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NOTE

From: To:	DK, EL, IE, PL, PT, SK Delegation 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 to clusters 1-3 by DK, EL, IE, PL, PT, SK

NOTAT

Ministry of Environment of Denmark
Department

Rent drikkevand og sikker kemi
Ref. KBH
December 12 2023

Detergents regulation revision – Danish written comments to clusters 1-3

The Spanish Presidency has invited delegations to provide written comments to the proposal to the draft from the Commission within a deadline of December 13th 2023.

We welcome the revision of the Detergents regulation. Our general view on the proposal is positive and we support the overall intention of the revision.

Our main concerns are the following:

- The most harmful substances in detergents should - in line with the Chemicals Strategy for Sustainability - be subject to a general ban.
- Online sale must be as safe as sale in physical shops
- Consumers should receive the same information when they purchase detergents in a refill format as they would if the product was sold as prepackaged
- Carry over preservatives should be labelled irrespective of their function and concentration

The Danish delegation has the following comments and suggestions:

Cluster 1

Article 2(1)(9)(10)

We support the proposal.

The definition of 'surfaces' would need specification in a following guidance document e.g. for determining whether drain rinse products will fall under the proposed definition.

We suggest to consider a limit value for the share of a detergent product that can consist of biocidal active substances and still solely be advertised as intented for cleaning in order to minimize grey-zone issues between the biocidals- and detergents regulations.

Art. 2(12) refers to 'new microbial cellular constituents'. These are not defined anywhere in the proposal.

We would propose a definition of "professional/industrial" detergents to be added, as it makes it difficult for market surveillance authorities to determine whether detergents used by consumers are in conformity with the rules (that in several cases are different for professional/industrial detergents) if there is no clear indication on the product.

NEW article and NEW annex:

In the Chemicals Strategy for Sustainability, detergents are mentioned as a consumer product group where an **automatic ban of the most harmful substances** 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 were therefore surprised to see that these ambitions have not been introduced in the Detergent's Regulation.

As such, we propose the addition of a general safety requirement in a new article after Article 3, which will also establish a general power to restrict the use of certain substances, mixtures, micro-organisms or organic substances as set out in a new annex. This annex should contain both a general prohibition upon the use of the most harmful substances in consumer detergents as well as exemptions to the general prohibition.

Exemptions should be possible if safe use (environment and health) can be demonstrated. The new annex should therefore specify the conditions under which exemptions will apply. Exemptions must also take into account both exposure to the substance from other sources as well as exposure to other substances having the same mode of action. Specifically, we believe it is important that exemptions should apply for enzymes for which safe use can be demonstrated, that can play an important role in reducing the climate impact of detergents as the use of enzymes will lower the temperature and increase the efficiency of the washing process.

Art. 4 and Annex 1

Denmark supports the proposed provisions and would like to suggest that the test requirements in annex I are supplemented with **test requirements for biodegradability under anaerobic conditions**. This addition is aimed at handling the apparent rise in the use of LAS in detergents, that has been observed during recent years. LAS present in sewage sludge can prevent the recycling of the sludge as a fertiliser since it is toxic in the environment.
Further, we propose that the **biodegradability shall be proved for the substance/surfactant itself and not in the mixture**, since no currently available test methods are suitable for determining the biodegradability of mixtures.

We have difficulties understanding the provisions concerning the **exemptions** in article 4.
Article 4, no. 2, litra a. Should the provision be understood as, biocidal active substances only within the product type 1, 2, 3, 4, and 5 (main group 1: Disinfectants) are exempted from article 4, no. 1? Could you please explain the reasoning for this exemption?
Article 4, no. 2, litra a(i) and litra c: The review programme are now planned to be prolonged to 2030, and many active substances have not yet been assessed under the BPR – and will not be until 2030. Further the corresponding biocidal products with those active substances have not been assessed under the BPR neither – and will first be assessed, when the active substances have been approved. We do therefore wonder, why those biocidal active substances should be exempted at this point in time?
Article 4, no. 2, litra c: Every member state has their own different national rules which still apply as transitional measures (article 89(2) in the BPR). Some member states have a national authorisation schemes, while in other member states the biocidal products can legally be marketed without any risk assessment and without authorisation. Therefore, this provision will present the opportunity for any surfactant present in any legal, but not authorized, biocidal product under the transitional measures on the marked in any member state to be exempted from article 4, no. 1. We don't think that this could be the intention, could you please clarify?

Article 5 and Annex II
Denmark supports the proposal.
In annex II, point 2, only bacteria are mentioned. Since the presence of mentioned bacteria would be a sign of contamination during the production process, why are no types of mould included in the list?

Annex II – microorganism requirements referred to in Point 1. (a) 'ribosomal DNA sequensing' should be '16S ribosomal RNA sequensing'.

Article 6
Denmark is – like the European Commission –party to the HELCOM convention on protection of the marine environment in the Baltic Sea Area. In line with the recommendation 29 in the Baltic Sea Action Plan from 2021[i] **the phosphorous limitations should be expanded to professional industrial detergent**s.

Furthermore, we propose that detergents for outdoor cleaning products are added to the list of detergents in Annex III with limitations on the content of phosphates and other phosphorus compounds, as such products are emitted directly to the environment without prior waste water treatment.

Article 26(6)
We support the proposal.

Article 32
We support the proposal.

Cluster 2

We have received input from the Danish market surveillance authorities, who in general prefers a high level of specificity of the provisions as it improves the possibility of enforcing the rules.

Art. 7
Denmark agrees that that manufacturers should continue to hold the main responsibility for ensuring product safety and drawing up the necessary documentation, including the new requirement to create a product passport.
(3)From what point in time does the 10 years count? From when the product was first or last placed on the market?
(7) It would be helpful for the market surveillance authorities to have more guidance as to the degree/severity of the non-compliance and the appropriate reactions (correction, withdrawal or recall) from the manufacturer in the case of non-compliant products on the market.

Art. 8
Denmark notes the Commission's implicit recognition, that there will be a particular problem for market surveillance authorities regarding third country manufacturers, as third country manufacturers will be required to appoint an authorised representative. This will help market

surveillance authorities gain necessary information from third country manufacturers. However, the responsibility of the authorised representative is limited and does not include a responsibility to ensure material compliance with the regulation, meaning that the authorised representative will not be held liable for the manufacturer's non-compliance with the safety requirements under the regulation.

Denmark believes, however, that 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**.

The Commission's proposal removes the requirement under the Article 3(2) of the Detergents Regulation as it stands today, that the manufacturer shall be established within the Union. The term *manufacturer* under the current regulation is of course closer to the term *economic operator* under the proposed regulation. Nonetheless, Article 3(2) today means that there will always be an economic operator established within the Union, who can be held responsible in the event of non-compliance. This has proved helpful for market surveillance authorities with regard to dialogue with manufacturers as well as for enforcement agencies when bringing cases against manufacturers for non-compliance.

While we are broadly supportive of the opening up of trade barriers, it is important that this is carried out in a way in which ensures that third country manufacturers play on a level playing field with their competitors who are established within the Union. Where third country manufacturers are in breach of the regulation, enforcement options will be limited as the third country manufacturer will be established outside the Union, making infringement proceedings at best complicated and at worst impossible. This is a particular problem with regard to private import, which can be contrasted to professional import, where issues also remain, but are less pronounced:

- Professional import: When third country manufacturers sell their products to importers, the importer must comply with certain safety obligations under Article 9 of the proposed regulation, which in turn creates a duty of care towards both the end users of these products as well as distributors. The importer will be established within the Union, and in the event of a detergent or surfactant's non-compliance with the regulation, if negligence can be established, enforcement agencies can potentially prosecute the importer resulting in sanctions. These sanctions can also, generally speaking, more easily be enforced as the importer will be based within the Union. Issues remain though with regard to holding the third country manufacturer accountable, as they are based outside of the territorial jurisdiction of the EU.

- Private import: Where third country manufacturers – or for that matter, third country sellers – sell directly to private individuals via, for instance, online platforms, there is no professional economic operator within the Union. The private individual imports the product into the EU, but does not make the product available according to the definition of making available according to Article 2(13) – the seller makes the product available and places the product on the market. The private importer is not acting in the course of a commercial activity and therefore does not make the product available, thereby falling outside of the definition of an importer. This leads to a particular problem for market surveillance authorities in the event of non-compliance. Assuming that the third country manufacturer/seller has appointed an authorised representative and created a product passport, the detergent or surfactant will be able to enter the Union market. However, if the product proves to be materially non-compliant

with the Regulation, enforcement agencies will be limited in their ability to sanction the third country manufacturer for non-compliance as the manufacturer is established outside of the territorial jurisdiction of the EU. Nor is there any other economic operator within the EU, that enforcement agencies can sanction.

This means that the incentives for third country operators to comply with the Regulation are lower than for Union based manufacturers. This creates a compliance risk, which is entirely attributable to the decision to open up the market to third country manufacturers.

The revised detergents regulation must therefore address this risk, so that the revision does not lead to a flood of non-compliant products entering the Union, with authorities rendered effectively powerless to deal with the problem. Already today, our market surveillance authorities have seized scores of non-compliant products sold by third country suppliers to private importers in Denmark – we believe the situation will worsen as a result of the proposals put forward.

One solution worth considering is to make the authorised representative responsible for ensuring the safety of the product in the event that there is no economic operator within the Union, that is responsible for the safety of the detergent or surfactant. This could be achieved through an amendment to Article 11. Instead of being a go-between, the authorised representative would take on some of the risk for ensuring the safety of the detergent or surfactant. The level of risk would be reflected in the price that the authorised representative would charge third country manufacturers, when taking on the role as an authorised representative. This will in turn create a cost incentive for third country manufacturers to comply with the Regulation, and will result in the de facto reduction or exclusion of the most unscrupulous third country from the Union market.

Inspiration can be drawn from the role of the responsible person under the Cosmetics Regulation, where it is the responsible person, who is primarily responsible for ensuring the safety of the product. Following this approach will significantly strengthen the ability of market surveillance authorities and enforcement agencies to close the loophole that the revised detergents regulation will create. Actions for non-compliance can be targeted against the authorised representative and addressed via national processes and, if necessary, through national courts within the EU.

Art. 9, 2(13) and 2(17)
Denmark supports the Commission's intention to introduce the role of the importer under the Detergents Regulation.

The Commission envisions that importers will take on a relatively complex role, that requires a certain level of professionalism, given the range of tasks set out under Article 9. We also note from the Commission's responses to our questions on this issue at the Working Party meeting of 31st October that private import is not covered within this definition.

The Danish Chemicals inspectorate has recently confiscated thousands of very dangerous products for toilet cleaning bought online from third countries. This highlights that private consumers might encounter immediate risks posed by hazardous detergents imported directly from third countries outside the EU, if this activity is not covered by the regulation and thus out of reach of the market surveillance authorities.

Given that, as outlined in our comments to Article 8, the revised Detergents Regulation will lead to the opening up of the market to third country sellers, it remains unclear to Denmark whether these considerations have been addressed in the impact assessment. Furthermore, given the issues on private import raised under Article 8, it may be appropriate to consider a how private consumers can be included in the definition of an importer or otherwise take on the obligations of a such. This can prove useful for the market surveillance authorities.

Art. 9, 7.
In order to be helpful for the market surveillance authorities, the obligations in relation to the register should preferably be more detailed; How far back should the register go back in time (10 years would keep the provision in line with the rest of the regulation). It should further be specified, if:
All recalls of the product and the reason for it should be added to the register.
All non-conformities that the importer has found during their inspection (complete with a description of the non-conformities and, if any correcting action/measures have been taken, what they are).
All complaints received in the period, the nature of the complaint and if any follow up action was taken (consider whether the company is mandated to keep a copy of the complaint in line with the GDPR-regulation).
It would also be relevant to have requirements regarding sampling, e.g. about
frequency of the checks (e.g. "the importer is obligated to check a product from each batch, or a product per X amount imported"); the nature of the checks (is it sufficient to check labelling and MSDS or is an chemical analysis required); what documentation is required to document the sampling has been performed.
The criteria for when sampling is required needs to be clear, in order to ensure a level playing field for all economic operators on the market.

The register should be in a digital format and should enable that a copy of the register be sent to the MS-authorities upon request in a nonproprietary format (e.g. pdf, excel, txt or similar format).

Art. 10
Denmark supports the introduction of clear obligations on the role of the distributor.

Do the responsibilities set out in Article 10 also apply to online marketplaces, as defined in the Digital Services Act, that make detergents sold by third country traders available to consumers within the Union?

Art. 11 and 12
Denmark supports the intentions behind the introduction of Article 12 and has no further comments at this point in time. Denmark suggests amendments to Article 11 in line with our comments to Article 8.

Art. 13
Denmark supports the intentions behind the introduction of Article 13, and proposes that this requirement be extended to online marketplaces and fulfilment centres.

Art. 14
Denmark supports the introduction of CE-labelling for detergents. It should be clarified how this requirement will apply to refill sales.

Annex IV

Denmark broadly supports measures to ensure clear a framework for manufacturers with regard to the information that should be included in the technical documentation.
We note that Annex IV point 1 refers to points 2, 3 and 4. However, there is no point 4 in Annex IV. Is the reference to point 4 a mistake, or is the absence of a point 4 the mistake?
Point 2.2. (e) EU citizens suffering from allergy need to be able to obtain information about all ingredients that might cause allergic reactions. Thus, **all known ingredients and impurities** should be included in the **ingredient data sheet** and not only intentionally added substances and preservatives.

Art. 22 (4) and (8)
(4) Will a system be set in motion to do this, or should it happen via RAPEX or ICSMS?

(8) Different member states may use different enforcement tools for similar non-compliance. Could the Commissions please clarify the procedure in the case when one member state complains about the harshness or leniency of another member state?

Art. 23
Denmark supports the intentions behind the introduction of Article 23 and has no further comments at this point in time.

Art. 24
Denmark proposes a slight adjustment of the scope of the safety clause, which should be expanded to enable member states to be able to introduce temporary restrictions on the availability of **groups of detergents**, where these detergents are identified by the presence of a particular substance. Widening the scope of the safety clause will enable authorities to act more quickly, when new evidence on harmful substances comes to light, and enable Member States to introduce temporary general restrictions on certain substances on safety grounds (both human and environmental), while the Commission investigates the validity of these concerns.
One particular issue experienced by market surveillance authorities is that restricted products being placed on the market again under a new brand name. Economic operators can then simply carry on trading, until market surveillance authorities become aware of the existence of these identical products being traded under a different brand name.

The proposed safety clause recognises the importance of involving the impacted economic actors, when activating the safety clause, and any widening of the scope of the clause must also respect these interests. To balance the interests of suppliers and the requirements of market surveillance authorities, Denmark proposes the addition of a new paragraph 5 in Article 24, where generic restrictions may only be introduced three months after notification of the Commission and after use of the procedure set out under Article 24(1) as a first resort. This power should only be available for serious risks. This will ensure that economic actors are involved in the process for use of the safety clause, while reflecting the difficulties faced by market surveillance authorities.

Article 24. We would like to suggest a new point 5.

> "5. Where the risk to health or the environment as set out in the first paragraph relates to the presence of a specific substance, mixture, micro-organism or organic substance, Member States may, if appropriate, introduce temporary general restrictions on the making available of detergents or surfactants containing this substance, mixture, micro-organism or organic substance. The risk to health or the environment must constitute a serious risk.

A generic restriction may only be introduced three months after the market surveillance authority has informed the Commission and the market surveillance authorities of the other Member States as required under the third paragraph.

Market surveillance authorities may only use this power after identifying products containing the specific substance, mixture, micro-organism or organic substance in question, that are made available to end-users in the Member State's national market. Until the temporary restriction takes effect, market surveillance authorities shall prioritise the identification of the applicable detergents and surfactants and use the procedure outlined under the first paragraph."

Article 29 - Penalties

While Article 29 is not listed as one of the provisions under discussion under Cluster 2, as it relates to enforcement of the regulation, we believe that this cluster is the appropriate place to raise this issue. Our market surveillance authority would like confirmation whether the changes made to Article 29 on penalties compared to the text of Article 18 will have a material effect on the type of sanctions that Member States are required to impose under the Regulation?

Cluster 3

Art. 15

We welcome the intention to simplify and streamline the labelling requirements which should of course also be streamlined with the CLP regulation and the Packaging regulation that are both currently being revised.

The dosage information mentioned in art. 15 4. would also be useful for a wider range of detergents, and contribute to their safe use and reduction of environmental impact. The relationship between dosage and use area (m2) should be available in the label.

We would like **a clear obligation to label carry over preservative**s to be established. As mentioned in recital (29), in order to ensure a high level of protection, the labelling requirements for preservatives should be expanded to cover not only intentionally added substances, but also 'carry over preservatives'. A large number of EU citizens are negatively affected by allergenic substances, and both groups of substances are known to be able to cause allergenic reactions. If a general obligation to label all carry over preservatives is not possible, it should be specified that specific groups of substances used as preservatives, that are known for triggering allergenic reactions at significantly lower thresholds than the elicitation threshold in CLP (eg. Isothiazolinones and formaldehyde releasers) should be labelled when they are present in the detergent. Specific concentration thresholds for these substances should be determined in the text.

It shall be clarified who is responsible for the information to the end-user in refill-situations. Article 15 (2) refers to the economic operator which covers the manufacturer, the authorized representative, the importer or the distributor (article 2, no. 19). Thus, it complicates the enforcement when more than one player can be responsible for potential alignments.

In addition to the provisions in Annex V, part A, 6. in relation to labelling of detergents containing microorganisms, we think that not only surfaces in contact with food but also food items themselves should be covered by the information that the product must not be used for this purpose.

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Finally, we would like to add another labelling requirement for products that are marketed for cleaning of the surface of fruit and vegetables (cf recital 6). These should be labelled with a statement that the food must be thoroughly rinsed with drinking water after use of the product.

Art. 16

Detergents marketed as refill products should be accompanied by the same information in physical format as if bought prepackaged. It is especially important to have the information on the physical label in cases of accidents. Thus we cannot support the exemption in article 16, point two.

Art 17: We support the introduction of digital labelling**. The most essential information for safe use should still be available on the physical label**. The digital label shall be available in the language or languages of the country of purchase.

Art 17(1): It is unclear how it is to be decided if a technology qualifies to be considered as 'widely used and compatible'
(e) Does this also include pensioners or other vulnerable groups who are not always assumed to be in possession of a telephone with the necessary technical specifications to access the digital label?

(f) How is major operating systems and browsers defined user base above X no. of users or X% of the market?

(g) It is unclear whether this provision implies that labelling requirements in Danish, for example, cannot be imposed if a product is marketed in DK and other Member States. If this is the case, it could cause problems.

Art. 26 (7)

Denmark prefers the existing provisions that **ensure automatic adaptation** to the updates in the cosmetics regulation and does thus not support the proposed changes.

[i] Baltic Sea Action Plan (2021) p. 25 (Action point E29) "Undertake efforts to reduce and where possible eliminate phosphorus in detergents for industrial & institutional use, in particular for institutional use of laundry and dishwater detergents no later than by 2030 based on the knowledge on best available techniques compiled during the first step".

Hellenic Republic

ΑΑΔΕ
Independent Authority
for Public Revenue (IAPR)

Independent Authority for Public Revenue
Directorate General
General Chemical State Laboratory
Directorate of Energy, Industrial and Chemical Products

Athens, 8.12.2023

EL CA General comments on the 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 and comments on Doc WK13972en23_Flash.

A. General comments on the Proposal

EL CA supports the Commission's Proposal for amendment of the Regulation on detergents aiming at the improvement of the coherence with REACH, CLP and BPR by removing duplications and the simplification of the regulation as well as allowing for incorporation of new technological developments of the EU industry. However, we don't agree with a number of provisions in the revision proposal as follows:

1. Product Passport (PP)

Although we welcome in principle the requirement of a product passport in other type of products we do not see that it is justified to introduce product passports in light of the requirements presented in the proposal. The requirement for product passport for every produced batch, which is absent from the Impact Assessment, only increases the administrative burden, especially for SMEs, without adding new essential information.

In addition, we consider that the introduction of CHAPTER V (articles 18,19,20,21) and ANNEX VI, where set out specific provisions for the Product Passport, is not mature considering that, there are still open issues in the Regulation on Ecodesign for Sustainable Products and negotiations are still going in the second trilogue.

2. CE marking

There is a lack of the Impact Assessment of the CE marking requirement on SMEs and the member state's Market Surveillance Authorities. We consider that the CE marking conformity assessment carried out by manufacturers (Module A), who may be established outside the Union, may not be a reliable indicator of conformity of the detergent bearing it, especially since its fraudulent use cannot be easily controlled. We do not see its real added value taking into consideration that, the effectiveness of the CE marking is highly questionable as well as it is expected to raise an administrative burden on MS.

3. Refill sales

The introduction of the refill sales will promote a sustainable practice that has significant environmental benefits in terms of packaging waste, however the inserted rules on refill sales such as:

i) the refill operation may be carried out by the "end user" in his own package,

ii) the labelling requirements may be provided in a digital label only with the exception of dosage information for consumer laundry detergents. The labelling of allergenic fragrances and preservatives are not included in the exception,

do not ensure that consumers when buying refilled detergents receive the relevant safety and use information, which is crucial e.g. in case of an accident or to ensure proper product use.
Thus, we propose the introduction of an Annex to the Regulation which will regulate in clear terms the refill operation and the placement on the market of refilled detergents in order to ensure end users safety and healthy competition between businesses.

Furthermore, the role in the supply chain of the "owner of the refill business" is not clear in the cases where the refill operation is carried out.
There is a lack of definitions i.e. "refill format" and "refill station" which are mentioned in the text.

B. EL CA comments on WK13972en23_Flash

1. Cluster 1 – Product Requirements

Article 2 – Definitions

Proposal:

We propose the word substance should be added in the definition -2nd indent because there are substances i.e. sodium carbonate which are bleaching agents.

'*detergent' means any of the following:*
– a substance, mixture or micro-organism, or two or more such materials in combination, which is intended for cleaning of fabrics, dishes or surfaces;
*– a **substance or** mixture intended for soaking (pre-washing), rinsing or bleaching fabrics or dishes;*
– a mixture intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;"

Annex I - Biodegradability requirements referred to in Article 4

Proposal:

It will be useful to add In the Annex I a reference to the equivalent OECD methods, facilitating the work of Market Surveillance Authorities since the surfactant's MSDS in many cases report biodegradability information related to OECD methods.

2. Cluster 2 – NLF & Market Surveillance

Article 7 - Obligations of manufacturers

Point 8**.**

Proposal:

Manufacturers shall, ~~further to a reasoned~~ **upon** request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, 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.

Justification

It is not clear the term "a reasoned request ". The Manufacturers should be obliged to provide all the necessary information to a competent national authority for the conformity assessment. We propose the replacement of the "a reasoned request" with "upon request".

Article 8 - Authorised representative

The role, responsibilities and obligations of the "Authorised representative" needs clarification taking into consideration that CLP applies to detergents as well. The new proposal should ensure coherence with CLP provisions in order to avoid confusion related to obligation and responsibilities among the economic operators for the same product in the supply chain.

In addition, in point 3b we propose the replacement of the "a reasoned request" with "upon request".

Justification same above.

Article 9 - Obligations of importers

Point 4

"The contact details shall be in a language easily understood by end-users and market surveillance authorities"

It is not clear what it means "in a language easily understood". It needs further clarification.

Point 10

We propose the replacement of the "a reasoned request" with "upon request".

Justification same above.

Article 10 - Obligations of distributors

Point 6

We propose the replacement of the "a reasoned request" with "upon request".

Justification same above.

Article 14 - Rules and conditions for affixing the CE marking

Point 3:

"Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking."
Comment
The CE marking is expected to raise an administrative burden on Member States

Article 22, Article 23 and Article 25 -Market surveillance
The control of detergents is already regulated in the Market Surveillance Regulation (EU) 2019/1020. The provisions on market surveillance in the proposal are not expected to lead to more effective enforcement.

Annex VII
It must be confirmed that the test methods described in Annex VII are still relevant, up-to-date and used by authorities otherwise the Annex can be deleted from the regulation.

3. Cluster 3 – Labelling & Digital labelling

Article 15 - General labelling requirements

Point 2.
Proposal:
"An economic operator making a detergent available on the market directly to an end-user in a refill format shall provide the physical label ~~or~~ ***and optionally may be provided*** *the data carrier through which the digital label is accessible to the end-user."*
Justification
The physical label of a detergent should be obligatory provided to an end-user, ensuring high degree of protection of health.

Point 3
"(b) the ***manufacturer's name****, registered trade name or registered trade mark and the postal and email address at which they can be contacted. The postal address shall indicate a single point at which the manufacturer can be contacted"*
Comment:
The information solely of the manufacturer's name is not sufficient if the manufacturer is established outside the European Union. The provision does not cover all the economic operators who make available a detergent on the market

Point 5
Proposal:
"The information referred to in paragraphs 3 and 4 shall be in ~~a~~ ***the official language(s) of the Member State(s) where the detergent or the surfactant is placed on the market unless the Member State(s) concerned provide(s) otherwise.*** *~~which can be easily understood by end-users, as determined by the Member State concerned, and~~* ***It*** *shall be clear, understandable and intelligible. The label shall be accessible for inspection purposes where the detergent or surfactant is made available on the market."*

Justification
The label should be in the official language(s) of the Member State(s) where the detergent or the surfactant is placed on the market in order to ensure that consumers when buying detergents

receive the relevant safety and use information in their language, which is crucial e.g. in case of an accident or to ensure proper product use.

Article 2 – Definitions

point 33: *'refill' means the operation by which the detergent is filled in-store from a large container in the end-users' own package either manually or through automatic or semi-automatic equipment;*

Proposal:

The definition of **"refill''** needs to be in alignment with the proposed definition in CLP regulation i.e *'refill' means an operation by which a consumer or a professional user fills a packaging which fulfils the requirements on packaging set out in Title IV, with a hazardous substance or mixture offered by a supplier in the course of a commercial activity, whether in return for payment or free of charge.*

In addition, there is a lack of definitions i.e. "refill format" and "refill station" which are mentioned in the text.

Article 16 Forms of labelling

Pont 2:

Proposal: Deletion

~~*"By way of derogation from paragraph 1, where detergents are made available on the market directly to an end-user in a refill format, the label elements set out in Article 15(3) and (4) may be provided in a digital label only, with the exception of dosage information for consumer laundry detergents as set out in point 1 and 2 of part B of Annex V, which needs to be provided also on a physical label."*~~

Justification

We believe that a physical label of a detergent in a refill format should be obligatory provided to an end-user, ensuring high degree of protection of health. In addition this will be in accordance with CLP revision.

Annex V – Labelling Requirements

PART A – LABELLING OF CONTENTS

Point 3 last paragraph

"*The condition listed in point (b) of the first subparagraph does not have to be met where preservatives do not exceed the elicitation thresholds referred to in point 3.4.3.3. / table 3.4.6. of Annex I to Regulation (EC) No 1272/2008* ~~*or they no longer have a preservation function in the final product even in synergies with other preservatives*~~*"*

Proposal:

We propose the deletion of the last sentence because the provision is vague and does not include criteria on how compliance will be demonstrated. Consequently, it lowers the level of protection of human health which is one of the main objectives and scope of the Regulation.

IE comments on Clusters 1, 2 and 3 of the Detergents proposal, as described in the Presidency flash WK 13972/23 presentation.

In addition to our previous comments on Clusters 2 and 3 (see below), IE has the following queries on Clusters 1 and 2:

Cluster 1 Product requirements regarding Scope and proposed definitions:
We would propose that the definition for Professional detergents is amended to "….*a detergent for cleaning carried out by specialised personnel using specific products*", i.e. remove wording referring to "*outside the domestic sphere*". Our preference is to not exclude professional cleaners working in private housing and homes.
We also recommend that definition #24 for CE marking should include the details of the relevant legislation for clarity.

Cluster 2 - NLF alignment & Market Surveillance

Comments concerning the proposed provisions for the Ingredient Data Sheet (Art. 7(6)):
Regarding the obligation for manufacturers to provide the ingredient data sheet (IDS) upon request to an appointed body, in the case of non-EU manufacturers, we would like clarity on how this provision may be enforced. There is no duty specified for an authorised representative or for an importer to provide an IDS on behalf of a non-EU manufacturer in the proposed text. We welcome clarity on how the appointed body should therefore gain access to the IDS from a non-EU manufacturer if they request it and in the case where they cannot gain access, how the provision may be enforced.

Comments on the main obligations of key economic operators:

Authorised representative obligations under Article 8:
Concerning the responsibilities of the authorised representative, it is unclear what purpose the authorised representative serves within the EU in the case of an imported detergent from a non-EU manufacturer. Under the current proposal both the authorised representative and the importer must verify that the technical documentation is in place, as required under Art. 7(2). However, under Art. 9(1) only the importer is responsible for placing only compliant products on the market. Therefore, the role/function of the authorised representative is not evident. Market surveillance activities by CAs and enforcement actions will be targeted at those actors with responsibilities in the EU, i.e. with importers for ensuring compliance of imported products being placed on the EU market. As the authorised representative unlike the importer, is not required to place their details on the label they will therefore not be known to market surveillance authorities.

Art. 8(3) states that an authorised representative may terminate the mandate with the manufacturer if the manufacturer does not comply with their obligations. We question the consequences for the (non-EU) manufacturer as there is no provision in this proposed Regulation to prevent placing on the market if an authorised representative is not in place.

As stated above, the authorised representative is not required to be named on a label nor is the authorised representative required to be named in the technical documentation, therefore, we seek clarity on how the authorised representatives are to be identified and whether they serve any role within the supply chain that is enforceable by market surveillance authorities.

Importer obligations under Article 9:
In relation to the obligations of importers, under Art. 9(1) importers are responsible for ensuring that detergent products are compliant and, where not in compliance, as per Art. 9(3), the importer should not place the product on the market. Again we, therefore, seek clarity on the purpose and role of the authorised representative, as the importer is the actor with greatest

responsibility and is also the actor who will be subject to compliance checks/enforcement activities.

Distributor obligations under Article 10:
Regarding obligations proposed for distributors under Art. 10(2)(c), we are of the opinion that these duties are onerous, in that, as the text is written, distributors must ensure that the manufacturer or importer have complied with the duties set out in Art. 7(2) and 7(3) or 9(2). While we agree that distributors have a responsibility to check compliance, the main responsibilities should be at the top of the chain, i.e. with the manufacturers and/or importers. Therefore, we propose that provisions are set out under Art. 7 and Art. 9 requiring the manufacturer and importer to provide the relevant information/proof of compliance to the distributor for proportionality.

<u>Prior Comments on Clusters 2 and 3:</u>

Cluster 2:

Article 7 - Obligations of manufacturers
While Article 7(1) states "When placing detergents or surfactants on the market, manufacturers shall ensure that those detergents or surfactants have been designed and manufactured in accordance with this Regulation." there are no requirements set out in Annex IV to demonstrate the detergents or surfactants have been so designed.

IE Queries on Article 7(4):
Question 1: What does the term "performance" refer to in the context of Article 7(4) - cleaning performance or environmental performance?

Question 2: Who deems it appropriate to initiate the actions referred to? Is it up to the operator to deem it appropriate to carry out the testing and inform the distributors of the results?

Question 3: Do these requirements refer to situations where indications of lack of performance or risks become apparent after the detergent or surfactant has already been placed on the market?

Similar clarifications are required regarding Article 9(7) - importer obligations.

Article 10 - Obligations of distributors
IE notes duplication in Articles 7, 9 and 10 on the Obligations of manufacturers, importers and of distributors which could be consolidated for a more concise legal text.

Article 12 - Packaging and repackaging by importers and distributors
On Article 12(a), IE proposes to change 'his or her' name to 'their' name.

Article 22 – Procedure at national level for dealing with detergents and surfactants presenting a risk
IE suggests that this could be refined with a simple reference to the Market Surveillance Regulation as the proposed legal text replicates the text of the Market Surveillance Regulation. IE proposes that Chapter VI need only, in the main, refer to the Market Surveillance Regulation rather than reiterating its provisions here.

Article 25 - Formal non-compliance
IE does not see the need for specifically highlighting the need for market surveillance authorities to take formal non-compliance under Article 25. The powers to take action are set out under the Market Surveillance Regulation as implemented through national legislation. Therefore, we propose that Art. 25 is amended.

IE proposes that sub-article 2 of this Article will suffice, i.e. *Where a non-compliance with the requirements of this Regulation persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the detergent or surfactant being made available on the market or ensure that it is recalled or withdrawn from the market.*

Article 2 – Definitions

IE requests that consideration be applied to ensuring consistency across definitions used in relevant legislation, i.e. REACH, CLP, the proposed revision of the Regulation on packaging and packaging waste throughout the text.

On definition of 'detergents' – IE editorial comment: Propose to delete the words 'a mixture' from indents 2 and 3 so as to include substances and micro-organisms within the scope of all three intended uses in order to future-proof the text. IE believes there is a need to amend the definition to ensure that the scope of detergents includes both substances and mixtures. The definition may also need to take into account new/novel products such as laundry sheets, which are considered part-mixture/part- article under CLP (see ID12049).

Cluster 3 – Labelling & Digital labelling

Article 17 – Requirements for digital labelling

IE suggests that technical details currently written in Articles 15-17 on labelling requirements may be more suited to the technical Annexes.

13th December 2023

Detergents Regulation - comments by POLAND on the Clusters 1

Technical Harmonisation Working Group – Hazardous substances (Chemicals)

Ad - Cluster 1 – Product Requirements

Poland believes that the draft regulations in scope of cleaning products based on microorganisms should comply with the following objectives:

• ensuring safety while supporting innovation. This will only be possible without limiting *a priori* the products or types of microorganisms to be used in microbiological cleaning products (detergents);

• a proportionate approach regarding the use and timing of distribution of microbiological cleaning products.

Regarding the testing detergents based on microorganisms in the form of a spray (i.e. potentially high inhalation toxicity), the research methodology -based on animal can only be accepted if there is no other possible way to demonstrate that the product is safe for human health

According the current OECD guidelines, the methodology for assessing the toxicity of substances/mixtures should be carried out using alternative methods, i.e. without the use of animals.

Furthermore, it is worth to point out that conducting this type of research (on animals) is contrary to the obligations of industry and European institutions in the field of animal protection. We are of the opinion, that the testing requirements should reflect the specificity of detergents and surfactants.

Proposal for a Regulation on detergents and surfactants

PT comments (14.12.2023)

1. **Cluster 1 – Product Requirements**

Article 2 (Definitions)

We believe that definitions (7), (8) and (9) should be provided directly in the text.

In point 10, a definition of Genetically Modified Microorganisms is presented that does not fully correspond with the definition of Genetically Modified Microorganisms presented in Directive 2009/41/EC, on the contained use of genetically modified microorganisms. The definition presented in the Directive is more detailed than the one in the present proposal, as it lists in an annex to the Directive which genetic modification techniques are considered to give rise to Genetically Modified Micro-organisms, and which are not considered to give rise to genetic modification. Therefore, we propose to consider modifying this definition.

Article 3 (Free movement)

Considering that the proposal foresees the definitions of «placing on the market» and «making available on the market», we believe paragraph 2 should be amended as follows: «Member States shall not prohibit, restrict or impede the placing **and making available** on the market of detergents or surfactants which comply with this Regulation».

Article 4 (Biodegradability)

Taking into account that only the surfactants used in detergents must pass final aerobic biodegradability tests and not detergents, article 4(1) should be amended as follows: « *Surfactants and **detergents containing** surfactants shall comply with the biodegradability requirements laid down in Annex I*".

Annex II (Requirements for detergents containing micro-organisms referred to in Article 5)

Annex II establishes the requirements applicable to detergents containing microorganisms provided for in article 5 of the proposed Regulation, including

limitation to microorganisms listed in several EU lists. However, these lists seem to be linked only to risks to human health.

Considering Recital 11, namely the concern regarding the capacity of micro-organisms to persist and multiply in different environments and to produce a range of different metabolites and toxins of potential toxicological significance, we consider that the risk for the environment should also be taken into account. In this sense, we consider that requirements and criteria for environment risk assessment for detergents containing microorganisms should also be included in Annex II. Please note that this kind of risk assessment is already foreseen for active microorganisms in the biocides Regulation.

2. Cluster 2 – NLF & Market Surveillance

Article 7 (Obligations of manufacturers)

We believe the text should explicitly state that the manufacturers are fully responsible for the products they place on the market.

Additionally, as mentioned by other MS, we agree that the ingredient data sheet for non-hazardous detergents should be provided proactively to health authorities. This kind of information is relevant for safety reasons, and it should be shared, especially with poison centres.

Article 8 (Authorised representative)

We have doubts about the added value of this «authorised representative». Thus, we suggest the deletion of this article.

Alternatively, if this "actor" is considered necessary, we propose to use the same terminology and criteria as established under article 8 of REACH Regulation («only representative»).

Article 9 (Obligations of importers)

We believe the text should explicitly state that the importers are fully responsible for the products they place on the market.

Article 10 (Obligations of distributors)

The wording of paragraph 1 seems unclear regarding the distributors' obligations.

Article 14 (Rules and conditions for affixing the CE marking)

The introduction of this article appears to be disproportionate to the additional administrative costs that will impose on companies and businesses, especially SMEs. Consequently, we propose the deletion of this article and all the references to CE marking in the text, including in the definitions.

Article 2 (Definitions)

We believe that definitions of manufacturer, importer, and distributor currently in effect should be kept and that definition 16 should be deleted. Additionally, we consider that all definitions in article 2 should be as much as possible aligned with REACH and CLP.

3. **Cluster 3 – Labelling & Digital labelling**

Article 15 (General labelling requirements)

Article 16 (Forms of labelling)

Article 17 – Requirements for digital labelling

We consider that these articles should be harmonized with CLP Regulation Revision.

Article 2 (Definitions)

We believe that definition 33 should be harmonized with the CLP Regulation Revision.

SK comment on the proposal of Detergents Regulation on working group Council for technical harmonisation

SK CA generally supports the goals of the proposal, to ensure higher protection of human health and environment, as well as assuring effectiveness of the market in the EU. The proposal takes into consideration reduction of the regulatory burden and innovations.

We have several comments to the Commission's proposal listed below.

Cluster 1 – Product requirements

Article 2 the definition of batch - SK CA supports the opinion to replace "batch" with "model" approach. Model would mean a combination of the Product name + Unique Formula Identifier (UFI), irrespective of whether a UFI code is required under CLP Annex VIII., The "model" approach would create one Digital Product Passport (DPP) for one detergent composition instead of many same DPPs on batch level.

Cluster 2 – NLF and market surveillance

Article 9(4) importers and Article 12a) importer or distributor packages or repackages a detergent or surfactant – we would like to propose also to add email address/website address/ phone number on label/package. We consider it more appropriate for online access and the flexibility for the actors in the supply chain.

Article 12 - we support the separate obligations for packaging and repackaging detergents separately for importers and separately for distributors.

Article 7(6a) Ingredient Data Sheet - we are of the opinion that submission of the ingredient data sheet to appointed body (poison centre) for non-hazardous detergents should be mandatory, not submission on request. In case of an accident, the appointed body needs to have available information on ingredients for the purpose of proper protection of human health.

Cluster 3 – Labelling a digital labelling

We support the simplification of labelling requirements. As regards terminology we appreciate the alignment with CLP Regulation.

Refill sales

Article 16, paragraph 2 detergents made available on the market directly to the end-user in refill format - in addition to the proposed possibility that label elements may be provided only in the digital label. We would also appreciate the possibility to provide physical label at the consumer's request. The physical label shall be also visible at the refill station.

Recital 28, Article 26 (7), Annex V part A paragraph 4 regarding allergenic fragrances - we are in favour of the addition of statement that fragrance allergens specified in Cosmetic Regulation (EC) No 1223/2009 directly apply to detergents under the Detergent Regulation as well as the same transition periods should apply to cosmetic and detergent products.