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NOTE

From:	Presidency
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 - Presidency steering note

Working Party on Technical Harmonisation – 29 April 2024 Detergents and Surfactants Regulation

This steering note reflects the main adaptations proposed by the Presidency, as laid out in document ST 8717 2024 INIT.

On 29 April, delegations will be invited to express their views on the latest text revised by the Presidency. The day will be divided as follows:

- in the morning, we will discuss the clusters 2 and 4;
- in the afternoon, the Presidency would like to hear the delegations' views on the new revised text on clusters 1 and 3.

Following the Working Party, delegations will be invited to submit their written comments on the whole text for 6 May.

Cluster 1 – Product requirements

1) General provisions

In Article 3, the terms “placing on the market” have been replaced by “making available on the market” in order to also cover the distribution of products.

In Article 27, to align with common practice, the empowerment of the Commission has been limited to 5 years, with a tacit extension.

Article 30, which is redundant with Article 33 has been deleted.

Delegations are invited to give their views on these proposals.

2) Definitions of detergents

In Article 2(1), the definition of “detergent” has been completed by products added to support cleaning processes. The term “substance” has been added next to mixture in all subparagraphs and the surfaces in the second subparagraph.

Delegations are invited to give their views on these proposals.

3) Biodegradability

With regard to delegated acts and the revision clause, the Presidency proposes a two-step approach to strengthen biodegradability requirements.

First, the Presidency proposes that organic polymers, notably of encapsulated detergents, would be subjected to appropriate biodegradation requirements.

Secondly, we suggest continuing to support innovation in the composition of detergents, through a cost-benefit approach of new biodegradability criteria for all ingredients as appropriate. The possibility to grant exemptions is also foreseen.

Delegations are invited to give their views on these proposals.

4) Microorganisms

To ensure the safety of detergents containing microorganisms, particularly in spray format and on food or surfaces in contact with food, we have added in Annexes II and V the obligation to carry out a specific risk assessment. In Article 5, we propose that the Commission adopts a delegated act to supplement Annex II with the appropriate methodology to assess their risks and ensure a high level of protection of health and the environment throughout their lifecycle.

The spray products are not limited anymore to industrial and institutional products. The warning for food and surfaces in contact with food is now only foreseen when no specific assessment has been carried out.

Other changes have been introduced in Annex II on the basis of the comments, for:

- the introduction of the restrictions foreseen in the QPS list
- the research and development, where there is no exemption anymore
- the provisions on the minimum shelf life
- the requirement of third-party testing for claims, which is now deleted.

The provision related to the QPS status has been maintained. However, this status is only based on a preliminary assessment and relates to food, feed but also plant protection products. Moreover, it does not cover all safety aspects.

As stated by EFSA, the following aspects are NOT covered by the QPS concept:

- the exposure of users handling the product, notably by dermal contact, ingestion, inhalation
- the potential allergenicity to microbial residual components
- the hazards linked to the formulation or processing of the product.

Delegations are invited to give their views on these proposals.

5) Phosphate and phosphorus

Following comments received, the limits proposed in the previous draft for industrial and institutional products have been deleted.

In addition, taking into consideration the comments received from several delegations, the Presidency maintains their proposal of an additional effort regarding the limits of phosphate contained in consumer laundry and dishwasher detergents.

Delegations are invited to give their views on these proposals.

6) Delegation's non-paper regarding the better protection of consumers and the environment from harmful substances in detergents

Regarding the delegation's non-paper (**WK 5228 2024 INIT**), the Presidency invites the delegation colleagues to present their non-paper at the Working Party of 29 April.

The Presidency intends to have a discussion with the delegations on the topics of biocidal active substances and of most harmful substances.

i. Biocidal active substances

Delegations will then be invited to indicate whether or not they can support the proposals presented in the non-paper, notably with regard to the ban of biocidal active substances in consumer detergents and surfactants, with the exception of cases where they are used as preservatives.

In the proposal, exemptions to the ban would still be possible for some substances on the basis of an assessment by ECHA and providing that there is no suitable alternative.

ii. Most harmful substances

As indicated in the Impact Assessment, a targeted review of REACH is being prepared as part of the Chemical Strategy for Sustainability to address a number of identified issues. In the Chemical Strategy, it is proposed to extend the generic approach to risk management to ensure that consumer products, including detergents, do not contain chemicals that cause cancers (C), gene mutations (M), affect the reproductive (R) or the endocrine system (ED), or are persistent and bio accumulative. In addition, a comprehensive impact assessment would be launched to define the modalities and timing for extending the same generic approach to further harmful chemicals, including those affecting the immune,

neurological or respiratory systems and chemicals toxic to a specific organ. This approach should then be extended to professional users to give them a similar level of protection.

The Impact Assessment points out that “Annex XVII to REACH (the restriction list, entries 28, 29 and 30) restricts the use of CMR Category 1A and 1B substances for supplies to the general public such as detergents and requires additional labelling for products intended for professional users. However, there is no similar requirement for Category 2 CMRs under REACH.”

Other hazard classes such as endocrine disruptors are also not yet covered by REACH.

While considering that a REACH review might be the best approach to regulate the most harmful substances, specific provisions could already be introduced in the Detergents Regulation to ensure the safe use of these products widely used by the general public, while awaiting for horizontal provisions.

In the light of some concrete proposals made by a delegation in its non-paper (shared on the Delegates Portal), the Presidency invites Member States to react to the following questions:

- **Do delegations agree to include in the Detergents Regulation, pending possible horizontal provisions, provisions on the ban of certain categories of the most harmful substances, with appropriate transition periods and possibilities for exemptions ?**
 - **If so, should the ban apply only to consumer detergents or also industrial and institutional detergents?**
 - **Which hazard classes should be covered by the ban?**
- **Should a review clause be introduced to assess the developments of relevance to detergents in other pieces of legislation?**

Cluster 2 – NLF and market surveillance

1) Authorised Representative

On the question of the authorised representative, the Presidency seeks guidance from delegations. Some delegations have stressed the lack of added value of this provision in light of the limited responsibilities of the authorised representative, while others have expressed the need for an alignment with the responsibilities in CLP and the notion of “supplier”.

The Presidency would also like to remind delegations of the questions that were asked about this matter in the document **WK 3020 2024 INIT**.

2) Rules and conditions for affixing the CE marking

In light of the comments made by some Member States, a digital CE marking is proposed and would only be mentioned on the product passport.

Delegations are invited to give their views on this proposal.

3) Conformity assessment procedure

In Annex IV, the content of the ingredient data sheet has been reworded in order to ensure that, as currently, all ingredients, except impurities, are listed; for preservatives however, they should only be listed if they are to be labelled in accordance with Annex V, Part A(3).

Delegations are invited to give their views on this proposal.

Cluster 3 – Labelling and digital labelling

1) Refill

The term “surfactant” has been added in the definitions of ‘refill’ and ‘refill station’, in order to cover surfactants or mixtures of surfactants that could be sold in refill format without mentioning a detergent function and thus not falling under the detergent definition.

Delegations are invited to give their views on this proposal.

2) Labelling

The importer’s name has been added in article 15 (3), but this could be revised in light of the discussions on the obligations of the different economic operators.

Minor changes have been introduced in the provisions of article 16(2) on refill stations and in article 17 on digital labelling.

iii. Labelling of preservatives

For the labelling of preservatives provided for in Annex V, Part A, point (3), last paragraph, the elicitation thresholds referred to in point 3.4.3.3. / table 3.4.6. of Annex I to the CLP Regulation has been supplemented by a reference to Note 1 of Table 3.4.6. to ensure that, for sensitising substances with a specific concentration limit, the limit for labelling is set at one tenth of its specific concentration limit. The limits provided are those considered safe for already sensitised persons.

Delegations are invited to give their views on these proposals.

iv. Labelling of allergenic fragrances

The reference to the CLP regulation has been adapted to clarify that the first sentence of point 4 of Annex V, Part A, does not apply when the allergenic fragrance is already labelled in accordance with the CLP Regulation.

On the other hand, given the lack of support for the labelling of allergenic fragrances listed in Annex II (= banned) of the Cosmetics Regulation, the reference to this Annex has been deleted. We are nevertheless looking for other means to address the risks posed by these substances.

Some allergenic fragrances have been introduced in the list of banned substances in the Cosmetics Regulation because their use has been deemed unsafe by the Scientific Committee on Consumer Safety (SCCS). It is for instance the case for HICC (Lyrall), atranol and chloroatranol for which the SCCS concluded the following in its opinion 1459/11 (available at https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf) :

“The SCCS considers that the number of cases of HICC allergy documented over the last decade is exceptionally high and that continued exposure to HICC by the consumer is not considered safe, even at concentrations as low as 200 ppm. Therefore, HICC should not be used in consumer products in order to prevent further cases of contact allergy to HICC and to limit the consequences to those who already have become sensitized.

The SCCP concluded in 2004 that chloroatranol and atranol, the main allergenic constituents of Evernia prunastri and Evernia furfuracea, should not be present in products for the consumer. The persistently high frequency of contact allergy to Evernia prunastri and Evernia furfuracea noted in eczema patients does point to a persisting problem with exposure to the allergenic constituents. The SCCS is of the opinion that the presence of the two constituents, chloroatranol and atranol, in cosmetic products are not safe.”

Delegations are invited to express their preference between the following options regarding allergenic fragrances banned for their sensitising properties in cosmetic products :

- **Option A: No labelling nor ban in detergents i.e. the initial proposal of the Commission.**
- **Option B: Labelling similar to the one provided for allergenic fragrances listed in Annex III to the Cosmetics Regulation: a detailed list of substances could be included in point 4**

of Annex V, Part A, and the Commission would update the list by delegated acts, as provided in Article 26(5).

- **Option C: Ban in detergents, on the basis of assessments done by the SCCS or other scientific official bodies: a list of banned substances could be introduced in a new Annex to the Regulation. This list could be updated regularly by delegated acts in accordance with Articles 26(5) and 27.**

v. Labelling of dosage information

In Part B of Annex V, the requirement to indicate on the label the recommended dilution and volume to be used per surface area has been added for consumer detergents for surface cleaning, as proposed, in order to ensure safe use and limit emissions.

Delegations are invited to give their views on this proposal.

Cluster 4 – Product Passport

Regarding the revised text of cluster 4 that delegations received in the document **WK 3020 2024 INIT**, *the Presidency invites delegations to give their views on these proposals.*