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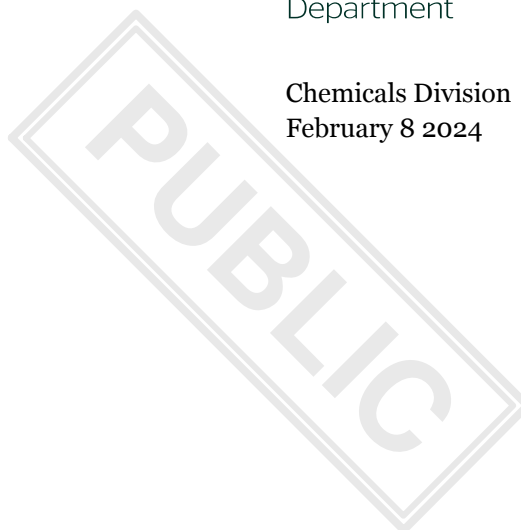
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NOTE

From:	DK and FI Delegations
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 DK and FI



Danish contribution to the Presidency: Key challenges in the proposal for a detergents regulation

At the meeting in the Council Working Group on December 13th 2023, the incoming Belgian Presidency invited Member States to send written remarks until February 15th 2024 on their main concerns regarding the KOMs proposal for a revised detergents regulation.

The Danish delegation welcomes the proposal overall, and we support the overall intention of the revision. We kindly refer to our previous written comments on the clusters, and would like to highlight certain points.

Our main concerns are the following:

1. **Online sale** must be as safe as sale in physical shops
2. Labelling requirements of **preservatives**
3. Rules for **refill sales** must ensure that consumers receive the same information as they would if the product was sold as prepackaged
4. A general **ban of the most harmful substances** in detergents should - in line with the chemicals strategy for sustainability - be included in this revision.
5. The obligation to issue the **digital product passport** should not relate to the batch, but rather to the model level.
6. The **safeguard clause** should be modernised to allow market surveillance authorities to proactively respond quickly to the presence of harmful substances in products.

1. Denmark believes it is important, that there is **always a party within the Union, that can be held responsible** in the event that a detergent fails to live up to the requirements set out in the Regulation. This is **especially important in relation to online sales**. Hence, we do not find the proposed provisions introducing an 'authorised representative' to sufficiently ensure that the responsibility can be identified unambiguously. Furthermore, slight adjustments to the contents of the passport and requirements relating to **the manner in which the data carrier is displayed online** can lead to significant restrict the ability of third country sellers in particular to evade the rules.

2. We welcome the clarification in the draft of the obligation to label **carry over preservatives**. However, for certain preservatives (e.g. isothiazolinones) the elicitation threshold in CLP will not be sufficient to protect consumers against allergic reactions. Thus, the regulation should allow to set lower thresholds that reflects the risk and ensures protection.

3. Detergents marketed as **refill** products should be accompanied by the **same information in physical format as if bought prepackaged**. Thus, we cannot support the exemption in article 16, point two.

4. In the Chemicals Strategy for Sustainability, published by the Commission October 2020, detergents are mentioned as a consumer product group where an **automatic ban of the most harmful substances** following a generic risk approach should be introduced. Likewise, in the strategy, detergents for consumers are mentioned as a product group, where **combination effects** of substances should be taken into account. We recognise that there may need to be exemptions to the automatic ban e.g. for enzymes – these should be kept to a minimum and only where strictly necessary.

5. The decision of the **level of granularity at which the issuing of a digital product passport** should take place should follow the Ecodesign Regulation, if product groups are regulated there. If it is not the case, the passport should be issued at model level, and changes in formulation that significantly affects the safety of the product to the environment or human health should be reflected in the product passport.

6. The **safeguard clause** should permit member states to **introduce temporary generic restrictions on the availability of detergents containing a particular substance**. To balance the interests of economic operators and the requirements of market surveillance authorities, this power should only be available as a last resort after use of the procedure set out under Article 24(1), where restrictions are placed upon individual products after dialogue with individual economic actors. As opposed to Article 24(1), the power to impose temporary generic restrictions should only be available, where there the harmful substance presents a serious risk for human health or the environment. Currently, transparent and reputable manufacturers are most likely to be impacted by product recalls, as they are open about the chemicals they use. By amending the safeguard clause, sanctions can be imposed on economic operators that attempt to evade the temporary prohibition, creating an incentive for economic actors to be open about the substances present in their products.

Finland's comments to the proposal on Detergents Regulation

We hereby resend our comments on clusters 1, 2 and 3 sent on 8 December 2023 in more readable/compact format.

In addition, please find a new comment on refill in the end of the document.

Article 1, paragraph 2:

For legal certainty and clarity reasons, we suggest to replace the phrase "does not affect" with the phrase "without prejudice to" as written in recital 8.

Should this regulation be underpinned by the precautionary principle?

Article 2, definition (1), first indent:

We propose to replace "or two or more such materials" with "or combination thereof".

Article 3

We wonder why this Article is entitled "Free movement" and whether it would be more suitable to separate the obligations of the economic operators (first paragraph) and obligations of MS (second paragraph) in different Articles. We also suggest to add the following words at the end of the first paragraph: "and to any other relevant Union legislation".

Article 7, paragraph 4

It seems unclear what is meant by "performance" of the detergent in this context. Is there a performance criteria or is this out of scope of the detergent regulation?

Article 7, paragraph 7 & 8

Why is it not the market surveillance authority (which is defined in Article 2) who would receive the information about the risk to health or to the environment? The same applies e.g. in paragraph 8.

Article 14

As a general comment regarding CE-marking and product passport, we do not have information or assessment on what is the actual impact on compliance for the inclusion of these elements in the detergents regulation.

Article 15

Current labelling requirement (Article 11(2): "The following information must appear **in legible, visible and indelible characters** on the packaging in which the detergents are put up for sale to the consumer." Should this also be included in the revised Regulation?

Is it necessary to include that there should be no fruit pictures on the label or other misleading pictures?

Article 15, paragraph 3

In (a) it is unclear what is meant by the type number. The batch number would possibly be sufficient and it is also used in the product passport.

In (e) "and relevant" is unnecessary and could possibly be removed.

Article 17, paragraph 1

In (a) it is unclear what is meant by “one place”.

Article 22, paragraph 2

It is unclear what is meant by 'controls' in the first sentence. Does it mean that the MSAs themselves are obliged to carry out tests, or does the word control alternatively refer to enforcement actions in general? It would be preferable from the standpoint of view of the MSA that the authorities are not directly obliged to accomplish testing, since the test results/reports can be required to be provided by the economic operators in association with administrative proceedings.

We would like to get clarification on what is meant by the second sentence, and what in practice are the particular situations where the economic operator is not obliged to pay for tests in case the product turns out to be non-compliant. The provision/wording of the sentence is not clear and understandable as such. In the absence of justification or further clarification we consider this provision redundant.

Annex I, test methods under 3(a) & 3(b)

Why are OECD tests not included in the list – should they be? Identified OECD TGs similar to those listed:

3(a)(i): OECD TG 310

3(a)(ii): OECD TG 301B

3(a)(iii): OECD TG 301F

3(a)(iv): OECD TG 301D (some differences)

3(a)(v): OECD TG 301C

3(b)(i): OECD TG 301A

3(b)(ii): OECD TG 301E

Regarding 3(a)(vi): As far as we know, not in use in REACH?

Annex II, requirements for detergents containing microorganisms

Requirement 1

We propose to replace condition (a) text with the following:

“The microbial strain used in the cleaning product should have been identified to the species level using a method appropriate to the bacterial species. In case the strain in question can be found in an internationally acknowledged culture collection of bacterial strains (IDA) such as ATCC, it also must have identification at species level;”

Justification: Having a number in an IDA is not enough, as there might be such strains in IDAs, which have not been identified at species level.

Requirement 2

We see the list as non-exhaustive and propose to extend it to cover all micro-organisms that should not be there: “The finished product shall not contain significant amounts of other micro-organisms than what have been reported as the microbial strains used as the cleaning agent(s)”

Requirement 5

Should also the highest limit for microbial density be determined here?

We propose to add “or if not suitable for the micro-organisms in question, other internationally recognized methods” in the end of the sentence. Justification: The method is not suitable for all possible micro-organisms that may be used in detergents. Therefore, some flexibility should be included.

Requirement 6

We propose to replace the text with the following:

“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 1×10^4 colony-forming units (CFUs) per ml in accordance with ISO 4833-1:2014, or corresponding method, at the end of the shelf-life.”

Justification: The original requirement is the same as the one set for micro-organisms (only for HSC for professional use) in Commission Decisions for the award of the EU Ecolabel for detergents and cleaning products (2017). However, we do not understand the rationale behind it. First, it should be noted that ISO 4833-1:2014 and similar methods are not reproducible enough to detect differences in CFU counts as small as 10%. Secondly, we believe it is extremely difficult to formulate a microbial product that does not demonstrate higher decrease in microbial counts than 10% per year. Microbes as living organisms are inherently unstable. Thirdly, we do not understand how the requirement is connected to safety or functionality of the product. It would be quite possible to formulate a product that would be functional at end of shelf life with microbial inactivation rates much higher than 10% in 12 months. Why this would not be allowed?

Requirement 9

We propose to remove requirement 9. To our understanding, some type of expert judgement would be needed to assess whether the claims are in fact supported by the tests. The experts would need to agree on terms of acceptability. This would be challenging as the action claims may be quite diverse. Therefore, we question whether such a requirement should be set at all. If the requirement is set, the implementation should be considered carefully.

If the requirement is set, we question whether testing should be limited to third party laboratories. The required tests would be mostly complex, non-standard tests that would need to be designed specifically for the purpose. It could be quite difficult to find a service laboratory that would deliver such tests. Third-party tests are not required e.g. to demonstrate efficacy of biocidal products in the product assessment according to Regulation (EU) No 528/2012. We wonder why the requirement is stricter here.

Alternative text “Identity of micro-organism(s) claimed to be contained in the product shall be confirmed by third party testing.” could be considered.

Requirement 11

We propose to remove reference to requirement 9 (which we propose to be removed).

The tests referred in the original requirement 9 would be, to our understanding, mostly complex, non-standard tests that would need to be designed specifically for the purpose. The number of laboratories that would offer such service and would be complying with the principles of good laboratory practice (GLP) or be accredited, is very limited. If the tests referred in requirement 9 are required, it should be possible to conduct them also by non-GLP, non-accredited laboratories. Again, this approach would be in line e.g. with the requirements set for laboratories conducting tests to demonstrate efficacy of biocidal products according to Regulation (EU) No 528/2012.

New comment regarding refill:

In general, provisions for refill sales should be aligned with the whole set of provisions of the revised CLP Regulation for supply via refill stations, since CLP is applied to refill sales for detergents classified as hazardous according to CLP in parallel to Detergents Regulation. For example, the definition of “refill” in the proposed Detergents Regulation and the revised CLP differs, which can cause confusion. The definitions in Detergents Regulation should be carefully aligned with the provisions of the revised CLP Regulation, and the definitions should be as consistent as possible. The proposed Detergents Regulation seems to restrict “refill” as in-store operation and does not address outdoor sales, and it remains unclear whether outdoor sales is allowed and what criteria would be applied to it. It would not be consistent that refill operations allowed for detergents classified as hazardous according to CLP would in this sense be more flexible compared to refill operations for non-hazardous detergents regulated by Detergents Regulation only. It would also create difficulties for refill operations covering both hazardous and non-hazardous detergents at the same location. Also the term “refill station” is mentioned in the text but not defined in the proposed Detergents Regulation, which would probably be beneficial in terms of consistency.