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NOTE

From:	AT, DE Delegation
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° Cion doc.:	ST 8904 2023 ADD 1-7
Subject:	Proposal for a Regulation of the European Parliament and of the Council on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004 - Comments by AT, DE, WP on 31/10/2023

Recital No. 2 and 8 and Art. 1:

AT explicitly welcomes the coordination with other EU legislation regarding information on detergents resulting from synergies with the REACH Regulation (EC) No. 1907/2006, the CLP Regulation (EC) No. 1272/2008 and the Biocidal Products Regulation (EU) No. 528/2012, thereby ensuring the avoidance of duplication with regard to the labeling of detergents.

Art. 4 and Annex I

AT suggests to add biodegradability requirements for detergents capsules containing plastics not only after a review period but now.

Recital No 16 - 23 and Art. 7 - 13:

The establishment of a graduated responsibility for compliance with detergents legislation with regard to the various economic operators (manufacturers, importers and distributors) is explicitly welcomed.

However AT doubts the usefulness of introducing an "authorized representative" in detergents legislation especially against the background of the already existing graduated responsibility in the supply chain (manufacturers, importers and distributors); especially because the revision of the CLP Regulation does not provide for an "authorized representative" and, according to the recitals (see above), coherence with other legal provisions (e.g. CLP Regulation) should be achieved with the present draft.

Recitals 15, 24 and 39 and Art. 14 - 19 (Annex VI):

AT asks the EC to explain the added value of the CE marking for economic operators and enforcement, in view of the fact that the product passport must include the information set out in Annex VI and also all legal frameworks the detergent or surfactant shall comply with because end users, market surveillance authorities, customs authorities and other economic operators have access to the "product passport" in accordance with Art. 18.

AT also asks the EC to clarify the question of the usefulness and feasibility of creating a product passport for each batch; the effort for the industry seems disproportionately high compared to the benefits.

The product passport register only contains the product identifier and the name of the economic operator. In order to determine further data for a detergent or surfactant it is necessary to additionally obtain the relevant information on the respective homepage of the economic operator. In this context, AT suggests that at least the essential hazard descriptions and their ingredients should also be entered in the product passport register, which would also make enforcement much easier (Note: Products may still be on the market even though the company responsible for placing them on the market no longer exists or the company's website is not operational).

AT proposes that the introduction of the product passport should be coordinated also in time with the application of the Ecodesign Regulation.

Art. 15 and 16:

AT suggests adapting the labelling of refill products to the labelling requirements of the CLP Regulation. According to the CLP Regulation all labelling information must be affixed to the physical label at refill stations.

Annex IV:

AT proposes that the Ingredient Data Sheet according to Annex IV point 2.2 (e) should be made available not only upon request from the MS appointed bodies (poison control center) but before the first placing on the market.

Federal Ministry for the Environment,
Nature Conservation, Nuclear Safety
and Consumer Protection

Berlin, 07.12.2023

Germany

German comments and proposed amendments on European Commission's proposal for a regulation on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004

Germany comments on the first three clusters of the proposed regulation as shown in the table below:

Column 1 of the table contains the European Commission's proposal for a regulation, column 2 contains comments on the provisions of the proposed regulation as well as the justifications for the proposed amendments, which are shown in column 3.

1. Cluster 1 - Product Requirements

Article 1 – Scope

Article 3 – Free movement

Article 4 – Biodegradability

Article 5 – Detergents containing micro-organisms

Article 6 - Limitations on the content of phosphates and other phosphorus compounds

Article 26(6) – Delegated powers

Article 32 – Micro-organisms review

Article 2 – Definitions

points (1), (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12)

Annex I - Biodegradability requirements referred to in Article 4

Annex II - Requirements for detergents containing micro-organisms referred to in Article 5

Annex III - Limitations on the content of phosphates and other phosphorus compounds referred to in Article 6

Annex VII - Test methods referred to in Article 22(2)

Commission Proposal (28. April 2023) COM(2023) 217 final	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in strikethrough , a
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		new text proposal in <u>underlined</u>)
CHAPTER I GENERAL PROVISIONS		
Article 1 Subject matter		
1. This Regulation establishes rules for the free movement of detergents and surfactants in the internal market while, at the same time, ensuring a high degree of protection of health and the environment.		
	In order to clarify that this regulation does not apply to cosmetic products within the scope of Regulation (EC) No 1223/2009, a corresponding derogation should be included. The lack of clarity is shown by the fact that this issue is also addressed by the FAQ Detergents, where it is explicitly stated that the Detergents Regulation does not apply to cosmetic products. As cosmetic products also contain surfactants, the requirements for biodegradability according to Article 4(1) should also be considered for cosmetic products. This would improve protection for the environment.	<u>2. This Regulation shall not apply to cosmetic products within the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council.</u>
2. This Regulation does not affect the application of the following legal acts:		
(a) Regulation (EC) No 1907/2006 of the European Parliament and of the Council ¹		
(b) Regulation (EC) No 1272/2008 of the		

¹ 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 (OJ L 396, 30.12.2006, p. 1).

European Parliament and of the Council ²		
(c) Regulation (EU) No 528/2012 of the European Parliament and of the Council ³		
Article 2 Definitions		
For the purpose of this Regulation, the following definitions apply:		
(1) ' detergent ' means any of the following:		
- a substance, mixture or micro-organism, or two or more such materials in combination, which is intended for cleaning of fabrics, dishes or surfaces;	We welcome the improved definition of detergent, which is now linked to its cleaning purpose. This also contributes to the elimination of ambiguities arising from the current definition. However, the definition is not comprehensive enough. For example, „water softeners“ may no longer be included. The definition should therefore be expanded. The definition should also include detergents to apply on animals (e.g. dog shampoo). If animal fur is not a surface, we would be grateful for an explanation of the criteria by which a surface is defined.	- a substance, mixture or micro-organism, or two or more such materials in combination, which is intended for cleaning of fabrics, dishes or surfaces <u>or added to support cleaning processes (e.g.: water softeners)</u> ;
- a mixture intended for soaking (pre-washing), rinsing or bleaching fabrics or dishes;	In order to include products which only consists of one substance the definition should also be expanded to substances.	- a <u>substance or</u> mixture intended for soaking (pre-washing), rinsing or bleaching fabrics or dishes;
- a mixture intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;	In order to include products which only consists of one substance the definition should also be expanded to substances. The definition is not comprehensive enough. For example, „Unstoppables“ (perfumes for laundry) may no longer be included. The definition should therefore be	- a <u>substance or</u> mixture intended <u>to care for fabrics or to modify the feel or the smell</u> of fabrics in processes which are to complement the washing of fabrics (e.g.: <u>perfumes, fragrances, inhibitors of discoloration for laundry, laundry starch, fabric softeners, impregnating agents</u>);

² 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 (OJ L 353, 31.12.2008, p. 1).

³ 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 OJ L 167, 27.6.2012, p. 1).

	<p>expanded. The Commission's view that „Unstoppables“ are not intended for cleaning purposes is correct, but this also applies to fabric softeners, which fall within the definition of „detergent“ and therefore within the scope of the Detergents Regulation.</p>	
Point 2 to 10	Currently no comments.	
<p>(11) ‘surfactant’ means any organic substance or mixture used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable to perform all of the following actions:</p> <ul style="list-style-type: none"> – to reduce the surface tension of water below 45 mN/m; – to form spreading or adsorption monolayers at the water-air interface; – to form emulsions and/or microemulsions and/or micelles; – to adsorb at water-solid interfaces; 	<p>The discussion about the introduction of a limit value was already held in 2006, since there are other substances, such as certain alcohols, which also reduce the surface tension by a certain amount. However, since these substances do not meet all other criteria, such as micelle formation, the introduction of a limit value was not pursued. We wonder why this issue is now addressed in the legislative proposal.</p> <p>Regardless, the introduction of a limit value for the reduction of surface tension in water would require a recognized test procedure to be mentioned in the regulation, because the reduction of surface tension depends on temperature of the mixture and the concentration of the surfactant.</p> <p>Regarding the requirement to reduce the surface tension of water below 45 mN/m, the question arises as to the introduction of a threshold value is necessary and whether this leads to relevant effects, i.e. whether this means that some surfactants no longer fall within the scope of the EU Regulation.</p> <p>The technical assessment for the introduction of a limit value has not yet been completed in Germany</p>	
<p>(12) ‘ultimate aerobic biodegradation’ means the level of biodegradation achieved when the substance or mixture is totally used by micro-</p>	<p>As there are no test methods for the ultimate biodegradability of mixtures, the reference should be deleted.</p>	<p>(12) ‘ultimate aerobic biodegradation’ means the level of biodegradation achieved when the substance or mixture is totally used by micro-</p>

organisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water and mineral salts of any other elements present, as measured by test methods listed in Annex I, and new microbial cellular constituents;		organisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water and mineral salts of any other elements present, as measured by test methods listed in Annex I, and new microbial cellular constituents;
(13) – (35) ...		
CHAPTER II PRODUCT REQUIREMENTS		
Article 3 Free movement	Currently no comments.	
Article 4 Biodegradability		
1. Detergents and surfactants shall comply with the biodegradability requirements laid down in Annex I.	We support the introduction of the possibility to extend the scope to the biodegradability of substances in detergents other than surfactants through delegated acts. However, we propose introducing a review clause to regularly review the biodegradability requirements for such substances.	
2. Paragraph 1 shall not apply to the following:	The wording of paragraph 2 leads to a regulatory gap with regard to the biodegradability of surfactants in biocidal products that do not meet the requirements of point a (point b and c). This would mean a significant deterioration in the requirements for the biodegradability of surfactants in biocidal products that also serve cleaning purposes. Therefore point b and c should be deleted.	
(a) surfactants that are active substances within the meaning of Article 3(1), point (c), of Regulation (EU) No 528/2012 and that are used as disinfectants where they meet any of the following conditions:		
(i) the surfactants are included in the Union list of approved active substances as laid down in Article 9(2) of		

Regulation (EU) No 528/2012;		
(ii) the surfactants are included in the review programme as set out in Commission Delegated Regulation (EU) No 1062/2014 ⁴ ;		
(b) surfactants that are constituents of biocidal products authorised in accordance with Regulation (EU) No 528/2012;	Point b should be deleted. Surfactants that are not biocidal active substances but ingredients of biocidal products have to meet the requirements for biodegradability according to Regulation (EC) No 648/2004. The proposed amendment that all surfactants contained in biocidal products do not have to meet the requirement of ultimate aerobic biodegradation means a deterioration with regard to the protection of the environment compared to Regulation (EC) No.648/2004.	(b) surfactants that are constituents of biocidal products authorised in accordance with Regulation (EU) No 528/2012;
(c) surfactants that are constituents of biocidal products and which may be made available on the market or used in accordance with Article 89(2) of Regulation (EU) No 528/2012.	Point c also needs to be deleted (see justification above).	(c) surfactants that are constituents of biocidal products and which may be made available on the market or used in accordance with Article 89(2) of Regulation (EU) No 528/2012.
Article 5 Detergents containing micro-organisms	Comments can be found in Annex II.	
Detergents containing micro-organisms shall comply with the requirements laid down in Annex II.		
Article 6 Limitations on the content of phosphates and other phosphorus compounds	We ask the COM to consider extending the P-limitation to the professional (I & I) sector. It seems technically feasible to set limits in the area of automatic dishwasher detergents and	

⁴ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

	<p>laundry detergents. The reduction of the use of less phosphorus in these products would be in accordance with the HELCOM Baltic Sea Action Plan and the measures proposed therein, to reduce eutrophication in the Baltic Sea. The Baltic Sea Action Plan envisages efforts to reduce and, where possible, eliminate phosphorus in detergents for professional (I & I) use, in particular for institutional use in laundry and dishwashing detergents, by 2030 at the latest. In a first step, a compilation of knowledge on best available techniques for P-free washing and cleaning for I & I use is planned. We therefore propose to include a review clause with the aim of evaluating the results of the HELCOM project by the COM with regard to a P-limitation for detergents used in the I & I sector.</p> <p>In addition, a P limitation in the I & I sector could save on expensive precipitation agents for P elimination in sewage treatment plants.</p>	
Detergents listed in Annex III shall comply with the limitations on the content of phosphates and other phosphorus compounds laid down in that Annex.		
Article 26 Delegated powers		
Paragraph 6	Currently no comments.	
Article 32 Micro-organisms review	Currently no comments.	

Commission Proposal (28. April 2023)	Comments	Proposed amendments
	Justification for proposed amendments	(The rejected text of the Commission proposal is marked in strikethrough , a new text proposal in <u>underlined</u>)
ANNEX I	Currently no comments.	

BIODEGRADABILITY REQUIREMENTS REFERRED TO IN ARTICLE 4 ULTIMATE BIODEGRADABILITY CRITERIA AND TEST METHODS FOR SURFACTANTS AND SURFACTANTS IN DETERGENTS		
Commission Proposal (28. April 2023)	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in striketrough , a new text proposal in <u>underlined</u>)
ANNEX II REQUIREMENTS FOR DETERGENTS CONTAINING MICROORGANISMS REFERRED TO IN ARTICLE 5	The requirements of points 1-6 as well as 9 and 10 of Annex II correspond to the environmental criteria for the award of the EU Ecolabel for hard surface cleaning products, except for the last subparagraph in point 1. In contrast to the Ecolabel criteria, the present Regulation proposal does not prohibit the use of micro-organisms in consumer products (see Commission Decision (EU) 2017/1217 – „Products for private use shall not contain micro-organisms that have been deliberately added by the manufacturer.“). Is it ensured that the specified requirements guarantee safe intended use by consumers of the private sector or should the use be restricted to the professional sector?	
1. Micro-organisms intentionally added to detergents shall comply with the following conditions:		
(a) shall have an American Type Culture Collection (ATCC) number, belong to a collection of an International Depository Authority (IDA) or have had their DNA identified in accordance with a “Strain identification protocol”	The term “...or have had their DNA identified in accordance with a “Strain identification protocol” (using 16S ribosomal DNA sequencing or an equivalent method);” should be adapted if necessary, as the mentioned method allows at most taxonomic identification at species level. A fully	

(using 16S ribosomal DNA sequencing or an equivalent method);	comprehensive strain-specific comparison is only possible through a comparative examination of the entire genome using genome sequencing.	
(b) shall belong to both of the following:		
(i) Risk Group I as defined by Directive 2000/54/EC – biological agents at work;		
(ii) The Qualified Presumption of Safety (QPS) list issued by the European Food Safety Authority (EFSA).		
This point shall not apply to micro-organisms intentionally added to detergents placed on the market for research and development purposes.	Micro-organisms added to detergents for research and development purposes and placed on the market should be clearly identified, as it should be clear at all times which micro-organisms are involved. Therefore, this subparagraph should be deleted.	This point shall not apply to micro-organisms intentionally added to detergents placed on the market for research and development purposes.
2. The following pathogenic micro-organisms shall not be present in any of the strains included in the finished product when screened using the indicated test methods or equivalent:		
(a) E. coli, test method ISO 16649-3:2005;		
(b) Streptococcus (Enterococcus), test method ISO 21528-1:2004;		
(c) Staphylococcus aureus, test method ISO 6888-1;		
(d) Bacillus cereus, test method ISO 7932:2004 or ISO 21871;		
(e) Salmonella, test method ISO 6579:2002 or ISO 19250.		
3. Intentionally added micro-organisms shall not be genetically modified microorganisms.		

<p>4. Intentionally added micro-organisms shall be, with the exception of intrinsic resistance, susceptible to each of the major antibiotic classes, namely aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones, in accordance with the European Committee on Antimicrobial Susceptibility Testing (EUCAST) disk diffusion method or equivalent.</p>		
<p>5. When placed on the market, detergents containing micro-organisms shall have a standard plate count equal to or greater than 1×10^5 colony-forming units (CFUs) per ml in accordance with ISO 4833-1:2014.</p>	<p>The figure given here should refer to the micro-organisms intentionally added and at the same time a target value should be set for contamination with other micro-organisms.</p>	
<p>6. The minimum shelf life of a detergent containing micro-organisms shall not be lower than 24 months and the microbial count shall not decrease by more than 10 % every 12 months in accordance with ISO 4833-1:2014.</p>		
<p>7. Micro-organisms contained in detergents that are placed on the market in a spray format shall pass the acute inhalation toxicity test in accordance with the test method B.2., described in Part B of the Annex to Regulation (EC) No 440/2008.</p>	<p>Test method B.2 of Regulation (EC) No. 440/2008 describes animal testing on mammals (preferably rats) to determine acute inhalation toxicity in accordance with REACH. Since there is no need for detergents in spray form that contain micro-organisms, this product form should be avoided in order to prevent animal testing. According to the criteria of the eco-label (see Commission Decision (EU) 2017/1217), no product containing micro-organisms may be used in trigger sprays. Furthermore, it can be assumed that spray applications pose additional</p>	<p>7. Micro-organisms contained in detergents that are placed on the market in a spray format shall pass the acute inhalation toxicity test in accordance with the test method B.2., described in Part B of the Annex to Regulation (EC) No 440/2008 <u>Detergents containing micro-organisms shall not be placed on the market in a spray format.</u></p>

	risks, especially for untrained consumers.	
8. Detergents containing micro-organisms shall not be placed on the market in a refill format.		
9. All claims made by the manufacturer regarding the actions of the micro-organisms contained in the product shall be supported by third-party testing.	The requirement is a criterion for the award of the EU Ecolabel. In the case of the EU Ecolabel, product tests appear to make sense, as the effectiveness of the product is important for acceptance compared to products without the EU Ecolabel. In the present case, such product tests do not appear to be necessary, especially as no recognised test procedure is envisaged. Furthermore, it is not clear what kind of actions the manufacturers will advertise with regard to the micro-organisms used. Therefore point 9 should be deleted.	9. All claims made by the manufacturer regarding the actions of the micro-organisms contained in the product shall be supported by third-party testing.
10. It is prohibited to claim or suggest on the label or by any other communication that the detergent has an antimicrobial or disinfecting effect, unless the detergent complies with Regulation (EU) No 528/2012.		
11. The tests referred to in points 2, 5, 6, 7 and 9 shall be conducted by laboratories meeting any of the following conditions:	The test referred to in point 4 is missing. The reference to point 9 should be deleted (see deletion of point 9)	11. The tests referred to in points 2, <u>4</u> , 5, 6, <u>and 7</u> and 9 shall be conducted by laboratories meeting any of the following conditions
(a) the laboratories are complying with the principles of good laboratory practice provided for in Directive 2004/10/EC of the European Parliament and of the Council ⁵ or international standards		

⁵ Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

recognised as being equivalent;		
(b) the laboratories are accredited in accordance with the standard for laboratories referred to in Regulation (EC) No 765/2008		

Commission Proposal (28. April 2023)	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in striketrough , a new text proposal in <u>underlined</u>)				
<p style="text-align: center;"><u>ANNEX III</u> LIMITATIONS ON THE CONTENT OF PHOSPHATES AND OTHER PHOSPHORUS COMPOUNDS REFERRED TO IN ARTICLE 6</p> <table border="1" data-bbox="204 1070 676 2063"> <thead> <tr> <th data-bbox="204 1070 384 1137">Detergent</th> <th data-bbox="384 1070 676 1137">Limitations</th> </tr> </thead> <tbody> <tr> <td data-bbox="204 1137 384 2063">Consumer laundry detergents</td> <td data-bbox="384 1137 676 2063"> <p>Shall not be placed on the market if the total content of phosphorus is equal to or greater than 0,5 grams in the recommended quantity of the detergent to be used in the main cycle of the washing process for a standard washing machine load as defined in Part B of Annex V for hard water:</p> <ul style="list-style-type: none"> – for 'normally soiled' fabrics in the case of heavy-duty detergents, – for 'lightly soiled' </td> </tr> </tbody> </table>	Detergent	Limitations	Consumer laundry detergents	<p>Shall not be placed on the market if the total content of phosphorus is equal to or greater than 0,5 grams in the recommended quantity of the detergent to be used in the main cycle of the washing process for a standard washing machine load as defined in Part B of Annex V for hard water:</p> <ul style="list-style-type: none"> – for 'normally soiled' fabrics in the case of heavy-duty detergents, – for 'lightly soiled' 	<p>In order to align the provision to the NLF and the legislative proposal, only the product requirement should be regulated here. The prohibition of placing on the market is already addressed by Article 3(1) in conjunction with Article 6.</p>	<p>Shall not be placed on the market if <u>The total content of phosphorus is shall not be</u> equal to or greater than 0,5 grams in the recommended quantity of the detergent to be used in the main cycle of the washing process for a standard washing machine load as defined in Part B of Annex V for hard water:</p>
Detergent	Limitations					
Consumer laundry detergents	<p>Shall not be placed on the market if the total content of phosphorus is equal to or greater than 0,5 grams in the recommended quantity of the detergent to be used in the main cycle of the washing process for a standard washing machine load as defined in Part B of Annex V for hard water:</p> <ul style="list-style-type: none"> – for 'normally soiled' fabrics in the case of heavy-duty detergents, – for 'lightly soiled' 					

	fabrics in the case of detergents for delicate fabrics.		
Consumer automatic dishwasher detergents	Shall not be placed on the market if the total content of phosphorus is equal to or greater than 0,3 grams in the standard dosage as defined in Part B of Annex V.		<p>Shall not be placed on the market if <u>The total content of phosphorus is shall not be equal to or greater than 0,3 grams in the standard dosage as defined in Part B of Annex V.</u></p>

Commission Proposal (28. April 2023)	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in strikethrough , a new text proposal in <u>underlined</u>)
ANNEX VII TEST METHODS REFERRED TO IN ARTICLE 22(2)	<p>Annex VII contains the reference method (confirmation test) from Annex VIII of the current EC Detergent Regulation. This test is intended as a confirmatory test for the primary biodegradation of surfactants in the context of market surveillance and is not suitable as a reference method for the ultimate aerobic biodegradation of surfactants.</p> <p>As the present Regulation proposal, in contrast to the current EC Detergents Regulation, no longer provides for any exceptions to the ultimate biodegradation of surfactants (e.g. for bottle cleaning/metal cleaning in accordance with Annex V of the EC Detergents Regulation), Annex VII should be deleted. Furthermore, it is not clear from the explanations in Article 22(2) what Annex VII is to be used for.</p>	Deletion of Annex VII.

2. Cluster 2 - NLF & Market Surveillance

Article 7 - Obligations of manufacturers

Article 8 - Authorised representative

Article 9 - Obligations of importers

Article 10 - Obligations of distributors

Article 11 - Cases in which obligations of manufacturers apply to importers and distributors

Article 12 - Packaging and repackaging by importers and distributors

Article 13 - Identification of economic operators

Article 14 - Rules and conditions for affixing the CE marking

Article 22 – Procedure at national level for dealing with detergents and surfactants presenting a risk

Article 23 - Union safeguard procedure

Article 24 - Compliant detergents and surfactants which present a risk to health or to the environment

Article 25 - Formal non-compliance

Article 2 – Definitions

points 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25

Annex IV - Conformity assessment procedure referred to in Article 7(2)

Commission Proposal (28. April 2023) COM(2023) 217 final	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in strike through , a new text proposal in <u>underlined</u>)
CHAPTER III OBLIGATIONS OF ECONOMIC OPERATORS	All technical requirements to be fulfilled by economic operators (e.g. data carrier, product passport, product passport register) must be laid down in implementing acts in time so that economic operators are able to apply and comply with the requirements.	
Article 7 Obligations of manufacturers		
1. When placing detergents or surfactants on the market, manufacturers shall		

<p>ensure that those detergents or surfactants have been designed and manufactured in accordance with this Regulation.</p>		
<p>2. Manufacturers shall draw up the technical documentation referred to in Annex IV and carry out the conformity assessment procedure referred to in that Annex. Where compliance of a detergent or surfactant with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall:</p>		
<p>(a) create a product passport in accordance with Article 18,</p>		
<p>(b) ensure that the data carrier is printed or otherwise placed on the label or on the packaging of the detergent or surfactant in a visible and legible manner in accordance with Article 18(3),</p>		
<p>(c) where relevant, affix the CE marking in accordance with Article 14,</p>	<p>See comment on Article 14</p>	
<p>(d) before placing detergents or surfactants on the market, manufacturers shall include a reference of the product passport in the registry referred to in Article 20(1).</p>		
<p>3. Manufacturers shall keep the technical documentation and the product passport for 10 years after the detergent or the surfactant covered by that documentation or product passport has been placed on the market.</p>	<p>The retention period should start at the last date of making the products available on the market by the manufacturers. Otherwise, for the products which are still on the market 10 years after they were first made available on the market, no documentation would be available from the manufacturer</p>	<p>3. Manufacturers shall keep the technical documentation and the product passport for 10 years after <u>having made available</u> the detergent or the surfactant covered by that documentation or product passport has been placed on the market <u>by the</u></p>

	(Alignment with Article 36(1) of the REACH Regulation).	<u>manufacturers for the last time.</u>
<p>4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the test methods by reference to which conformity of a product is declared shall be adequately taken into account.</p> <p>When deemed appropriate with regard to the performance of, or the risks presented by, a detergent or surfactant, manufacturers shall carry out sample testing of such detergents or surfactants, investigate, and, if necessary, keep a register of complaints, of non-conforming detergents or surfactants and recalls of such detergent or surfactants, and shall keep distributors informed of any such monitoring.</p>		
<p>5. Manufacturers placing on the market detergents or surfactants shall ensure that they comply with the labelling requirements laid down in Articles 15, 16 and 17.</p>		
<p>6. Manufacturers placing on the market detergents that do not meet the criteria for classification as hazardous within the meaning of Regulation (EC) No 1272/2008, shall provide to Member States' appointed bodies referred to in Article 45 of that Regulation, the ingredient data sheet referred to in point 2.2 (e) of Annex IV.</p>	<p>The requirement „that do not meet the criteria for classification as hazardous within the meaning of Regulation (EC) No 1272/2008“ leads to a regulation and protection gap. Detergents consisting of only one substance and classified as hazardous within the meaning of Regulation (EC) No 1272/2008 would be excluded from the submission of an ingredient data sheet to Member States' appointed bodies (the same applies to</p>	<p>6. Manufacturers placing on the market detergents <u>for which there is no obligation to provide information according to Article 45 in conjunction with Annex VIII that do not meet the criteria for classification as hazardous within the meaning of Regulation (EC) No 1272/2008</u>, shall provide to Member States' appointed bodies referred to in Article 45 of that Regulation, the</p>

	<p>detergents (mixtures and substances) which are only classified as hazardous to the environment). This would mean that there would be no obligation to submit information on this detergent under either Regulation (EC) No 1272/2008 or the Detergents Regulation.</p>	<p>ingredient data sheet referred to in point 2.2 (e) of Annex IV <u>before placing the detergent on the market.</u></p> <p><u>When the detergent for which a data sheet has already been provided no longer corresponds to the information included in that datasheet, the manufacturer shall provide an updated data sheet to the Member states' appointed body before placing the detergent, as changed, on the market.</u></p>
<p>Manufacturers shall provide the ingredient data sheet to the Member States' appointed bodies referred to in the first subparagraph in the following cases:</p> <p>(a) upon request from the Member States' appointed bodies;</p> <p>(b) when the detergent for which a data sheet has already been requested no longer corresponds to the information included in that datasheet.</p>	<p>Before placing the detergent on the market, the data sheet should be submitted to the Member States' appointed bodies without being requested (alignment with Article 45(1) and Annex VIII Part A point 3.1 of the CLP Regulation). This is absolutely important and necessary and the only way to ensure timely medical advice in emergencies. Detergents are not only relevant in allergy emergencies, but also in poisoning emergencies, e.g. when swallowed by children. Therefore point a should be deleted. The content of point b should be inserted in the first subparagraph in a slightly modified form and "before placing a detergent on the market" should be named explicitly.</p>	<p>Manufacturers shall provide the ingredient data sheet to the Member States' appointed bodies referred to in the first subparagraph in the following cases:</p> <p>(a) upon request from the Member States' appointed bodies;</p> <p>(b) when the detergent for which a data sheet has already been requested no longer corresponds to the information included in that datasheet.</p>
<p>The appointed body referred to in the first subparagraph and the medical personnel to which the information contained in the datasheet has been provided shall keep it confidential and use it for medical purposes only.</p>	<p>The use of the ingredient data sheet information should be aligned with Article 45(2) of the Regulation (EC) No 1272/2008.</p>	<p><u>The information included in that data sheet may only be used:</u></p> <p><u>(a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency;</u></p> <p><u>and</u></p> <p><u>(b) where requested by the Member State, the</u></p>

		<p><u>Commission or the European Chemical Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.</u></p> <p><u>The information shall not be used for other purposes.</u></p> <p>The appointed body referred to in the first subparagraph and the medical personnel to which the information contained in the datasheet has been provided shall keep it confidential and use it for medical purposes only.</p>
<p>7. Manufacturers that consider or have reason to believe that a detergent or surfactant which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that detergent or surfactant into conformity, to withdraw it or to recall it, as appropriate.</p> <p>Furthermore, where manufacturers consider or have reason to believe that a detergent or surfactant which they have placed on the market presents a risk to health or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the detergent or surfactant available on the market to that effect, giving details, in</p>		

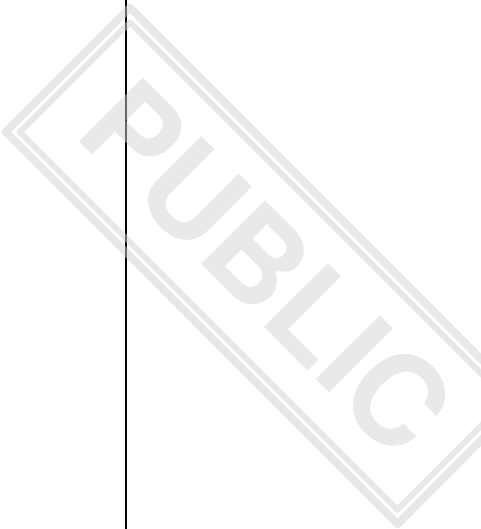
particular, of any non-compliance and of any corrective measures taken.		
8. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the detergent or surfactant with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by a detergent or surfactant which they have placed on the market.		
Article 8 Authorised representative		
1. Manufacturers may, by a written mandate, appoint an authorised representative.	<p>Could the authorised representative become the addressee of market surveillance measures (e.g. recall)? This is our understanding of Article 25(1), as the authorised representative is also an economic operator.</p> <p>For effective market surveillance, the authorised representative should have to comply with all market surveillance measures, even with regard to the elimination of a formal non-compliance. The mandate should cover this.</p> <p>The relationship between the authorised representative under Article 8 of the Regulation proposal and the supplier under Article 4(11) of the draft CLP Regulation (Council Mandate) should be reviewed. This is because the obligations to be fulfilled by both actors differ</p>	

	considerably, e.g. with regard to compliance with the labelling requirements for detergents from manufacturers outside the Union. Uniform regulations should be provided for in the CLP Regulation and in the Detergents Regulation, as around 90 % of detergents also fall within the scope of the CLP Regulation.	
2. Where the manufacturer is not established in the Union, the detergent or surfactant may only be placed on the Union market if the manufacturer designates, by a written mandate, an authorised representative.	In the prohibition of placing on the market the obligation to indicate the name and address of the authorised representative on the label should be included. Otherwise, market surveillance authorities will not be able to contact the authorised representative.	2. Where the manufacturer is not established in the Union, the detergent or surfactant may only be placed on the Union market if the manufacturer designates, by a written mandate, an authorised representative <u>and if the name and the postal and email address at which the manufacturer's authorised representative can be contacted are indicated on the label of the detergent or surfactant.</u>
3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request. The mandate shall allow the authorised representative to do at least the following:		
(a) verify that the product passport has been created in accordance with Article 7(2), point (a), that the technical documentation has been drawn up and the conformity assessment procedure has been carried out by the manufacturer in accordance with Article 7(2);	The authorised representative has also to verify that the ingredient data sheet has already been provided to Member States' appointed bodies according to Article 7(6).	(a) verify that the product passport has been created in accordance with Article 7(2), point (a), that the technical documentation has been drawn up and the conformity assessment procedure has been carried out by the manufacturer in accordance with Article 7(2) and that the

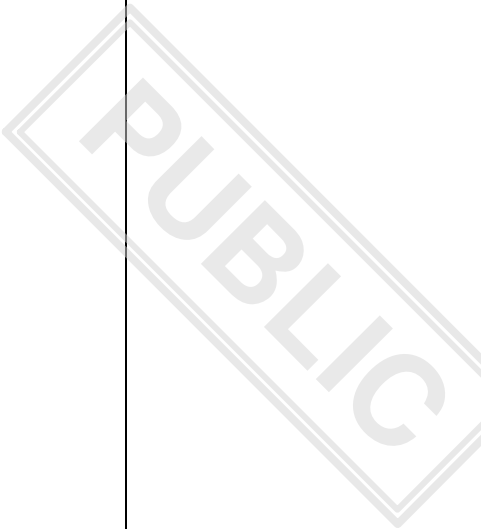
		<u>ingredient data sheet has been provided to Member States' appointed bodies in accordance with Article 7(6);</u>
(b) keep the product passport and technical documentation at the disposal of national market surveillance authorities for 10 years after the detergent or surfactant covered by those documents has been placed on the market;	See justification relating to Article 7(3).	(b) keep the product passport and technical documentation at the disposal of national market surveillance authorities for 10 years after the <u>manufacturer who appointed the authorised representative has made available the detergent or surfactant covered by those documents has been placed on the market for the last time;</u>
(c) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the detergent or surfactant with the requirements laid down in this Regulation;		
(d) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by a detergent or surfactant covered by the authorised representative's mandate.		
(e) terminate the mandate if the manufacturer does not comply with the obligations of the manufacturer under this Regulation.		
4. The obligations laid down in Article 7(1) and the obligation to draw up technical documentation		

referred to in Article 7(2) shall not form part of the authorised representative's mandate.		
Article 9 Obligations of importers		
1. Importers shall place only compliant detergents or surfactants on the market.		
2. Before placing a detergent or surfactant on the market importers shall ensure the following:		
(a) the manufacturer has carried out the conformity assessment procedure and drawn up the technical documentation referred to in Article 7(2);	The importer has also to ensure that the manufacturer has provided the ingredient data sheet to Member States' appointed bodies referred to in Article 7(6). According to CLP Regulation the importer shall have an obligation to submit the data sheet.	(a) the manufacturer has carried out the conformity assessment procedure and drawn up the technical documentation referred to in Article 7(2) <u>and provided the ingredient data sheet to Member States' appointed bodies referred to in Article 7(6);</u>
(b) the detergent bears the CE marking referred to in Article 14;		
(c) the manufacturer has created the product passport referred to in Article 7(2);		
	The attachment of the data carrier to the label in accordance with Article 7(2) point b must also be ensured.	<u>(d) the data carrier is printed or otherwise placed on the label or on the packaging of the detergent or surfactant in a visible and legible manner in accordance with Article 18(3);</u>
(d) the relevant information on the product passport has been included in the registry referred to in Article 20(1).		
3. Where an importer considers or has reason to believe that a detergent or surfactant is not in conformity with this Regulation, the importer shall not place the detergent or surfactant on the market until it has been brought into		

<p>conformity. Furthermore, where the detergent or surfactant presents a risk to health or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</p>		
<p>4. Importers shall indicate their name, registered trade name or registered trade mark and the postal and email address at which they can be contacted on the label of the detergent or surfactant. The contact details shall be in a language easily understood by end-users and market surveillance authorities.</p>		
<p>5. Importers shall ensure that detergents and surfactants that they place on the market comply with the labelling requirements laid down in Articles 15, 16 and 17.</p>		
<p>6. Importers shall ensure that, while a detergent or surfactant is under their responsibility, its storage or transport conditions do not jeopardise its compliance with this Regulation.</p>		
<p>7. When deemed appropriate with regard to the performance of a detergent or surfactant or the risks presented by them, importers shall carry out sample testing of such detergents and surfactants, investigate, and, if necessary, keep a register of complaints, of non-conforming detergents and surfactants and recalls of such detergents and surfactants, and shall keep distributors informed of any such monitoring.</p>		

<p>8. Importers that consider or have reason to believe that a detergent or surfactant which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that detergent or surfactant into conformity, to withdraw it or to recall it, as appropriate.</p> <p>Furthermore, where importers consider or have reason to believe that a detergent or surfactant which they have placed on the market presents a risk to health or the environment, they shall immediately inform the competent national authorities of the Member States in which they made the detergent or surfactant available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.</p>		
<p>9. Importers shall keep the reference to the unique product identifier at the disposal of the market surveillance authorities for a period of 10 years after the detergent or surfactant has been placed on the market and shall ensure that the technical documentation can be made available to those authorities, upon request.</p>	<p>See justification relating to Article 7(3).</p>	<p>9. Importers shall keep the reference to the unique product identifier at the disposal of the market surveillance authorities for a period of 10 years after <u>having made available</u> the detergent or surfactant has been placed on the market <u>by the importers for the last time</u> and shall ensure that the technical documentation can be made available to those authorities, upon request.</p>
<p>10. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information</p>		

<p>and documentation, in paper or electronic form, necessary to demonstrate the conformity of the detergent or surfactant with this Regulation in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by a detergent or surfactant which they have placed on the market.</p>		
<p style="text-align: center;">Article 10 Obligations of distributors</p>		
<p>1. When making a detergent or surfactant available on the market distributors shall act with due care in relation to the requirements of this Regulation</p>	<p>In general, the obligations arising from this and CLP Regulation (EC) No 1272/2008 should be harmonised.</p>	
<p>2. Before making a detergent or surfactant available on the market distributors shall verify that the following conditions have been met:</p>		
<p>(a) the detergent or surfactant is accompanied by the required documents and by a label that meets the requirements laid down in Articles 15, 16 and 17;</p>		
<p>(b) the detergent bears the CE marking referred to in Article 14;</p>		
<p>(c) the manufacturer has complied with the requirements set out in Article 7(2) and (3) or, as applicable, the importer has complied with the requirements set out in Article 9(2).</p>	<p>The distributor should also have the obligation to verify that the manufacturer has provided the ingredient data sheet to Member States' appointed bodies referred to in Article 7(6).</p>	<p>(c) the manufacturer has complied with the requirements set out in Article 7(2), and (3) <u>and (6)</u> or, as applicable, the importer has complied with the requirements set out in Article 9(2).</p>
<p>3. Where a distributor considers or has reason to believe that a detergent or surfactant is not in</p>		

<p>conformity with this Regulation, the distributor shall not make the detergent or surfactant available on the market until it has been brought into conformity.</p> <p>Furthermore, where the detergent or surfactant presents a risk to health or the environment, the distributor shall inform the manufacturer and, where relevant, the authorised representative or the importer to that effect as well as the market surveillance authorities.</p>		
<p>4. Distributors shall ensure that, while a detergent or surfactant is under their responsibility, its storage or transport conditions do not jeopardise its compliance with this Regulation.</p>		
<p>5. Distributors that consider or have reason to believe that a detergent or a surfactant which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that detergent or surfactant into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where distributors consider or have reason to believe that a detergent or surfactant which they have made available on the market presents a risk to health or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the detergent or surfactant available on the market to that effect,</p>		

<p>giving details, in particular, of any non-compliance and of any corrective measures taken.</p>		
<p>6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the detergent or surfactant with this Regulation. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by detergents and surfactants which they have made available on the market.</p>		
<p style="text-align: center;">Article 11 Cases in which obligations of manufacturers apply to importers and distributors</p>		
<p>An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer under Article 7 where that importer or distributor places a detergent or surfactant on the market under his or her name or trademark or modifies a detergent or surfactant already placed on the market in such a way that compliance with this Regulation may be affected.</p>	<p>According to our understanding, Article 11 applies to importers and distributors who rebrand detergents or change the characteristics of detergents. However, Article 11 should also apply to importers or distributors who change or create the labelling of a detergent. Otherwise, in our opinion, there would be a regulatory gap. The importer or distributor who changes the label would have no obligation to update the product passport or the technical documentation so that those documents would not reflect the actual label of the detergent after the change.</p>	
<p style="text-align: center;">Article 12 Packaging and repackaging by importers and distributors</p>		

<p>Where an importer or distributor packages or repackages a detergent or surfactant and is not subject to the obligations of the manufacturer pursuant to Article 11, that importer or distributor, as applicable, shall have the following obligations:</p>	<p>It is necessary that, in addition, the requirements of Article 10 are met.</p>	<p>Where an importer or distributor packages or repackages a detergent or surfactant and is not subject to the obligations of the manufacturer pursuant to Article 11, that importer or distributor, as applicable, shall have <u>in addition to the obligations pursuant to Article 10</u> the following obligations:</p>
<p>(a) to ensure that the package bears his or her name, registered trade name or registered trade mark and postal address preceded by the words 'packaged by' or 'repackaged by';</p>		
<p>(b) to ensure compliance with Articles 14 to 17;</p>		
<p>(c) to keep the reference to the unique product identifier at the disposal of the market surveillance authorities for 10 years after having made the detergent or surfactant available on the market.</p>	<p>Here, it should be clarified that the making available on the market for the last time should be the starting point for the 10 years period. If a detergent is placed on the market unchanged for more than 10 years, no information would eventually be available.</p>	<p>(c) to keep the reference to the unique product identifier at the disposal of the market surveillance authorities for 10 years after having made <u>available the detergent or surfactant on the market for the last time</u> having made the detergent or surfactant available on the market.</p>
<p>Article 13 Identification of economic operators</p>		
<p>1. Economic operators shall, on request, identify the following to the market surveillance authorities: (a) any economic operator who has supplied them with a detergent or a surfactant;</p>		
<p>(b) any economic operator to whom they have supplied a detergent or a surfactant.</p>		
<p>2. Economic operators shall be able to provide the information referred to in paragraph 1 for 10</p>	<p>Here, it should also be clarified that the time of the last supply is the starting point of the 10 years period.</p>	<p>2. Economic operators shall be able to provide the information referred to in paragraph 1 for 10</p>

<p>years after they have been supplied with the detergent or surfactant and for 10 years after they have supplied the detergent or surfactant.</p>		<p>years after <u>being</u> have been supplied with the detergent or surfactant <u>for the last time</u> and for 10 years after <u>they have having</u> supplied the detergent or surfactant <u>for the last time</u>.</p>
<p>CHAPTER IV CE MARKING AND LABELLING</p>		
<p>Article 14 Rules and conditions for affixing the CE marking</p>		
<p>1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.</p>		
<p>2. The CE marking shall be affixed visibly, legibly and indelibly before a detergent is placed on the market. The CE marking shall be affixed either to the label or the packaging of a detergent or, where the detergent is supplied in bulk, to a document accompanying the detergent. Where, in accordance with Article 16(2), economic operators may provide a digital label only, the CE marking shall be provided on the digital label.</p>	<p>It is noted that the CE-marking according to Article 14 (2) shall be affixed “visibly, legibly and indelibly” to the label or the packaging (or to a document accompanying a detergent supplied in bulk). However, there seems to be no corresponding requirement for all the other mandatory labelling requirements when a physical label is used. A requirement should be added that the labelling elements in Article 15 (3) and, where applicable, 15 (4), when provided on a physical label, shall be visibly, legibly and indelibly affixed to the label. In addition, specification of a minimum font size for characters printed on the physical label would be desirable.</p>	
<p>3. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.</p>		
<p>Article 22 Procedure at national level for dealing with detergents and</p>		

surfactants presenting a risk		
Paragraph 1	Currently no comments.	
2. Where the market surveillance authorities of one Member State have sufficient reason to believe that a test carried out in accordance with the methods listed in Annex I or Annex II has produced false results, they shall perform controls to verify the compliance of the detergent or surfactant with this Regulation in accordance with the reference methods set out in Annexes I, II and VII. Economic operators shall not be obliged to pay for any repeat or additional test, provided that the initial test has shown compliance of detergents, or surfactants, with this Regulation.	The reference to Annex VII should be deleted (see comment on Annex VII). At the same time, there is no reference to testing the P-limitation in accordance with the specifications in Annex III, including recognised test methods which should be added.	2. Where the market surveillance authorities of one Member State have sufficient reason to believe that a test carried out in accordance with the methods listed in Annex I or Annex II has produced false results, they shall perform controls to verify the compliance of the detergent or surfactant with this Regulation in accordance with the reference methods set out in Annexes I and II and VII . Economic operators shall not be obliged to pay for any repeat or additional test, provided that the initial test has shown compliance of detergents, or surfactants, with this Regulation.
Paragraph 3 to 10.	Currently no comments.	
Article 23 Union safeguard procedure		
1. Where, on completion of the procedure set out in Article 22(3), (4) and (5), objections are raised against a measure taken by a market surveillance authority, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the market surveillance authorities and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt	Paragraph 6 of Article 22 should be added, as we believe that this concerns the assessment of the national measure by the Commission.	1. Where, on completion of the procedure set out in Article 22(3), (4) and (5) <u>and (6)</u> , objections are raised against a measure taken by a market surveillance authority, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the market surveillance authorities and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt

<p>an implementing act determining whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall without delay communicate it to them and the relevant economic operator or operators.</p>		<p>an implementing act determining whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall without delay communicate it to them and the relevant economic operator or operators.</p>
<p>2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant detergent or surfactant is withdrawn from their market, and shall inform the Commission accordingly.</p>		
<p>3. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.</p>		
<p>Article 24 Compliant detergents and surfactants which present a risk to health or to the environment</p>	<p>Currently no comments.</p>	
<p>Article 25 Formal non-compliance</p>		
<p>1. Without prejudice to Article 22, where a market surveillance authority makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:</p>		
<p>(a) the CE marking has been affixed in violation of Article 14 or not affixed at all;</p>		
<p>(b) the product passport has not been drawn up in accordance with Articles 18 and 19;</p>	<p>Formal non-compliance must also refer to the uploading of the product passport in the registry before the detergent is placed on the market.</p>	<p>(b) the product passport has not been drawn up in accordance with Articles 18 and 19 <u>and not been uploaded in the product passport registry in accordance with Article 20</u> ;</p>

(c) the technical documentation referred to in Article 7(2) is either not available or incomplete;		
(d) the data carrier through which the product passport and, where relevant, the digital label is accessible is not present on the detergent or surfactant, their packaging, the documentation accompanying them or on the refill station, as applicable;		
(e) the label has not been provided or the labelling information referred to in Articles 15 and Annex V is false or incomplete;	Non-compliance should also refer to incorrect labelling in relation to the requirements of Articles 16 and 17.	(e) the label has not been provided <u>or has not been provided correctly in accordance with Article 16 and 17</u> or the labelling information referred to in Articles 15 and Annex V is false or incomplete;
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the detergent or surfactant being made available on the market or ensure that it is recalled or withdrawn from the market.		

Article 2 Definitions		
For the purpose of this Regulation, the following definitions apply:		
(1) – (12) ...		
Point 13 to 25	Currently no comments.	
(26) – (35) ...		

Commission Proposal (28. April 2023) COM(2023) 217 final	Comments Justification for proposed amendments	Proposed amendments
		(The rejected text of the Commission proposal is marked in strike through , a new text proposal in <u>underlined</u>)

ANNEX IV CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7(2)		
Module A - Internal production protocol		
1. Description of the module		
Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the detergent or surfactant concerned satisfy the requirements of this Regulation that apply to them.	In Annex IV, in relation to the obligations a manufacturer has to fulfil in the conformity assessment procedure, it is referred to “points 2, 3 and 4”. However, Annex IV does not contain a point 4.	
2. Technical documentation		
2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess conformity of the detergent or surfactant with the relevant requirements, and shall include an adequate analysis and assessment of the risks.		
2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the detergent or surfactant. The technical documentation shall contain, where applicable, at least the following elements:		
(a) a general description of the detergent or surfactant and a description of the intended use;		

(b) the test reports demonstrating the compliance with Annex I and, where applicable, with Annexes II and III;		
(c) a list of test methods used to demonstrate compliance with the requirements of this Regulation ;		
(d) results of calculations made and examinations carried out;		
(e) an ingredient data sheet which meets the following requirements:		
(i) lists all intentionally added substances and preservatives referred to in Part A of Annex V;	<p>(1) It is absolutely important and necessary that</p> <ul style="list-style-type: none"> • all added substances are listed in the ingredient data sheet not only those listed in Part A of Annex V (knowledge of all such ingredients is medically necessary in a case of poisoning), • the name of the detergent and of the manufacturer are given in case of queries • the intended use of the detergent is stated. <p>Knowledge of all components is necessary for various medical reasons. Especially for the emergency health response, the all-clear can only be safely given if all components are known. If only selected ingredients are known (especially since they are not selected according to toxicological aspects), this can also contribute to an overtreatment that may not be necessary, which can lead to increased costs or pose a health risk to the patient.</p> <p>(2) The word "intentionally" could lead to ambiguity and should be deleted. The wording was obviously intended to</p>	<p>(i) <u>the name of the detergent and of the manufacturer and the intended use of the detergent;</u></p> <p>(ii) lists all <u>intentionally</u> added substances <u>including</u> and preservatives <u>whereas impurities are not taken into account</u> referred to in Part A of Annex V;</p>

	exclude impurities (see proposed addition).	
(ii) the common chemical name or IUPAC name and, where available, the INCI name, the CAS number, and the European Pharmacopoeia name, is given for each ingredient;	In addition to the CAS number, the EC number of the substance should be reported (analogous to Annex VIII of the CLP Regulation).	(iii) the common chemical name or IUPAC name and, where available, the INCI name, the CAS number, and the EC number, and the European Pharmacopoeia name, is given for each ingredient;
(iii) all substances are listed in order of decreasing abundance by weight, and the list is subdivided into the following weight percentage ranges:		(iii) all substances are listed in order of decreasing abundance by weight, and the list is subdivided into the following weight percentage ranges:
(1) 10 % or more,		
(2) 1 % or over, but less than 10 %,		
(3) 0,1 % or over, but less than 1 %,		
(4) less than 0,1 %.		
For the purposes of point (e), a perfume, an essential oil, or a colouring agent shall be considered to be a single component.		
3. Manufacturing		
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the detergent or surfactant with the technical documentation referred to in point 2 and with the requirements of this Regulation that apply to them.		

3. Cluster 3 – Labelling & Digital Labelling

Article 15 - General labelling requirements

Article 16 - Forms of labelling

Article 17 – Requirements for digital labelling

Article 26 (7), (8) and (9) – Delegated Powers

Article 2 – Definitions

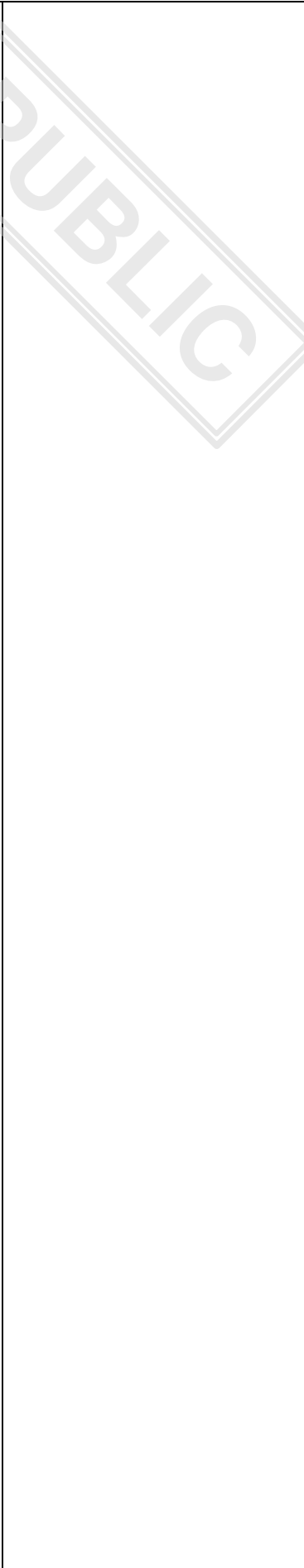
points 27, 32, 33, 35

Annex V – Labelling Requirements

Commission Proposal (28. April 2023) COM(2023) 217 final	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in striketrough , a new text proposal in <u>underlined</u>)
Article 15 General labelling requirements		
1. Detergents and surfactants that are made available on the market in individual packaging or in a refill format shall be accompanied by a label.		
2. An economic operator making a detergent available on the market directly to an enduser in a refill format shall provide the physical label or the data carrier through which the digital label is accessible to the end- user.		
3. The label of detergents and surfactants shall contain the following information:		
(a) a type number, batch number or other element		

allowing their identification;		
(b) the manufacturer's name, registered trade name or registered trade mark and the postal and email address at which they can be contacted. The postal address shall indicate a single point at which the manufacturer can be contacted;	The telephone number should also be indicated (see CLP Regulation)	(b) the manufacturer's name, registered trade name or registered trade mark and <u>the telephone number</u> , the postal and email address at which they can be contacted. The postal address shall indicate a single point at which the manufacturer can be contacted;
(c) the name and trade name of the product;		
(d) the content of the detergent or surfactant in accordance with part A of Annex V;		
(e) instructions for use and special precautions, where necessary and relevant.		
The information referred to in points (a), (b) and (c) of the first subparagraph shall appear on all documents accompanying detergents and surfactants transported in bulk.	In order to ensure legibility of the information on the physical label, a corresponding sentence should be inserted. In addition, it would be desirable to specify a minimum font size for the characters printed on the physical label.	The information referred to in points (a), (b) and (c) of the first subparagraph shall appear <u>on a physical label in legible, visible and indelible characters and</u> on all documents accompanying detergents and surfactants transported in bulk.
4. In addition to the information referred to in paragraph 3, the label of consumer laundry detergents and consumer automatic dishwasher detergents shall contain dosage information in accordance with part B of Annex V.	Consequential amendment to the insertion in paragraph 3.	4. In addition to the information referred to in paragraph 3, the label of consumer laundry detergents and consumer automatic dishwasher detergents shall contain dosage information in accordance with part B of Annex V. <u>This information shall appear on a physical label in legible, visible and indelible characters.</u>
5. The information referred to in paragraphs 3 and 4		

<p>shall be in a language which can be easily understood by end-users, as determined by the Member State concerned, and shall be clear, understandable and intelligible. The label shall be accessible for inspection purposes where the detergent or surfactant is made available on the market.</p>		
<p>Article 16</p> <p>Forms of labelling</p>		
<p>1. Where detergents or surfactants are made available on the market, they shall be accompanied by the label elements set out in Article 15(3) and, where applicable, Article 15(4) in the following form:</p> <p>(a) on a physical label;</p> <p>(b) on a digital label and duplicated on a physical label.</p> <p>By way of derogation from point (b) of the first subparagraph, the labelling elements set out in part C of Annex V do not have to be duplicated on the physical label. In addition, where the dosage information for consumer laundry detergents in accordance with points 1 and 2 of part B of Annex V is provided on the digital label, a simplified dosage grid as set out in part D of Annex V may be provided on the physical label.</p>	<p>In principle, the labelling requirements for detergents should be aligned with the requirements of the draft CLP Regulation (see Article 34a(1) – Council mandate - below), as many detergents are mixtures that are classified as hazardous under the CLP Regulation. Since both labelling requirements must be met, it makes no sense to use different labelling formats.</p> <p><u>[Council mandate: Article 34a(1)</u></p> <p><u>Physical and digital labelling</u></p> <p><u>1. The label elements for substances and mixtures referred to in Article 17 shall be provided on a label in a physical form ('physical label'). In addition to the physical label, the label elements referred to in Article 17 may be provided in a digital form ('digital label').]</u></p> <p>In order to protect consumers, all ingredients to be labelled shall be listed on the physical label and may not be transferred, even partially, to digital-only labelling. Therefore the empowerment in Article</p>	<p>...</p> <p>By way of derogation from point (b) of the first subparagraph, the labelling elements set out in part C of Annex V do not have to be duplicated on the physical label.</p> <p>...</p>

	<p>26(9) and Part C of Annex V should be deleted.</p> <p>In the case of poisoning with a detergent containing surfactants or soap, for example, foaming with possible blockage of the airways or aspiration into the lungs (risk of respiratory distress and suffocation) can be prevented or reduced by the rapid administration of defoaming medication. However, this requires the first aider to be aware of the presence of surfactants/soap in the mixture. It can be assumed that this information is available much more quickly if it is provided on the physical label than if the data carrier has to be read out first, especially if there is no or a faulty internet connection. Therefore, the various surfactants as well as soap should always be on the physical label.</p> <p>Furthermore, we propose to use the digital product passport as the single source of information provided digitally. We therefore firmly reject the parallel introduction of a digital label as well as a digital product passport. Since both concepts are leading towards the same objective we advocate to streamline the wording to avoid fragmentation and the build-up of parallel structures and similar obligations for economic operators. We propose to use the Digital Product Passport concept as it is being introduced in the Ecodesign for Sustainable Products Regulation (ESPR) and rolled out in a variety of product legislations of the EU (Batteries, Toys, etc.). There would be no lack of information since the digital product passport already contains the list</p>	
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	of ingredients (Annex VI). Only the weight ranges would additionally have to be specified in the product passport.	
2. By way of derogation from paragraph 1, where detergents are made available on the market directly to an end-user in a refill format, the label elements set out in Article 15(3) and (4) may be provided in a digital label only, with the exception of dosage information for consumer laundry detergents as set out in point 1 and 2 of part B of Annex V, which needs to be provided also on a physical label.	<p>The labelling requirements for detergents made available on the market in a refill format should be aligned with the requirements of the CLP Regulation.</p> <p>Currently, the draft CLP Regulation does not provide for digital labelling for refill stations. This should also apply to detergents sold in refill stations. Therefore, the labelling requirements set out in Articles 14 and 15 shall be applied to a physical label for each refilled package.</p>	2. By way of derogation from paragraph 1, where detergents are made available on the market directly to an end user in a refill format, the label elements set out in Article 15(3) and (4) may be provided in a digital label only, with the exception of dosage information for consumer laundry detergents as set out in point 1 and 2 of part B of Annex V, which needs to be provided also on a physical label.
Article 17 Requirements for digital labelling	The digital labelling requirements for detergents and surfactants should in principle be aligned with the requirements of the CLP Regulation.	
1. Where detergents and surfactants carry a digital label in accordance with Article 16, the following rules shall apply to that label:		
(a) all label elements referred to in Article 15(3) and, where applicable, Article 15(4) shall be provided in one place and separated from other information;		
(b) the information on the digital label shall be searchable;		
(c) the information on the digital label shall be accessible to all users in the Union;		

<p>(d) the digital label shall be accessible free of charge, without the need for prior registration, download or installation of applications, or to provide a password;</p>		
<p>(e) the information on the digital label shall be presented in a way that addresses the needs of vulnerable groups and supports, as relevant, the necessary adaptations to facilitate access to the information by those groups;</p>		
<p>(f) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;</p>		
<p>(g) when the digital label is available in more than one language, the choice of language shall not be conditioned on the geographical location of the end-user;</p>		
<p>(h) the digital label shall remain available for a period of 10 years from the moment the detergent or surfactant is placed on the market, also in cases of an insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created it, or for a longer period as required under other Union legislation covering the information that it contains;</p>	<p>See above Article 7(3).</p>	<p>(h) the digital label shall remain available for a period of 10 years from the moment the detergent or surfactant <u>is made available on the market for the last time</u>placed on the market, also in cases of an insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created it, or for a longer period as required under other Union legislation covering the information that it contains;</p>

<p>(i) the information on the digital label shall be accessible via the data carrier</p>		
<p>2. The data carrier shall be physically present on the detergent or surfactant, their packaging or the documentation accompanying them.</p> <p>In addition to the requirement in the first subparagraph, where detergents and surfactants are made available on the market in a refill format, the data carrier shall be present on the refill station.</p> <p>The data carrier shall be clearly visible to the end-user before any purchase and to market surveillance authorities, including, where applicable, in cases where the detergent or surfactant is made available through distance sales.</p>	<p>A requirement should be added to the first subparagraph of Article 17(2) that the physical attachment of the data carrier must be clearly visible, legible and indelible so that the data carrier can be easily found in the event of a subsequent emergency (case of poisoning).</p> <p>For the same reason, in the case of "refill", the requirement should be included that dispensing in this form is only permissible if the data carrier is physically, "clearly visibly, legibly and indelibly" affixed on the end-users' own packaging or on any accompanying documents that may have to be provided.</p>	
<p>3. Where economic operators provide a digital label, the data carrier shall be accompanied by the statement 'More comprehensive information on the product is available online' or by a similar statement.</p>		
<p>4. Economic operators providing a digital label shall not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the information on the digital label online.</p>		

5. Economic operators providing a digital label shall provide the information present in the digital label by other means in any of the following cases:		
(a) upon oral or written request by the end-user;		
(b) when the digital label is temporarily unavailable, including at the time of purchase. Economic operators shall provide the information referred to in the first subparagraph independently from a purchase of a detergent or surfactant and free of charge.		
		Article 17a (new) Distance sales offers
	Alignment with Article 48a of the draft CLP Regulation (Council mandate).	<u>When detergents or surfactants are made available on the market through distance sales, the offer shall clearly and visibly indicate the label elements referred to in Article 15.</u>

Article 26 Delegated powers		
(1) – (6) ...		
Paragraph 7 and 8	Currently no comments.	
9. The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annex V, as regards the labelling information, which economic operators are allowed to provide only digitally in accordance with Article 16, for the purposes of adapting it to technical and scientific progress and to the level	As noted on Article 16, the empowerment should be deleted in order to ensure that labelling of ingredients/content information referred to in Part A of Annex V should always be provided on the physical label.	9. The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annex V, as regards the labelling information, which economic operators are allowed to provide only digitally in accordance with Article 16, for the purposes of adapting it to technical and scientific progress and to the level

of digital readiness among the end-users of detergents. When adopting those delegated acts, the Commission shall take into account the need to ensure a high level of protection of health and environment.		of digital readiness among the end-users of detergents. When adopting those delegated acts, the Commission shall take into account the need to ensure a high level of protection of health and environment.
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Article 2 Definitions		
For the purpose of this Regulation, the following definitions apply:		
(1) – (26) ...		
Point 27	Currently no comments.	
(28) – (31) ...		
Point 32 and 33	Currently no comments.	
(34) ...		
Point 35	Currently no Comments.	

Commission Proposal (28. April 2023) COM(2023) 217 final	Comments Justification for proposed amendments	Proposed amendments (The rejected text of the Commission proposal is marked in <u>strikethrough</u>, a new text proposal in <u>underlined</u>)
ANNEX V LABELLING REQUIREMENTS PART A – LABELLING OF CONTENTS		
The information to be included on the labels of detergents and surfactants made available on the market		
1. The weight percentage ranges 'less than 5 %', '5 % or over but less than 15 %', '15 % or over but less than 30 %', '30 % and more', shall be used to indicate the content of the constituents listed below where they are added in a concentration above 0,2 % by weight:		
(a) phosphates, (b) phosphonates,		

<p>(c) anionic surfactants, (d) cationic surfactants, (e) amphoteric surfactants, (f) non-ionic surfactants, (g) oxygen-based bleaching agents, (h) chlorine-based bleaching agents, (i) EDTA and salts thereof, (j) NTA (nitrilotriacetic acid) and salts thereof, (k) phenols and halogenated phenols, (l) paradichlorobenzene, (m) aromatic hydrocarbons, (n) aliphatic hydrocarbons, (o) halogenated hydrocarbons, (p) soap, (q) zeolites, (r) polycarboxylates.</p>		
<p>2. The following classes of constituents, if added, shall be listed irrespective of their concentration:</p>	<p>To avoid ambiguities „if added“ should be deleted or replaced by “if contained”.</p>	<p>2. The following classes of constituents, if added, shall be listed irrespective of their concentration:</p>
<p>(a) enzymes, (b) micro-organisms, (c) optical brighteners, (d) perfumes.</p>		
<p>3. Preservatives shall be listed, using where possible the system referred to in Article 33 of Regulation (EC) No 1223/2009, irrespective of their concentration, provided that they meet the following conditions:</p>		
<p>(a) contribute to the qualification of the detergent as a treated article within the meaning of Article 3(1), point (l), of Regulation (EU) No 528/2012;</p>		

<p>(b) are labelled on a constituent of the detergent.</p> <p>The condition listed in point (b) of the first subparagraph does not have to be met where preservatives do not exceed the elicitation thresholds referred to in point 3.4.3.3. / table 3.4.6. of Annex I to Regulation (EC) No 1272/2008 or they no longer have a preservation function in the final product even in synergies with other preservatives.</p>	<p>The half-sentence at the end should be deleted because market surveillance authorities are not able to objectively check whether this requirement has been met.</p> <p>It is hard to determine what the term „function“ implies. It is eventually up to a subjective assessment whether or not a function is given. Furthermore, it is not clear how the synergistic effects of different preservatives in a mixture are determined and proven with regard to their labelling (test procedure?).</p> <p>It should also be noted that the trigger thresholds for contact allergic reactions are individually very different. It cannot be assumed that mandatory labelling only above the trigger thresholds defined in the CLP Regulation can protect each individual from triggering contact dermatitis.</p> <p>Taking these considerations into account, a labelling requirement for preservatives with sensitising hazard potential, regardless of the concentration or the preservative effect present in the product, would be better suited to protect already sensitised individuals from triggering allergic contact dermatitis by giving them the opportunity to avoid the product.</p>	<p>(b) are labelled on a constituent of the detergent.</p> <p>The condition listed in point (b) of the first subparagraph does not have to be met where preservatives do not exceed the elicitation thresholds referred to in point 3.4.3.3. / table 3.4.6. of Annex I to Regulation (EC) No 1272/2008 or they no longer have a preservation function in the final product even in synergies with other preservatives.</p>
<p>4. If added at concentrations exceeding 0,01 % by weight, the allergenic fragrances that are listed in entries 45, 67-92 and [X] to [X] of Annex III to Regulation (EC) No 1223/2009, shall be labelled using the system referred to in Article 33 of that Regulation. The first sentence shall not apply to allergenic fragrances that meet the labelling thresholds under</p>	<p>It needs to be ensured that allergenic fragrances which are prohibited for use in cosmetics and therefore have been removed from Annex III and included in Annex II of Regulation (EC) No 1223/2009 continue to be labelled on detergents, as they are not prohibited for use in detergents. To protect consumers, it would even be more appropriate if the ban on certain fragrances in cosmetic products (Annex II) also applied to detergents (e.g.: Lyril und Lilial).</p>	<p>4. If added at concentrations exceeding 0,01 % by weight, the allergenic fragrances that are listed in entries 45, 67-92 and [X] to [X] of Annex III to Regulation (EC) No 1223/2009 or <u>have been removed from Annex III and included in Annex II of Regulation (EC) No 1223/2009</u>, shall be labelled using the system referred to in Article 33 of that Regulation.</p>

Regulation (EC) No 1272/2008.	We would also request to check whether the reference to individual entries in Annex III of the Cosmetics Regulation (EC) No 1223/2009 is necessary or whether a sliding reference to the entire Annex III is sufficient, perhaps to the corresponding labelling of allergenic fragrances in column h (“other restrictions”) of Annex III. In the latter case, the empowerment in Article 26 paragraph 7 could be deleted.	
5. The requirements referred to in points 1 to 4 shall not apply to professional detergents and surfactants, provided that the equivalent information to that required in those points is provided in section 15 of the safety data sheet drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006.		
6. In addition to the information listed in points 1 to 5, as applicable, the label of detergents containing micro-organisms shall bear the following information:		
a) an indication or a precautionary statement that the product is not to be used on surfaces in contact with food;		
(b) an indication of the shelf life of the product;		
(c) use instructions or special precautions, where relevant.		
PART B – LABELLING OF DOSAGE INFORMATION	Currently no comments.	
PART C – DIGITAL LABELLING	All ingredients/content information referred to in part A shall always be indicated on the physical label as well and therefore may not be available only digitally (see comment on Article 16 and amendment on	PART C – DIGITAL LABELLING

	Article 26(9)). PART C can therefore be deleted completely.	
The following content information referred to in part A, may be provided on the digital label only, in accordance with Article 16(1), second subparagraph, in the manner specified in that part:		The following content information referred to in part A, may be provided on the digital label only, in accordance with Article 16(1), second subparagraph, in the manner specified in that part:
(a) anionic surfactants; (b) cationic surfactants; (c) amphoteric surfactants; (d) non-ionic surfactants; (e) phosphates; (f) phosphonates; (g) soap.		(a) anionic surfactants; (b) cationic surfactants; (c) amphoteric surfactants; (d) non-ionic surfactants; (e) phosphates; (f) phosphonates; (g) soap.
PART D – SIMPLIFIED DOSAGE INFORMATION FOR CONSUMER LAUNDRY DETERGENTS	Currently no comments.	