

29 April 2024

Subject: Comments on Commission Proposal for a Regulation on detergents and surfactants

CESIO, the European Committee of Organic Surfactants and their Intermediates, which is a sector group of Cefic that represents manufacturers and suppliers of surfactants in the EU, has reviewed the Commission's Proposal for amendment of the Regulation on detergents and surfactants. Whilst CESIO welcomes the proposal for amendments aiming at simplification of existing practices and better alignment with other existing EU regulations CESIO would like to highlight that **surfactants are already well regulated within EU REACH and EU CLP, offering a high degree of safety for humans and the environment**. CESIO recommends that any new rules proposed in the current revision should be both considerate of and consistent with the provisions laid down in other EU regulations already in force, in order to avoid unnecessary duplication and elevated administrative burden for industry both raw material suppliers and downstream users.

Concerning the proposed regulation, CESIO would like to raise remarks on the following issues:

1. Article 2 (11) - A clear and unique definition of 'surfactant' is needed

We question the applicability and usefulness of some of the criteria mentioned in the definition of surfactants:

- "adsorption at water-solid interfaces" cannot be evaluated, when the type of solid is not specified, and does not allow to discriminate between surfactant and non-surfactant (e.g. in case of activated carbon as solid)
- "forming spreading or adsorption monolayers at the water-air interface". The analytical method to study such adsorption layers are surface tension measurements, but surface tension reduction is already one of the criteria.

Therefore, **CESIO suggests using the following definition which is more clear**: *Surfactant means any surface-active organic substance or mixture which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of fulfilling both of the following criteria:*

- *forms a clear micellar solution or a translucent microemulsion or stable emulsion without separation of insoluble matter when mixed with water at a concentration of 0.5 wt% and left to stand for one hour at 20°C*
- *reduces the surface tension of water to <45 mN/m (at a concentration of 0.5 wt% at 20 °C)*

2. Title and body of regulation – Unnecessary extension of the proposal to "surfactants"

CESIO would like to underline that surfactants are raw material chemicals used in B2B transactions in the formulation of finished products and are not designated for use in isolation by consumers. Therefore, all of the necessary information to ensure safety and protection of industrial and professional workers and the



environment is already implemented in standard documentation laid down by appropriate parallel legislation (SDS and label according to EU CLP, UFI number for poison centre notification). Consequently, all the information requested by the new proposal is overloaded and not necessary, aside from biodegradability requirements which are already in force in the existing Regulation EU 648/2004 and updated Regulation (EU) No 259/2012. Therefore, **surfactants should continue to be excluded from the title and the main articles of the proposal. They are already covered by other legislation.**

3. Digital Passport & additional information requirements

Because surfactants are B2B molecules, all important information can be found on the standard documentation that is already available through parallel regulation (e.g. SDS and labels according to EU CLP, UFI number for poison centre notification). As a result, CESIO believes that additional information, such as would be required through the Digital Passport including the unique product identifier/unique operator identifier, and additional data sheet and labels for surfactants is not needed as it only serves to increase administrative burden without providing proportionate benefits. If a Digital Passport is planned to be in any case introduced in future according to ESPR (Ecodesign for Sustainable Product Regulation), CESIO asks to keep it as simple as possible and to define exactly which information should be reported. The ingredient data sheet intended to be provided under the Detergents Regulation serves a similar purpose to the information that needs to be provided to poison centers for hazardous mixtures already implemented under the recently added Annex VIII to EU CLP. Hence, it has been said that there is an overlap in the requirements stemming from these pieces of legislation and that there is scope for efficiency improvements if both requirements are consolidated.

CESIO does not support the unique product identifier, linked to an individual batch of production. This scale is simply not workable for the raw material surfactants industry.

4. Label requirements listed in Annex V

Labelling of surfactants is already well regulated by EU CLP, and requirements listed in Annex V of the proposal could create difficulties in application, without providing any significant benefits. This would lead to unnecessary administrative burden especially in the context of B2B, where industrial users are already aware of the type of surfactant that they are purchasing. **Hence, this requirement should not be applicable to surfactants.**

5. Articles 4, and Annex I, Art. 3. (a) and (b) and Annex VII - Biodegradability

Biodegradability requirements for surfactants are already in force in the existing Regulation EU 648/2004 and updated Regulation (EU) No 259/2012, and the related testing methods should be clearly maintained or updated where this makes sense to avoid unnecessary duplication of tests and to reflect the latest science.

- The current detergent regulation EC 648/2004 in paragraph 30 provides the possibility not to perform additional biodegradability tests on surfactants when previous reliable and scientifically robust studies are available. This derogation, which has been removed from the Commission proposal must be maintained. It should clearly be made possible to use tests or to use CESIO data, literature data and Ecolabel DID list data that has been assessed as reliable. This would help to avoid the unnecessary duplication of tests without any benefit.

- The methods listed in Annex I remain the same as those listed previously and should now be updated. CESIO does not understand the scientific rationale as to why the EN ISO 14593 (CO₂ headspace test) that matches the OECD 310 protocol should be the reference method. The appropriate method for ready biodegradability testing depends on the type of substance and its physical properties and characteristics such as solubility, volatility and sorption. There is no scientific reason to use preferably the CO₂ headspace test rather than any other method listed in Annex I, Art. 3. (a) and (b). If the authorities need to control the biodegradability, we recommend choosing among the standard test methods listed in Annex I, Art. 3. (a) and (b) accounting for the substance characteristics.
- The methods listed in Annex VII are no longer used and should be updated. The reference method (confirmatory test) according to the standard EN ISO 11733 is a complicated, long, and expensive method. The methods described in 2. (anionic surfactants) and 3. non-ionic surfactants of Annex VII are nonspecific and use a toxic solvent (chloroform). Titration methods were used in the past when the methods for TOC determination were less to non-existent. Substance specific analysis could be the best alternative in specific cases.

6. Transition period

A sufficiently long transition period is necessary to allow industry to be compliant with the many changes resulting from this revision. The transition period of 30 months is not long enough for industry to adapt to the proposed amendments. Regarding the implementing act for the digital product passport, the start of transitional periods for implementation of the revised Detergents Regulation should commence only following the completion of the Commission's legislative obligations.

Conclusions

- A clear and unique definition of 'surfactant' is needed
- Surfactants are raw material chemicals that are already well regulated and do not need to be treated as detergents
- The Digital Product Passport must be kept as simple as possible and with clear information to be requested. It cannot be linked with every produced batch
- The possibility to use existing and reliable data on biodegradability should be introduced
- Reference method on biodegradability cannot be unique and should rather be linked to the surfactant characteristics
- Annex VII reports obsolete methods that should be removed
- Sufficiently long transition timelines needed for implementation

As a responsible industrial sector, we are committed to the safe and responsible manufacture and use of surfactants which contribute substantially to the EU economy and society as effective ingredients in a range of products. CESIO stands available to provide any further input necessary. Please do not hesitate to contact us for any further input or clarification.

Annex to CESIO comments, including some technical explanations

Points covered in this paper:

1. *Points of the regulation where surfactants should not be involved*
2. *Definition of surfactants*
3. *Biodegradability of surfactants*

1. POINTS OF THE REGULATION WHERE SURFACTANTS SHOULD NOT BE INVOLVED

→ TECHNICAL DOCUMENTATION.

ARTICLE 7: PARAGRAPH 2: [Obligation for surfactant producers to create technical documentation that complies with the requirements described by Annex IV and which has the purpose of certifying compliance with the Detergent Regulation](#)

Surfactants already have technical documentation as they are chemical substances. It makes no sense for surfactant manufacturers to create a new document of compliance with this regulation and for the document to contain, as required by Annex IV, the description, the method of use of a surfactant and its ingredient list. The biodegradability certification requested by Annex IV is more reasonable. Surfactants already have the following mandatory documents: safety data sheet, technical data sheet, certificate of analysis (quality control) and, when relevant, are notified to the poison notification center (PCN) portal according to (EU) 1272/2008 (CLP) obligation.

In particular, it should be noted that CESIO and the European Commission had recommended reporting in section 12 or 15 of the safety data sheet the conformity of surfactants with the biodegradability criteria of the Detergent Regulation, therefore it is not necessary to request a new documentation of conformity to Regulation itself. Specific CESIO guidance is found in the links below:

https://single-market-economy.ec.europa.eu/sectors/chemicals/chemicals-legislation_en
<https://ec.europa.eu/docsroom/documents/14121/attachments/1/translations/>

Moreover, information on degradability shall be given in section 12.2 of the safety data sheet in accordance with the Annex II of 1272/2008 (REACH)

ANNEX IV: [Documentation requirements certifying compliance with the Detergents Regulation](#)

Surfactants, as chemical substances, already have mandatory technical documents according to the REACH and CLP Regulations, such as e.g. the REACH registration dossier, the safety data sheet, the technical data sheet, the certificate of analysis and, where necessary, the UFI number.

- **Point 2.2 – Letter A:** [The technical document must contain the description and use](#)

A surfactant is a chemical substance used in different supply chains and industrial sectors. The use of a surfactant within a formulation, including detergent products, is not always the same. It makes no sense to report "surfactant for detergents" in a technical document.

- **Point 2.2 – Letter E:** [Requirements of the ingredients data sheet](#)

Surfactants are marketed as 100% active substance or in aqueous solution to which a preservative is added. For aqueous solutions, the safety data sheet contains the concentrations of the dangerous

substances and the UFI number, the alphanumeric code that unequivocally links the information transmitted on the composition of a mixture to the PCN portal.

Therefore, it makes no sense to define and provide for the obligation for a new ingredient sheet for surfactants.

See also explanation of article 15 paragraph 3 – point D (Labelling)

ARTICLE 15 – PARAGRAPH 3 - POINT D: Obligation to label surfactants with their contents following the requirements of part A of Annex V

Surfactants are marketed as 100% active substance or in aqueous solution to which a preservative is added. In the case of a mixture, the safety data sheet reports the concentration of the dangerous substances and the UFI number, which is obtained by notifying the ingredient data sheet on the PCN portal. It makes no sense to define and require the labeling of surfactant ingredients.

Annex V – part A – point 5 would seem to be able to exempt surfactants from this labeling obligation.

See also explanation Annex IV – Point 2.2 – Letter E (Technical documentation)

ARTICLE 15 – PARAGRAPH 3 – POINT E: Obligation to label surfactants with precautions and instructions for use

Art. 17 of the CLP Regulation already defines where necessary the warning phrases and precautionary advice to be included on the label. Surfactants are intended for industrial users, therefore it makes no sense to add instructions for use on the label. It is unclear whether “where necessary” excludes surfactants from the requirement.

It should be noted that precautions are a specific type of communication for products intended for consumers (example: "keep out of reach of children"), while for chemical substances such as surfactants, warning phrases and precautionary advice defined by the CLP are used.

ANNEX V – PART A – POINT 5: Exclusion of surfactants and professional detergents from the obligation to label the ingredients because they are already reported on the safety data sheet as required by the CLP Regulation

Unclear. Surfactants do not have to list the ingredients on the label. Are points D and E excluded from art. 15 paragraph 2?

Annex V talks about "professional detergents and surfactants". Are surfactants excluded or are only “professional surfactants” excluded? Please note that all surfactants are professional.

It is suspected that the exemption is similar to that of Annex VI which speaks of "surfactants for professional detergents"; in this case, see the explanation of Annex VI – point F (Digital passport)

→ SANCTIONS

ARTICLE 29: Description of a new system of sanctions

It is advisable to consider Regulation 1020 of 2019 without adding new redundant or misaligned provisions. Furthermore, Regulation 1020/2019 includes the figure of the authorized representative, and alignment with the Article 8 is therefore necessary (Authorized Representative).

2. DEFINITION OF SURFACTANTS

Surfactants manufacturers must currently deal with different definitions: some products identified as surfactants under the EU Customs Tarriff Regulations may not fall under the requirements of the Detergent regulation and vice versa: **therefore we call for an harmonization of the definition with the EU Customs Tarriff Regulation.**

Detergent Regulation- Commission Proposal (current version):

‘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:

- 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

Customs Tariff Regulation:

“organic surface-active agents” are products which when mixed with water at a concentration of 0.5% at 20°C and left to stand for one hour at the same temperature:

- (a) Give a transparent or translucent liquid or stable emulsion without separation of insoluble matter; and
- (b) Reduce the surface tension of water to <45 mN/m

CESIO Comments on Definition – including EU Customs Tarriff Regulations

From a standpoint of physical chemistry, the definition in the Detergent Regulation is only partially useful and applicable; the third and fifth criteria are on the one hand redundant, but on the other hand, unfortunately, also pretty much undefined, and since the five criteria are connected by “and”, the current definition is difficult to apply.

In view of the observed drawbacks CESIO concluded **that the following definition would describe surfactants more clearly:**

Surfactant means any surface-active organic substance or mixture which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of fulfilling both of the following criteria:

- **forms a clear micellar solution or a translucent microemulsion or stable emulsion without separation of insoluble matter when mixed with water at a concentration of 0.5 wt% and left to stand for one hour at 20°C**
- **reduces the surface tension of water to <45 mN/m (at a concentration of 0.5 wt% at 20 °C)**

3. BIODEGRADABILITY OF SURFACTANTS

→ BIODEGRADABILITY TEST

ARTICLE 4 – PARAGRAPH 1: The surfactants used in detergents must have successfully passed the Annex I tests

See explanation Annex I – Point 1 (biodegradability test: CO2 headspace test).

See explanation Recital 30 of Reg 648 (biodegradability test)

ANNEX I – POINT 1: Preferred method for testing the biodegradability of surfactants

The methods listed in point 3 of Annex I are correct and regularly used to determine the biodegradability of surfactants (including polymeric surfactants), but only the CO2 headspace test has been indicated in point 1 as the preferred method. In practice, there is no preferential method, because the correct method is chosen based on the chemical characteristics of the surfactant.

For non-surfactants and more particularly complex polymers, these methods listed in Annex 1 are not appropriate and AISE is working on a proposal.

ANNEX VII: Methods for verifying the biodegradability of surfactants

Some of the methods listed are obsolete titrations, not precise and accurate and which, in one case, also use a toxic solvent (chloroform). The current practice for testing biodegradability is using the methods listing in Annex I (OECD 301 A_F and 310).

Recital 30 of Reg. 648/2004: Possibility of using biodegradability data and tests, not only carried out in certified laboratories.

This possibility has been removed in the new proposed Regulation. It is advisable to add the possibility of exploiting data obtained from scientific literature, from sector associations (e.g. CESIO), from the EcoLabel detergent ingredients database, from read-across and in silico methods.

The surfactant industry already has experience with biodegradability because it was also foreseen by Regulation 648/2004. Adding this possibility would allow us to avoid unnecessary duplication of tests.

It is advisable to modify art 4 – paragraph I by inserting this possibility.

ARTICLE 22 – PARAGRAPH 2: Surveillance activities on the biodegradability of surfactants must be carried out according to the methods of Annex I, Annex II and Annex VII.

See explanation Annex I – point I and Annex VII (biodegradability test)