border within the EU. These two factors lead to think that the Regulation may have increased consumer choice.

Most stakeholders (17 out of 41 responses) including industry associations (4), public bodies(8) one consumer organisation, one company, one NGO and two others, did not know whether the Detergents Regulation has led to benefits for other industry sectors for example, tourism and commercial fisheries due to reduced phosphorus emissions to the aquatic environment. The majority of industry stakeholders (11 out of 14 negative responses) disagreed or strongly disagreed that the Regulation has led to benefits for these sectors, six neither agreed nor disagreed and only eight agreed or strongly agreed it has¹⁵⁹.

In the EEN survey, SMEs were asked whether the Detergents Regulation has resulted in benefits to other industry sectors, with the example of the commercial laundry sector. 41% of organisations that responded to the survey agreed that the Regulation has resulted in benefits to other industry sectors, while only 3% of respondents disagreed.

¹⁵⁹ One industry association, two NGOs, one consumer organisation, one company and one public body.

4.4.3 To what extent are the costs involved in implementing the Detergents Regulation justified given the benefits which have been achieved?

The detergents sector has incurred an estimated cost of between EUR 764 million and EUR 1.8 billion as a result of the Detergents Regulation (2004-2016). This equates to an annual cost of approximately EUR 63.7 million to EUR 149 million that accounts for less than 0.5% of the industry annual turnover (see section 4.4.1.1 above). As no quantified estimates of benefits were available, the answer to the question whether costs of implementing the Detergents Regulation are justified takes into account stakeholder views expressed during different consultation activities carried out for the purposes of this evaluation.

The majority view of stakeholders is that the Regulation has been successful in terms of protecting the environment and, to some extent, human health.

Out of the 40 organisations that responded to this question during the public consultation, 70% indicated that the costs are justified given the benefits that have already been achieved. 50% of organisations indicated that the costs are justified given the benefits that will be achieved in the longer term. In both instances, this is higher than the proportion that disagreed (5% and 23% respectively).

It is notable that 42% of industry stakeholders indicated that the costs involved with the implementation of the Detergents Regulation are not justified given the benefits that will be achieved in the longer-term, while 76% of other stakeholders believed that the benefits would be worth the costs in the longer-term.

In comparison, 26% of SMEs agreed that the costs involved in implementing the Detergents Regulation are justified given the benefits that they have already received and 38% of SMEs agreed that the costs involved are justified given the overall benefits to the economy, environment and society. A fifth of SMEs (21%) did not think that the costs involved in implementing the Regulation are justified given the benefits that they have received, while 16% thought that they were not justified given the benefits to the economy, environment and society.

4.5 EU value added

The principle of subsidiarity requires that legislating at the EU level should occur only when and where there is evident added-value of doing so, i.e. where the intervention at the EU level is necessary and more effective. This section looks at whether there is added value in regulating detergents at the EU level as opposed to solely at the national level and, if there is one, what this added value is.

4.5.1 To what extent has the Regulation permitted achievements which could not be reached at Member State level? To what extent is EU level intervention still warranted?

The findings of this evaluation suggest that harmonising the rules on limiting the content of phosphorus in consumer laundry detergents and consumer automatic dishwasher detergents has delivered much better outcomes for the environment than could have been achieved at a Member State level. National restrictions already in place before the harmonised limit values across the EU were leading to market fragmentation and the voluntary action via e.g. ecolabels was not providing manufacturers with sufficient incentive to opt for it.

In the case of consumer automatic dishwasher detergents, the added value of regulating the phosphorus limits at the EU level is even more significant. This is because before 2012 (when such restrictions were introduced¹⁶⁰), national rules regulating the use of phosphorus in consumer automatic dishwasher detergents only existed in 4 out of 28 EU Member States¹⁶¹. According to AISE, this accounted for only 5% of consumer automatic dishwasher detergents that were then available on the market which means that 95% of these products were reformulated as a direct result of the Detergents Regulation (for more information see section 4.3.1.2B above).

Moreover, harmonised rules on the use of phosphorus in detergents potentially serve as a means of stimulating progress towards better management of transboundary pollution in regions such as the Baltic Sea and the Danube River Basin¹⁶². The currently available data does not, however, allow for a clear conclusion whether the Regulation has actually contributed to this effect or not¹⁶³.

As previously outlined (see section 4.3.1.2A) the Detergents Regulation is often regarded internationally as the "golden standard" for the biodegradability of surfactants. European companies can therefore benefit from perception of quality of detergents manufactured in the EU, which could, potentially, bring important advantages in terms of international trade.

The Regulation has also delivered added value with regards to the protection of human health (particularly the provisions on the labelling of fragrance allergens). However, this added value has been somehow watered-down due to the overarching impact of other pieces of EU chemicals legislation (such as REACH and CLP) that were adopted after the entry into force of the Detergents Regulation and have rendered some of its provisions superfluous.

Harmonising the rules and standards for the placing on the market of detergents across the EU has, according to stakeholders¹⁶⁴, levelled the playing field for detergents manufacturers and made it easier for companies to trade detergents and surfactants cross-border within the EU.

During the consultation, there was consensus among stakeholders that the issues addressed by the Detergents Regulation continue to require action at the EU level, with this reflected in the views of most stakeholders interviewed, including SMEs and respondents to the public consultation.

¹⁶⁰ Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents.

¹⁶¹ As illustrated by AISE during the public consultation: *"A level playing field for all detergent manufacturers in terms of surfactants biodegradability and Phosphorous content would not have been achievable: as of 2009 about 11 EU Countries had in place measures to restrict Phosphorous mostly on laundry detergents. It can be assumed that in these countries reformulation on laundry detergents was already achieved/under implementation. Only a limited number of EU countries (4) had in place Phosphates restrictions for ADW. Existing national rules were proposing country specific rules; therefore, the Detergents regulation has provided a level playing field."*

¹⁶² European Commission (2010): Regulation (EU) No ... / ... of the European Parliament and of the Council amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in household laundry detergents, COM (2010) 997 final. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52010PC0597>.

¹⁶³ One international NGO noted that having such EU legislation helps to bring other countries on board and is a good way of convincing them to act.

¹⁶⁴ Including Organisations and SMEs.

4.5.2 To what extent have MS issued national rules on detergents that go beyond the scope of the Detergents Regulation?

For the purposes of this evaluation this question should be interpreted as referring to measures applicable to detergents that are adopted in Member States and which do not fall within the scope of harmonisation of the Detergents Regulation as described in its Article 1. It should be noted that for none of these measures have there been any indications, either by Stakeholders or by Member States' authorities, that they pose a barrier to the free movement of detergents in the internal market. Based on the information gathered through literature review and consultation these measures are the following:

- A "use by" date is included in the label of certain detergents sold in three Member States.
- Provisions on certain detergents' ingredients prohibited for use in professional cleaning products (industrial and institutional detergents) that are used in the food industry appear to exist in two Member States.
- In three Member States, companies have to notify the authorities before placing a detergent on the market and in one Member State they need to notify a designated public body before placing professional detergent products on the market.

5 Conclusions

5.1 Relevance

The findings of this evaluation indicate that the objectives of the Detergents Regulation (i.e. to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health) are still relevant considering the evolution of societal needs and technological developments. The new limits introduced in 2012 on the phosphorus content of consumer laundry detergents and consumer automatic dishwasher detergents, for example, were seen as a positive adaptation to changing needs.

A key issue that was identified is that the concepts and definitions used in the Detergents Regulation may not always be in line and coherent with the meaning they have gained over time and in practice. This results in lack of clarity on whether certain products available on the market fall under the scope of the Regulation or not (e.g. microbial cleaning products).

There are some areas where the Regulation has not kept pace with technical and other developments. For example, the labelling requirements of the Regulation are not well adapted to the recently developed practice of the refill sale of detergents and the dosing instructions might need to be adapted to the current size of standard washing machine loads.

5.2 Coherence

The provisions of the Detergents Regulation were found to be internally coherent with no major gaps or inconsistencies existing among them.

Some gaps were identified between the Detergents Regulation, the Cosmetic Products Regulation and the Biocidal Products Regulation. These gaps relate to the lack of specific provisions to restrict or ban the use of category 2 Carcinogenic Mutagenic and Reprotoxic

substances ('CMRs') in detergents and the lack of specific labelling requirements for nanomaterial ingredients in the Detergents Regulation. While no evidence exists about the use of category 2 CMRs in detergents, it is however true that these substances are treated differently under the Detergents Regulation and the Cosmetic Products Regulation even though detergents and cosmetics are similar formulations to a large extent and certain detergents are comparable to rinse-off cosmetics in the sense that they come in contact with the human skin. No impacts have been reported from this inconsistency neither from the detergents industry's point of view nor from a consumer perspective.

A similar gap exists with regards to nanomaterial ingredients in detergents. While for both biocides and cosmetics specific labelling requirements are in place under the respective Regulations, no such requirements exist under the Detergents Regulation. It should, however, be noted that substances in nanoform that trigger a classification under the CLP Regulation would be labelled on detergents following the labelling requirements of the CLP Regulation. The only difference with the requirements for cosmetic and biocidal products would be that in this case the word 'nano' would not be added next to the substance contained in the detergent in a nanoform. While it is understandable that such a reference would improve the communication of information to consumers, the extent to which this information would be useful to them needs to be further explored.

Some overlaps and inconsistencies were identified between the Detergents Regulation and other pieces of EU chemicals legislation, i.e. the REACH Regulation, the CLP Regulation, the recently added Annex VIII to the CLP Regulation harmonising the information relating to emergency health response and the Biocidal Products Regulation. These overlaps often result in duplications in the labelling of substances/ingredients on detergents' labels. The principal areas of overlap/inconsistency are as follows:

1. **The Detergents Regulation and the REACH Regulation:**
 - i. An overlap between the ingredient data sheet under the Detergents Regulation and the safety data sheet under REACH was identified. The findings of this evaluation do not allow however to conclude with certainty what exactly the impact of this overlap is and whether it would be possible to rely on only one of these data sheets to achieve the purposes of both.
 - ii. Inconsistencies were found between the requirements for compiling a safety data sheet under REACH and the labelling requirements of the Detergents Regulation for industrial and institutional detergents that can be provided in this safety data sheet (as an alternative to on-pack label). These inconsistencies could result in lack of clarity for workers and create an unnecessary burden on micro and small-sized manufacturers dealing with multiple pieces of legislation with differing requirements.
2. **The Detergents Regulation and the CLP Regulation:** Legislative overlaps were identified between the Detergents Regulation and the CLP Regulation, notably with regard to the labelling of allergenic fragrance ingredients. As the labelling of detergents falls by default under these two pieces of EU legislation, this overlap may lead to the labelling of the same substance twice or thrice on the same label and most of the time under completely different names. This contributes to the overload of detergents labels, which on one hand can be detrimental to consumer understanding and on the other creates an unnecessary regulatory burden for the detergents industry.
3. **The Detergents Regulation and Annex VIII to the CLP Regulation:** the ingredient data sheet under the Detergents Regulation serves a similar purpose as

the harmonised information that will need to be provided to poison centres under the recently added Annex VIII to the CLP. When the CLP requirements start applying, the abolishment of the ingredient data sheet related provisions under the Detergents Regulation should be considered in order to avoid duplication and reduce administrative burden for detergents' manufacturers.

4. **The Detergents Regulation and the Biocidal Products Regulation:** an overlap exists between the Detergents Regulation and Biocidal Products Regulation in the sense that detergents that are also disinfectants are subject to the labelling requirements of both Regulations which however often differ from one another. This overlap creates a duplication in the labelling requirements that contributes to the overload of detergents labels and can be detrimental to the communication of use and safety information to consumers and an unnecessary regulatory burden for the detergents industry. A potential inconsistency also exists between these two Regulations with regards to the labelling requirements for what are often referred to as 'carry-over preservatives'. The relevant provision of the Detergents Regulation is currently subject to different interpretations by manufacturers and Member State authorities alike. Discussions on the correct implementation of this provision of the Detergents Regulation are already being held between the Member States' competent authorities and the European Commission in the Working Group on detergents.

The above-mentioned duplications and overlaps in the labelling requirements for detergents result in unclear information to consumers. As a result, consumers may not easily understand the information provided on the label with negative impacts on the protection of their health and the environment. Duplications in the labelling requirements also create an unnecessary burden for the detergents industry. Therefore, this issue needs to be addressed with priority.

5.3 Effectiveness

The Detergents Regulation has helped to harmonise the rules in place in different Member States, thus making it easier for companies to trade cross-border. The harmonised rules for placing detergents and surfactants for detergents in the internal market have levelled the playing field for detergents manufacturers. Data from Eurostat, supported by more concrete and recent data from the detergents industry show a steady growth of both the detergents market and the detergents industry since the entry into force of the Detergents Regulation.

The biodegradability requirements for surfactants provide a high degree of protection of the environment. Moreover, the restrictions on the phosphorus content for consumer laundry and consumer automatic dishwasher detergents have been largely effective in reducing the amount of phosphorus/phosphate used in these products. The impact of the harmonised limits is more noticeable in the case of consumer automatic dishwasher detergents where only four Member States had restrictions in place before the intervention at EU level. Due to several limitations it has not, however, been possible to quantify the exact contribution of these limits in reducing eutrophication.

Dosing instructions are generally perceived as an effective means of reducing the over consumption of detergents. However, part of the dosing information that is currently required under the Detergents Regulation is out of date (e.g. size of standard washing machine loads). This factor combined with the fact that consumers may not read, understand or correctly follow these instructions, reduces the effectiveness of the Regulation to protect the

environment. Updating and simplifying the dosing instructions of the Detergents Regulation should therefore be considered.

A key issue that has arisen is a duplication in the labelling requirements for detergents that fall within the scope of multiple pieces of EU legislation (i.e. the Detergents Regulation, the CLP Regulation and the Biocidal Products Regulation). Detergents labels can become overloaded with information e.g. too much text, too long and not meaningful chemical names to non-professional users that make it difficult for consumers and downstream users to focus on the essential hazard and safety information and use instructions. Too much information provided on detergents labels may be detrimental to consumer understanding and reduces the effectiveness of the Regulation in terms of protecting human health. It also creates an unnecessary regulatory burden for industry.

This issue could be addressed with the use of innovative communication methods and digital tools (e.g. Q-R codes) which are now available and already used on some detergents available on the EU market. This way, some of the ingredient information currently indicated on detergents labels would be provided online, and linked to the product using a Q-R code. Several aspects related to the use of digital tools, such as data safety issues, access to an internet enabled portable device (e.g. mobile phone, tablet computer, etc.) and assessment of the type of information that could be provided through these tools need however to be further examined.

Member States have put in place a variety of sanctions for infringements of the Detergents Regulation. Based on the available information these sanctions were found in theory to be dissuasive, effective and proportionate. However, due to lack of sufficient data, it has not been possible to conclude with certainty whether the enforcement activities of Member States are able to ensure the appropriate enforcement of the Detergents Regulation. Based on the perception of stakeholders the enforcement of the Detergents Regulation is at least “somewhat effective”. In this respect, the introduction of reporting obligations for Member States under the Detergents Regulation could improve the availability of data, thus allowing us to better assess its enforcement.

5.4 Efficiency

The total cost to the detergents industry from the Detergents Regulation has been estimated at EUR 764 million to EUR 1.8 billion (2004-2016). Compared to the annual turnover of the detergents industry these costs appear to be proportionate (the costs are less than 0.5% of the annual turnover). The largest costs are estimated to have arisen as a result of the need to use different raw materials in place of phosphorus, from having to provide ingredient data sheets to poison centres and from the research and development necessary for reformulation in order to meet the phosphorus limitations for consumer laundry and consumer automatic dishwasher detergents ('CADD'). No quantification of costs incurred by other actors than industry authorities was carried out. No quantified cost figures were available regarding enforcement costs borne by public authorities.

In terms of benefits, the Detergents Regulation and its amendments are generally perceived by different groups of stakeholders as providing an enhanced level of protection to human health as well as improved information on product ingredients for consumers. There was general agreement among stakeholders that the Detergents Regulation has helped to level the playing field for manufacturers of detergents and surfactants within the EU. This is also supported by Eurostat and industry data that show a steady growth of both the detergents market and the

detergents industry since the entry into force of the Detergents Regulation. The Regulation has also had a positive impact on the environment. This was achieved through the improved biodegradability of surfactants and the reduced amount of phosphorus/phosphate used in consumer laundry and consumer automatic dishwasher detergents. Industry stakeholders also considered that the Detergents Regulation has had a positive impact in terms of innovation. Finally, most industry stakeholders were of the opinion that the Regulation has improved the corporate image of the sector.

It is difficult to attribute any quantified benefits associated with reduced eutrophication to the Detergents Regulation via the introduction of limits of phosphorus content in detergent products.

As no quantified estimates of benefits were available, the answer to the question whether costs of implementing the Detergents Regulation are justified takes into account stakeholder views expressed during the different consultation activities carried out for the purposes of this evaluation. These views suggest that costs involved in implementing the Detergents Regulation are justified.

5.5 EU added value

The harmonisation of rules for making available and placing on the market of detergents has levelled the playing field for detergents' manufacturers and ensured to a large extent the free movement of detergents in the internal market. The Regulation's delivered added value on the protection of human health is also substantive as consumers have now access to the full list of ingredients contained in detergents and can therefore make more informed choices and better protect themselves. The Regulation also had a positive impact on the environment through improved biodegradability rules that require surfactants to be totally broken down into water, carbon dioxide and biomass. These harmonised rules for the biodegradability of surfactants are often regarded internationally as the "golden standard", potentially conferring a competitive advantage to detergents manufactured in the EU. In addition, the phosphorus limits, especially the limits for consumer automatic dishwasher detergents ('CADD'), were seen as having raised the bar in many countries, where similar limits were not already in force. For these reasons, there was widespread consensus among all stakeholders that the issues addressed by the Detergents Regulation continue to require action at the EU level.

6 Annex 1 Procedural information

6.1 Lead DGs and internal references

The Detergents Regulation has not undergone an evaluation since its entry into force in October 2005. An *ex post* evaluation was therefore considered necessary in the context of the Commission's Better Regulation policy¹⁶⁵ and complementary to the Fitness Check on the most relevant chemicals legislation (excluding REACH) ('The Fitness Check')¹⁶⁶.

The evaluation of the Detergents Regulation was led by DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH).

6.2 Organisation and timing

An Inter-service Group to steer and provide input for the evaluation was set up in April 2016 with representatives from the Directorate Generals for Environment (ENV); Internal Market, Industry, Entrepreneurship and SMEs (GROWTH); Health and Food Safety (SANTE); Justice and Consumers (JUST), Joint Research Centre (JRC) and the Secretariat General (SG).

The group met 5 times during the evaluation process (Table 2).

DATE	TOPICS OF DISCUSSION
12 January 2017	Kick-off meeting - Introduction to the supporting study, presentation of the methodology, tasks allocation and project management by the contractor (RPA)
3 March 2017	Presentation of the draft inception report by the contractor (RPA), status of the consultation activities, questionnaires for the public consultation.
20 June 2017	Update on project tasks and overall progress by the contractor (RPA), preliminary results of the consultation, preliminary agenda for validation workshop and participants list, second interim report and project timeline.
11 September 2017	Progress update by the contractor (RPA), results of the public consultation, project timeline, and validation workshop.
14 March 2019	State of play of the evaluation, presentation of the first draft of the staff working document (SWD) on the evaluation of the Detergents Regulation, timeline for publishing the evaluation.

Table 2 ISG meeting dates and topics of discussion

¹⁶⁵ Agenda planning (DECIDE): PLAN/2016/305, available here: https://intragate.ec.europa.eu/decide/sep/entrance?Unicorn_v3.9.8.14648-2019-03-20T16:06:56.475+01:00#/overview-screen/view=search&display=summary&query=PLAN/2016/305&searchType=&sortFilter=1&groupFilter=1&timeFilter=1&languageFilter=EN&docsCategFilter=&dgsFilter=&stepsFilter=&dossierUuid=&numPage=1&dossier-details-uuid=DORSALE-DOSSIER-2016-52935&planning-id=SPECIFIC-DOSSIER-2016-36121&displayDetailsOn=INITIATION

¹⁶⁶ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses: <http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF>

6.3 Exceptions to the better regulation guidelines

No exceptions were made to the Better Regulation Guidelines¹⁶⁷ during this evaluation.

6.4 Evidence

The evidence for this evaluation was gathered via an external study commissioned by DG Internal Market, Industry, Entrepreneurship and SMEs (see Annex 3 explaining the methodology applied)¹⁶⁸. The supporting study was launched in December 2016. The final report was published in December 2018.¹⁶⁹

Stakeholder consultation and targeted data collection were also an important element of the data and information gathering process (for more information see Annex 2 to this evaluation).

¹⁶⁷ https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

¹⁶⁸ By Risk & Policy Analysts Ltd (RPA) and Mayer Brown LLP.

¹⁶⁹ <https://ec.europa.eu/docsroom/documents/32561>

7 Annex 2 Synopsis report: stakeholder consultation activities

7.1 General overview

Stakeholder consultation was an important component of this evaluation. The objectives of the consultation activities were to:

- Collect information and evidence related to the effectiveness, efficiency and relevance of the provisions and mechanisms of the Detergents Regulation.
- Collect relevant information on the implementation of the provisions of the Detergents Regulation.
- Collect qualitative and (wherever possible) quantitative data on costs and benefits associated with the implementation of the Detergents Regulation.
- Identify provisions and mechanisms that work well and the added value of the EU intervention in this area.

A wide range of consultation activities was therefore carried out for the purposes of this evaluation. These activities included a public consultation for organisations¹⁷⁰ and citizens, a survey designed specifically for SMEs run through the Europe Enterprise Network ('EEN'), telephone interviews with relevant organisations and targeted email consultation. The timing of the various consultation activities is summarised in Table 3 below.

Timeline	Activity
October 2016 to November 2016	Roadmap consultation
May to July 2017 (12 weeks)	Public Consultation
May to June 2017 (8 weeks)	SME survey, launched through EEN
May to July 2017	Targeted email consultation
May to August 2017	Telephone interviews
13 October 2017	Validation workshop

Table 3 Summary of stakeholder consultation

In line with the consultation strategy, input from a wide range of stakeholders was collected:

- Public authorities, notably competent authorities responsible for the implementation and enforcement activities;
- Industry associations and companies focusing in particular on SMEs;
- Civil society organisations, NGOs and consumer associations;
- Consumers / workers /citizens.

These different consultation activities and tools allowed receiving feedback from a wide range of stakeholder groups. A summary of these views is provided below.

¹⁷⁰ Including public authorities and bodies responsible for implementing and/or enforcing the Detergents Regulation; companies (large and small); industry associations and sector groups representing companies in the detergents sector; trade unions; environmental and consumer NGOs; and universities and research institutes.

7.2 Outcome of the consultation activities

7.2.1 Public consultation (PC)

7.2.1.1 General overview

Two separate questionnaires were developed for the purposes of the public consultation: one for citizens and one for organisations. The latter was targeted at a broad range of stakeholder groups including public authorities; companies (large and small); industry associations; trade unions; environmental and consumer NGOs, universities and research institutes; and any other organisations interested in responding to the survey. Both questionnaires were made available in English, German and French and uploaded to the EU Survey tool.

The public consultation generated a total of 102 responses from industry associations (12), business (7), consumer associations (3), NGOs (3), public authorities (13), intergovernmental organisations (1), citizens (61) and other organisations (2). No position papers were received.

7.2.1.2 Summary of stakeholder views received during the public consultation

The following stakeholder views were received during the public consultation .

A. Relevance

During the public consultation, stakeholders from various groups including industry associations (13), public authorities (9), companies (6), consumer organisations (3) and NGOs (4) agreed that the objectives of the Detergents Regulation (i.e. to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health) are still relevant considering the evolution of societal needs and technological developments, and a similar view was reflected among most participants during the telephone interviews.

There are, however, some areas where stakeholders identified that the Regulation has not kept pace. For instance, several industry representatives indicated that innovative communication methods (e.g. Q-R codes) are now available and which could help to reduce the amount of information presented on product labels. It was suggested that this could help to improve the clarity of information provided to consumers, particularly as some of the information that is currently presented, e.g. % surfactant content, is not information that most consumers need or understand¹⁷¹. Industry stakeholders also noted that using digital communications tools could help to alleviate the administrative burden for the detergents industry.

Stakeholders also identified a range of new issues related to detergents, their use and their impacts on the environment and human health that are not currently addressed through the Regulation. For example, it was noted that the labelling requirements of the Regulation are not well adapted to the refill sale of detergents and that the dosing instructions required under Annex VII B need to be updated to take account of modern load sizes, and new detergent products (e.g. concentrated products, pre-measured products and auto-dosing products/machines).

¹⁷¹ As noted by both MS authorities and consumer organisation.

A key issue that was identified during the consultation is that it is not always clear to the industry whether some products available on the market are included within the Regulation's scope. For instance, there is some confusion as to whether 'microbial cleaning products' with a claimed cleaning effect based on the action of bacteria fall within the scope of the Detergents Regulation. Other products that might also pose an issue include washing eggs/balls, cleaning wipes/scouring pads impregnated with detergents, related household products (e.g. waxes, polishes and textile dyes), and some 'do-it-yourself' cleaning products.

B. Coherence

Although the majority (23 out of total 41 responses) of industry associations, public bodies, companies (4 large and one small) and NGOs that responded to the public consultation indicated that there are gaps, overlaps and inconsistencies/contradictions within the provisions of the Detergents Regulation, it would appear from looking at stakeholders' discursive responses that these relate mainly to perceived gaps in the legislative framework or to areas where the Regulation is unclear. For example, one of the issues raised during the consultation was a lack of clarity surrounding the definitions and the scope of the Detergents Regulation (e.g. a lack of clarity regarding the definition of a "manufacturer" in the context of refill detergent sales¹⁷²; and gaps in the Detergents Regulation pertaining to air fresheners¹⁷³ and surfactant-free cleaning enhancers¹⁷⁴). Some consumer organisations were also concerned that a lack of detailed ingredient lists restricts the ability of consumers and downstream users to make informed decisions and thus avoid products containing certain ingredients.

Consumer organisations, environmental NGOs and citizens were concerned about some of the ingredients that are still permitted for use in detergents. From the perspective of human health, consumer organisations commented that CMRs¹⁷⁵ and SVHC should not be permitted for use in detergents and that if nanomaterials are hazardous, then they should be labelled or removed from detergent products. From the perspective of the environment, the use of microplastics in detergents was seen as a particularly important issue that remains to be addressed - either by the Detergents Regulation or by other means (such as REACH). Other substances identified as a concern for the environment included PBTs and hormone distributors (identified by one MS authority); odoriferous substances and complexing agents (identified by one 'other' organisation); and brighteners, colourants and perfumes (identified by one consumer organisation).

Some Member States' (MS) authorities and environmental NGOs suggested that the biodegradability criteria for surfactants should be applicable to all organic compounds included in detergents and not just surfactants, and that the anaerobic biodegradability of detergents should also be considered within the Detergents Regulation. However, the Commission has made it clear that it does not view these as gaps in the legislation. Furthermore, industry associations have noted that non-surfactant ingredients are already adequately regulated through REACH and CLP.

¹⁷² As noted by at least two MS authorities

¹⁷³ As noted by one environmental NGO

¹⁷⁴ As noted by one MS authority

¹⁷⁵ Note that CMR categories 1A and 1B are prohibited in consumer products under REACH. However, CMR 2 can still be used in detergents for consumer use and CMRs 1A, 1B and 2 could still be used in detergents for industrial/institutional purposes.

Stakeholders also suggested a range of other information that should potentially be included on product labels, including the scope of application/intended use for the product (as noted by one MS authority), the environmental footprint/biodegradability score (as noted by two consumer organisations), security advice (e.g. “keep out of reach of children”) (as noted by one MS authority) and a suggestion to use the lowest recommended washing temperature (as suggested by one environmental NGO).

Nearly two thirds (64%) of the respondents to the public consultation, including industry associations, public authorities, companies (large and small) and one NGO identified overlaps and inconsistencies/contradictions between the Detergents Regulation and other pieces of EU legislation. The principal areas of overlap/inconsistency were identified as being between:

- **the Detergents Regulation and Biocidal Products Regulation.** During the consultation, several stakeholders noted that there is an overlap between the Detergents Regulation and Biocidal Products Regulation in the sense that some products would need to comply with the provisions (notably the labelling provisions) of both. Stakeholders explained that, in some cases, MS authorities and companies differ in their interpretation of the scope of the two Regulations, and that overlaps between these two pieces of legislation can result in duplicate labelling. There may also be differences between countries in the way the provisions on ‘carry-over’ preservatives¹⁷⁶ are implemented (by companies) and enforced (by MS authorities), which may arise from differences in the wording of the legal text of the Regulation and the guidance provided by AISE.
- **the Detergents Regulation and Cosmetic Products Regulation.** During the consultation, some stakeholders noted that there is a difference between the Cosmetic Products Regulation and the Detergents Regulation in the treatment of CMRs (i.e. CMRs 1A, 1B and 2 are not permitted for use in cosmetics (unless exempted) but some CMRs¹⁷⁷ can still be used in detergents). Stakeholders also noted that there is an inconsistency between the labelling of nanos under the Detergents Regulation and Cosmetic Products Regulation (i.e. nanos must be indicated on the label for cosmetics; this is not the case for detergents). Furthermore, some stakeholders indicated that cosmetics must be labelled with a full ingredient list, unlike the Detergents Regulation that only requires some ingredients to be labelled. One MS authority noted that it would be beneficial if the labelling of ingredients under the Detergents Regulation could be harmonized with the labelling of cosmetic ingredients using the INCI nomenclature according to the Cosmetic Products Regulation.
- **the Detergents Regulation and REACH and CLP.** During the consultation, stakeholders identified some inconsistent definitions (e.g. “placing on the market”, “manufacturer”) between the Detergents Regulation, REACH and CLP. Inconsistencies were identified between the information that must be presented in the SDS under REACH and the information that must be provided for industrial and institutional detergents under the Detergents Regulation. There are also legislative overlaps between the Detergents Regulation and the CLP Regulation with regard to the labelling of allergens. During the consultation, several industry associations

¹⁷⁶ Carry-over preservative refers to preservatives added to the raw materials or ingredients that are subsequently used as an ingredient in the final detergent product.

¹⁷⁷ CMR categories 1A and 1B are prohibited in consumer detergents under REACH. This means that CMR Category 2 may still be used in consumer detergents; while CMR categories 1A, 1B and 2 may still be used in industrial/institutional detergent products.

explained that as Regulation 542/2017 (Annex VIII of CLP) comes into effect, the provisions of Article 9(3) and Annex VII C of the Detergents Regulation should become obsolete.

C. Effectiveness

The main view of stakeholders (across all stakeholder groups) was that the Detergents Regulation has helped to harmonize the rules in place in different EU MS and that this has levelled the playing field and made it easier for companies to trade cross-border. For example, 53% of SMEs that participated in the survey conducted by the Enterprise Europe Network ('EEN') agreed that the Detergents Regulation has levelled the playing field for manufacturers of detergents and surfactants within the EU (6% disagreed). Three quarters of organisations, (75%) that participated in the public consultation indicated that the Regulation has made it easier to trade detergents and surfactants cross-border within the EU (only 3% disagreed).

During the public consultation, 85% of organisations agreed that the Detergents Regulation has been effective in protecting the environment. Some industry stakeholders even noted that the Detergents Regulation is seen internationally as the “golden standard” for the biodegradability of surfactants. Furthermore, the new limits on the phosphorus content of consumer laundry detergents and consumer automatic dishwasher detergents ('CADD') introduced by Regulation (EU) No. 259/2012 were seen, by both MS authorities and industry, as having successfully directed the market to producing more environmentally friendly products.

While dosing instructions are generally perceived as an effective means of reducing the over consumption of detergents, some stakeholders were concerned that the dosing information that must be provided according to the Regulation is now out of date (as noted by at least one company during the consultation) and that consumers may not read, understand or correctly follow the instructions (as explained by at least one consumer association).

Nearly two thirds of organisations (63%) that participated in the public consultation agreed that the Detergents Regulation has been effective in achieving its objective of ensuring a high degree of protection of human health (24% disagreed), although it was also noted (particularly by industry stakeholders) that compared to other chemicals legislation (e.g. REACH, CLP and Biocides), the Detergents Regulation has had a lesser impact. There was general agreement among stakeholders (all types) that the labelling requirements of the Detergents Regulation are sufficient to inform consumers and downstream users about potential allergenic substances in detergents (71% of organisations that participated in the public consultation agreed). Some stakeholders, however, were concerned about some of the substances/ingredients that are still being used in detergent products and that a lack of detailed ingredient lists on product labels restricts the ability of consumers and other downstream users to make informed decisions and avoid products containing certain substances.

In general, the sanctions put in place by the MS for infringements of the Detergents Regulation are perceived by MS authorities as dissuasive, effective and proportionate. However, many authorities appear to lack the resources to carry out proactive enforcement of the Regulation. Furthermore, inspections tend not to be carried out for the Detergents Regulation in isolation, rather they are coordinated with inspections for other chemicals legislation, such as CLP and REACH.

Finally, one instance has been identified of the safeguard clause being used (for the product POR-ÇÖZ, placed on the market in Germany). There was a split in view among respondents

regarding the safeguard clause. While MS authorities and consumer associations generally agreed that the safeguard clause is an important, and beneficial, element of the Detergents Regulation, even if (to date) it has rarely been used, some industry representatives noted that if the detergent complies with the Detergents Regulation, then there is no need for the safeguard clause.

D. Efficiency

During the consultation, industry associations and companies clarified that the costliest elements of the Detergents Regulation for industry have been the one-off costs associated with reformulation (to reduce the total phosphorus content), keeping information for websites and medical personnel up to date, and the one-off and ongoing costs associated with labelling changes (which may impact SMEs more than larger companies due to the need to dispose of old labels). Detergent manufacturers have also faced on-going costs associated with using different raw materials in place of phosphorus in consumer laundry detergents and CADD. Several industry representatives noted that switching to producing phosphorus-free detergents led to a 10% increase (approximately) in raw material costs. Industry stakeholders indicated that these costs have not been passed on to consumers (as higher prices).

About a fifth (21%) of industry stakeholders that responded to the public consultation said that the Detergents Regulation had led to market opportunities (compared to 42% that disagreed). Stakeholders noted that the Detergents Regulation has had a mixed effect in terms of innovation. On the one hand, stakeholders (including industry) have noted that new products have been developed in response to the Detergents Regulation, particularly in response to the phosphorus limits introduced for CADD. On the other hand, several industry stakeholders noted that resources had to be used to ensure compliance and that this reduced the total resources available for innovation. During the public consultation, three quarters (74%) of industry associations and companies indicated that the Detergents Regulation has improved the corporate image of the sector.

Most of the stakeholders consulted (including most SMEs) have indicated that the costs involved in implementing the Detergents Regulation are justified given the benefits that have been achieved, or that will be achieved in the longer term.

E. EU added value

The general view of stakeholders (all groups) during the public consultation was the Detergents Regulation has delivered better outcomes for the environment than could have been achieved by MS acting on their own. The phosphorus limits, especially the limits for CADD, were seen as having raised the bar in many countries, where similar limits were not already in force. Similarly, stakeholders noted that creating a level playing field for manufacturers in terms of the biodegradability of surfactants would not have been achievable in the absence of EU legislation.

While some stakeholders indicated that the Detergents Regulation has delivered added value in terms of human health (particularly the provisions on the labelling of fragrance allergens), it was indicated that multiple other pieces of EU legislation covering detergents (e.g. REACH, CLP and Biocidal Products Regulation) are also important in this regard. Overall, there was consensus among stakeholders (all groups) that the issues addressed by the Detergents Regulation continue to require action at the EU level (83% of organisations during the public consultation).

7.2.2 SME survey

In order to ensure that SMEs were adequately represented in the consultation, a simplified questionnaire was developed and distributed to SMEs via the Enterprise Europe Network (EEN). The SME survey generated a total of 41 responses, split almost equally between micro-enterprises (<9 employees), small enterprises (10 to 49 employees) and medium-sized enterprises (50 to 249 employees). Most SME respondents indicated that they were distributors (33%), formulators (27%) and/or a manufacturer (22%). Other downstream users that responded to the survey clarified that they were a “retailer”, involved in the “building materials trade” and “cleaning”.

7.2.3 Telephone interviews

To examine stakeholders’ views in greater depth, a series of targeted interviews were held: 45 telephone interviews were held with EU officials (4), industry associations/sector groups (18), public authorities (7), companies (3 SMEs and 3 large companies), environmental NGOs (2), consumer NGOs (2), trade unions (2) and others (2).

7.2.4 Targeted email consultation

In addition to interviews, complementary data, information and views were gathered via targeted emails. Such tailored emails were sent to a variety of organisations such as market surveillance authorities (e.g. to obtain data on enforcement related to the Detergents Regulation), national poison centres (e.g. to obtain information on detergents’ related illnesses/incidents) and regional seas conventions (to obtain data in relation to phosphorous loads in EU water bodies).

7.2.5 Validation workshop

7.2.5.1 General overview

The aim of the stakeholder workshop, which took place on 13 October 2017 in Brussels, was to discuss and validate the findings of the evaluation study to confirm (or otherwise) the information obtained from the desk-based research and consultation activities undertaken.

7.2.5.2 Summary report of stakeholder views expressed during the validation workshop

A. Detergents Regulation and the environment

Stakeholders generally agreed with the finding of the supporting study that the Detergents Regulation has been successful in protecting the environment. The findings of the enforcement project (EuroDeter) undertaken by the Chemical Legislation European Enforcement Network (CLEEN) were mentioned to support this view. The EuroDeter project found that 97% of inspected surfactants were compliant with the biodegradability requirements of the Detergents Regulation. According to one stakeholder this indicates that this aspect of the Detergents Regulation has been successfully implemented by the sector. The industry stakeholder noted that the ultimate biodegradability testing requirements introduced by the Detergents Regulation have enhanced the environmental profile of detergents and overall the environmental performance of detergents has improved.

Mixed views were expressed with regards to the extension of the biodegradability requirements to non-surfactant organic ingredients used in detergents. Some stakeholders were of the

opinion that further investigation should be undertaken on this matter while others thought that the evaluation already undertaken by the European Commission¹⁷⁸ and which found that the biodegradability requirements are sufficient and should not be extended to non-surfactant organic ingredients, is sufficient.

Further, it was indicated that, since the introduction of the 2012 amendment restricting the use of phosphates and other phosphorus compounds in consumer laundry detergents and CADD, there has been a considerable reduction in the quantity of phosphorus used in detergents.

The possibility to extend the phosphorus/phosphate limits to industrial and institutional laundry detergents and CADD was discussed. One industry representative noted that while considering this possibility it is important to investigate whether industrial/institutional detergents are an important source of phosphorus to the environment relative to emissions from other sources to determine the impact/potential benefit of extending the phosphate restriction in a broader context.

A MS authority expressed some concerns with regards to some ingredients used in detergents that may be harmful to the environment (e.g. odoriferous substances, certain complexing agents, brighteners, colourants and perfumes). An industry representative indicated that detergent ingredients of potential concern are addressed through the most globally ambitious legislative framework for safety and the environment with these substances covered by the REACH Regulation (including the chemical safety report), CLP Regulation, Biocidal Products Regulation and the Detergents Regulation. The stakeholder considered the current situation both appropriate and sufficient.

As regards dosing instructions, it was noted that these are an important aspect of user information, but that it is unclear how detergent users are interpreting the classification of “lightly soiled” and “normally soiled”. Potential improvements could be made to ensure that consumers use the correct dose depending on water hardness. It was indicated that there is a forthcoming consumer habits survey undertaken by AISE that should provide further information regarding the dosing habits of consumers. A consumer NGO noted that there is a need to make the correct dosing of detergents easier for consumers.

Finally, a MS authority indicated that some of the definitions provided in Article 2 of the Detergents Regulation are ambiguous, although it was noted that these are often addressed in the Frequently Asked Questions document that accompanies the Regulation. The discussion also revolved around the definition of “detergent” and whether this definition should be extended to cover other products too.

B. Detergents Regulation and human health

Few stakeholders expressed the view that the packaging of detergent products should be labelled with a full list of ingredients and that the possibility of using the INCI nomenclature should also be considered. Some stakeholders found that stating the type of surfactant and its concentration on the label is not useful for consumers.

¹⁷⁸ Report from the Commission to the European Parliament and the Council Pursuant to Article 16 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, concerning the biodegradation of main non-surfactant organic detergent ingredients, COM/2009/0208. Available at: <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52009DC0208>

Issues related to weblinks provided on detergent labels and which fail to either provide the correct data/complete set of ingredients or navigate to the correct webpage were also discussed.

A big part of the discussion revolved around the labelling requirements of the Detergents Regulation. The main topics that were raised concerned: the information to be included on the label (e.g. allergenic fragrances), the labelling of preservation agents and ways of improving the communication of information to consumers and the relative format that needs to be used. Stakeholders noted that the labelling requirements for detergents are an important administrative burden borne by the detergents industry.

Some concerns were raised with regards to some ingredients that could potentially be harmful to human health (e.g. CMRs, nano-ingredients).

One MS authority noted that the wording of Article 11(2) of the Detergents Regulation (which relates to labelling) should be adapted to account for situations where consumers refill detergent packages in order to ensure that the bulk container and the packaging used by the consumer are both properly labelled. A consumer organisation similarly indicated that it is necessary to recognise that the refill sale of detergents is occurring and that there is therefore a need to ensure that a labelling solution is in place to protect consumers. An industry stakeholder indicated that the bulk sale of detergents has the potential to contribute to improved sustainability and the circular economy. The stakeholder clarified that there is no vulnerability in terms of safety as the detergent products sold must be compliant with the CLP Regulation, Biocidal Products Regulation, Detergents Regulation, etc.

Finally, stakeholders discussed whether the requirement for manufacturers to make available an ingredient datasheet to medical personnel upon request is still relevant especially in view of the recent adoption of Regulation (EU) 2017/542 on a harmonised format to provide information related to emergency health response (poison centres).

C. Detergents Regulation and the internal market

I. Effectiveness

It was noted that information obtained from AISE members suggests that there is overall satisfaction regarding the value and effectiveness of the Regulation and that the Regulation has been successfully implemented. However, there is also evidence to suggest there are opportunities to simplify the labelling requirements of the Regulation, to use digital means (in order to reduce the amount of information on product labels and allow consumers to focus on the most important elements), to tackle overlaps with other legislation (e.g. the CLP Regulation and the Biocidal Products Regulation) and to align the requirements relating to the provision of medical information sheets with the CLP Regulation.

An industry stakeholder noted that the detergents sector is evolving and indicated that market data suggests that the use of liquid laundry detergents has now overtaken the use of powder laundry detergents in the EU. It was also noted that there has been a significant move across the EU towards producing concentrated detergent products with significant reductions in the use of standard detergents observed between 2011 and 2016 (79% and 42% reduction observed over this period in Western Europe and Eastern Europe respectively).

In addition, it was noted that the Detergents Regulation has made it easier for companies to trade detergents and surfactants cross-border within the internal market with the provisions on the biodegradability of surfactants and the limits on the use of phosphates and other phosphorus compounds in detergents considered to be important factors in this regard.

An industry stakeholder indicated that although there are aspects that could be improved (e.g. areas that could be simplified and streamlined), the objectives of the Detergents Regulation have been met and thus the Regulation should not be recast (i.e. the core of the legislation should be preserved).

A MS authority similarly noted that, in general, the Detergents Regulation can be considered successful, but suggested that the understanding of the Regulation could be improved (i.e. some of the definitions could be clarified and better dosage instructions provided).

II. Cost estimates and assumptions

A MS authority noted that in addition to costs of complying with the Detergents Regulation, costs associated with detergents are also created by industry through marketing and voluntary labelling updates. It was also noted that costs also arise from complying with other legislation, such as the CLP Regulation and REACH Regulation, as well as the Detergents Regulation. RPA indicated that the interplay between legislation means that it is difficult to attribute costs to the Detergents Regulation (as opposed to other legislation).

III. Biodegradability testing

An industry stakeholder explained that the one-off cost of testing the ultimate biodegradability of a surfactant is around €4,000 (higher than the assumption used in the consultants' calculations). The stakeholder also noted that there are differences between the cost of testing for primary biodegradability and ultimate biodegradability; however, it is not possible to state which is more/less expensive because it is difficult to find testing laboratories that provide tests for primary biodegradability compared to the in the past.

IV. Costs for society

An industry stakeholder noted that the cleaning performance of detergents is key. Companies have invested in developing alternative detergent ingredients (e.g. as a result of biodegradability requirements and limits on the use of phosphates and other phosphorus compounds introduced by the Detergents Regulation), which have maintained and even enhanced cleaning performance. It was therefore noted that the Detergents Regulation has not had any adverse impacts in terms of the cleaning performance of detergents or consumer choice.

In terms of innovation, one industry stakeholder noted that the Detergents Regulation has led to the development of new ways of cleaning. However, in the case of SMEs, budget limitations and cost constraints mean that companies have focussed on regulatory compliance, rather than R&D. In this regard, the Detergents Regulation is considered to have set back innovation (particularly for SMEs). It was also noted that lower classification thresholds for eye irritation/severe damage introduced by the CLP Regulation have resulted in many more detergent formulations being classified. One industry stakeholder indicated that a corrosive classification for a detergent will be sufficient for some companies to stop research.

8 Annex 3 Methods and analytical models

The purpose of this Annex is to summarize the main methodologies applied and the information sources used for the evaluation of the Detergents Regulation. As described in Annex 2 above, a supporting study was commissioned and was carried out by external consultants¹⁷⁹. In addition, other sources of information were used, including stakeholder consultation (see Annex 2 Synopsis Report).

8.1 The supporting study of the Detergents Regulation

8.1.1 General overview of the methodology

8.1.1.1 Tasks

The supporting study comprised the following tasks:

- **Task 0: Project inception.** In order to obtain a clearer understanding of the work to be undertaken and to clarify the main aspects of the proposed methodology, a kick-off meeting was held in Brussels on the 12 January 2017. Following the meeting, an Inception Report was provided to the Commission on 31 January 2017, with the finalised version submitted on the 28 March 2017.
- **Task 1: Establishment of evaluation methodology.** This task involved laying the foundations for the evaluation, including establishing the intervention logic and defining the questions and indicators for the evaluation. This task also involved establishing the baseline for the evaluation, and gathering appropriate data and information to define it.
- **Task 2: Analysis of sector.** To support the evaluation, a comprehensive desk-based review was carried out to gather data and information on the detergents industry in the EU and EEA. This involved analysing the composition of typical detergent products on the market, levels of production and consumption of detergents and surfactants, as well as data on the number of enterprises operating in the sector in the EU/EEA. Information was also gathered on the main sustainability aspects and on recent trends in the detergents sector. The results are available in Annex 2 to the supporting study.
- **Task 3: Stakeholder consultation.** The following consultation methods have been used to elicit information from stakeholders for the purposes of the evaluation: a Public Consultation (PC), a targeted survey of SMEs, telephone interviews, targeted email consultation and a validation workshop.
- **Task 4: Support in evaluation of the Detergents Regulation.** The aim of this task was to set out clearly the answers to the evaluation questions, based on a comprehensive desk-based literature review, and the results from the consultation activities (Task 3). The results are shown in sections four to nine of this report.
- **Task 5: Validation workshop.** To validate the results of the evaluation, a one-day workshop was held in Brussels on the 13 October 2017. The aim of this workshop was to set out the preliminary findings of the study and to obtain feedback from the participating stakeholders. A summary of the workshop findings is provided in the Report on the Validation Workshop, provided in Annex 5 to the supporting study.

Figure 7 below shows how the above tasks fit together.

¹⁷⁹ By Risk & Policy Analysts Ltd (RPA) and Mayer Brown LLP. The supporting study is available at: <https://ec.europa.eu/docsroom/documents/32561>

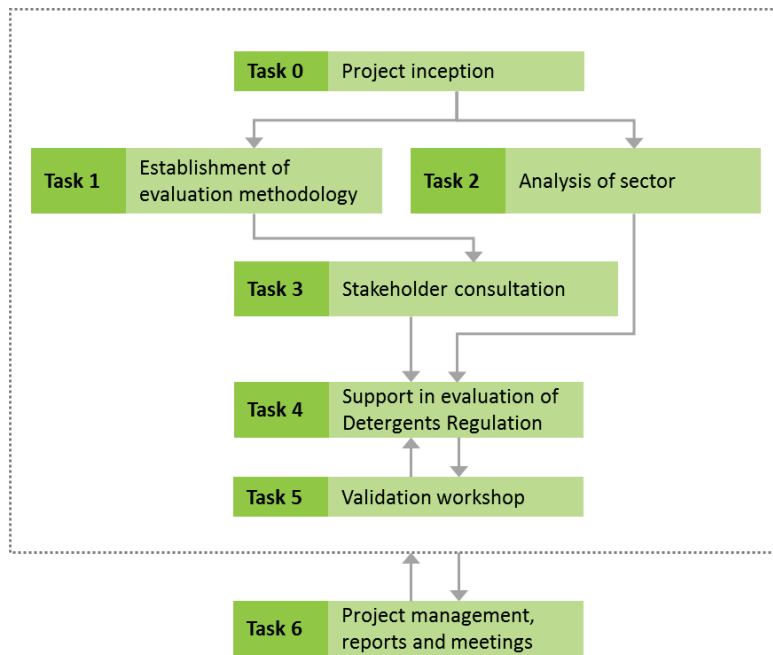


Figure 7 Tasks

8.1.1.2 General overview of the approach, the methodology applied and different sources of information

Building on the intervention logic, the list of questions presented in the evaluation roadmap¹⁸⁰, the technical specifications for the study, the Better Regulation Guidelines and the relevant evaluation questions already addressed as part of the supporting study for the Fitness Check¹⁸¹, the study team developed a list of evaluation questions and indicators for each of the five evaluation criteria (i.e. relevance, coherence, effectiveness, efficiency and EU added value). These questions and indicators are presented in Table 4Tableau 1 below, which also provides details on the methods and data sources used to gather relevant information and the baseline used for the assessment.

¹⁸⁰ http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_305_evaluation_detergents_en.pdf

¹⁸¹ RPA et al. (2017): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation – Evaluation Report. For the European Commission. Available at: <http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/>

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
Effectiveness					
To what extent does the Detergents Regulation meet its objectives, i.e. establishment of a true internal market for detergents, while ensuring a high degree of protection of the environment and human health?	Extent to which key stakeholders agree that the labelling/packaging requirements of the Detergents Regulation are clear and sufficient to inform downstream users and consumers about the ingredients and instructions regarding detergent use.	Question in the PC questionnaire for organisations and citizens	Stakeholders asked to compare the situation before the Regulation came into force (in October 2005) with the situation from October 2005 to the present day	Public Consultation Targeted consultation Workshop Supporting study to the Fitness Check	Section 6.1.3; and Annex 3, Section A3.2.2
	Extent to which stakeholders (by type) agree that the Regulation has met its objectives in terms of (i) establishment of a true internal market for detergents, (ii) ensuring a high degree of protection of the environment, (iii) ensuring a high degree of protection of human health	Question in the PC questionnaire for organisations and citizens Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force (in October 2005) with the situation from October 2005 to the present day	Public Consultation Targeted consultation SME survey Workshop Supporting study to the Fitness Check	Section 6.1
	Value and/or volume of detergents and surfactants traded across borders within the EU	Comparison of data on value/volume of detergents and surfactants traded	The baseline is the situation before October 2005, with impacts measured up to the present day	Literature review Targeted consultation with industry	Section 6.1.1

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
		across borders within the EU before and after the legislation came into force		associations) Market analysis (see Question 15)	
	Number of cases of detergents-related illness/incidents if possible (note that these data will be sought during the targeted consultation); acute incidents as reported in poison centre data (although only a subset of countries have had poison centres in place over this time period)	Comparison of data on number of detergents-related illnesses (e.g. skin sensitisation) before and after legislation came into force (e.g. number of cases of allergic reaction).	There are two baselines for the analysis – firstly October 2005, when the Detergents Regulation came into force, and secondly June 2006 when amendments were made concerning the declaration of allergenic fragrances	Literature review Targeted consultation (e.g. poison centres) Supporting study to the Fitness Check Publicly available information on consumer complaints, court cases and product recalls	Section 6.1.3 and Annex 3, Section A3.2.2
	Number of countries with national legislation or voluntary initiatives in place to limit the content of phosphorus in detergents before the 2012 amendment to the Regulation came into force	Qualitative analysis	There are two baselines for the analysis – June 2013 for laundry detergent, and January 2017 for automatic dishwasher detergent	Supporting study to the Fitness Check Literature review	Section 6.1.2 and Annex 2, Section A2.4
	Average P concentrations in water bodies (e.g. rivers, lakes, seas, etc.)	Average P concentrations in water bodies (subject to data being available from 2013)	Limitations on P content have applied to consumer laundry detergents since 30 June 2013. The situation before June	DG Environment (WFD country reports and synthesis reporting) European Environment	Annex 2, Section A2.4

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
		<i>onwards)</i>	2013 therefore forms the baseline for our assessment.	Agency Targeted consultation with Regional Seas Conventions	
	Extent to which key stakeholders agree that consumer laundry detergent products on the market today contain less P than they did in the past as a direct result of the Detergents Regulation and its amendments coming into force	Question in the PC questionnaire for organisations	Stakeholders asked to compare the situation before June 2013 with the situation today	Public consultation Targeted consultation Workshop	Section 6.1.2
	Extent to which key stakeholders agree that automatic dishwasher detergent products on the market today contain less P than they did in the past as a direct result of the Detergents Regulation and its amendments coming into force	Question in the PC questionnaire for organisations	Stakeholders asked to compare the situation before January 2017 with the situation today	Public consultation Targeted consultation Workshop	Section 6.1.2
	Proportion of manufacturers that have amended the formulation of their laundry and dishwasher detergent	Quantitative analysis Question in the PC questionnaire for organisations	There are two baselines for the analysis – June 2013 for laundry detergent, and January 2017 for automatic dishwasher	Public consultation SME survey Targeted consultation (with manufacturers of	Section 6.1.2

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
	products to reduce the total P content as a direct result of the Detergents Regulation and its amendments.	Question in the survey for SMEs	detergent	detergent products) Workshop	
Which provisions or parts of the Detergents Regulation have met their objectives (i) most effectively, (ii) least effectively, and which parts have not met their objectives?	Stakeholder assessment of provisions or parts of the Detergents Regulation that have met their objectives (i) most effectively, (ii) least effectively or (iii) not at all.	Qualitative analysis	N/A	Targeted consultation Workshop Supporting study to the Fitness Check	Section 6.2
To what extent is the Regulation effectively implemented across EU MS (e.g.	Number of MS that have enacted the safeguard clause	Quantitative analysis	N/A	Targeted consultation (with EU officials and MS authorities)	Section 6.3.7 and Annex 3, Section A3.6
	Number of times the safeguard clause has been enacted in the MS	Quantitative analysis	N/A	Targeted consultation (with EU officials and MS authorities)	Section 6.3.7 and Annex 3, Section A3.6

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
enforcement , use of safeguard procedure)? What are the implementation and enforcement measures that have been put in place? Were they adequate?	Extent to which stakeholders (by type) agree that the safeguard clause has a role to be used in the future	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation Workshop	Section 6.3.7 and Annex 3, Section A3.6
	Number of proactive and reactive inspections undertaken	Analysis of data on number of inspections	N/A	Targeted consultation (with EU officials and MS authorities). <i>It should be noted that data on inspections may be aggregated at a high-level covering, for instance, both CLP and REACH alongside detergents</i>	Section 6.3.4
	Total budget available to enforcement authorities in the MS	Analysis of data on budget and resources available to enforcement authorities in the MS	N/A	Targeted consultation (with EU officials and MS authorities). <i>It should be noted that data on resources for enforcement may be aggregated at a high-level covering, for instance, both CLP and REACH alongside detergents</i>	Section 6.3.4
	Total resources (e.g. number of personnel) available to enforcement authorities in the MS		N/A		Section 6.3.4

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
	Extent to which key stakeholders believe that enforcement carried out by the responsible authorities is effective in their country	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation Workshop Supporting study to the Fitness Check	Section 6.3.4
	Type and level of sanctions for infringement by country	Analysis of type and level of sanctions for infringement by country	N/A	Targeted consultation (with EU officials and MS authorities) Literature review	Section 6.3.3
	Extent to which key stakeholders agree that existing sanctions are dissuasive, effective and proportionate	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation Workshop	Section 6.2.4
Efficiency					
What are the costs for industry associated with the implementation of the Detergents Regulation? What are the key drivers for those costs?	Quantitative analysis – estimation of the total costs for industry of <i>inter alia</i> testing, reformulation of products (e.g. to reduce P content) and associated labelling changes, labelling products, preparing ingredient datasheets for medical personnel, publishing a list of ingredients on a website, etc.	In line with the cost quantification methodology set out in the Better Regulation Toolbox under the following categories: Direct compliance costs Hassle costs Indirect compliance	Costs from October 2005 to the present day	Supporting study to the Fitness Check Legislative text of the Regulation Literature review Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop Market analysis (see Question 15)	Section 7.2.

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
		<p>Direct costs</p> <p>Other indirect costs</p> <p>Identification of the costliest elements of the Regulation for industry – via text analysis of the provisions of the Regulation followed by literature review and consultation on the associated costs for companies</p> <p>Estimation of the total costs for the detergents sector using the Standard Cost Model, and taking into account the baseline costs</p>			
	Qualitative analysis – difficulties faced by companies in implementing the Detergents Regulation	<p>Qualitative analysis</p> <p>Question in the PC questionnaire for organisations</p> <p>Question in the survey for SMEs</p>	N/A	<p>Literature review</p> <p>Public Consultation</p> <p>SME survey</p> <p>Targeted Consultation (with companies and industry associations)</p> <p>Workshop</p>	Section 7.2.8

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
What are the benefits for industry associated with the implementation of the Detergents Regulation?	Qualitative and, if possible, quantitative analysis – extent to which industry stakeholders agree that the implementation of the Detergents Regulation has reduced costs for the sector (e.g. due to harmonised rules and facilitation of intra-EU trade)	Qualitative and, if possible, quantitative analysis (using the Standard Cost Model) Question in the PC questionnaire for organisations	Costs from October 2005 to the present day	Supporting study to the Fitness Check Literature review Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop Market analysis (see Question 15)	Section 7.3.2
	Extent to which industry stakeholders agree that the implementation of the Detergents Regulation has improved the corporate image of the sector	Question in the PC questionnaire for organisations Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force in October 2005, with the situation up to the present day	Public Consultation SME survey Targeted consultation (with companies and industry associations) Workshop	Section 7.3.2
	Extent to which industry stakeholders agree that the implementation of the Detergents Regulation has reduced the risk (and associated cost) of litigation for the sector (e.g. due to a reduction in the number of allergic reactions, poisoning incidents)	Question in the PC questionnaire for organisations Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force in October 2005, with the situation up to the present day	Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop	Section 7.3.2

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
	Extent to which industry stakeholders agree that the implementation of the Detergents Regulation has led to a more level playing field across the EU	Question in the PC questionnaire for organisations Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force in October 2005, with the situation up to the present day	Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop	Section 7.3.2
	Extent to which industry stakeholders agree that the Detergents Regulation has led to innovation in the sector	Question in the PC questionnaire for organisations Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force in October 2005, with the situation up to the present day	Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop	Section 7.3.2
	Extent to which industry stakeholders agree that the Detergents Regulation has led to market opportunities	Question in the PC questionnaire for organisations Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force in October 2005, with the situation up to the present day	Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop	Section 7.3.2
	Qualitative (and where possible quantitative) analysis – examples of other key benefits of the Detergents Regulation, as identified by industry stakeholders	Qualitative analysis Question in the PC questionnaire for organisations Question in the survey for SMEs	Stakeholders asked to compare the situation before the Regulation came into force in October 2005, with the situation up to the present day	Literature review Public Consultation Targeted consultation (with companies and industry associations) SME survey Workshop	Section 7.3.2

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
	Qualitative (and where possible quantitative analysis) of the benefits for other industry sectors (e.g. tourist industry, commercial aquaculture/fisheries)	Qualitative analysis Benefit transfer method Question in the PC questionnaire for organisations Question in the survey for SMEs	Two key baselines for this assessment - firstly October 2005 when the Regulation first came into force, and secondly June 2013 when new limits were introduced on the P concentration of consumer laundry detergent	Literature review Public Consultation Targeted consultation (e.g. with industry associations and NGOs) SME survey Workshop	Section 7.3.3
What are the costs for society associated with the implementation of the Detergents Regulation?	Extent to which key stakeholders say that the costs of the Detergents Regulation for companies are passed through to consumers	Question in the survey for SMEs	N/A	Targeted consultation (with companies and industry associations) Workshop	Section 7.4
	Qualitative analysis of the changes in product performance	Question in the PC questionnaire for citizens Qualitative analysis <i>Note that it will be necessary to establish first whether, and how, the formulation of detergent products has changed as a result of the Detergents Regulation and its amendments</i>	Two baselines for the analysis – June 2013 for consumer laundry detergent, and January 2017 for consumer automatic dishwasher detergent	Literature review (e.g. publications from industry, MS authorities, etc.) including relevant impact assessments Targeted consultation with industry associations and companies Public Consultation	Section 7.4

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
What are the economic, social and environmental benefits for society associated with the implementation of the Detergents Regulation?		<i>coming into force (see sub-questions under Question 1)</i>			
	Quantitative analysis – estimation of the costs avoided for phosphates removal at waste water treatment plants	Estimation of the P emissions avoided as a result of the Detergents Regulation, followed by estimation of the associated costs avoided at water treatment plants	Costs avoided from June 2013 to the present day.	Literature review	Section 7.3.3 (quantitative analysis possible) not
	Quantitative analysis – estimation of the medical/healthcare costs avoided for the treatment of allergic reactions	Estimation of the number of allergic reactions avoided as a result of the Detergents Regulation, followed by estimation of the associated costs avoided for their treatment	Costs avoided from June 2006 to the present day	Literature review	Section 5.1.2 (quantitative analysis possible) not
	Qualitative (and where possible, quantitative) analysis of the following benefits for society: Enhanced value of waterside properties Reduced clean-up costs for waterways (e.g. weed cutting)	Qualitative analysis Benefit transfer method	Two key baselines for the analysis – October 2005 when the Regulation first came into force, and then June 2013 when new limits were introduced on the concentration of P in consumer laundry detergents	Literature review	Section 7.3.4 and Annex 2, Section A2.4 Note that quantitative analysis was not possible

Table 4 Evaluation questions, indicators, methodology and data sources

Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
	Increased recreational and amenity value of waterbodies (e.g. for water sports, angling, etc.)				
	Quantitative analysis – value of savings to consumers of using the correct dosage of laundry detergent	Quantitative analysis	Costs avoided from October 2005 to the present day	Literature review Market analysis (see Qu.15)	Section 6.1.2 and Annex 2, Section A2.5 Note that quantitative analysis was not possible
	Extent to which key stakeholder groups believe the labelling requirements of the Detergents Regulation are sufficient to inform downstream users and consumers about potential allergenic substances in detergents	Qualitative analysis Question in the PC questionnaire for organisations	Three key baselines for the analysis – October 2005 when the Regulation first came into force, June 2006 when minor amendments to Annex VII were introduced and March 2012 when additional amendments were made to section B of Annex VII	Public Consultation Targeted consultation (e.g. with industry associations and NGOs) Supporting study to the Fitness Check	Section 6.1.3 and Annex A3, Section A3.2.2
To what extent are the costs involved in implementing the Detergents	Cost-benefit ratio	Calculation of cost-benefit ratio based on costs and benefits calculated (covered in previous questions). Note that this will require	Various baselines, depending on the indicator – refer to previous questions.	Results of cost and benefit calculation	Not possible to quantify, but covered qualitatively in Section 7.6

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
Regulation justified given the benefits which have been achieved?		monetisation of benefits for comparability, which may not be possible in all cases			
	Extent to which key stakeholders believe the costs involved in implementing the Detergents Regulation are justified given the benefits which have been achieved	Question in the PC questionnaire for organisations Question in the survey for SMEs	N/A	Public Consultation Targeted consultation SME survey Workshop	Section 7.6
Coherence					
To what extent are the Detergents Regulation provisions internally coherent ? Do provisions overlap or contradict, do they co-act as	Extent to which key stakeholders (by type) agree that the Detergents Regulation is internally coherent	Question in the survey for SMEs	N/A	Public Consultation SME survey Targeted consultation Workshop	Section 5.1
	Qualitative analysis – examples of relevant overlaps and contradictions within the provisions of the Detergents Regulation	Legal analysis and comparison of the provisions of the Regulation Qualitative analysis Question in the PC questionnaire for organisations Question in the survey for SMEs	N/A	Legislative text of the Regulation SME survey Public Consultation Targeted consultation Workshop	Section 5.1

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
intended? Are there gaps between the Regulation and other pieces of legislation?	Qualitative analysis – examples of gaps within the Detergents Regulation and between the Detergents Regulation and other pieces of legislation	Legal analysis Qualitative analysis Question in the PC questionnaire for organisations Question in the survey for SMEs	N/A	Literature review Public Consultation Targeted consultation SME survey Workshop Supporting study to the Fitness Check	Section 5.1.2
	Qualitative analysis – key stakeholders' views on the impacts that have arisen as a result of the identified inconsistencies, gaps or overlaps	Qualitative analysis Question in the PC questionnaire for organisations Question in the survey for SMEs	N/A	Public Consultation Targeted consultation SME survey Workshop Supporting study to the Fitness Check - maybe	Section 5.1
To what extent is the Detergents Regulation coherent with other EU legislation? Do provisions overlap or contradict, do they co-act as intended?	Qualitative analysis – examples of relevant overlaps and contradictions	Text analysis and comparison of the Detergents Regulation and other relevant EU legislation	N/A	Legislative text of the Regulation and other EU texts (e.g. REACH, CLP, Cosmetic Products Regulation, Biocidal Products Regulation, Ecolabel, PEF/OEF, Water Framework Directive, Directives on Good Laboratory Practice, etc.) Results from study	Section 5.2

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
What impacts do these overlaps have?				supporting Fitness Check (undertaken by RPA)	
	Extent to which key stakeholders agree that the Detergents Regulation is coherent with other key pieces of EU legislation	Question in the PC questionnaire for organisations Question in the survey for SMEs	N/A	Public Consultation SME survey Targeted consultation Workshop	Section 5.2
	Qualitative analysis – examples of overlaps and contradictions as identified by key stakeholders	Question in the PC questionnaire for organisations Question in the survey for SMEs Qualitative analysis	N/A	Public Consultation SME survey Targeted consultation Workshop Supporting study to the Fitness Check	Section 5.2
	Qualitative analysis – key stakeholders' views on the impacts that have arisen as a result of the identified overlaps and contradictions	Question in the PC questionnaire for organisations Question in the survey for SMEs Qualitative analysis	N/A	Public Consultation SME survey Targeted consultation Workshop Supporting study to the Fitness Check	Section 5.2
Relevance					
To what extent are the concepts and definitions used in the	Extent to which key stakeholders agree that the concepts and definitions used in the Detergents Regulation (particularly those in Article 2) are in	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation Workshop	Section 4.2

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
Detergents Regulation in line and coherent with the meaning they have gained over time in practice and do they cover all the commonly accepted detergent products available on the market?	line and coherent with the meaning they have gained over time in practice				
	Qualitative analysis – examples of where there are inconsistencies between the concepts and definitions used in the Detergents Regulation and associated meanings gained over time in practice	Question in the PC questionnaire for organisations Qualitative analysis	N/A	Public Consultation Targeted consultation (with industry associations and companies) Workshop	Section 4.2
	Extent to which key stakeholders agree that the scope of the Detergents Regulation covers all the commonly accepted detergents products available on the market	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation (with industry associations and companies) Workshop	Section 4.2
	Qualitative analysis – examples of key products available on the market (or that may be put on to the market in the coming years) that are not currently covered by the concepts and definitions included within the Detergents Regulation	Question in the PC questionnaire for organisations Qualitative analysis	N/A	Literature review Public Consultation Targeted consultation (with industry associations and companies) Workshop	Section 4.2
Size of the market for		Question in the PC	N/A	Market analysis	Section 4.2 and

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
	products (e.g. sales volume/value, production volume/value) that are not currently covered by the concepts and definitions included within the Detergents Regulation	questionnaire for organisations Quantitative analysis		(see Question 15)	Annex 1
To what extent are the objectives of the Detergents Regulation still relevant considering the evolution of societal needs and technological developments?	Extent to which key stakeholders agree that the objectives of the Detergents Regulation are still relevant considering the evolution of societal needs and technological developments	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation Workshop	Section 4.1
	Qualitative analysis – examples of where the Detergents Regulation has adapted well / not so well to changing societal needs and technological developments, as identified by stakeholders	Question in the PC questionnaire for organisations Qualitative analysis	N/A	Public Consultation Targeted consultation Workshop	Section 4.1
Have there been any technical or other developments since the	Qualitative analysis – examples of technical or other developments that have occurred since the adoption and further amendment of the	Qualitative analysis	N/A	Literature review Market analysis Supporting study to the Fitness Check Targeted consultation Workshop	Section 4.3

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
<p>adoption (and further amendments) of the Regulation that were not foreseen in the Regulation that have impacts on the relevance of the Regulation? Have there been any new problems/issues related to detergents, their use and their impact on the environment and human health that are currently not addressed</p>	<p>Detergents Regulation that have impacted on the relevance of the Regulation</p>				
	<p>Qualitative analysis – examples of new problems/issues related to detergents, their use and their impacts on the environment and human health that are not currently addressed through the Detergents Regulation</p>	<p>Question in the PC questionnaire for organisations and, if possible, quantitative analysis</p>	<p>N/A</p>	<p>Public Consultation Targeted consultation Workshop Supporting study to the Fitness Check Literature review</p>	<p>Section 4.3</p>

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
through the Detergents Regulation?					
EU added value					
To what extent has the Regulation permitted achievements which could not be reached at MS level?	Extent to which key stakeholders agree that the Detergents Regulation has made it easier to trade detergents and surfactants cross-border within the EU	Question in the PC questionnaire for organisations Questions in the survey for SMEs	Situation before 2005 compared to the situation from 2005 up to the present day	Public Consultation Targeted consultation Workshop SME survey	Section 6.1.1
To what extent have MS issued national rules on detergents that go beyond the scope of the Detergents Regulation?	Extent to which key stakeholders agree that the Detergents Regulation has delivered better outcomes for the environment and human health than could have been achieved at the MS level alone	Question in the PC questionnaire for organisations	N/A	Public Consultation Targeted consultation Workshop	Section 8.1.1
To what extent is EU level intervention still	Qualitative analysis – examples of achievements that could not have been reached at the MS level alone, as identified by key stakeholders Qualitative analysis – examples of national provisions related to	Question in the PC questionnaire for organisations Qualitative analysis	N/A	Public Consultation SME survey Targeted consultation Workshop	Section 8.1.1
			N/A	Targeted consultation Workshop	Section 8.1.2

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
warranted?	detergents that go beyond the scope of the Detergents Regulation, as identified by key stakeholders			Policy documents from the MS Supporting study to the Fitness Check	
	Extent to which key stakeholders agree that the issues addressed by the Detergents Regulation continue to require action at the EU level	Question in the PC questionnaire for organisations Questions in the survey for SMEs	N/A	Public Consultation SME survey Targeted consultation Workshop	Section 8.1.3
	Qualitative analysis – stakeholders' views regarding the most likely outcome if some or all of the provisions of the Detergents Regulation were removed at the EU level	Qualitative analysis	N/A	Targeted consultation Workshop	Section 8.1.3
Analysis of EU market					
What is the current state of play of the detergents market (main product types and their share	Number of enterprises manufacturing detergents and surfactants, by size. <i>Note: the term "manufacturer" is specifically defined in Article 2(10) of the Detergents Regulation</i>	Diachronic analysis	Data from before the Regulation came into force in 2004 up to the present day.	Eurostat Targeted consultation (with industry associations, particularly AISE)	Annex 1, Section A1.3.3
	Levels of turnover in the	Diachronic		Eurostat	Annex 1, Section

Table 4 Evaluation questions, indicators, methodology and data sources					
Evaluation questions	Indicator	Methodology	Baseline	Data sources	Relevant sections of the supporting study
in the market; new technologies, products or sales practices)? What are the main sustainability aspects of detergents currently being marketed?	sector, by size of enterprise	analysis			A1.3.3
	Value and volume of detergents and surfactants traded across borders within the EU	Diachronic analysis		Comext database	Section 6.1.1
	Value and volume of production of detergents and surfactants within the EU	Diachronic analysis		Eurostat	Annex 1, Section A1.3
	Main product types and their share in the market	Quantitative and, if possible, diachronic analysis		Literature review Targeted consultation (with industry associations, particularly AISE)	Annex 1, Section A1.4
	Total and per capita consumption of detergents and surfactants in the EU	Diachronic analysis		Eurostat	Annex A1, Section A1.4
	Change in the concentration of selected chemicals (particularly phosphates) in detergents	Analysis of changes to the composition of detergents over time		Literature review	Annex 1, Section A1.2

Tableau 1 Evaluation questions, indicators, methodology and data sources

8.1.2 Methodology used for cost assessment

8.1.2.1 *Costs associated with reformulation to reduce the phosphorus content*

A. Cost of reformulating a single product

The 2012 amendment to the Detergents Regulation (Regulation (EU) No 259/2012) introduced new limits on the content of phosphates and other phosphorus compounds in detergents designed for washing laundry and dishes, by machine, in the home. Regulation (EU) No 259/2012 sets a limit of 0.5 grams of phosphorus for laundry detergents (for use in a machine), with this coming into force in June 2013. Annex VIa also sets a limit of 0.3 grams of phosphorus for CADD, applicable from January 2017. It would therefore be anticipated that the detergents industry may have incurred a substantive compliance cost¹⁸² as a result of this requirement.

The European Commission's 2010 impact assessment accompanying the proposal for Regulation (EU) No 259/2012¹⁸³ predicted that larger detergent formulators, operating across several MS, would find it relatively easy to substitute detergents containing phosphorus with comparable alternative formulations, as most of them were already offering phosphate-free products in the MS that had such limitations in place before 2012. The impact assessment stated, however, that smaller formulators serving only their domestic markets with detergents based on phosphates might find the situation more complicated. The Report estimated that one-off reformulation costs for replacing phosphates would be, on average, around €10,800 per product reformulated. Based on the number of SME formulators across the EU27 in 2007 (i.e. 600) and assuming that each of these would have to reformulate on average between four and 22 products, the report predicted that **the total one-off (CAPEX) reformulation costs across the EU would be between €26 million and €142 million.**

SMEs that participated in the survey disseminated by EEN were asked to estimate the one-off costs of research and development for the purposes of reformulation. Most of the SMEs (18%) that provided a response to this question indicated that the one-off cost of reformulating a detergent was in the region of €10,000 to €20,000. A substantial proportion (12%) of SMEs that responded to this question indicated that reformulating a detergent to reduce the total phosphorus/phosphate content costs more than €20,000, but an equal percentage indicated that it costs less than €10,000.

As a comparison, the following information on the cost of reformulation was provided during the interviews:

1. One industry association, quoting figures from one of its member companies, noted that for 50 CADD formulas to be reformulated to reduce the total phosphorus content to meet the new restrictions, it took one company 49,500 person-days (or around 1,000 person-days per CADD formula). This includes the days required for research and development and manufacturing, but does not include efforts in marketing and

¹⁸² Substantive compliance costs are the costs that businesses incur as a result of having to adapt their activities in order to comply with a legal obligation.

¹⁸³ European Commission (2010): Commission Staff Working Document accompanying document to the Proposal for a Regulation (EU) No ... of the European Parliament and of the Council amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in household laundry detergents, SEC(2010) 1277 Final, available at: <http://www.ipex.eu/IPEXL-WEB/dossier/document/SEC20101277FIN.do>

distribution, which for ease of calculation were assumed not to have been increased by the move. These figures seem unrealistically high compared to both those quoted in the Commission's 2010 impact assessment and responses by SMEs to the EEN survey.

2. One SME noted that to change one product, it would require two people to work for three years. If it is assumed that the average working year comprises 240 working days, it can be estimated that this equates to 1,400 person-days per product. Again, this figure seems unrealistically high.
3. A large company estimated that it costs around €5,000 to €10,000 to reformulate a detergent, where this includes the cost for the employees.
4. Another large company noted that one of its departments spent almost the whole of 2016 dealing with the new phosphate limits for CADD and that, as a result, almost all of the costs of that department (estimated at €200,000) can be attributed to the phosphorus requirements of the Detergents Regulation. The company explained that this includes the cost of reformulation but also other associated activities, such as spending time searching for new raw materials, looking for new sources and relabelling. About 20-30 products were reformulated, within this total cost of €200,000. The cost per product can therefore be estimated at €6,500 to €10,000. The company noted that a significant amount of work was also done before the new phosphorus limits for consumer laundry detergents came into force, but the company was unable to estimate the costs associated with this.
5. A large company noted that it works on the basis of 'framework formulations' from which it develops several individual products ('Stock Keeping Units' or SKUs¹⁸⁴). The company noted that it would cost several hundred thousand Euros to reformulate a framework formulation to reduce the phosphorus/phosphate content and that it would cost in the region of €30,000 to €40,000 to reformulate an SKU.

The reformulation costs provided by SMEs during the consultation are broadly consistent with those of the Commission's 2010 impact assessment, as well as the figures provided in bullet points 2 and 3 above. However, the person-day estimates provided in the first two bullet points suggest that these could be a significant underestimate for some companies (for further explanation, see the box below). One possible interpretation is that the person-day estimates (shown in the first two bullet points above) refer to the costs involved in reformulating a framework formulation (as explained in bullet 5) and that the cost of reformulating a single product would be much lower.

A range of €10,000 to €20,000 per product is therefore considered to reflect the average cost of reformulation across the SMEs and their product portfolios. During the consultation, one large company noted that the cost of reformulating a single CADD product would be about the same as the cost of reformulating a single laundry detergent product. Thus a cost range of €10,000 to €20,000 per product is assumed across both product groups.

¹⁸⁴ Each SKU would be a slight variation of the framework formulation, e.g. with a different colour or smell.

Cost estimates based on person-days

Eurostat data¹⁸⁵ shows that the average annual personnel cost¹⁸⁶ for a worker employed in ‘scientific research and development’ in the EU was €54,000 in 2012. Assuming that it takes three workers two whole years to reformulate a single product (as suggested in the second bullet point above), the total cost for that product would be €324,000 in personnel costs alone. If it takes 1,000 person-days (or 4.17 person-years¹⁸⁷) to reformulate a single product (as suggested in the first bullet point above), the total cost would be €225,180 per product, based on an average personnel cost of €54,000.

It should be noted that the average annual personnel cost for workers varies enormously between EU MS; ranging from €9,700 in Latvia to €93,600 in Belgium for a worker employed in scientific research and development.

The European Commission’s 2010 impact assessment¹⁸⁸ predicted that SME formulators would need to reformulate on average between 4 and 22 products. During the survey, SMEs were asked how many different formulations they have in their portfolio. Most SMEs have indicated that they have up to 15 formulations in their portfolio for laundry detergents and up to 15 formulations in their portfolio for CADD. This suggests that the original figure of between 4 and 22 products is likely to be broadly accurate.

If it cost companies, on average, between €225,000 and €325,000 to reformulate each detergent product, as the person-day estimates would suggest, and if each company had to reformulate between 4 and 22 products, the average cost per company would have been between €900,000 and €7,150,000.

Data from Eurostat shows that the total turnover for the EU28 detergents sector (defined as NACE Code 2041) was €26.9 million in 2014.¹⁸⁹ It also shows that there were approximately 4,000 enterprises in the detergents sector (NACE Code 2041) in 2014. This means that the average turnover per enterprise was €6.7 million in 2014, covering both SMEs and larger enterprises. The person-day figures (€900,000 to €7,150,000) would therefore appear to be a significant overestimate, as such costs would have driven many companies (especially SMEs) out of business. These numbers have not, therefore, been taken further in the analysis. As noted previously, a cost range of €10,000 to €20,000 per product is considered to better reflect the average costs of reformulation.

In using the above data and developing estimates of the costs of reformulation, there are several factors that must be borne in mind when attributing costs for reformulation to the Detergents Regulation:

- Firstly, during the consultation, several companies and industry associations noted that the reformulation of products started some years before the 2012 amendment to the Detergents Regulation came into force, in part because national limits on the phosphorus content of detergents were already in place in some countries (this is discussed further in Section 6.1.2);
- Secondly, it was noted by at least two companies during the consultation that a peak in phosphorus prices in the late 2000’s was a key driver for reformulation at least in their company; and
- Finally, it is also important to note that detergent manufacturers reformulate their products regularly to maintain competitiveness (see the box below). As such, the cost

¹⁸⁵ Eurostat (sbs_na_sca_r2)

¹⁸⁶ Made up of wages, salaries and employers' social security costs.

¹⁸⁷ Based on a working year comprising 240 working days.

¹⁸⁸ European Commission (2010): Commission Staff Working Document accompanying document to the Proposal for a Regulation (EU) No ... of the European Parliament and of the Council amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in household laundry detergents, SEC(2010) 1277 Final, available at: <http://www.ipex.eu/IPEXL-WEB/dossier/document/SEC20101277FIN.do>

¹⁸⁹ Eurostat (sbs_na_ind_r2)

of the limits for CADD could – to some extent - be considered a business as usual cost, given that companies were given around five years to comply (2012-2017).

Frequency of reformulation

The following information has been gathered from literature review and consultation on the frequency of reformulation:

- According to Bio by Deloitte (2014)¹⁹⁰, detergent manufacturers reformulate their products regularly to maintain competitiveness, averaging every three and a half years.
- One large company noted that it reformulates 35% of its consumer detergent products every year and the remaining 65% of its consumer detergent products every two years.
- One company noted that in the fast-moving CADD market, products may need to be reformulated every year (even in the absence of the Detergents Regulation), while for other products, reformulation might occur once every five years.
- AISE has suggested that it can be assumed that 50% of consumer detergent products are reformulated every two years, and 50% are reformulated every five years. In the industrial and institutional detergent sector, AISE has suggested that it can be assumed that 50% are reformulated every year and 50% every two and a half years.

Based on the available information, the figures quotes by AISE can therefore be taken a broadly representative of the sector.

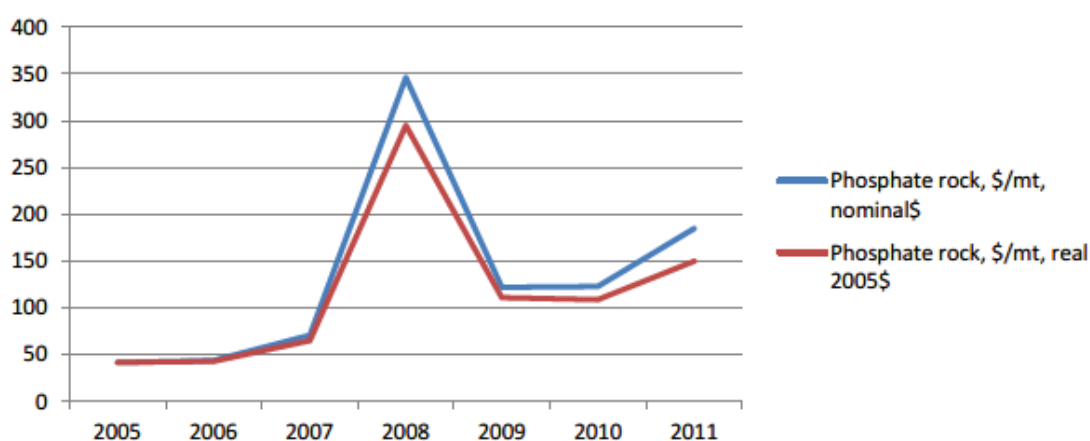


Figure 8 Price of phosphate rock, US\$/mt¹⁹¹

B. Number of companies and products affected

A recent (2016) socio-economic analysis undertaken by The Huggard Consulting Group for AISE¹⁹² notes that manufacturing activity within the household care and professional cleaning and hygiene products industry involves between 650 and 700 separate facilities throughout the EU, Norway and Switzerland, more than 85% of which are operated by

¹⁹⁰ Bio by Deloitte (2014): Evaluation of the use of phosphates in Consumer Automatic Dishwasher Detergents (CADD), Report prepared for the European Commission – DG ENT. Available at: <http://ec.europa.eu/DocsRoom/documents/7245/attachments/1/translations/en/renditions/native>

¹⁹¹ www.phosphorusplatform.eu/images/download/HCSS_17_12_12_Phosphate.pdf

¹⁹² The Huggard Consulting Group (2016): The household care and professional cleaning and hygiene products industry, A socio-economic analysis. Available at: https://www.aise.eu/documents/document/20160628174212-aise_sea_final_report_jan2016.pdf

SMEs. Output is, however, concentrated in 80-90 large-scale plants operated by multinational companies. The report notes that these large sites are concentrated in Germany, the UK, France, Italy, Spain, the Benelux countries and Poland.

During the consultation for the supporting study to the Fitness Check, detergent manufacturers were asked how many formulations they currently have in their portfolio (covering all product types; and including both consumer and industrial/institutional detergents). As shown in Table 5 below, most SMEs indicated that they have between 50 and 250 formulations in their portfolio, while most non-SMEs indicated that they have in excess of 250. It should be noted that data from Eurostat show that around 98% of all companies in the detergents sector (defined as NACE Code 204¹⁹³) are SMEs, and that 73% are micro-enterprises (with between one and nine employees). Care must therefore be taken in using the data in the table below, as these are likely to overestimate the number of formulations in most detergent manufacturers' portfolios.

<i>Table 5 How many mixtures (formulations) do you currently have in your portfolio?</i>		
	Non-SME (n=10)	SME (n=23)
<50	0.0%	8.7%
50 to 100	10.0%	26.1%
100 to 250	10.0%	26.1%
250 to 500	40.0%	17.4%
500 to 1500	20.0%	17.4%
>1500	20.0%	4.3%

Source: RPA et al. (2017)

During the SME survey undertaken for this evaluation, SMEs were asked how many different formulations they have in their portfolio. Most SMEs indicated that they have up to 15 formulations in their portfolio for laundry detergents and up to 15 formulations in their portfolio for CADD. These figures are more closely aligned with the European Commission's 2010 impact assessment¹⁹⁴ that predicted that SME formulators would need to reformulate on average between 4 and 22 detergent products.

When presented with these figures, AISE suggested that these are too low and instead proposed the following split covering the manufacture of consumer detergent formulations across the EU/EEA:

- 50 large manufacturers, with on average 150 to 250 consumer detergent formulations each;
- 600 to 650 SME manufacturers, with on average 40 to 60 consumer detergent formulations each.

¹⁹³ sbs_sc_sca_r2

¹⁹⁴ European Commission (2010): Commission Staff Working Document accompanying document to the Proposal for a Regulation (EU) No ... of the European Parliament and of the Council amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in household laundry detergents, SEC(2010) 1277 Final, available at: <http://www.ipex.eu/IPEXL-WEB/dossier/document/SEC20101277FIN.do>

This equates to 31,500 to 51,500 consumer detergent formulations (covering laundry detergents, dishwashing detergents, and other types) across the EU/EEA. This figure has, therefore, been taken forward in the analysis.

According to AISE (2016)¹⁹⁵, laundry care products account for approximately 47% of the total household care market, by value. This figure will, of course, change from year to year. It can therefore be assumed that about 40% to 50% of consumer detergent formulations available on the market are designed for washing laundry at home. This assumption was verified by a large company during the consultation. Based on this assumption, we estimate that there are, across the EU/EEA, between 12,600 and 25,750 consumer detergent formulas designed for washing laundry at home (by hand and in a machine).

AISE (2016)¹⁹⁶ data shows that dishwashing products account for approximately 15% of the total household care market, by value. It can therefore be assumed that around 10% to 20% of consumer detergent formulations are used for washing dishes across the EU/EEA. Based on this assumption, we estimate that, across the EU/EEA, there are between 3,150 and 10,300 detergent formulations designed for washing dishes at home (by hand and in a machine).

As previously remarked, national limits on the phosphorus content of detergents were already in place in some countries before the 2012 amendment to the Detergents Regulation came into force; and it is likely that some manufacturers in the other countries (without national limits) would have voluntarily switched to producing phosphate-free products before 2012 (e.g. to meet consumer demand, or due to an increase in the price of phosphorus).

A 2011 position paper by WWF¹⁹⁷ lists 12 countries (Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Sweden and the UK) with pre-existing regulations in place to limit the amount of phosphate in laundry detergents to a maximum of 0.5% (for more information see Annex 2 to the supporting study, Table A2-11). In 2011, half of the companies in the detergents sector (defined as NACE Code 2041) were located in these 12 countries (for the raw data see Annex 1 to the supporting study, Table A1-18).

The WWF paper shows that there were three countries in the EU (France, Germany and Sweden) with pre-existing legislation in place to limit the amount of phosphate in CADD to a maximum of 0.5%. In 2011, only 20% of companies in the detergents sector (defined as NACE Code 2041) were located in these three countries (see Annex 1 to the supporting study, Table A1-18). It should be noted that the Detergents Regulation limits the phosphorus content of CADD to 0.3% and is therefore more stringent than the cut off (of 0.5%) used in the analysis by WWF. This means that it is possible that some companies in France, Germany and Sweden were still producing detergents with a phosphorus concentration of between 0.3% and 0.5%. These companies would have been required to reformulate their products in

¹⁹⁵ AISE (2016): Activity & Sustainability Report 2015-16 – Cleanliness & Hygiene at Home and in Society. Available at: http://www.sustainable-cleaning.com/content_attachments/documents/AISE_AR15_16_FINAL.pdf

¹⁹⁶ AISE (2016): Activity & Sustainability Report 2015-16 – Cleanliness & Hygiene at Home and in Society. Available at: http://www.sustainable-cleaning.com/content_attachments/documents/AISE_AR15_16_FINAL.pdf

¹⁹⁷ WWF (2011): Washing our Dishes and Clothes without Polluting our Rivers and Seas – The importance of an EU restriction of phosphate detergents for laundry and dishwashers. Available at: http://d2ouvy59p0dg6k.cloudfront.net/downloads/web_phosphate_brochure_1.pdf

order to comply with the new, and stricter, 0.3% limit introduced by Regulation (EU) No 259/2012.

A proportion of companies selling products outside those countries with pre-existing legislation may also have voluntarily reduced the phosphorus content of their products. The analysis by WWF shows that in 2011 there were four countries (Hungary, Ireland, Poland and Slovakia) with regulation or voluntary initiatives in preparation or in place with a threshold for phosphate >0.5%. In 2011, 10% of companies in the detergents sector (defined as NACE Code 2041) were located in Hungary, Ireland, Poland and Slovakia. For CADD, there were six countries (Austria, Denmark, Finland, Italy, Latvia and UK) with regulation or voluntary initiatives in preparation or in place with a threshold for phosphate >0.5%. In 2011, 26% of companies in the detergents sector (NACE Code 2041) were located in these six countries.

AISE has noted that 30% of consumer laundry detergent products were reformulated as a direct result of the 2012 amendment to the Detergents Regulation (Regulation (EU) No 259/2012). Assuming that there are between 12,600 and 25,750 consumer detergent formulas designed for washing laundry at home (as previously estimated), this would equate to 3,780 to 7,725 products in total across the EU/EEA.

AISE has also noted that 95% of CADD were reformulated as a direct result of Regulation (EU) No 259/2012. For the purposes of this analysis, it can be assumed that between 40% and 50% of all consumer dishwashing detergents are designed for use in a machine and, hence, that 1,197 to 4,893 CADD formulae were reformulated as a direct result of Regulation (EU) No 259/2012.

C. Estimate of the total one-off cost

Given the above, the total one-off cost to the detergents industry of research and development for the purposes of reformulating laundry detergents to reduce the total phosphorus content can be estimated at between €37.8 million and €154.5 million, based on the following assumptions:

- There were 31,500 to 51,500 consumer detergent formulations available on the market across the EU/EEA;
- Between 40% and 50% of all consumer detergent products were designed for washing laundry at home (i.e. 12,600 to 25,750 products in total);
- 30% of consumer laundry detergents were reformulated as a direct result of the Detergents Regulation (i.e. 3,780 to 7,725 products in total);
- It costs each manufacturer/formulator between €10,000 and €20,000 per laundry detergent product to carry out the research and development necessary for reformulation.

As previously outlined, the cost to the detergents industry of research and development for the purposes of reformulating CADD can, at least in part, be considered a business as usual cost. However, it should be recognised that replacing phosphorus in CADD with other ingredients constitutes a more fundamental level of reformulation than, for example, simply tweaking the fragrance or colour and that, as a result, some companies formulating CADD may have incurred substantial costs. With this in mind, the total one-off cost to the detergents industry of research and development for the purposes of reformulating CADD (to reduce the total phosphorus content) can be estimated at between €12.0 million and €98.0 million based on the following assumptions:

- There were 31,500 to 51,500 consumer detergent formulations available on the market across the EU/EEA (as previously assumed);
- That 10% to 20% of all consumer detergents were designed for washing dishes (i.e. 3,150 to 10,300 products in total);
- That 40% to 50% of all consumer dishwashing detergents were designed for use in a machine (i.e. 1,260 to 5,150 products in total);
- That 95% of CADD were reformulated as a direct result of the Detergents Regulation (i.e. 1,197 to 4,893 products in total);
- That it cost each manufacturer/formulator between €10,000 and €20,000 per CADD product to carry out the research and development necessary for reformulation.

8.1.2.2 *Costs associated with labelling requirements*

A. Overview

In order to quantify the costs driven by the Detergents Regulation's labelling provisions, it is critical to consider not only the pre-existing legislative context, but also the labelling requirements of other legislation applicable to (some) detergent products. It is also important to consider the frequency at which manufacturers would voluntarily relabel their products (e.g. to update the artwork) in the absence of the Detergents Regulation.

Pre-existing legislation on detergents (Council Directive 73/404/EEC) only required the name of the product and name and address of the party responsible for placing the product on the market. Unlike the Detergents Regulation, it did not require, for example, the content of the detergent to be labelled, an indication of the dosage to use, or specific languages to be used.

When CLP came into force, it introduced new requirements, some of which overlap with those of the Detergents Regulation. In addition to that, the Detergents Regulation is clear on the fact that its labelling provisions are “without prejudice” to the provisions of the CLP. For example, where applicable, CLP requires the use of hazard pictograms, signal words, hazard statements and precautionary statements that, to some extent, overlap with Article 11(3) of the Detergents Regulation (i.e. “instructions for use and special precautions”). Similar to Article 11(5) of the Detergents Regulation, Article 17(2) of CLP also requires the label to be written in the official language(s) of the MS where the mixture (detergent) is sold.

Detergents that contain an active substance are, in addition to Detergents and CLP obligations, subject to provisions of the Biocidal Products Regulation either as biocidal products (e.g. when the product is a detergent-disinfectant) or as a treated article (e.g. a detergent which contains an in-can preservative). Unfortunately, it has not been possible to ascertain what proportion of detergents fall within the scope of both pieces of legislation, although it is expected to be a relatively small proportion overall. This is important because it means that, for most detergent products, the labelling requirements (and associated costs) are driven by the Detergents Regulation rather than the Biocidal Products Regulation.

It should be noted that the labelling of dosage information is exclusively a provision of the Detergents Regulation and did not exist as a requirement of EU legislation before the Detergents Regulation came into force.

Based on the available information, it is possible to conclude that additional labelling requirements are driven by the Detergents Regulation representing additional labelling costs which can, therefore, be attributed to the Detergents Regulation.

In estimating the total costs attributable to the labelling provision of the Detergents Regulation it is important to remember that some of the labelling requirements only apply to consumer detergent products. For example, Annex VII A to the Regulation requires information on the content of detergents to be provided on the packaging of detergents sold to the general public. For detergents intended to be used in the industrial and institutional sector, and not made available to members of the general public, content information can be provided by means of a technical datasheet, safety datasheet, or in a similar appropriate manner.

As previously outlined, AISE has suggested that, in the consumer detergent subsector, there are approximately 50 large manufacturers in the EU, with on average 300 to 500 consumer detergent formulations each; and 600 to 650 SME manufacturers, with on average 80 to 120 consumer detergent formulations each. In the industrial/institutional subsector, AISE has suggested that there are approximately 50 large manufacturers, with an average portfolio containing 150 to 300 industrial/institutional detergent products; and 600 to 650 SME manufacturers, with 40 to 60 industrial/institutional detergent products each. In other words, there are an estimated 63,000 to 103,000 detergent products in total covering both consumer and industrial/institutional subsectors across the EU/EEA (31,500 to 49,000 consumer detergent products and 31,500 to 49,000 detergent products in the industrial/institutional subsector).

B. One-off cost of producing new labels for consumer detergents

Stakeholders noted that the labelling provisions in the Detergents Regulation have been particularly costly for companies and that SMEs may have been disproportionately affected by the changes because they tend to buy-in labels, rather than produce them in-house. This is important because companies that do not produce their own detergent labels may have been required to throw some (non-compliant) stock away when the new rules came into force. During the consultation, several companies (both large and small) noted that they incurred costs because labels and packaging had to be thrown away.

SMEs responding to the EEN survey were asked to indicate the one-off costs associated with “changes to labelling including the disposal of old labels”. 17% of SMEs indicated that the one-off costs were greater than €20,000. Around one quarter of SMEs that participated in the survey indicated that the average one-off cost per formulation of fulfilling the labelling requirements specific to the Detergents Regulation was less than €250. It is not clear why the responses to these two questions vary so significantly, other than that the question explicitly includes disposal of old packaging within a description of part of the costs rather than just re-design of artwork and reprinting of labels.

During the interviews, stakeholders were asked about the costs associated with labelling changes:

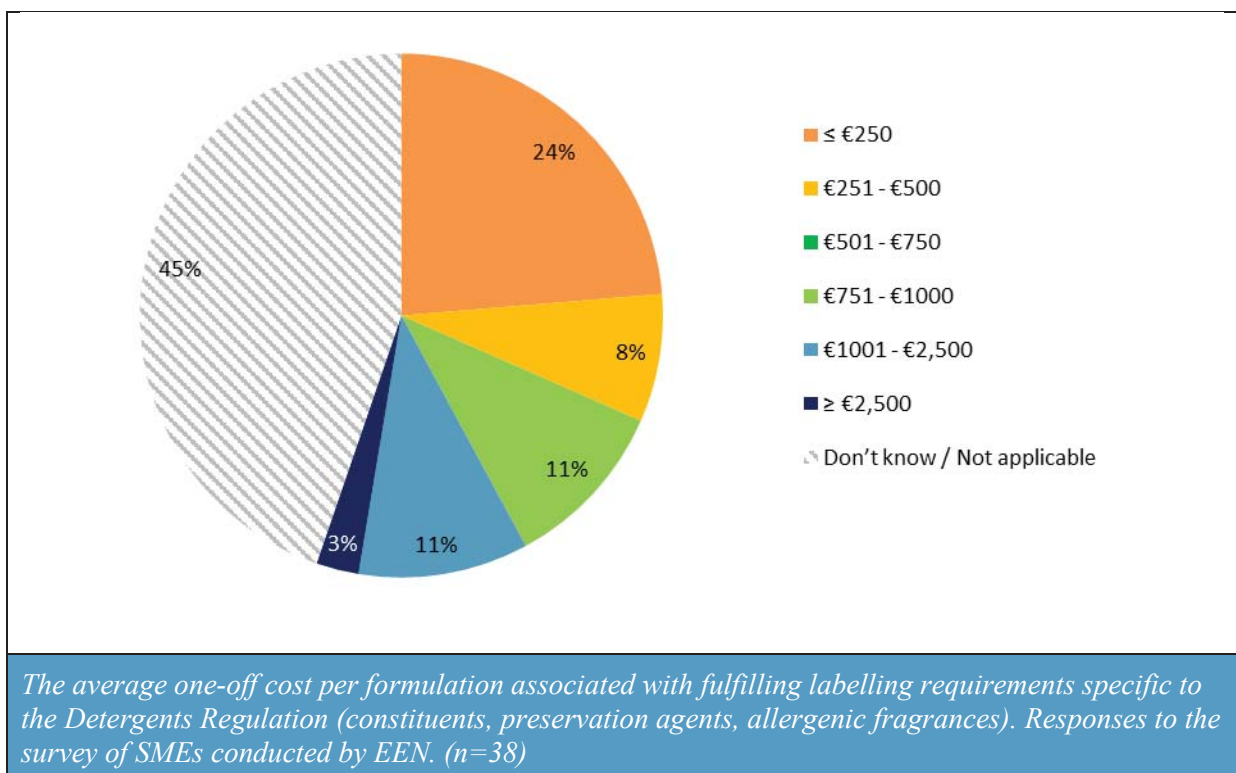
- An SME from the Netherlands noted that the cost of relabelling a detergent is around €200 to €300 per product;
- An SME from Germany noted that for each labelling and packaging change, the associated cost is between €2,000 and €3,000;
- An SME from Belgium explained that new labels have a one-off cost of approximately €500 per product, where this includes the cost of producing the new label but also the cost of throwing away the stock of old labels that can no longer be used. The company noted that for all labelling requirements to be met (including

Detergents Regulation but also CLP), it costs the company approximately €50,000 per year for the 80-100 products in its portfolio;

- A large company from Austria noted that it incurs costs of €500/month (€6,000/year) as a result of the labelling requirements under the Detergents Regulation. The company noted that this is, in part, because old labels are thrown away;
- A large company from the Netherlands confirmed that it tries to keep the cost to €2,000 per product for updating the artwork on its detergent labels. The company noted that it buys in labels and typically has €10 million worth of labels available in stock at any one time. The company noted that for the introduction of CLP, the company had to throw €100,000 worth of labels away, but that the company had managed its stock of labels carefully in advance of the changes to ensure that this cost was kept to a minimum. The company noted that with CLP they were given 18 months to comply and so they were able to plan ahead and keep costs to a minimum. Unfortunately, the company was not able to confirm the level of costs it incurred as a result of the Detergents Regulation.

The information in this last bullet point is important because it shows that some large companies will also have incurred costs as a result of having to throw non-compliant labelling stock away.

Although AISE additionally noted that the overall cost for one large company alone had been of the order of a couple of million Euros, we have assumed that this is not typical for all large companies given that this implies a 100-fold increase in such costs relative to SMEs (although it is recognised that large companies will have a larger number of units for each product and a larger product portfolio overall).



The total one-off cost of labelling changes (covering the revision of labels and artwork) to the detergents industry can be estimated at €6.3 million to €154.5 million, based on the following assumptions:

- Firstly, that there were between 31,500 and 51,500 consumer detergent products that had to be relabelled as a result of the Detergents Regulation; and
- That the one-off cost, per product, of producing new labels (labelling and artwork) was between €200 and €3,000;

The total one-off cost of throwing label stock away can be estimated at €3.2 million to €9.0 million, based on the following assumptions:

- That there are 50 large manufacturers and 600 to 650 SMEs manufacturing consumer detergent products in the EU/EEA;
- That 30% of large companies and 80% of SMEs had to throw some of their label stock away; and
- That each large company that threw some of its labelling stock away incurred a one-off cost of between €50,000 and €250,000 and that each SME that threw some of its labelling stock away incurred a one-off cost of €5,000 to €10,000.

This gives a total one-off cost of producing new labels for consumer detergents of €9.5 million to €163.5 million across the EU/EEA.

C. On-going costs of keeping consumer detergent labels up to date

Consultation undertaken for the supporting study for the Fitness Check¹⁹⁸ found that, in the absence of REACH and CLP, almost 70% of products would retain the same labels for over 24 months (and up to much longer periods, e.g. 5-10 years in some cases) with only 30% normally changing their labels within this time frame (for reasons of marketing, changes in consumer demand, reformulation, etc.)¹⁹⁹. With CLP in force, it is likely that detergent manufacturers would update their labels more often. For example, if a product is reformulated and a new ingredient is used, the detergent might fall within a different hazard class under CLP and require new hazard pictograms, and therefore new labels. However, new labels may not be required under CLP every time a product is reformulated (e.g. if the hazard class remains the same). Thus, there are some costs stemming from the labelling provisions of the Detergents Regulation that go beyond those that would arise in the Regulation's absence.

In the absence of other legislation (namely CLP and the Biocidal Products Regulation), under the Detergents Regulation, labels would probably be updated (in most cases) when a product is reformulated. However, the label would not necessarily be updated every time reformulation occurs. For most ingredients in consumer detergent products, Annex VII A to

¹⁹⁸ RPA et al. (2017): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation – Annex II. For the European Commission. Available at: <http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/>

¹⁹⁹ As part of targeted data collection, industry was asked “On average, how often would you expect to modify or redesign the labels on the products that you place on the market for reasons other than CLP and REACH (i.e. for marketing reasons or to respond to changes in consumer demand)”.

the Detergents Regulation requires the manufacturer to label the content using the nomenclature provided in Annex VII A which includes general terms such as “anionic surfactant”, “cationic surfactant”, “enzymes”, etc. This means that, even if a product is reformulated, it may not always be necessary to update the content list and label (e.g. if a different anionic surfactant is used at a similar weight percentage range).

During the consultation, one large company noted that it updates the labels on its products about 60% to 70% of the time when its products are reformulated. AISE, quoting information from one of its member companies, suggested that product labels would be updated approximately 80% of the time.

The total on-going cost of updating consumer detergent product labels can be estimated at €0.8 million to €1.5 million per year, based on the following assumptions:

- Firstly, that as a result of the Detergents Regulation, half of all consumer detergent products are reformulated every two years, while the other half are reformulated every five years;
- That the product label is updated 60% to 70% of the time when consumer detergent products are reformulated;
- That there are between 31,500 and 51,500 consumer detergent products in the EU/EEA (as previously assumed);
- That is costs between €120 and €200 to update the label for a single detergent product.

The total cost to the detergents industry for the period 2004-2016 can be estimated at €9.5 million to €18.5 million.

During the consultation, one large company noted that it normally allows a cost of €2,000 per product to update labels but that, to some extent, this can be considered a business as usual cost because the company’s marketing team would take the opportunity to update other aspects of the label at the same time. AISE similarly commented that one of its member companies had indicated a one-off cost of about €1,000 to update a product label. It would therefore seem prudent to carry out a sensitivity analysis on the above cost estimates. Assuming that each company incurred a cost of €1,000 to update the label for each detergent product (and based on the same assumption as before), the total cost would be of the order of €79.4 million to €92.6 million (2004-2016).

8.1.2.3 *Costs associated with providing information in ingredient datasheets*

The on-going cost of keeping technical datasheets and safety datasheets up-to-date can be estimated at €0.7 million to 2.5 million per year, based on the following assumptions:

- Firstly, that as a result of the Detergents Regulation, half of all industrial and institutional detergent products are reformulated every year, while the other half are reformulated every two and a half years;
- That the datasheet is updated 60% to 70% of the time when industrial and institutional detergent products are reformulated;
- That there are between 31,500 and 51,500 industrial and institutional detergent products in the EU/EEA (as previously assumed);
- That is costs between €50 and €100 to update the datasheet for a single detergent product.

The cost for the period 2004-2016 can be estimated at €7.9 million to €30.3 million.

8.1.2.4 *Costs of familiarization and keeping up to date with the provisions of the Detergents Regulation*

During the interviews, stakeholders clarified that, although the one-off cost of compiling an ingredient datasheet is relatively small, the on-going costs add up because the datasheet needs to be updated even for a very small change in the formulation²⁰⁰.

For consumer detergent products, the total annual cost of keeping ingredient datasheets up-to-date can be calculated at €1.7 million to €4.5 million per annum, or €19.8 million to €54.1 million for the period 2004-2016, based on the following assumptions:

- Firstly, that there are 31,500 to 51,500 consumer detergent products in the EU/EEA 50% of which are reformulated (and therefore require a new ingredient datasheet) every two years; and 50% of which are reformulated (and require a new ingredient datasheet) every 5 years; and
- Secondly, that it costs €150 to €250 per product to update the ingredient datasheet.

For industrial and institutional detergent products, the total annual cost of keeping ingredient datasheets up-to-date can be calculated at €3.3 million to €9.0 million, or €39.7 to €108.1 million over the period 2004-2016, assuming that:

- Between 31,500 and 51,500 industrial and institutional detergent products are available on the market in the EU/EEA 50% of which require a new ingredient datasheet every two and a half years; and 50% of which require a new ingredient datasheet every year.
- That it costs between €150 and €250 per product to update the ingredient datasheet.

8.1.2.5 *Costs of testing of biodegradability*

According to JRC (2014a)²⁰¹, there are between 40 and 50 companies in the home and fabric care speciality ingredients market²⁰², with the dominant players mainly being speciality surfactants companies. CESIO – the EU industry association for surfactants – has membership covering approximately 75% of European surfactant manufacturers and includes among its members nine individual companies, eight national associations (representing a number of SMEs in addition to the larger companies), and two associate member companies.²⁰³ Information received from CESIO during the consultation shows that its eight national member associations represent 23 companies (excluding direct member companies and only counting subsidiaries once). This means that, in total, there are 34 separate companies represented by CESIO. Although it has not been possible to determine whether all of these companies supply surfactants to the detergents market, the detergents market

²⁰⁰ In the ingredient datasheet, ingredients must be listed by their common chemical name or IUPAC name and, where available, the INCI name, the CAS number, and the European Pharmacopoeia name, rather than the broader nomenclature used for labelling in Annex VII A.

²⁰¹ JRC (2014a): Revision of European Ecolabel Criteria for Laundry Detergent, Preliminary Report. Available at: <http://susproc.jrc.ec.europa.eu/detergents/docs/LD%20Preliminary%20Report.pdf>

²⁰² Which includes fabric washing and care; hard surface cleaners; car interior and upholstery cleaners; furniture, shoe and leather polishes; and dishwashing products.

²⁰³ CESIO (2017): Our members. Available at: <http://www.cesio.eu/index.php/about-cesio/our-members>

accounts for around 50% of the downstream uses of surfactants; as a result, CESIO suggests that it is reasonable to assume that all of its members do supply the detergents industry. If these 34 companies make up 75% of the market, as CESIO's website shows, this suggests that there may be in the region of 40 to 50 companies in the EU/EEA producing surfactants for use in detergent products. This figure is consistent with the estimate from JRC.

BASF lists on its website²⁰⁴ 67 surfactant products, including one amphoteric surfactant product, one anionic surfactant product and 65 non-ionic surfactant products; although, presumably, not all are suitable for use in detergents. Dow's product portfolio²⁰⁵ includes 45 surfactant products that are designed for use in detergents, cleaners, pre-wash spot removers and washing processes. As large companies, BASF and Dow probably have more surfactants in their portfolio than the industry average overall.

Assuming that each of the 40 to 50 companies producing surfactants in the EU/EEA have between 20 and 60 surfactants in their portfolio, the total number of surfactant formulations that would have required testing would be between 800 and 3,000. Although the total number of different surfactant formulations may be lower than this, given that several companies may have access to the same formulation; for the purposes of estimating the total cost of testing, it is assumed that companies do not share their testing data.

During the consultation, CESIO clarified that the cost of testing a surfactant is between €3,000 and €6,000 per test. While this is somewhat higher than the average testing cost reported by detergent manufacturers and formulators in the survey of SMEs, 13% of SMEs indicated that the average one-off cost per formulation of testing the ultimate biodegradability of a surfactant is between €501 and €1,000; 12% of SMEs indicated that the cost is higher than this and 15% indicated that it is lower, CESIO's estimate has been taken to be more reliable on the basis that surfactant manufacturers (rather than detergent manufacturers/formulators) will have been responsible for carrying out these tests.

Assuming that 800 to 3,000 surfactants each had to be tested to ensure they meet the requirements on ultimate biodegradability introduced by the Detergents Regulation, and that the cost of testing for each surfactant was between €3,000 and €6,000 per test, the total cost across the industry would have been between €2.4 million and €18.0 million. Given the large range of cost estimates provided by SMEs during the consultation, it would seem prudent to carry out a sensitivity analysis on this figure. If 800 to 3,000 surfactants were each tested to ensure they meet the requirements on ultimate biodegradability at a cost per surfactant of between €501 and €1,000, the total cost across the industry would have been between €400,800 and €3 million.

It is important to recognise that pre-existing legislation in the EU already required certain surfactants (anionic and non-ionic; which before the Detergents Regulation came into force accounted for about 90% of the total surfactants on the EU market²⁰⁶) to be tested for their (primary) biodegradability and so, to some extent, these costs can be considered business as usual costs. Unfortunately, consultees were not able to confirm whether there is a difference

²⁰⁴ BASF (2017): Surfactants. Available at: https://worldaccount.basf.com/wa/NAFTA~en_US/Catalog/ChemicalsNAFTA/pi/BASF/Productgroup/surfactants/productgroup_top/

²⁰⁵ Dow (2014): Dow Surfactants, Reference Chart. Available at: http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0949/0901b80380949ccd.pdf?filepath=surfactants/pdfs/noreg/119-01491.pdf&fromPage=GetDoc

²⁰⁶ Intertek (2012): Understanding & attaining compliance to the EU Detergent Regulation, available at: www.intertek.com/WorkArea/DownloadAsset.aspx?id=48909

in cost between testing for primary and ultimate biodegradability and so it has not been possible to subtract the costs that would have arisen even in the absence of the Detergents Regulation.

8.1.2.6 Administrative costs of compiling ingredient datasheets

The Detergents Regulation requires manufacturers placing detergent products (all types within the Regulation's scope) on the market to compile ingredient datasheets.

During the consultation, SMEs were asked to indicate the one-off costs per formulation of compiling an ingredient datasheet. 24% of SMEs indicated that it costs less than €100 to compile an ingredient datasheet, while 16% of SMEs indicated that it costs between €100 and €200. During the interviews, one small company from Belgium noted that it prepares ingredient datasheets using a computer programme but that concentrations have to be added manually meaning that additional time is required. The company noted that to prepare an ingredient datasheet for a single product takes about half a day, although the exact amount of time will depend on how much information needs to be gathered. Based on an hourly personnel cost of €29.94 for a worker employed in office administrative/support activities (as previously estimated and based on Eurostat data²⁰⁷), the cost can be estimated at approximately €120 based on it taking around four hours to complete this task. This is broadly consistent with the results from the survey of SMEs. During the consultation, one large company noted that it would probably cost about €250 to compile an ingredient datasheet for a single product. The one-off costs of compiling an ingredient datasheet can therefore be seen as relatively small compared to the one-off costs of reformulation and labelling.

Across the industry, the total one-off cost of compiling ingredient datasheets can be estimated at €9.5 million to €25.8 million, based on the following assumptions:

- Firstly, that 63,000 to 103,000 detergent products required an ingredient data sheet (as previously assumed);
- That the average cost of producing a single ingredient datasheet was between €150 and €250.

8.1.2.7 Administrative costs of providing information to poison centres

A. One-off cost of providing ingredient datasheets to poison centres

Article 9(3)(2) of the Detergents Regulation gives MS the right to request that ingredient datasheets (as stipulated in Annex VII C) are made available to a specific public body (poison centre), to which the MS has assigned the task of providing this information to medical personnel; the idea being that medical professionals could obtain this information directly from a poison centre in the case of a medical emergency. This provision is applicable to all mixtures that fall within the scope of the Detergents Regulation, including consumer, industrial and institutional detergent products.

When CLP came into force in 2009, it introduced a formal requirement (Article 45) for EU countries to set up an appointed body (poison centre) for receiving data (from importers and downstream users placing mixtures on the EU market) on the composition of hazardous

²⁰⁷ Eurostat (sbs_na_sca_r2)

mixtures (including detergents). Commission Regulation (EU) 2017/542 amends CLP by adding an Annex that harmonises the information that must be provided to appointed bodies relating to emergency health response (commonly known as poison centers). To comply with this regulation, any company selling hazardous mixtures (i.e. mixtures classified as hazardous under CLP) to consumers in the EU will have to submit harmonized information electronically to the appointed bodies by 2020. Hazardous mixtures used in professional or industrial settings will need to comply by 2021 and 2024, respectively. Because most detergent products will be classified as hazardous mixtures under CLP, there are potential overlaps between Article 9(3)(2) of the Detergents Regulation and the recently added Annex VIII to CLP²⁰⁸.

During the consultation, several industry stakeholders noted that this overlap may give rise to some unnecessary administrative burden for the detergents industry. Indeed, one large company estimated that about 95% of all detergent products on the market would be classified as hazardous under CLP. This means that going forward (from 2020 onwards for consumer detergent products, 2021 for professional products and 2024 for industrial products) a large proportion of detergent products may be affected by this overlap and, if the Detergents Regulation is not amended/recast, an administrative burden may arise. However, it is worth noting that, by harmonising the rules for providing information to poison centres, the 2017 amendment to the CLP Regulation is anticipated to lead to significant cost savings for the industry (as cited in Recital 3 of Commission Regulation (EU) 542/2017).

The following table shows the submission fees that must be paid to poison centres in the EU/EEA. Data are not available for all countries. The highest fees appear to be in Belgium, where companies must pay €200.

<i>Submission fees payable to poison centres</i>	
Country	Submission fee
Austria	€0.00
Belgium	€200.00
Bulgaria	No information
Croatia	No information
Cyprus	€0.00
Czech Republic	No information
Denmark	€0.00
Estonia	€0.00
Finland	€38.00
France	€0.00
Germany	€0.00
Greece	No information
Ireland	Yes, there is a fee, but unspecified
Italy	No information
Latvia	No information
Lithuania	€0.00
Luxembourg	No information

²⁰⁸ Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response.

<i>Submission fees payable to poison centres</i>	
Country	Submission fee
Malta	No information
Netherlands	€0.00
Norway	€0.00
Poland	€0.00
Portugal	€0.00
Romania	€0.00
Slovakia	€0.00
Slovenia	Fee for written submissions; no fee for online submissions and amendments
Spain	€30.00
Sweden	€0.00
UK	€0.00

Source: Amec Foster Wheeler & Ricardo-AEA (2015): 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), Available at: <http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations>

The total one-off cost of providing ingredient datasheets to poison centres can be estimated at €11.3 million to €72.0 million, based on the following assumptions:

- Firstly, that there are 63,000 to 103,000 products that require an ingredient datasheet (as previously assumed);
- That one hour is required to provide an ingredient datasheet to a poison centre, at a cost of €29.94;
- That, on average, each detergent product is sold in five to ten different countries²⁰⁹, and that an ingredient datasheet must be provided to the national poison centre in each of the countries where products are sold;
- That 20% of products are sold in countries where a fee is payable to poison centres;
- That the average fee payable to poison centres per product (in countries where a fee is payable) is between €30 and €200.

B. On-going costs of providing ingredient datasheets to poison centres

The on-going costs of providing ingredient datasheets to poison centres can be estimated at €71.3 million to €453.8 million over the period 2004-2016, based on the following assumptions:

- Firstly, that it takes one hour (per product) to provide an ingredient datasheet to a poison centre, at a personnel cost of €29.94;
- That 50% of consumer detergents need new ingredient datasheets to be provided to poison centres every two years, and 50% need new ingredient datasheets to be provided every 5 years (as before);
- That 50% of industrial/institutional detergents need new ingredient datasheets to be provided to poison centres every year, and 50% need new ingredient datasheets to be provided every two and a half years (as before);

²⁰⁹ This assumption was verified by one large company which stated that while it sells products to a larger number of countries, an average figure of five to ten countries would seem reasonable overall.

- That each product is sold, on average, in five to ten different countries (as before);
- That 20% of products are sold in countries where a fee is payable to poison centres (as before);
- That the average fee per product in countries where a fee is payable to poison centres is €30 to €200 (as before).

8.1.2.8 *Administrative costs of providing information to medical personnel*

During the consultation, industry noted that it is a relatively infrequent occurrence for medical professionals to seek ingredient lists directly from manufacturers.

Assuming that it takes a manufacturer one hour to deal with a request for an ingredient datasheet, at an hourly cost to the company of €29.94 (as previously assumed), and that each of the 650 to 700 manufacturers in the EU and EEA receive on average three requests per year, the total annual cost to the detergents industry would be €58,400 to €62,900, or €0.70 million to €0.75 million in total over the period 2004-2016.

8.2 Other studies used for the purposes of the evaluation of the Detergents Regulation

8.2.1 Study on the regulatory fitness of chemicals legislation (excluding REACH), in particular the CLP Regulation and related legislation (1st FC Study)

8.2.1.1 *Methods and analytical models*

The first Fitness Check study ('1st FC study')²¹⁰ was conducted between July 2015 and December 2016 and published in January 2017. The study evaluated the CLP Regulation ((EC) No 1272/2008) and its interface with other related chemicals legislation in terms of effectiveness, efficiency, coherence, relevance and EU added value. Mapping was undertaken to establish the scope of relevant legislation followed by desk research and a suite of stakeholder consultation activities, which assisted in answering a range of evaluation questions. The evaluation considered the rules and processes for classifying the hazards of substances and mixtures, the methods of communication of the associated hazard information and the properties of concern that require consideration. It also considered linkages between the CLP Regulation and downstream legislation, with a focus on assessing risk management based on generic risk considerations (triggered automatically by a CLP classification).

As the different pieces of legislation within the scope of the Fitness Check only have high-level general objectives in common, for which few quantifiable indicators exist, and as there is no single baseline for a framework of +40 pieces of legislation implemented at different times with different scopes, it was clearly going to be challenging to try and assess the effectiveness and efficiency at the framework-wide level. Therefore, the study focused on the CLP Regulation and on specific issues at the interface between the CLP Regulation and downstream legislation. As a result, a number of different reference points and timeframes were used. For example, the reference point for assessing the costs of transition to the CLP Regulations was the previous Dangerous Substances and Dangerous Preparations Directives

²¹⁰ The evaluation report is available online <http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/>. Annex I-V is available here <http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/>. Annex VI is available here <http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/>.

(67/548/EEC and 1999/45/EC) over a time period of 2008-2015 whilst the assessment of on-going costs for meeting the requirements of the CLP Regulation were assessed in present time (2016) using a zero-counterfactual (i.e. a scenario of no regulation in place at the Member State level in the absence of EU legislation) as the point of reference. The (partial) assessment of human health and environmental benefits of the CLP Regulation also used a zero counterfactual and considered benefits generated under the previous DSD/DPD regime together with those generated after the implementation of the CLP Regulation thus covering a timeframe of 2000-2016.

The assessment of on-going cost reflects the cost implications of a situation where there are no other regulatory requirements on manufacturers and importers of hazardous substances and mixtures (i.e. a 'zero counterfactual'). The reality is that, had the DSD, DPD and subsequently the CLP Regulation not been introduced to provide overarching requirements, some/all Member States are likely to have introduced their own requirements under national legislation. Some or all might have been similar in emphasis and requirements to the CLP Regulation, while others might have varied significantly. Clearly there is no definitive way of knowing either way; hence, there is no means of identifying whether costs would have been higher or lower than those presented in the study assessment. Thus, when considering the individual cost components presented below from the perspective of the burden on industry, it should be borne in mind that similar costs might have been incurred under an alternative non-EU regulatory reality, with this also being the case for health and environmental benefits.

The study was organised into four tasks:

1. Evaluating the implementation of the CLP Regulation,
2. Evaluating the horizontal links between EU legislation on hazard identification and communication,
3. Evaluating the vertical links between the CLP Regulation and relevant EU and national downstream legislation identifying risk management measures based on hazard classification, and
4. Supporting the Commission in organising a public consultation, SME panel and workshop. A number of industry sector and stakeholder specific surveys and workshops were also organised (see Annex 2 Synopsis Report to the Commission's Staff Working Document on the Fitness Check of the most relevant chemicals legislation (excluding REACH) as well as related aspect of legislation applied to downstream industries). In line with the Fitness Check roadmap, when analysing risk management measures under Task 3, the study distinguished risk management based on generic risk considerations (i.e. risk management measures automatically triggered by a hazard classification under CLP, without further assessment of the risk) and risk management based on specific risk assessment (i.e. risk management measures following an assessment of both the hazards and specific exposure).

The evaluation methodology was developed around the needs of these four tasks. The work included a literature review to obtain key information from impact assessments, position papers, academic and scientific research etc.; legal mapping to identify relevant legislation and specific provisions within this; consultation activities including the Public Consultation, a Stakeholder Workshop, an SME Panel, consultation as part of case study work as well as targeted consultation (including surveys) of key stakeholder groups; and case study research involving a more in-depth examination of some of the more pertinent issues identified as part of initial research (see [Table 6](#) below). Importantly, the aim of the case studies was not to reconsider specific decisions that have already been taken; instead, it was to examine the

mechanisms and procedures of the CLP Regulation and to assess whether the current linkages are appropriate (which may necessitate examining some of the impacts of past decisions). The study assessed the costs of transition to the CLP Regulation from the two Directives that it replaced (the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD)) in 2008 as well as the on-going regulatory costs faced by industry and by EU and Member State authorities. This included consideration of the cost impacts ('transition costs') of moving from a Directive based system to a Regulation, any national differences in implementation of the CLP Regulation, and the costs (and benefits) of the harmonisation of information requirements across the national Poison Centres. It also examined the impacts from different provisions, for example, CLP packaging requirements (in particular child resistant closures and tactile warning devices), labelling requirements, obligations placed on regulators and authorities, etc. The work drew on the Fitness Check cumulative costs (CCA1) and the cumulative benefits (CuBA) studies, as well as the 2006 Impact Assessment for the implementation of CLP.

With respect to calculating the costs of transition to CLP, the approach followed the cost assessment model set out in the Better Regulations Toolbox, as illustrated in below. The cost types outlined in this diagram are described in further detail as follows:

- **Direct Costs:** Within this category are two sub-categories of costs: direct compliance costs and hassle costs. The first of these consists of regulatory charges which include fees, levies and taxes; substantive compliance costs which entail the costs of investing in human and physical capital, as well as other expenses incurred in complying with legal requirements introduced by new legislation; and, administrative burdens which encompass the costs borne in performing administrative activities for complying with the information obligations set out under the legislation. Hassle costs include the costs associated with corruption, annoyance and waiting times. Note that direct compliance costs can be further categorised as CAPEX where they relate to capital expenditure, OPEX where they are annual operating costs and administrative costs where they relate to reporting obligations. This study also categorised regulatory charges under the monetary obligations category.
 - **Indirect Costs:** Indirect costs are those incurred in the sector targeted by the legislative measures, which are not directly related to the measure, or by other sectors or stakeholders which are not directly targeted by the legislative measure (i.e. downstream sectors). These indirect costs can be transmitted through price increases or changes in the supply of certain goods and services to the market. In some cases, this can have a multiplier effect (for example if a substance is withdrawn when the impact downstream was actually higher than the cost of keeping it on the market). For the purposes of this study, our attention will be focused on the indirect costs relating to re-formulating products or removing certain product lines from the market due to the changes induced by the CLP Regulation.
- Enforcement Costs:** Enforcement costs are those incurred by Member States, public bodies and the European Commission through activities relating to the implementation of legislative measures. Costs can be categorised under the following: monitoring; enforcement; adjudication.

Table 6 Case study research undertaken for the purposes of the Fitness Check

Case study	Case study title	Case study description
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1	Impacts of differences in the uptake of UN GHS building blocks for costs, competitiveness health and the environment	Different countries have adopted different building blocks both in terms of hazards covered and sectors covered. Consideration will be given to differences in the potential costs and benefits for chemical suppliers, as well as for consumers (public health) and the environment. The focus is on building blocks within the GHS which have (not) been implemented in the EU and North American countries and any differences in costs and benefits arising as a result.
2	Suitability of the CLP Regulation classification criteria for metals	It may be the case that there is a gap in the legislation as the CLP contains no criteria for the classification of metal alloys, with this potentially impacting on their treatment under other horizontal legislation, e.g. REACH, waste legislation, etc. The case study would identify problems arising from this gap. It could also consider the extent to which default classification rules under the CLP regulation may trigger under/over classification of metals more generally.
3	Lack of consistency in parallel hazard assessments under different legislation	Different bodies are responsible for the hazard assessment and classification of a substance/mixture under the CLP, Biocides and PPP. This case study would focus on the coherence of the parallel procedures under these three Regulations and, time permitting, also take into account other legislation such as the CAD (depending on the scope of other case studies and hence resources available).
4	Relevance and coherence as regards the introduction of new test methods and GLP within chemicals legislation	The classification criteria under the CLP for some hazards are linked to the outputs from existing animal test methods, with these used to fulfil REACH information requirements. This case study would examine the relevance of the CLP classification criteria in terms of their ability to respond to changes in scientific methods, and the horizontal coherence of these also taking into account prohibitions on animal testing under the Cosmetics Regulation.
5	Coherence of classifications, definitions and the labelling requirements for detergents	This case study will explore whether there are any negative impacts on industry and on the single market as a result of a lack of coherence in the definitions of 'placing on the market' and 'manufacturer' between the CLP Regulation and Detergents legislation. It will also examine requirements under the Cosmetics and the Biocidal Products Regulation.
6	Inconsistencies in assessment procedures for PBT and vPvB as properties of concern	The CLP Regulation does not include classification and labelling requirements based on PBT and vPvB properties. This case study looks at whether there are inconsistencies or overlaps in the identification or risk management of PBTs, what types of risk management measures are triggered by PBTs, what issues arise in relation to the coherence of risk management, whether the current processes are effective and views on integration of PBT/vPvB into CLP.
7	SME awareness of ATPs and changes in classification and of labelling and packaging requirements	This case study focus on the awareness of SMEs of the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur every two years. It will also look at issues regarding SME understanding of packaging requirements under CLP and international transport legislation.
8	Awareness of Chemical Safety Assessment and labelling requirements for Toys	The TSD lays down toy safety rules which include requirements for Chemical Safety Assessments, compliance with specific chemical requirements laid down in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.), and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. This case study would examine SMEs awareness of this range of obligations. The case study will examine the awareness of SMEs in of labelling requirements, including traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for

Case study	Case study title	Case study description
		use, precautions and warnings.
9	Consumers comprehension of and relevance of safety information on product labels	The focus of this case study will be on the hazard pictograms that the CLP introduced when implementing the GHS. Research suggests that comprehension of the various pictograms amongst EU citizens is variable; findings indicate that a low percentage of citizens may understand all of the hazard pictograms or equally understand only a few of the pictograms. Some EU legislation uses different safety phrases and does not rely on the pictograms. Similarly, where the GHS building block for consumer products has not been implemented (e.g. North America) different communication tools may be used
10	Linkages with Occupational Health and Safety Legislation	The case study is looking at whether there are overlaps and inconsistencies between CLP and OSH legislation: <ul style="list-style-type: none"> • If there are inconsistencies or overlaps what causes these? • What are the implications of these? • Do the inconsistencies give rise to incoherence? • Are there measures that could be taken to address them? Formaldehyde will be used as a case study substance to illustrate some of the issues.
11	Risk management procedures triggered by harmonised classifications under the CLP Regulation	This is an overarching case study involving a comparative assessment of the procedures triggered by a CMR or other health classification (e.g. sensitiser). It will cover REACH, PPPR, BPR, cosmetics, toys, food contact materials and CMD. This case study will also consider selected substances, such as lead, TCEP, gallium arsenide, etc. This case study will also include a comparison between RMM based on generic risk considerations and specific risk assessment.
12	Use of CLP classifications for waste management	There appears to be national, regional and local authorities using CLP classification criteria and packaging requirements as the basis for the sorting and recycling of domestic wastes. These are unintended uses of the packaging and labelling aspects of the CLP Regulation and may be leading to a lack of coherence and impact on achievement of other EU objectives related to recycling and the circular economy. In addition, inconsistencies have been identified with regard to the linkages between CLP and the Waste Directive, in particular in relation classification for toxic to the aquatic environment and bioavailability. This case study will examine the consequences of both of national implementation of waste legislation, as well as what the constraints are to recycling if a waste is classed as hazardous and whether a logic can be developed with regard to bioavailability considerations.
13	Linkages between the CLP and Seveso III Directive, including risk management under Seveso III	Seveso III aligns, amongst others, requirements for establishments using or storing hazardous chemicals with the CLP Regulation. Due to the alignment some establishments may change tier or fall out of scope all together because for some hazard classifications the criteria in DSD are CLP are not identical. The case study will review the procedures for risk management under Seveso as a potential example of best practice, and the procedures for excluding substances from the scope of the Directive and whether the linkages between CLP and Seveso III are efficient and effective.

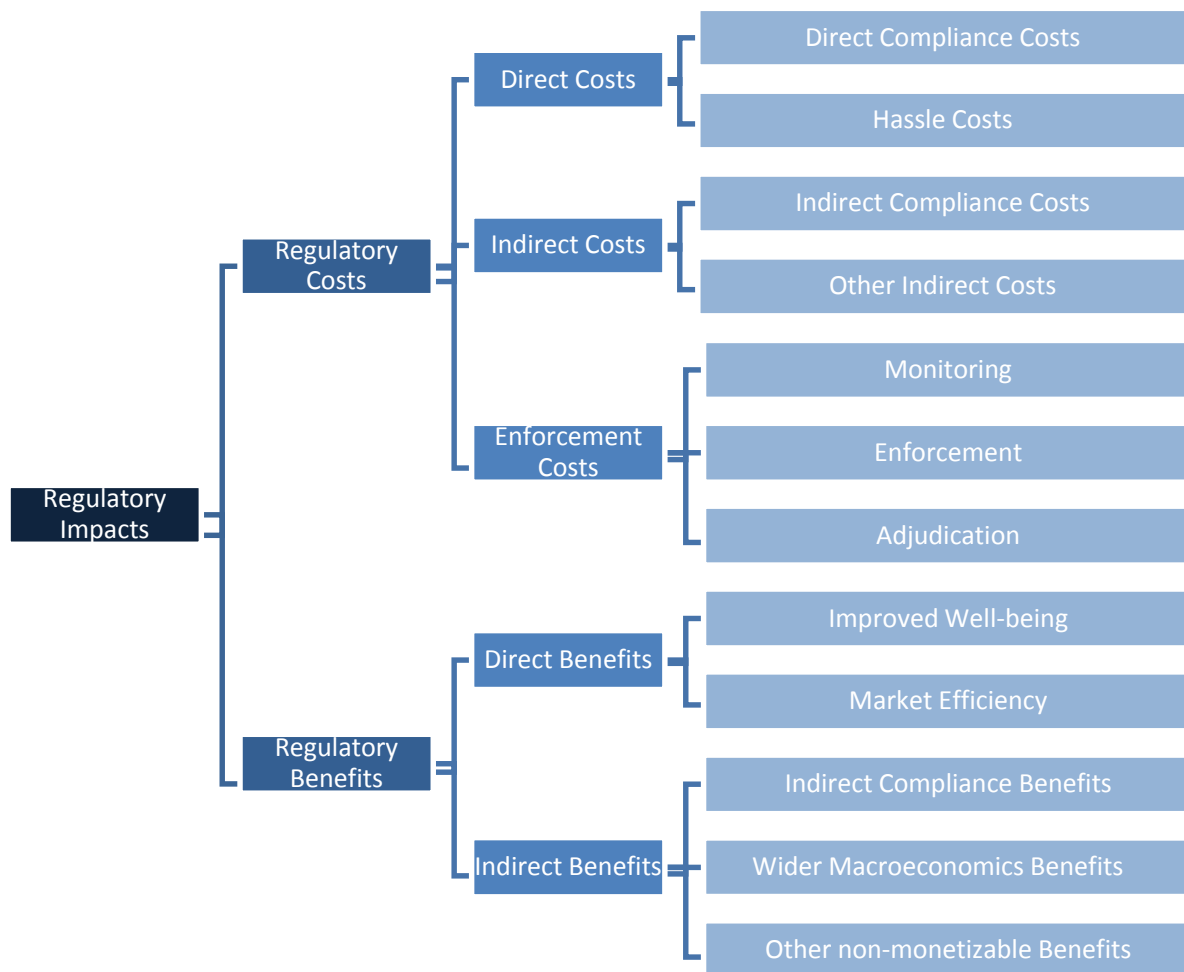


Figure 9 Regulatory Impacts

In line with the approach to calculating the transition costs of CLP, the study employed the methodology set out in the Better Regulation Toolbox which categorizes costs under the types listed in Table 7 below. The cost elements which make up our model for ongoing costs are listed under each relevant cost type.

Type of Cost	Cost elements for which estimates have been generated
Direct Costs	
Regulatory Charges	Fees or penalties paid in complying with regulation
Substantive Compliance Charges	Costs of updating IT systems Costs of training staff to understand updates in requirements of CLP Costs of employing FTEs for compliance activities Costs of Child Resistant Closures and Tactile Warning Devices
Administrative Burdens	See Chapter 8
Hassle Costs	Costs of checking CLI
Indirect Costs	
Indirect compliance Cost	Opportunity cost of removing a product line from the market

Table 7 Data collected for each cost type for ongoing costs

The Standard Administrative Costs Model acted as the basis for estimating administrative costs to industry, and complementary approaches were adopted for the estimation of compliance costs. Where appropriate, separate consideration was given to SMEs compared to larger companies. In this respect, efforts were made to ensure SME views were represented, for example, through use of the Commission's SME Panel, discussions with national associations, and separate analysis of cost information provided by SMEs where relevant.

All assumptions in this respect are made clear in the more detailed study Task reports (see the 1st FC study, Annex II: Evaluating the implementation of the CLP regulation pp55-125). In addition to developing its own estimations, the study used figures from other sources, in particular in relation to costs and benefits of measures under downstream legislation with vertical linkages to CLP for risk management purposes.

The final report²¹¹, its annexes²¹² and case studies²¹³ are available online.

8.2.1.2 Evidence base and limitations

As with any study of this scale, numerous challenges were encountered in gathering the data needed to provide a robust evidence base, as well as in providing quantitative estimates of impacts. Although extensive efforts were made to overcome the challenges and to ensure that accurate and reliable information acted as the basis for the evaluation, many remained and some could not be overcome. There are therefore limitations that ultimately impact on the study conclusions. These include limitations stemming from the following (with further details provided in Annex I of the 1st Study Report):

- The broad scope of the study and the number of pieces of legislation to be considered.
- The lack of available information on the scale of some of issues identified (both positive and negative) and the subsequent need to rely on information provided by stakeholders.
- The limited response received from civil society stakeholders. However, further desk-based research of published information from NGOs was undertaken to inform the study.
- The limited data available to assist in determining the effectiveness and efficiency of the legislative framework (particularly in quantitative terms).

²¹¹ <http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/>

²¹² <http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/>

²¹³ <http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/>

- The inability or unwillingness of companies to provide certain data creating difficulties in quantifying some aspects of the impacts (e.g. costs and benefits) of the CLP Regulation and other legislation.
- The lack of up-to-date information regarding the effect of the CLP Regulation on consumer behaviour.

8.2.2 Cumulative Cost Assessment for the EU Chemical Industry (the CCA1 Study)

8.2.2.1 *Methods and analytical models*

In 2014, the Commission launched a study analysing cumulative costs of the most relevant EU legislation for the EU chemical industry during the period 2004-2014. The EU legislation subject to analysis includes chemicals legislation, energy, emissions and industrial processes, workers' safety and health and product-specific legislation. The study objectives were to:

- provide for quantification of the cumulative costs related to those packages of EU legislation with the highest cost impact, and quantify the cumulative costs in the subsectors of the chemical industry;
- demonstrate how the costs have changed over time; and
- compare the costs with relevant financial indicators for the chemical industry.

The study was completed in July 2016. The CCA1 study conclusions are available online²¹⁴.

The study covered the whole chemical sector, although cost is assessed only for the subsectors for which the available data are sufficient to produce reliable estimations. These are, according to the statistical classification of economic activities in the European Community (NACE): 20.13 — inorganic basic chemicals; 20.14 — organic basic chemicals; 20.16 — plastics in primary forms; 20.20 — pesticides and agrochemical products; 20.41 — soaps and detergents, and cleaning and polishing preparations; 20.30 — paints, varnishes and similar coatings and 20.59 — other chemicals products.

Among the pieces of legislation affecting the EU chemicals industry, only those incurring high cost directly to chemical companies were included. Legislation that affects upstream non-chemical companies, which then pass on costs to the chemicals industry through the prices of inputs, was not within the scope of the study. Similarly, indirect costs — such as opportunity cost due to forgone business or transaction cost and costs related to national legislation exceeding EU requirements — were not taken into account.

As opposed to other methods assessing the costs of policies, the CCA1 Study provides a quantitative assessment of all costs (monetary obligations, capital expenditure, operating expenses and administrative burden) incurred by EU chemical companies with regards to the EU legislation most relevant to them. The study did not assess the benefits of EU legislation and did not aim to provide insights related to the proportionality of costs and benefits of legislation, nor its efficiency or effectiveness. The main steps for implementing the cumulative cost assessment and the methodology for estimating legislation costs are summarised in Figure 10 and Figure 11 respectively.

Furthermore, a cumulative approach is to be distinguished from a non-cumulative approach as traditionally used in a cost-benefit analysis (CBA). The standard cost-benefit approach examines the incremental costs and benefits related to policy proposals against a baseline.

²¹⁴ <http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/>

This implies that a CBA focuses on the net change in costs and benefits, relevant to a specific policy decision, not the aggregate (or cumulative) level of regulatory costs and benefits (European Commission, 2015). On the other hand, the cumulative cost assessment (CCA) focuses on the whole sector, rather than on a particular policy proposal or legislation, and aggregates the costs generated by all relevant existing EU legislation. Hence, this cumulative cost assessment did not focus on a policy field and did not aim at assessing whether the regulatory framework is fit for purpose in a policy field, which is an approach used when conducting fitness checks.

While there is no recognised standard methodology for the assessment of cumulative impacts, the methodology of this study drew on previous similar cumulative cost assessment exercises performed by Member States and the European Commission. For the overall CCA approach the previous studies on the aluminium and steel industries have been consulted. In particular, for the estimation of the various types of costs, CCA studies are based on established methodologies that have been used for several years by Member States and the European Commission, including the Standard Cost Model, or the Cost-driven Approach to Regulatory burden (CAR) developed for the Dutch Government. The Standard Cost Model methodology (SCM) is used by several Member States (Network Standard Cost Model, 2005), as well as the European Commission, as part of its REFIT programme and the “Better Regulation Toolbox” (European Commission, 2015). The CAR methodology, used by the Dutch government (SIRA, 2015), is similar to the SCM, yet its scope is broader regarding the types of cost covered and gives more emphasis to linking legislation cost with the cost structure of companies.

Methodologies to measure legislation burden follow the principle, summarised by the European Commission in its presentation of the SCM: “the purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in different regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates” (European Commission, n.d.)

To facilitate the collection of data and the estimation of costs, the pieces of legislation were grouped into seven packages on the basis of their overarching and specific policy objectives as follows: chemicals, energy, emissions and industrial processes, workers’ safety, product-specific, customs and trade, and transport legislation.

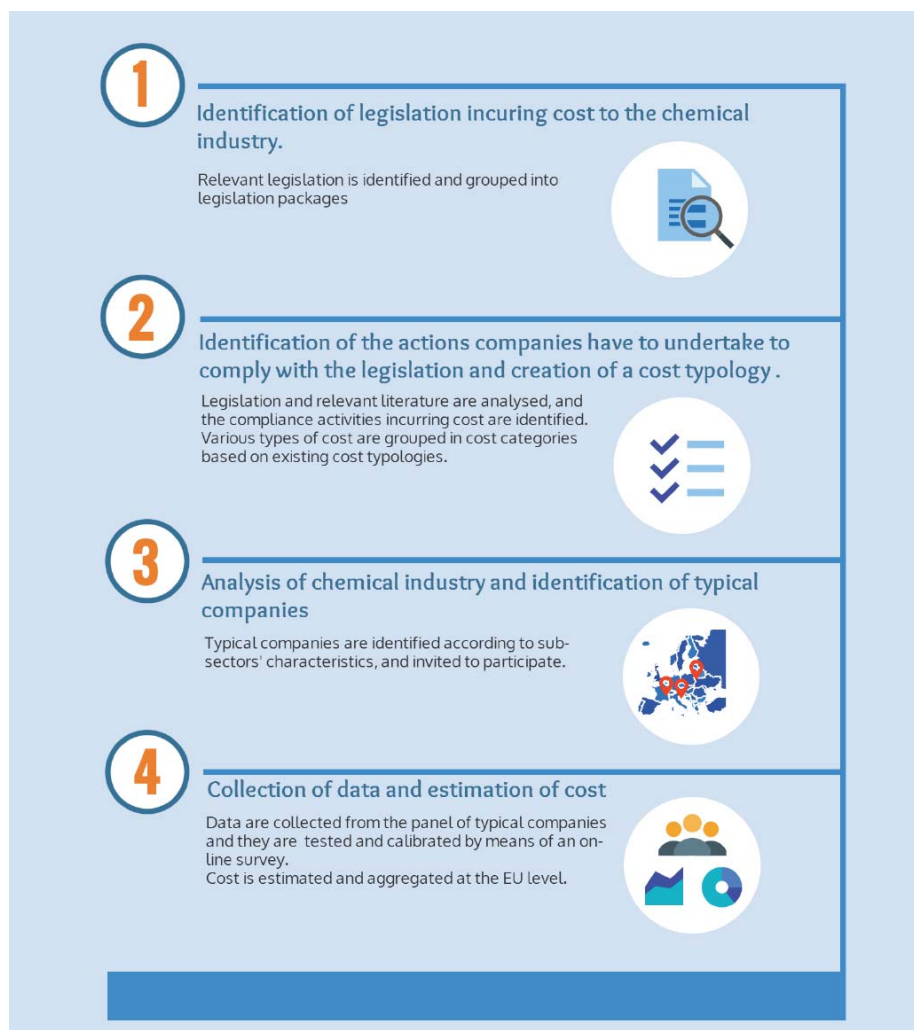


Figure 10 Steps for implementing the cumulated cost assessment

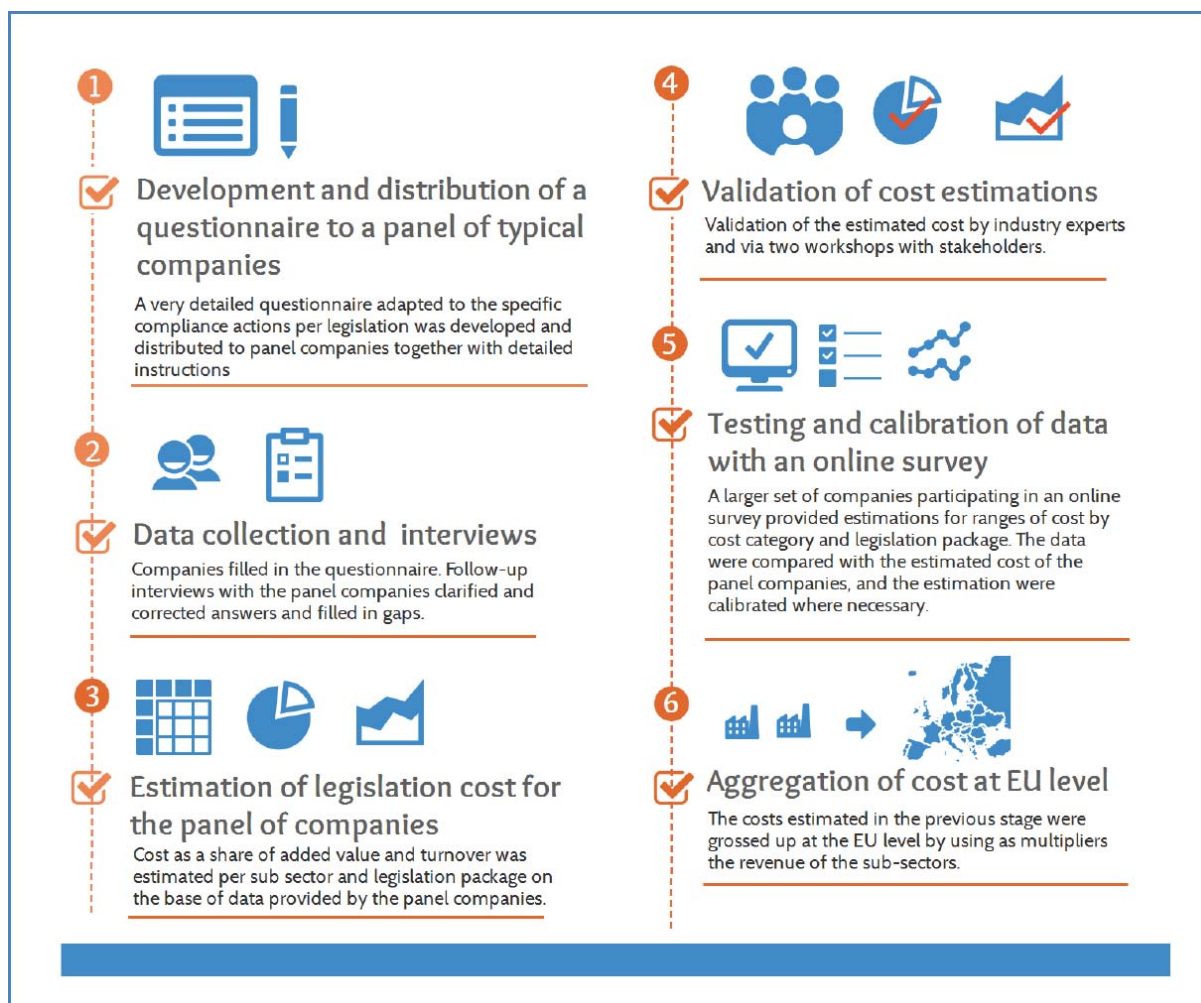


Figure 11 Methodology for estimating legislation cost

To facilitate the collection of data and the estimation of cost, the pieces of legislation have been grouped into seven packages based on their overarching and specific policy objectives. In some packages, pieces of legislation were further grouped into sub-categories based on the similarity of their cost generation mechanism. Framework legislation (e.g. the Waste or Air Quality Framework Directive) and their “daughter” legislation are presented together, as the former sets the general principles while the latter sets the implementation measures and therefore costs. The results of this grouping, indicating the relevance of packages to specific subsectors, are shown in Table 8 below.

National legislation that is not related to EU legislation is excluded from the study. Companies participating in the panel and the online survey were therefore asked to report only the costs associated with the requirements set out in the EU legislation. However, in the case of energy taxes a distinction between the costs generated by the EU policy and those by the national legislation was not possible. Therefore, the estimated cost in this case includes also the effects of national legislation.

In addition, to the selected subsectors, a rough picture of legislation’s effects on the wholesale costs of chemical products (NACE 46.75) is presented, based on information collected during the study.

Sub-sectors	Packages						
	Chemicals	Energy	Emissions & ind. proces.	Worker safety	Product specific	Customs Trade	Transport
Industrial gases	●	●	●	●			●
Dyes and pigments	●						
Inorganic basic chemicals	●	●	●	●		●	●
Organic basic chemicals	●	●	●	●	●	●	●
Fertilisers and nitrogen		●	●	●	●		●
Plastics in primary forms	●	●	●		●		
Rubber in primary forms	●		●	●	●		
Pesticides and agrochem.	●		●	●		●	●
Paints, coatings	●		●	●	●		
Soap and detergents	●		●	●	●		●
Perfumes and toilet	●				●		
Explosives				●	●		
Glues	●						
Essential oils	●				●		
Other chemicals	●	●	●	●			
Man-made fibres	●		●	●			

Subsectors not included in cost estimation
Subsectors included in the cost estimation

Table 8 Legislation packages per subsector

8.2.2.2 Evidence base and limitations

Data collection in the CCA1 study did not rely on statistical methods. Detailed data were collected from a panel of 31 typical companies, which were selected according to a set of criteria. The estimated costs for this panel of companies were validated in two workshops with industry experts and stakeholders. Then the data were adjusted based on the results from an online survey that addressed a larger sample of 90 companies. The results from the online survey appeared to be in line with the cost figures provided by the panel companies, supporting the premise that the initial panel consisted of typical firms. Finally, the data were grossed up to represent the whole population of each subsector by multiplying the turnover of each subsector by the adjusted cost per turnover of the typical companies of the sub sector. The grossing up by using multipliers that represent the whole population of a particular group relies on the hypothesis of full compliance, which however is not always the case. Therefore, in certain cases, it could lead to an overestimation of absolute values by assuming that all companies fully comply with the legislation.

Despite its significant advantages regarding feasibility, the method is less accurate when compared to statistical methods, and it can only provide an estimate of the order of magnitude of cost borne by companies due to EU legislation. Furthermore, the cost estimates derived in the CCA1 study cannot be considered as an entirely accurate estimate of the cost of the EU chemicals *acquis* due differences of scope between the study and Fitness Check and certain limitations with the methodology applied:

- The period covered (2004-2014) corresponds only partly to the one covered by this Fitness Check.

- Costs correspond to only six subsectors (organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) and not all the industry and companies.
- Costs presented above also include regulatory costs for several pieces of legislation that are not in the scope of the Fitness Check (REACH, Sustainable Use of Pesticides Directive, Large Combustion Plant Directive, EU Emissions Trading System (ETS) Directive, National Emissions Ceilings (NEC) Directive, Air Quality framework Directive and related, OSH Framework Directive, Directive on Personal Protective Equipment, Construction Products Regulation, Paints Directive, Tyre Labelling Regulation, Drug Precursors Regulation). In addition, several other pieces of legislation although within the scope of the Fitness Check, were not covered by the abovementioned cumulative cost assessment attempt.
- While the OSH Framework Directive, *per se*, is not in the scope of the Fitness Check, it can be reasonably assumed that the costs related to occupational health and safety legislation in the chemicals sector derive primarily from the daughter regulations (the Chemical Agents Directive, the Carcinogens and Mutagens Directive, etc.) which are within the scope of the Fitness Check. That said, it should also be noted that the estimated occupational health and safety costs probably include costs of worker safety protection beyond specific risks posed by exposure to hazardous chemicals (e.g. falls from heights, electrocution, burns, etc.) which are substantive but are not within the scope of the Fitness Check.
- Regarding the emissions and industrial processes legislative package, it should be noted that the ETS related legislation is not in the scope of the Fitness Check. In this legislative package, most of the monetary obligations are due to ETS. Therefore, the regulatory costs of emissions and industrial processes legislative package as assessed for the purposes of the Fitness Check can be estimated to represent EUR 2.6 billion (instead of EUR 3.1 billion).

9 Annex 4 Enforcement of the Detergents Regulation

9.1 Sanctions

A variety of sanctions have been implemented in different EU Member States, as elaborated in Table 9 below. The sanctions range from administrative options (such as verbal or written advice) to more stringent penalties such as fines, bans (e.g. forcing products to be withdrawn from the market), and in some cases, imprisonment. The following paragraphs describe the sanctions available in some of the MS. Unless otherwise indicated, the information presented below is drawn from consultation.

Table 9 Sanctions available in the MS

Austria

The Austrian Chemicals Act lays down provisions for fines as well as for product withdrawals and bans.

Denmark

As supervising authority, the Chemical Inspection Service must cause an illegal act to be made legal, unless the illegal act is considered to be of minor importance, cf. section 48 in the Danish Chemicals Act. There are various administrative options available to the supervising authorities in case of violations: enjoining of the rules, imposing a sales ban or enforcement notices on e.g. withdrawal of illegal products from the market or disposal of the products. The punishment may increase to imprisonment up to 2 years, in case the violation is committed intentionally or in the case of gross negligence and if the violation has inflicted injury on humans, animals or the environment or if financial gain or cost savings have been obtained. Still, it will depend upon a specific assessment from case to case whether administrative sanctions are sufficient or if it is necessary to report the company to the police.

Finland

According to the national Chemicals Act, if the operator does not comply with the provisions of the Detergents Regulation (or other chemicals legislation of the European Union), the national enforcement authority may ban the operator from continuing operations or repeating procedures in violation of the provisions or it may order the operator to otherwise fulfil the obligations laid down by law. The Finnish Safety and Chemicals Agency may issue orders concerning a chemical with respect to banning them from being placed on the market or from being made available on the market, the return procedure or notification of the hazard inflicted, or it may order that the chemical be made harmless by taking appropriate measures. Fines and other criminal sanctions may only be issued by the court after taking the case to court by the prosecutor after a police investigation.

Ireland

Table 9 Sanctions available in the MS

The Detergents Regulation is enforced under the Chemicals Act of 2008 as amended in 2010 which gives effect to Detergents and other EU chemicals legislation. This Act nominates the relevant competent authorities, provides for powers of inspectors, enforcement tools, and other legal provisions, as well as a number of administrative provisions.

Sanctions available to enforcement authorities range from verbal or written advice, to enforcement notices (contravention and prohibition), to criminal prosecution as provided for in The Chemicals Act 2008. Part 4 of the Chemicals Act 2008 outlines the sanctions that can be used. It states, for example:

- Appointment of inspectors with extensive powers that include the power to enter, inspect, examine and search any place to which the inspector has reasonable grounds for believing that the relevant chemicals statutory provisions apply; the power to remove and detain records; and the power to require the removal from the market of a chemical by the person who has placed that chemical on the market, where it appears to the inspector that, in relation to that chemical, the relevant chemicals statutory provisions have been contravened.
- An inspector may direct the person in control of an activity to submit an improvement plan in situations where the inspector considers that an activity is occurring or is likely to occur that involves or is likely to involve a risk to human health and the environment. The inspector confirms whether he or she is satisfied that the plan is adequate or may direct that the plan be revised and re-submitted.
- An inspector has the power to issue a contravention notice on the person who has control of the activity concerned. This arises where an inspector is of the opinion that the person has contravened any of the provisions of the relevant chemicals statutory provisions, or has failed to comply with a direction from the inspector to submit an improvement plan or a revised improvement plan or has failed to implement the plan or revised plan. The inspector may direct the person to remedy the contravention or remove a chemical from the market, among others.
- An inspector has the power to issue a prohibition notice which prohibits the carrying on of an activity until the matters that give rise to a serious risk to health or the environment identified by the inspector are remedied. Where a prohibition notice is contravened, the inspector may apply to the High Court for an order prohibiting the continued contravention of the notice.
- A national authority can apply to the High Court for an order restricting or prohibiting an activity which involves or is likely to involve a contravention of the relevant chemicals statutory provisions and a serious risk to health or to the environment.

Table 9 Sanctions available in the MS

The Chemicals Act 2008 (as amended) allows for the issuing of fines on summary conviction of up to €5,000 and/or imprisonment for up to 12 months and for conviction on indictment up to €3,000,000 and/or imprisonment for up to 24 months for contraventions of the relevant legislation, including requirements of Article 4 of Regulation (EC) 648/2004. Additionally, inspectors who have reasonable grounds for believing a person has committed an offence, including one relating to Article 4 of Regulation (EC) 648/2004, and is liable to summary prosecution, may serve the person with a fine, referred to as a “fixed payment notice”, for an amount up to €2,000. A person on whom such a fine is served is not obliged to pay the fine and can contest the notice in the courts. Additionally, the legislation allows for directions to be made to economic operators who have placed non-compliant detergents on the market for the withdrawal of those materials from the market and their appropriate management at the expense of the operator.

Latvia

Administrative penalties are provided in the case of violation of the Detergents Regulation. Products that do not comply with the requirements of the Regulation can be temporarily banned or be withdrawn from the market until they are brought into conformity. An administrative act is issued on administrative penalties.

Slovakia

If deficiencies are identified, companies can be called upon to remove these deficiencies on a voluntary basis. If the controlled products could harm human health or the environment, the Slovak Trade Inspection can impose a ban on the sale of such products. Companies that repeatedly violate the terms of placing detergents on the market or that fail to comply with the measures taken to remedy the identified deficiency, can be fined in administrative proceedings.

Sweden

The most stringent sanction available is a ban, but fines also exist.

United Kingdom

Under the Detergents Regulations 2010, enforcement officers from the constituent councils in the UK can issue enforcement notices if there is a breach of the Detergents Regulation, setting out the action that needs to be taken and the time period in which the problem should be rectified.²¹⁵ Due to the potential environmental or public health consequences that could result from a breach of the Detergents Regulation, criminal sanctions are also available under the Detergents Regulations 2010. The most serious offences will be triable

²¹⁵ HSE (no date): Detergents Guidance Document, available at: <http://www.hse.gov.uk/detergents/detergents-guidance-document.htm>

Table 9 Sanctions available in the MS

either way and punishable by up to two years imprisonment and/or an unlimited fine.

Norway

Sanctions laid down in national legislation include the possibility to give verbal and written advice, administrative orders, impose coercive fines and product withdrawals.

9.2 Enforcement of the Detergents Regulation

During the consultation, market surveillance authorities confirmed that, in most cases, inspections on detergents tend not to be carried out for the Detergents Regulation in isolation, rather they are coordinated with inspections for other chemicals legislation, such as CLP and REACH.

Only two countries reported data separately in relation to the Detergents Regulation as part of official MS reporting on market surveillance activities in the chemicals sector. Table 10 below presents information on market surveillance activities related to the Regulation in Estonia, while Table 11 provides data on market surveillance activities carried out in Greece. It should be recognised that both countries are relatively small players in the market for detergents and cannot, therefore, be taken as representative of the sector overall; for example, Estonia has less than 1% of the total enterprises in the sector (defined as NACE Code 2041), while Greece has less than 5%. Together, these two countries account for less than 2% of all detergents (by value) produced in the EU.

In addition to Greece and Estonia, the following countries provided data for the purposes of this evaluation, and are reported on below: Ireland, Romania, Austria, Latvia, Denmark, Slovakia, Finland and Norway. Again, these countries account for a relatively small share of the overall detergents market.

9.2.1.1 Enforcement in Estonia

As shown in Table 10 below, there were 264 inspections carried out in Estonia in 2013 in relation to the Detergents Regulation, with 510 products inspected overall. Out of these, 167 products (about a third of the total inspected) were found to be non-compliant. The table shows that 28 memos were issued as a result. No fines were imposed, and no products were withdrawn from the market.

Table 10: Market surveillance activities in Estonia related to the Detergents Regulation

	2010	2011	2012	2013
Total number of inspections	173	178	145	264
Total number of products inspected	364	527	365	510
Number of products tested	0	0	2	15
Number of non-compliant products	194	162	53	167
Number of products presenting a serious risk	0	0	0	0
Number of memos	81	44	14	28
Number of orders	12	0	0	0
Number of penalty payments and total amount	0	0	0	0
Number of substitutive enforcements	0	0	0	0
Number of misdemeanour procedures	0	0	0	0
Fines imposed as part of a misdemeanour procedure	0	0	0	0
Total number of products withdrawn from the market	0	0	0	0
Number of products recalled from consumers	0	0	0	0

Number of voluntary measures taken by economic operators	0	0	0	0
<i>Source: European Commission (2015): Sector 22 Chemicals (Detergents, Paints, Persistent organic pollutants), Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008. Available at: http://ec.europa.eu/DocsRoom/documents/13923/attachments/1/translations</i>				

9.2.1.2 Enforcement in Greece

Table 11 shows that in 2013, there were 65 inspectors employed full-time and available to market surveillance authorities in Greece for the purposes of enforcing the Regulation. During the consultation, the Greek competent authority (the General Chemical State Laboratory) reported that there are now only 40 inspectors (public employees) available to the market surveillance authorities in Greece.

As shown in Table 11 below, in 2013, 375 inspections were carried out in Greece in relation to the Detergents Regulation. In total, 78 instances of non-compliance were found, which resulted in 73 restrictive measures being taken by the market surveillance authorities and 32 sanctions/penalties being issued. During the consultation, the General Chemical State Laboratory stated that in 2016, it carried out 147 inspections and checked the compliance of 576 products.

Table 11: Market surveillance activities in Greece related to the Detergents Regulation				
	2010	2011	2012	2013
Total number of inspections	272	438	341	375
Number of inspections based on:				
- tests performed in laboratories	132	220	200	208
- physical checks of products	803	782	583	587
Number of inspections resulting in:				
- finding of non-compliance	36	107	39	78
- restrictive measures taken by market surveillance authorities	23	63	67	73
- application of sanctions/penalties	11	19	30	32
Number of inspectors available to market surveillance authorities (full-time equivalent units)	65	65	65	65
<i>Source: European Commission (2015): Sector 22 Chemicals (Detergents, Paints, Persistent organic pollutants), Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008, available at http://ec.europa.eu/DocsRoom/documents/13923/attachments/1/translations</i>				

9.2.1.3 Enforcement in Ireland

In Ireland, detergent products may be inspected during REACH and CLP inspections. Table 12 below provides data from the Irish Health and Safety Authority on the number of inspections carried out in the last few years in Ireland, where detergent products were the focus of inspection activities. Note that, in Ireland, the Health and Safety Authority is responsible for monitoring compliance with the health and safety provisions of the Detergents Regulation (e.g. provisions pertaining to the provision of information), while the Irish Environmental Protection Agency is responsible for monitoring compliance with the biodegradation requirements.

Table 12: Market surveillance activities in Ireland - detergents					
	2012	2013	2014	2015	2016
Total number of inspections	26	19	36	22	71
<i>Source: Irish Health and Safety Authority, pers. comm. (2017)</i>					

During the consultation, it was indicated that there are generally no resources (financial or labour) available to the Environmental Protection Agency of Ireland exclusively dedicated to surveillance activities relating to requirements under Article 4 of the Detergents Regulation (which covers limitations based on the biodegradability of surfactants). As a result, the resources available are not considered adequate for the effective enforcement of requirements stipulated under Article 4 of Regulation (EC) 648/2004.

9.2.1.4 Enforcement in Romania

Table 13 below shows data provided by the National Authority for Consumer Protection of Romania on enforcement activities related to detergent products in Romania. The data cover inspections related solely to the Detergents Regulation and show that the number of proactive inspections has increased over the last few years.

	2014	2015	2016	2017 (to 22/06/2017)
Number of proactive inspections	59	139	147	63
Number of reactive inspections	12	25	16	5

Source: National Authority for Consumer Protection of Romania, pers. comm. (2017)

9.2.1.5 Enforcement in Austria

During the consultation, the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) of Austria noted that enforcement of chemicals legislation (including detergents) in Austria is coordinated by means of a national “enforcement platform” and that enforcement priorities are defined on a regular basis. The stakeholder explained that, as regards detergent products, there has been no specific enforcement of the Detergents Regulation over 2015-2016; however, horizontal enforcement activities in the area of REACH and CLP have been of some relevance. It was noted that there are about 18 persons (“Chemical Inspectors”) in Austria, who deal (part of the time) with the enforcement of chemicals legislation including the Detergents Regulation. The annual budget varies to a large extent depending on defined (proactive) priorities and also on the extent of necessary reactive inspections.

9.2.1.6 Enforcement in Latvia

In Latvia, the Health Inspectorate is responsible for control of chemical substances, chemical mixtures (detergents, mixtures containing volatile organic compounds (VOC)), biocides, cosmetic products, tobacco products, electronic cigarettes. During the consultation, the Health Inspectorate explained that there are between three and eight inspectors performing inspections at companies in Latvia. Usually inspections are combined – covering different legal acts: REACH, CLP, other chemicals legislation, e.g. VOC, detergents, biocides, and cosmetics legislation.

According to the Health Inspectorate, in the last five years, 58 proactive controls were made on average each year, as shown in Table 14 below. There have not been any reactive controls between 2014-2016. On average, 236 detergent products are controlled each year.

	2012	2013	2014	2015	2016
Number of proactive inspections	47	46	72	66	60

Source: Health Inspectorate of Latvia, pers. comm. (2017)

9.2.1.7 Enforcement in Denmark

According to the Danish Environmental Protection Agency, in 2016, the Chemical Inspection Service (at the Danish Environmental Protection Agency) did not run any proactive inspection projects but did receive three reactive cases about detergents (compared to 47 reactive cases about CLP). In Denmark, the Detergents Regulation is enforced as part of the enforcement of CLP, when it is relevant. There are three inspectors at the Chemical Inspection Service charged with inspections for CLP and the Detergents Regulation.

9.2.1.8 Enforcement in Slovakia

According to the Central Inspectorate of the Slovak Trade Inspection, in Slovakia, 1,377 detergents have been tested over the period 2006 to 2016 (which equates on average to about 138 products per year). Furthermore, 24 samples have been taken for analysis of the product composition, its biodegradability and washing efficiency. Only one sample did not meet with the mentioned requirements. In 2016, no fines were imposed.

9.2.1.9 Enforcement in Finland

Tukes, the Finnish Safety and Chemicals Agency has noted that, in Finland there are roughly around 100 inspections annually in relation to detergent products (also covering CLP/REACH). Of those concerning also the Detergents Regulation, the recorded number of inspections is around 20 inspections per year; however, these data are not exact and the inspections may have concerned several products at a time. All of the inspections were reactive, since Finland does not conduct any proactive enforcement of the Detergents Regulation.

For detergents, sanctions (typically ban) are issued annually a few times (in practice subjected to between one and thirty detergents annually) depending on random factors, the case/product specific risk factors (CLP-classification, sales volume, use) and how the company reacts during the administrative proceeding.

In terms of personnel, the enforcement authorities in Finland have 0.5 people per year.

9.2.1.10 Enforcement in Norway

In Norway, the Detergents Regulation is controlled in conjunction with other chemical inspections. During the consultation, the Norwegian Environment Agency noted that enforcement of the Detergents Regulation in Norway has a low priority based on the country's risk-based approach to enforcement of chemicals.

10 Annex 5 - Evolution of intra-EU trade between 2002-2015

One of the primary goals of the Detergents Regulation is to ensure the free movement of detergents and surfactants for detergents in the internal market. To this end, the Detergents Regulation harmonises the rules for placing detergents and surfactants for detergents on the market throughout the EU and EEA (i.e. Norway, Iceland and Lichtenstein).

Data from Eurostat can be used to analyse changes to intra-EU trade in detergents and surfactants over the period 2002 to 2015. The data are presented according to the United Nations' Standard International Trade Classification (SITC) codes. Table 15 below presents the SITC codes that most closely match the products covered by the Detergents Regulation. Relevant SITC codes have been highlighted in grey.

Table 15: SITC code descriptions		
SITC Code	SITC Code Description	
55 4		Soap, cleansing and polishing preparations
	5541	Soap; organic surface-active products used as soap in bars, cakes, or shapes; paper, wadding, etc. impregnated or coated with soap or detergent
	55411	Soap and organic surface-active products in bars, cakes or shapes and paper, etc. impregnated or coated with soap or detergent, for toilet use
	55415	Soap and organic surface-active products in bars, cakes or shapes and paper, etc. impregnated or coated with soap or detergent, not for toilet use
	55419	Soap, n.e.s. ²¹⁶
	5542	Organic surface-active agents other than soap; surface-active, washing and cleaning preparations, whether or not containing soap, n.e.s.
	55421	Organic surface-active agents, put up for retail sale or not
	55422	Surface-active washing or cleaning preparations, n.e.s, put up for retail sale
	55423	Surface-active washing or cleaning preparations, n.e.s, not put up for retail sale
	5543	Polishes and creams (except artificial and prepared waxes), for footwear, furniture, floors, glass, metal, etc.; scouring pastes and preparations
	55431	Polishes, creams and similar preparations (except artificial and prepared waxes), for footwear and leather
	55432	Polishes, creams and similar preparations (except artificial and prepared waxes), for the maintenance of wooden furniture, floors and other woodwork

²¹⁶ N.e.s stands for not elsewhere specified.

	55433	Polishes and similar preparations (except metal polishes, artificial and prepared waxes), for coachwork
	55434	Scouring pastes, powders and other scouring preparations
	55435	Polishes, creams and similar preparations (except artificial and prepared waxes), for glass or metal
<i>SITC codes that are relevant to the Detergents Regulation have been highlighted in grey.</i>		

In reviewing these data, it should be recalled that some polishes do not fall within the scope of the Detergents Regulation; only those that claim to have a cleaning action are covered. If a polish contains a surfactant but only applies a wax layer to a surface without any cleaning action, then it is not covered by the Detergents Regulation. Note that ‘scouring’ refers to the removal of dirt from a hard surface and thus implies a cleaning action. Thus, scouring pastes fall within the scope of the Regulation.

The following figures illustrate changes in intra-EU trade of detergents and surfactants since 2002 for the ten statistical classifications highlighted in Figure 12. Data are available for both imports and exports. While, in theory, the international trade balance between countries of the EU28 should be zero (i.e. the total value of imports and exports should be the same), it would appear that there are some discrepancies, particularly for SITC Code 55415 (Figure 12). Potential reasons for this may include thresholds, non-response and related adjustments; statistical confidentiality; triangular trade; time lags in the registration of the transactions; misclassification of goods; or other methodological differences (Eurostat, no date)²¹⁷ (European Commission, Eurostat, Unit G5, no date)²¹⁸. It is worth noting that Eurostat considers intra-EU exports of goods as the more reliable measure of total intra-EU trade in goods at aggregated levels (Eurostat, 2016)²¹⁹.

²¹⁷ Eurostat (no date): International trade in goods, Reference Metadata, available at: http://ec.europa.eu/eurostat/cache/metadata/en/ext_go_esms.htm

²¹⁸ European Commission, Eurostat, Unit G5 (no date): International trade – productions, Frequently asked questions, available at: <http://ec.europa.eu/eurostat/documents/64445/4439642/FAQ-XT-WEB-EN-final-January2012.pdf/2c387c03-5064-45bc-a949-2d3c75567973>

²¹⁹ Eurostat (2016): Statistics explained, Intra-EU trade in goods – recent trends, available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Intra-EU_trade_in_goods_-_recent_trends

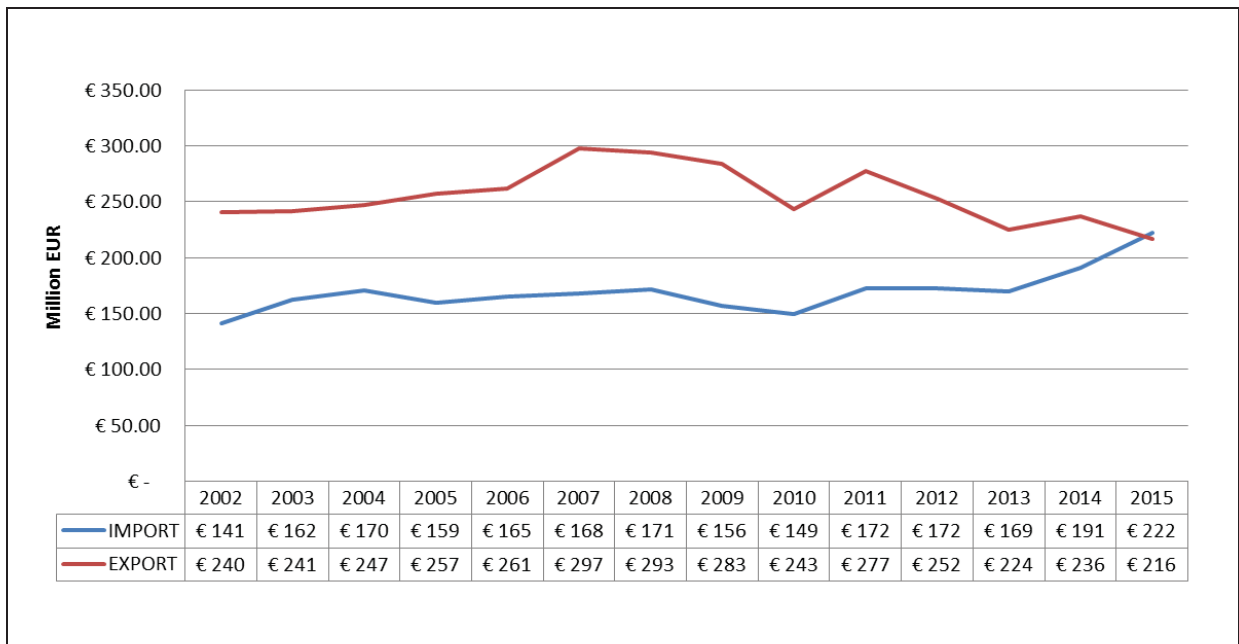


Figure 12: Intra-EU trade, SITC 3 Code 55415, soap and organic surface-active products and preparations, in the form of bars, cakes, moulded pieces or shapes, and paper, wadding, felt and non-wovens, impregnated, coated or covered with soap or detergent, for other uses

Source: Eurostat (DS-018995)

Figure 12 shows intra-EU trade in soap, in forms other than those shown in Figure 18 (SITC 3 Code 55419) from 2002 to 2015. It shows that there was a sharp increase in intra-EU trade in soap between 2004 and 2006, followed by a steady decline between 2006 and 2012.

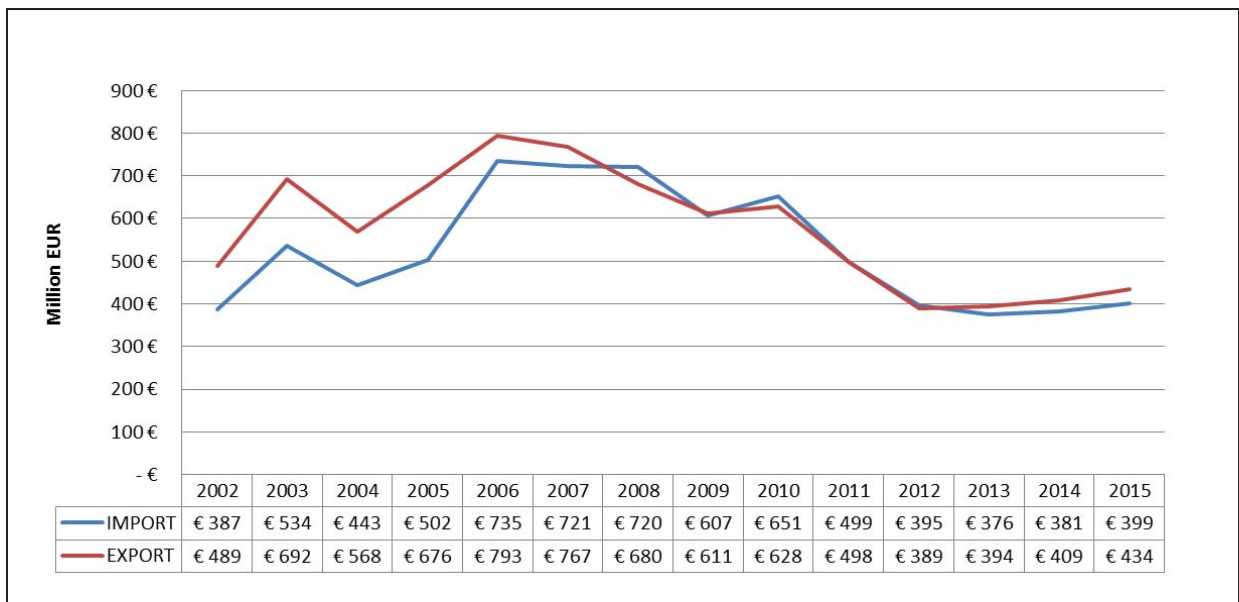


Figure 13: Intra-EU trade, SITC 3 Code 55419, soap in other forms

Source: Eurostat (DS-018995)

Figure 14 shows that since the Detergents Regulation came into force in 2005, the value of intra-EU trade in (SITC Code 55421) organic surfactants, whether or not put up for retail sale, has increased. Nevertheless, it is important to note that the Regulation may not be the only factor driving this increase, and that other exogenous factors may be at play. A clear dip

can be observed in 2009, which it is possible to speculate may be linked to the financial crisis.

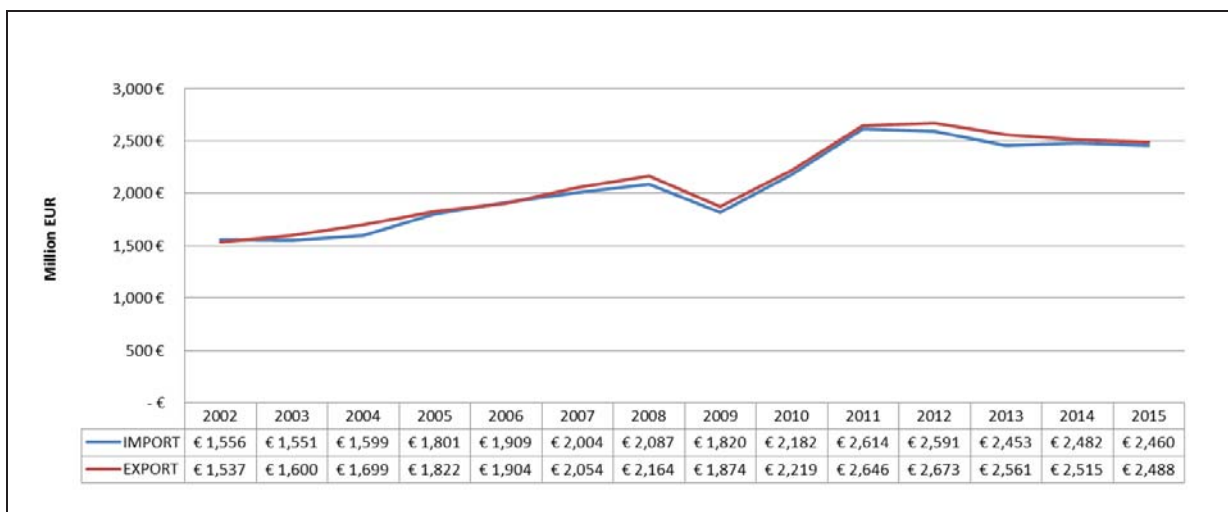


Figure 14: Intra-EU trade, SITC 3 Code 55421, organic surface-active agents, whether or not put up for retail sale

Source: Eurostat (DS-018995)

The value of intra-EU trade in (SITC Code 55422) surface-active washing or cleaning preparations, N.E.S put up for retail sale has also increased throughout this period (Figure 15).

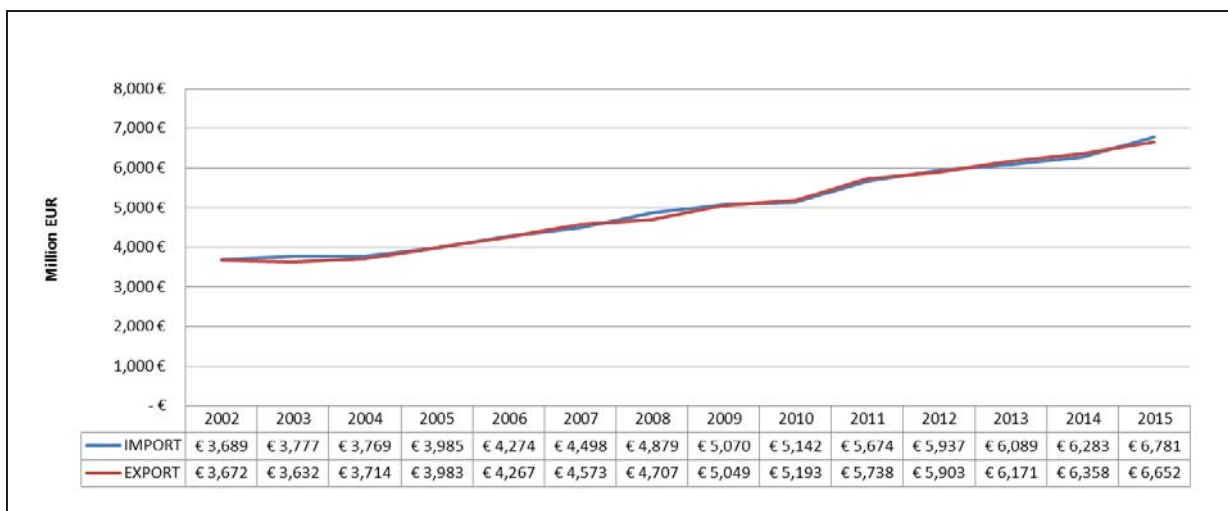


Figure 15: Intra-EU trade, SITC 3 Code 55422, surface-active washing or cleaning preparations, N.E.S. put up for retail sale

Source: Eurostat (DS-018995)

Intra-EU trade in (SITC Code 55423) surface-active washing or cleaning preparations, N.E.S. not put up for retail sale increased up until 2007, before falling slightly between 2008 and 2009. Intra-EU trade in surface-active washing or cleaning preparations, N.E.S. not put up for retail sale has increased steadily since 2009 (see Figure 16 below).

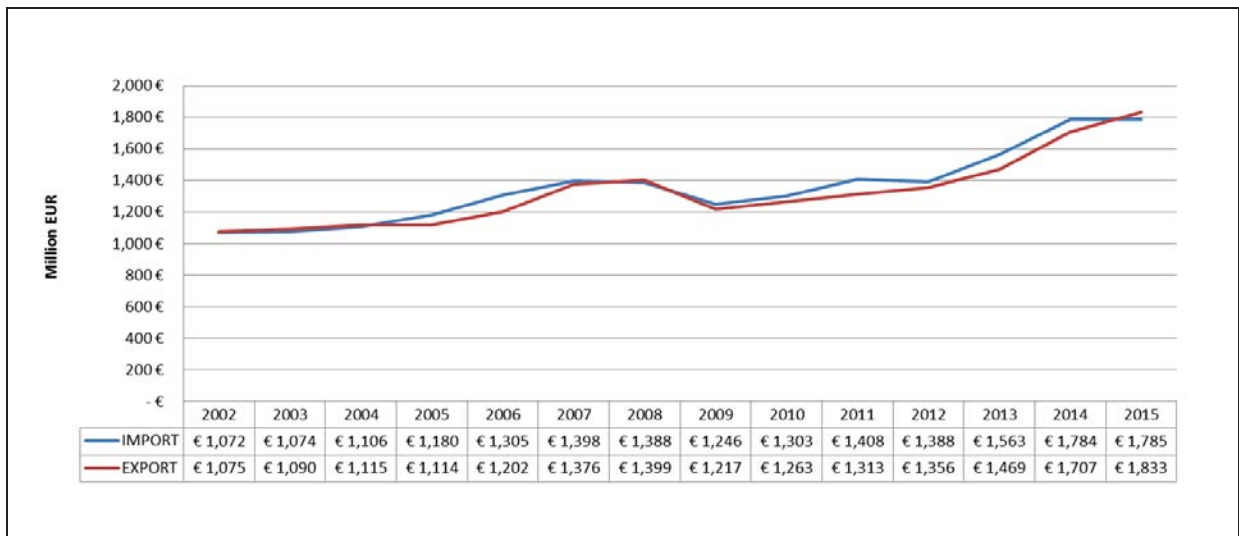


Figure 16: Intra-EU trade, SITC 3 Code 55423, surface-active washing or cleaning preparations, N.E.S. not put up for retail sale

Source: Eurostat (DS-018995)

The value of intra-EU trade in polishes, creams, scouring pastes and preparations is smaller than the value of trade in soaps and surfactants. Figure 17 below shows the value of intra-EU trade in polishes, creams and similar preparations (except artificial and prepared waxes), for footwear and leather.

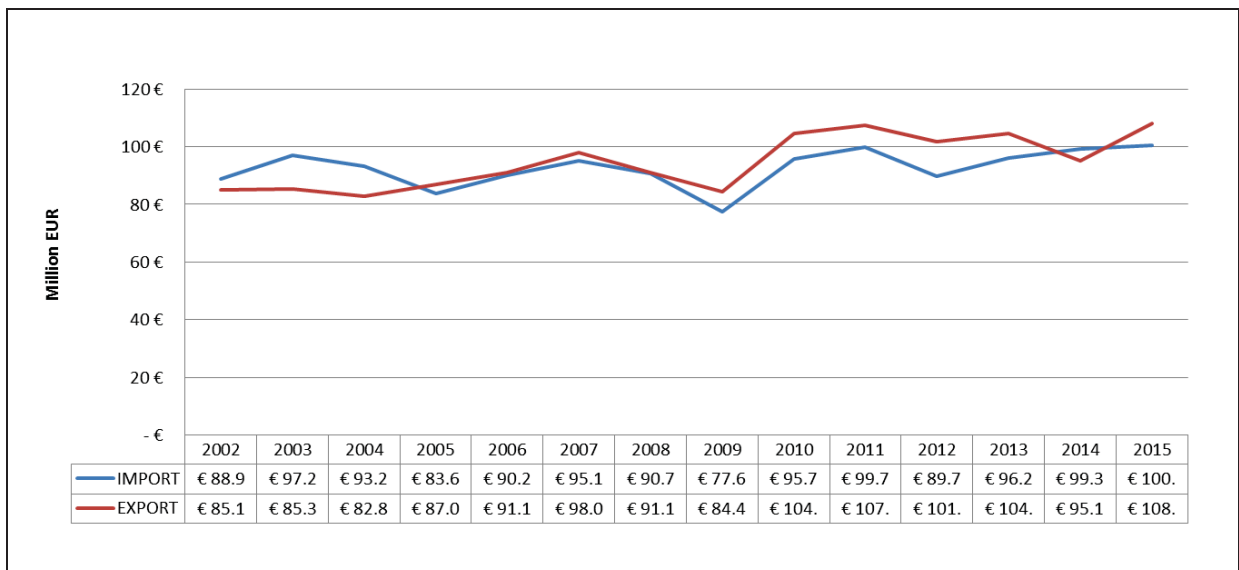


Figure 17: Intra-EU trade, SITC 3 Code 55431, polishes, creams and similar preparations (except artificial and prepared waxes), for footwear and leather

Source: Eurostat (DS-018995)

Exports of (SITC Code 55432) polishes, creams and similar preparations (except artificial and prepared waxes) for the maintenance of wooden furniture, floors and other woodwork dipped in 2009, as shown in Figure 18 below. Intra-EU trade in 2014 and 2015 was at a similar level to that in 2002 and 2003.

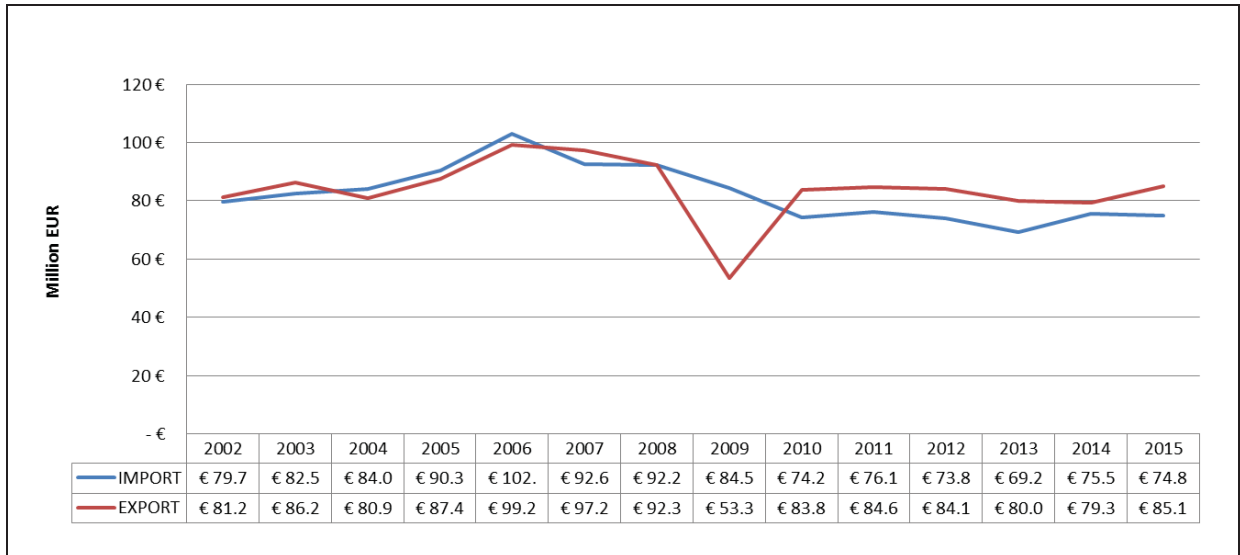


Figure 18: Intra-EU trade, SITC 3 Code 55432, polishes, creams and similar preparations (except artificial and prepared waxes), for the maintenance of wooden furniture, floors and other woodwork

Source: Eurostat (DS-018995)

Intra-EU trade in (SITC Code 55433) polishes and similar preparations (except metal polishes, artificial and prepared waxes) for coachwork has increased since 2004 (Figure 19).

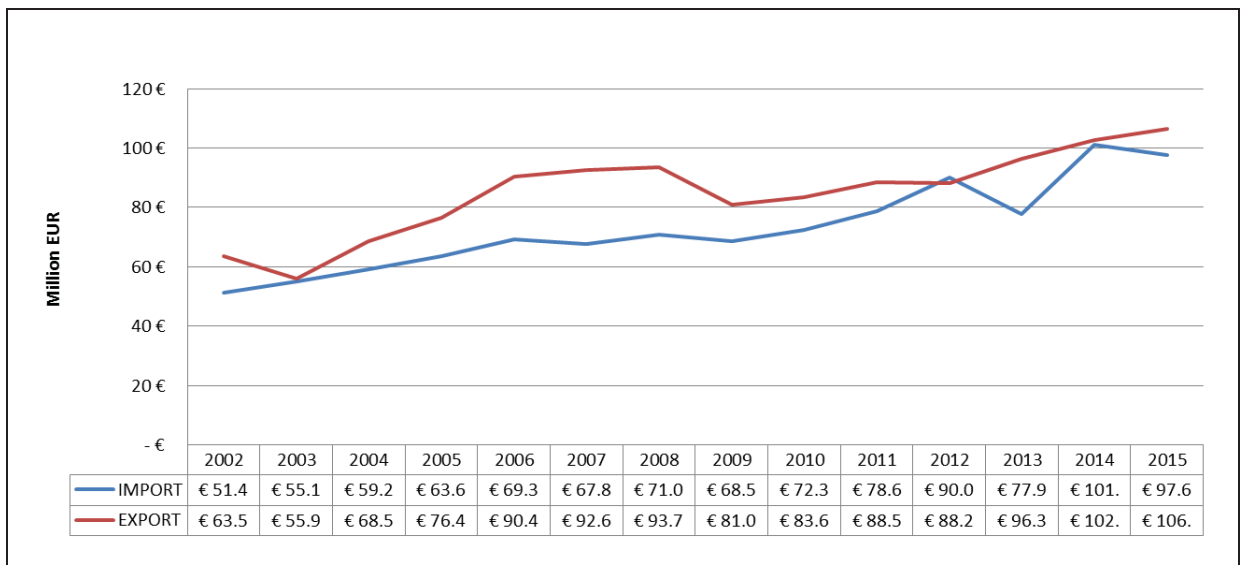


Figure 19: Intra-EU trade, SITC 3 Code 55433, polishes and similar preparations (except metal polishes, artificial and prepared waxes), for coachwork

Source: Eurostat (DS-018995)

Data on the value of intra-EU trade in (SITC Code 55434) scouring pastes, powders and other scouring preparations is shown in Figure 20 below.

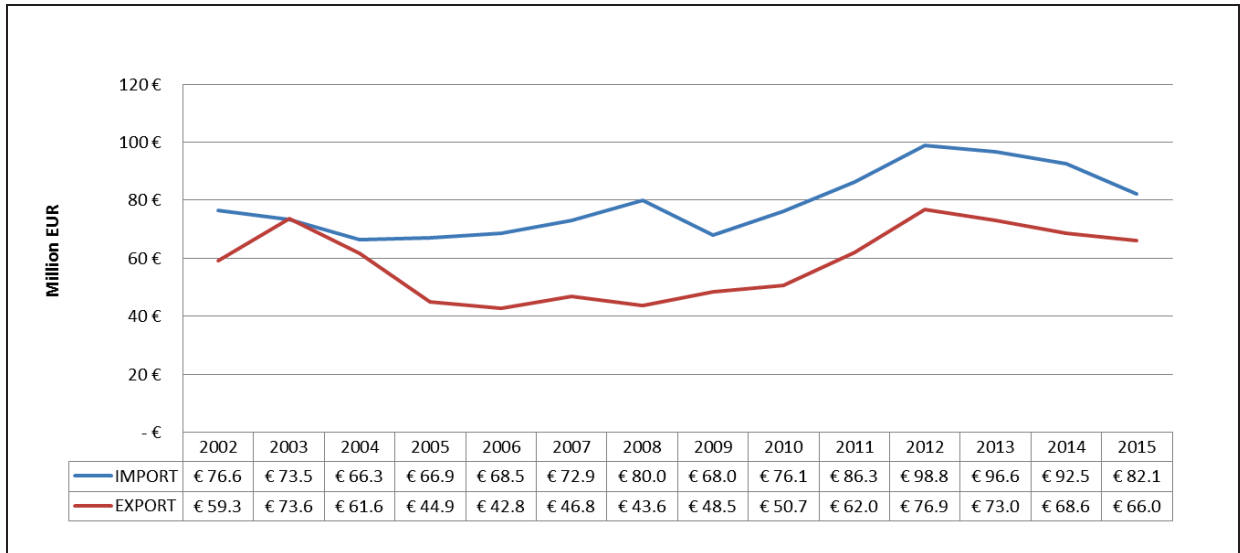


Figure 20: Intra-EU trade, SITC 3 Code 55434, scouring pastes, powders and other scouring preparations

Source: Eurostat (DS-018995)

Figure 21 below provides data on the value of intra-EU trade in (SITC Code 55435) polishes, creams and similar preparations (except artificial and prepared waxes) for glass or metal. It shows that intra-EU trade in this product group has increased since 2004.

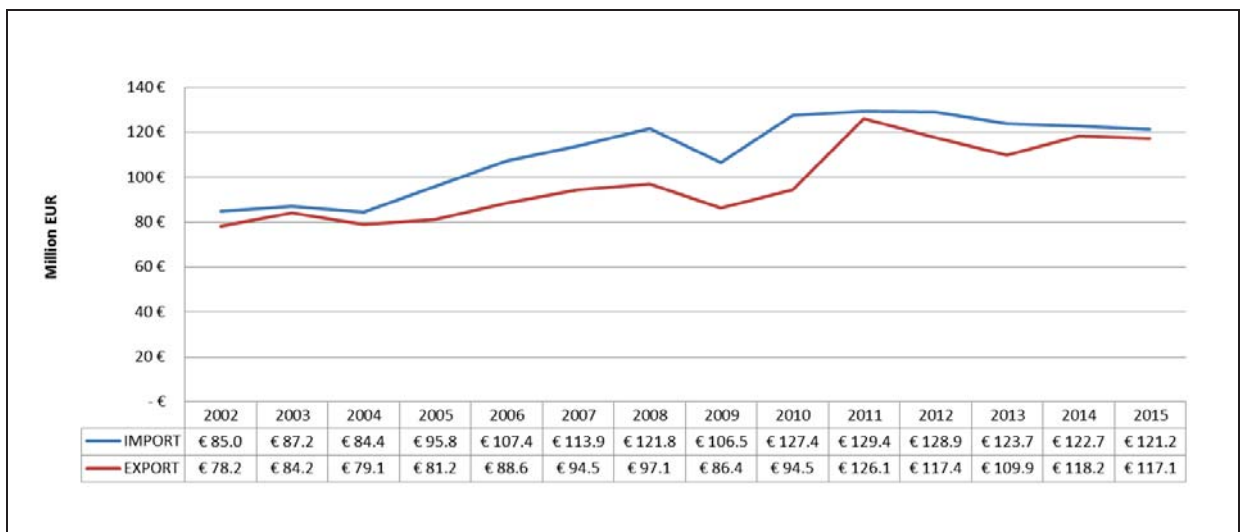


Figure 21: Intra-EU trade, SITC 3 Code 55435, polishes, creams and similar preparations (except artificial and prepared waxes), for glass or metal

Source: Eurostat (DS-018995)

Overall, it would appear that intra-EU trade in detergents and surfactants has increased since 2002, particularly for the following statistical groups:

55421: Organic surface-active agents, put up for retail sale or not;

55422: Surface-active washing or cleaning preparations, n.e.s, put up for retail sale;

55423: Surface-active washing or cleaning preparations, n.e.s, not put up for retail sale;

55431: Polishes, creams and similar preparations (except artificial and prepared waxes), for footwear and leather;

55433: Polishes and similar preparations (except metal polishes, artificial and prepared waxes), for coachwork; and

55435: Polishes, creams and similar preparations (except artificial and prepared waxes), for glass or metal.

However, for the remaining four statistical groups, the changes in terms of intra-EU trade are less certain:

55415: Soap and organic surface-active products in bars, cakes or shapes and paper, etc. impregnated or coated with soap or detergent, not for toilet use;

55419: Soap, n.e.s.;

55432: Polishes, creams and similar preparations (except artificial and prepared waxes), for the maintenance of wooden furniture, floors and other woodwork; and

55434: Scouring pastes, powders and other scouring preparations.

The extent to which any of the observed changes can be attributed to the Detergents Regulation is, however, unclear.