Council of the European Union
General Secretariat

PUBLIC

Interinstitutional files:
2023/0124 (COD)

Brussels, 16 May 2025

WK 6381/2025 REV 1

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WORKING DOCUMENT

From:	Commission services
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
Subject:	Discussion paper Drafting suggestions : Articles 26, 31, 32 and other technical adaptations

Discussion paper

Drafting suggestions

Articles 26, 31, 32 and other technical adaptations

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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.

[unless otherwise mentioned, the track changes mark changes to the text in the 4th column of the 4CD]

1. Ingredients data sheet

Following the provisional agreement in the second trilogue on 6 May, the obligations of operators need to be adapted to the communication of information via IUCLID and aligned to the corresponding obligation in the CLP Regulation. Thus, the communication of the ingredients data sheet is to be made by importers or authorised representatives for manufacturers established outside the Union, and corresponding obligations should be set out for distributors making the products available in additional Member States. Finally, provisions should be adapted to allow the identification of the notification (via UFI).

New row 119a

(28a) 'unique formula identifier' means a unique identifier as referred to in point 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008;

Row 159

6. ~~***Before placing detergents and end-user surfactants on the market,***~~ M~~m~~anufacturers established within the Union placing on the market detergents ~~*that do not meet the criteria for classification as hazardous within the meaning*~~***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 ~~*45 of that Regulation, the ingredient datasheet*~~***, the ingredients data sheet*** referred to in point 2.2 (e) of Annex IV before placing the products on the market. ***When the detergent or end-user surfactant for which an ingredients data sheet has already been submitted no longer corresponds to the information included in that ingredients data sheet, an updated ingredients data sheet shall be submitted*** ~~*in accordance with the first sentence*~~***.***

The ingredients data sheet shall be submitted by electronic means in the format provided by the Agency established by Regulation (EC) No 1907/2006 and made available free of charge for notifications in accordance with point 2 of Chapter 3 of Part A of Annex VIII to Regulation (EC) No 1272/2008,

Row 175c [only point a]

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

New rows 183a and row 190

New row 183a

(2a) Importers shall communicate the ingredients data sheet before placing detergents or end-user~~r~~s surfactants on the market in the conditions set out in Article 7(6).

Row 190 – delete the reference to IDS

New row 197a

Distributors making available on the market in another Member State detergents or end-user surfactants for which an ingredients data sheet is to be communicated in accordance with Article 7(6) shall submit to the appointed body in that Member State the ingredients data sheet unless they can demonstrate that the appointed body already received the same information from another economic operator.

New row 225a

(ab) the unique formula identifier for detergents or end-user surfactants;

Row 340b

(f) the ingredients data sheet has not been provided or updated in accordance with Article 7(6), Article 8(3a), point (a~~b~~), ~~or~~ Article 9(2a~~9~~) or Article 10(2a), as applicable;

Row 460a

(i) the name or trade name of the detergent or surfactant, the unique formula identifier, the name, registered trade name or registered trade mark of the manufacturer and the intended use of the detergent;

Finally, the terminology should also be aligned in the whole proposal to use only 'ingredient' and not also 'constituent'. The two notions are currently used, without a clear distinction between them.

2. Detergents containing micro-organisms

Row 355a

6a. By [30 months from the entry into force of this Regulation] the Commission shall adopt a delegated act in accordance with ~~Article 27 para\graph 2~~ 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, ~~[potential endocrine-disrupting effects]~~ and potential risks in case of ingestion of detergents used on food or on surfaces in contact with food.

[The methodology shall be established by using non-animal new approach methodologies, without prejudice to any other relevant Union law, and shall not prevent the use of historical data.]

Row 356

(the redrafting is proposed to cover also solid microbial products)

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~~milliliter or gram in accordance with European or international standards or test methods.***

Row 357

(the redrafting is proposed to cover also solid microbial products)

6. ***The minimum shelf life of a detergent containing micro-organisms shall not be shorter than 18 months and shall have a standard plate count equal to or greater than 1x10^4 colony-forming units (CFUs) per mililiter or gram ~~ml~~ at the end of shelf-life in accordance with European or international standards or test methods.***

Row 428

(request testing for pathogens at the level of intentionally added microorganism and not the final product)

2. ***The following pathogenic micro-organisms shall not be present in any of the strain intentionally added in the finished product detergents containing micro-organisms, in accordance with European or international standards or test methods***

Row 467a

6. ***The minimum shelf life of a detergent containing micro-organisms shall not be shorter than 18 months and shall have a standard plate count equal to or greater than 1x10^4 colony-forming units (CFUs) per ~~ml~~ milliliter or gram at the end of shelf-life in accordance with European or international standards or test methods.***

3. Biodegradability

The Commission reiterates its strong concerns on setting out an obligation for the Commission to develop additional biodegradability criteria for ingredients of detergents, irrespective of the outcome of the future assessment on the need and feasibility to set out such criteria. In addition, based on a comment from the Parliament, the definition of films could be slightly amended to cover possible future developments of films which are not polymeric, while the Commission assessment within specific deadlines should be on polymeric films, the only ones identified as being currently on the market.

Row 103a

(keep the definition of films as in the latest COREPER mandate of 28.4.2025)

(12a) 'Films' means water-soluble polymeric films used as detergents capsules;

Row 141a

(to be coherent with revised proposal for EU Ecolabel criteria on biodegradability of films)

2a. By [6 years from the entry into force of this Regulation], films or polymers within films shall comply with the biodegradability requirements set out in Part B of Annex I.

Rows 354-354d

[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;
[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.
[row 354d]
~~***By [3 years from the entry into force of this Regulation], the Commission shall adopt delegated acts setting out biodegradability criteria and test methods for films.***~~

~~***By [5 years from the entry into force of this Regulation], the Commission shall adopt delegated acts setting out biodegradability criteria and test methods for organic substances intentionally added in concentration of at least 10% in detergents, other than surfactants and films.***~~

By [3 years from the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and the Council, assessing the scientific evidence pointing to the need to introduce biodegradability criteria for films and polymers within films and the availability of testing methods. If justified by the results of the report, the Commission shall act in accordance with Article 27.

By [5 years from the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and the Council, assessing the scientific evidence pointing to the need to introduce biodegradability criteria for other organic substances intentionally added in detergents in concentration of at least 10 % w/w of the total mass of substances, excluding water, the availability of testing methods and the existence of alternatives. If justified by the results of the report, the Commission shall act in accordance with Article 27.

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4. Animal testing

Rows 145c-145m

The Parliament text on animal testing is inspired from Article 18 of the Cosmetic Products Regulation EUR-Lex - 02009R1223-20250501 - EN - EUR-Lex. *Should the Parliament amendment be takn over, technical adaptations are needed.*

Article 6a

Animal testing

1. The ~~safety of detergents and surfactants and~~ conformity of detergents and surfactants with this Regulation shall be established by using non-animal new approach methods validated ~~and adopted~~ at Union or international level.

2. Without prejudice ~~to the general obligations pursuant~~ to Article 1(1), ~~the following shall be prohibited:~~

~~(a) the placing~~ making available on the market of detergents and surfactants where the final formulation or ingredients or combinations of ingredients have been the object of animal testing with a view to meeting the requirements of this Regulation shall be prohibited~~;~~.

~~(b) the performance within the Union of animal testing of finished detergents and surfactants or ingredients or combinations of ingredients with a view to meeting the requirements of this Regulation.~~

3. Paragraphs 1 and 2 shall be applicable without prejudice to relevant Union law, and shall not prevent the use of data acquired before .... [the date of entry into force of this Regulation].

4. In exceptional circumstances, where concerns arise as regards the safety of a detergent ingredient, the Commission may adopt an implementing decision granting a derogation from paragraphs 1 and 2,~~.~~ ~~The Commission may act~~ on its own initiative or on the basis of a reasoned request from an economic operator or a Member State.

When the Commission acts on the basis of a reasoned request from an economic operator or a Member State, that request shall contain an evaluation of the situation and indicate the necessary measures. On that basis, the Commission may consult the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, ~~, after consulting the relevant scientific Committee, Agency or body, adopt a decision authorising the derogation~~.

That decision shall lay down the conditions associated with that derogation in terms of specific objectives, duration and reporting of the results. A derogation shall be granted only where:

(a) the ingredient is widely used and cannot be replaced by another ingredient capable of performing a similar function;

(b) the human health or environmental problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

5. Commission empowerment

Rows 343a-364a

[Rows 345-350]

~~2~~1. The Commission is empowered to adopt delegated acts in accordance with Article 27, amending Article 20(1) by requiring that additional information among the information listed in Annex VI be stored in ~~*stored in*~~***uploaded into*** the registry.

When adopting the delegated acts in accordance with the first subparagraph, the Commission shall take into account the following criteria:

(a) coherence with other relevant Union acts where relevant;

(b) the need to allow for the verification of the authenticity of the ***digital*** product passport;

(c) the relevance of information for improving the efficiency and effectiveness of market surveillance checks and customs controls for detergents and surfactants; ***and***

(d) the need to avoid disproportionate administrative burden for economic operators ***and national authorities***.

[Row 343a]

~~***2Ia.***~~***The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annexes I to*** ~~***V and***~~ ***VI***~~***aI***~~ ***where necessary to adapt those annexes to technical*** ~~***and***~~ ***or scientific progress.*** ~~***When drafting these acts, the Commission shall take into account any relevant European standards.***~~

[Row 364]

9. ~~The Commission is empowered to~~ When adopting delegated acts in accordance with ~~Article 27~~paragraph 2 amending Annex V, as regards the labelling information, which economic operators are allowed to provide only digitally in accordance with Article ~~*16, for*~~***16(1), second paragraph***~~***,.***~~ ~~***Those delegated acts shall pursue***~~ ~~the purposes of adapting it~~***the Annex*** ~~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 and the level of digital readiness among the end-users of detergents.

[Row 344]

~~1.~~ When adopting delegated acts in accordance with paragraph 2, ~~The Commission is empowered to adopt delegated acts in accordance with Article 27~~ amending Annex VI, as regards the information to be provided in the ***digital*** product passport, ~~for the purposes of adapting it to technical and scientific progress and to the level of digital readiness of market surveillance authorities and of end-users,~~***the Commission shall take~~***~~***ing***~~*** ***into account*** the level

of digital readiness of market surveillance authorities and of end-users and ***the applicable Union law on the protection of undisclosed business information and on public access to environmental information***.

[Rows 354-354d - biodegradability as above]

[Row 355a – empowerment micro-organisms methodology – see above]

[Rows 357-363]

8. By [OP please insert the date = the first day of the month following 30 months after the date of entry into force of this Regulation], the Commission shall adopt delegated acts in accordance with Article 27 to supplement this Regulation, by determining the specific requirements for the digital labelling of detergents. Those requirements shall at least establish the types of IT solutions, which economic operators may use, and the alternative means for providing the information on the digital label, referred to in Article 17.

When adopting the delegated act referred to in the first subparagraph, the Commission shall take into account the following criteria:

(aa) the need for the digital labelling not to compromise the safety of the end-users and the environment;

(a) coherence with other relevant Union acts where relevant;

(b) the need to encourage innovation;

(c) technological neutrality characterised by absence of constraints or prescriptions on the choice of technology or equipment, within the bounds of compatibility and avoidance of interference;

(e) the level of digital readiness among all population groups in the Union ***as well as the readiness of the necessary wireless and other technological infrastructure allowing unrestricted access to the information on detergents and surfactants***.

[Row 355g]

6c. The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annexes IV by setting out harmonised requirements, including a harmonised format, on the way the ingredients data sheet is to be communicated in accordance with Article 7(6) as well as setting out the details of the notification, and the conditions requiring an update of the ingredients data sheet. When developing these requirements and conditions, 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.

[Row 356]

7. Where individual risk-based concentration limits for fragrance allergens are ~~*established*~~***introduced or amended*** in Regulation (EC) No 1223/2009 of the European Parliament and of the Council[1], the Commission shall adopt delegated acts in accordance with Article 27 amending Annex V in order to adapt ***it to*** the limit of the ~~*allergenic fragrances*~~***fragrance allergens*** listed in Annex III to that Regulation. ~~*accordingly.*~~

[Row 356a]

7a. Where new fragrance allergens are listed in Annex II or Annex III of Regulation (EC) No 1223/2009[1] ~~of the European Parliament and of the Council~~, the Commission shall adopt delegated acts in accordance with Article 27 in order to add these fragrance allergens in the Appendix to Annex V.

[Row 364a]

10. The Commission is empowered to adopt delegated acts in accordance with Article 27 amending Annex VIa to update the list of commodity codes and product descriptions of detergents and surfactants. Those adaptations shall be based on the list set out in Annex I to Regulation (EEC) No 2658/87.

The new order proposed: (i) empowerment concerning Article 19; (ii) empowerment for adaptatons to technical progress of Annexes + specific applications and other empowerment (adaptations to Annexes to ensure coherence with other EU law + supplementing provisions).

6. Commission review/report

Rows 381-384g

[row 381]
Article 31
Report ***and review***

[rows 382 and 383 – deleted]

[row 384]

By [***OP: please insert the date = 7 years from the date of entry into force of this Regulation*** ~~*OP: please insert the date = 3 years from the date of application of this Regulation*~~], the Commission ~~shall assess the effectiveness and relevance of the requirements of this Regulation *for detergents containing micro-organisms as well as the possibility to*~~ ***and shall 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***, including the impact on small and medium-sized enterprises ***and shall*** include ~~*new micro-organisms or strains of micro-organisms allowed in detergents in Annex II.*~~***at least the following elements:***

[rows 384a-]

i. As regards detergents containing micro-organisms, ~~the list of micro-organisms or strains of micro-organisms allowed or banned in detergents in Annex II and~~ the suitability of the ~~other requirements~~~~paragraphs~~ of Annex II to ensure the safety of these products for health and the environment;

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% w/w of the total mass of substances, excluding water***, other than surfactants and films;***

iii. As regards the protection of health and the environment from the most harmful substances ~~and biocidal active substances~~, an assessment of the need to include ~~or adapt~~ provisions in this Regulation in respect of the presence of these substances in detergents and surfactants,~~;~~ ~~this assessment shall~~ taking into account the interaction of this Regulation with other relevant Union law;

(iiia) as regards detergents containing biocidal active substances, ~~, and shall exclude biocidal active substances~~ other than those listed in Annex I ~~of~~ to Regulation (CE) No 528/2012, an assessment of the need to introduce stricter rules; ~~; and~~

iv. As regards detergents containing phosphates and other phosphorus compounds, the possibility to limit further the phosphorus content or add limitations of phosphorus content on other products categories to Annex III,~~;~~ ~~this assessment should~~ takinge into account the impact on the environment, the availability of ~~suitable~~ alternatives ~~with less or no phosphorus~~ and the socio-economic impact of substitution;~~:~~

[row 384f - deleted]

[row 384g]

~~By ... [OP: please insert date – 3 years from the date of application of this Regulation], the Commission shall submit a report to the European Parliament and to the Council assessing~~(v) the necessity, feasibility, technical consequences and benefits for health, climate and the environment of the introduction of mandatory targets for renewable raw materials and recycled content in detergents and surfactants,~~:~~ ~~In that report, the Commission shall specifically~~ takinge into account socio-economic impacts, competitiveness of economic operators in the Union, sustainable sourcing and use of renewable feedstock as well as the ~~global warming~~climate change mitigation potential and~~,~~ the potential for using food waste in detergents and surfactants~~the potential land use change associated with alternative feedstock and food security in the Union~~.

The report shall be accompanied, where appropriate, by a legislative proposal.

7. Electronic/paper

Rows 165, 191 and 201

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*~~***format*** ~~***and, on request, in paper format***~~, 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.

Similar changes should be introduced in rows 191 (importers) and 201 (distributors). Communication with market surveillance authorities should be made only in electronic form. This is linked to ongoing work on an Omnibus which would propose similar changes in other regulations.

8. Other rows

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 226

The reference to authorised representative should not be a mandatory element on the labels. This information is already part of the digital product passport, where it can be easily kept up-to-date, in case of changes in the contractual arrangements between economic operators. Adding this information on the label raises concerns: what if the manufacturer changes its authorised representative? They should not be asked to recall the products and update the labels. To avoid un-necessary administrative burden, and the risk of having confusing outdated information on the labels, this should remain in a digital form, in the DPP.

Row 247

(g) ~~***the digital label shall be available in the official language(s) of the Member State(s) where the detergent or surfactant is made available on the market, unless the Member State(s) concerned provide(s) otherwise; when the information on***~~*when* ~~when~~ the digital label is ~~*available*~~***accessible*** in more than one language, the choice of language shall not be conditioned ~~***on***~~***by*** the geographical location ~~***of***~~***from where it is accessed by*** the end-user;

The purpose of this point is not to set out the language regime of digital labels, but to impose an obligation to keep all available languages accessible, irrespective of the geographical location. The language regime, and other general requirements, are set out in Article 15(5) (row 232), for all labels, physical and digital. By repeating the language regime, confusion could be created on the application of Article 15(5) to digital labels, which is not the intention. The text should be kept aligned to CLP Regulation (Article 34b(1)(h)).

Row 254

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. ~~***In particular, that usage information shall not be used for targeted advertising, shared with third parties or collected or stored as personal data.***~~

Proposal to keep the text aligned to CLP Regulation (Article 34b(2)).

Row 258

Economic operators shall provide the information referred to in the first subparagraph independently from a purchase of a detergent or surfactant~~***, without delay***~~ and free of charge.

Proposal to keep the text aligned to CLP Regulation, Article 34a(2), second paragraph.

Rows 293c-293d

Proposal to delete the Article on the web-portal, to keep the text aligned with the Toys Safety Regulation. The web-portal developed under the ESPR will also cover DPP for detergents and surfactants, even if this Article is not introduced. By deviating from toys, questions may be raised on the reasons behind a different drafting.

Row 311

1. ~~*Where*~~ The market surveillance authorities of one Member State ~~*have sufficient*~~***shall carry out an evaluation when there is*** ~~reason to believe that a detergent or surfactant *presents*~~***present*** a risk to health~~***, [safety]*** or the environment, ~~***and they***~~ ***may***~~*they shall*~~ carry out

an evaluation in relation to ~~*the*~~***a*** detergent or surfactant ~~*concerned*~~ covering ~~*all relevant*~~ requirements laid down in this Regulation. W***hen there is*** reason to believe that a detergent or surfactant ~~*presents*~~***present*** a risk to health***, [safety]*** or the environment, the market surveillance authorities shall carry out that evaluation, The relevant economic operators shall cooperate as necessary with the market surveillance authorities ~~for that purpose~~.

Drafting suggestion – to start with routine and move to obligations in case of evidence of a risk.

Row 539

(f) a full list of substances ~~*intentionally*~~ intentionally added in the detergent or surfactant~~*, ordered by the following weight percentage ranges: 'less than 5 %', '5 % or over but less than 15 %', '15 % or over but less than 30 %', '30 % and more',*~~ *and of preservatives labelled in accordance with part A, point 3, first subparagraph, point (b), of Annex V*, identified in accordance with Article 18(3) of Regulation (EC) No 1272/2008 ~~using *the International Nomenclature of Cosmetic Ingredients, or where it is not available, the European Pharmacopoeia name and, when also the latter is not available,* the common chemical name or International Union of Pure and Applied Chemists ***(IUPAC) name and, where available, the INCI name and the CAS number***~~***; carry-over preservatives and fragrance allergens shall also be listed if they must be included in the label led in accordance with Article 18(3), point b, of Regulation (EC) No 1272/2008, Article 58 of Regulation (EU) No 528/2012 or point 3 or 4 of Part A of Annex V;***~~*name.*~~

Point 540

The obligation referred to in point (f) shall not apply to ~~professional~~ industrial and institutional detergents, or to surfactants ~~for professional detergents~~, for which the equivalent information is provided by means of a safety data sheet referred to in Article 31 of Regulation (EC) No 1907/2006 ~~is available~~.

To avoid administrative burden. Proposal to re-introduce Commission proposal with some changes.

Rows 541 and the followings

Proposal to remove Annex VII. The way it is currently drafted, the references to Annex VII are confusing. Article 4 requires products to comply with the biodegradability requirements in Annex I. Nevertheless, market surveillance authorities can check the compliance of the product with the testing methods in Annex VII. It is not clear what would be the consequences of a contradiction of the results between the tests performed by manufacturers in accordance with Annex I and those by the market surveillance authorities in accordance with Annex VII. To avoid any uncertainty, both the manufacturers and the market surveillance authorities should use the same testing methods.

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