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WORKING DOCUMENT

From:	Commission services
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
Subject:	Regulation on detergents : Discussion paper

Discussion paper

Disclaimer: this document aims to support the technical discussion in the ongoing negotiations for the adoption of a Regulation of the European Parliament and the Council on detergents and surfactants (2023/0124(COD)). It is not necessarily the official position of the European Commission.

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Ingredients data sheet

Rows concerned: 159-163h, 171b, 190

Supporting documents: see the explanations already provided in WK 2944/2025 (no changes to the draft included in that discussion paper)

Article 7(6) [rows 159-163h]

6. Manufacturers placing on the market detergents **or end-user surfactants** for which **there is no obligation to provide information in accordance with Article 45 of Regulation (EC) No 1272/2008**, shall provide to Member States' appointed bodies referred to in that Article, the ingredients data sheet referred to in point 2.2 (e) of Annex IV in the following cases:

(a) upon request from the Member States' appointed bodies;

(b) when the detergent or **end-user** surfactant for which an ingredients data sheet has already been **provided** no longer corresponds to the information included in that data sheet.

The information included in the data sheet referred to in point 2.2 (e) of Annex IV shall be kept confidential by the appointed bodies and by medical personnel and may only be used:

(a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; or

(b) where requested by a Member State, the Commission or the Agency established by Regulation (EC) No 1907/2006, to undertake a statistical analysis to identify where improved risk management measures may be needed.

Article 8(3) – tasks of authorized representative [row 171b]

(ab) ensure that the ingredients data sheet can be made available under the conditions set out in Article 7(6);

Article 9(9) – importers [row 190]

… and shall ensure that the ingredients data sheet can be made available under the conditions laid down in Article 7(6).

Article 26 – add a new para 6c

The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annexes IV by setting our requirements on the way the ingredients data sheet is to be communicated in accordance with Article 7(6). When developing these requirements, the Commission shall take into account the need to ensure effective access to the ingredients data sheet to appointed bodies referred to in Article 45 of Regulation (EC) No 1272/2008, as well as the need to limit the administrative burden.

Authorised representative

Rows concerned: rows 166-176

Article 8

Authorised representative

[row 167]

1. Manufacturers may, by a written mandate, appoint an authorised representative. **The mandate shall be valid only when accepted in writing by the authorised representative.**

The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

[row 168]

2. ~~Where the~~ Manufacturer**s** ~~is not~~ established **outside** ~~in~~ the Union, **placing a** ~~the~~ detergent or surfactant ~~may only be placed~~ on the Union market**,** ~~if the manufacturer~~ **shall appoint** ~~designates, by a written mandate,~~ an authorised representative **in the conditions set out in paragraph 1**.

[row 169]

3. ~~*An*~~***The*** 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.*~~

[row 170]

The mandate shall **require** ~~allow~~ the authorised representative to do at least the following:

[row 171]

(a) verify that the ***digital*** 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);

[row 172]

(b) keep the ***digital*** 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;

[row 173]

(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***, in a language that can be easily understood by that authority***;

[row 173a]

(ca) when having reason to believe that a detergent or surfactant presents a risk, inform the manufacturer and the market surveillance authorities thereof;

[row 174]

(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***; and***

[Row 175]

(e) terminate the mandate ***and inform the competent national authorities thereof*** if the manufacturer does not comply with the obligations of the manufacturer under this Regulation***.***

[new row]

3a. In addition to the tasks referred to in paragraph 3, the mandate of the authorized representative appointed in accordance with paragraph 2 shall require the authorized representative to do the following as regards detergents and surfactants covered by that mandate:

[row 171b]

(a) ensure that the ingredients data sheet is communicated under the conditions set out in Article 7(6);

[row 171c]

(b) verify that detergents and surfactants comply with the labelling requirements laid down Articles 15(1), (3)-(5), 16(1) and 17(1)-(4), [and, where applicable, Articles 15(2), 16(2) and 17(5).]

[row 171a]

(c) make best efforts to verify that the documentation and information provided by the manufacturer in accordance with Article 7(6a) demonstrates compliance of the products with the requirements laid down in this Regulation.

[row 176]

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

Biodegradability

Rows concerned: 103a, 134-141d, 354-355, 355c, 384b

Article 2

Definitions

[add a new row 103a]

(12a) 'Film polymers' means polymers used in water-soluble films to encapsulate detergents;

Article 4

Biodegradability

1. Surfactants and surfactants contained in detergents shall comply with the biodegradability criteria laid down in Annex I.

2. Paragraph 1 shall not apply to 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:

(a) 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, or included into Annex I to that Regulation;

(b) the surfactants are included in the review programme as set out in Commission Delegated Regulation (EU) No 1062/2014;

(c) the surfactants are constituents of disinfectants which may be made available on the market or used in accordance with Article 55 of Regulation (EU) No 528/2012.

Article 26

[row 354]

The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annex I and, where appropriate, Article 4 to:

[row 354a]

(a) amend the biodegradability criteria and corresponding test methods for surfactants or surfactants contained in detergents;

[rows 141a, 141b, 354b]

(b) set out biodegradability criteria and corresponding test methods for intentionally added organic substances other than surfactants; or

[row 354c]

(c) set out exceptions authorising the limited use in detergents of specific organic substances that do not comply with the biodegradability criteria laid down in accordance with point (b), when duly justified.

For the purpose of point (b), the Commission shall assess the need to set out biodegradability criteria for:

- Film polymers by [3 years from the entry into force of this Regulation] and
- Other intentionally added organic substances in concentration of at least 10% in detergents, by [5 years from entry into force of this Regulation].

[rows 141a, 355]

The purpose of the delegated acts referred to in the first sub-paragraph shall be to ensure a high level of protection of human health and the environment. When adopting such delegated acts, the Commission shall take into account:

i. the impact on human health and the environment, including scientific evidence pointing to the existence of a risk.

ii. manufacturing practices

iii. the availability of technically and economically feasible alternatives,

iv. the consequence on wastewater treatment plants,

v. the impacts to small and medium-sized enterprises.

Article 32

[row 384]

By [7 *years from the date of entry into force of this Regulation*], the Commission s**hall submit to the European Parliament and to the Council a report on the application of this Regulation. The report shall contain an assessment of how this Regulation is achieving its objectives,** the effectiveness and relevance of the requirements of this Regulation, **and, in particular, the following:**

[row 384b]

ii. As regards biodegradability, an assessment of the feasibility and the need to introduce biodegradability criteria for organic substances intentionally added in detergents in concentrations lower than 10%, other than surfactants and film polymers;

Detergents containing micro-organisms

Rows concerned: 97, 142-143, 355a, 355e, 355f, 420-444, 457, 467a, 438b-438d and 505-508, 539b.

Supporting documents: see the explanations already provided in WK 4604/2025 with some updates highlighted in yellow)

Article 2 [Row 97]

(10) 'genetically modified micro-organisms' means micro-organisms in which the genetic material has been altered ~~**using gene or cell technology or in any other way that does not occur naturally by mating or natural recombination.**~~**in a way that does not occur naturally by mating and/or natural recombination;**

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in part 1 of Annex I A to Directive 2001/18/EC (1);

(b) the techniques listed in part 2 of Annex I A to the same Directive are not considered to result in genetic modification;

(1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/2021-03-27

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Article 5 [Rows 142-143 – no change]

Detergents containing micro-organisms

Detergents containing micro-organisms shall comply with the requirements laid down in Annex II.

Article 26 [replace rows 355a, 355e and 355f by the following wording]

Delegated powers

(...) By [30 months from the entry into force of this Regulation] the Commission shall adopt a delegated act in accordance with Article 27 amending point 8a in Annex II by setting out a methodology for a risk assessment at strain level and product level under all foreseeable use conditions as claimed by the manufacturer.

The methodology shall contain the criteria to determine that the detergent is safe for human health and the environment, including the dermal and respiratory sensitisation potential of products in a spray format and potential risks in case of ingestion of detergents used on food or on surfaces in contact with food.

Annex II [rows 420-444)

REQUIREMENTS FOR DETERGENTS CONTAINING MICROORGANISMS REFERRED TO IN ARTICLE 5

1. **All** ~~M~~**m**icro-organisms intentionally added to detergents shall comply with the following conditions:

(a) shall ~~have an American Type Culture Collection (ATCC) number,~~ belong to **or be deposited in** a collection of an International Depository Authority (IDA) ~~or have had their DNA identified in accordance with a "Strain identification protocol" (using 16S ribosomal DNA sequencing or an equivalent method);~~

(aa) shall be identified and characterised using whole genome sequence (WGS) analysis in accordance with the methodology to be established by the Commission in accordance with Article 26(…)

(ab) shall be identified with the following taxonomic information considering the latest published information in the International Codes of Nomenclature (ICN): genus, species and strain name or code.

~~*(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.*~~

*2. The following pathogenic micro-organisms shall not be present in ~~any of the strains included in the finished product~~ **detergents containing micro-organisms**, ~~when screened~~ **in accordance with European or international standards or** ~~using the indicated~~ test methods ~~or equivalent~~:*

(a) E. coli~~, test method ISO 16649-3:2005~~;

(b) Streptococcus spp (Enterococcus spp), ~~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 spp; ~~test method ISO 6579:2002 or ISO 19250.~~

(ea) Pseudomonas aeruginosa;

(eb) Candida albicans.

3. **Detergents containing ~~I~~ i**ntentionally added **genetically modified** micro-organisms ~~shall not be genetically modified microorganisms~~ ***shall not be placed on the market, unless the genetically modified micro-organisms have been authorised for that use in accordance with Part C of Directive 2001/18/EC or are exempted in accordance with Article 3(1) of that Directive*.**

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.

5. When placed on the market, detergents containing micro-organisms shall have a standard plate count equal to or greater than $1x10^5$ colony-forming units (CFUs) per ml

in accordance with ~~ISO 4833-1:2014~~ ***European or international standards or test methods****.*

6. The minimum shelf life of a detergent containing micro-organisms shall not be shorter ~~lower~~ than 18~~2~~4 ~~-~~ months and ~~the microbial~~ ***shall have a standard plate*** *count ~~shall not decrease by~~* ***equal to or greater than*** *~~more than 10 % every 10 months 10% every 12 months~~* ***1x10^4 colony-forming units (CFUs) per ml at the end of shelf-life*** *in accordance with ~~ISO 4833-1:2014~~* ***European or international standards or test methods****.*

~~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.~~

~~8. Detergents containing micro-organisms shall not be placed on the market in a refill format.~~

8a. Detergents containing micro-organisms shall be placed on the market only if the safe use for the human health and the environment is demonstrated based on a risk assessment performed in accordance with the methodology to be established by the Commission based on Article 26 (…) or in accordance with Directive 2001/18/EC.

9. ~~All claims made by t~~**T**he manufacturer **shall substantiate all claims** ~~-~~regarding the actions **or performance** of the micro-organisms **intentionally added** ~~contained~~ **to**~~in~~ the product ~~shall be~~**with appropriate** ~~supported by third-party test~~**s**~~ing~~.

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 **1,** 2, **4,** 5, 6, ~~7~~ 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[4] or international standards recognised as being equivalent;

(b) the laboratories are accredited in accordance with the standard for laboratories referred to in Regulation (EC) No 765/2008.

Annex IV [row 457]

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7(2)

Add in point 2.2.b **'the risk assessment referred to in point 8a of Annex II'**

row 467a

the list of all intentionally added micro-organisms providing their taxonomic classification (genus, species and strain name or code), the deposition accession number of each microbial strain at an International Depository Authority (IDA), and the standard plate count of the micro-organisms in the detergent, expressed in colony-forming units (CFUs) per ml of product.

Annex V [rows 505-508 and 438b-438d]

LABELLING REQUIREMENTS

PART A – LABELLING OF CONTENTS

6. In addition to the information listed in points 1 to **4**~~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 **food, nor on** surfaces in contact with food**, unless if the product has been found safe for such applications on the basis of the risk assessment referred to in point 8a of Annex II;**

(b) an indication of the shelf life of the product;

(c) use instructions or special precautions, where relevant.

Annex VI, point (fa) [row 539b]

the list of all intentionally added micro-organisms providing their taxonomic classification (genus, species and strain name or code).

Other drafting suggestion

Refill sales requirements

Rows concerned: 258c-258ij

Article 17b

Supply in refill format

Without prejudice to Regulation (EU) No 2023/988 on general product safety[1] and Regulation (EU) 2025/40 as regards safety and hygiene requirements for refill including the risk of confusion with foodstuff, when detergents or end-user surfactants are made available on the market in refill format, the economic operator making the product available to end-users shall ensure that the following conditions are met:

(a) risk mitigation measures are applied to minimise the exposure of humans, especially of children, including by preventing children to use the refill station unsupervised and by training appropriately their staff; and

(b) the detergents or end-user surfactants provided through a refill station do not react with each other in a way that could endanger human health.

Urban Wastewater Treatment Directive

Rows concerned: 19, 82a

COM proposal: to replace the Council text with a reference to the Directive in the following recital (row 19):

(10) Phosphorus is ~~a~~***an other*** key ingredient used in detergents. However, phosphorus and its compounds could cause damage to ecosystems and aquatic environments as they contribute to eutrophication. **Significant progress is made to recover phosphorus from urban wastewater following the adoption of Directive (EU) 2024/3019 of the European Parliament and of the Council. It is nevertheless important to continue to address the issue at source by limiting the content of phosphorus in the types of detergents which are used in the highest volumes. Therefore**, to further ensure a high level of protection of the environment, and reduce the contribution of detergents to that phenomenon, it is necessary to establish harmonised limits on the content of phosphates and phosphorus compounds in consumer laundry and consumer automatic dishwasher detergents. (…)

Reasons:

Article 1(2) [rows 79-82] clarified that the new Detergents and surfactants Regulation is to apply without prejudice to other Regulations which set out requirements on placing on the market substances or mixtures (points a and b on REACH and CLP Regulations) and biocidal products (point c). Detergents and surfactants, when placed on the market, will have to fulfil the requirements from those Regulations, where applicable, in addition to the requirements in this Regulation.

The Urban Wastewater Treatment Directive lays down rules on the collection, treatment and discharge of urban wastewater, to protect the environment and human health.

Articles 7 and 8 of the Directive set out detailed rules on the tertiary and quaternary treatment of wastewater, to reduce the content of nitrogen and phosphorus and, respectively, certain microplolutants, before being discharged into receiving waters. Member States have to ensure that the wastewater is treated in such a way as to reduce the content of those substances at various degrees, depending on the size of the wastewater treatment plant and the place where it is located.

The Directive does not set any requirements for placing on the market products, to avoid the presence of certain pollutants in wastewaters. While they have a common goal, to protect human health and the environment, the Directive and this Regulation have

different ways of addressing them. This Regulation is to reduce the impact of detergents and surfactants on the environment, by laying down requirements at product level, while the Directive addresses the treatment of wastewater.

Other comments on the 4CD – provisions referring to (end-user) surfactant not yet included in the 4CD

[insert a new definition – new row 102a]

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

(11a) 'End-user surfactant' means a surfactant made available on the market to professional users and/or consumers;

[changes in point (32) - row 123]

(32) 'individual packaging' means packaging in which the detergent or **end-user** surfactant is made available on the market and which is intended to accompany the content to the place of use;

[row 183]

(d) the relevant information on the ***digital*** product passport has been included in the registry referred to in Article 20(1), **where applicable**;

[row 190 – to add reference following the rules on end-user surfactant]

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 **end-user** surfactant has been placed on the market and (…)

[row 203 – simplified drafting compared to previous discussion paper on end-user surfactant]

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:

(a) places a detergent or end-user surfactant on the market under his or her name or trademark;
(b) modifies a detergent or end-user surfactant already placed on the market in such a way that compliance with this Regulation may be affected; or
(c) makes a surfactant that is not an end-user surfactant available to end-users.

[row 229 – to add a labelling requirement for surfactants]

For surfactants, the label shall contain an indication that the product is suitable to be used for detergents.

[row 269 – same, add reference to end-user surfactant]

… 10 years after the detergent or **<u>end-user</u>** surfactant …

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