



Revision of EU Ecolabel Criteria for awarding the EU Ecolabel for Cosmetic products and Animal care products (previously Rinse-off cosmetic products)

**TABLE OF COMMENTS**  
**Post –EUEB April 2021**  
**June 2021**

# Table of contents

ANNEX I ..... 3

ANNEX II ..... 64

ANNEX III ..... 153

DRAFT

## ANNEX I

Comments received after the 1<sup>st</sup> Ad-Hoc Working Group meeting (Nov 2019). Comments refer to the first version of the revised criteria proposal.

Comments received in AHWG1/written form	JRC Dir. B response
<p>To include MOUTHRINSE products as part of oral care hygiene. These products are included in Nordic Swan.</p>	<p><b>ACCEPTED</b> The reason to prioritize only some of the categories was to include only the categories for which evidence exists that it would be feasible to be included in the scope (by comparison to other schemes, similarity to other products that are already included in the scope,...) and to comply with the current proposal criteria. Considering that the EU Ecolabel aim is to cover the 10-20% of products in the market with the best environmental profile, thresholds that are feasible to be accomplished need to be proposed. Finally, the scope has been further extended to align as much as possible with Nordic Swan and mouthwashes have been included in the new scope.</p>
<p>Denmark support the presented scope and would also like to see it extended even more. Even if the environmental benefit or the marked potential might be small, we do not see the need to limiting the scope. Often retailer aim at labelling a whole series of products which might not be possible with the scope presented in the draft. Example toothpaste is included but mouthwash is not.</p>	<p><b>ACCEPTED</b> We have made the change in the Technical Report. Moreover, we have inserted a clarifying sentence in the general assessment and verification, stating that "Label and/or instructions information accompanying the product shall be used to categorize the product. Where a cosmetic product is marketed for different uses, the category for which stricter criteria applies shall be assigned to the product."</p>
<p>By concept, a mouthwash is a leave on product. However, it should take into account that in some cases a mouthwash product can also be considered as rinse off. Thereof, we would like to propose to include both categories in the document</p>	<p><b>ACCEPTED</b> Decorative cosmetics have been proposed to be included in the new scope.</p>
<p>We support broadening of the scope. However, the JRC proposal is limited to some cosmetics only, while it would be easier to apply to all cosmetics (except biocides). At least decorative cosmetics are in the scope of both The Nordic Swan and Bra Miljöval. Apply to all cosmetics. At least include decorative cosmetics. Since decorative cosmetics are being washed of in the sink, most of the product will end up in the wastewater, just as rinse-off products. The conclusion that there is a low risk of being released into water is probably wrong.</p>	<p><b>ACCEPTED</b> Decorative cosmetics have been proposed to be included in the new scope.</p>
<p>Hair styling and treatment products are proposed to be excluded from the scope, since the formulations differs largely from products included in the existing scope. This is a strange reasoning. By setting criteria for a broad spectrum of product types, although challenging for certain product categories, the EU ecolabel will give incentives for innovative companies.</p>	<p><b>ACCEPTED</b> All products that have been awarded with the Nordic Swan Ecolabel have been proposed to be included in the new scope: Hair styling and treatment products, deodorants and antiperspirants, decorative cosmetics, nail enamel removers and wet wipes. Mouthwashes have also been proposed to be included in the new scope. On the other hand, health (or safety) is well covered by Cosmetic Regulation 1223/2009, as all cosmetic products (Ecolabel awarded or not) in the market must comply with this regulation, hence a risk assessment has to be performed.</p>
<p>Why is there a need to limit the scope to only certain categories? Why not all? The priority is given on environment, but considerations should also cover health. Health is also a reason to include all types of cosmetics. The reasoning on rinse of vs leave on is also somewhat misleading. A certain amount of leave on is also rinsed off, just x hours later. Unless you assume an unlikely 100% skin absorption. Most likely some of the leave-on cosmetics will be transferred to the clothes, from which it will be washed off an end in the aquatic environment. The Nordic swan has a licensed a range of leave on cosmetic products including for instance:</p>	

<ul style="list-style-type: none"> <li>- Deodorants</li> <li>- Lotions</li> <li>- Decorative cosmetics</li> <li>- Sun care</li> <li>- Lip care</li> <li>- Hair care</li> <li>- Hair styling</li> <li>- Baby care</li> </ul> <p>They also include</p> <ul style="list-style-type: none"> <li>- Toothpaste</li> <li>- Mouth wash</li> </ul> <p><i>This means that there is a wide interest for a broader scope. Include all categories of cosmetics excluding biocides. If not possible, at least include hair treatment/ styling products. These will to a great degree also reach aquatic environment when rinsed off. Also consider if relevant baby products are in the scope. There is a high demand for ecolabel on these products (e.g. baby oils, ointments etc.). All cosmetic products are included in Nordic Swan except biocides. We support the exclusion of biocides (e.g. antibacterial soaps) as studies show that the they have the same efficacy on cleaning the hand (and eliminating the germs) than normal soaps but can contribute for the bacterial resistance.</i></p>	
<p><i>Overall, we welcome aligning the definitions used for the ecolabel criteria with the relevant EU legislation. With regard to the scope of the ecolabel, from a chemicals point of view we cannot see the benefit of limiting the extension of the scope to certain product types as it is the case in the current proposal. This is as it appears that the same chemicals related criteria would likely be applicable and as while there is a difference of the share and timing of the release to water of the different product types, it is difficult to exclude the possibility of the release.</i></p>	
<p><i>We do not support the inclusion of sunscreen products in the scope. UV filters represent a large part of sunscreen products formula, and they are not biodegradable. Thus, we consider that including those products in the scope could discredit the reputation of the EU Ecolabel.</i></p>	
<p><i>Sunscreens contained UV filter that are not biodegradable at a high level of incorporation (more than 10%). For us EU ECOLABEL certification is incompatible with formulas that contain a big amount of non biodegradable raw materials. We consider that including those products in the scope could discredit the reputation of the EU Ecolabel.</i></p>	<p><b>REJECTED</b></p> <p>The probability of sunscreen to finish into the water is higher than other not rinse-off products. The aim to include the sunscreen products in the scope is to award the sunscreens with the lowest environmental impact, therefore to motivate companies to formulate environmental-friendly products. Moreover, sunscreens are included in the scope of the Nordic Swan: 68 products are certified under the Nordic Swan ecolabel, enabling the certification of sunscreens under the EU Ecolabel.</p>
<p><i>It will be difficult for sunscreens to fill the criteria of biodegradability; this product should be excluded from the scope</i></p>	
<p><i>Deletion of sunscreen products</i></p>	
<p><i>Regarding the broad inclusion of skin care product, their end-of life impact should be analysed: most of the product is likely to stay on the skin, but some may also be found</i></p>	<p><b>ACCEPTED</b></p> <p>CDV and biodegradability thresholds of skin care products have been aligned with</p>

<p><i>in the water. Criteria related to the CDV and biodegradability should be adapted if they are included in the scope (the thresholds for rinse-off products may not be adequate).</i></p>	<p>Nordic Swan Ecolabel. There are licences for skin care products in Nordic Swan.</p>
<p><i>We wonder if solid shampoos and solid toothpastes are included in the proposed scope for the revision and we would support their inclusion as they represent a growing part of the market.</i></p>	<p><b>CLARIFIED</b> Solid shampoos and solid toothpastes are included in the scope. A sentence has been included in the definition section in order to clarify the inclusion of the solid shampoos (in accordance with the other type of soaps).</p>
<p><i>Is it possible to include deodorant in the new scope? Indeed, we generally use deodorants at least once a day and after shower, there should be residues in water. Moreover, there is a lot of concern about substances included in these products like aluminium salt. So, I think we should reconsider the idea to include deodorants and antiperspirants in the new scope</i></p>	<p><b>ACCEPTED</b> Deodorants have been proposed to be included in the new scope.</p>
<p><i>Is it correctly understood that the preservatives added to the raw materials are also covered? Since additives such as preservatives and stabilizers are added to the raw materials, they can remain in the product. It is important to ensure that they are also covered by the criteria. Add "including preservatives etc. used in raw materials". The Nordic Swan Ecolabel specifies this in the definition of "ingoining substances": all substances in the Nordic Swan Ecolabelled cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials.</i></p>	<p><b>ACCEPTED</b> The definition of ingoining substance has been aligned with Nordic Swan: "all substances in the Nordic Swan Ecolabelled cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoining substances (e.g. formaldehyde, arylamine, in situgenerated preservatives) are also regarded as ingoining substances"</p>
<p><i>We understand that the official definition of substances in REACH has been used. Although in this definition solvents are excluded, we assume that they are covered in the EU Ecolabel. However, we recommend clarifying whether solvents present in the product are included. It would be acceptable excluding (process) substances that are not present in the final product, but not if they remain.</i></p>	
<p><i>In Table 2, for skin products we miss a reference for the hand creams, which have a high risk of going to the water (being washed out).</i></p>	<p><b>REJECTED</b> Hand creams, as other skin care products, are not intended to be removed with water after their application. However considering that the scope has been extended to skin care products, hand creams are included in the scope for this revised version of the proposal.</p>
<p><i>With regards to the inclusion of animal care products, the newly proposed name might need to be revisited to avoid confusion, as these products are not covered under the Cosmetic Products Regulation. In line with the comment on the extension of the scope, the inclusion of animal care products under this Ecolabel product group could be beneficial to encourage companies to adapt their products to become eligible for the EU Ecolabel.</i></p>	<p><b>ACCEPTED</b></p>
<p><i>We also support to include animal care products, even they are not covered by the Cosmetic directive. But the products are similar to products included, hence we can offer a better environmental choice for the ones who are washing their animal. Another benefit is that the EU Ecolabel requires a total list of ingredients, which is not mandatory for such products, which gives more information to the users and the possibility to use the most gentle products.</i></p>	<p>The animal care products are proposed to be covered by a separate annex only applicable to this subcategory.</p>

<p><i>Italy is in favour of including pet's products only if the name is changed accordingly. Meaning that if the name stays with referment to COSMETIC than the Scope has to be consistent with the Cosmetics Regulation.</i></p>	
<p><i>We support the inclusion of animal care products. However, since the Cosmetics regulation does not cover animal products, legal restrictions that are missing for animal products must be included in the criteria document.</i></p>	
<p><i>Please take into account that animal care products are out of the scope of the cosmetic product regulation.</i></p>	
<p><i>That's a good thing to put in the scope animal rinse off product. Just take into account these products are not covered by Cosmetic regulation.</i></p>	
<p><i>We support the inclusion of animal care products in the scope. However, French industrials have concerns regarding the inclusion of those products in the scope, as they are not covered by the Regulation on cosmetic products.</i></p>	
<p><i>Please take into consideration that animal care products are not cosmetics according to the cosmetics regulation 1223/2009.</i></p>	
<p><i>Recommend that animal care products are not included in the scope as they do not fall under the Cosmetics Regulation. Another scheme should be developed.</i></p>	
<p><i>Animal care products are out of scope of the EU Cosmetic Regulation where products are intended for humans under Art 2(1)(a). Therefore, such products should not be covered by this Regulation attributed to the EU Ecolabel. Other EU Ecolabel criteria may be applicable but not cosmetics.</i></p>	<p><b>PARTIALLY ACCEPTED</b> The animal care products are proposed to be covered by a separate annex (Annex II) only applicable to this subcategory.</p>
<p><i>Animal products are outside the scope of the definition of a cosmetic product under EU legislation.</i></p>	
<p><i>Animal products should not be included as not included in Cosmetic Regulation</i></p>	
<p><i>We are not in favour of the inclusion of animal care products because animal care products are not subjected to the same regulation.</i></p>	
<p><i>Animal products are not under the Cosmetics Regulation and should be out of the scope of this EU Ecolabel. A specific one could be created.</i></p>	<p><b>REJECTED</b></p>
<p><i>We are in favour of having a scope as broad as possible. But we are not in favour of including animal products into the scope. They don't have to fulfil the cosmetic regulation so they do not have to fulfil the same safety level as cosmetics.</i></p>	<p>Although animal care products are not covered by the Cosmetic Regulation, their formulation is very similar to the one of human shampoos and their impacts on the environment are expected to be similar to the ones caused by products manufactured for human use. Therefore, it is important that consumers can have the possibility to choose for an environmentally better product.</p>
<p><i>Cosmetic products are only for human use, and so animal care products are outside of scope. The scope of the EU Ecolabel should be remain aligned to the EU Cosmetic Regulation.</i></p>	<p>To take into account the need for specific legal restrictions (compared to cosmetic products), the animal care products are proposed to be covered by a separate annex only applicable to this subcategory.</p>
<p><i>Below part to be excluded as animal care products are not in the scope of Cosmetic Regulation. 'Animal care products include rinse-off products intended to be in contact with animal hair to clean them or to improve the condition of it, such as shampoos and conditioners for animals.'</i></p>	
<p><i>Please take into consideration that hand sanitizer products are not always cosmetics.</i></p>	<p><b>ACKNOWLEDGED</b></p>

	Only the hand sanitizers covered by the cosmetic regulation are in the scope (considering the definition of the product group).
Please take into consideration that intimate gels or lubricants are not cosmetics according to the cosmetics regulation 1223/2009.	<b>ACKNOWLEDGED</b> Only intimate products covered by the Cosmetics Regulation are included in the proposed scope.
Yes, provided that the wording is clear enough that cosmetic products are for external use only (intended to wash feminine intimate parts, such as intimate cleansers) For instance reference below in Table 1 is made to "INTIMATE GELS/LUBRICANTS PRODUCTS: Intimate products with formulations similar to products covered by the Cosmetics Regulation such as lubricants, anal creams and orgasm gels." Please the cosmetic Borderline Manual ( <a href="https://ec.europa.eu/docsroom/documents/32897">https://ec.europa.eu/docsroom/documents/32897</a> ) in case of uncertainty when it comes to what is considered in and out of scope with regards to the definition of a cosmetic product	<b>ACKNOWLEDGED</b> The product feminine hygiene cosmetic is included in the group of shower, bath and other body cleanser preparations. Intimate gels or lubricant products are not covered in the scope of the Commission Decision as they are not covered by the Cosmetics Regulation.
Intimate products are not cosmetic products by the legal definition of Cosmetic Regulation.	
We are not in favour to expand the product group and would prefer to spend the resources of JRC and us in other product groups. It might be a specific situation in German-speaking countries, because in Austria and as far as I know also in Germany labels different from the EU Ecolabel have been established years ago and are quite successful and highly demanded, e.g. BDIH, EcoCert, and others. Therefore, we don't expect many license holders who would justify the upcoming discussions and work on several (new) issues. We welcome that at least no decorative cosmetics and hair dyes are included and are sceptical that feminine hygiene cosmetic products shall be included and are even explicitly mentioned as those products are not very welcomed by gynaecologists.	<b>REJECTED</b> Labels such as BDIH or EcoCert are more focused on the origin of the ingredients than on the general environmental impact of the product. For example, in the BDIH packaging and environmental requirements are only recommendations, they are not mandatory. Other schemes like Nordic Swan and Blue Angel revealed high number of licences for a number of cosmetics categories. There is a general agreement on the scope extension for this product group.
According to the cosmetic definition of the cosmetic regulation 1223/2009: 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.	<b>CLARIFIED</b>
The definition of a cosmetic product is already determined in Art.2(1)(a) of Regulation (EC) No. 1223/2009 cf.: 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. There is no legal basis or practical reason to change this definition.	The definition included in the Annex I is specific for the product group Cosmetic Products of the EU Ecolabel. In general, the EU Ecolabel Commission Decision has to specify the products covered. A list of the specific products included has been included in the text of the Commission Decision and examples will be included in the User Manual.
The group name is Cosmetics products but not all cosmetics products are concerned	

<p>Maybe the words "under this legislation" could be added to be more precise about the scope of the EU Ecolabel in this case.</p>	
<p>The definition for "Cosmetic products" should be clearer and technically correct. We recommend to following the definition for cosmetics of EC Regulation No 1223/2009 on cosmetic products: 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours</p>	<p><b>PARTIALLY ACCEPTED</b> The definition has been modified in order to make it clearer.</p>

Comments received in AHWG1/written form	JRC Dir. B response
<p>Measurement threshold Denmark agree that requirements shall be for all intentional added substances regardless of concentration – and if deviating from this it should be mentioned in the relevant criterion. However we do not find the definition of "Substance" in the draft to be sufficient. We suggest using the definitions made by the Nordic Swan Ecolabel since this is accepted by both CB's and applicants. Note that listing the concentration limits are important when implementing the requirements. Ingoing substances: all substances in the Nordic Swan Ecolabelled cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances. Impurities: residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the Nordic Swan Ecolabelled product in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the Nordic Swan Ecolabelled rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the Nordic Swan Ecolabelled leave on product. Impurities in the raw materials <math>\geq 1000</math> ppm (<math>\geq 0.1000</math> w-% <math>\geq 1000</math> mg/kg) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product. Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.</p>	<p><b>ACCEPTED</b> We have aligned the definition of ingoing substances and impurities to Nordic Swan in the new version of the TR.</p>
<p>Already a requirement under Article 16 of the EU cosmetic regulation. If compliance as a cosmetic product is a prerequisite for the EU EcoLabel criteria applicable to cosmetics, then there is no explicit need to redefine compliance requirements</p>	<p><b>PARTIALLY ACCEPTED</b> The new proposal is to establish criteria in separated Annexes: one specific for products included in the cosmetic regulation and one specific for animal care products. The sentence is proposed to be maintained only for those products not covered by the Cosmetic Regulation.</p>
<p>"As a prerequisite, the product shall meet all applicable legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement." Does this point have relevancy when the application of the EU EcoLabel is in the single market?</p>	<p><b>CLARIFIED</b> This sentence is horizontal across all EU Ecolabel products. This sentence is included in all the EU Ecolabel product groups recently revised. EU Ecolabel products are marketed in EU but could be produced in a country outside EU.</p>

<p>Point of clarification only, as under Art19(1)(g) of the EU Cosmetic Regulation:  <i>"For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing: (i) impurities in the raw materials used; (ii) subsidiary technical materials used in the mixture but not present in the final product."</i>  <i>The ingredients (as recorded on-pack by law) are the intentionally added substances.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>finished product instead of final product to link to the EU Cosmetic Regulation wording</i></p>	<p><b>REJECTED</b>  Wording used in all the EU Ecolabel product groups has been kept.</p>
<p><i>It would be a good idea to maintain this measurement thresholds. A lot of natural ingredients are used in cosmetics and they contain different substances in very low concentrations. Often the toxicity data and data about biodegradability of those ingredients are unknown.</i></p>	<p><b>ACCEPTED</b></p>
<p><i>Measurement threshold</i>  Denmark agree that requirements shall be for all intentional added substances regardless of concentration – and if deviating from this it should be mentioned in the relevant criterion. However we do not find the definition of "Substance" in the draft to be sufficient. We suggest using the definitions made by the Nordic Swan Ecolabel since this is accepted by both CB's and applicants. Note that listing the concentration limits are important when implementing the requirements.  Ingoing substances: all substances in the Nordic Swan Ecolabelled cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.  Impurities: residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the Nordic Swan Ecolabelled product in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the Nordic Swan Ecolabelled rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the Nordic Swan Ecolabelled leave on product.  Impurities in the raw materials <math>\geq 1000</math> ppm (<math>\geq 0.1000</math> w-% <math>\geq 1000</math> mg/kg) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product. Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.</p>	<p><b>ACCEPTED</b>  We have aligned the definition of ingoing substances and impurities to Nordic Swan in the new version of the TR.</p>
<p><i>Already a requirement under Article 16 of the EU cosmetic regulation. If compliance as a cosmetic product is a prerequisite for the EU EcoLabel criteria applicable to cosmetics, then there is no explicit need to redefine compliance requirements</i></p>	<p><b>PARTIALLY ACCEPTED</b>  The new proposal is to establish criteria in separated Annexes: one specific for products included in the cosmetic regulation and one specific for animal care products. The sentence is proposed to be maintained only for those products not covered by the Cosmetic Regulation.</p>
<p><i>"As a prerequisite, the product shall meet all applicable legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement."  Does this point have relevancy when the application of the EU EcoLabel is in the single market?</i></p>	<p><b>CLARIFIED</b>  This sentence is horizontal across all EU Ecolabel products. This sentence is included in all the EU Ecolabel product groups recently revised. EU Ecolabel products are marketed in EU but could be produced in a country outside EU.</p>

<p>Point of clarification only, as under Art19(1)(g) of the EU Cosmetic Regulation:  <i>"For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing; (i) impurities in the raw materials used; (ii) subsidiary technical materials used in the mixture but not present in the final product."</i>  <i>The ingredients (as recorded on-pack by law) are the intentionally added substances.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>finished product instead of final product to link to the EU Cosmetic Regulation wording</i></p>	<p><b>REJECTED</b>  Wording used in all the EU Ecolabel product groups has been kept.</p>
<p><i>It would be a good idea to maintain this measurement thresholds. A lot of natural ingredients are used in cosmetics and they contain different substances in very low concentrations. Often the toxicity data and data about biodegradability of those ingredients are unknown.</i></p>	<p><b>ACCEPTED</b></p>
<p><i>The use of Life Cycle Assessment should be done comparatively between two products with the same function, with regards to a functional unit, i.e. washing of hair. For instance, it is mentioned on page 11 that the use phase of shampoo causes 90% of the CO2 emissions because of heat of water during use. And that makes the shampoo itself seem irrelevant. In the criteria development it is not relevant to look at shampoo as one product, the comparison should rather be between two shampoos. Which difference does shampoo 1 make to shampoo 2 regarding environment and health? Also keep in mind that the LCA does not consider the direct effects of chemicals to humans, including for instance endocrine disrupting effects and allergy. This also means that widening the scope to more types of cosmetics has a higher relevance that the performed LCA indicates.</i></p>	<p><b>PARTIALLY ACCEPTED/CLARIFIED</b>  The revised functional unit defined to quantify the environmental performance of the products is <b>"A daily use of a cosmetic product with the main objective of providing hygienic results and/or aesthetic improvements"</b>.   While we agree with the comment on the comparative nature of LCA, a comparison between shampoo 1 and shampoo 2 was not possible to perform due to lack of data. It has been clarified in the TR2 that "the intention was not to compare across different products. The scope of the LCA was to identify main environmental hotspots of each product investigated with the goal of setting criteria in those areas, wherever relevant and feasible."</p>

<p><i>In general, we support the evolutions proposed between the first technical report and the second for the following criteria:</i></p> <p><i>3(c) - Substances of very high concern (SVHCs)</i></p> <p><i>3(e) - Preservatives</i></p> <p><i>7 - Information appearing on the EU Ecolabel</i></p> <p><i>Finally, we wish to emphasise that we would like to add a criterion stating clearly that the EU Ecolabel products should not be tested on animals (see COSMOS and Nature et Progrès referentials). Indeed, as per an NGO (<a href="https://animaltesting.fr/4170-guide-cosmetiques-cruelty-free">https://animaltesting.fr/4170-guide-cosmetiques-cruelty-free</a>) : "First of all, [the 2013 law on cosmetics] does not concern products tested and marketed before 2013, which are still on the market. Moreover, this prohibition does not apply to so-called "multi-use" products, that is to say which are not used only in cosmetics, but also in the agri-food, pharmacology or even in the building, like some perfumes, solvents or preservatives. Finally, the ban also does not apply to substances which may affect the safety of workers exposed to them during the manufacturing process." The current Regulation on cosmetic products forbids animal testing on finished products, but not on each substance contained in the product. Thus, we recommend adding a criterion based on Nature et Progrès referential: "Animal testing is prohibited. This cosmetic prohibition covers: Ingredients used in cosmetic products; The development of cosmetic specialities; Tests on finished product."</i></p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>The EU Ecolabel is based on the Regulation (EC) No 66/2010, which includes the following general requirements for EU Ecolabel criteria in the Article 6:</p> <p>EU Ecolabel criteria shall be determined on a scientific basis considering the whole life cycle of products. In determining such criteria, the following shall be considered:</p> <p>(g) as far as possible the principle of reducing animal testing.</p> <p>According to the Cosmetics Regulation, marketing of cosmetics or its ingredients that have been tested on animals is banned unless the testing was done in order to meet the requirements under REACH Regulation</p> <p>No further restriction is considered for the EU Ecolabel</p>
<p><i>The user manual shall be available at the same time as the decision.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>We need to have clarifications and examples in the user manual, in particular for pouches.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>Usually liquid soaps and shampoos have the highest amount of water in formulation compared to conditioner, body lotion or solid soap. Moreover it is surprising that conditioners that include silicones have a better impact on the environment, as they are known to be poorly or not biodegradable.</i></p>	<p><b>CLARIFIED</b></p> <p>The results presented in TR1 were presented considering the FU "A common day washing action of a part of the body with the main objective of providing hygienic results and/or aesthetic improvements."</p> <p>The estimated daily amount applied of hair conditioners is lower than for the other products (cfr Table 9 in the Preliminary Report), and this was reflected by a lower environmental impact.</p>
<p><i>We appreciate the use of REACH and CLP data as the basis information source for the analysis of the hazard profile for the most common ingredients in the selected cosmetic products to be included (toothpaste and skin care products) in the extended scope of the EU Ecolabel.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>not all the Sun care product have titanium dioxide as UV-filter</i></p>	<p><b>CLARIFIED</b></p> <p>In the absence of more specific data, and since 35% of the products analysed in the preliminary report contains titanium dioxide as UV filter (see section 3.3.3. of Preliminary Report), the environmental assessment of sunscreens has been done considering that the formulation of the product includes titanium dioxide.</p>

<p>We suggest to clarify the pharagraph, thus it seems that titanium is the responsible of generating the 70% of climate change.</p>	<p><b>ACCEPTED</b> The sentence has been deleted</p>
<p>We suggest to take care with this kind of sentence given that this will be a public report: "the highest environmental impact across all impact categories are solid soap, sun care products and liquid soap, all of them in the same order of magnitude."</p>	<p><b>ACCEPTED</b> The sentence has been deleted, and a new sentence has been added: "[...] the intention was not to compare across different products. The scope of the LCA was to identify main environmental hotspots of each product investigated with the goal of setting criteria in those areas, wherever relevant and feasible."</p>
<p>It's very important when the new Decision will be adopted to have a correct transition period leadtime to have all the certification renewals. In this aim, it's mandatory to have all the tools (user manual, calculation sheets, decalarations to fill etc...) meantime to the decision or only begin the transition period only after all the tools will be available. We had in France for the last update (on cosmetic products and detergent product category) bad experiences for the renewal period that was too short to renew all the products regarding the big amount of products to renew and the too late transmission of user manual and tools that were mandatory to ask for the new criteria requests.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>It would have been relevant to have an idea of the existing number of rinse-off product that have the EU Ecolabel. On the EU Ecolabel, you have not the number for all EU Member States as it is voluntary. So some figures miss and it should have been good to have the number by category of products.</p>	<p><b>CLARIFIED</b> The number of EU Ecolabels for rinse-off products is 2270. More information about market data can be consulted in the preliminary report. All the information regarding current licences of Rinse-off products is included in the Section 2.2.</p>
<p>No reference to the current situation of rinse-off products with the Eu Ecolabel. How many products are concerned (if you take the number published on the Ecolabel website plus the number on the French market, the EU Ecolabel has been granted for 563 products in EU</p>	
<p>What kind of respondents you refer to? Cosmetics industry? Public authorities? NGOs?</p>	<p><b>CLARIFIED</b> The stakeholders that provided feedbacks belong to industries, public authorities and NGOs. More information about the respondents and the responses of the questionnaire can be consulted in Section 1.7 of the preliminary report.</p>
<p>Deletion of other preparations from the animal care products</p>	<p><b>CLARIFIED</b> This category has been modified: other washing preparations.</p>
<p>It is good that we are lowering the CDV for the rinse off products such as shampoo and soap. Request is to align on the value from the Nordic Swan for divers reasons. It will allow to maintain a certain amount of the fragrance, which is still very important to the customers. The fragrances are specifically designed for Nordic Swan and EU Ecolabel but the value in the did list remains the same, meaning that even if the fragrance is improved, the CDV is unchanged and restricted. When a product is certified under both certifications, the alignment on the value will facilitate the handling of the certifications under both schemes.</p>	<p><b>PARTIALLY ACCEPTED</b> While the use of fragrances is partly limited with the reduction of the threshold value, it is still possible to maintain a certain amount of fragrance in the product. The revised limit for solid soap is proposed to be 2200. Nordic Swan will be revised in the near future. To keep alignment in both schemes is difficult due to the different revisions timelines.</p>

<p>According to the existing ecolabel product calculation, the proposed threshold puts limits on the fragrance's use. Put the limits to 2500 for solid soaps.</p>																												
<p>We support the lowered CDV values. However, as shown in Table 5 the value for shampoo, shower preparations and liquid soaps could be even stricter. We suggest setting a value a slightly higher than the average, i.e. 8000.</p>	<p><b>REJECTED</b> If 8000 value is proposed for these products, the following percentage of licenced products will not comply with the requirements and will be out of the UE Ecolabel:</p> <ul style="list-style-type: none"> <li>- 30% of liquid soaps</li> <li>- 58% of shampoos</li> <li>- 70% of shower preparations</li> </ul> <p>The threshold for shampoo, shower preparations and liquid soaps has been proposed to 11000l/g AC</p>																											
<p>We are in favour of aligning the CDV value for solid soap to the Nordic Swan (as suggested in the proposal).</p>	<p><b>ACKNOWLEDGED</b></p>																											
<p>We welcome the proposed reduction of CDV limits in this revision and the stated aim to align the EU Ecolabel with other regional ecolabels. Since the average CDV value of Ecolabelled shampoos is 7063, there is potential for setting a stricter value than 11000. As the Nordic Swan will be revised it is possible that the thresholds will be lowered further, and this possibility should be further investigated. We see no reason to have a higher CDV for shaving products (i.e. 20000). The requirements should be aligned with the Nordic Swan Ecolabel, which has approved several shaving foams complying with a limit of 12000. The requirements should be aligned with the Nordic Swan, considering as far as possible the upcoming revision of the Nordic label. We strongly recommend investigating the CDV values achieved by cosmetics certified with the Nordic Swan and consider them for setting the values of the EU Ecolabel. Reduce the shaving foam limit from 20.000 to 12.000 (page 22), as suggested during the Ad Hoc Working Group by the JRC. The document report states "that there is no data available for shaving foams; therefore the current CDV threshold of 20000 l/g AC remains valid". Please correct and add a reference to existing shaving foams certified by the Nordic Swan which can comply with the limit of 12000.</p>	<p><b>PARTIALLY ACCEPTED</b> If 8000 value were to be proposed for shampoos, the following percentage of licenced products will not comply with the requirements and will be out of the UE Ecolabel:</p> <ul style="list-style-type: none"> <li>- 30% of liquid soaps</li> <li>- 58% of shampoos</li> <li>- 70% of shower preparations</li> </ul> <p>The threshold for shampoo has thus been proposed to 11000l/g AC.</p> <p>In Nordic Swan, the CDV limit for products rinsed off with water immediately after use (which include shaving creams) is 12000, which is the limit proposed in the TR2. Please note that there was a mistake in the first Technical Report and the CDV limit for shaving products was set at 12000 l/g AC. Data on CDV values of shaving products will be welcomed and used to define the threshold value for these products.</p>																											
<p>The data collected from French industrials support the decision of the JRC to lower CDV thresholds. Indeed, the following data has been collected:</p> <table border="0"> <tr> <td>-</td> <td>Average</td> <td>CDV</td> <td>for</td> <td>liquid</td> <td>soaps:</td> <td>5558</td> <td>l/g</td> <td>AC</td> </tr> <tr> <td>-</td> <td>Average</td> <td>CDV</td> <td>for</td> <td>shampoos:</td> <td></td> <td>10409</td> <td>l/g</td> <td>AC</td> </tr> <tr> <td>-</td> <td>Average</td> <td>CDV</td> <td>for</td> <td>shower</td> <td>preparations:</td> <td>9234</td> <td>l/g</td> <td>AC</td> </tr> </table> <p>Thus, we support the revision of CDV thresholds.</p>	-	Average	CDV	for	liquid	soaps:	5558	l/g	AC	-	Average	CDV	for	shampoos:		10409	l/g	AC	-	Average	CDV	for	shower	preparations:	9234	l/g	AC	<p><b>ACKNOWLEDGED</b></p>
-	Average	CDV	for	liquid	soaps:	5558	l/g	AC																				
-	Average	CDV	for	shampoos:		10409	l/g	AC																				
-	Average	CDV	for	shower	preparations:	9234	l/g	AC																				

<p><i>The current threshold for solid soaps seems too restrictive, as not any is labelled EU Ecolabel in France. As the use of solid soap is increasing, we suggest requesting from the Nordic Swan the number of solid soaps labelled and the market share they represent to determine if the current threshold is appropriate.</i></p>	<p><b>ACCEPTED</b>  The threshold value has been relaxed in order to include all the products currently certified under this product category. The new threshold is 2200 l/g AC. Please note that the CDV limit for solid soap in Nordic Swan is 2000 l/g AC and there are 7 licenced products that can comply with this requirement.</p>
<p><i>Are you sure that there are solid soaps certified according Nordic Swan with this strict threshold (2.000)? How much? What percentage of certified NS cosmetics does it represent? It's important to have this information in order to determine if these requirements are attainable. Indeed, you considered to promote solid soaps during the first meeting but the threshold for this kind of products seems to be too restrictive.</i></p>	
<p><i>The number needs to be increased for solid soap.</i></p>	
<p><i>Several applicants and license holders told us that the former threshold (3.300) was already unattainable, so we are surprised of this proposal.</i></p>	
<p><i>Regarding the newly integrated products, we also suggest requesting from the Nordic Swan the number of products labelled and the market share they represent to determine if the proposed thresholds are appropriate.</i></p>	<p><b>ACCEPTED</b>  Information about the number of products certified with the Nordic Swan has been included in Table 1 of the TR2.0, while market share is shown in Figure 1.</p>
<p><i>We strongly recommend reviewing the calculation methodology of the CDV. With the current calculation methodology, the CDV of each substance is linked to the share of other substances. Therefore, industrials are incentivized to add substances in the product formulation in order to decrease the CDV that is the antithesis of ecological practice and therefore goes against the fundamental principles of the European Ecolabel. To avoid this bias, we strongly advise to use a calculation method similar to the one used for detergents and express the toxicity per gram or litre of product instead of litre of active content.</i></p>	<p><b>REJECTED</b>  CDV is simple to apply since only two parameters are required per substance; furthermore, the DID-list facilitate the calculation of such parameters. The use of alternative methods, USEtox for instance, requires the use of a high number of parameters is needed. Moreover, other method would make the verification method more complex and costlier and it is not possible to do it in the revision timeline as longer time for assessment of a new method would be needed. For this reason, the introduction a new methodology to assess the toxicity of the products is not proposed in this revision. The CDV is calculated based on the active content because the dose cannot be always determined. Only for the products with dispenser, the dosage can be controlled. Nevertheless, the consumer behaviour cannot be controlled, and the dose used in each application is not easy to estimate. Moreover, determining standard doses for shampoos and hair conditioners would not be straightforward e.g. the dosage is dependent to the length of the hair washed.</p>

<p>It's really important to review the calculation method of the CDV. With the actual calculation, due to the AC taking into account, if you have a too high CDV value, you just need to add a need raw material to lower the CDV result that is not in correlation with the ecological point of view.</p> <p>Whereas the detergent EU ECOLABEL decision where we take into account a "reference dose". More you add substances, more the CDV is high that is logical. The CDV calculation must be linked to the amount of product and not only the AC. If the method calculation is modified, the CDV thresholds should also be modified.</p>	
<p>What is the meaning of "intentionally added"? In the case of a mixture which is intentionally added, are the different substances included in this mixture to be considered? In particular, how shall we deal with by-products which exceed 0,01% by weight in the final formulation?</p>	<p><b>CLARIFIED</b></p> <p>"Intentionally added substances" are now referred to in the TR as "ingoing substances", in alignment with Nordic Swan. The definition is included in the section "Complementary definitions".</p> <p>By-products which exceed 0,01% by weight in the final formulation shall be regarded as ingoing substances, as clarified in the section "Complementary definitions".</p>
<p>What is considered as the final product? Is there a minimum concentration to consider a substance as an "intentionally added substance" or not?</p>	<p><b>CLARIFIED</b></p> <p>The final product is the product certified under the EU Ecolabel.</p> <p>"Intentionally added substances" are now referred to in the TR as "ingoing substances", in alignment with Nordic Swan. The definition is included in the section "Complementary definitions". There is no minimum concentration for considering a substance an "ingoing substance".</p>
<p>Can you confirm that rubbing/abrasive agents are not included in the calculation of CDV toxicity because the calculation of CDV is connected to the calculation of AC?</p>	<p><b>ACCEPTED</b></p> <p>Under the definition of 'active content' it is now clearly mentioned that rubbing/abrasive agents are not included in the calculation of the active content.</p>
<p>How shall we deal with a mixture with a chemical substance diluted in a solvent? Shall we report in the calculation sheet the part of solvent (except if the solvent is water)? If not, it is a problem because any solvent (except water) has an impact on the user and/or the environment</p>	<p><b>CLARIFIED</b></p> <p>The definition of intentionally added substance has been changed to 'ingoing substance', according to Nordic Swan. Solvents should be reported in the calculation sheet.</p>
<p>It is essential to change the definition of "weight". Because:</p> <ol style="list-style-type: none"> <li>1) it is more complicated to deal with CDV depending on CA and</li> <li>2) it is not environmentally friendly to add substances to reduce the ratio of CDV/CA. This practise goes against principles of the European Ecolabel.</li> </ol> <p>We propose to define thresholds as in detergents products (in l/g). If our proposal is accepted, it will be necessary to review thresholds but if necessary, we can send our values with the methodology used in detergents.</p>	<p><b>REJECTED</b></p> <p>The method used in detergent products cannot be used as the dose of the products used by consumers is often not defined in the packaging, and not necessarily followed by consumers that may have different body/hair needs.</p>

<p>Normalized the CDV for 1g of active content implies in most cases that the more substances are added, the lower the CDV, anBO and anNBO are, which does not make sense. A product with less Active Content should be more ecological and have less impact on aquatic ecosystems than a high surfactant concentrated product. The calculation method should be based on the same method of EU Ecolabel Detergent.</p>	
<p>We suggest pondering the result of the CDV by the expected use of the cosmetic product.</p>	
<p>OK with the new threshold because our average for:  - liquid soaps: it is 7.785  - shampoos it is 10.410  - shower preparations is 9.230</p>	<p><b>ACKNOWLEDGED</b></p>
<p>Also on the CDV, particularly the TF (toxicity factor) calculation, we consider it problematic that the applied Safety factors differ by a factor of 1000 solely based on the number of tested trophic levels instead of considering the toxicity of a given substance. Thus, one and the same L(E)C50 or NOEC/EC10 value would result in completely different TFs that feed into the calculation of the CDV for the product, thus providing a distorted picture. We therefore recommend to base the toxicity factor on the actual toxicity endpoint of the substances tested rather than the number of available tests.</p>	<p><b>REJECTED</b>  The toxicity factor calculation of the DID-list is out of the scope of this revision. The CB responsible of the DID-list is Ecolabelling Norway.</p>
<p>The use of the DID list (Detergents Ingredients Database) is laid down in (EC) 66/2010, however, we would like to comment on the CDV (Critical Dilution Volume) approach used in this list and, in particular, the calculation of the chronic toxicity factor (TFchronic). It is stated that the median should be used within each trophic level from validated test results without specifying the test conditions or considerations on differences in species sensitivity further. Under CLP the median value is used for several studies within a trophic level provided certain conditions are met, such as at minimum 4 data points, similar test conditions (pH, DOC level, etc.). It is recommended to reconsider this aspect in the revision of the technical report and to take into account a potential alignment with the standards as outlined in the CLP Regulation (also reflecting on Article 6(6) provisions of (EC) 66/2010).</p>	
<p>Worst case approach – please note that the rationale for the chosen threshold is contradicting Article 6(6) of (EC) 66/2010 - at present it would be the same value as for classification as Aquatic Acute 1. It is therefore proposed to set the acute toxicity value to &gt; 1 mg/L.</p>	<p><b>CLARIFIED</b>  Article 6 (6) is addressed by criterion 3 which is mandatory for all cosmetics under the scope.  The use of an alternative methodology to assess the aquatic toxicity would not be possible in the revision timeline, as longer time for assessment of a new method would be needed. Classification as hazardous to the aquatic environment according to CLP will not be permitted according to criterion 3.</p>
<p>We note that the Swedish Ecolabel uses aquatic toxicity cut-offs for Criterion 1 (Aquatic toxicity), comparable to cut-off values used in CLP for environmental hazard classification, whereas other ecolabelling schemes, including the EU Ecolabel, use the aquatic toxicity CDV, which defines the maximum volume of the product that is expected to not harm the aquatic environment. Please take note that in a random check of Part A of the DID list several listed toxicity endpoints (L(E)C50 and NOEC values) would result in classification as hazardous to the aquatic environment according to CLP. It is not clear how this complies with the provisions set out in Article 6(6) of (EC) 66/2010. We suggest to discuss the possibility of considering other methods than the CDV to assess Criterion 1.</p>	

<p>We can support the listed values with the following comments:</p> <ul style="list-style-type: none"> <li>- Requirements are harmonized to a large degree with the Nordic Swan requirements version 3 this will ensure stringent requirements.</li> <li>- The Nordic Swan have more that 2000 licensed products hence the stated limits are feasible, also for products containing fragrance.</li> <li>- The Nordic Swan label requirements will be updated in 2021 with more stringent values.</li> </ul>	<b>ACKNOWLEDGED</b>
<p>We welcome the clarification at the meeting that the calculation is done on all ingoing substances regardless of concentration – as it is done today.</p>	<b>ACKNOWLEDGED</b>
<p>We welcome the lower cdv limits.</p>	<b>ACKNOWLEDGED</b>
<p>As feminine hygiene cosmetic products are similar too Shampoo, shower preparations and liquid soaps the same cdv tox limit should be used</p>	<p><b>REJECTED</b>  CDV vales have ben decreased to 10000 for Shampoo, shower preparations and liquid soaps. There is no evidence to support the decreasing of the CDV value for feminine hygiene cosmetics. An alignment with Nordic Swan threshold has been proposed for feminine hygiene cosmetics (12000 l/g AC).</p>
<p>We suggest to include the units of all parameters, i.e. TF (mg/L)</p>	<b>ACCEPTED</b>
<p>We saw you add for the new subcategory the CVDtox limits of the Nordic Swan existing limits. Did you ensure that these limits are reachable for our product in European market?</p>	<p><b>CLARIFIED</b>  While we have no data available to make sure that products marketed in the Nordic countries can have an uptake in the rest of Europe, we welcome substantial evidence of it. Please keep in mind that the EU Ecolabel is a label of excellence and consumer perception is key in this sense.</p>
<p>It would be better to differentiate the CDV limits for the different products as they vary from 6000 to 11000</p>	<p><b>REJECTED</b>  With the new information gathered from current products certified the threshold it is suggested to keep a single value for shampoos, shower preparations and liquid soaps. More information can be found in the rationale for criterion 1.</p>
<p>Italy agrees that solid soaps are better for the environment, but we think that the problem is the market itself and that even if promoted somehow by the Ecolabel, they would stay a small part of the market.</p>	<b>ACKNOWLEDGED</b>
<p>Shampoo category should be differentiated between liquid and solid shampoos</p>	<p><b>ACCEPTED</b>  Solid shampoo has been included in the category with solid soap.</p>
<p>It must be kept in mind that solid and liquid form of rinse-off products are made with different kind of surfactants with different performances and so CDV can't be the same.</p>	<b>ACKNOWLEDGED</b>
<p>We welcome to reduce the CDV-values as in our experience the existing thresholds are not very demanding.</p>	<b>ACKNOWLEDGED</b>
<p>Nordic Swan includes the following exemptions on criterion on biodegradability of surfactants:  "The following are exempt from the requirement on anaerobic degradability:  -  - Surfactants in Emulsifiers toothpaste"  Proposal to maintain these exemptions for toothpaste.</p>	<p><b>PARTIALLY ACCEPTED</b>  The following exemption has been added to the criterion text:  "Surfactants with cleaning and/or foaming function in toothpastes"</p>

<p>We do not support to exempt any surfactants from the requirement on anaerobic degradability. Such an exemption is simply not necessary since there are suitable surfactants being both aerobically and anaerobically degradable which are used in toothpaste. The exemption for emulsifiers with regard to anaerobic degradability is justified.</p>	<p><b>REJECTED</b> The objective to exempt surfactants with cleaning and/or foaming function in toothpastes on criterion 2 is to facilitate the formulation of these products as Sodium Lauryl Sulphate (a very used surfactant in non- Ecolabel products) is banned in EU Ecolabel according to criterion 3 (b).</p>
<p>The aNBO and anNBO limits should be lowered and aligned with the Nordic Swan limits for shampoo, shower preparations and liquid soaps, as well as solid soaps. For several of these product types there are a relatively many products being labelled with the Nordic Swan, demonstrating that these limits are achievable. In addition, as shown in Table 7 of TR1.0, 15 (aNBO) is above the 50 percentile value for products currently certified with EU Ecolabel. Proposal for modification: Shampoo, shower preparations and liquid soaps: aNBO (mg/g AC): 15 anNBO (mg/g AC):15 Solid soap: aNBO (mg/g AC): 5 anNBO (mg/g AC):5</p>	<p><b>PARTIALLY ACCEPTED</b> If a complete alignment with Nordic Swan were to be defined, a large percentage of licensed products would not comply with the requirements and would be out of the scope of EU Ecolabel. However, the aNBO and anNBO thresholds have been lowered for shampoos and hair conditioners. For more information see the rationale of criterion 2 in the TR2.0.</p>
<p>The requirements should be aligned with the Nordic Swan Ecolabel.</p>	
<p>The criteria stipulate that data from structurally related compounds can be used for extrapolation, for example to demonstrate that a surfactant is anaerobically degradable. However, it should be clarified that the same applies the other way around too. Proposal for modification: Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable, and vice-versa if a structurally similar surfactant has been shown not to be anaerobically degradable.</p>	<p><b>ACCEPTED</b> The text of criterion 2 has been modified according to this comment.</p>
<p>We support the decision to keep requirements on anaerobic degradability. The fact that it is not mandatory to generate such data according to the REACH regulation must not be used as an excuse to not include requirements in the EU ecolabel criteria. On the opposite, to give incentives for generating data is a very important aspect of independent ecolabels.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>In response to the question to Stakeholders, "please note that one possibility in those cases where suppliers of raw materials do not want to share the results of biodegradability tests" would be the use of (Q)SAR calculations which would allow an improved verification of criterion 2 (Biodegradability). However, it is not clear on which basis suppliers would not provide the relevant test results. We note that the registrants need to include all relevant hazard information in the registration dossiers and ECHA disseminates information on registered substances on its websites according to the provisions set out in REACH Article 119(e) which encompasses the publication of results of each toxicological and ecotoxicological study reported in the registration dossiers.</p>	<p><b>ACCEPTED</b> (Q)SAR calculations have been proposed as a possible methodology to predict biodegradability when results are not available.</p>
<p>Surfactants not classified for the environment (i.e. not H400, H410, H411, H412 or H413) should be exempted from the requirement of anaerobic biodegradation, since they do not pose any risk to the aquatic environment. It is the same that happens with EU Ecolabel schemes for detergents.</p>	<p><b>ACCEPTED</b> Criterion 2 has been modified in TR2.0 including this exemption.</p>

<p>We think this criterion shall be fulfilled by impurities as proposed in criterion 3. So, we suggest to add : "For the purpose of criterion 2, impurities stated in the SDS, whose presence in the final product equals or exceeds 0,01% shall comply with the same requirements as the intentionally added substances."</p>	<p><b>ACCEPTED</b> The new definition of "ingoing substances" included in the list of complementary definitions states no limit (regardless of the concentration, instrument detection limit valid only) for all substances added to the formulation. By-products and impurities equal or above 0,01% w/w for rinse-off or 0,001% w/w for leave-on in the final formulation have to comply with the requirement.</p>
<p><i>What is the meaning of "intentionally added" ? If it is a mixture which is intentionally added, are the different substances included in the mixture to consider? In particular, how shall we deal with by-products which exceed 0,01% by weight in the final formulation?</i></p>	
<p><i>Are there leave-on skin care products certified according to Nordic Swan (NS)? How much? What percentage of certified NS cosmetics does it represent? It's important to have this information in order to determine if these requirements are attainable.</i></p>	<p><b>CLARIFIED</b> Leave-on cosmetic products represent a 33% of total cosmetic products in the Nordic Swan Ecolabel. For more information on Nordic Swan licenses see the rationale of criterion 2.</p>

<p>Biodegradability of organic ingoing substances  We support the JRC proposal regarding biodegradability thresholds.  However, currently liquid soaps, shower gels and shampoos are subjected to the same aNBO and anNBO thresholds (25 mg/ g AC). Data collected from French industrials show that liquid soaps, shampoo and shower formulas show very diverse biodegradability values:</p> <p>aNBO:  Average biodegradability of liquid soaps: 11 aNBO (mg/g AC)  Average biodegradability of shampoos: 25 aNBO (mg/g AC)  Average biodegradability of shower preparations: 6 aNBO (mg/g AC)  anNBO:  Average biodegradability of liquid soaps: 18 anNBO (mg/g AC)  Average biodegradability of shampoos: 25 anNBO (mg/g AC)  Average biodegradability of shower preparations: 6 anNBO (mg/g AC)</p> <p>Thus, we would recommend defining specific thresholds for each type of product. For 3-in-1 products, the less restrictive threshold should apply.  We do not have comments regarding the biodegradability thresholds for leave-on products but agree that they should be specific of this product family.  Regarding sunscreen products, UV filters represent a large part of their formula, and they are not biodegradable. More especially, sunscreen products contain TiO2, a molecule having a strong negative impact on aquatic environment. Thus, sunscreen products cannot meet this criterion and we consider that including them in the scope could discredit the reputation of the EU Ecolabel.</p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>If a complete alignment with Nordic Swan is defined, a large percentage of licensed products would not comply with the requirements and would be out of the scope of EU Ecolabel. However, the aNBO and anNBO thresholds have been lowered for shampoos and hair conditioners.  The category "shampoo, shower preparations and liquid soaps" has been divided in "shampoo and liquid soaps" and "shower preparations".  For more information see the rationale of criterion 2 in the TR2.0</p> <p>The aim to include the sunscreen products in the scope is to promote the sunscreens with the lowest environmental impact, motivating companies to formulate more environmental-friendly products.  Sunscreens may contain a high concentration of not biodegradable UV filters. In line with Nordic Swan, UV filters are proposed to be exempted from compliance with criterion 2, but all other ingredients added to sunscreens have to comply it. Sunscreens are still obliged to comply with other criteria such as, particularly relevant in this case, criterion 1 (toxicity to aquatic organisms) and criterion 3 (excluded or limited substances and mixtures) and specifically 3(g).  Moreover, sunscreens are included in the scope of the Nordic Swan and 68 products are certified, enabling the certification of sunscreens under the EU Ecolabel.</p>
--	--

<p>According to the information provided by Competent Bodies (Table 7 in TR1.0), all provided products include surfactants in their formulation. Regarding the aerobic non-biodegradability of the products currently certified as EU Ecolabel, the maximum threshold is 25,0 mg/g AC. The 75th percentile is 24,6 mg/g AC, this means that the 75% of the products considered are at or below that value.</p> <p>For the anaerobic non-biodegradability, the situation is similar to that for aerobic non-biodegradability. The maximum biodegradability and the 75th percentile values are the same as for the aerobically non-biodegradability (Table 8 in TR1.0). Nevertheless, the average of anaerobic non-biodegradable ingredients is higher than the average of aerobic non-biodegradable ingredients, indicating that the products have more ingredients with higher values of anaerobic non-biodegradability.</p> <p>Nordic Swan includes stricter restrictions than EU Ecolabel for the different products. Nevertheless, according to the information provided by CBs of current licences only the threshold value for hair conditioners could be lowered.</p> <p>We communicated our values and we think it's necessary to divide this category :</p> <ul style="list-style-type: none"> <li>- liquid soaps : the average is 12mg/g of AC for aNBO and anNBO</li> <li>- shower preparations : the average is 6 mg/g of AC for aNBO and anNBO</li> <li>- shampoos : values of 25 for aNBO and anNBO must be kept.</li> </ul> <p>Nevertheless, if the product is intended for different functions (for example shampoo and shower), the highest threshold (less restrictive) shall be considered (for example 25 for a product shampoo and shower).</p>	
<p>All values should be harmonized with the Nordic Swan for the following reasons: The Nordic Swan have more than 2000 licensed products hence the stated limits are feasible, also for products containing fragrance The Nordic Swan label requirements will be updated in 2021 with more stringent values.</p>	
<p>Is it a mistake to only indicate "ingoing substances" (word in the farmer decision which you proposed to replace)?</p>	<p><b>CLARIFIED</b> The wording proposed in the TR2 is "ingoing substances", in accordance with Nordic Swan. Please see the definition in the "Complemetnary definition" section.</p>
<p>Can you indicate what kind of tests shall be provided to prove the substance is non-bioaccumulating?</p>	<p><b>ACCEPTED</b> Test methods for bioaccumulation have been proposed. For more information see rationale of criterion 2.</p>
<p>Animal care products: Category not within scope of the definition of a cosmetic product</p>	<p><b>PARTIALLY ACCEPTED</b> The animal care products have been proposed to be covered by a separate annex (Annex II).</p>
<p>Modify final for finished</p>	<p><b>REJECTED</b> Wording used in all the EU Ecolabel product groups has been kept.</p>
<p>In the table 2 of criterion 2, for the new category of products, it would be relevant to have indication about if these thresholds can be applied to them and maybe they should not be aligned with the thresholds for rinse-off products</p>	<p><b>PARTIALLY ACCEPTED</b> Criterion 2 has been divided into two sub-requirements: criterion 2(b)(i) applying to rinse-off products and criterion 2(b)(ii) to leave-on products.</p>

<p><i>A same molecule can't be excluded if called surfactant and approved if called emulsifier. No derogation should be applied.</i></p>	<p><b>ACCEPTED</b></p> <p>In general terms, a surfactant (short-term for surface-active-agent) is a substance which exhibits some superficial or interfacial activity providing different properties such as surface tension lowering, soap, detergent, emulsifier, wetting agent, dispersant, etc. Surfactants are often named after their use.</p> <p>Cleaning products (shampoos, shower preparations, toothpastes...) include mainly surfactants with cleaning function in their formulations. However, other surfactants with different functions can be found in these products, usually in lower concentrations.</p> <p>Emulsions are the most common type of formulations used in cosmetics, usually for skin care products (creams, lotions, serums...). In this kind of formulations micro- or nano-droplets of oil are dispersed in water (O/W emulsions) or vice-versa (W/O emulsions). Since oil and water are immiscible fluids, emulsifiers allow a kinetically stable system.</p> <p>No exemption is considered for surfactants with emulsifying functions.</p>
<p><i>For the purpose of criterion 3 impurities stated in the SDS, whose presence in the final product equals or exceeds 0.010%, shall comply with the same requirements as the intentionally added substances. In SDS impurities are not always mentioned and difficult to identify. Propose to remove reference /criterion for impurities.</i></p>	<p><b>CLARIFIED</b></p> <p>In criterion 3, the REACH definition of substance apply, as existing criteria in force.</p> <p>Under REACH, 'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.</p> <p>Thresholds in criterion 3 have been specified for each sub-requirement. While some requirements apply to substances above certain concentration in final product, other sub-requirements apply to all substances disregards its concentration in final product. According to this, "any impurity deriving from the process used" is considered a substance.</p>
<p><i>For the purpose of criterion 3 impurities stated in the SDS, whose presence in the final product equals or exceeds 0.010%, shall comply with the same requirements as the intentionally added substances. The criterion should apply to all impurities exceeding 0.010% by weight in the final product, regardless if they are stated in the SDS or not.</i></p>	

<p><i>For the purpose of criterion 3 impurities stated in the SDS, whose presence in the final product equals or exceeds 0.010%, shall comply with the same requirements as the intentionally added substances</i>  <i>According to Art19(1)(g) of Regulation EC 1223/2009:</i>  <i>For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing. The following shall not, however, be regarded as ingredients: (i) impurities in the raw materials used; (ii) subsidiary technical materials use</i>  The described approach treats impurities as ingredients when according to the EU Cosmetic Regulation they are not in terms of their requirement for labelling.  For assessment of this conformity criterion, however, it is understood that a threshold limit has been set previously.</p>	
<p><i>New knowledge from SCCS opinions should be taken into consideration, so that the approval of products is up to date with new assessments.</i>  <i>Nordic swan requirements: Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions, must be complied with where there is an unambiguous conclusion from SCCS. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.</i></p>	<p><b>ACCEPTED.</b>  This sentence is proposed to be included in the User Manual.</p>
<p><i>It is very unclear if the substances are prohibited, or if they are allowed for use up to 0,01%. There are wordings that indicate both. It is odd allowing the use of CMR if used below 0.01%. It would be ok with 0,01% impurities/contamination, but not intentionally added. Also, for leave on cosmetics the threshold of 0.001% is more relevant.</i></p>	<p><b>ACCEPTED</b>  Thresholds for rinse-off products and leave-on cosmetics have been set and adjusted. The text in the criterion has been amended as to clearly state that CMR substances shall not be present in the product. Moreover, a table of thresholds has been included in the "General assessment and verification" section, clarifying what criterion applies to what substances and in what concentration.</p>
<p><i>What is the meaning of "intentionally added"?</i>  <i>In the case of a mixture which is intentionally added, are the different substances included in this mixture to be considered?</i>  <i>In particular, how shall we deal with by-products which exceed 0,01% by weight in the final formulation?</i></p>	<p><b>CLARIFIED</b>  Definitions in the TR2 have been changed. The definition of "ingoing substances" applies to criterion 3, but with different thresholds for each sub-requirement  . A table of thresholds has been produced and is included in the "General assessment and verification" section, clarifying what criterion applies to what substances and in what concentration.</p>

<p><i>If the aim of the Ecolabel scheme is to provide a risk based scheme and not just a hazard based approach then rather than align with Nordic Swan just because it is the most stringent of the Ecolabel schemes it would be more scientific to align limits to REACH restrictions, CLP cut-off limits for classification (where deciding if a substance should be considered as part of the calculation process) and the Cosmetics regulation.</i></p> <p><i>For example, for specific hazards look to have limits of 10% of the CLP classification limit rather than a flat limit of 0.01%.</i></p> <p><i>This would work as 10% of an SVHC that is a CMR or ED material but in the case of many of the other hazards listed is much more stringent.</i></p>	<p><b>REJECTED</b></p> <p>The approach used in EU Ecolabel is a horizontal one, applied across all product groups (with some product specific differences) and based on exclusions of substances due to their hazard classification.</p>
<p><i>Allow microorganisms in rinse-off cosmetics, analogue to the EU Ecolabel criteria for hard surface cleaning products. As mentioned in the preliminary report there is the trend of using probiotics in cosmetics. "Hair care products include new formats avoiding plastic bottles, including probiotics and vegetables as new ingredients, or hair care specialized products."</i></p>	<p><b>ACCEPTED</b></p> <p>Microorganisms are not excluded per se. They are allowed as soon as they comply with the criteria set.</p>
<p><i>In analogy with the Detergent groups it would be useful to specify the measurement threshold for each criterion (for example like the table 1, Dec 2017/1217)</i></p>	<p><b>ACCEPTED.</b></p> <p>Definitions and thresholds have been further clarified in the text. A table of thresholds has been produced and is included in the "General assessment and verification" section, clarifying what criterion applies to what substances and in what concentration.</p>
<p><i>Cosmetics regulation are not familiar with the use of "hazardous substances" as under the Regulation 1223/2009 only forbidden substances or restricted substances are mentioned. The wording use there is not in link with the approach on cosmetics regulation based on the risk assessment. The previous wording is more accurate.</i></p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>The EU Ecolabel Regulation requires that the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 (REACH).</p> <p>Criterion 3 makes reference to the CLP Regulation which defines the hazard classes of substances/mixtures. Nevertheless, the wording has been changed to "Restrictions on substances/mixtures classified under the Classification, Labelling and Packaging (CLP) Regulation".</p>
<p><i>"An analysis of other ecolabels..."</i></p> <p><i>Cosmetics products are regulated by a specific regulation/sectorial regulation to take into account of the specificity of the products; It's not the case for all the other products that could receive the EU Ecolabel. The wording and the philosophy under the Cosmetics regulation should be kept. Hazard substances is not mentioned in the Cosmetics regulation as this regulation is based on a risk assessment approach.</i></p>	

<p><i>"Aligning the wording of the requirement to the latest voted EU Ecolabel products." The wording should not be aligned with the other EU Ecolabel products already voted as it is a specific products with a sectorial legislation.</i></p>	<p><b>CLARIFIED.</b></p> <p>We try to align the wording with the one on the latest voted EU Ecolabel products for common, relevant criteria which do not depend on the chemical nature of the product. There are some specific criteria which won't be aligned with other EU Ecolabel schemes.</p>
<p><i>"This criterion shall be fulfilled by each intentionally added substance present at or above the concentration of 0,010 % weight by weight in the final product." Some of these hazard classes are already excluded in the cosmetics regulation - for example, CMR-substances 1A and 1B and with some possibilities to get derogations also of cat. 2. As there have been some discussions on how to interpret the first clause, we ask to fix the exclusion of CMR substances of each category (1A, 1B, 2) without any derogation.</i></p>	<p><b>ACCEPTED.</b></p> <p>The new criterion states that CMR substances or mixtures shall not be added in the final product or its ingredients, regardless of their concentration.</p>
<p><i>"This criterion shall be fulfilled by each intentionally added substance present at or above the concentration of 0,010 % weight by weight in the final product." The threshold should be fixed to 0,01% for rinse-off and 0,001% for leave-on cosmetics.</i></p>	<p><b>ACCEPTED</b></p> <p>Thresholds for rinse-off products and leave-on cosmetics have been set and adjusted. These thresholds are aligned to the ones which were set by Nordic Swan.</p>
<p><i>This criterion shall be fulfilled by each intentionally added substance present at or above the concentration of 0,010 % weight by weight in the final product. The criterion should apply to all intentionally added substances, not only to those that exceed 0.010% by weight in the final product.</i></p>	<p><b>CLARIFIED</b></p> <p>The wording on the thresholds has been clarified in each sub-criterion.</p>
<p><i>"This criterion corresponds to the existing criterion 3 (b) Hazardous substances and mixtures, currently in force. It is directly linked to the requirements given in the EU Ecolabel Regulation (EC) No 66/2010 in Article 6(6) which states: "the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008". General remark (observation) on Regulation (EC) 66/2010 on the EU Ecolabel, Article 6(6): Reference is made to substances classified as 'toxic' under the CLP Regulation. Note that this term is not used in CLP, nor do the hazard classes listed in Table 3 of the Commission decision on EU Ecolabel criteria for rinse-off cosmetic products correspond with the former categories of danger as T (toxic) and T+ (very toxic) and their corresponding classifications as Acute Toxicity categories 1 to 3, Specific Target Organ Toxicity, Single and Repeated Exposure category 1, respectively, of the previous legislation under DSD (Dangerous Substance Directive 67/548/EEC). In general, we recommend to consistently align the terminology with the legislations currently in force, for example the use of the term hazardous instead of dangerous substances.</i></p>	<p><b>ACCEPTED</b></p> <p>The term "classified as toxic" has been replaced by "fulfilling the classification criteria for Acute Toxicity, Specific Target Organ Toxicity Single Exposure and / or Specific Target Organ Toxicity Repeated Exposure".</p>
<p><i>We think that it would be better to lower the threshold for some hazard statements (like the carcinogenic H)</i></p>	<p><b>ACCEPTED</b></p> <p>The revised criterion states that CMR substances or mixtures shall not be added in the final product or its ingredients, regardless of their concentration.</p>

<p><i>The final product shall not be classified in accordance with any of the hazard statements included in Table 3. Change to "Finished product" instead of "final product".</i></p>	<p><b>REJECTED</b> Difference between final product and finished product is not clear. In the Regulation EC 1223/2009 both terms are indistinctly used. Therefore, it is preferred not to modify it in the proposal criteria, as this term is used also in other EU Ecolabel product groups.</p>
<p><i>This title must be changed for "substances and mixtures" Indeed, for each "intentionally added" mixture, we need to check the classification of all the substances AND the classification of the mixture because it's essential to evaluate the cumulative effect in the product which is intended to apply on skin's humans or animals (high hazardousness level). However, there should be a derogation to not consider the classification of mixture for H314 and H317 classifications because having an allergic reaction with substance A does not necessarily cause an allergic reaction with substance B: there is not a cumulative effect for these specific classifications.</i></p>	<p><b>ACCEPTED</b> Mixtures are also taken into consideration under this criterion.</p>
<p><i>For particularly hazardous compounds criterion 3 (a) (ii) "Substances" it is not protective enough. CMR substances as well as some highly sensitizing substances should not be intentionally added to an EU ecolabelled product, regardless of concentration. Hence, we propose to remove them and introduce a more restrictive criterion, 3 (a) (iii) Severely hazardous substances"</i></p>	<p><b>PARTIALLY ACCEPTED</b> The new criterion states that CMR substances or mixtures shall not be added in the final product or its ingredients, regardless of their concentration.</p>
<p><i>Substances that meet the criteria for classification with the hazard statements listed in Table 3 shall not be intentionally added in the final product. Substances must have the official hazardous classification in CLP ANNEX VI. Proposed hazardous classification not included in CLP ANNEX VI will not be taken into account.</i></p>	<p><b>REJECTED</b> In case a substance does not have a harmonized classification according to Annex VI of Regulation EC 1272/2008, classifications from the REACH submitted dossier (in case of absence of REACH registration dossier, the one with the highest number of notifications in the C&amp;L Inventory) have been considered in order to evaluate the specific exclusions included in criterion 3 (c)</p>
<p><i>The final product shall not be classified in accordance with any of the hazard statements included in Table 3. Editorial: 3(a)(i) – modify sentence to "[...] not to be classifiable for any hazard categories included in Table 3."</i></p>	<p><b>REJECTED</b> This subcriterion has been removed considering that Regulation EC 1272/2008 (CLP Regulation) only impacts chemical substances/mixtures that are used to manufacture cosmetic products. Final cosmetic products are exempt from this Regulation. Instead, the formula used in Blue Angel scheme is proposed.</p>
<p><i>Substances that meet the criteria for classification with the hazard statements listed in Table 3 shall not be intentionally added in the final product. It is understood that the approach of the EU EcoLabel is pre-selective to exclude certain substances although the principle here is in direct conflict with the EU Cosmetic Regulation assessment of risk.</i></p>	<p><b>CLARIFIED</b> Regulation EC 1223/2009, Regulation EC 1272/2008 and Regulation EC 1907/2006 must be fulfilled by the products under consideration in this EU Ecolabel scheme. When a proposed criterion is stricter than what is mentioned in any of these 3 Regulations, the EU Ecolabel Regulation prevails.</p>

<p><i>Derogated substances.</i>  <i>Surfactants: The derogation for surfactants classified with H412 is justified. However, it should only apply to surfactants that are both aerobically and anaerobically degradable.</i>  <i>With regard to H413, it is an unnecessary exemption and should be removed.</i></p>	<p><b>REJECTED</b>  As no derogation request was received, this substance was not derogated.</p>
<p><i>A derogation for classification with H301 is necessary for sodium fluoride in toothpaste (since it has a harmonized classification with H301).</i></p>	<p><b>REJECTED</b>  As no derogation request was received, this substance was not derogated. Further research on benzoic acid can be found in the TR 2.0.</p>
<p><i>Fragrances: The derogation for fragrances classified with H412 may only be kept if a maximum limit for fragrances in the final product is introduced, in order to limit environmental effects.</i>  <i>With regard to H413, it is an unnecessary exemption and should be removed.</i></p>	<p><b>CLARIFIED</b>  Fragrances are not derogated as no derogation request have been received.</p>
<p><i>Derogated substances.</i>  <i>Preservatives: The derogations for preservatives classified with H411, H412 and H413 should be removed, since better (less environmentally hazardous) alternatives are available.</i></p>	<p><b>CLARIFIED</b>  Preservatives have not been derogated as derogations requests have not been received.  Data on alternative preservatives are welcome.</p>
<p><i>One of the better alternatives for preservation (No H4XX-classification), benzoic acid has a harmonized classification with H372 (lungs) (inhalation). We suggest a specific derogation for benzoic acid when used in products where inhalation is not a relevant route of exposure.</i></p>	<p><b>REJECTED</b>  As no derogation request was received, this substance was not derogated. Further research on benzoic acid can be found in the TR 2.0.</p>
<p><i>Surfactants classified as H412 should be exempted, provided that they are biodegradable under aerobic and anaerobic conditions</i></p>	<p><b>REJECTED</b>  As no derogation request was received, this substance was not derogated. Further research can be found in the TR 2.0.</p>
<p><i>Fragrances classified as H317 and H334 (sensitizers) should be derogated from the requirement above.</i></p>	<p><b>REJECTED</b>  As no derogation request was received, this substance was not derogated. Further research can be found in the TR 2.0.</p>
<p><i>The content of the below table will be filled in as a result of the evaluation of justified derogation requests substantiated with technical rationale for the need of derogation, provided by the stakeholders to the project team</i></p> <ul style="list-style-type: none"> <li>- <i>The H412 derogation for surfactants needs to be kept. Near all the anionic surfactants are H412. They have a major role in rinse off cleaning cosmetics products</i></li> <li>.</li> <li>- <i>Regarding the H412 derogation for fragrances, we suggest keeping it. It's difficult to propose a fragrance that doesn't contain H412 substances with a good smelling. The fragrance part on a cosmetic product is not very high in the whole product, the part of H412 substances could be quite low. if you would to keep a H412 restriction for fragrance, perhaps we can allow until 0.2% on the complete product</i></li> <li>.</li> </ul>	<p><b>REJECTED</b>  As no derogation request was received, this substance was not derogated. Further research can be found in the TR 2.0.</p> <p>The derogations will be considered when the derogation requests are received by JRC.</p>

<p>Our company has developed a chemical substance named Ethyl Lauroyl Arginate HCl (LAE) which is included in Annex V of Commission Regulation (EU) No 1223/2009 as a preservative for cosmetic products. Its harmonized classification is Eye Dam.1 H318 and Aquatic Acute 1 H400 and self-classification Aquatic Chronic 2 H412.</p> <p>It's also included in some formulations which are already certified by ECOCERT, COSMOS and NATRUE.</p> <p>Regarding that in COMMISSION DECISION of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products, some exemptions are established for substances classified as Aquatic Chronic 1, Aquatic Chronic 2, Aquatic Chronic 3 and also Aquatic Acute 1 (H400, for example Zinc Pyrithione), we would like this working group to consider the possibility to include the Ethyl Lauroyl Arginate HCl (LAE) as a permitted substance for rinse-off cosmetic products.</p> <p>On the other hand, surfactants, classified as H400 and H412, are derogated substances according to different Commission Decisions establishing the EU Ecolabel criteria for detergents. Ethyl Lauroyl Arginate HCl (LAE) has also surfactant properties besides antimicrobial activity.</p> <p>Finally, other regulations such as Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes also indicates exemptions for preservatives with these hazard classifications for the environment.</p>	<p><b>REJECTED</b></p> <p>As no derogation request was received, this substance was not derogated. Further research can be found in the TR 2.0.</p>
<p>Surfactants (in total concentrations &lt; 20 % in the final product)</p> <p>We have reservation on the availability of main surfactants used in cosmetics that are not classified H412 after CLP reassessment. Please provide a list for review.</p>	<p><b>REJECTED</b></p> <p>As no derogation request was received, this substance was not derogated. Further research can be found in the TR 2.0</p>
<p>Specified excluded ingoing substances and mixtures</p> <p>In application of the precaution principal, we support the removal of all derogations unless industrials provide evidenced request of derogations for specific substances or substance groups. However, we wish to point out that French industrials are concerned about the possibility to find alternatives for substances classified with H412 and H413. We wish to receive feedback from the JRC on which alternatives industrials could use.</p>	<p><b>ACCEPTED</b></p> <p>See section "further research and main changes" in TR2 under criterion 3 (a). Industry input is needed in order to find out if alternatives are available. For the moment, no derogations have been granted as derogations requests have not been provided.</p>
<p>The proposal to remove the derogation for Zinc pyrithione (ZnPT) considering the recently adopted harmonised classification as Reprotoxic category 1B substance is further supported by its high toxicity to aquatic organisms which is reflected in the harmonised classification as hazardous to the aquatic environment and in particular the high M-factors (acute M=1000, chronic M=10) assigned to the classification which in our view this should not be dismissed.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>We support the removal of the derogation of zinc pyrithione (ZnPT), with reference both to environmental and human health concerns.</p>	<p><b>ACKNOWLEDGED</b></p>

<p>Concerning the ZPT derogation, French industrials point out that it might be a challenge to find alternative substances for anti-dandruff shampoo. We wish to have the JRC feedback on which alternative of ZnPT could be used for this type of product.</p>	<p><b>REJECTED</b></p> <p>Following further analysis, the following alternatives for ZnPT on anti-dandruff shampoos were found:</p> <ul style="list-style-type: none"> <li>- Selenium sulphide.</li> <li>- Salicylic acid.</li> <li>- Coal-tar solution.</li> <li>- Dandrilyls®.</li> </ul> <p>Out of these alternatives, selenium sulphide and Dandrilyls® are the ones which could fit under EU Ecolabel criteria. Salicylic acid is excluded due to H361d and Coal-tar is excluded due to H350. Further analysis can be found in the TR.</p>
<p>"...Removing the derogation on Zinc pyrithione (ZnPT) used in anti-dandruff shampoos..." There should be a coherent approach between the different services of the European Commission as this substance is under scrutiny by the Cosmetics unit.</p>	<p><b>CLARIFIED</b></p> <p><a href="https://echa.europa.eu/es/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181221490">https://echa.europa.eu/es/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181221490</a></p> <p>22/01/2020: the proposed harmonized classification for ZnPT (CAS n° 13463-41-7) has been adopted, but it has not been included in Annex VI through an ATP amendment and it is not known the publication date of this ATP yet.</p>
<p>There is a clear overlap in the criteria 3(a), (b) and (c) and we recommend careful consideration in the decision under which conditions specified (groups of) substances should be listed under criterion 3(b) and whether these are not also covered under criterion 3(a) and/or 3(c). In this context we would like to stress the need for clarity whether the requirements of the criteria refer to:</p> <p style="padding-left: 20px;">Harmonised entries listed in Annex VI to CLP; or PBT/vPvB substances included in the Candidate list set out in accordance with 59 of REACH; or Endocrine disruptors contained in the Candidate list set out in accordance with 59 of REACH or being confirmed under Regulation EC 1107/2009 or Regulation (EU) 528/2012.</p> <p>In relation to the above, it is proposed to insert a link to the ECHA website which provides regular updates of the lists of harmonised classifications in the Classification and Labelling Inventory as well as identified SVHCs listed in the Candidate list for eventual inclusion in Annex XIV to REACH.</p>	<p><b>ACCEPTED</b></p> <p>Harmonised entries which are listed in Annex VI of CLP are taken into account for the evaluation of the restricted substances under criterion 3, but it is not the only source to look for the CLP classification of a substance under evaluation.</p> <p>Regarding SVHC and ED, the link to the dynamic table of the Candidate List of SVHC for Authorization was already included in the 1<sup>st</sup> proposal and it is kept in the 2<sup>nd</sup> one.</p>

<p><i>Criterion 3b specified excluded substances</i>  Denmark supports that the limit should be "intentionally added", please refer to our comments on definitions. Having agreed on this limit also mean that some of the arguments from the technical report shall be reconsidered, reference page 45 – 51 in the technical report. Some substances are not on the list since they should already be regulated by requirements 3c SVHC, 3d Fragrance or 3e Preservatives. But these 3 requirements have another "limit" which is 0,010%. We suggest that these substances (example D4, D5 and D6) are added to the list again - this will also make the requirements more transparent for applicants.</p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>The criterion has been clarified and now the CMR, SHVCs and specific list of substances in 3 (b) shall not be included in the final product (regardless of their concentration). Substances meeting the CLP hazard classifications in 3 (a) (i) shall not be included in the final product, at or above the concentration of 0.010 % weight by weight for rinse-off products and 0.001% weight by weight for leave-on cosmetics.</p> <p>Octamethylcyclotetrasiloxane (D4) was added to Annex II of Cosmetics Regulation and therefore excluded to be used in cosmetics. For this reason, it was removed in TR1.0. In addition, D4, D5 and D6, are included in REACH SVHC Candidate List, being classified as vPvB substances. Therefore, they are restricted by revised sub-criterion 3(c) on SHVCs.</p>
<p><i>We support the inclusion of new compounds in the list of specified excluded substances. In particular, butylated hydroxyanisole (BHA), cocamide DEA and the phthalates di-n-octyl-phthalate (DNOP) and diethyl phthalate (DEP).</i>  <i>In addition to the problematic properties of these chemicals described in the proposal text, both butylated hydroxyanisole (BHA) and Cocamide DEA are classified by the International Agency for Research on Cancer as "Possibly carcinogenic to humans". BHA, DNOP and DEP are also identified as endocrine disruptors and listed on the SIN list (established by the International Chemical Secretariat).</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>Per- and polyfluorinated compounds are a group of extremely stable compounds and are excluded in cosmetics ecolabelled with the Nordic Swan Ecolabel as well as Bra Miljöval. Many of them are bioaccumulative.</i>  <i>The proposal text describes the negative effects of PFOA and PFOS, which have rendered them classifications prohibiting them from being used in the EU Ecolabel. However, PFAS is a huge group of chemicals, now comprising 4700 compounds. Hence, it is probable that many other per- and polyfluorinated compounds may possess the same hazardous properties as PFOA and PFOS, although not yet being enough studied.</i>  <i>The EU Ecolabel should therefore introduce a ban on the group as such (i.e all per- and polyfluorinated compounds).</i>  <i>It is crucial that an ecolabel prevents the substitution of hazardous chemicals to structurally similar alternatives with a high risk of being just as problematic.</i>  <i>In Sweden, major pharmacy companies (Apoteket AB, Apoteket Hjärat, Apotea), grocery stores (Willys) and cosmetics brands (e.g. L'Oréal, H&amp;M , Lumene) are phasing out the whole group of per- and polyfluorinated compounds. The EU ecolabel should not be less restrictive than those voluntary initiatives. In addition, unless a ban on the whole group is introduced, the EU Ecolabel cannot be used as a verification of products allowed to be sold in these stores.</i></p>	<p><b>ACCEPTED.</b></p> <p>Due to the high persistence, global distribution, bioaccumulation potential, and toxicity, this group of chemicals is proposed to be banned in criterion 3 (b).</p>

<p><i>The cyclic siloxanes octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) have all been identified as substances of very high concern (SVHC). Consequently, they are prohibited according to criterion 3 (c). Other cyclic siloxanes that may occur in cosmetic products, such as hexamethylcyclotrisiloxane (D3), will most likely possess similar problematic properties.</i></p> <p><i>EU Ecolabel should therefore exclude the group as such (i.e all cyclic siloxanes) in the criteria. It is crucial that an ecolabel prevents the substitution of hazardous chemicals to other alternatives with high risk of being just as problematic.</i></p>	<p><b>REJECTED</b></p> <p>There is not enough evidence to prohibit all cyclic siloxanes due to the same reason as the ones behind the restriction on D4, D5 and D6.</p> <p>D4, D5 and D6 are included in the Candidate List of SVHC, because it is confirmed that they meet the criteria to be classified as PBT (Article 57d) and vPvB (Article 57e) according to REACH regulation.</p> <p>According to the REACH registration submission dossier for D3: "This substance and its hydrolysis product (dimethylsilanediol) do not meet the criteria for PBT or vPvB. But a degradation product meets the P criterion". It should be kept in mind that the substances not listed in criterion 3 (b) have to fulfil criteria 1 and 2. Therefore, their persistence and negative effect on the aquatic environment should be limited already.</p>
<p><i>Substances meeting the criteria for PBT or vPvB, but which have not yet been investigated with regard to inclusion in the Candidate list should also be banned, since they possess the same hazardous properties</i></p>	<p><b>REJECTED</b></p> <p>Substances which have not been identified as PBT or vPvB were not proposed to be included in criterion 3(b) as the assessment of whether a substance is suspected to be PBT or vPvB or not may be subjective and therefore difficult and costly for the CBs.</p>
<p><i>Contrary to what you state in page 49 (53), "Phosphates" are not mentioned as excluded substance in this revised criterion 3(b). Therefore, it is proposed that these substances are included in the revised criterion 3 (b) as excluded substances in EU Ecolabel products. As mentioned in page 39 (43), "Phosphates" are missing in the revised criterion 3(b).</i></p>	<p><b>ACCEPTED</b></p> <p>There was a mistake in the TR1. Phosphates have been added to the list.</p>

As described in the background report perfluorinated compounds are used in cosmetics (p.49). While the most common PFAS (PFOS, PFOA, PFNA and PFSOA) have a harmonised classification under CLP Regulation and are therefore restricted through criterion 3 (a), many other PFAS not covered by this requirement are being used in cosmetics.

The Nordic Swan Ecolabel has therefore set a general ban of Perfluorinated and polyfluorinated substances, which would be more relevant for the EU Ecolabel vs only restricting the substances listed in page 49,

In Danish cosmetics these fluorinated substances have been found in cosmetics:

C9-15 fluoroalcohol phosphate

Polyperfluoromethylisopropyl ether

Ptfe

Perfluorooctylethyl triethoxysilane

Perfluorooctyl triethoxysilane

Perfluorodecalin

Acetyl trifluoromethylphenyl valylglycine

Perfluorononylethyl carboxydecyl peg-10 dimethicone

Tetradecyl aminobutyroylvalylaminobutyric urea trifluoroacetate  
(others may also be used, but not yet encountered)

Fluorinated substances pose a threat to both the environment as well as health. Researchers appeal to phase out all non-essential use:

Madrid Statement:

<https://ehp.niehs.nih.gov/doi/10.1289/ehp.1509934>

Zürich Statement:

<https://ehp.niehs.nih.gov/doi/10.1289/EHP4158>

Background links

Danish Consumer Council survey on which PFAS are used in cosmetics

<https://kemi.taenk.dk/bliv-groennere/fluorinated-substances-found-lotion-mascaras-and-shaving-foam>

Danish EPA work on PFAS in cosmetics. The report shows impurities of PFOA in ptfe, and a possible risk.

(please note that the risk assessment was performed before EFSA reduced the TDI by almost 2000 times. <https://www2.mst.dk/Udgiv/publications/2018/10/978-87-93710-94-8.pdf>)

Replace "Their use" by "The use of D5 and D6".

**ACCEPTED.**

Due to the high persistence, global distribution, bioaccumulation potential, and toxicity, this group of chemicals are proposed to be banned in criterion 3 (b).

**ACCEPTED**

It has been implemented in the rationale text.

<p>Given the existing concerns on potential hazardous properties of nanomaterials and methodology gaps to assess them, and based on the precautionary principle, the EU Ecolabel should exclude nanomaterials. Specific nanomaterials could be accepted based on conclusions from the SCCS. The EU Ecolabel could be aligned with the Nordic Swan Ecolabel. The Swan excludes nanomaterials/particles as defined in the Cosmetics Regulation. An exception is made to this requirement for:</p> <p>a) hydrated silica, which is used as an abrasive in toothpaste.  b) TiO<sub>2</sub> approved in SCCS opinion SCCS/1516/13. I.e. TiO<sub>2</sub> must not be photocatalytic, coating must be stable and TiO<sub>2</sub> may not be included in spray products.  Article 7 of Regulation 2018/848 on organic production and labelling of organic products sets principles applying to the processing of organic feed. One of the principles implies the exclusion of food containing, or consisting of, engineered nanomaterials. This is a precedent that could be used for excluding nanomaterials in the EU Ecolabel for cosmetics and other product groups.</p>	<p><b>ACCEPTED</b>  Nanomaterials were proposed to be excluded in EU Ecolabel unless an EU regulatory authority has evaluated the use of the nanomaterial and found that it is safe from health and environmental perspective</p>
<p>Criterion 3 (b) "Specified excluded substances" (vii). The criterion should include all nanomaterials, unless an independent party has evaluated the specific use and found it to be safe from a health and environmental perspective.</p>	
<p>Lip care products should not contain ingredients based on mineral oils (petroleum based)</p>	<p><b>REJECTED</b>  Based on the Risk Assessment issued by BfR and the recommendations from Cosmetics Europe, no health effects are to be expected from oral intake of mineral oils. Therefore, there is proposed not to include MOSH and MOAH under criterion 3 (b).</p>
<p>In order to allow a clear identification of the (groups of) substances listed under criterion 3, we propose to include numerical substance identifiers, such as EC and or CAS numbers, where possible. In case of Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives (3(b)(i)), an indicative list of substances covered under this group is available on the ECHA website.</p>	<p><b>REJECTED</b>  As far as possible, the CAS and EC numbers will be included in the User Manual.</p>
<p>No microorganisms.</p>	<p><b>REJECTED</b>  No evidence have been provided on the need to restrict microorganisms.</p>
<p>The JRC should evaluate the possibility to restrict:</p> <ul style="list-style-type: none"> <li>- MOAH (mineral oil aromatic hydrocarbons) which can be a source of potentially carcinogenic compounds, such as polycyclic aromatic hydrocarbons (PAHs)</li> <li>- MOSH (Mineral oil saturated hydrocarbons), although its health impact of is little known we know that they are likely to be more easily absorbed with a carbon number less than 25.</li> </ul> <p>And nanoparticles, given their potential health impact.</p>	<p><b>ACCEPTED</b>  Further research has been carried out and can be found in TR2.0.</p>
<p>Concerning phosphates, we support the proposal of the JRC to exclude them from EU Ecolabel cosmetic products. However, in the revised criterion 3.b), phosphates are not listed in excluded substances. They should be included in this list, as stated by the JRC in the technical report.</p>	<p><b>ACCEPTED.</b>  Disodium phosphate) and Trisodium phosphate have been added to the list of Specified Restricted Substances (sub-criterion 3(b)).</p>

<p><i>Rather than just have a blanket exclusion of phosphates consideration needs to be given to</i></p> <p><i>a) the classification of the REACH registered product (not all phosphates are classified as Corrosive)</i></p> <p><i>b) their form in the final formulation as they are often neutralised.</i></p>	<p><b>CLARIFIED</b></p> <p>In order to evaluate the substances of study under "Criterion 3: Excluded or limited substances and mixtures", it has been used the following methodology in order to determine the classification of a substance according to Regulation (EC) No 1272/2008 (CLP Regulation)</p> <ul style="list-style-type: none"> <li>- Entry on Annex VI of Regulation (EC) No 1272/2008 (harmonized classification).</li> <li>- Notified classification in the registration submitted dossier according to Regulation (EC) No 1907/2006 [REACH Regulation].</li> <li>- Entry in the C&amp;L Inventory with higher number of notifiers.</li> </ul> <p>Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate have been proposed to be banned in EU Ecolabel.</p>
<p><i>Paraben preservatives of long alkyl chain type, MIT (methylisothiazolinone) and MCI (methylchloroisothiazolinone) should not be found in cosmetic products (rinsed and leave-on)</i></p>	<p><b>ACCEPTED</b></p> <p>Paraben preservatives are already included in the list of Specified Excluded Substances (criterion 3 (b)).</p> <p>Isphthiazolinones have been added to the list of excluded substances in criterion 3(b).</p>
<p><i>Formaldehyde – we note that formaldehyde is prohibited from use in cosmetic products, however, we are not aware of an explicit ban for animal care products falling under the provisions of the GPSD. We would propose to consider setting specific rules for this product type and to assess which impact this would have on the use of formaldehyde and releasers in these products?</i></p>	<p><b>CLARIFIED</b></p> <p>It exists an entry under Annex VI of CLP Regulation for Formaldehyde. Among other criteria, it meets the criteria to be classified as H341 and H350. According to what it is proposed in criterion 3 (a) (ii), substances which meet these criteria must not be used in cosmetic EU Ecolabel products, regardless their concentration.</p> <p>It is proposed that substances included in annex II of Cosmetics regulation (excluded in cosmetics), are also excluded for animal products.</p> <p>Therefore, there is no need to set specific rules to allow formaldehyde on animal care products.</p>

<p><i>There is no relevant reason to forbid it. It should be removed from the list.</i></p>	<p><b>REJECTED</b></p> <p>The following CAS / EC accepts "benzalkonium chloride" as IUPAC name:</p> <ol style="list-style-type: none"> <li>1) CAS 8001-54-5 (EC 616-786-9)</li> <li>2) CAS 68391-01-5 (EC 269-919-4)</li> <li>3) CAS 63449-41-2 (EC 264-151-6)</li> <li>4) EC 939-350-2</li> </ol> <p>After further analysis, all of them are classified as H302 and H314, and 3 out of 4 are classified as H400. The inclusion in the Specified Restricted List is justified.</p>
<p><i>Phenoxyethanol should be removed from all leave-on products for children.</i></p>	<p><b>ACCEPTED</b></p> <p>Despite its use is accepted as alternative for parabens, it is proposed to ban its use on leave-on products for children, due to their risk of swallowing (due to H302)</p>
<p><i>The definition for Microplastics is currently included as footnote under criterion 3(b) – we appreciate the alignment with the restriction proposal for Microplastics under REACH. However, we would suggest replacing the definition by referring to the future restriction entry in case the definition may change over time.</i></p>	<p><b>ACCEPTED</b></p> <p>The "microplastic" definition has been replaced for the definition on Annex XV of Regulation EC No 1907/2006 (REACH) (restriction proposal for microplastics).</p>
<p><i>Please take into consideration that microplastics have been proposed by ECHA to be regulated. The regulation is under evaluation right now.</i></p>	<p><b>ACCEPTED.</b></p> <p>Under this sub-criterion, "microplastic" has been defined as it appears on Annex XV of Regulation EC No 1907/2006 (REACH) (restriction proposal for microplastics). Examples of categories which fall under this definition can be found on Annex A and Annex B of the Annex XV report.</p>
<p><i>*'microplastic' means particles with a size of below 5 mm of insoluble macromolecular plastic, obtained through one of the following processes: (a) a polymerisation process such as polyaddition or polycondensation or a similar process using monomers or other starting substances; (b) chemical modification of natural or synthetic macromolecules; (c) microbial fermentation. Is this a working definition based upon the work from ECHA or subject to change as/if legislation in this area evolves?</i></p>	
<p><i>Legislation have to be coherent and for microplastics there is a differentiation between microbeads that will be forbidden in 2020-2021 (already applicable in some Member States) and microplastics that will be forbidden in rinse-off products from 2024-2025 and for other leave-on products from 2026-2027....</i></p>	
<p><i>There is also a definition of microplastics for cosmetics and restriction of them are spread on different years (2020-2021 for microbeads, 2024-2025 for rinse-off products, 2026-2027 for leave-on products)</i></p>	
<p><i>The definition of microplastics should be aligned with the final decision of the proposed REACH restriction in order to simplify communication in the supply chain.</i></p>	

<p>Regarding microplastics, a restriction will come into force on January 1, 2020 restricting the use of microbeads but for other microplastics a derogation is envisaged until 2024/2025 for rinsed products and until 2026 / 2027 for leave-on products. It would therefore be necessary to specify which microplastics are actually targeted by the criterion. We would support the total restriction on microplastic in EU Ecolabel products.</p>	
<p>Not only nano silver might be a problem; to be safe we ask on SCCS opinions, therefore we ask for following exclusion: Nanomaterials unless a SCCS opinion is published with the conclusion that they are safe (for example 3 TiO2-Monomers, SCCS, Opinion on additional coatings for Titanium Dioxide (nano form) as UV-filter in dermally applied</p>	<p><b>ACCEPTED</b> In the second version of the TR it is proposed to exclude nanomaterial unless an EU regulatory authority has evaluated its use and found that it is safe from health and environmental perspective.</p>
<p>Substance OTNE has not a harmonized classification. Substance must be removed from this "prohibited substances" list.</p>	<p><b>REJECTED</b> Despite OTNE (EC 915-730-3) has no harmonized classification according to Annex VI of CLP Regulation, it exists a REACH registration submission dossier for this substance. According to this document, the substance is classified as H315, H317, H410 (M(chronic)=1). Due to its allergic skin reaction and its high environmental hazard potential, it is still recommended not to remove this substance from the proposal.</p>
<p>French stakeholders have expressed doubts about the exclusion of Sodium Lauryl Sulphate (SLS) and Sodium hypochlorite. These substances have the same irritation potential and environmental impact as other anionic surfactants that are not excluded. We wonder why those two anionic surfactants should be excluded when all other anionic surfactants are not. We expect to receive further explanation about the exclusion of those substances from the JRC before expressing a position on this criterion.</p>	<p><b>CLARIFIED</b> Sodium hypochlorite has a harmonized classification according Annex VI of CLP Regulation: H314, H318, H400 and H410.  Due to its oxidising properties (reflected through H314) and high environmental hazard potential (H400 and H410), it is still recommended not to remove this substance from the proposal.  After further analysis on the classification submitted in the REACH registration dossier, the main risk of SLS which is associated to the products under the scope of this EU Ecolabel is the possibility to be swallowed. The substance meets the criteria to be classified as Acute Toxicity, Category 4 – H302: Harmful if swallowed. Therefore, it is proposed to ban this substance, exclusively, for toothpaste applications.  The level of usage in cosmetic products encourages companies to look for safer alternatives.</p>
<p>SLS is largely used in cosmetics products and classification is not present in CLP Annex VI. This substance must be removed from this "prohibited substances" list.</p>	

<p><i>Cocamide DEA is already forbidden due to its CLP classification (it is registered under REACH). There is no need to list it here. It also denigrates this ingredient, which is in contradiction with the guidelines of claims on cosmetic products.</i></p>	<p><b>REJECTED</b> According to the CLP classification in the REACH submitted dossier for Cocamide DEA (EC 931-329-6), it is classified as Aquatic Chronic 2 (H411).</p> <p>Table 3 from criterion 3 (a) (i) states that substances which meet the criteria to be classified as H411 shall not be intentionally added in the final product in a certain % (0.01% for rinse-off products and 0.001% for leave-on cosmetics).</p> <p>Criterion 3(b) bans the use of this substance, regardless of its content in the final product.</p>
<p><i>Some substances are excluded only according to rumours. For example, Cocamide DEA is already excluded because under sub-criterion 3(a) (H411). Why to remark?</i></p>	
<p><i>Remove from the list. Sodium Lauryl Sulphate is forbidden in Nordic Swan only for toothpaste. It makes no sense to forbid it for all applications. We are strongly against the proposal to ban SLS, because most anionic surfactants used in cosmetic formulations are classified in the same manner as SLS or worst.</i></p>	<p><b>PARTIALLY ACCEPTED</b> After further analysis on the classification submitted in the REACH registration dossier, the main risk of SLS which is associated to the products under the scope of this EU Ecolabel is the possibility to be swallowed. The substance meets the criteria to be classified as Acute Toxicity, Category 4 – H302: Harmful if swallowed. Therefore, it is proposed to ban this substance, exclusively, for toothpaste applications.</p>
<p><i>SLS have the same irritation potential and environmental impact as other anionic surfactants that are not excluded. We wonder why this anionic surfactant should be excluded when all other anionic surfactants are not. We suggest deleting this raw material from specific excluded substances</i></p>	
<p><i>Product is produced in liquid form and powder is obtained as result of additional steps, so inhalation on the molecule as produced is not an issue. Furthermore, sarcosinates that are quoted as milder in powder form are classified as more toxic (ECHA Dossiers). Flammability depends on powder bulk density and other characteristics are the same for the main part of surfactants, so this inclusion is only a market issue with no scientific evidence.</i></p>	
<p><i>Sodium Lauryl Sulphate (SLS) can be made from petrochemical and natural origin.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>(xiv) Substances classified as endocrine disruptors.</i></p> <p><i>-EC Priority List of substances suspected ED must not be taken into account.</i></p> <p><i>-Only confirmed ED Substances must be referenced as prohibited.</i></p>	<p><b>ACCEPTED</b> Sub-criterion 3 (b) (xv) has been renamed to "Substances and mixtures identified to have endocrine disrupting properties". These are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</p>

<p>Scientists increasingly link endocrine-disrupting chemicals (EDCs) to a range of severe diseases and disorders, including infertility, obesity and cancer. Cosmetics ingredients with endocrine-disrupting (ED) properties represent a significant, potential source of cumulative consumer exposure to EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. They also have environmental impacts as they affect wildlife. EDCs are used in cosmetics, and as label for environmental excellence the EU Ecolabel should address them.</p> <p>We welcome the JRC proposal to exclude EDCs, however the proposed requirement is very limited as this classification is taking place through REACH. Considering the precautionary principle at the heart of the Ecolabel Regulation, the requirements should also cover substances that are not yet classified as EDCs but suspected of being endocrine disrupters. The Nordic Swan Ecolabel has this requirement although it refers to an old EU list and we think that considering more updated lists instead is preferable.</p> <p>We strongly recommend referring to the EC list published on May 2019 (including group A and B), which should be assessed by the SCCS. Applying the precautionary principle at the heart of the EU Ecolabel Regulation, all the substances in the list should be excluded in the EU Ecolabel. BEUC comments on each of the substances included in this list can be found in this position paper.</p> <p>The UN has also published a list of endocrine disrupting chemicals or potential EDCs which support the consideration of suspected EDCs by the EU Ecolabel. All the substances included in this list have gone at least through one thorough scientific assessment.</p> <p>The European Parliament and Council have called for a swift preparation of the long-overdue non-toxic environment strategy, as well as action on endocrine disrupting chemicals (EDCs).</p> <ul style="list-style-type: none"> <li>- European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors</li> <li>- Council conclusions June 2019 Towards a Sustainable Chemicals Policy Strategy of the Union</li> <li>- Council conclusions on 8th Environmental Action Program, October 2019.</li> </ul>	<p><b>REJECTED</b></p> <p>Sub-criterion 3 (b) (xv) has been renamed to "Substances and mixtures identified to have endocrine disrupting properties". These are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</p> <p>Substances which have not been identified as EDs were not proposed to be included in criterion 3(b) as the assessment of whether a substance is suspected to be EDs or not may be subjective and therefore difficult and costly for the CBs.</p>
<p>We strongly recommend including suspected EDCs and referring to the EC list published on May 2019 (including group A and B), which should be assessed by the SCCS.</p> <p>To only include endocrine disruptors that have been identified as SVHC is without doubt not protective enough. In addition, it is far below the ambitions expressed in most other requirements of the proposal, for example concerning aquatic toxicity and other aspects of human health hazards.</p>	
<p>Endocrine disruptors under which criteria/definition? This should be indicated in order to avoid any misunderstandings.</p>	<p><b>CLARIFIED</b></p> <p>"Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009. This aspect has been clarified also in the TR2.</p>

<p><i>Endocrine disruptors are defined as "an exogenous substance or mixture that alters function(s) of the endocrine system and, consequently, causes adverse health effects in an intact organism, or its progeny, or (sub)populations"</i>  <i>This definition is too vague. It is necessary to provide the comprehensive list of forbidden substances.</i></p>	<p><b>ACCEPTED</b>  The definition which was used on the TR1.0 was provided by the International Programme on Chemical Safety (IPCS), a joint programme of various United Nation Agencies, including the World Health Organisation.</p> <p>In the 2<sup>nd</sup> proposal, sub-criterion 3 (b) (xv) has been renamed to "Substances identified to have endocrine disrupting properties". These are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</p>
<p><i>It is necessary to provide the comprehensive list of substances considered as endocrine disruptors.</i></p>	<p><b>CLARIFIED</b>  "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</p>
<p><i>The commission should define the exhaustive list of prohibited endocrine disruptors.</i></p>	
<p><i>As written, there is no reference to indicate what 'classified' refers to i.e. by whom and according to what. It should be clarified precisely what is mean here. For instance, suspected or established EDs. With the work in this field only commencing it would be prudent to focus on a scientific based approach taking into account opinions from ECHA, EFSA, SCCS, and the JRC fitness check.</i></p>	
<p><i>Are there any other substances with potential endocrine disrupting properties that should be covered by criterion 3 (b)?</i>  <i>Please the comment previous concerning endocrine disruptors. Consideration should be to take into account the work in cosmetics on EDs with input to come from the SCCS, and more horizontally from other EU agencies. the value of any arbitrary listing is questionable.</i></p>	
<p><i>Concerning substances classified as endocrine disruptors, no official list of substances classified as endocrine disruptors currently exists. As we agree that this substance group should not be authorized in EU Ecolabel products and to ease the verification process, we recommend that the JRC defines an exhaustive list of substances to be excluded.</i></p>	
<p><i>Substances classified as endocrine disruptors. - The meaning of a 'classified' endocrine disruptor would need to be clarified. If it is understood to be a confirmed ED, i.e. identified as an SVHC under REACH, Article 57(f) or any other legislative process. We note that criterion 3(c) already covers the endocrine disruptors identified under the REACH Regulation. Overall, there are diverging levels of uncertainty based on which to consider a substance as ED, such as known ED properties but not yet regulated, suspected ED but possibly further data needs to be generated to confirm the status, etc.. It is important to consider these aspects in the revision of the Technical Report.</i></p>	
<p><i>Editorial: Substances identified (not classified) as endocrine disruptors.</i></p>	<p><b>ACCEPTED</b>  This has been amended.</p>

<p><i>"The Cosmetics Regulation does not contain specific provisions for endocrine disruptors" Please, be careful with this kind of sentence. This will be a public report. Article 15 of the current cosmetic regulation contains specific provision for ED.</i></p>	<p><b>ACCEPTED</b></p> <p>This sentence has been removed from the rationale.</p>
<p><i>This criterion should be out as there is not an official list of ED</i></p>	<p><b>REJECTED</b></p> <p>Despite there is no official list with identified and suspected to have ED properties substances, the risk of this group of substances is too high and the sub-criterion is proposed to be kept. "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</p>
<p><i>There is some work done by the European Commission on endocrine disruptors and the results are not known. It should be better to wait. And, there is no official list of ED so which one will fall under this legislation?</i></p>	<p><b>REJECTED</b></p> <p>Sub-criterion 3 (b) (xv) has been renamed to "Substances identified to have endocrine disrupting properties". These are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, , in Regulation 528/2012 or in Regulation 1107/2009.</p>

Correct "Substances classified as endocrine disruptors" into "Substances suspected of being endocrine disruptors, mentioned at the "call for data on ingredients with potential endocrine-disrupting properties" published on May 2019 (including group A and B).

<https://ec.europa.eu/growth/content/call->"

as

Many endocrine-related diseases and disorders are on the rise

Consumers are worried

There no criteria for the classification of EDCs

The political will support the application of the precautionary principle

Many endocrine-related diseases and disorders are on the rise

From: State of the Science of Endocrine Disrupting Chemicals 2012 Summary for Decision-Makers / WHO

Large proportions (up to 40%) of young men in some countries have low semen quality, which reduces their ability to father children.

The incidence of genital malformations, such as non-descending testes (cryptorchidisms) and penile malformations (hypospadias), in baby boys has increased over time or levelled off at unfavourably high rates.

The incidence of adverse pregnancy outcomes, such as preterm birth and low birth weight, has increased in many countries.

Neurobehavioral disorders associated with thyroid disruption affect a high proportion of children in some countries and have increased over past decades.

There is a trend towards earlier onset of breast development in young girls in all countries where this has been studied. This is a risk factor for breast cancer.

The prevalence of obesity and type 2 diabetes has dramatically increased worldwide over the last 40 years. "WHO" estimates that 1.5 billion adults worldwide are overweight or obese and that the number with type 2 diabetes increased from 153 million to 347 million between 1980 and 2008.

Global rates of endocrine-related cancers (breast, endometrial, ovarian, prostate, testicular and thyroid) have been increasing over the past 40–50 years.

There are no criteria for the classification of EDCs.

The only official rules are the one for "identification of EDCs", incorporated in the biocides and plant protection regulations and recently applied for such substances.

[https://ec.europa.eu/health/endocrine\\_disruptors/process\\_en](https://ec.europa.eu/health/endocrine_disruptors/process_en)

The only way of "classification" for EDCs in REACH is these days the identification as "property of equivalent concern" for the identification as chemical as a substance of very high concern SVHC according to article 57 (f) REACH. As this is a time-consuming process up to now only 14 substances are identified -

<https://echa.europa.eu/candidate-list-table>

Find here the 14 substances identified as EDCs, underlined the only 2 substances which were used in cosmetics – both of them forbidden in cosmetics since years.

Endocrine disrupting properties (Article 57(f) - human)

Dicyclohexyl phthalate (DCHP)

4,4'-isopropylidenediphenol (Bisphenol A; BPA) (also environment)

Diisobutyl phthalate

Benzyl butyl phthalate (BBP)

Bis (2-ethylhexyl)phthalate (DEHP) (also environment)

Dibutyl phthalate (DBP)

Endocrine disrupting properties (Article 57(f) - environment)

4-tert-butylphenol

Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with  $\geq 0.1\%$  w/w of 4-nonylphenol, branched and linear (4-NP)

1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor; 3-BC)

Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with  $\geq 0.1\%$  w/w 4-heptylphenol, branched and linear (4-HPbl)

4,4'-isopropylidenediphenol (Bisphenol A; BPA) (also human)

4-tert-butylphenol, branched and linear

## REJECTED

Sub-criterion 3 (b) (xv) has been renamed to "Substances identified to have endocrine disrupting properties". These are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.

Substances which have not been identified as EDs were not proposed to be included in criterion 3(b) as the assessment of whether a substance is suspected to be EDs or not may be subjective and therefore difficult and costly for the CBs.

<p><i>Same criteria that will be used for cosmetics under Cosmetic Regulation should be used.</i></p>	<p><b>REJECTED</b></p> <p>Article 15 (4) of Regulation (EC) No 1223/2009 (Cosmetics Regulation) is the only article which refers to endocrine disruptors. It is stated there: "When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties".</p> <p>This is not enough protective to prohibit the use of these substances.</p>
<p><i>Substances with endocrine disrupting effects should be banned. A list is required</i></p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>Sub-criterion 3 (b) (xv) has been renamed to "Substances identified to have endocrine disrupting properties". These are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</p>
<p><i>Concerning substances classified as endocrine disruptors, no official list of substances classified as endocrine disruptors currently exists. As we agree that this substance group should not be authorized in EU Ecolabel products and to ease the verification process, we recommend that the JRC defines an exhaustive list of substances to be excluded.</i></p>	
<p><i>Similar to microplastics condition, EDs should be aligned with materials specifically listed as SVHC under REACH because of ED properties.</i></p>	
<p><i>Denmark supports the inclusion of the new substances especially "Endocrine disruptors".</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>No intentional use of SVHC should be allowed, as done for the EU Ecolabel for Detergents. They are currently proposed for restriction restricted in the criteria proposal for cosmetics but only above 0.01%.</i></p>	<p><b>ACCEPTED</b></p> <p>Article 6 (6) of EU Ecolabel Regulation (EC) No 66/2010 states that "The EU Ecolabel may not be awarded to [...] goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.". It is justified to set a criterion which these substances are restricted, regardless its content, either in the final product or in the ingredients used in the cosmetic formulation.</p>

<p>Criterion 3 (c) "Substances of very high concern (SVHC)" it is not protective enough. Substances of very high concern should not be intentionally added to an EU ecolabelled product, regardless of concentration.</p>	
<p>It is more than justified to exclude SVHCs at all. Moreover, as those substances are excluded in the detergents group in that way it isn't justifiable to allow them up to 0,01%.</p>	
<p>In analogy with the Detergent groups they need to be evaluated "regardless of concentration"</p>	
<p>With respect to criterion 3(c), for the clarity and enforceability we see the need for setting a cut-off value. One possibility would be to base such a cut off value on the detection limit at least for substances included in the Candidate list. In principle, the same could apply to criterion 3(b).</p>	<p><b>ACCEPTED</b> It has been proposed the total restriction of the use of the substances in the SVHC Candidate List (following the indications of Article 6 (6) of EU Ecolabel Regulation (EC) No 66/2010).</p>
<p>Perfume substances that are known allergens The Nordic Swan Ecolabel requires that fragrances/flavouring/fragrance substances in plant extract which are judged to be sensitising with the hazard statement H317 and/or H334, or being subject to declaration may be included at a maximum of 0.001% (10 ppm) in leave-on products and a maximum of 0.01% (100 ppm) in rinse-off products. At the moment, the substances meeting hazard classifications H334 and H317 are also restricted by criterion 3 (a)(ii) for the EU Ecolabel but with a general concentration of 0.01%. For leave on cosmetics this restriction should be set at 0.001%. The EU Ecolabel should also take into account the substances established as contact human allergens by the SCCS opinion from 2012, as they are of equivalent concern than the 26 fragrances covered by the Swan (<a href="https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_102.pdf">https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_102.pdf</a>)</p>	<p><b>ACCEPTED</b> Allergens which meet the criteria to be classified as H317 and/or H334 would be covered by the requirement on criterion 3 (a) (i) [at a maximum of 0.001% (10 ppm) in leave-on products and a maximum of 0.01% (100 ppm) in rinse-off products]. No derogation is required. This will be aligned with Nordic Swan Ecolabel and the conclusion from SCCS/1459/11.</p>
<p>From 0,01% (rinse-off products) and 0,001% (leave-on products) following substances are excluded: - Sensitizing fragrance ingredients listed in Table 13-1 of the SCCS-opinion on fragrance allergens in cosmetic products, 26-27 June 2012 (54 individual chemicals, 28 natural extracts (mixtures of chemicals), including all 26 fragrance allergens identified by SCCNFP in 1999)</p>	
<p>Finally, based on the feedback of a consumer association, we have the following comments: The number of allergens on the restriction list should be increased: currently, a proposal to move from 26 to 87 is being studied by the European Commission. Polyethylene glycol (PEG) and silicones should be given more consideration since they bioaccumulate in the environment, in particular because of their slow degradation and the creation of substances toxic to the aquatic environment.</p>	<p><b>REJECTED</b> Polyethylene glycol (PEG) and silicones are not classified and are not considered in other schemes. However criterion 1 and 2 on bioaccumulation and aquatic toxicity are considered strict enough and all cosmetics will need to comply with these criteria in order to be awarded with the EU Ecolabel.</p>
<p>Lower thresholds for leave-on products</p>	<p><b>ACCEPTED</b> Thresholds for leave on products have been specified in line with Nordic Swan.</p>

<p><i>Differentiate baby products</i></p>	<p><b>ACCEPTED</b> Baby products have been defined in line with Nordic Swan. 'Infant, baby and/or children's products' are considered to be products that are marketed for or have words such as baby and/or children (&lt;12) on the label.</p>
<p><i>The age limit for "products intended for children" must be defined. We suggest 12 years of age to align with other ecolabels.</i></p>	
<p><i>We wish to receive information from the JRC about other stakeholders' feedback on this criterion and on the possibility of authorizing some fragrance with additional restrictions for products marketed as designed and intended for children.</i></p>	<p><b>ACKNOWLEDGED</b> All feedback received during the consultation is reflected in this table.</p>
<p><i>(i)Products marketed as designed and intended for children shall be fragrance-free. In the French market, a fragrance-free product for children can't be sold. We understand products for children needs to have more restrictive criteria, but you can establish more restrictive criteria about fragrance for children without ban it totally. Some fragrances can be for example without skin allergens, without skin sensitizing substances, to be safer for children, without being banned from EU ecolabel. Today, a few of fragrances in the market reach our proposed restriction because it's very restrictive, but it's possible and technically feasible. It's important to take into consideration allergens and sensitizing raw material are essentially emanated from fragrances but all raw materials that can be in fragrances are not allergens, or sensitizing. It's important to let the stakeholder to choose, either he wants to add fragrance with bigger restrictions, or he'll choose to not include "classical" fragrance that can be sensitizing or contains allergens.</i></p>	<p><b>REJECTED</b> The wording for criterion 3 (d) has not changed. There is no need to modify this requirement which is already present in criteria in force. It is considered that the revised proposal of criteria must be, at least, as much restrictive as currently criteria in force.</p>
<p><i>We suggest sharpening this criterion so that to only preservatives that are approved as food additives are permitted in toothpaste.</i></p>	<p><b>ACCEPTED</b> There is an evident risk of swallowing toothpaste. Therefore, establishing preventive measures is justified. A new clause has been added allowing in the case of toothpastes only the use of preservatives which are approved by Regulation (EC) No 1333/2008 on food additives.</p>
<p><i>Note that MIT/C(M)IT are confirmed to be toxic to the aquatic environment. Restriction on the use of isothiazolinones is supported in general but in particular for EU Ecolabel eligibility.</i></p>	<p><b>ACCEPTED</b> Isothiazolinones have been added to the list of excluded substances in criterion 3(b)</p>
<p><i>Editorial: it should refer to criterion 3(e) instead of 3(d).</i></p>	<p><b>ACCEPTED.</b> Criterion 3 (d) refers to "Fragrances". The correct criterion for isothiazolines is criterion 3(e), which refers to "Preservatives". The typing mistake has been amended.</p>

<p><i>(ii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF &lt; 100 or log Kow &lt; 3,0. If both BCF and log Kow values are available, the highest measured BCF value shall be used.</i></p> <p><i>Criterion 3(e) refers to cut-off values of DSD, whereas CLP uses higher cut-off values based on scientific considerations. While stricter cut-offs would be more protective, the Swedish Ecolabel is consistent with CLP, thus possible harmonisation of the EU Ecolabel with CLP could be considered. The same applies to criterion 3(g) on page 40.</i></p>	<p><b>REJECTED</b></p> <p>Despite alignment the cut-off values to CLP Regulation would be reasonable to include, these values are less strict than the ones on the proposal (coming from Dangerous Substances Directive (DSD) – which was replaced by CLP Regulation).</p>
<p><i>(ii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF &lt; 100 or log Kow &lt; 3,0. If both BCF and log Kow values are available, the highest measured BCF value shall be used.</i></p> <p><i>Editorial remark: Criterion 3(b) should be changed to 3(a) which makes reference to hazardous substances.</i></p>	<p><b>ACCEPTED.</b></p> <p>Existing criterion 3(a) in the Ecolabel in force has now been changed to criterion 3(b) in the proposed second version of the technical report</p>
<p><i>Isothiazolinones</i></p> <p><i>They should be limited but with a valid alternative that does not cost too much.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>Isothiazolinones should be added to the list or should be explicitly excluded in requirements 3d. The problematic in regard to these substances is well known and they are already regulated by the Cosmetic regulation, but the EU Ecolabel should go further. It is possible to completely band these substances in cosmetic products, unfortunately the opposite is written in the technical report (p42), and this should be updated. The Nordic Swan Ecolabel do not allow Isothiazolinones (due to the H317 classification), hence more than 2000 products are using another preservative.</i></p>	<p><b>ACCEPTED.</b></p> <p>Isothiazolinones have been added to the list of excluded substances in criterion 3(b)</p>
<p><i>Kemiluppen shows that none of the Nordic Swan cosmetic products contain isothiazolinones, so it is (very) possible to make products free from MI/MCI.</i></p>	
<p><i>Criterion 3 (b) "Specified excluded substances" (v). The criterion should also include isothiazolinones as a group and all preservatives classified with H317</i></p>	
<p><i>Colorants not allowed in food + azo colours</i></p> <p><i>The Nordic Swan Ecolabel allows only food colorants. This is also the case for the Bra Miljøval Ecolabel.</i></p> <p><i>We recommend adding as well a (precautionary) exclusion of azo colourants. These substances are problematic in many ways: some can form carcinogenic primary aromatic amines, some are allergenic, and some are linked to hyperactivity in children. They may be harmful to the environment.</i></p> <p><i>EFSA has highlighted that more information is needed on genotoxic potential of sulphonated mono azo dyes. This concern covers the food (and cosmetic) colorants Allura Red AC (E 129)7 /(CI 16035), Amaranth (E 123) (CI 16185), Ponceau 4R (E 124)/( CI 16255), Sunset Yellow FCF (E 110)/( CI 15985), Tartrazine (E 102) /(CI 19140) and Azorubine/Carmoisine (E 122)/(CI 14720).</i></p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>Hazardous azo colours are restricted by criteria 3(a) on CLP hazards and 3(c) on SHVCs.</p>
<p><i>We suggest sharpening this criterion so that to only colorants that are approved as food additives (colour) are permitted in toothpaste</i></p>	<p><b>ACCEPTED</b></p> <p>Due to the risk of swallowing toothpaste products, it is justified to add a clause to allow the colorants which have been previously approved by Food Additives Regulation.</p>
<p><i>Criterion 3f Colorants</i></p> <p><i>Denmark suggest updating the requirements as it is for the Nordic Swan Ecolabel today:</i></p> <p><i>Organic colorants must not be bioaccumulating in line with the testing methods in Appendix 9 (BCF&lt;500 / log Kow &lt;4). Alternatively, the colour must be approved for use in food.</i></p> <p><i>It is important that there are two alternatives.</i></p>	<p><b>REJECTED.</b></p> <p>Despite the proposed cut-off values come from CLP Regulation (current EU Regulation in force), these values are less restrictive than the ones from DSD (not valid anymore). Therefore, we suggest keeping the stricter ones instead.</p>

<p>Stakeholders are requested to give their opinion on whether to limit a maximum content of colorants in the final product. If the aim is to have a wider product category appeal, then this proposal could be counterproductive. For instance, if decorative cosmetics were to be included.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>Alternatively, stakeholders are asked to provide their opinion whether the approach should be harmonised with Nordic Swan and accept only colorants approved as food additives Not all colorants on Annex IV of the EU cosmetic regulation may be food additives. for JRC reference please find a positive list of accepted colorants from the NATRUE standard (found in Annex 2): <a href="https://www.natrue.org/our-standard/natrue-criteria-2/">https://www.natrue.org/our-standard/natrue-criteria-2/</a></p>	<p><b>ACKNOWLEDGED</b></p>
<p>UV filters in general possess problematic environmental properties and should therefore only be allowed in products where they are necessary, i.e sunscreen products.</p>	<p><b>CLARIFIED</b> The following is state in the criterion text: "UV filters may only be added to leave-on products and only to protect the user – not the product."</p>
<p>To harmonize with CLP, there should be a tenfold difference between NOEC/ECx and LC50/EC50.</p>	<p><b>PARTIALLY ACCEPTED</b> Despite the cut-off values refer to a Regulation which is not in force anymore (DSD), it is recommended to keep them as they are stricter than the ones from CLP Regulation. These cut-off values will let companies to be awarded if they fulfil the criterion in a higher level in comparison to what it is define at CLP Regulation.  Regarding aquatic toxicity cut-off values, these values are aligned with Nordic Swan ecolabelling scheme, which holds licences for sunscreen products.</p>
<p>"...- must not be bioaccumulating (BCF&lt;100 / log Kow&lt;3) or must have a lowest measured toxicity of NOEC/ECx &gt; 0.1 mg/l or EC/LC50 &gt; 10.0 mg/l" The cut-off values for bioaccumulation refer to DSD, while these changed in CLP to log Kow ≥4 and BCF ≥ 500. Suggest aligning with CLP. Furthermore, the rationale behind the cut-off values selected for aquatic toxicity is not clear. At present these seem to be too low for not resulting in potential classification for environmental hazards. Please reconsider.</p>	
<p>Titanium Dioxide (TiO2) It might be useful to consider not only the confirmed health hazard for which the substance has been harmonised classified but also the potential environmental hazards. While available data indicates that titanium is very toxic to aquatic organisms, we note that no harmonised classification is available. Moreover, the Cosmetic Products Regulation does not include the protection of the environment in its aims nor does the SCCS normally address environmental aspects in its opinions.</p>	<p><b>ACKNOWLEDGED</b> TiO2 has been reclassified as H351 and therefore excluded by criterion 3. Industry needs to submit formal derogations request if its use is still needed.</p>

<p><i>To our understanding UV-filters are only added to leave-on products. When it is said "and only to protect the user – not the product", this sentence seems redundant when considering the word protect to mean preserve since this is not the function of these substances. Consideration should be taken for inorganic mineral UV-filters approved by law on Annex VI of the EU Cosmetic Regulation (in particular), since these can have a dual function as colorants (approved under Annex IV) and for some operators they will not want to use organic UV-filters.</i></p>	<p><b>REJECTED</b> It is preferred to keep this wording despite it could sound redundant. UV-filters can be used to protect (stabilize) some ingredients of the product from sun exposure. Such UV-filters are proposed not to be allowed in EU Ecolabel products.</p>
<p><i>Stakeholders are asked to provide information of the form (powder, liquid, etc.) in which TiO2 is added to the cosmetic formulation Unclear if this describes manufacture or the form of the cosmetic based upon the word 'added'. Is this the final form of the product or the form which the TiO2 is added during production? For instance, TiO2 is used as a colorant in decorative cosmetics (powders) and is also found in liquid form both as a UV-filter and colorant.</i></p>	<p><b>CLARIFIED</b> It was requested information on the form TiO<sub>2</sub> is used/added as ingredient during production of the cosmetic formulation. Moreover, a questionnaire on the use of TiO<sub>2</sub> in cosmetic products has been sent out to industries and CBs.</p>
<p><i>We strongly disagree with the creation of this criteria. There don't exist biodegradable alternative to UV filters. Thus, we think that the inclusion of sunscreen products in the scope represents a substantial risk for the EU Ecolabel reputation.</i></p>	<p><b>REJECTED</b> Although comments on the poor biodegradability of UV filters are correct, the inclusion of sunscreens in the scope for EU Ecolabel of cosmetics aims at providing environmentally preferable products to the consumers. UV-filters are exempted from criterion 2 (biodegradability) in line with Nordic Swan.</p>
<p><i>This criterion should be deleted as it seems that it will be difficult to fill the criteria of biodegradability.</i></p>	
<p><i>UV filters We strongly disagree with the creation of this criteria. French stakeholders have expressed a shared opinion on the fact that there exists no biodegradable alternative to UV filters. Thus, we think that the inclusion of sunscreen products in the scope represents a substantial risk for the EU Ecolabel reputation.</i></p>	
<p><i>Nanomaterials Italy disagrees with a total ban but also with a case by case approach. A list is required.</i></p>	<p><b>REJECTED</b> The following sentence has been proposed in criterion 3(b) (total exclusion): "Nanomaterials, unless an EU regulatory authority has evaluated the use of the nanomaterial and found that it is safe from health and environmental perspective"</p>

<p><i>For TiO2 UV filters suggest make future proof by linking to Annex VI of cosmetics regulation and final SCCS opinions that post-date the latest version. This will allow for any newly approved coatings to be included and for opinions developed in response to the anticipated change in CLP classification of Titanium Dioxide. This principle of linking Cosmetic Regulation and opinions from other EU Commission Scientific Committees, such as the SCCS, should be applied to all CMRs and substances considered "safe" for use in cosmetics.</i></p>	<p><b>ACCEPTED</b> The new proposal takes into consideration this fact. The text will be amended as follows:  "To demonstrate compliance with 3(g) the applicant shall provide: copies of the SDS of any UV filter added together with information on its BCF and/or log K<sub>ow</sub> value, or lowest available NOEC/EC<sub>01</sub>/EC/LC50 value. In addition, a declaration that, if used, nano TiO<sub>2</sub> fulfils the conditions expressed in Annex VI of Regulation EC 1223/2009 and its latest amendments must be provided."</p>
<p><i>Assessment and verification: It is suggested in the proposal that safety data sheets should be used to demonstrate compliance with criteria 3 (a)(ii), 3 (b) and 3 (c). However, this will in several cases not be sufficient to control the compliance with the criteria. For example, chemicals being classified with some of the prohibited hazard statements only have to be listed in the SDS if they are present above 1 or 10% in an ingredient. As a consequence, other verifications/documents are needed to demonstrate that prohibited substances are not present above a concentration of 0.01%, especially in complex mixtures such as perfumes.</i></p>	<p><b>ACCEPTED</b> It is acknowledged the limitations on providing only SDS to prove fulfilment. Therefore, the applicant shall provide a signed declaration of compliance with all sub-requirements, supported by declarations from suppliers.</p>
<p><i>How shall we deal with a mixture with a chemical substance diluted in a solvent (except if the solvent is water)? Should we check the SDS of mixture or the SDS of the chemical substance in the pure form? If the requirement is only checking the SDS of the chemical substance in the pure form, it is a problem because any solvent (except water) has an impact on the user and/or the environment.</i></p>	<p><b>CLARIFIED</b> In this case, it must be checked the SDS of the added mixture, taking into consideration each substance which conforms the mixture. The solvent should be included in the calculation sheet.</p>
<p><i>"...a declaration that, if used, nano TiO2 fulfils the conditions expressed in SCCS/1516/13 (*) and SCCS/1580/16 (*) must be provided. The declaration shall be provided by the manufacturer of UV filter.</i></p>	<p><b>CLARIFIED</b> The potential license holder must collect all declarations from upper supply-chain suppliers as proof of fulfilling the criterion. These declarations shall be provided to the relevant CB for evaluation.</p>
<p><i>"...the self-declaration can be provided for the verification of nano TiO2 use in criterion 3(g)" The declaration shall be provided by the manufacturer of UV filter.</i></p>	

<p>"In addition, a declaration that, if used, nano TiO<sub>2</sub> fulfils the conditions expressed in SCCS/1516/13 (*) and SCCS/1580/16 (*) must be provided."  Unnecessary since titanium dioxide has been entered into the Annexes of the EU Cosmetic Regulation. Can either quote the legislation:  <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1143">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1143</a>  <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.286.01.0003.01.ENG&amp;toc=OJ:L:2019:286:TOC">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.286.01.0003.01.ENG&amp;toc=OJ:L:2019:286:TOC</a>  ...or Annex VI entry 27 and 27a for bulk and nano titanium dioxide from the EU Cosmetic Regulation  For completeness zinc oxide (bulk and nano) is now included in Annex VI as well cf. entries 30 and 30a respectively.  Therefore, no declaration to the SCCS Opinions is required nowadays.</p>	<p><b>ACCEPTED</b></p> <p>The revised proposal takes into consideration this fact. The text will be amended as follows:</p> <p>"To demonstrate compliance with 3(g) the applicant shall provide: copies of the SDS of any UV filter added together with information on its BCF and/or log K<sub>ow</sub> value, or lowest available NOEC/EC<sub>x</sub>/EC/LC50 value. In addition, a declaration that, if used, nano TiO<sub>2</sub> fulfils the conditions expressed in Annex VI of Regulation EC 1223/2009 and its latest amendments must be provided."</p>
<p>The "Take back criteria" was previously used in the Nordic Swan for example in the detergents for professional dishwashers and professional laundry. It is now removed. A reason could be the difficulty to implement or track, through the distributors. Very big packaging's (&gt;200L) are the ones being taken back and reused most of the time. Small packaging's are more difficult to get back or they can be recycled. Some packaging's can also be sealed off for dispensing purpose and cannot be reused without damaging the integrity of the design. Please provide more information on how this criterion would be set up if wish is to keep it. mandatory? volunteering? with commitment to increase? (considering the implementation time needed and supply chain difficulty through many distributors or exemption due to design restriction) and if a split consumer market (going back directly to the store) vs professional market could be reviewed.</p>	<p><b>PARTIALLY ACCEPTED</b></p> <p>Considering the feedback received after the consultation period, it was decided to modify the criterion and propose to make criterion 4(e) mandatory only for amenities used for tourist accommodations. More information can be found in the rationale to criterion 4(e).</p>
<p>Denmark can not support the proposal 4e on a mandatory take back system for license holders. We do not think this is possible to implement in praxis and furthermore not something all license holder can control. How do we ensure that such system is by license holders which produce only private label products?</p>	
<p>We are not in favour of a take back system for the packaging. In our opinion this is practically not feasible. Instead of that we would like to encourage circular economy by requiring a certain % of recycled plastic in the packaging.</p>	
<p>Will it be compulsory to have the take back system to obtain the ecolabel certification?</p>	
<p>We support to introduce a requirement on take-back systems. However, the suggested criterion in the proposal is very vague and has to be significantly more well-defined in the final version.</p>	
<p>We don't see any environmental benefit due to the take back system. The Nordic Ecolabelling's Criteria Group decided on the 9 October 2017 to remove this requirement. therefore, there is no necessity to introduce such criterion</p>	
<p>The JRC proposal regarding the implementation of a take-back system in order to collect empty products from consumers is on contradiction with the existing schemes aiming at collecting the waste for recycling. We do not support this proposal.</p>	
<p>Should we verify service conditions and audit one site with take-back system?</p>	
<p>Whilst the principle of a take-back scheme is a good one it is unlikely to be able to be mandated into any revision of the EU Ecolabel for cosmetics at this stage.</p>	

<p><i>It's necessary to only initiate with this criterion (take back system) and not make it mandatory (as in Detergent EU Ecolabel decision). Moreover, it's on contradiction with the existing schemes aiming at collecting the waste for recycling.</i></p>	
<p><i>For SMEs it will be a high cost and there are already some services put in place by public authorities to collect empty products. The take back system should be deleted</i></p>	
<p><i>The trademark mentioned are big enterprise but a SMEs and very small enterprises will not have access to the EU Ecolabel as it will be a cost that they could not assume. There are some collect system put in place by national authorities and it is sufficient.</i></p>	
<p><i>We think "take-back system" should not be mandatory because it's difficult to set in, in particular with large-scale distribution. However, it can be an option as for HSC to encourage applicants to develop it when it's possible. In order to promote it, we can propose to facilitate the PIR criterion for products included in take-back system.</i></p>	
<p><i>PVC should not be excluded when combined with PP or HDPE. Limit the exclusion of PVC when combined with PET. Contrary to PET/PVC, the density difference between PP or HDPE and PVC is sufficient to allow very easy separation by the sink/float method</i></p>	
<p><i>PVC should not be excluded when combined with PP or HDPE. Limit the exclusion of PVC to the combination PET/PVC. PVC can easily be separated from PP or HDPE by the sink/float method, in view of the large density difference</i></p>	<p><b>REJECTED</b> PVC material is incompatible with some plastic materials commonly used in the packaging of cosmetic products. The use of PVC will difficult the recycling process of the packaging and it is against the European strategy for plastics in a Circular Economy.</p>
<p><i>The exclusion of PVC when combined with PP or HDPE is not justified. Limit the exclusion of PVC to cases when it is combined with PET. The density difference between PVC on the one hand and PP or HDPE on the other hand ensures easy separation by the sink/float method.</i></p>	
<p><i>The exclusion of PVC when combined with PP or HDPE is not justified. Limit exclusion of PVC to cases when it is combined to PET. The density difference between PP/HDPE and PVC is large enough to allow easy separation by the sink/float method.</i></p>	
<p><i>PVC is recyclable, but is possibly not collected. Replace "PVC is the polymer less recyclable" by "PVC is the polymer less recycled in this application".</i></p>	
<p><i>Closures: Caps in PS and PVC do not exist on the market, it is interesting to prohibit them, but these materials are not suitable for caps making this requirement not relevant.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>When introducing recycled material in the packaging, it should be ensured, that no problematic substances are in the recycled material. I.e. heavy metals, UV-filters, etc. Recycled material should only be sourced from known "clean" materials.</i></p>	<p><b>REJECTED</b> The use of recycled materials is one of the key aspects of the circular economy and allows more flexibility to manufacturers while also removing reusing existing materials. To avoid a complex verification the proposal has not been included.</p>
<p><i>From the perspective of recyclability, PVC and other halogenated plastics should not be permitted. PVC and other halogenated plastics shall not be used in any part of the packaging.</i></p>	<p><b>REJECTED</b> Only combinations of materials that difficult the recycling process been excluded. Single polymers are recyclable when properly collected.</p>

<p><i>It is of high importance for future recyclability to not use Substances of very high concern (SVHC), when using virgin materials in the manufacturing of packaging. The packaging shall not contain any substances that have been identified in accordance with the procedure described in Article 59(1) of Regulation (EU) No 1907/2006 which establishes the candidate list for substances of very high concern, at or above the concentration of 0.10% weight by weight.</i></p>	<p><b>REJECTED</b> Although this comment is valid it is not seem a feasible way to implement/verify such requirements. Following other similar product groups of the EU Ecolabel (detergents and lubricants for instance), this criterion it is not suggested to be introduced.</p>
<p><i>We wish to receive from the JRC information supporting the choice of the 2g of formula delivered per full press.</i></p>	<p><b>CLARIFIED</b> The criterion has been aligned with the Nordic Swan requirements.</p>
<p><i>We wish to point out that French stakeholders have issued the following reservation: the requirements on mandatory provision of refill bottles and the delivery of 2g of formula per full press seems difficult to apply to companies selling refills for dispensers.</i></p>	
<p><i>We support the removal of the exception on secondary packaging intended to group two or more products or a refill. Removing plastic packaging only used for product grouping is one of the pillars of work of the French National Pact on plastic packaging. In addition, it should be possible to purchase the refill independently of the bottle.</i></p>	<p><b>PARTIALLY ACCEPTED</b> The secondary packaging will be only allowed to group the product and its refill.</p>
<p><i>We also recommend aligning the packaging criterion with recently voted referents on the inclusion of recycled content in the primary packaging. The pressure to reduce the environmental footprint of packaging and plastic waste discharged in the environment is increasing and the EU Ecolabel should put adequate requirement on this topic. See example below: Lubricant referential: Recycled content (applicable only in the case of lubricants sold in plastic packaging/container): plastic packaging/container shall be made of a minimum of 25% of post-consumer plastic. Finally, and for information, 40% of French licensed products include renewable or recycled materials in the packaging, with an average content of 46%.</i></p>	<p><b>PARTIALLY ACCEPTED</b> In order to promote the use of recycled materials in packaging an exemption for the section b) Packaging Impact Ration has been included. For more information, see the rationale of the criterion in TR2.0.</p>
<p><i>We recommend lowering the PIR, as the average PIR among French license holder is 15g, with 74% of PIR being below 20g.</i></p>	<p><b>ACCEPTED</b> Considering the information gathered after the 1AHWG the threshold value of PIR has been reduced.</p>
<p><i>The value of PIR shall be more restrictive and reduced. We sent you our values: we have only 4 products by 34 certified products with this huge value and the average is 0,15. It's essential to reduce this value if we want that the criterion remains selective.</i></p>	
<p><i>Label or sleeves: CPET (or PETC ...) is a crystallized PET that can be put in the microwave or oven. There is no CPET sleeve on the market and manufacturers are working on non-PET polyester sleeves and will be conducting recyclability tests on their inventions. We do not recommend adding CPET on the excluded materials list. To be complete, an OPP label (by default in paper) will always be better in terms of recycling than a sleeve or direct printing. Therefore, instead of the requirement on CPET, we recommend adding a criterion to restrict the use of sleeves on EU Ecolabel products. The line "sleeves made of different polymer than the bottle" is in contradiction with the previous requirements, for example the reason not to limit the PETG sleeve on PP or HDPE is that PETG is currently managed by PE and PP recyclers even if they prefer OPP labels in absolute terms. We propose to delete this requirement.</i></p>	<p><b>PARTIALLY ACCEPTED</b> Considering the information of The Association of Plastic Recycling (<a href="https://plasticsrecycling.org/images/pdf/design-guide/APR_Design_Guidance_Label_Summary_Table.pdf">https://plasticsrecycling.org/images/pdf/design-guide/APR_Design_Guidance_Label_Summary_Table.pdf</a>), the CPET labels are not the best option to obtain good results on the different criteria considered to improve the recycling process. A restriction the use of full sleeves has been included.</p>

<p>Barrier coatings: 3 layers Polyamide is the best possible barrier at the disposal of industrials to make a recyclable PET packaging barrier, the 3 European standards agree on this point. We recommend removing this exclusion. Similarly, the EVOH is the best possible barrier at of industrials to make a recyclable PE or PP barrier packaging, the 3 European standards agree on this point. We recommend removing this exclusion.</p>	<p><b>PARTIALLY ACCEPTED</b> The EVOH material has been permitted with a maximum percentage of 3% by weight. See TR2.0 for further explanation</p>
<p>Moreover, we wish to receive information from the JRC on whether this criterion is applicable to plastic bags or only on plastic bottles.</p>	<p><b>CLARIFIED</b></p>
<p>For each "bottle" mentioned in the following table: Does this criterion apply to all plastic containers or only to bottles? Are pouches concerned by the restriction? We need to have clarifications and examples in the user manual, in particular for pouches.</p>	<p>All plastic packaging is affected by the criterion. The table has been modified in order to clarify the issue.</p>
<p>Shall we check the real number of sold refilling the following year? If yes, can you indicate this precision?</p>	<p><b>CLARIFIED</b> To our knowledge this data is not available. The real number of sold refillings depends on the consumer behaviour and it not easily accessible.</p>
<p>It's important to prohibit small bottles &lt;300ml (used for example in hotels) because it's a huge waste of plastic : a major environmental issue! Moreover, these products can be replaced by dispensers with EU Ecolabel products. If you choose to keep these small packagings, the proportion of cardboard (including these small bottles) should be taken into account in the calculation of W (proportion of secondary). Indeed, the weight of cardboard is not included in the current calculation because we consider the customer of the hotel as the final user and this cardboard is used as transport packaging but it's not only a transport packaging, it's a storage packaging too!</p>	<p><b>PARTIALLY ACCEPTED</b> A restriction has been included for the amenities used in hotels and accommodations: for products sold in a packaging lower than 75ml of capacity, a take back service should exist.</p>
<p>Small packagings are not an ecological option, so they should not be certified.</p>	
<p>Please provide more information if this residual quantity criterium applies when the packaging has a dosing system (pump) that can be removed without specific tool and leftover product could be easily rinsed with water.</p>	<p><b>CLARIFIED</b> Yes, the criterion applies to such products as well.</p>
<p>We are not forced to duplicate other schemes. We can define our own restrictions for the European Ecolabel.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>As mentioned during the meeting and knowing that the residual amount of the product in the container disrupts the recycling, it's essential to reduce the value of R because the value of 10% is too easy to achieve. Values you have already collected confirm this fact. As proposed, we can send you our values, if necessary. Thus, we shall require more than 90% of the product can be easily removed from the container.</p>	<p><b>ACCEPTED</b> Considering the information gathered after the 1AHWG the residual amount of the product in the container has been reduced from 10% to 8%.</p>
<p>We are in favour of this proposal: In order to reduce plastic waste – a major environmental issue – it's essential to encourage applicants to provide refills because there is a huge waste of plastic whereas bottles could be refilled! At least, it must be mandatory for packagings using pumps. Moreover these refills must have an equivalent or higher capacity to the capacity of the bottle for refilling. Indeed, providing refills with a lower capacity is not an ecological option. It's necessary to force applicants to provide these refills, to sell them and to promote their use by consumers thanks to information provided on labels.</p>	<p><b>PARTIALLY ACCEPTED</b> A requirement for those products sold with pump or dispenser has been included in the sub-criterion (a).</p>

<p><i>A principle issue, from the experience of natural-based formulations, whilst emptying and potential refill may be more feasible for certain rinse-off products for leave-on products such as hand creams, emptying the packaging can result in the cutting or destruction of the integrity of the packaging; thereby limiting the ability to refill. Equally, since all cosmetics must be risk assessed as safe by law under the EU cosmetic legislation this also involves the assessment of migration of substances from product to the packaging and vice versa. Hence, for some products refilling may be possible (if in glass - although this will require collection) and plastic can present issues for refill.</i></p>	
<p><i>We support the proposal of the JRC to include a requirement on mandatory provision of refill bottles for some cosmetics. We recommend making it mandatory for packaging sold with a pump. The verification element could be the communication displayed in the product's label. We recommend to also investigate the specificities of products that could be purchased in bulk, and to compare the feasibility, the consumer acceptance and the LCA modelling of refills with bulk and reuse systems.</i></p>	
<p><i>In relation to the sustainable origin of palm oil and palm kernel oil derivatives the proposed criterion allows as proof of compliance the use of the Book and Claim supply chain model. This verification system is much weaker and can be misleading for consumers in relation to identity preserved, segregated and mass balance. Other certification schemes for cosmetics do not use Book and Claim and have set mass balance as the minimum verification scheme. Delete the reference to Book and Claim.</i></p>	<p><b>REJECTED</b> Currently, there are 50% of the licences including ingredients certified with B&amp;C credits. The deletion of this reference will suppose an important impact in the number of products certified. Therefore it is propose to keep the B&amp;C system. However, it is important to remark that the Bokk and Claim system is accepted only for palm oil and palm kernel oil derivatives.</p>
<p><i>It is unclear whether or not RSPO Book and Claim is accepted or not. Only RSPO Mass Balance or higher should be accepted. However, stricter requirements should apply to unmodified palm and palm kernel oil, which should come from organic production. If other certification schemes than RSPO are to be accepted there should be an accompanying practice document stating which they are, at any given time.</i></p>	
<p><i>Mass Balance as a minimum quality is acceptable. Book and claim is not as stringent.</i></p>	
<p><i>We appreciate the proposal of setting requirements for the organic production of plant-based ingredients. However, recommend that the JRC investigates how this can be done without favouring synthetic ingredients. Most important, for consumers it would be relevant to have clear rules for when it is possible to make a claim of organic production, to avoid misleading consumers. The Nordic Swan includes an informative requirement on the origin of ingredients. However, the report states that this option is not feasible for the EU Ecolabel scheme where only prescriptive requirements should be set. It should be further why this is not allowed in the Ecolabel Regulation.</i></p>	<p><b>CLARIFIED</b> Minimal presence of synthetic materials is ensured by criterion 1, 2 and 3.</p>
<p><i>We support the introduction of a minimum requirement of organic plant-based ingredients. We recommend that the JRC investigates how this can be done without leading to the use of more synthetic ingredients. A mandatory content of plant-based ingredients should also be associated to its sustainable sourcing. Furthermore, similar to the Nordic Swan, the EU Ecolabel could introduce a demand that whenever there is a claim of organic production, clear rules are required to avoid misleading consumers. The Nordic Swan includes an informative requirement on the origin of ingredients. However, this option is not feasible for the EU Ecolabel scheme where only prescriptive requirements should be set</i></p>	<p><b>ACCEPTED</b> The goal of this criterion is not to penalize renewable materials, but to ensure that they are sourced according to sustainability principles and have a good environmental profile in line with the goals of EU Ecolabel. The market of organic certified products is showing a significant increase, facilitating the compliance of the</p>

<p>As it is written, it is not clear if the JRC proposal intend to foster plant-based ingredients in general, natural ingredient (as per ISO 16128 standard) or organic ingredients. A definition of a plant-based ingredient must be given to clarify this criterion.</p> <p>Should plant-based ingredients refer to bio-based ingredients, we will not support the JRC proposal to settle a threshold for plant-based content. In fact, even though they are substitutes for fossil raw materials, products made from biomass material do not systematically guarantee a lower environmental impact. A bio-based product can partly limit the consumption of non-renewable resources but in no case guarantees an environmental added value which must be established over the entire life cycle of the product to ensure that it does not present a degraded review or pollution transfers (eg. via a more energy-intensive processing process, or land use change to grow the bio-based materials and associated potential soil pollution, ...).</p> <p>Should this criterion refer to organic ingredients, we will support the JRC proposal, but we would recommend to also consider the sustainability of ingredients used in cosmetic products.</p>	<p>criterion. Organic fragrances will still have to comply with criterion 3.</p>
<p>We're not sure Eu Ecolabel needs to force to use organic ingredients. Moreover, in some cases, organic ingredients can be in contradiction with some EU Ecolabel restriction. (e.g. organic fragrances are essentially essential oil that are H317 that is banned from EU ECOLABEL)</p>	
<p>It is of great importance that this criterion (Certification of plant based ingredient) is formulated in order to ensure that plant based ingredients are produced in a sustainable manner, without creating incentives for using an increased proportion of fossil raw materials.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>We don't agree with the introduction of this criterion (Certification of plant based ingredient). The introduction of this criterion could lead to an increase of the prices for the manufacturing of a cosmetic product.</p>	<p><b>REJECTED</b></p>
<p>Having a certification of ingredients of vegetable origin could lead to a significant increase in the cost of the basic paste. Certified organic soaps represent a very small slice of the market because of their cost</p>	<p>There are many certified products and ingredients under COSMOS Standard, the inclusion of a percentage of ingredients from organic certified sources doesn't seem to be a problem.</p>
<p>Given the relevance of the requirement and in relation to the complexity of meeting and verifying compliance with this criterion (Certification of plant-based ingredients), this criterion should be deleted.</p>	<p>The criterion sets that it should be organic the <b>20% of the ingredients eligible to be organic</b>, not of all ingredients used in the product.</p>
<p>Based on the feedback of French stakeholders, we have the following comments:</p> <ul style="list-style-type: none"> <li>- Fulfilling this criterion is very complex and all French licenced products include derivatives from palm oil and palm kernel oil (but none of them contains palm or palm kernel oil). It is not clear which evidences are required for the assessment and verification of this criterion, and whether the third-party verification should be done annually and for each certified product or not.</li> <li>- The certification schemes used are questionable and have been subject to controversy. More especially, publications have pointed out that palm oil certification does not guarantee the absence of deforestation.</li> <li>- The improved environmental performance of certified palm oil, palm kernel oil and their derivatives has not been scientifically proven. We wish to receive information from the JRC on this topic.</li> </ul> <p>Considering the above comments and the fact that intensive cultivation of palm oil, palm kernel oil and their derivatives has a direct link with environment destruction (including deforestation, habitat destruction and associated biodiversity loss), we believe that the possibility of defining a threshold regarding the percentage of palm oil, palm kernel oil and their derivatives contained in a product should be discussed with stakeholders.</p> <p>The JRC could investigate Ecocert, REDcert and ISCC certification schemes as for the certification of other vegetables oils.</p>	<p><b>REJECTED</b></p> <p>The 2018 RSPO P&amp;C included new requirements to ensure the effective contribution of RSPO to halting deforestation. Other certifications have been considered, nevertheless the equivalence can not be ensured, and the introduction of new schemes have not been considered in the revision.</p> <p>Since palm oil and palm kernel oil derivatives can be present in 93% of EU Ecolabel licences, this suggestion would be difficult to implement. Moreover, these oils would be replaced with other types of vegetable oils for which large established certification schemes do not exist.</p>

<p><i>With the current criterion we have no guarantee that EU Ecolabel certified products contain sustainable derivatives of palm oil (only with « segregated » certification) whereas it's particularly difficult and time-consuming to check different proofs.</i></p> <p><i>Since the low benefit in comparison with the high complexity, we ask for the removal of this requirement. It's necessary to find another scheme to deal with palm oil issue.</i></p>	<p><b>REJECTED</b></p> <p>The RSPO system is the largest one which supports the production of sustainable oil palm product. Equivalent certification schemes are accepted in order to comply with the requirement.</p>
<p><i>If you choose to keep this criterion (Sustainable sourcing of palm oil, palm kernel oil and their derivatives), it's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p>	<p><b>ACCEPTED</b></p> <p>The Assessment and verification text has been modified accordingly.</p>

DRAFT

The RSPO Standard applicable to the cultivation practices (RSPO Principles and Criteria) is a deforestation-free Standard, opposite to the information shown in the slide 163 of the ppt:

The independent Certification Bodies (CBs) accredited to audit against RSPO Standard does not certify forest, but oil palm plantations.

The Standard applicable to the cultivation practices is called Principles and Criteria (P&C). The reviewed version of November 2018 includes the following:

7.7 No new planting on peat, regardless of depth after 15 November 2018 and all peatlands are managed responsibly. Please refer to 7.7.5, 7.7.6 and 7.7.7. for the sustainable practices applicable to plantations planted on peat, as the mentioned drainability assessment.

7.12 Land clearing does not cause deforestation or damage any area required to protect or enhance High Conservation Values (HCVs) or High Carbon Stock (HCS) forest. HCVs and HCS forests in the managed area are identified and protected or enhanced.

7.12.1 (C) Land clearing since November 2005 has not damaged primary forest or any area required to protect or enhance HCVs. Land clearing since 15 November 2018 has not damaged HCVs or HCS forests.

7.12.4 (C) Where HCVs, HCS forests after 15 November 2018, peatland and other conservation areas have been identified, they are protected and/ or enhanced. An integrated management plan to protect and/or enhance HCVs, HCS forests, peatland and other conservation areas is developed, implemented and adapted where necessary, and contains monitoring requirements.

As mentioned in the meeting, there are 6 HCVs areas as you can see here, which include primary and secondary forest. The HCS approach can be found here and it includes the category of regenerating forest too.

The previous version (P&C 2013) also included the following:

5.2. The status of rare, threatened or endangered species and other High Conservation Value habitats, if any, that exist in the plantation or that could be affected by plantation or mill management, shall be identified and operations managed to best ensure that they are maintained and/or enhanced.

7.3. New plantings since November 2005 have not replaced primary forest or any area required to maintain or enhance one or more High Conservation Values (HCVs).

7.8.2 There shall be a plan to minimise net GHG emissions which takes into account avoidance of land areas with high carbon stocks and/or sequestration options.

7.4 Extensive planting on steep terrain, and/or marginal and fragile soils, including peat, is avoided.

Moreover, new oil palm plantings starting January 1, 2010, must be in accordance with the RSPO Procedures for New Plantings (NPP), more info here. This involves:

3.2. The HCV assessment will evaluate the six categories of HCVs, and specify areas required to maintain or enhance the HCVs identified and will include HCV maps and management recommendations. From 1 January 2015, the HCV assessment shall be led by an HCV lead assessor licensed under the HCV Resource Network (HCVRN) Assessor Licensing Scheme (ALS).

3.5. The greenhouse gas (GHG) assessment shall identify and estimate carbon stocks and major potential sources of emissions in the proposed development area (also called the carbon stock assessment).

Therefore, in no plantation certified P&C 2013, with the NPP approved and certified P&C 2018 deforestation is allowed. Neither oil palm developments in peatlands are allowed.

The verification of the RSPO certificate shall be done via the RSPO website, where the RSPO certified actors are updated in real time basis. Checking just the RSPO Certificate provided by the company is risky because the 5-years validity of the RSPO Certificate given after the Initial Audit is subject to undergo an annual audit. It may happen that a company stopped the certification in year 3 but still keep the Certificate in its domain. This verification via RSPO website is to avoid fraudulent use of the RSPO Certificates.

**ACKNOWLEDGED**

**PARTIALLY ACCEPTED**

The RSPO certificate should be verified annually by the CB. The text has been included in the criterion proposal.

<p>to add "...corresponding to that specific derivatives", to avoid double selling.</p>	<p><b>ACCEPTED</b></p>
<p><i>The B&amp;C model is not greenwashing, as other stakeholders titled it during the meeting. The idea behind the B&amp;C model is to link sustainable production of palm oil with the markets when the physical supply chain is not possible, as for logistic reasons. In addition, RSPO members who have purchased RSPO Credits are entitled to claim their support for the production of certified sustainable palm oil; being not allowed messaging anything that can lead consumers to believe that the product contains sustainable oil palm products. Please refer to the MODULE E – BOOK AND CLAIM SPECIFIC RULES on the RSPO Rules on Market Communications &amp; Claims, here. As mentioned during the meeting, and seeing all the rejection that the B&amp;C model seem to create in some stakeholders, I would recommend to promote the use of Independent Smallholder (IS) Credits as a first option in the text. It is a fact that 40% of the oil palm plantations in the world belong to smallholders and that the RSPO credits system allows them to have a livelihood complying with sustainable practices. It ensures that independent smallholders with not possibility of reaching the physical supply chain are linked to international markets and can also have the benefit of cultivating oil palm in a sustainable way. Please you can find more information about this here.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>While we acknowledge the research reports on the topic facilitated by JRC Sevilla, we consider that the statement 'Palm oil is seen as one of the most controversial, because of the issue of deforestation and land use change (direct and indirect) involving loss of natural habitats, associated with their plantations in Southeast Asia and Amazon rainforest' is not 100% correct, as palm oil cultivation is not the agri-commodity/activity driving the most (unfortunate) Amazon deforestation. To quote some of the statements in the research reports facilitated:</i></p> <ul style="list-style-type: none"> <li><i>- Clear sectoral expansion guidelines and ongoing initiatives to demarcate individual rural properties, combined with improved enforcement capacities through the adoption of technologies to monitor deforestation at the plot level, have ensured that expansions over the 2010s in the oil palm sector have taken place predominantly on previously deforested lands. (The state of oil palm development in the Brazilian Amazon. 2015)</i></li> <li><i>- According to a land use change analysis undertaken by Adami et al. (2015), approximately 66% of land deforested during 2008–2012 in Pará was initially converted to pasture and 34% to secondary vegetation. Approximately 0.7% of forestland that was converted to pasture during this period was later converted to annual agriculture, suggesting that the expansion of soy, for example, has not been a recent driver of direct deforestation. Since the secondary vegetation category is not disaggregated into more detailed land use categories, existing data does not provide insights into whether oil palm contributed to deforestation in the state during 2008–2012. (Figure 2. The state of oil palm development in the Brazilian Amazon. 2015)</i></li> </ul>	<p><b>ACCEPTED</b> The sentence has been deleted</p>
<p><i>to add shea (butter) and canola (oil), as these commodities can also bring environmental and social negative impacts in the field.</i></p> <p><i>Regardless of the lack of sustainability schemes, a due diligence shall be done on the major sustainability issues (environmental and social), otherwise you are allowing the use of unsustainable sources in EU-Ecolabel products.</i></p> <p><i>EU organic is not enough at it does not tackle all the environmental and social issues that these commodities may create.</i></p>	<p><b>REJECTED</b> The introduction of other raw materials have not been considered in the process revision, the schemes available to certify these products are not as robust as the RSPO scheme.</p>

<p>We obviously fully support the RSPO emphasis. We take issue with the comment in the summary section; Rationale of proposed assessment and verification, where it states: The assessment and verification of existing Criterion 5 has the support of 60% of the revision questionnaire's respondents, while 24% of them consider it difficult to check the proofs to guarantee the sustainable origin of the raw material, as not all ingredients are RSPO Certified. RSPO Certification is passed "tipping point" in Home and Personal Care and now the norm. There is clearly a majority (60%) in favour, we cannot subscribe to the difficulty the 24% have to check proof of sustainable (RSPO) certification/origin.</p>	<p><b>ACCEPTED</b> The RSPO certification has been maintained as an evidence of the criterion.</p>
<p>We are not in favour of asking for a certain % of organic ingredients. It seems strange to impose additional requirements on plant-based ingredients and not on mineral ingredients</p>	<p><b>REJECTED</b> Considering the number of certified products with COSMOS Standard and the increasing number of products including organic ingredients, it seems easy to meet the criterion.</p>
<p>We were wondering if it would be a good idea to exclude animal products in EU Ecolabel cosmetics. This is something that consumers are worrying about and would be a clear communication message.</p>	<p><b>ACKNOWLEDGED</b> This aspect has not been identified as an environmental hotspot.</p>
<p>Do all schemes for sustainable palm (kernel) oil on the market, including derivatives thereof, meet this criterion on every point?</p>	<p><b>CLARIFIED</b> The specific cases should be studied by the CB, who will be the responsible to evaluate the equivalence between schemes. Nevertheless, the RSPO certification is the most widely used.</p>
<p>It is not always possible to produce derivatives from certified sustainable origin, does sustainable production include organic agriculture? Will there be a positive list of schemes? Mass Balance quality is a reasonable default</p>	<p><b>CLARIFIED</b> RSPO or equivalent is requested in criterion for palm oil and derivatives. Organic agriculture is not considered equivalent to RSPO A positive list (if possible) will be included in the UM. Mass balance is accepted for derivatives.</p>
<p>There is no harmonised criteria concerning the terms natural or organic. <a href="https://ec.europa.eu/docsroom/documents/13179/attachments/1/translations/">https://ec.europa.eu/docsroom/documents/13179/attachments/1/translations/</a> There are no legal provisions under article 20 of the EU cosmetic regulation, nor in regulation 655/2013, nor the non-binding technical document released in 2017, to define when a natural or organic product claim is considered misleading or not. Organic ingredients falling under the scope of the existing EU organic regulation (Regulation (EC) No 834/2007) can increase under Regulation (EU) 2018/848, which enters into force in 2021. However, raw materials outside the scope of food legislation by derived from food/agricultural produce can be used in cosmetics e.g. certain plant extracts. The text therefore permits only physically processed organic grade, cosmetically applicable, substances that are food grade. All certification of organic production is certified by a third-party by law; therefore, limited need to highlight this point provided that a list of accepted schemes or reference (legislation or IFOAM Family of Standards) is given in the text.</p>	<p><b>CLARIFIED</b> Criteria only applies to ingredients falling under the scope of the existing EU organic regulation</p>

<p><i>In respect of the following text:</i>  <i>"To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certifications for the ingredients covered by the scope of the EU Organic Regulation. Certifications accepted shall include those awarded by Competent Bodies appointed through the EU Regulation on organic production 834/2007, as well as IFOAM family of standards, COSMOS, or any equivalent scheme."</i></p> <p><i>suggested rewording for accuracy:</i>  <i>"To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certifications for the ingredients covered within the scope of the EU Organic Regulation. Certification must be carried out by a duly recognized certification body or authority appointed through Regulation (EC) No. 834/2007 or to an equivalent Regulation to that of the EU.</i></p> <p><i>For consideration it may be possible to extend the last line to read:</i>  <i>Regulation (EC) No. 834/2007 or to an equivalent regulation or standard listed in the IFOAM Family of Standards.</i></p> <p><i>However, there may be standards in the IFOAM scheme that are not deemed equivalent, for the EU, with the EU Organic Regulation.</i></p> <p><i>Please note that COSMOS is a private standard for cosmetic application and whilst certifiers like EcoCert are also duly recognised control bodies for products falling under the scope of the EU organic regulation, the COSMOS standard, like the NATRUE standard, includes organic substances that are outside the scope of food legislation, as described above.</i></p>	
<p><i>For accuracy it is officially NATRUE not NaTrue nowadays</i></p>	<p><b>ACCEPTED</b>  This has been changed in TR2.0</p>
<p><i>GMOs not OGMs in English</i></p>	<p><b>ACCEPTED</b>  This has been changed in TR2.0</p>
<p><i>Generally-speaking requirements and promotion of organic grade ingredients is welcomed. Consideration in the word is important to ensure that only those that fall under the scope of legislation can be called organic based upon the current legal framework for cosmetics, and that the EU EcoLabel is not a natural/organic cosmetic product scheme and should not give the impression it is under the current provisions, scope and criteria in the proposed review.</i></p>	<p><b>ACCEPTED</b>  At the moment, the information to consumers about the certified organic ingredients is not considered. There are specific schemes which can be used to certify the organic and natural products.</p>

<p><i>Point of clarification:</i>  the EcoCert scheme for cosmetics does not formally exist since EcoCert is a founder member of COSMOS, and the provisions of this private standard exclude the approved control body to COSMOS from certifying to another standard after the end of the transition period (ending 31/12/2016). This means the criteria, which reflect more what is required from products that raw materials, in the first paragraph is redundant / no longer accurate.  The NATRUE requirements are correct for raw material requirements in order to certify the product as organic (as well as additional formulation requirements in Table 1 of the NATRUE standard).  IFOAM Family of Standards is further explained here: <a href="https://www.ifoam.bio/en/organic-landmarks/ifoam-family-standards">https://www.ifoam.bio/en/organic-landmarks/ifoam-family-standards</a>  COSMOS has existed since 2010 but the standard only entered the end of its transition period for its founders on 31/12/2016, and so became an obligation for its founders to certify to since 01/01/2017. Certified ingredients can also include those that are not under the scope of the EU Organic Regulation (as explained previously).  The suggestion to provide a minimum content of organic certified ingredients when plant based ingredients (covered by the EU organic regulation) is positive, however it would require (a) further discussion concerning the determination of a threshold provisions to define what is acceptable for product - as a % of the total in a finished product - too high a threshold will never be achieved if the only substances are, for example, undervated oils or essential oils and waxes &amp; minimum content may alter depend on the category of finished product and whether it is rinse-off/leave-on; (b) only ingredients within the scope of the EU organic regulation would be eligible to contribute to this percentage; (c) products should only claim that certain ingredients are organic but there should not be the acceptance to refer to the product as organic (consistent with existing legislation for misleading claims even in the absence of harmonised criteria to define what is an organic cosmetic).  The most transparent method is presentation of a % on-pack and/or indicate which ingredients are organic (from organic agriculture) on the labeling provisions.</p>	<p><b>ACKNOWLEDGED</b>  The threshold value has been defined in the 2<sup>nd</sup> revision: 20% w/w of the ingredients within the scope of the EU Organic Regulation should be produced according to organic production.</p>
<p>A good criterion to promote the development and procurement of natural / organic raw materials for cosmetic end use.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>A definition of a plant-based ingredient must be given to clarify this criterion.</p>	<p><b>REJECTED</b>  The criterion applies to those products covered by the scope of the EU organic Regulation (EC 834/2007).</p>
<p>The current system (RSPO) can be kept and some criteria defined by standardisation organisation should be considered.</p>	<p><b>ACKNOWLEDGED</b></p>
<p>This is aligned with the existing legislation but there are different labels with different thresholds. Specific thresholds should be defined.</p>	<p><b>ACCEPTED</b>  The threshold has been defined: 20% w/w of the ingredients used shall be produced according to organic production and certified by a third-party.</p>
<p>Difficult to find some organic derivatives and to trace product. RSPO is at the moment the simplest solution.  A standard is needed for sun care testing.</p>	<p><b>ACCEPTED</b>  <b>REJECTED</b></p>

<p><i>Since a defect in quality of sunscreen products and toothpaste may be associated with health risks, product specific requirements for these product types should be introduced.</i></p>	<p>Safety and efficacies of cosmetic products are regulated by Cosmetics Regulation (EC) No 1223/2009. More information is available on the rationale of the criterion.</p> <p>The applicant shall ensure compliance with the relevant obligations set out in the Cosmetic Regulation No 1223/2009 before EU Ecolabel request, therefore ensuring efficacy, safety, and truthfulness and veracity of the claims.</p> <p>To ensure that all cosmetic products available on the Union market are safe they must undergo an appropriate safety assessment set out in Part B of Annex I of Cosmetics Regulation. Therefore, it is not necessary to include safety assessments in Ecolabel criteria for cosmetic products as it is covered by Cosmetics Regulation.</p>
<p><i>We support the upholding of this criterion for the following reasons: The requirement on the demonstration of the product's capacity to fulfil its primary function and any secondary functions claimed should be kept in order to maintain EU Ecolabel credibility. The test on the ease of application of the product is essential, as it is an important decision criterion for consumers. However, French cosmetic companies have argued that the objective and the relevance of this criterion are not clear, especially on the ease of dose delivery. The latter is highly subjective and is more linked to the equipment used than to the product itself. It is also hardly applicable to refills that can be sold wholesale. Thus, we wish to receive further explanation from the JRC to justify this criterion.</i></p>	<p><b>ACCEPTED</b></p> <p>Criterion on packaging details that "the primary packaging shall be designed to make correct dosage easy" and for liquid hand soaps dose must be lower than 2g. It is proposed to include in the text of thenow criterion 7 a requirement on the ease of application, which was only detailed in the user manual.</p>
<p><i>It's necessary to force applicants to provide a convenient dosage system. In order to control the dosage of certified products and avoid any overdosage, we should require : applicants shall define the correct dosage, then they shall test the product with this dosage, applicants shall provide a convenient dosage system (as for detergents), applicants shall indicate the correct dosage on the label and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money. This requirement should replace the question « How easy is it to apply the desired dosage of the product in comparison with the market-leading product? » because : it's not a scientific and reliable method and it's binding because applicants shall provide a new test when they change their packaging. It's important to keep the requirement concerning the application ease of the cosmetic product because it's a relevant selection criterion for consumers.</i></p>	<p>"For consumer tests, the consumers must be asked about the product's efficiency compared to a market-leading product. The questions to the consumers must cover at least the following aspects:</p> <ol style="list-style-type: none"> <li>1) How well does the product perform in comparison with a market-leading product using the same dosage?</li> <li>2) How easy is it to apply the dosage of the product in comparison with a market-leading product?</li> <li>3) How easy is it to apply and rinse-off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?"</li> </ol>
<p><i>It's essential to require tests to prove that primary function and any secondary functions claimed on the label of certified EU Ecolabel products are fulfilled in order to maintain the credibility of the European Ecolabel.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>As mentioned during the first meeting, there is a mistake: it's 15 participants in the current decision.</i></p>	<p><b>ACCEPTED</b></p> <p>The text has been corrected in TR2.0 and a new value of 20 for the minimum participants has been given.</p>

<p><i>It's important to keep the requirement concerning the application ease of the cosmetic product because it's a relevant selection criterion for consumers.</i></p>	<p><b>ACCEPTED</b> It is proposed to modify this criterion to detail the "ease of application" requirement. More information is available on the rationale of the criterion.</p>
<p><i>Nordic Ecolabel allows for existing products that have been on the market for at least 3 years, the use of sales as documentation of the primary functions. Sales must be increasing or stable to demonstrate their fitness for use. This point could be kept under consideration when revising this requirement in the EU Ecolabel scheme: We are not in favour of this practise.</i></p>	<p><b>ACCEPTED</b> Increase or stabilization of specific product sales can be related with marketing campaigns more than efficacy of primary function.</p>
<p><i>We agree that 80% is a too high level to achieve and it may force industrials to make more than once the consumer tests, which increase a lot the global costs. 70% would be a more reasonable limit. And it is indeed a very subjective criteria depending of the panel, number of testers, market-leading product, perfume, etc. For example the fragrance used can change a lot the results, even for the questions/answers that are not related to the perfume/odor. Same formulas with a different perfume can have very different results.</i></p>	<p><b>REJECTED</b> At least 80% of the consumers must be <b>at least as satisfied</b> with the product as with the market-leading product. It is important to highlight that 80% of consumers do not have to be more satisfied with the test product, but equally satisfied at least. Nordic Swan and Blue Angel have the same threshold of satisfied testers, in order to be aligned with these labelling schemes, 80% is a good level to achieve. If the efficacy feelings of the majority of consumers of a panel test are negatively affected by the parfum, they need to be also considered. Independently of the source of feeling the product needs good efficacy opinions to be sold in the market.</p>
<p><i>This criterion is very difficult to judge. A consumer test gives a very randomly result. We already launched user test on a product vs a reference product. We made the same test in the same condition. We can have between 40% of satisfied surveys to 90% of satisfied surveys. Some points requested on the user manual are very subjective. For example the question "How well does the product perform in comparison with the market-leading product" the consumer takes into account his subjective opinion on the fragrance. The fragrance doesn't have to take into account on efficiency of the product. We know the fitness for use is an important EU Ecolabel criteria, but we need to review all the requests defined on the user manual on this criteria, meantime of the Decision discussion.</i></p>	
<p><i>In respect of claims please refer to the six common criteria outlined in Regulation (EC) No. 655/2013 which supports the implementation of Art.20 of the EU cosmetic regulation. All claims require evidential support as one of these criteria. There is also the a non-binding technical document to support Regulation 655/2013 cf.: <a href="https://ec.europa.eu/docsroom/documents/24847">https://ec.europa.eu/docsroom/documents/24847</a> The Cosmetic Europe document is a reference for users but the link is broken - can only be searched for the title. What is being tested here? "Assessment and verification: The applicant shall document the test protocol that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging." ...given that all claims must be substantiated in order to not be misleading by law. This criterion (6) appears to unnecessarily duplicate existing legislation. For protocols we recommend taking contact with bodies such as stiftung warentest for example.</i></p>	<p><b>PARTIALLY ACCEPTED</b> Laboratory tests performed to comply with Regulations 1223/2009 and 655/2013 can be used to demonstrate the primary or secondary functions of the products.</p>
<p><i>The Responsible Person has to fill a product information file in which functions have to be demonstrated and tests on which the evaluation is based have to be provided.</i></p>	<p><b>ACKNOWLEDGED</b></p>

<p><i>Italy thinks that 10 people are not enough for a user test</i></p>	<p><b>ACCEPTED</b>  There is a mistake in the rationale of the proposed criterion text, 15 people (not 10 as it is mentioned) are the minimum number of participants according to the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products". The text has been corrected in the TR2.0.  The number of satisfied people has been increased to 20.</p>
<p><i>In our opinion, the word "limited" in the sentence "Limited impact on aquatic environment" may be confusing to consumers. It is hard to understand what it says in relation to unlabelled products in the same category.  Since there are a number of strict requirements on hazardous substances, we think that the one of the sentences should contain information about this (although this is subject to the agreed ambition on hazardous substances).  Hence, we suggest two new sentences which we consider more general and more easily understood by the general consumer. The optional label with box shall contain the following information:  Proposal for modification:  Delete: - Limited impact on aquatic environment  - Fulfills strict environmental requirements.  - Fulfills strict requirements regarding hazardous substances  - Limits packaging waste</i></p>	<p><b>REJECTED</b>  The sentences proposed have been aligned with other EU Ecolabel product groups. The information aims to inform about the lower impact of the products certified against the non-certified products.  According to Regulation 655/2013 the claim "fulfills strict requirements regarding hazardous substances" can denigrate or create confusion, implying that non-Ecolabelled products can contain hazardous substances. More information is available in TR2.0.</p>
<p><i>In addition it's necessary to force applicants to provide a convenient dosage system. Moreover it's necessary to add a criterion about information provided on labels which requires :  - information on product's use: dosage which shall be easily achievable with the provided convenient dosage system (applicants shall also indicate on the label how to use it),  - applicants have to prove different claims,  - information on the reuse – requirement connected to packaging criterion, recycling and correct disposal of packaging,  - In order to harmonise with good practises used in detergents products &gt;&gt; A text shall appear on the primary packaging indicating the importance of using the correct dosage and to refill the product in order to minimise energy and water consumption, reduce water pollution and save money.</i></p>	<p><b>REJECTED</b>  The sentences proposed have been aligned with other EU Ecolabel product groups. The information aims to inform about the lower impact of the products certified against the non-certified products.  Convenient dosage system is addressed in other criteria.  Criterion 4 specify: the primary packaging shall be designed to make correct dosage easy. Pump or dispenser for liquid hand soaps does not may provide more than 2g for full press.  In addition, according to Cosmetics Regulation, instructions for use and disposal, and other important indications for human health have to be available.</p>
<p><i>It's important to modify information appearing on the EU Ecolabel to add a sentence concerning conducted tests in order to highlight also the performance of EU Ecolabel certified products.</i></p>	<p><b>ACKNOWLEDGED</b></p>
<p><i>Substitute limited to limits</i></p>	<p><b>REJECTED</b>  The sentence is aligned with other EU Ecolabel product groups (detergents).</p>
<p><i>No further changes needed. It is strongly recommended not to include any reference to health or safety since this approach has the potential to undermine the fact that all cosmetics must be safe by law. Therefore, claims references avoidance of hazardous substances etc. must be avoided.</i></p>	<p><b>ACKNOWLEDGED</b></p>

## ANNEX II

Comments received after the 2<sup>nd</sup> Ad-Hoc Working Group meeting (June 2020). Comments refer to the second version of the revised criteria proposal.

Comments received in AHWG2/written form	JRC Dir. B response
<p><i>We strongly disagree with the inclusion of animal care products.</i></p>	<p><b>Comments partially accepted</b> There are at least 12 products certified under Nordic Swan scheme for this category. It is considered important to give consumers the opportunity to choose a better option for animal care products. Although these products are not covered by the Cosmetics Regulation, this EU Ecolabel sets strict requirements for these products aligned to cosmetic products. In addition, considering the expressed concern on the animal testing, fitness for use criterion has been modified to ensure the absence of animal testing.</p>
<p><i>As mentioned on BATIS, we are not in favour of the inclusion of animal care products because animal care products are not subjected to the same regulation.</i></p>	
<p><i>a stakeholder was reluctant to include these products under the same Commission Decision: "it will raise again the confusion of animal testing in cosmetics and these products will be evaluated with animals". In addition, it was mentioned: "I recommend removing the animal shampoos from the scope. They are not cosmetics and are not subject to the same strict legal requirements as cosmetics."</i></p>	
<p><i>Although it is recognised that EU EcoLabel criteria for animal care products rinsed-off and entering the environment supports a positive action, there is no official definition to describe what an animal care product is. The mixing of cosmetics and non-cosmetic products remains confusing and is avoidable. Hence, only cosmetic products should be covered within the scope of this update.</i></p>	
<p><i>If there is interest in providing criteria for animal care products, then this should be treated separately from this work.</i></p>	
<p><i>We do not see this inclusion together with cosmetic products as necessary. If animal care products are to be treated by the EU EcoLabel they should be treated separately for consistency of topic.</i></p>	
<p><i>We would like to have animal care products excluded from the scope because not really fitting and because will be tested on animals and that would create confusion</i></p>	
<p><i>Other stakeholders welcomed the inclusion of these products (animal products) which are very successful under other schemes.</i></p>	<p><b>Comments partially accepted</b> Fitness for use has been modified accordingly: Ingredients and finished product for animal care products shall not be tested on animals.</p>
<p><i>We support the inclusion of animal care products in the scope and the separation of the repository into 2 appendices seems to be relevant. However, French stakeholders have expressed concerns regarding animal testing for those products. We wish to receive more information on how the JRC will address this issue and more especially how the fitness for use will be verified while ensuring the absence of animal testing. We strongly recommend adding a criterion based on Nature et Progrès referential: "Animal testing is prohibited. This prohibition covers:</i></p> <ul style="list-style-type: none"> <li><i>Ingredients used in cosmetic products;</i></li> <li><i>The development of cosmetic specialities;</i></li> <li><i>Tests on finished product."</i></li> </ul>	

<p><i>Also, it should be ensured that the thresholds are the same between animal products and cosmetics, particularly in terms of biodegradability.</i></p>	
<p><i>Denmark also supports to include Animal care products</i></p>	
<p><i>We strongly disagree with the inclusion of wet wipes.</i></p>	
<p><i>We do not support the inclusion of wet wipes in the scope of the ecolabel as these products are discordant with ecolabel philosophy.</i></p>	
<p><i>in case they are included, stronger criteria have to be defined in order to make the difference with non ecolabel products. the proposed standard for the support and raw materials are not adequate.</i></p>	
<p><i>We are not in favor of including wet wipes into the scope.</i></p>	
<p><i>Several stakeholder were against its inclusion. A stakeholder commented: "How do you consider taking into account the environmental impact of wet wipes in the end-of-life phase in addition to the requirement on consumer recommendations presented in criterion 6b? Lots of wet wipes are found in water treatment plants and in the nature, and they are hard to recycle". It was expressed strongly disagreement on the inclusion of these products under the scope since they are single use products. Other stakeholder mentioned that if these products are included strict requirement on biodegradability of the substrate need to be included.</i></p>	<p><b>Comments accepted</b></p>
<p><i>We are not in favour of the inclusion of wet wipes because we are seriously concerned about the environmental impact the existence of them (waste increase).</i></p>	<p>It has been decided to remove wet wipes from the scope for this revision. Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.</p>
<p><i>This kind of products is not environmentally friendly and we consider this inclusion risks to promote wet wipes. That's why we strongly disagree with this inclusion because we consider that this kind of products is not in the spirit of the EU Ecolabel.</i></p>	<p>Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products. In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>We do not support the inclusion of wet wipes in the scope as this goes against the current trend on waste reduction and single-use products prohibition (SUP – Single-Use Plastic directive, French law on waste reduction and circular economy). Wet wipes have a significant environmental impact during the end of life phase. They represent a large amount of waste that cannot be easily recyclable or biodegradable because of the association of a fibre substrate with chemicals, which is a main issue considering that they can be found in the nature or in flush.</i></p>	
<p><i>Moreover, even if the wet wipes are biodegradable, they should not be thrown in the toilet. This should be mentioned on the packaging, and the biodegradability of the wipes should not be emphasized. This could create confusion for consumers and be counterproductive. Finally, we would like to recall that being biodegradable is not necessarily synonymous with better environmental impact.</i></p>	
<p><i>Considering alternatives available on the market, we do not support the inclusion of wet wipes in the scope.</i></p>	
<p><i>We are against the inclusion of wet wipes as there are alternatives to their use</i></p>	

<p><i>Wet wipes are not included in the Cosmetics Regulation, in addition they are disposable products, so we are not in favour</i></p>	
<p><i>We are against the inclusion of wet wipes</i></p>	
<p><i>We are not in favour wet wipes</i></p>	
<p><i>We are against the inclusion of wet wipes because their inclusion goes against the waste minimization principle</i></p>	
<p><i>in favour of inclusion of most of the new categories, except for wet wipes. The reason behind this decision is that although useful for some occasions, their use should be limited. We are afraid that finding on shelves certified wet wipes could end in some kind of justification for their use.</i></p>	
<p><i>If wet wipes are included, it's important that they should be fragrance free</i></p>	<p><b>Comments rejected</b>  Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.  Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products.  In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>We are in favour of the inclusion of wet wipes because they are very much used, most of all in baby care. And we need to have them fragrance-free</i></p>	
<p><i>We are in favour of inclusion of wet wipes but they should be fragrance-free, and as a minimum the substrate should come from 100% FSC. Moreover there should be a clear indication on the packaging that the wet wipes are not to be flushed.</i></p>	
<p><i>A stakeholder mentioned that biodegradable wipes are increasingly on the market.</i></p>	
<p><i>We are not in favour of the inclusion of tanning creams (too specific) and sun screens (because they contain problematic substances).</i></p>	<p><b>Comments rejected</b>  Sunscreen needs to be used during summer to avoid solar radiation, it is an essential product. It is important to recognise better alternatives through EU Ecolabel. Nordic Swan has 58 certified sunscreen products (+ 10 sunscreens for children).  It is proposed to keep sunscreens under the scope.</p>
<p><i>We are not in favor of the inclusion of sun screen products. They contains a high level of UV filters that are persistent for the environment , and have a very bad ecological profile. Moreover UV filters are more than 20% of the sun screen formula that is really important.</i></p>	
<p><i>UV filters more respectfull of the environment are very few and not as efficient, that is not possible to put consumer security in the background.</i></p>	
<p><i>These product go straight into the marine world so good biodegradability is essential. if ECOLABEL accept the non biodegradable UV filters for sunscreen, it can discredit ECOLABEL in the global</i></p>	
<p><i>We are not in favour of including sun products in the scope of the ecolabel as no filters can be considered as friendly for the environment.</i></p>	
<p><i>In case they are included in the scope of the ecolabel, stronger criteria needs to be applied, and a preference should be made for organic products. The criteria curently defined, and especially the prohibition of CMR substances would exclude the Titanium dioxide and would bann every organic products from the scope of the ecolabel. As the titanium dioxide is classified for an inhalation concerns, we alert on the need to include an exemption for the use of titanium dioxide, at least for sun products.</i></p>	

<p><i>We do not support the inclusion of sunscreen products in the scope. UV filters represent a large part of sunscreen products formula, and they are not biodegradable. Thus, we consider that including those products in the scope could discredit the reputation of the EU Ecolabel.</i></p> <p><i>Moreover, we consider that self-tanning creams should be treated in the same way as sun creams because these products can end up in the sea.</i></p> <p><i>If sunscreen products remain in the scope and given that they are partially discharged into the sea, a criterion on marine toxicity should be added.</i></p>	
<p><i>Denmark supports the suggested scope which includes wet wipes and sunscreen.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>We think it's not relevant to add mouthwash because as you mentioned during the first AHWG their composition is different of products included in the existing scope and their market share is small.</i></p> <p><i>We are not in favour of the inclusion of this kind of products (decorative cosmetics &amp; nail enamel remover), in particular for nail polishes and nail enamel removers, because as you mentioned during the first AHWG, there is a low risk of release into water and we consider that this kind of products is not in the spirit of the EU Ecolabel.</i></p>	<p><b>Comments partially accepted</b></p> <p>At the first AHWG meeting a general agreement was expressed to extend the scope to all cosmetics included in the cosmetics Regulation.</p> <p>There are 3100 ecolabelled products certified under the Nordic Swan ecolabel<sup>1</sup>.</p>
<p><i>We are in favour of this extended scope.</i></p>	
<p><i>We agree to keep in the new scope :</i></p> <ul style="list-style-type: none"> <li>- lotions, creams and oils (including massage products and after-sun creams) ;</li> <li>- cleanser.</li> </ul> <p><i>We agree to keep in the new scope toothpastes</i></p> <p><i>We strongly appreciate the inclusion of deodorants and antiperspirants because as we already mentioned, we generally use deodorants at least once a day and after shower, there should be residues in water and there is a lot of concern about substances included in these products like aluminium salt.</i></p>	<p>The most important group of products certified is skin care (leave on), representing 20% of the total amount of Nordic Swan-certified products (19% of such skin care products are specific for children). Hand soaps (liquid) represent the 19% of the Nordic Swan-certified products, followed by shampoos and shower gels (16% and 10% respectively).</p> <p>Leave-on cosmetic products represent a 33% of total cosmetic products in the Nordic Swan Ecolabel, denoting the importance of including this group of products in the EU Ecolabel.</p>
<p><i>We support the extension of the scope, including the sunscreens, dry shampoos and wet wipes, provided that strong criteria are set.</i></p>	<p>The products with fewest licences are: massage oil, nail polish remover, deodorants, intimate wash, makeup, lubricants, lip care products and solid hand soap, each of these products below 0.5% of total Nordic Swan-certified products.</p>
<p><i>We highly appreciate that the scope has been widened to a full scope of personal care and cosmetics. However, we would suggest not including cosmetics which have ingredients with biocide activity. biocidal products.</i></p> <p><i>Include all categories of cosmetics excluding biocides.</i></p> <p><i>Add:</i></p> <p><i>"Products with ingredients with biocidal or antimicrobial activity are not eligible for EU</i></p>	<p>It is proposed to keep the alignment to Nordic Swan.</p>

<sup>1</sup> List of certified products within the product group of Cosmetic Products in the Nordic Swan ecolabel: <https://www.svanen.se/en/search-for-ecolabelled-products-and-services/?productgroup=090>

<p><i>Ecolabel and are therefore excluded".</i></p> <p><i>All cosmetic products are included in Nordic Swan except biocides.</i></p> <p><i>We favor an exclusion of cosmetics with ingredients that have biocides properties (e.g. antibacterial soaps) as studies show that they have the same efficacy on cleaning the hand (and eliminating the germs) than normal soaps but can contribute for the bacterial resistance.</i></p>	
<p><i>Biocides should only be permitted if they are used to preserve the product or its ingredients</i></p> <p><i>Introduce a new requirement stating this</i></p> <p><i>In general, biocidal substances are associated with higher risks than other chemicals. To minimise this risk, biocidal substances should only be allowed in order to preserve the product, or the ingoing ingredients, during storage and use.</i></p>	<p><b>Comment partially accepted</b></p>
<p><i>Regarding antiperspirants, health professionals and consumers have expressed concerns about them. They contain aluminium salts that are not covered by any regulation even though they are irritant molecules causing inflammation, skin thickening and eventually pore obstruction. In addition, aluminium salts are considered as endocrine disruptors by some researchers. The inclusion of antiperspirants would therefore be inconsistent with criterion 3(b). If antiperspirants are included in the standard, we would recommend adding a criterion specifying that the following information should appear on the packaging: "Do not use after shaving or in case of skin injury". Finally, the extraction of bauxite used to produce aluminium raises societal (child labour, forced labour, exposure to toxic substances) and environmental (deforestation, water and soil pollution) issues that should be considered in this standard.</i></p>	<p><b>Comment partially accepted</b></p> <p>For a deodorant to be awarded, strict requirement on substances will be met including suspected endocrine disruptors, as it is required according to criterion 4b.</p>
<p><i>We raise doubts on the inclusion of nail polish and its remover.</i></p>	<p><b>Comment rejected</b></p>
<p><i>Nail polish, nail enamel removers and hair coloring are not essentials and may contain controversial substances and we would recommend excluding them from the scope. □</i></p>	<p>These products are not essential but its use is very much extended. These products present licences under the Nordic Swan. It is important to give consumers the option to select better alternatives for these type of products.</p>
<p><i>Toothpaste can be liquid or solid. Shouldn't the limits be different as in solid and liquid soap?</i></p>	<p>There is no available data to allow us differentiate among solid and liquid toothpaste.</p>
<p><i>Shower preparations: could you clarify where the "2 in 1" fits between the shampoo liquid and the shower prepartaion? for instance a body soap and shampoo. Criteria 2b have different thresholds depending if it is a shampoo or a shower preparation. which one to use ?</i></p>	<p>If a product present more than one function, the stricter criteria shall always applies as specified in the note included in the general assessment and verification.</p>
<p><i>Suggest to replace " oral care perfume " by " mouth spray "</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>To massage the skin: Recommendation: reference to the borderline manual when it comes to amssage products since there is a specific entry in 3.3.32 of VERSION 5.1 (FEBRUARY 2020) found here: <a href="https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en">https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en</a></i></p>	<p><b>Comment accepted</b></p> <p>Reference to borderline manual will be included in the User Manual.</p>

There are 2 different thresholds for impurities : > = 1000 ppm in the raw materials (point 3) and > = 100 ppm (or 10 ppm) in the final product (point 4). What threshold shall be considered ?

Denmark supports the suggested definitions for substances and impurities, which is in line with the Nordic Swan Ecolabel.

The definition for ingoing substances should be better defined. We propose to adapt the definition which is already present in the Ecolabel Decision on detergent products. Our proposal is the following:

Ingoing substances means all substances intentionally added in the cosmetic product, including additives (e.g. preservatives and stabilisers) and impurities from raw materials in the final product formulation. Ingoing substances shall be indicated at or above the concentration of respectively 0.0100% (w/w) for final rinse-off product formulations and 0.0010% (w/w) for final leave-on cosmetic formulations.

The definition for impurities should be better defined. We propose to adapt the definition which is already present in the Ecolabel Decision on detergent products.

Impurities means residuals, pollutants, contaminants, by-products from production, including production of raw materials, that remains in the final product formulation. They have not been intentionally added to the formulation and may have an impact on its health and environmental safety.

Please also keep in mind that your definition concerning impurities (page 7 of Annex I: 'impurities' means residuals, pollutants, contaminants, by products, etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the final product in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the leave on product) does not align with Article 17 of the CR which mentions only "impurities of natural or synthetic ingredients" without specifying the threshold, while the focus is on the definition of permitted traces: The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.

The use of the word 'impurities' could be linked to how this is used in the EU Cosmetic Regulation cf.: Art.17

"The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3."

Possible rephrasing suggestion:

'Impurities' means the non-intended presence of residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials that remain in the raw

#### Comments acknowledged

Considering the general alignment on the scope and criteria with Nordic Swan, it is considered important to keep the definition of ingoing substances and impurities for the EU Ecolabel for cosmetics in line with Nordic Swan.

Minor modification has been included: removal of the example "in-situ generated preservatives" under "Substances known to be released from ingoing substances". It is not a defined term in the EU Cosmetic Regulation and preservatives per definition are ingoing substances.

<p>material and/or in the in the final product, which is technically unavoidable in good manufacturing practice, in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the leave on product.</p> <p>Does this cover migration from packaging or just the bulk cosmetic product as a composite of its raw materials? Assumed so since the broader term on Page 10 indicates 'contaminants'.</p>	
<p>e.g. formaldehyde, arylamine, in situ-generated preservatives The license holders do not know from which substances aryl amines come from. You should either name azodyes in the definition or add them to the "forbidden list" like the formaldehyde releasing preservatives. If so done, you need to copy the requirement made for azodyes in the criteria document from tissue and graphic paper, as well, as not all azodyes are problematic and some are approved to be used in packaging intended for food.</p> <p>Same remark about in situ-generated preservatives. Either forbid them because they usually generate chlorine, bromine and peroxides or take them away from the definition if yo don't see them as relevant in cosmetic products</p>	
<p>Ingoing substances already mentioned in the EU Cosmetic Regulation cf. Article 19 (1) (g) as are impurities so it should be made clear that impurities are treated as substances like ingredients even if they are not listed on-pack of course.</p> <p>Shorten to:</p> <p>'Ingoing substances/ means all substances in the cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances. In the context of this Regulation, impurities in the raw materials <math>\geq 1000</math> ppm (<math>\geq 0.1000</math> w-% <math>\geq 1000</math> mg/kg) are always regarded as ingoing substances, regardless of the concentration in the final product.</p>	
<p>in-situ generated preservatives does not appear to be a defined term since preservatives (cf. Annex V of the EU Cosmetic Regulation) are intentionally added substances and not, therefore, generated in-situ.</p> <p>If this refers to substances that have antimicrobial function then it a rephrasing is needed or a deletion of this example i.e. in-situ generated preservatives.</p>	
<p>"The limit on 0,1% impurities seem quite high. Can we lower this?".</p>	
<p>excluding the water content of the ingredients W e strongly appreciate this clarification</p>	<p><b>Comment acknowledged</b></p>
<p>How shall we deal with products marketed as "family products" ? Can you confirm they are considered as children's products too ?</p>	<p>The definition of children product has been modified to reflect that family product should also be considered as children product for the purpose of this EU Ecolabel.</p>
<p>No definition at point 3 is present.</p>	<p><b>Clarified</b></p>

	This was a formatting mistake and has been corrected.
<i>Ingredient is not a term in the EU Cosmetic Regulation so propose to delete or refer to substance, which is described earlier in this document and EU legislation.</i>	<b>Comment partially accepted</b> Ingredient term is commonly used across all EU Ecolabel products and other schemes. However, in the context of cosmetics the wording has been revised to refer to substances as far as possible.
<i>We have no fundamental objections to include dry shampoos but thresholds shall be achievable for this kind of shampoos.</i>	<b>Comment partially accepted</b> No available data to differentiate thresholds for dry shampoos. It is suggested that dry shampoos must comply with threshold for general category of shampoos.
<i>Dry shampoo is a product that is growing on the market and we can't see why it should be left out. There are requirements in the criteria proposal that can be applied on them. The questions is though, is it a rinse of or leave on product.</i>	
<i>Dry shampoos should be included only for animal products where they are more used</i>	
<i>On microplastics I agree with the exception from the scope of materials containing microplastics.</i>	<b>Comment acknowledged</b>
<p>1) <i>We note that the definition used in the shared document to describe the cosmetic products is different from the one in the Cosmetics Regulation (CR) and we have commented on this in past.</i></p> <p><i>More specifically, we consider that the wording is not precise as regards cosmetic products placed in contact with teeth and mucous membranes of the oral cavity. Note: Teeth and mucous membranes are not considered external parts of the human body.</i></p> <p><i>COM Decision establishing the EU Ecolabel Article 1 (Draft Act): The product group 'Cosmetic products' shall comprise any substance or mixture intended to be placed in contact with the external parts of the human body and falling under the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council, which is marketed and designed to be used to fulfil one or more of the following functions:</i> (...) <i>- intended to be placed in contact with the epidermis, teeth and mucous membranes of the oral cavity, and/or the hair system with a view exclusively or mainly to cleaning them</i></p> <p><i>For comparison under CR, Article 2(1) (a), a cosmetic product means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.</i></p> <p><i>We would propose to align the definition to the Cosmetics Regulation definition to have the same definitions for the same terms, which is preferable as regards harmonisation of approaches, but also legal drafting. In particular now when leave-on products are included in the Ecolabel scheme, so the Ecolabel covers all cosmetic products, we do not see a compelling reason to deviate from the definition of the cosmetic products from the CR. Moreover, once you have the aligned definition, it is easier to apply our Borderline Products</i></p>	<b>Comment partially accepted</b> Considering the extension to all cosmetics included under the Cosmetics Regulation it makes sense to align the definition to the mentioned Regulation. Text has been revised accordingly.

<p>Manual (a result of work of a sub-group to our Working Group on Cosmetic Products, comprising member states and the industry) and other guidance documents, see below:  <a href="#">Borderline products manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a))</a> (February 2020, version 5.1) (1 MB)  <a href="#">Guidance document on the relationship between the General Product Safety Directive (GPSD) and certain sector directives with provisions on product safety</a> (500 kB)  <a href="#">Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products</a> (450 kB)  <a href="#">Guidance document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83</a> (66 kB)  There would be no need to regulate separately in your draft entries which we have included in the Borderline Manuals and those which are explained in other guidance documents (you may wish to mention these documents in your draft, however please note they have no binding force). Moreover, please note that our document is much more extensive as it covers more examples than few entries you have included in your draft and it is regularly updated.</p>	
<p>Article 1 of the Draft Act: "Anti-dandruff shampoos are allowed" – this sentence is unclear. Does it mean that they are covered by your legislation? See our remarks above, the anti-dandruff shampoo is a borderline product (cosmetic/medicinal product), so once the definitions of the cosmetic product are aligned, no need to include it separately in your draft . Please note that in some circumstances anti-dandruff shampoos may be medicinal products, so please consider whether it is your intention to cover medicinal products under your scheme/ consult relevant services of DG SANTE.</p>	
<p>Article 1 of the Draft Act: Massage products are borderline products and only some qualify as cosmetics . Once a definition from the CR is applied, entry 3.3.32 of the Borderline Manual could be applicable (no need to mention it as a separate entry in your draft).</p> <p>3.3.32. Massage products  217. Question: Are massagic products cosmetic products?  218. Answer: The exclusive or main purpose, of a cosmetic product is defined by the Cosmetics Regulation as "cleaning", "perfuming", "changing the appearance", "protecting", "keeping in good condition", or "correcting body odours".  219. The assessment of the product should be made on a case-by-case basis, taking into account all characteristics of the product. 220. A product, for example an oil, which is only aimed to help the act of massage may not fall within the scope of application of the Cosmetics Regulation.  221. However, a product, for example an oil, with an exclusive or main cosmetic purpose, such as protecting the skin, moisturizing, nourishing or perfuming it, which might be used for a massage falls within the scope of application of the Cosmetics Regulation. The overall presentation of the product, product claims and ingredients will provide a useful indication over its intended main purpose.</p>	<p><b>Comment accepted</b>  Borderline manual reference has been included in the TR and will be included in the User Manual</p>
<p>COM Decision establishing the EU Ecolabel (Draft Act):  - Art. 1: straighten it  o (soaps (liquid and solid), shampoos (liquid, solid and dry), shower preparations,</p>	<p><b>Comment accepted</b>  Clerical mistakes have been corrected in the ACT.</p>

<p><i>feminine hygiene cosmetic products, toothpastes (liquid and solid) and mouthwashes);</i>  <i>o intended to take care of the epidermis or to massage the skin (skin care products),;</i>  <i>o intended to remove polish from the nails (nail enamel remover).</i>  - <i>Art. 8(2): submitted on or within two months from the date of adoption of this Decision – rather submitted on the date of adoption of this Decision or up to two months thereafter</i>  - <i>rinse-off cosmetics, leave-on cosmetics – throughout the Decision used with or without a hyphen)</i></p> <p><i>Draft Annex I:</i>  - <i>In particular, the criteria aim to promote products that are have limited impacts</i>  - <i>set requirements to ensures</i>  - <i>and promotes plastics recyclability and the minimisation of use of packaging material and plastics recyclability;</i>  - <i>sSet requirement that guarantees that the substrate (wipe) complies with EU ecolabel requirements and informs consumers on the correct disposal of the product;</i>  - <i>guarantees that the product</i></p>	
<p><i>Article 1 of the Draft Act: Wet wipes are not cosmetic products (only the substance that they may release may be a cosmetic product). The issue of wipes is explained in the Borderline Manual (no need for a separate entry in your draft once the definition from the CR is applied):</i></p> <p><i>"1.6. Wipes</i>  30. <i>Question: Is a wipe which releases a substance or a mixture a cosmetic product?</i>  31. <i>Answer: A wipe itself is neither a substance nor a mixture. However, a wipe may be the "vehicle" to deliver a substance or mixture to the human skin. This substance or mixture, if it is intended to be placed in contact with the various external parts of the human body, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours falls within the scope of application of the Cosmetics Regulation."</i></p>	<p><b>Comment acknowledged</b>  In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>Where a cosmetic product is marketed for different uses, the category for which stricter criteria applies shall be assigned to the product.</i>  <i>License holders inform us it is not possible. If the product is intended for different functions (for example shampoo and shower), the highest threshold (less restrictive) shall be considered (for example 25mg/g AC for aNBO and anNBO for a product which claims a shampoo function and a shower function).</i></p> <p><i>Note: Label and/or instructions information accompanying the product shall be used to categorize the product. Where a cosmetic product is marketed for different uses, the category for which stricter criteria applies shall be assigned to the product.</i></p> <p><i>Unclear if this is in reference to cosmetic products or non-cosmetics.</i></p> <p><i>Please see suggestion based upon the understanding that this section refers to cosmetics only.</i></p>	<p><b>Comment accepted</b>  The wording of the note has been slightly modified according to the suggestion: <i>Label and/or instructions information accompanying the product shall be used to categorize the cosmetic product. Where a cosmetic product is marketed for different cosmetic uses, the cosmetic product category for which stricter criteria applies shall be assigned to the product.</i></p>

<p><i>Note: Label and/or instructions information accompanying the product shall be used to categorize the cosmetic product. Where a cosmetic product is marketed for different cosmetic uses, the cosmetic product category for which stricter criteria applies shall be assigned to the product.</i></p>	
<p><i>If Criterion 5a for fragrances is not applicable (N/A), criteria 5(b) rinse-off and 5(b) leave on should be N/A as well.</i></p>	<p><b>Comment rejected</b> There was a mistake in the table, which has now been corrected. Criterion 5 is applied to all substances</p>
<p><i>There should be a limit, as in 3 a(i) (rinse-off)</i></p> <p><i>Some unavoidable impurities, traces, by-products in raw materials and &gt;1000ppm (thus, considered as ingoing substances under this new criteria) are classified.</i></p> <p><i>We suggest to use the same limit as criterion 3 a(i) rinse-off: <math>\geq 0,010</math></i></p>	
<p><i>There should be a limit, as in 3 a(i) (leave-on)</i></p> <p><i>Some unavoidable impurities, traces, by-products in raw materials and &gt;1000ppm (thus, considered as ingoing substances under this new criteria) are classified.</i></p> <p><i>We suggest to use the same limit as criterion 3 a(i) leave-on: <math>\geq 0,001</math></i></p>	<p><b>Comments rejected</b> The limit in this case in the analytical detection limit; no detectable presence of these substance should be found</p>
<p><i>Some raw materials contain those substances as antioxidants, impurities &gt;1000ppm and are then considered as ingoing substances... We should allow those to a maximum limit of <math>\geq 0,010</math>, as in criteria above</i></p>	
<p><i>'no limit' means: regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection).</i></p> <p><i>In the detergents we had some difficulties with this strict no limit definition because it turned up that some impurities were inevitable in the production process of some ingredients. So an amendment was needed. I would like to avoid this by using a similar same definition as in the detergent criteria: "regardless of the concentration (analytical limit of detection) for all ingoing substances with the exception of by-products and impurities from raw materials, which can be present up to a concentration of 0,0010 % by weight in the final formulation</i></p>	
<p><i>In regard to 3a we suggest to change the limit in table 2 into "No limit". We do not see the need to differentiate the limit for the CLP limitations in comparison to the rest of criteria 3. This causes confusion especially to substances which normally is added to the products in lower concentration than 0,001% - like fragrance and preservatives. This led to the misleading idea that these substances are regulated in 3a. The needed information to evaluate based on a limit of "no limit" is present since this data is used in criterion 2 (CDV calculation). A "no limit" will bring more transparency into the criteria document. The discussion on how fragrance and preservatives, and other ingredients, shall be regulated shall be linked to the other criteria.</i></p>	<p><b>Comments partially accepted</b> We have modified the wording. 'No limit' has been changed for 'regardless of the concentration'. Impurities shall comply with this requirement. No detectable presence should be found</p>
<p><i>The table can be misinterpreted "no limit" - does it mean no requirements, or there is no threshold for when the requirements apply.</i></p>	

<p>Add « requirements apply” to the definition provided for no limit:</p> <p>« 'no limit' means: Requirements apply regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection).</p>	
<p>The sentence "Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture" indicates that assessing the SDS for the mixture is sufficient, but it may not be the case, if the substance is present below the concentration where It has to be stated in the SDS of the mixture.</p> <p>Add</p> <p>"Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture. Notice that a written confirmation from the applicant that the criteria is fulfilled is also needed for the assessment"</p> <p>(Criterion 3 restricts the use of substances, e.g due to certain CLP classifications. Hence, the assessment and verification must be done on substance level (and not on mixtures).)</p>	
<p>We welcome the revised draft and thank the JRC for the further work carried to update the report. We acknowledge that important input from NGOs has been considered. We strongly recommend that these achievements are retained, such as:</p> <p>The definition of ingoing substances is now much more comprehensive and protective for consumers and the environment. It includes also additives used in the raw materials (e.g. preservatives and stabilisers) and substances that can be released from ingoing substances (e.g. formaldehyde).</p> <p>New knowledge from SCCS opinions should be taken into consideration, so that the approval of products is up to date with new assessments.</p> <p>The following problematic groups of substances are fully excluded in line with our demands:</p> <p>SVHC and CMRs at any concentration (i.e. previous tolerance thresholds are now removed).</p> <p>All nanomaterials unless an EU regulatory authority has evaluated the use of the nanomaterial and found that is safe from health and environmental perspective (in line with the approach followed in other Ecolabels and the Organic Regulation). As far as I know, Bra Miljöval is the only ecolabel that takes both health and environment into consideration, so suggest to delete that sentence and just express that we agree to the suggested criteria</p> <p>Perfluorinated and polyfluorinated substances Isothiazolinones Comment acknowledged</p> <p>Comments addressed in the relevant criteria section.</p> <p>We wish to emphasise the following positions which are further described in the document:</p> <p>We do not support the inclusion of the following products in the scope of the EU Ecolabel for cosmetic products: sunscreen products, self-tanning creams, nail polish, nail enamel removers, hair coloring, and antiperspirants.</p> <p>We strongly recommend reviewing the calculation methodology of the CDV;</p>	<p><b>Comment accepted</b> The suggested text has been included.</p>

We recommend that the JRC defines an exhaustive list of endocrine disruptors to be excluded, as we think it is crucial for the EU Ecolabel credibility to ban these substances from the labelled products;  
We recommend implementing a maximum threshold regarding the percentage of palm oil, palm kernel oil and their derivatives contained in a product. Comment acknowledged  
Comments addressed in the relevant criteria section.  
We would like to emphasise that the transition period must last at least 18 months.  
The user manual shall be available at the same time as the decision ! Comment Accepted  
It's really essential that the essential documents (user manual, performance test protocols, declarations to be fill, calculation sheets) are available meantime of the application of the new decision.  
During the last updates (rinse off cosmetics, detergents) user manual and some of performance test protocols were only available several months after the application of the new decision. This situation makes stakeholders, R&D departments and competent bodies in strong difficulties: when all documents were finally available, we hadn't enough time to evolve the products, submit ECOLABEL renewals, and CB to certify product before the cut-off date of the old decision.  
That situation was really damaging for companies that promote ECOLABEL trough their brand, the consumer didn't understand why a product that had ECOLABEL didn't have it anymore for administrative reason. They believed that the product is not respecting environment anymore that is damaging for companies but also for ECOLABEL itself.  
It's really important if all essential document are not available to postpone the application of the new decision  
We are in favour of representing the 10-20% and if northern and southern European markets are different, we should meet somewhere in the middle, keeping in mind a lower ambition level would mean a loss of reputation for the EU Ecolabel Comment accepted  
The thresholds have been revised  
We would welcome an alignment with the strictness of the criteria of Nordic Swan  
We would welcome an alignment with Nordic Swan

We should harmonize the requirements (strictness level) with the Nordiic Ecolabel. Nordic Ecolabel allows moderate use of fragrances. Comments partially accepted  
Given the overall tendency towards stricter thresholds that emerged from the 2nd Ad-Hoc Working Group meeting and from the EU Ecolabelling Board meeting, and keeping in mind the upcoming revision of the Nordic Swan ecolabel criteria, CDV thresholds were decreased for liquid soaps and shower preparations (10 000 l/g AC). The threshold for shampoos was maintained at 11 000 l/g AC.

As shared in previous comments on the first technical report, the data collected from French industrials support the decision of the JRC to lower CDV thresholds for shampoo, shower preparations and soaps (liquid form) to 11 000 l/g AC. Indeed, the following data has been collected:

Average CDV for liquid soaps: 5558 l/g AC  
Average CDV for shampoos: 10409 l/g AC

*Average CDV for shower preparations: 9234 l/g AC*

*However, we think that the JRC could lower even more liquid soaps and shower preparations' thresholds by dividing the shampoo, shower preparations and soaps category into three different categories and defining more accurate thresholds.*

*OK with the new threshold because our average for :*

*- liquid soaps : it is 7.785*

*- shampoos it is 10.410*

*- shower preparations : is 9.230*

*However, for liquid soaps, you could reduce again the threshold.*

*As mentioned during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel.*

*We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market.*

*Stricter limits for CDV and Biodegradability reflect better EU policy priorities for a non-toxic environment.*

*Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.*

*The CDV limits should be further lowered. The reasoning behind setting the limits, i.e to include as many products as possible that are already labelled is strange. The idea behind a revision of ecolabel criteria is to give incentives for further improvements with regard to the environment.*

*Based on the data in the Technical report, we suggest the following adjustments:*

*Liquid soaps: 8000*

*Shampoos: 10.000*

*Shower preparations: 10.000*

*We agree in not further reducing CDV limits Comments partially accepted*

*Nordic Swan holds 15 licences for solid soaps with a CDV value below 2000 l/g AC. This shows that the limit is attainable. Therefore, the limit is proposed to be maintained at 2 200 l/g AC.*

*2200*

*It's a positive first step to raise this threshold (2000 in the first draft) but maybe it's not enough. Indeed several applicants and license holders told us that the former threshold (3.300) was already unattainable, so we are surprised of this proposal.*

*How many solid soaps are certified according Nordic Swan with this strict threshold (2.200) ? What percentage of certified NS cosmetics does it represent ?*

*It's important to have this information in order to determine if these requirements are attainable.*

*Indeed, you considered to promote solid soaps during the first meeting but the threshold for this kind of products seems to be too restrictive.*

*Denmark can support the suggested CDV values, except for Solid soap. For solid soap we suggest to follow the Nordic Swan Ecolabel and set the limit at 2000. A present the Nordic Swan have certified 15 different products which are certified. The argument for setting a higher limit was 2 EU Ecolabeled products would not comply. We think the number of products Swan certified shows the limit at 2000 is feasible.*

*Having this prerequisite that the 80th percentile should fulfill the new requirement is a bit too shallow, especially if it does not take into account the size of the license (turnover, number of products...). EU Ecolabel should have ambitious requirements and should not make them too easy to fulfill. So we think that 2200 is too relaxed limit*

*The current CDV calculation methodology encourages to add substances in order to decrease the CDV. this is not in line with the ecolabel philosophy.*

*Other methods could be investigated. For a reference dosage, reference dosage defined by the SCCS for the cosmetic safety evaluation could be determine as a reference, or a dosage per liter or per gram could be considered. Comments rejected*

*While the setting of a CDV calculation method based on a reference dosage was studied, the lack of data that would imply moving away from the method shared with Nordic Swan makes it impossible to set thresholds based on reference dosage. Please see the TR3.0 for details.*

*Most of stakeholders disagreed with the CDV calculation used as a method to evaluate the toxicity to aquatic organisms. It was questioned that "the more you add ingredients, the lower will be the CDV, in contradiction with the aim of the criteria. It's very important to have the same calculation as the detergent products to have a good impact of CDV limits. COLIPA reference dosage quantity exists".*

*As shared in previous comments on the first technical report, we strongly recommend reviewing the calculation methodology of the CDV. With the current calculation methodology, the CDV of each substance is linked to the share of other substances. Therefore, industrials are incentivized to add substances in the product formulation in order to decrease the CDV, which is the antithesis of ecological practice and therefore goes against the fundamental principles of the European Ecolabel. We agree with the JRC on the complexity and the cost associated with the use of the USEtox method. However, we believe that it is possible to determine reference dosage for cosmetic products in order to calculate the CDV. Indeed, the SCCS standard used in toxicology provides reference dosage for each product category. Another alternative is to use the litre or gram of product as a reference dose, as it is done in the EU Ecolabel standard for detergents to calculate the CDV. We thus strongly advise to use a calculation method similar to the one used for detergents and express the toxicity per gram or litre of product instead of litre of active content.*

*Stakeholders were generally in favour of setting a reference dosage and align the criterion to the structure used in EU Ecolabel criteria for detergents, as exemplified by the following comment:*

*"In detergents we have also ready-to-use (RTU) products so without determined dose but in the RTU detergents decision, their thresholds are however defined per liter of product. Indeed, the reference dosage for RTU products is defined as "1 litre of RTU products". We can use the same definition of reference dosage for cosmetics products. We reiterate our request to change the current calculation to delete the fact CDV is based on the active content because: 1) it is more complicated to deal with CDV depending on CA and 2) it is not environmentally friendly to add substances to reduce the ratio of CDV/CA. This practise goes against principles of the European Ecolabel."*

*It is essential to change the definition of "weight".*

*Because :*

1) it is more complicated to deal with CDV depending on CA and  
2) it is not environmentally friendly to add substances to reduce the ratio of CDV/CA. This practise goes against principles of the European Ecolabel.

We propose to define thresholds as in detergents products (in l/g).  
We don't agree with your explanation because in detergents we have also ready-to-use (RTU) products so without determined dose but in the RTU detergents decision, their thresholds are however defined per litre of product.  
Indeed, the reference dosage for RTU products is defined as "1 litre of RTU products".  
We can use the same definition of reference dosage for cosmetics products.  
We reiterate our request to change the current calculation to delete the fact CDV is based on the active content.  
If our proposal is accepted, it will be necessary to review thresholds but we will send our values with the methodology used in detergents in the coming weeks (by email).  
It's really important to change the CDV calculation method by aligning to detergent calculation by removing the AC.  
We have COLIPA dosing in all the cosmetics category to have average dosage to put it on a base of the calculation.  
If you disagree to use COLIPA dosage, you can use the same method as RTU HSC cleaners and use "for 1L of product"  
That will permit to have a real impact on the ingoing substances.  
With the actual calculation, if you are above the limit, you only have to put more ingoing substance to automatically decrease the CDV.  
Usetox seemed not to have the support of the participants, as exemplified by the following comment:  
"We disagree on using USEtox as we are pilots cover around 2500 to 3000 substances for aquatic ecotoxicity and about 1000 substances for human toxicity . This has been elevated to around 3100 chemicals in the actual downloadable version of the mode . In February 2020, data for freshwater ecotoxicity of additional 4064 substances have been published. This is still less compared to about 100 000 single chemicals to play a major industrial role.

- (Eco)-toxicity is frequently excluded from LCA studies based on the argument that with high uncertainty factors in the range of 102 to 105 it is still too uncertain (or even immature) and deemed not useful (at first sight) to proceed with the comparative analyses, as the output is considered not to provide information in a meaningful way (from 9).
- Some dangerous properties, at least PBT and vPvB , mutagenic, reprotoxic and endocrine disrupting chemicals seem not adequately captured." Comment accepted

USEtox is not proposed to be used as an indicator of the aquatic toxicity of the product.  
One stakeholder asked on the rationale behind not setting CDV limits on leave on products.  
Comment clarified  
The main reason for not setting CDV limits on leave-on products is the absence of data to back up the limits with.  
One stakeholder suggested considering toothpaste as leave on products (in line with Nordic Swan and due to the lack of data). Comment clarified  
The fact that toothpaste is considered as a leave-on product in Nordic Swan implies that toothpastes have to fulfil the biodegradability criteria. In the TR3.0 criteria, all products have to fulfil the biodegradability criteria, including toothpaste. Therefore, EU Ecolabel and Nordic Swan are already aligned from this point of view.

*we think it is important to calculate criterion 1 also for sun screen as well as the release in water is part of the use itself (in fact it is always recommended to put it on again in the course of the day)* Comment rejected

*While we agree on the importance of setting CDV limits for sunscreens, the JRC does not have access to the formulation of such products (for which licences do not exist yet). Other ecolabelling schemes do not set CDV limits on sunscreens, therefore it is impossible to set a robust and attainable criterion. The low aquatic toxicity of the product would still be ensured by criterion 3 a (iii)*

*For leave-on cosmetics, the main release of the fragrance component will be evaporation from the skin into the air i.e. at the end of the day there will be no/negligible amounts remaining on the skin for subsequent wash off. Thus if an EU Ecolabel is introduced for such product groups, criteria related to the aquatic environment are not necessarily relevant for the fragrance substance. This would include toxicity to aquatic organisms (CDV), biodegradability of organic ingoing substances and environmental hazard labels. This should be considered appropriately in the development of such an Ecolabel.*

*The percentage of the fragrance in some of the proposed product groups (e.g. 5-10% in deodorants and antiperspirants;) is significantly higher than the level used in wash off cosmetics (maximum 1.5%). If an Ecolabel is developed for these product groups, it is likely to have a significant impact for the fragrance industry in terms of creative constraints for the perfume part and our support to Consumer Goods Companies (CGC) in ecolabel product applications.* Comment clarified

*CDV limits are not proposed to be set for leave-on cosmetics, therefore, also not for deodorants and transpirants. These products have to comply with the new criterion 3 on the aquatic toxicity and biodegradability of leave on products*

*This is a complex criterion because the CDV limit applies to the final cosmetic product and is the sum of all in-going substances. Fragrance is one of these in-going substances. Typically the perfume default values in the DID-List Part A (DF = 0.5, TF = 0.002) are used. Sometimes these do not allow the final product to pass the CDV criterion. In such cases, the Ecolabel applicant will request an actual DF and TF for the perfume, which requires assessment of the perfume at the ingredient level (i.e. calculations based on composition and ingredient data). This is accepted by Ecolabel Competent bodies. However, the fragrance supplier typically receives the request for this information at the final stages of product development i.e. after the fragrance has already been created, selected and undergone performance testing. If additional constraints on the DF and TF of the perfume are required in order for the product to meet the CDV limit, it would be preferable to have this information up front. This may be difficult for the CGCs to do because of the complex nature of the CDV calculation. However, it is impossible for the fragrance supplier to handle in isolation because the CDV limit for the product depends not only on the dosage of the fragrance but also the contribution from the other ingoing substances in the product.*

*Comment acknowledged*

*New CDV limits took into account values from existing licences, as well as the limits set by Nordic Swan. However, the aim of the EU Ecolabel is to create improved criteria in order to provide better solutions from an environmental performance point of view.*

*What is considered as the final product ? Is there a minimum concentration to consider a substance as a "intentionally added substance" or not ?*

*How shall we deal with a mixture with a chemical substance diluted in a solvent ? Shall we*

<p>report in the calculation sheet the part of solvent (except if the solvent is water)?  If not, it is a problem because any solvent (except water) has an impact on the user and/or the environment. Comment clarified  The final product is considered as the ingredient formulation ready to be placed on the market.  Please note that the wording has changed and in the TR3.0 reference is made to "ingoing substances" and not to "intentionally added substances" anymore. The minimum concentration to consider an "ingoing substance" is 100 ppm (0.0100 w-%, 100 mg/kg) in rinse-off products and 10 ppm (0.0010 w-%, 10.0 mg/kg) in leave-on products, in line with the definition of impurity.  When a substance/mixture is diluted in a solvent, the part of the solvent shall be reported in the calculation sheet. Water shall not be reported.  Can you confirm that rubbing/abrasive agents are not included in the calculation of CDV toxicity because the calculation of CDV is connected to the calculation of AC ? Comment clarified  Inorganic rubbing/abrasive agents are not included in the calculation of active content. Organic rubbing/abrasive agents should be included in the calculation of CDV toxicity. Further guidance will be given in the user manual  Add shower preparations in solid and dry form in the category limit Comment accepted</p> <p>We would like to know if a new DID-list is on its way to be published. Comment clarified  The JRC is not responsible for the development and update of the Did-list  If the manufacturer is not satisfied with the DID-list value of the ingredients used because considered too general, toxicity tests can be performed and submitted with the application.</p> <p>inappropriate suitability of the detergents ingredients database (DID) list, which integrate new data coming e.g. from REACH, lacks data for natural extracts and toothpaste/mouthwash ingredients and gives the same weight to all fragrances, regardless their hazard classification.  Another stakeholder also commented against the current CDV calculation: "The active content apart of being more complicated has no interest and allow dilution by ingredients. Other point is the fragrance contribution which does not take into account the risk phrase restriction. The did-list must be revised to take into account fragrance differences (H412 has the same value that non classified fragrance)."</p>	
<p>strongly support the continued inclusion of fragrances in ecolabel products.</p> <p>Many fragrance ingredients are biodegradable and perfumes typically contain relatively high % w/w of biodegradable ingredients (e.g. typically &gt; 75% for detergents based on a recent IFRA survey)</p> <p>However, the default values for a perfume in the DID list in relation to biodegradation do not reflect this:</p> <p>aerobic degradation = Inherently biodegradable</p>	<p><b>Comment acknowledged</b></p> <p>According to CB forum information on the assessment of fragrances:</p> <p>The CBs are in favor of separating a fragrance mixture that for single fragrance substances a dossier for toxicity and degradability can be submitted and that these values can be used for CDV calculation and aNBO/anNBO calculation of the whole formulation of the final product:</p> <ul style="list-style-type: none"> <li>• Provided that specific data for the ingoing substances are known and valid they can be used;</li> </ul>

*anaerobic degradation = Not biodegradable under anaerobic conditions.*

*This means for the purposes of aNBO (aerobically non-biodegradable; not readily biodegradable) and anNBO (anaerobically non-biodegradable) limits, the "perfume" as an ingoing organic substance is considered as 100% non-biodegradable (both aNBO and anNBO). From experience, Ecolabel bodies do allow the "perfume" to be split into components on the DID list e.g. x% dipropylene glycol and 100-x% "remaining perfume". However, the "remaining perfume" is still treated as aNBO and anNBO based on the DID default values.*

*As mentioned above many fragrance ingredients are biodegradable. Therefore, we request the flexibility of assessing the perfume based on individual fragrance ingredient data. Thus, for the aNBO criteria, the perfume could be split into the %w/w of readily biodegradable fragrance ingredients and % w/w of not readily biodegradable; the latter then being the fraction that would contribute to the aNBO limits.*

*Anaerobic biodegradation data for fragrance ingredients is rare but some would be exempt from the requirement based on "readily biodegradable and non bioaccumulating"*

*This criteria also applies to the final product and concerns the content of all ingoing substances, of which the fragrance is one. The DID-list Part A default values for perfume are: aerobic degradation = inherent, anaerobic degradation = not biodegradable. This means the whole perfume is considered non-biodegradable for both the aNBO and anNBO limits. Key points or issues related to this criterion for fragrances are:*

*Anaerobic biodegradation test data is not typically available for fragrance ingredients. Thus a value of "not tested" rather than "not biodegradable" would be a better reflection for the perfume in the DID-List.*

*The fragrance dosage in cosmetic rinse-off products is low and therefore the fragrance itself when using the defaults (i.e. treated as non-biodegradable) does not result in the product exceeding the aNBO and anNBO limits. However, fragrance suppliers have recently been requested by at least one Consumer Goods Company to provide a fragrance which contributes less to the % of non-biodegradable organics content, presumably because there are other ingoing substances in the product that are non-biodegradable that they cannot / do not want to replace or lower. This has been very difficult to manage for the following reasons:*

*The lowering of the fragrance dosage leads to poor performance in the product*

*In order to keep original dosage levels, the splitting of the fragrance into the % weight of non-biodegradable and biodegradable ingredients was proposed. A large number of fragrance ingredients are readily biodegradable. Thus, scientifically it does not make sense to treat the whole perfume as non-biodegradable for the purpose of the aNBO limits. Furthermore, some fragrance ingredients would be exempt from the requirement for anaerobic degradation i.e. readily biodegradable and non-bioaccumulating. How-ever, the*

- Is better to use single ingoing substances constituting the perfume instead of the general values present in DID list;
- If tests for aerobic and anaerobic biodegradability of the fragrance substance (F1) are reliable, like OCDE, they can be used.

It is suggested to include this information in the User manual.

<p><i>Ecolabel competent body in question was unsure whether this approach was acceptable under the Ecolabel regulation and has submitted a query to the CB virtual forum for discussion at the EU level. As yet we have had no response.</i></p> <p><i>The issue may be one of interpretation of the footnote in DID-List A "As a general rule licence applicants must use the data on the list. Perfumes and dyes are exceptions. If toxicity data is submitted by the licence applicant the submitted data shall be used to calculate the TF and determine the degradability. If not, the values on the list shall be used."In our opinion this would apply to both criterion 1, which has been allowed, and criterion 2, which is under question. From a fragrance perspective, there is a need for flexibility to assess the perfume based on individual ingredient data, when the conservative defaults to not allow final products to pass these criteria.</i></p> <p><i>The splitting out of ingredients that are on the DID List (e.g. solvent / solubiliser) was allowed with the remainder of the fragrance formulation treated as default perfume. However, it is difficult to check for materials that are on the DID list in company inventories, since the DID list does not contain CAS numbers.</i></p>	
<p><i>it was expressed: "If fragrances are not sufficiently biodegradable, they should not be included in ecolabelled products." and mentioned the availability of fragrance free products on the market.</i></p> <p><i>While other stakeholders mentioned: "If fragrances are not accepted anymore, you won't sell any rinse off cosmetics nor cosmetics as bold milk in southern Europe" and "Fragrance free products are not common at all in France and Southern Europe"</i></p> <p><i>It was pointed out by several stakeholders that there are Fragrances with low anNB<sub>0</sub> so it is no banning perfume, but using the better ones meaning that stricter values does not equal excluding fragrances.</i></p>	
<p><i>With regards BCF and Log Kow values, stakeholder asked to clarify why these values are different from the cut off values used in REACH.</i></p> <p><i>A stakeholder mentioned that DID list have presents lack of data and that to test log Kow is challenging.</i></p> <p><i>A stakeholder commented: "General remark on the cut-off values for BCF/log Kow (which stems from the previous DSD legislation). The higher cut-offs in CLP (and implemented in the Nordic Ecolabel) are based on scientific reasons. Hence, for example a substance with a BCF of let's say 150 would not be classified for environmental hazards (if not toxic to aquatic environment) but excluded from EUEL. We would recommend to reconsider."</i></p> <p><i>Another stakeholder mentioned: "The log 3 was from the old classification under 1999/45/EG, log 4 was from the new REGULATION (EC) No 1272/2008." and several stakeholders supported to continue using the strict value of the EU ecolabel.</i></p>	<p><b>Comments acknowledged</b></p> <p>Considering that existing values correspond to the old classification under 1999/45/EG, and the general harmonization with Nordic Swan, the log Kow values and BCF has been harmonized to Nordic Swan values and the new REGULATION (EC) No 1272/2008the (BCF &lt; 500 and log Kow &lt; 4). The values have been amended and harmonized across the entire document.</p>
<p><i>In this section it is stated that a BCF less than 500 is accepted. This is not congruent with the rest of the document. Please adjust.</i></p> <p><i>1)Until 1 March 2009:The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent. The pass levels shall be &lt; 100 or log Kow is &lt; 3,0.</i></p> <p><i>The OECD 305 test on fish. For a (replace BCF &lt; 500 by) BCF &lt; 100 the substance is</i></p>	

<p><i>considered not bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.</i></p>	
<p><i>Clarity on the non-bioaccumulating criterion is required for exemption of anaerobic degradation. A log Kow of &lt; 3 was assumed based, for example, on the bioaccumulation criterion for preservative and colorants in the EU Ecolabel regulation. However, we would propose that the bioaccumulating criterion for Ecolabels is brought in-line with the CLP classification cut-off value of log Kow of 4 which is as well in line with the Nordic Swan Ecolabel. The cut-off value of log Kow of 4 in the CLP classification is related to a BCF of 500. As a BCF of 500 is here as well the limit for a substance being considered as bioaccumulative, the corresponding log Kow of 4 should be used here as well. This applies as well to the criterion 3(g).</i></p>	
<p><i>Clarity on the non-bioaccumulating criterion is required for exemption of anaerobic degradation. Our recommendation is BCF &lt; 500 (or if unavailable, log Kow &lt; 4, which is in line with the EU CLP classification criterion for bioaccumulation potential.</i></p>	
<p><i>With regards thresholds and ambition level, several stakeholders asked to further restrict biodegradability thresholds. The existing values of Nordic Swan are from 2016. At least EU Ecolabel should align to these values even if EU Ecolabel licences are lost. Stakeholders highlighted the need of a continuous improvement of the EU Ecolabel scheme.</i></p>	<p><b>Comments partially accepted</b> The values have been revised and made stricter as a result of the general request from stakeholders to further reduce the values.</p>
<p><i>Therefore, we ask the JRC to consider the possibility of a full EE alignment with the Nordic Swan for this criterion. Indeed the thresholds of the Nordic Swan will be revised next year and they would become even more restrictive and widen the gap with the EE.</i></p> <p><i>We also recommend to aligning thresholds for cosmetic products and animal care products.</i></p>	
<p><i>We appreciate the first step to subdivide categories but we think this is not sufficient.</i></p> <p><i>Indeed we communicated our values and we think it's necessary to divide this category again to reduce threshold of the liquid soap:</i></p> <ul style="list-style-type: none"> <li>- liquid soaps : the average is 12 mg/g of AC for aNBO and anNBO</li> <li>- shampoos : values of 25 for aNBO and anNBO must be kept.</li> </ul> <p><i>It's crucial to reduce the value for liquid soap if we want that the criterion remains selective.</i></p> <p><i>As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel.</i></p> <p><i>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market. Stricter limits for CDV and Biodegradability reflect better EU policy priorities for a non-toxic</i></p>	

<p>environment.</p> <p>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.</p> <p>It's crucial to reduce the value for liquid soap if we want that the criterion remains selective.</p>	
<p>For 2b Denmark can not support higher limits than set by the Nordic Swan Ecolabel (criteria version 3). There are more than 2200 product certified on the Danish marked which clearly demonstrates that the Nordic Swan limit is feasible. The list of certified products includes both fragranced and fragrance free products. For us this indicates that the Nordic Swan limit is feasible also for fragranced products – but perhaps only fragrances with better environmental performance, which is what the EU Ecolabel is all about.</p>	
<p>The aNBO and anNBO limits should be lowered and aligned with the Nordic Swan limits for shampoo, shower preparations and liquid soaps, as well as solid soaps. Shampoo, shower preparations and liquid soaps :</p> <p>aNBO (mg/g AC): 15</p> <p>anNBO (mg/g AC):15</p> <p>Solid soap:</p> <p>aNBO (mg/g AC): 5</p> <p>anNBO (mg/g AC):5</p> <p>For several of these product types there are a relatively many products being labelled with the Nordic Swan, demonstrating that these limits are achievable.</p> <p>In addition, as shown in Table 7 in TR1 , 15 (aNBO) is above the 50-percentile value for products currently certified with EU Ecolabel.</p>	
<p>We appreciate the first step to subdivide categories but we think this is not sufficient.</p> <p>Indeed we communicated our values and we think it's necessary to divide this category again to reduce threshold of the liquid soap and shower preparations :</p> <ul style="list-style-type: none"> <li>- liquid soaps : the average is 12 mg/g of AC for aNBO and anNBO,</li> <li>- shower preparations : the average is 6 mg/g of AC for aNBO and anNBO</li> <li>- shampoos : values of 25 for aNBO and anNBO must be kept.</li> </ul>	

<p><i>It's crucial to reduce values for liquid soap and shower preparations if we want that the criterion remains selective.</i></p> <p><i>As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel.</i></p> <p><i>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market. Stricter limits for CDV and Biodegradability reflect better EU policy priorities for a non-toxic environment.</i></p> <p><i>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.</i></p> <p><i>It's crucial to reduce values for liquid soap and shower preparations if we want that the criterion remains selective.</i></p>	
<p><i>We appreciate the first step to reduce these thresholds (25 in the first draft) but we think this is not sufficient.</i></p> <p><i>Indeed we communicated our values and we think you can still reduce them because for shower preparations, the average is 6 mg/g of AC for aNBO and anNBO.</i></p> <p><i>It's crucial to reduce the value for shower preparations if we want that the criterion remains selective.</i></p> <p><i>As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel.</i></p> <p><i>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market. Stricter limits for CDV and Biodegradability reflect better EU policy priorities for a non-toxic environment.</i></p> <p><i>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.</i></p> <p><i>It's crucial to reduce the value for shower preparations if we want that the criterion remains selective.</i></p>	
<p><i>We think that the limits for liquid/solid shampoo/soap are too easy to fulfill. They should not be the same as the previous generation.</i></p>	
<p><i>As mentioned above, if the product is intended for different functions (for example shampoo</i></p>	<p><b>Comment rejected</b></p>

<p><i>and shower), the highest threshold (less restrictive) shall be considered (for example 25mg/g AC for aNBO and anNBO for a product which claims a shampoo function and a shower function).</i></p>	<p>Where a cosmetic product is marketed for different cosmetic uses, the cosmetic product category for which stricter criteria applies shall be assigned to the product.(See note in general assessment and verification)</p>
<p><i>How many leave-on products are certified according to Nordic Swan (NS) ? What percentage of certified NS cosmetics does it represent ?</i></p> <p><i>It's important to have this information in order to determine if these requirements are attainable.</i></p>	<p>At the time of drafting the TR2.0, there were 1496 ecolabelled products certified under the Nordic Swan ecolabel. (DK communicated that at the present there are more than 2200 certified products)</p> <p>The most important group of products certified is skin care (leave on), representing 20% of the total amount of Nordic Swan-certified products (19% of such skin care products are specific for children). Hand soaps (liquid) represent the 19% of the Nordic Swan-certified products, followed by shampoos and shower gels (16% and 10% respectively).</p> <p>Leave-on cosmetic products represent a 33% of total cosmetic products in the Nordic Swan Ecolabel, denoting the importance of including this group of products in the EU Ecolabel.</p>
<p><i>Regarding the new rinse-off proposed categories, as the only data available is from Nordic Swan Ecolabel, a complete alignment with this Ecolabel is proposed. Minor "How many products are certified according to Nordic Swan (NS) ? What percentage of certified NS cosmetics does it represent ?</i></p> <p><i>It's important to have this information in order to determine if these requirements are attainable.</i></p>	
<p><i>Regarding the new leave-on proposed categories, as the only data available is from Nordic Swan Ecolabel, a complete alignment with this Ecolabel is proposed. Therefore, a new sub-criterion 2 (b) (ii) has been suggested consisting on the specific restrictions proposed in TR1.0. Minor "How many products are certified according to Nordic Swan (NS) ? What percentage of certified NS cosmetics does it represent ?</i></p> <p><i>It's important to have this information in order to determine if these requirements are attainable.</i></p> <p><i>"</i></p>	
<p><i>by de use</i> <i>Mistake ?</i></p>	<p><b>Comment accepted</b> The text has been corrected.</p>
<p><i>Documentation of bioaccumulation</i> <i>We appreciate this adding.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>This criterion shall be fulfilled by each ingoing substance specified below present at or above the concentration of 0,010 % weight by weight in the final product.</i> <i>Why is this sentence different from the sentence from cosmetic products (Annexe I) ?</i></p>	<p><b>Comment accepted</b> The text has been revised and harmonised for both annexes.</p>

<p><i>All surfactants classified as hazardous to the aquatic environment: Acute Category 1 (H400) or Chronic Category 3 (H412), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council shall be in addition anaerobically biodegradable. Clarification would be very welcome why reference is made to these two specific hazard categories only and not to other chronic hazard categories implemented in the CLP Regulation.</i></p>	<p><b>Comment accepted</b> Considering the general request for stakeholders, this exemption has been removed and the text has been reverted to the original text in force.</p>
<p><i>Biodegradability of surfactants</i></p> <p><i>We do not support the exemption of the requirement of anaerobic biodegradability for surfactants not classified for the environment. Indeed, such exemption does not exist in other ecological labels such as Nordic Swan and COSMOS. In order to remain aligned with those labels, we recommend that the JRC establishes a list of surfactants not classified for the environment to be excluded based on their potential impact on the environment.</i></p>	
<p><i>We agree on the exemption of anaerobic biodegradability for surfactants not classified for the environment.</i></p>	
<p><i>Why is it not required that all surfactants should be both aerobically and anaerobically biodegradable?</i></p> <p><i>- In this case, why only surfactants classified as H400 and H412? Why not also surfactants classified as H410 and H411??</i></p>	
<p><i>In relation to the newly included exemption of anaerobic biodegradability for surfactants not classified for the environment in line with detergents product group, it was mentioned by several stakeholders that is better to keep current formulation and not to include such exemption.</i></p>	
<p><i>In Technical Report 2 it is suggested to exclude surfactants that are not classified as hazardous to the environment from the requirement on anaerobic biodegradability. We do not support this suggestion. Anaerobic degradation is an important property of its own. In addition, the current EU Ecolabel criteria, as well as Bra Miljöval and the Nordic Swan have absolute requirements on anaerobic degradability for surfactants, regardless of CLP classification.</i></p> <p><i>All surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.</i></p> <p><i>Delete: All surfactants classified as hazardous to the aquatic environment: Acute Category 1 (H400) or Chronic Category 3 (H412), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council shall be in addition anaerobically biodegradable.</i></p>	
<p><i>For 2a Denmark can not support the suggested criterion. We suggest keeping the proposal from the 1. Technical report (and the present criteria document) where all surfactants shall be biodegradable under both anaerobe and aerobic conditions. Harmonization with other product groups is important but should not supersede the possibility to set stricter but feasible requirements. We do not see the need to set less stricter requirements to</i></p>	

<p><i>biodegradability of surfactants than today.</i></p>	
<p><i>Reference to test methods to be used "until 1 December 2015" are deemed redundant, as this date lies in the past. It is recommended to adapt the text under the section 'Documentation of ready biodegradability' accordingly.</i></p> <p><i>Similar would apply to section 'Documentation of bioaccumulation'.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>We do not support the exemption of UV filter from biodegradability criteria.</i></p> <p><i>If sun products are not excluded from the scope of the ecolabel, UV filters shall comply with some biodegradability requirements, and with some eco-toxicity criteria. The formulation of sun products in the scope of the ecolabel should be encouraged with the use of filters having the less impact on the environment.</i></p>	<p><b>Comments rejected</b></p> <p>Sunscreen needs to be used during summer to avoid solar radiation, it is an essential product. It is important to recognise better alternatives through EU Ecolabel. Nordic Swan has 58 certified sunscreen products (+ 10 sunscreens for children).</p> <p>It is proposed to keep sunscreens under the scope.</p> <p>In line with Nordic Swan UV filters are exempted of biodegradability criterion however there is a specific criterion on UV filters on criterion 3 to ensure non bioaccumulation and low toxicity for organic UV filters.</p>
<p><i>Regarding sunscreen products, UV filters represent a large part of their formula, and they are not biodegradable. More especially, sunscreen products contain TiO2, a molecule having a strong negative impact on aquatic environment. Thus, sunscreen products cannot meet this criterion and we consider that including them in the scope could discredit the reputation of the EU Ecolabel.</i></p>	
<p><i>We do not support the exemption of fiber material in wet wipes from biodegradability criteria.</i></p> <p><i>If wet wipes are not excluded from the scope of the ecolabel, the fiber material shall comply with strict criteria in order to make the difference with no ecolabel products. Even if the wet wipes do not have to be left in the environment, more biodegradable fibers, as cellulose should be encouraged.</i></p>	<p><b>Comment acknowledged</b></p> <p>In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>We do not support to exempt any surfactants used in toothpaste from the requirement on anaerobic degradability. Such an exemption is simply not necessary since there are suitable surfactants being both aerobically and anaerobically degradable which are used in toothpaste.</i></p> <p><i>Delete: The following are exempt from the requirement on anaerobic biodegradability: Surfactants with cleaning and/or foaming function in toothpastes</i></p> <p><i>According to the Bra Miljöval criteria, only surfactants that are both aerobically and anaerobically degradable are allowed in toothpastes and there are labelled products available on the market.</i></p>	<p><b>Comments rejected</b></p> <p>Considering that thresholds have been decreased to further align with Nordic Swan it is decided to keep the exemption to not create additional burden. In addition it is unknown the number of licences of Bra Mijoval for toothpastes it is representative enough. It is suggested to explore the possibility to remove this exemption for next revision.</p>
<p><i>It should be clarified that QSAR should only be accepted if actual test data is missing</i></p> <p><i>Test data from actual testing is more reliable than data from QSAR modelling</i></p>	<p><b>Comment accepted</b></p> <p>Text has been modified accordingly</p>
<p><i>It was mentioned that QSAR method should be verified by independent parties or toxicologist.</i></p>	<p><b>Comment rejected</b></p> <p>QSAR method is included in other EU Ecolabel group (EU Ecolabel for</p>

	<p>Lubricants) and no reference to third party toxicologist is made for this product group.  However, a question box has been included in relation to this comment to further explore if CBs will considered necessary the need of third party assessment.</p>
<p><i>The newly introduced text about structural similarity and anaerobic biodegradation is hard to interpret. We suggest using the following sentence instead.</i></p> <p><i>"If a structurally similar surfactant has been shown not to be anaerobically biodegradable, it should be considered not degradable"</i></p> <p><i>Replace "Nevertheless, vice-versa if a structurally similar surfactant has been shown not to be anaerobically degradable, it can be assumed that a similar type of surfactant is also anaerobically biodegradable".</i></p> <p><i>By: If a structurally similar surfactant has been shown not to be anaerobically biodegradable, it should be considered not degradable.</i></p>	<p><b>Comment accepted</b>  The text has been revised accordingly</p>
<p><i>Readily degradable and has high desorption (D &gt; 75 %);  Data on adsorption and desorption can be hard to find or hard to grasp in ECHAs registration dossier for a substance. We would like to have more guidance related to the parameter Koc and its relation to adsorption/desorption.</i></p>	<p><b>Comment clarified</b>  Adsorption/desorption is a standard information requirement for Annex VIII registrations (10 tonnes and above) and is provided under the 'Environmental fate &amp; pathways' section of the disseminated REACH registration dossiers on the ECHA website. There is extensive ECHA guidance available to be consulted for guidance related to the parameter Koc (chapter R.7a Endpoint specific guidance, section R.7.1.15 page 151 available under the following link: <a href="https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f">https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f</a>)</p>
<p><i>Apply reasonable extrapolation.  A third party assessment should be required here. It is not reasonable to require that the application handling officer has the deep competence that is needed here.</i></p>	<p><b>Comment partially accepted</b>  A question box has been included in relation to this comment to further explore if CBs will considered necessary the need of third party assessment.</p>
<p><i>is also anaerobically biodegradable  We think it should be written "is also not anaerobically biodegradable"</i></p>	<p><b>Comment accepted</b></p>
<p><i>Leave on products:  Except the biodegradation requirement, it looks impossible to check this for a perfume oil as the NOECs/ECx values of the constituents of the perfume oil are not mentioned on the SDS of the perfume oil. We would suggest to use a criteria based on the classification H412 instead – like for the surfactants as well.</i></p>	<p><b>Comment partially accepted</b></p> <p>According to CB forum information on the assessment of fragrances:</p> <p>The CBs are in favor of separating a fragrance mixture that for single fragrance substances a dossier for toxicity and degradability can be submitted and that these values can be used for CDV calculation and aNBO/anNBO calculation of the whole formulation of the final product:</p> <ul style="list-style-type: none"> <li>• Provided that specific data for the ingoing substances are known and valid they can be used;</li> <li>• Is better to use single ingoing substances constituting the perfume</li> </ul>

	<p>instead of the general values present in DID list;</p> <ul style="list-style-type: none"> <li>• If tests for aerobic and anaerobic biodegradability of the fragrance substance (F1) are reliable, like OCDE, they can be used.</li> </ul> <p>It is suggested to include this information in the User manual. Testing is not a requirement but if the applicant is not satisfied with the DID data a test will be needed.</p>
<p>What is the difference between liquid soaps and shower preparations? There should be more detailed definitions</p>	<p>There is not a clear distinction under Cosmetic Regulation for this products: "bath and shower preparations (salts, foams, oils, gels)". Thresholds have been unified for these products.</p>
<p>A general comment was to increase the clarity of the criteria text, e.g. defining the word "unambiguous" when referring to SCCS opinions, or when indicating the limit of 0% for carcinogenic, mutagenic or toxic to reproduction (CMR) substances.</p>	<p><b>Comments accepted</b></p> <p>The criterion text referring to the requirement of complying with published SCCS's opinions has been amended to better define the word unambiguous. Please check the TR3.0</p>
<p>unambiguous conclusion from SCCS Major Please provide some further description as to how 'unambiguous' is defined.</p>	
<p>We don't understand the meaning of the word unambiguous.</p>	
<p>SCCS opinions should be adopted</p>	
<p>Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions, must be complied with where there is an unambiguous conclusion from SCCS. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.</p> <p>To consider restriction/ prohibit only when final SCCS opinions are published in Cosmetic Products Regulation.</p>	<p><b>Comment rejected</b></p> <p>The EU Ecolabel should go beyond the mandatory legislation and implement the conditions for the safety of substances/mixtures as soon as an opinion is published, without waiting for publication in the Cosmetics Regulation.</p>
<p>In 3a, as mentioned above, Denmark suggest that the limit for verification shall be "no limit".</p>	<p><b>Comment rejected</b></p> <p>The wording 'no limit' was used in the past for Eu Ecolabel for Cosmetics as well as for other products. However, this wording has often be misinterpreted. Many stakeholders asked to refer to regardless of the concentration, which is why we have changed the wording.</p>
<p>Moreover, one stakeholder stated that some of the text should refer only to ingoing substances, and not mixtures: "Substances/mixtures classified with any of the H-statements which are included in Table 3 shall not present, in the final product, at or above the concentration of 0.010 % (w/w) for rinse-off products and 0.001% (w/w) for leave-on cosmetics. This must refer to incoming substances, not mixtures". Some stakeholders agreed with this position, "to ensure alignment with other EU Ecolabel product groups and because dangerous properties of the substances are always "diluted" in mixtures - therefore it is sufficient to look at individual substances".</p>	<p><b>Comment rejected</b></p> <p>It is important to ensure that mixtures of substances also comply with the requirements detailed in sub-criterion 3(a), in order to prevent any cumulative effect. Therefore, the harmonised classification of mixtures should also be verified.</p>
<p>However, one stakeholder disagreed with deleting the reference to mixtures because "it is essential to evaluate the cumulative effect in the product which is intended to apply on skin's humans or animals".</p>	<p><b>Comments accepted</b></p> <p>The structure of the criterion referring to substances and mixtures has not been changed as to avoid any risk of cumulative effect of substances with a harmonised classification used in a cosmetic product in the form of mixtures.</p>
<p>Restrictions on ingoing substances/mixtures classified under the Classification, Labelling</p>	

<p><i>and Packaging (CLP) Regulation</i></p> <p><i>Regarding the field of application of this criterion, we suggest to maintaining its application to both ingoing substances and mixtures in order to consider the aggregate effect of substances in a product.</i></p>	<p>The criterion text has been changed for the hazard classes H314 and H317, that now targets substances only.</p>
<p><i>We appreciate the modified title to include "mixtures".</i></p> <p><i>We don't agree with CB Austria to exclude mixtures.</i></p> <p><i>Indeed, for each "intentionally added" mixture, we need to check the classification of all the substances AND the classification of the mixture because it's essential to evaluate the cumulative effect in the product which is intended to apply on skin's humans or animals (high hazardousness level).</i></p>	
<p><i>This sentence must be changed for "NEITHER substances NOR mixtures".</i></p> <p><i>We don't agree with CB Austria to exclude mixtures.</i></p> <p><i>Indeed, for each "intentionally added" mixture, we need to check the classification of all the substances AND the classification of the mixture because it's essential to evaluate the cumulative effect in the product which is intended to apply on skin's humans or animals (high hazardousness level).</i></p> <p><i>However there should be a derogation to not consider the classification of mixture for H314 and H317 classifications because having a allergic reaction with substance A does not necessarily cause a allergic reaction with substance B : there is not a cumulative effect for these specific classifications.</i></p>	
<p><i>Could you clarify how to assess the mixture ? if the details of the mixture is available, should the assessment in concentration (vs threshold) and classification be carried on on the individual substances disclosed and not the overall mixture? example, a mixture is H412, triggered by one substance. this particular substance is below 0.01% in the rinse-off product, is the mixture allowed ?</i></p>	
<p><i>Stakeholders asked on the procedure to follow for derogating substances</i></p>	<p><b>Comment clarified</b> If the details of the mixture are available, the assessment should be carried on on the overall mixture. If the mixture is H412 and the weight of the mixture is below 0.01% in rinse-off products, the mixture is allowed. If the substance is below 0.01% but the mixture is above 0.01%, the mixture is not allowed.</p> <p><b>Comment clarified</b> The template for derogating substances can be found in the Annex I to the technical report</p>
<p><i>JRC should share any derogations requests from industry with the working group before approving it. It would be necessary to contrast the information with data available from other Ecolabel schemes.</i></p>	<p><b>Comment partially accepted</b> The derogation requests received by industries are confidential and cannot be disclosed. A sub-group meeting was held with representative of the industries, NGOs and other ecolabelling schemes. A discussion paper and the minutes of the meeting are available on the website. The aggregated information of the derogations have been included in the TR3.0.</p>
<p><i>At present Denmark can not support any derogation on the following substances:</i></p>	<p><b>Comment acknowledged</b></p>

<ul style="list-style-type: none"> <li>• <i>Fragrances</i></li> <li>• <i>Zink pyrithione</i></li> </ul>	
<p><i>Regarding the use of ZPT in anti-dandruff shampoo, Alternatives presented by the JRC are not considered as efficient as ZPT. Ingredients (or combination of ingredients) used as alternatives to ZPT and having equivalent efficacy are also classified for the environment and require a derogation request.</i></p>	<p><b>Comment rejected</b> The derogation of ZPT was not taken into consideration, because of the RAC's opinion from 2018 favourable of the inclusion of ZPT in Annex VI of the CLP Regulation. Alternatives presented in the TR3.0 can be considered effective anti-dandruff agents, since they are used in the market and in Nordic Swan products. For example, the natural agent Dandrilyis is considered 33% more effective than ZPT after 6 days of treatment (autoevaluation). Moreover, the industry did not submit any derogation request, and no relevant data were received that substantiated this statement.</p>
<p><i>Zinc pyrithione for anti-dandruff shampoos</i> " <i>Zinc pyrithione is replaced mainly by Piroctone Olamine in dandruff shampoos (This information is retrieved from the app Kemiluppen)" "</i> <i>We suggest adding to the technical report that Piroctone Olamine is used widely as a replacement."</i></p>	<p><b>Comment accepted</b> This substance was added to the Technical Report</p>
<p><i>Additionally, we wish to point out that French industrials have expressed the following comments:</i></p> <p><i>They are concerned about the possibility to find alternatives for substances classified with H412. More especially, prohibiting substances classified with H412 would make it impossible for industrials to use surfactants. We wish to receive feedback from the JRC on which alternatives industrials could use;</i></p>	
<p><i>Table X. Derogations to restrictions on ingoing substances/mixtures classified under the CLP Regulation and applicable conditions</i> Major <i>We need H412 derogation for surfactant : Most of anionic surfactant are H412 classified, some of non ionic surfactant are H412. If H412 surfactant isn't accepted anymore, we won't be compliant to the restrictions.</i></p>	<p><b>Comments partially accepted</b> A sub-group meeting was held with representative of the industries, NGOs and other ecolabelling schemes in order to gather as much information as possible on the need of derogating these substances. A discussion paper and the minutes of the meeting are available on the website.</p>
<p><i>Fragrances</i> <i>A derogation for environmental classified fragrances (H412-H413) should be done, otherwise too many fragrances could be involved</i></p>	<p>A derogation was granted for H412 surfactants in rinse-off products, provided that the total concentration is below 20%</p>
<p><i>for the surfactants H412 under criteria 3a. The derogations (confidential) are about 2 specific surfactants types essential in our certified products for performance. I hope they will be received positively.</i></p> <p><i>Potentially, one change that could be done for this derogation could be to allow surfactants H412 but to reduce the % from 20% active content to a lower one to work by step?</i></p>	
<p><i>Dear Sir/Madam,</i></p> <p><i>Our company has developed a chemical substance named Ethyl Lauroyl Arginate HCl (LAE) which is included in Annex V of Commission Regulation (EU) No 1223/2009 as a preservative for cosmetic products.</i></p>	<p><b>Comment rejected</b> A sub-group meeting was held with representative of the industries, NGOs and other ecolabelling schemes in order to gather as much information as possible on the need of derogating these substances. A discussion paper and the minutes of the meeting are available on the website. A derogation was not granted for LAE. Please see the rationale in the TR3.</p>

<p><i>Its harmonized classification is Eye Dam.1 H318 and Aquatic Acute 1 H400 and self-classification Aquatic Chronic 2 H412.</i></p> <p><i>It's also included in some formulations which are already certified by ECOCERT, COSMOS and NATRUE.</i></p> <p><i>Regarding that in COMMISSION DECISION of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products, some exemptions are established for substances classified as Aquatic Chronic 1, Aquatic Chronic 2, Aquatic Chronic 3 and also Aquatic Acute 1 (H400, for example Zinc Pyrithione), we would like this working group to consider the possibility to include the Ethyl Lauroyl Arginate HCl (LAE) as a permitted substance for rinse-off cosmetic products.</i></p> <p><i>On the other hand, surfactants, classified as H400 and H412, are derogated substances according to different Commission Decisions establishing the EU Ecolabel criteria for detergents. Ethyl Lauroyl Arginate HCl (LAE) has also surfactant properties besides antimicrobial activity.</i></p> <p><i>Finally, other regulations such as Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes also indicates exemptions for preservatives with these hazard classifications for the environment.</i></p> <p><i>For all these reasons, we would like to consider the possibility of establishing exemptions for preservatives substances classified as H400 for use in rinse-off cosmetic products. Or consider the substance Ethyl Lauroyl Arginate HCl (LAE) as an exemption to allow its use. Please let us know if we need to submit any further information.</i></p> <p><i>Thanking you in advance.</i></p> <p><i>Best Regards,</i></p> <p><i>Consider the substance Ethyl Lauroyl Arginate HCl (LAE) as an exemption to allow its use in rinse-off cosmetic products.</i></p>	
<p><i>In general, we support the evolutions proposed by the JRC. However, we recommend an alignment with the EU Ecolabel for detergents by clarifying that CMR substances/mixtures are banned regardless of their concentration.</i></p>	<p><b>Clarified</b> The TR2.0 has a requirement that bans CMR substances/mixtures regardless of their concentration. This was clarified further in TR3.0</p>
<p><i>No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall be added in the final product or its ingredients, regardless of their concentration.</i></p> <p><i>We think we should define better the sentence and the definition. "We would prefer to write: No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall be intentionally added in the final product or its ingredients, regardless of their concentration.</i></p> <p><i>CMR substances are already regulated by the Cosmetic Regulation through Cosmetic Acts called Omnibus Acts which are alligned with the CLP adoption classification.</i></p>	<p><b>Comment rejected</b> In order to fully align with Nordic Swan, as the majority of the stakeholders requested, we prefer to keep the wording proposed in TR2: "No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall be added in the final product or its ingredients, regardless of their concentration"</p>

<p>"Substances and mixtures presenting CMR hazards are banned regardless of their concentration" – please add something about limit of detection; maybe copy-paste from the Amendment to the six Ecolabels for detergents.</p>	<p><b>Comment partially accepted</b>  The limit of detection as a limit for CMRs was already introduced in the TR2, in a note to Table 2 of the criterion text: "no limit" means: regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection)."  For further clarity, a small addition was inserted in the text of criterion 3 (a) (ii) (see TR3.0)</p>
<p>Stakeholders commented that substances classified as sensitizers to the skin according to the hazard classes H317 and H334, "should not be allowed in EU Ecolabel cosmetics, regardless of their concentration", since these substances are used in very little amounts and would be used in EU Ecolabel products despite the restriction limit of 0.01% w/w for rinse-off products and 0.001% w/w for leave-on products.</p> <p>No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall be added in the final product or its ingredients, regardless of their concentration</p> <p>We welcome the introduction of a requirement excluding CMR hazards regardless of the concentration. We strongly recommend adding an exclusion regarding of concentration for substances meeting properties for classification as H317 and H334 (the latest particularly when inhalation is an exposure route, like in sprays).</p> <p>The Blue Label (Denmark) has requirements excluding totally H317.</p> <p><a href="https://www.thebluelabel.eu/documents/12151/342794/Criteria+Hygiene+and+Tissue+16.10.2017.pdf/7f4ae0ee-466e-4f6f-a09a-fa0d78a00980">https://www.thebluelabel.eu/documents/12151/342794/Criteria+Hygiene+and+Tissue+16.10.2017.pdf/7f4ae0ee-466e-4f6f-a09a-fa0d78a00980</a></p>	<p><b>Comments rejected</b>  The total ban of substances with a harmonised classification as H334 and H317 has not been included because the EU Ecolabel is an environmental label, and the restrictions should focus at the improved environmental profile on cosmetic products. The restriction of sensitizing substances is in place via criteria 1, 2, 3a and 3d, which has now been made stricter, restricting 26 extra fragrance allergens. Moreover, strong sensitizers such as HICC, Atranol and Chloroatranol have been banned completely in criterion 3b. This set of criteria will limit the problem of allergic or skin reactions significantly. For the most sensitive segment of the population, minimum reactions can be ensured via those products that are developed as mild or for sensitive skins.</p>
<p>H317 May cause allergic skin reaction</p> <p>In addition to this restriction of classified allergens, the 26 fragrance allergens which are obligatory to declare if present in products above 10 ppm or 100 pmm (for leave-on and rinse-off respectively) should be restricted in the same manner.</p>	<p><b>Comment accepted</b>  The 26 fragrance allergens as identified by the SCCS decision from 2012 have been restricted in sub-criterion 3d and can be used in concentration up to 0.01% in rinse-off products and up to 0.001% in leave-on products. Please check sub-criterion 3d.</p>
<p>Despite 13 ingredients from Table 11 meet the criteria to be classified as hazardous according to CLP Regulation, only 7 are affected by the proposed criterion 3 (a): Cedar wood oil, Chamomile, Frankincense, Hemp seed oil, Lavander oil, Rosemary extract and Turmeric.</p> <p>"For these 7 ingredients (Cedar wood oil, Chamomile, Frankincense, Hemp seed oil, Lavander oil, Rosemary extract , Turmeric ) it is a challenge and limitation for cosmetics ecolabel formulators in order to meet both criteria 3 and 5 (b).</p>	<p><b>Comment rejected.</b>  While it is acknowledged that these ingredients heavily contribute to the organic share of the formulation of a cosmetic product, the wording of criterion 5b (now 6b) has been changed to clarify that it is 20% of the ingredients that are eligible to be organic that should be taken into account, and not 20% of the product formulation. Please see TR3 for further explanation.</p>
<p>(iii) Ingoing substances or mixtures classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum:</p> <p>The JRC justifies this proposal on an alignment with the Blue Angel requirements. However,. this opens a wider acceptance of hazardous substances than necessary.</p>	<p><b>Comments rejected</b>  The formula in sub-criterion 3 (a) (iii) is not in contradiction with 3 (a) (i): sub-criterion 3 (a) (i) sets restrictions on individual substances and mixtures, whereas sub-criterion 3 (a) (iii) sets restrictions on the final product, to make sure that, even if complying with criterion 3 (a) (i), the total amount of substances with harmonised classification does not exceed a certain amount.</p>

<p><i>"Delete: Substances classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum: <math>100 \cdot c[H410] + 10 \cdot c[H411] + c[H412] \leq 2.5\%</math>, where c is the fraction of the product, measured in percentage by weight, made up of the classified substance. We suggest adding derogations for specific substances where necessary."</i></p>	<p>The formula is used in other ecolabels like Nordic Swan and Blue Angel, and its use stems from the fact that the CLP regulation cannot be applied to the cosmetic products in its finished state.</p>
<p><i>Hazardous to the aquatic environment</i></p> <p><i>This prohibition is contradictory with the formula in point (iii). If substances with these classifications are forbidden, then the formula makes no sense.</i></p> <p><i>One of the two should be removed, either this prohibition or the formula.</i></p> <p><i>If the formula is forbidden, then there should be an exemption for surfactants at least H400 and H412 if they degrade under aerobic and anaerobic conditions, as with other EU Ecolabel schemes (laundry detergents, hard surface cleaners, dishwashers...)."</i></p>	
<p><i>Ingoing substances or mixtures classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum:</i></p> <p><i>We do not support the new requirement of allowing, in general terms, environmentally hazardous compounds. This clearly contradicts the EU Ecolabel Regulation (EC) 66/2010, which states that derogations (from e.g H4XX classification) can only be permitted under specific circumstances.</i></p> <p><i>Hence, a general approval of environmentally hazardous substances as long as they are used in limited concentrations is not in accordance with EU Ecolabel Regulation.</i></p> <p><i>For the same reason, the old system of assessing specific requests for derogations of specific compounds should be kept.</i></p> <p><i>In addition, we would like to point out that this requirement is in direct conflict with criteria 3(a), (i).</i></p> <p><i>However, if this criterion is introduced, it is of crucial importance to be very restrictive to any other derogation with regard to environmental properties."</i></p>	
<p><i>Is it a mistake : 25% instead 2,5% ?</i></p> <p><i><math>100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%</math>      Major      "Calculation is too restrictive. See if it's possible to increase 2.5% limit. For example derogation for surfactants must be asked otherwise it would be very difficult to obtain effective rinse-off products as fast all surfactants are classified H412.</i></p> <p><i>The level must be 25%.</i></p> <p><i>2.5% of H412 substances is impossible to reach (even more for 10x H411 + 100x H410)</i></p> <p><i>Most of anionic surfactants are classified H412. So the limit of 2.5% isn't reachable.</i></p>	<p><b>Comments clarified</b></p> <p>There was not a mistake in the formula. The limit is 2.5%. However, surfactants classified as H412 are exempted from the formula, i.e. they should not be included in the calculation. This has now been amended in TR3.0.</p>

<p>The sub criterion 3 (a) (iii) was welcomed by stakeholders, who nevertheless pointed at a mistake in the formula in the technical report: "please confirm it's a mistake for 2.5% and the right value is 25%".</p>	
<p><math>100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%</math></p> <p>This is extracted from Nordic Ecolabel, and the following text is missing. It should be updated as per:</p> <p>Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation. Surfactants, regardless of their function, classified with H411 or H412 are exempted from the requirement, on condition that they are readily degradable and anaerobically degradable."</p> <p>where <i>c</i> is the fraction of the product, measured in percentage by weight, made up of the classified substance.</p> <p>Will there be a derogation for surfactants classified as H411/H412?</p>	<p><b>Comment partially accepted</b> We have updated the formula to take account of the formulation of zinc creams put on the market. surfactants classified as H412 are exempted from the formula, i.e. they should not be included in the calculation, in line with the derogations granted.</p>
<p><math>100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%</math> Minor For clarification purpose for the assessment, for example, if there are 2 classified substances H412 at 2.3%, each substance will be compliant, even with a total of H412 at 4.6%, correct ?</p>	<p><b>Comment clarified</b> The concentration of each substance with H-class H410, H411 and H412 have to be inserted in the formula. if there are 2 classified substances H411 at 2.3%, the result will be 4.6% and the formulation would not be compliant. However, surfactants classified as H412 are exempted from the formula, i.e. they should not be included in the calculation.</p>
<p>In 3b Denmark supports the limit set at 0 % (detection limit).</p>	<p><b>Comment acknowledged</b></p>
<p>Criterion 3b: maybe you should align with detergents PG where it is stated:  The substances indicated below shall not be included in the product formulation regardless of concentration:</p>	<p><b>Comments accepted</b> The sentence was modified to clarify that the sub-criterion refers to all ingoing substances, irrespective of when and how they are added. The criterion text is kept the same as in the existing criterion in force.</p>
<p>The substances listed below shall not be added in the final product:  Why limit the exclusion to substances "added in the final product"? How does this relate to and comply with the definition of ingoing substances? It is also difficult to see how it should work in practise. For example, BHT/BHA are not "added in the final product", they are added to e.g. fragrances. The same holds for many of the other substances on the list (e.g. fragrance substances, EDTA, EDs, phtalates, preservatives, aluminium, etc)</p>	
<p>Cr. 3b Excluded substances: by excluding the following preservatives : triclosan, parabens, formaldehyde releasers, benzalkonium chloride, phenoxyethanol, the EU Ecolabel will only add another layer by banning an additional set of substances. We suggest to refer only to preservatives listed in Annex 5 of Cosmetic Reg. please remember that BPR (Biocidal Product Regulation) doesn't apply to Cosmetic products</p>	<p><b>Comment rejected</b> While Annex V of the Cosmetics Regulation restricts the use of these substances up to a certain concentration (e.g. benzalkonium chloride up to 0.1%), criterion 3(b) restricts them regardless of the concentration. It is important to ban listed substances completely to ensure the credibility of the label, since most of these substances are added in very low amounts.</p>

<p>General remark on groups of substances as listed under criterion 3(b): It may not be always clear what substances are covered under the different groups of substances, without further specification. This said, companies applying for EUEL would probably need more clarity on the substances covered to be able to ensure that they comply with the EUEL criteria. The same applies to authorities checking the compliance. For this reason, ideally the EUEL criteria should already provide sufficient clarity.</p>	<p><b>Comment acknowledged</b></p>
<p>Additionally, based on the feedback of a consumer association, we recommend increasing the number of allergens on the restriction list, as the European Commission is currently studying a proposal to move from 26 to 87. Finally, polyethylene glycol (PEG) and silicones should be given more consideration since they bioaccumulate in the environment, in particular because of their slow degradation and the creation of substances toxic to the aquatic environment.</p>	<p><b>Comment partially accepted</b> The restriction of allergens has been tightened through sub-criterion 3(d), where allergens listed in the SCCS opinion have been restricted to 0.01% in rinse-offs and 0.001% in leave-ons. The possibility of restricting PEGs compounds and silicones through adding them to criterion 3(b) has been analysed. However, it was finally decided not to restrict them. Please see TR3.0 for further details.</p>
<p>we welcome the exclusion of endocrine disruptors</p>	<p><b>Comment acknowledged</b></p>
<p>Endocrine disruptors: Cefic supports including "if they are identified as ED according to Article 57(f)", also for legal clarity.</p>	<p><b>Comment accepted</b> This reference was included in the note [4] to the criterion text.</p>
<p>Substances and mixtures identified to have endocrine disrupting properties [4]; Major Substances and mixtures confirmed classification as endocrine disruptors and classification published in CLP Annex VI.</p>	<p><b>Comment rejected</b> The proposed wording would limit the exclusion of identified EDs to being applied after the publication on the CLP Annex VI. However, the time gap between the identification of a substance as ED and its publication on CLP may be long. To avoid this, it is preferred keep the current wording.</p>
<p>"Substances identified and suspected to have endocrine disrupting properties" are the ones which have been identified to have endocrine How should it be assessed and verified what substances are EDs under BPR and PPPR? It's quite complicated to find and conclude from ECHA/EFSA databases. For the substances indentified under EU legislation (REACH, BPR, PPPR, CR) we propose to use list I at the website <a href="http://www.edlists.org">www.edlists.org</a>. Please also note that we think the criterion for EDs is too weak in this TR2.0 proposal, see earlier comment.</p>	<p><b>Comment clarified</b> It is proposed to insert in the user manual the following paragraph: No list exists for ED substances in the Biocidal Products Regulation. ECHA's endocrine disruptor (ED) assessment list (<a href="https://echa.europa.eu/ed-assessment">https://echa.europa.eu/ed-assessment</a>) can be consulted, as it includes the substances with ongoing or concluded ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group</p>
<p>On EDs  "The definition is clearer but we think it is always necessary to provide the comprehensive list of forbidden substances.  It will facilitate the verification by CBs."</p>	<p><b>Comments rejected</b> As the classification of substances as identified EDs has an evolving nature, JRC believes that specifying a list of excluded EDs would limit the flexibility of the label to update together with the legislation. Therefore, a list of identified EDs will not be made available</p>
<p>In this 2nd proposal for criteria modification, it is proposed to include to sub-criterion 3(b) the substances which have already been identified to have endocrine disrupting properties through Article 57 (f) of REACH Regulation, Regulation 528/2012[42] on biocidal products and Regulation 1107/2009[43] on plant protection products.  Major "The definition is clearer but we think it is always necessary to provide the comprehensive list of forbidden substances.</p>	

<p><i>It will facilitate the verification by CBs."</i></p>	
<p><i>Specified excluded substances</i></p>	
<p><i>Regarding substances classified as endocrine disruptors, French stakeholders have pointed out that the Candidate List of SVHC in Regulation 528/2012 and in Regulation 1107/2009 are evolving lists. We thus recommend that the JRC defines an exhaustive list of substances to be excluded, as does the Nordic Swan.</i></p>	
<p><i>[4] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.</i></p> <p><i>The definition is clearer but we think it is always necessary to provide the comprehensive list of forbidden substances.</i></p> <p><i>It will facilitate the verification by CBs."</i></p>	
<p><i>Substances and mixtures identified to have endocrine disrupting properties</i></p> <p><i>"Example list of confirmed EDs could be included. The list should reflect those substances evaluated and harmonised at EU level. Suspected or proposed but not confirmed substances should be avoided pending the outcome of evaluation (e.g. by ECHA or SCCS) to avoid discrimination. If suspected substances are included these should only be introduced where there is consensus reference.</i></p> <p><i>The use of the ECHA reference is consistent with this point."</i></p>	
<p><i>Substances and mixtures identified to have endocrine disrupting properties [4];</i></p> <p><i>"We insist on a specific list of substances considered as and endocrine disruptor and banned from the ecolabel.</i></p> <p><i>the proposed lists ""Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009." are not appropriate :</i></p> <ul style="list-style-type: none"> <li><i>- the regulation 528/2012 and 1107/2 can not be used as a reference as the substances identified may be not appropriated (ex for essential oil, which can be used safely).</i></li> <li><i>- exclusion have to be considered for the ED ""confirmed"", and well identified, but can not include the substances only presumed nor suspected.</i></li> <li><i>- the list should be well defined in the ecolabel</i></li> </ul>	

<p><i>Ingoing substances and mixtures meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006[31] that have been identified according to the procedure described in Article 59 of the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation shall not be added to the product, regardless of their concentration.</i></p> <p><i>This requirement is not enough to restrict the content of endocrine disruptors. We have to set stricter requirement for them.</i></p>	<p><b>Comment rejected</b> It is the opinion of the JRC that the strictest requirement possible has been set for identified EDs, i.e. the strict exclusion regardless of the concentration of the ingoing substance. Please note that this requirement applies also to impurities, by-products and the like</p>
<p><i>"We support the proposal of Austria to ban the substances on the priority list of potential endocrine disruptors used in cosmetic products. Only for one ingrediënt we disagree, namely salicylic acid because a recent opinion of the SCCS exists already <a href="https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf">https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf</a> "</i></p>	
<p><i>3(b) Specified excluded substances</i></p> <p><i>"We strongly recommend including the suspected EDCs by referring to the EC list published on May 2019 (including group A and B), which should be assessed by the SCCS (<a href="https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en">https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en</a>). Applying the precautionary principle is at the heart of the EU Ecolabel Regulation, all the substances in the list should be excluded in the EU Ecolabel. BEUC comments on each of the substances included in this list can be found in this <a href="https://www.beuc.eu/publications/beuc-x-2019-009_potential_hormone_disruptors_in_cosmetics.pdf">position paper</a> (<a href="https://www.beuc.eu/publications/beuc-x-2019-009_potential_hormone_disruptors_in_cosmetics.pdf">https://www.beuc.eu/publications/beuc-x-2019-009_potential_hormone_disruptors_in_cosmetics.pdf</a>).</i></p> <p><i>Should it be relevant to discuss single substance use instead of referring to the lists, it is important to put main emphasis on the most used substances which are not yet covered by the requirements.</i></p> <p><i>These substances are found in many cosmetic products (based on consumer organisations tests) and are already not allowed under the current proposal:</i>  <i>BHT/Butylated Hydroxytoluene (antioxidant)</i>  <i>Cyclopentasiloxane (wide use in many products, for instance cream and hair products).</i>  <i>Cyclomethicone (Possible content of cyclopentasiloxane)</i>  <i>Ethylparaben (preservative, wide use)</i>  <i>Methylparaben (preservative, wide use)</i>  <i>Propylparaben (preservative, wide use)</i>  <i>Butylparaben (preservative, wide use)</i>  <i>Salicylic acid (mainly shampoo &amp; anti blemish products)</i>  <i>The below substances are found in many cosmetics but are not currently excluded:</i>  <i>Ethylhexyl Methoxycinnamate (UV filter, decorative cosmetics, lipcare, sunlotions, perfume etc)</i>  <i>Resorcinol (haircolor)</i>  <i>Benzophenone-1 (UV filter, mainly nailpolish)</i>  <i>Benzophenone-3 (UV-filter, Lipcare, suncare etc)</i></p>	<p><b>Comments partially accepted</b> Further work and discussions with relevant European Agencies and NGOs were carried out. As a conclusion, a list of 8 compounds with potential endocrine disrupting properties commonly found in cosmetic products have been added for exclusion in sub-criterion 3(b)</p>

*Benzophenone-4 (UV-filter, wide use, for example shampoo and hand soap)*  
*Butylphenyl metylpropional (perfume substance, wide use)*

*Octocrylene (UV-filter, mainly suncare)*  
*Homosalate (UV-filter, mainly suncare)*  
*Benzyl salicylate (wide use)*  
*Triphenyl phosphate (nailpolish)*

*These substances have been found in cosmetics, but rarely used (\*=already excluded):*

*Benzophenone*  
*Benzophenone-2*  
*Benzophenone-5*  
*\* BHA/Tert.-Butylhydroxyanisole*  
*\* Cyclotetrasiloxane (Prohibited, but still found occasionally)*  
*\* Diethyl Phthalate (DEP)*  
*\* Triclosan (toothpaste, deodorants)*  
*Octoxynol*  
*Kojic acid*  
*4-Methylbenzylidene Camphor*  
*Genistein*

*These substances have not been found in cosmetics:*

*4-Hydroxybenzoic Acid*  
*Acetyl Hexamethyl Tetralin*  
*Dihydroxybiphenyl*  
*Deltamethrin*  
*Hydroxycinnamic Acid*  
*Hexamethylindanopyran*  
*Nitrophenol*  
*Resmethrin*  
*Styrene*  
*T-butyl methyl ether (MTBE)*  
*Triclocarban*

*Source : Kemiluppen Database, Danish Consumer Council THINK Chemicals*  
*<https://kemi.taenk.dk/bliv-groennere/kemiluppen-tjek-din-personlige-pleje-uoensket-kemi>*  
*"Revise to :*

*Substances and mixtures identified to or suspected to have endocrine disrupting properties*  
*[4];*

*[4] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.*  
*Substances suspected to have endocrine disrupting properties from the Commission priority list on potential endocrine disruptors*

[[https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine\\_en](https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine_en)]

Or

[4] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009. Substances suspected to have endocrine disrupting properties from the National Authorities lists of potential endocrine disruptors (EDs) <https://edlists.org/>

Alternatively add to criterion 3b the exclusion of at least the following most used substances from the EC list, that are not yet covered by requirement 3b:

Ethylhexyl methoxycinnamate – UV filter

Resorcinol – Hair dye

Benzophenones – quote a concern on ED

Homosalate – eifrluy used in sunscreen

Octocrylene

Butylphenyl metylpropional - perfume

Benzyl salicylate – perfume

Triphenyl phosphate – mainly in nail poshish

[Some of these will most likely already not fulfill other criteria, but a specific listing would be preferable]

Furthermore add these substances from the National authorities list as they are not covered in the EC list:

Ethylhexyl salicylate

Isoamyl P-methoxycinnamate"

Substances identified to have endocrine disrupting properties [3].

"In our opinion, the requirement ought to include also suspected EDs, where a minimum should be the cosmetic ingredients prioritised by the Commission in 2019 (see TR2.0 ANNEX II. Substances under "call for data on ingredients with potential endocrine-disrupting properties used in cosmetic products"). Which also means that once a substance has been identified as an ED by the SCCS, it should fall under the category ""identified"" EDs and be treated equally to EDs under REACH, BPR and PPPR as mentioned in this current TR2.0 proposal (even if SCCS should consider them safe to use in cosmetic applicatins that is).

Considering comparisons to the Nordic Swan, the requirement on EDs in cosmetics will likely soon be updated to cover the substances prioritised by the commission in 2019. In the next complete NS cosmetics criteria revision, the requirement will likely be extended further to cover all three lists at [www.edlists.org](http://www.edlists.org). "

(xv) Substances and mixtures identified to have endocrine disrupting properties [4];  
Major "It is crucial to introduce stricter criteria on endocrine disruptors (EDs) in

*the EU Ecolabel for Cosmetic Products compared to the proposal published. Therefore Austria will vote against the criteria if the in case the proposed meaningless criteria EDs aren't improved.*

*We strongly ask to introduce the precautionary principle for EDs in the EU Ecolabel as alarming information and studies are on the table since years. Furthermore this is essential in order that the EU Ecolabel doesn't lose credibility in the eyes of consumers.*

*" We ask to exclude the 28 substances on the priority list of potential endocrine disruptors in cosmetic products established by the EU commission.*

*[https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine\\_en](https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine_en)*

*until the publication of an evaluation of the SCCS. After a substances is freed from the suspicion of having endocrine disrupting properties it shall be deleted from the list.*

*A second and even more comprehensive alternative would be the exclusion of all of the substances under evaluation for endocrine disruption under an EU legislation compiled as well in the website edlists.org:*

*<https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption?page=1>*

*"*

*Denmark also supports the list of excluded substances. In regards to Endocrine disruptors Denmark suggest to refer to the Commissions list of ingredients with potential endocrine-disrupting properties used in cosmetic products from 2019 and excluded substances on the "EDLIST" list I, II and III (please refer to <https://edlists.org/>). Referring to the two lists will give a more up to date references and will not cause any more administrative burden when handling applications.*

*We could support the exclusion of suspected EDs but we would welcome more info from the JRC*

*Suspected EDs have to be banned. We will vote negative if not banned*

*Suspected EDs have to be banned. EC list would be okay but maybe relevant to look at the joint Member States list as well (EDlist.org). it may be needed to derogate some substances for use in UV filters*

*We cannot support the criteria if Suspected EDs are not banned.*

*Suspected EDs have to be banned*

*We are in favour of excluding suspected EDs*

*Stakeholders expressed their concern on the proposed exclusion of identified endocrine disruptor compounds (EDs). They suggested to extend the exclusion also to suspected EDs, referring in the criterion to the list that the European Commission made in 2019 (the "call for data" list A and B) and to the list that was developed by the collaboration between five Member States: Belgium, Denmark, France, The Netherlands and Sweden. Another stakeholder suggested to "exclude identified and confirmed EDs". However, it was also commented: "it may be very relevant to know what criteria are used to make a substance a suspected ED".*

<p><i>agrees that only substances and mixtures identified to have endocrine disrupting properties are included in sub-criterion 3(b) (based on the SVHC list)</i></p> <p><i>Suspected endocrine disruptors should not be included under sub-criterion 3(b) as the criteria for making them a suspected ED are not transparent and as long as no scientific assessment on the ED properties of a substance has taken place it should not be banned from the Ecolabel list.</i></p>	<p><b>Comments partially rejected</b></p> <p>The JRC acknowledges that the EU Ecolabel criterion for potential endocrine disruptors (EDs) need clarity on the wording and on the basis (criteria) on which the assessment is made of what a potential ED is. Therefore, the EC list of potential EDs was screened for those substances that are commonly found in cosmetic products and are not restricted by other EU Ecolabel criteria. The 8 compounds that passed the screening are proposed to be banned in EU Ecolabel products by adding them to sub-criterion 3(b) list.</p>
<p><i>[3] "Substances identified and suspected to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009</i></p> <p><i>Please consider amending the footnote accordingly. Despite we understand the preference to include also suspected EDs in the EU Ecolabel criteria, we would like to reiterate our concerns on this approach: There is no current list of suspected EDs that is designed to be used for regulatory risk management or ecolabelling purposes. Moreover, there are no criteria for a substance to fall into the 'suspected' category. This said, we would have significant concerns about taking this approach as this could result in spending a lot of time arguing over whether a substance is a suspected ED or not which would be better spent actually finding out if it really is. Overall, we propose to be very clear in the systematic wording used and if we were to introduce a suspected category the criteria would have to be very clear and unambiguous.</i></p>	
<p><i>Since these substances will be listed, what happens when these substances are delisted and recognised as 'safe' e.g. by SCCS review?</i></p>	<p><b>Comment clarified</b></p> <p>An amendment would be needed in those cases</p>
<p><i>This implementation allows EU Ecolabel to be in-line with other Ecolabel schemes, as Nordic Swan and Bra Miljöval</i></p> <p><i>. Minor Might be relevant to add here that the Organic Regulation also has in place an exclusion of nanomaterials.</i></p> <p><i>We strongly welcome the exclusion of nanomaterials and call on the Commission to maintain this requirement, aligning the EU Ecolabel with the Organic Regulation which also excludes nanomaterials.</i></p>	<p><b>Comments acknowledged</b></p>
<p><i>" We recommend that regarding EU regulatory authorities' opinions from the RAC (ECHA) and SCCS are taken as reference. Given the existing concerns on potential hazardous properties of nanomaterials and methodology gaps to assess them, and based on the precautionary principle, the EU Ecolabel should exclude nanomaterials.</i></p> <p><i>The SCCS will only consider risks to human health, not environmental impacts – therefore, if this condition is kept the relevant authority would be ECHA (RAC).</i></p> <p><i>The EU Ecolabel could take inspiration from the wording of the Nordic Swan Ecolabel:</i></p> <p><i>O5 Prohibited substances</i></p>	

[...]

*Nanomaterials/particles as defined in the Cosmetics Regulation\*\*\*\* An exception is made to this requirement for*

- a) Synthetic amorphous silica, which is used as an abrasive in toothpaste.*
- b) TiO2 approved in SCCS opinion SCCS/1516/13. I.e. TiO2 must not be photocatalytic, coating must be stable and TiO2 may not be included in spray products*
- c) TBPT as UV-filter as approved in SCCS opinion SCCS/1429/11. D.v.s. inte i sprayprodukter. [not spray products]*
- d) MBBT som UV-filter i godkänt i SCCS opinion SCCS/1546/15. D.v.s. inte i sprayprodukter.[not spray products]*

*The update below on political process, makes it even more relevant the exclusion of nanomaterials using a precautionary approach:*

*As regards policy developments in the area of nanomaterials, ECHA this week has postponed publishing the updated guidance documents on nano registrations under REACH because the absence of internationally recognised test methods is seen as an obstacle by industry and stakeholders. Companies should have registered their nano forms under REACH by 1 January 2020 but ECHA received only a limited number. EEB denounced that between 95 and 99% of the nanomaterials thought to be on the market are not registered and almost half of the registration dossiers are not even complete. The guidance documents are now expected in August 2021 for human health and in September 2022 for environmental endpoints.*

*Nanomaterials, unless an EU regulatory authority has evaluated the use of the nanomaterial and found that it is safe from health and environmental perspective*

*Since mention it may be useful for the read to have either an example list (e.g. <https://ec.europa.eu/docsroom/documents/38284> or <https://euon.echa.europa.eu/search-for-nanomaterials>) or reference to legislation (e.g. entries within the EU Cosmetic Regulation)*

*EU regulatory authority*

*Please name more specific the EU regulatory authority that is meant?*

*Nanomaterials, unless an EU regulatory authority has evaluated the use of the nanomaterial and found that it is safe from health and environmental perspective;*

*The competent body is SCCS and ist decision is adopted by DG Grow*

*Nanomaterials, unless an EU regulatory authority has evaluated the use of the nanomaterial*

<p><i>and found that it is safe from health and environmental perspective</i></p> <p><i>The criterion stipulates that only nanomaterials that have been evaluated by an EU regulatory authority and found to be safe from both health and environmental perspective are permitted. We strongly support this criterion, but we think the criterion should specify which EU regulatory authorities that are to be considered.</i></p> <p><i>Our suggestion is SCCS for human health and RAC and SCHEER for environmental aspects.</i></p>	
<p><i>Would it be necessary to better specify "EU regulatory authorities" on nanomaterials exclusion criterion? Major Yes</i></p>	
<p><i>Proposed to allow the use of a specific nanomaterial only if an EU regulatory authority has evaluated its use and found that it is safe from health and environmental perspective: if not explicit at the very least the verification is going to be difficult and not equal for all the member states. In general the Decision should name the actual limits or derogation or substances excluded or anything that has to be checked otherwise the objectivity of the verification cannot be guaranteed</i></p>	
<p><i>Nanomaterials: nanomaterials are not dangerous per se. Like any other chemical, some are dangerous and some are not (see TR 1 0: "use of nanomaterials would be evaluated on a case by case basis"). Furthermore, nanomaterials are allowed by the cosmetic regulation if their classification is not of concern. That implies that "an EU regulatory authority has evaluated its use and found that it is safe from health and environmental perspective". Therefore we do not understand the issue</i></p>	<p><b>Comment rejected</b> Nanomaterials that have been proved safe are not proposed to be excluded in the Ecolabel.</p>
<p><i>Microplastics: proposal to include also the derogations of paragraph 3 and 5 (natural polymers, biodegradable polymers and soluble polymers; cease to be a microplastic during use) of the restriction, since those materials do not contribute to the concern.</i></p>	<p><b>Comments partially accepted</b> The proposal in the TR3.0 was to align with RAC and SAEC opinion for what concerns the definition of microplastic . The derogations to this definition are automatically also included, without the need to specify them. Please check TR3.0.</p>
<p><i>In relation to microplastics it was mentioned: "As a result of the discussion about microplastics and other polymers, a new criterion for the degradation of synthetic polymers was introduced at the Blue Angel. All synthetic polymers must be inherently biodegradable."</i></p>	
<p><i>In addition it was expressed that the inclusion must be defined correctly - not all polymers are plastics, but all plastics are polymers.</i></p>	
<p><i>The emerging ECHA definition of microplastics should be used which makes a distinction between particulate polymers and non particulates. Also it defines biodegradation criteria - inherent biodegradation testing is not always suitable for polymers; a wider range of biodegradability tests should be included. Please align with ECHA on this</i></p>	
<p><i>"We strongly recommend to consider a definition of microplastics which will be the most restrictive and protective for the environment as possible.</i></p> <p><i>The definition that is used within the EU Ecolabel for Detergents seems more protective than the one that is currently under consideration by ECHA, and which is proposed in the technical report. We should retain at least the definition provided for detergents.</i></p> <p><i>We will provide further details on this point in written form after submission of these comments taking into account ongoing policy developments."</i></p>	

<p><i>Microplastics</i></p> <p><i>"We should use ECHA definition and biodegradability criteria when fixed.</i></p> <p><i>We must also remember that not all polymers are microplastics."</i></p>	
<p><i>Microplastics [3];</i></p> <p><i>The current definition of microplastics written by ECHA might not be its final version. What will happen to this requirement if the definition changes?</i></p>	<p><b>Comment clarified</b></p> <p>Reference is made to the Annex where the definition appears. If the legislation changes, the change will be automatically adopted in the EUEL</p>
<p><i>Cocamide DEA is classified as H411, and hence excluded by Criterion 3 a (i).</i></p> <p><i>Not only is there no need to include it here, but it also denigrates this ingredient, which is against the scope of cosmetics regulation and EU Ecolabel. It should be removed from the list.</i></p>	<p><b>Comment rejected</b></p> <p>Criterion 3(a) (i) restricts substances to a maximum concentration of 0.010% w/w in rinse-off products and 0.001% w/w in leave-on products. Criterion 3(b) completely bans the substance, regardless of its concentration. The inclusion of Cocamide DEA in criterion 3(b) is intended to ban the use of this substance</p>
<p><i>The exclusion on isothiazolines was considered as doable by stakeholders, which reminded that this exclusion is already in force in some certification schemes and private standards on the market.</i></p>	<p><b>Comments accepted</b></p> <p>The exclusion of isothianolinones is kept.</p>
<p><i>"BEUC welcomes the exclusions of isothianolinones and call on the Commission to maintain this restriction.</i></p> <p><i>" Keep the exclusion</i></p> <p><i>Isothiazolinones are not used in the Nordic Swan. There is a wide product range of cosmetics with certified with this label, which shows that an exclusion is very doable, and there is no need to expose consumers to these highly allergenic substances.</i></p> <p><i>Isothiazolinones are not allowed in leave on cosmetics. Their use in rinse off cosmetics is also regulated (0,0015% is allowed of either MI/MCI or MI). Annex V LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS, V39 and V57</i>  <a href="https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.results&amp;annex_v2=V&amp;search">https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.results&amp;annex_v2=V&amp;search</a></p> <p><i>The use of isothiazolinones is being reduced, and test have shown, that it is not a problem to make products without them.</i></p> <p><i>A test of shampoos from the Danish market in 2019 showed that only 10 out of 87 contained isothiazolinones:</i>  <a href="https://kemi.taenk.dk/bliv-groennere/test-25-shampoos-without-unwanted-chemicals">https://kemi.taenk.dk/bliv-groennere/test-25-shampoos-without-unwanted-chemicals</a>  <i>Similarly, only 4 out of 79 liquid hand soaps contained Methylisothiazolinone</i>  <a href="https://kemi.taenk.dk/bliv-groennere/test-chemicals-liquid-hand-soap">https://kemi.taenk.dk/bliv-groennere/test-chemicals-liquid-hand-soap</a></p>	
<p><i>Isothiazolines exclusion doable? Major yes</i></p>	
<p><i>Isothiazolines exclusion doable? Yes</i></p>	
<p><i>Isothiazolines.</i></p> <p><i>Please don't not forget the preservative DTBMA in this case. It should be regarded as an isothiazoline.</i></p>	
<p><i>BEUC finds it positive to add extra protection for the consumers in special products groups</i></p>	<p><b>Comments partially accepted</b></p>

<p><i>where relevant because of special content or exposure routes.</i></p> <p><i>We highlight that lip care products (incl. lipsticks) should have requirements on mineral oils out of an precautionary approach (see more in our comment regarding this).</i></p>	<p>In the TR3.0 it is proposed to exclude MOSHs and MOAHs unless the Cosmetic Europe recommendations for mineral oil are complied with and compliance is demonstrated</p>
<p><i>One stakeholder asked to review the decision on mineral oils in order to exclude them from lip care products due to the risk of ingestion.</i></p>	
<p><i>The dose of mineral oils ingested orally via lip care products contributes to less than 10% of the ADI value. If the recommendation of Cosmetics Europe is complied with, no health effects are to be expected from oral intake.</i></p>	
<p><i>"The recommendation from Cosmetics Europe is not mandatory and tests have shown that cosmetics do not necessarily comply with it. Therefore, the EU Ecolabel should set a requirement excluding mineral oils, or at the very least oblige compliance with Cosmetics Europe recommendation. " We still recommend that mineral oils are not used in lip products. However, if this not acceptable at least JRC should add a requirement requesting that producers follow Cosmetic Europe recommendations for mineral oil and document compliance (based on the methods provided by Cosmetics Europe). <a href="https://www.cosmeticseurope.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf">https://www.cosmeticseurope.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf</a></i></p> <p><i>Based on this rationale, it is proposed not to include MOSHs and MOAHs under the list of Specified Excluded Substances (criterion 3 (b)).</i></p>	
<p><i>"We would like to exclude MOAH and MOSH. The recommendation of cosmetics Europe are no legislation, so not legally required. In 2017 Test-Aankoop, a Belgian consumer organisation, performed a test. 15 of 21 lip balsams were not consistent with the recommendations of Cosmetics Europe. <a href="https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/lippenbalsem">https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/lippenbalsem</a></i></p> <p><i>In 2019 the same organisation conducted a test with lip balm products meant for children and also here 15 of 21 were not consistent with the recommendations of cosmetics Europe <a href="https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/merendeel-lippenbalsems-mogelijk-schadelijk">https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/merendeel-lippenbalsems-mogelijk-schadelijk</a> "</i></p>	
<p><i>Tests show that problematic mineral oils can be found in lip care products:</i></p> <p><i>A Danish declaration test showed that 35 out of 50 contained ingredients based on mineral oils or similar synthetic substances.</i></p> <p><i><a href="https://kemi.taenk.dk/bliv-groennere/test-lipsticks-may-contain-perfume-mineral-oils-and-suspected-endocrine-disrupting">https://kemi.taenk.dk/bliv-groennere/test-lipsticks-may-contain-perfume-mineral-oils-and-suspected-endocrine-disrupting</a></i></p>	
<p><i>BfR emphasises, that the recommendations are not always complied with</i></p> <p><i>« Analysis of lip care products in Switzerland and Germany demonstrate, however, that mineral oils which do not comply with this recommendation were also used in a number of products. The BfR advises manufacturers of lip care products to comply with the recommendation of Cosmetics Europe. «</i></p> <p><i><a href="https://mobil.bfr.bund.de/cm/349/highly-refined-mineral-oils-in-cosmetics-health-risks-are-not-to-be-expected-according-to-current-knowledge.pdf">https://mobil.bfr.bund.de/cm/349/highly-refined-mineral-oils-in-cosmetics-health-risks-are-not-to-be-expected-according-to-current-knowledge.pdf</a></i></p>	

<p>Tests performed in a range of European countries showed that 32 out of 32 58 tested products contained problematic mineral oils</p> <p>"18 products did follow the adapted recommendations of Cosmetics Europe: that is, they contained no more than ten per cent MOSH with a chain-length of 25 or less. When applied to long-chained MOSH (C16-C35) where accumulation in organs has been demonstrated, however, only four products comply with the Cosmetic Europe recommendation. Yet, these four products were among the 28 products where the test detected MOAH."</p> <p><a href="https://www.beuc.eu/publications/beuc-x-2017-128_problematic_mineral_oils_in_lip_care_products.pdf">https://www.beuc.eu/publications/beuc-x-2017-128_problematic_mineral_oils_in_lip_care_products.pdf</a></p>	
<p>Some stakeholders questioned the rationale behind the exclusion of phenoxyethanol in products for children, pointing that "its safety has been confirmed by the SCCS, and there is no reason for its prohibition in the Ecolabel".</p>	<p><b>Comments accepted</b></p> <p>In line with the SCCS opinion of 2016, the ban on phenoxyethanol in requirement 3(b) was removed.</p>
<p>Finally, one French cosmetic association has pointed out that phenoxyethanol has been considered as safe both for adults and children up to a concentration of 1%.</p>	
<p>"The ban of the phenoxyethanol, even for leave-on products under 12 years old is not justified.</p>	
<p>the safety of phenoxyethanol has been confirmed by the SCCS up to 1% in every kind of cosmetics products, including products for child/baby.</p>	
<p>There is no reason for its prohibition in the ecolabel. "</p>	
<p>If you ban phenoxyethanol there is not going to be many gentle preservatives left to use.</p>	<p><b>Comment rejected</b></p> <p>A SCCS opinion from 2016 states the safety of phenoxyethanol in concentrations below 0.01%, also in products marketed for children. Nordic Swan also removed the requirement after the publication of the SCCS opinion. Therefore, it is proposed not to ban phenoxyethanol in sub criterion 3(b)</p>
<p>We agree with the exclusion of phenoxyethanol in leave on products for children).</p>	<p><b>Comment accepted</b></p> <p>An exception is proposed for BHT in perfumes up to a total content of 100 ppm and a concentration in the final product of 0.001%.</p>
<p>Butylated Hydroxi Toluene (BHT) and Butylated hydroxyanisole (BHA);</p> <p>BHT is an antioxidant needed in perfumes in order to reduce the content of allergenic fragrance metabolites. We suggest to limit its use to perfumes within safe concentration levels.</p>	<p><b>Comment rejected</b></p> <p>Because the definition of ingoing substances counts release products also as ingoing substances, azo dyes that release arylamine or other CMR substances are automatically excluded (regarless the limit) according to sub-criterion 3(a) (ii)</p>
<p>formaldehyde releasers,</p> <p>If formaldehyde-releasers are mentioned here, then a requirement on azodyes should be implemented too. We suggest that you check the criteria for graphic and tissue paper.</p>	<p><b>Comment rejected</b></p> <p>The fragrance OTNE has been found by the SCCS opinion from 2012 to be an established contact allergen in humans. Moreover, according to the classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life with long lasting effects, causes skin irritation and may cause an allergic skin reaction. Therefore, it is proposed to</p>
<p>Substance OTNE has not official classification , it is in the CORAP list .</p> <p>Not to be part of "Excluded substances list".</p>	
<p>"We would like to know the rationales behind the banned material list, especially the naming of tetramethyl acetyloctahydranophthalenes (OTNE).This comment is most</p>	

<p><i>important, to ensure there is more transparency on why these ingredients are included and provide industry stakeholders a chance to comment and provide additional scientific evidence to prove this ban is not needed. Also to be noted OTNE is made predominantly from renewable feedstock and this ban will likely result in increased use of petrochemical based ingredients.</i></p>	<p>keep the ban on the substance. Relevant data from the industry will be welcomed and analysed.</p>
<p><i>Sodium fluoride Health authorities recommend using sodium fluoride in tooth paste to improve dental health. It is a dilemma. If the substance is not allowed, the toothpaste will not be recommendable for dental health.</i></p> <p><i>"We recommend derogating sodium fluoride in toothpaste.</i></p>	<p><b>Comment partially accepted</b> In the interest of preserving the dental health of the consumers and to facilitate compliance with criterion 6, the ban of sodium fluoride in EU Ecolabel products is derogated for its use in oral care products.</p>
<p><i>possibility to derogate "sodium fluoride" for use in toothpaste products.</i></p> <p><i>"We support the derogation of Sodium Fluoride and Sodium Monofluorophosphate as active ingredients in toothpaste and mouthrinse products, as these active substances contribute to caries prevention. These are multiple studies to proof safety use of these products containing fluoride. "</i></p>	
<p><i>Due to the classification as H301, and the likely ingestion of part of toothpaste, the derogation of sodium fluoride is not considered.</i></p> <p><i>A toothpaste with sodium fluoride protects the teeth. There is more harm caused by a toothpaste lacking fluoride, than what is caused in terms of possible irritation or intoxication.</i></p>	
<p><i>"SCCS has published a new opinion on the use of Aluminium in cosmetics: <a href="https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf">https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf</a> New safe values have been given for a number of product types. They do not mention the extended use of MICA (aluminium silicates) in make-up. This requirement will make the certification of make-up products difficult."</i></p>	<p><b>Comments accepted</b> The JRC has revised the documents suggested by stakeholders and has decided to delete the requirement for the exclusion of aluminium salts in EU Ecolabel products. Compliance with the safety thresholds specified in the SCCS opinion from 2019 is guaranteed by the requirement that SCCS opinions must be taken into account.</p>
<p><i>"Exclusion of aluminium and all its salts has no scientific basis. Please refer to the latest SCCS opinion: <a href="https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf">https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf</a></i></p> <p><i>The issue under debate is in relation to certain aluminum containing substances but not the element itself or all substances associated with it. The scope of this exclusion has to be reviewed in light of the recent SCCS Opinion and what substances, specifically, might be excluded if any given the SCCS Opinion and subsequent discussion in the DG GROW WG (June 2020). Limits for affected INCI's must be consistent with safe use by law and it is disproportionate to prohibit all aluminium salts."</i></p>	
<p><i>As a very recent opinion of SCCS concluded that the use of aluminium in cosmetic products is safe (concentrations of 6.25% and 10.60% in non-spray antiperspirants and spray</i></p>	

<i>antiperspirants respectively and at concentrations of 2.65% in toothpaste and 0.77 % in lipstick) we think that we should take into account this most recent scientific opinion.</i>	
<i>The European Aluminium Association, a member of Eurometaux, wishes to express its concerns regarding the proposed restriction on aluminium and its salts in leave-on products. These concerns are expressed in the attached document</i>	
<i>Substances that are not aerobically readily biodegradable cannot be used in EU Ecolabel products according to current criteria 2.</i>	<b>Comment clarified</b>
<i>This is not correct, the amount of substances that are not aerobically readily biodegradable is limited but there is no ban. So Phosphonates which are aerobically not readily biodegradable have to stay in this list</i>	Phosphonates which are aerobically not readily biodegradable have already been included in the exclusion list in TR2.0
<i>Table 14: CLP classification for the alternatives for SLS</i>	<b>Comment rejected</b>
<i>Excepted for Sodium N-lauroylsarcosinate, all the proposed alternative are either H411 either H317 that is worst than SLS classification</i>	Some organisations are critical of the use of sodium lauryl sulphate (SLS) in toothpaste. Alternatives to SLS such as sodium-C14-C16 oleofin sulphonate, sodium, lauryl sarcosinate, cocamidopropyl betaine or Stearath 30, all of which are less irritating to the skin. It is proposed to keep the ban of SLS in toothpaste, but data from industries will be welcomed and analysed.
<i>We are against the exclusion of all phthalates. DEP is not classified and it should be exempted from the requirement.</i>	<b>3(b) - phthalates Accepted</b>
<i>P hthalates: only if classified with one or more "forbidden" H phrases. Alignment with other ecolabels is desirable, but it may not trump science.</i>	Only phthalates classified with one or more H phrases listed in Table 3a are banned
<i>Additionally we would like to understand the complete ban of all phthalates (incl. Diethylphthalate)"</i>	
<i>H alogenated and/or aromatic solvents: only if classified with one or more "forbidden" H phrases.</i>	<b>Comment rejected</b>
	Most halogenated and aromatic solvents are prohibited in cosmetics according to the Cosmetics Regulation. Moreover, they will be restricted if being assigned one or more H classes. Therefore, there is no need to specify this requirement.
<i>P lease give a definition on "perfluorinated and polyfluorinated compounds" (preferably REACH-based)</i>	<b>Comment partially accepted</b>
	It was not possible for the JRC to find a definition of PFAS in a piece of legislation. However, a footnote has been added to the criterion text for clarification purposes
<i>On the way the ban is introduced in existing criteria, do I understand correctly that what is banned is the addition to the final product, so if there are PFAS in the materials used or in parts, they can still be present in the final product? In practice, are they often added to the final product or is it the case only for specific applications (fire-fighting, contact with food...)?</i>	<b>Comment clarified</b>
	The exclusion list refers at the substance/mixtures level which is added to the product, regardless of the stage at which the addition is done. This has been clarified in TR3 and the opening sentence of criterion 3(b) has been amended to increase its clarity
<i>N anosilver is a biocide, as far as I am aware, would it not be excluded from the beginning?</i>	<b>Comment clarified</b>
	Nanosilver is an antimicrobial agent that can be seen as a biocidal under certain condition. To be on the safe side, nanosilver is mentioned
<i>The proposal for criterion 3(c) now excludes substances identified as SVHCs from being added to the product, regardless of their concentration. Since the concentration limit has</i>	<b>Comment rejected</b>
	While it would make sense to add SVHCs to the 3(b) list, in the interest of

<p><i>now be dropped it could be considered to merge this criterion with the previous one 3(b) and add it to the list of specified excluded substances.</i></p>	<p>aligning with the structure of the criteria with other similar product groups (e.g. detergents), the structure has not been modified</p>
<p><i>It is very positive from the consumer perspective, that SVHCs are excluded. If the SVHCs are allowed, it will be very difficult to communicate to consumers why they are allowed, and it will lower the potential impact of the EU-flower on cosmetics. SVHCs are fully restricted in the Ecolabel Nordic Swan showing that the restriction is doable.</i></p>	<p><b>Comments acknowledged</b></p>
<p><i>Based on the EU Ecolabel Regulation SVHC shall not be present in any Ecolabelled products!</i></p>	
<p><i>Do stakeholders agree with the increase of ambition level with regards SVHCs? Major YES!</i></p>	
<p><i>Restrictions on Substances of Very High Concern (SVHCs)</i></p> <p><i>We support the evolutions proposed between the first technical report and the second for this criterion.</i></p>	
<p><i>3c SVHC. Denmark can support the proposal.</i></p>	<p><b>Comment clarified</b></p> <p>Criterion 3(c) applies to all ingoing substances, which means all substances in the cosmetic products. However, impurities may still be found that do not comply with criterion 3(c). impurities are defined as Impurities' means residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the final product in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the leave on product. Therefore, impurities technically unavoidable are already exempted by this requirement</p>
<p><i>Firstly, we would like to emphasize that substances included in the candidate SVHC list are not prohibited in cosmetics until a restriction is regulated (for instance, with the publication of Regulation CMR Omnibus).</i></p> <p><i>Furthermore, according to article 15.1 and 15.2. of Regulation 1223/2009:</i></p> <p><i>"1. The use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. [...]"</i></p> <p><i>"2. The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.</i></p> <p><i>However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, all of the following conditions are fulfilled:</i></p> <p><i>(a) they comply with the food safety requirements as defined in Regulation (EC) No 178/2002</i></p> <p><i>(b) there are no suitable alternative substances available, as documented in an analysis of alternatives;</i></p> <p><i>(c) the application is made for a particular use of the product category with a known exposure; and</i></p>	

<p><i>(d) they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups."</i></p> <p><i>So, if the cosmetics industry get an exception of a substance classified as CMR, because it has been evaluated and considered safe by SCCS and by the competent authorities, the presence of that substance must be allowed in the final product.</i></p> <p><i>On the other hand, according to Article 17 "Traces of prohibited substances" of the CPR:</i></p> <p><i>"The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3</i></p> <p><i>Therefore, we consider that impurities technically unavoidable under GMP should not be subject to restrictions, provided that their use is shown to be safe under normal or reasonably foreseeable conditions for use, as set out in the cosmetic regulation.</i></p>	
<p><i>Most of stakeholders expressed their interest in setting a specific exclusion on fragrances, which in their opinion are quite overlooked in this set of criteria. This exclusion should target the 26 fragrances officially recognized by SCCS as sensitizers and additionally the 82 fragrance allergens object of the public consultation in the framework of the Cosmetics Regulation. One stakeholder mentioned that "if SCCS opinions are adopted when unambiguous, the exclusion of the 26 fragrances mentioned above would follow implicitly".</i></p>	<p><b>Accepted</b> A new item has been added to the exclusion list: "the 26 fragrances officially recognized by SCCS as sensitizers and additionally the 82 fragrance allergens object of the public consultation in the framework of the Cosmetics Regulation"</p>
<p><i>The discussion mainly focused on criterion 3 (d) on fragrances. Stakeholders suggested to ban completely the use of fragrances marketed for children, while restricting its use in other products, as illustrated in the following comments:</i></p> <p><i>"Regarding the fragrances, we ask for exclusion from 0,01% (rinse-off products) and 0,001% (leave on products)</i></p> <ul style="list-style-type: none"> <li>- <i>all H317 and H334 substances and especially</i></li> <li>- <i>Sensitizing fragrance ingredients listed in Table 13-1 of the SCCS-opinion on fragrance allergens in cosmetic products, 26-27 June 2012 (54 individual chemicals, 28 natural extracts (mixtures of chemicals), including all 26 fragrance allergens identified by SCCNFP in 1999)"</i></li> </ul> <p><i>"Moreover, specifically for children, I suggest if we improve the restriction of fragrances to allow it for children product as we'll guarantee a good health security."</i></p>	<p><b>Comments partially accepted</b> In the TR3.0 it is proposed that the 82 substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' are restricted in EU Ecolabel products up to 0.01% in rinse-off products and 0.001% in leave-on products. HICC, Atranol and Chloroatranol are already forbidden according to the Annex II of Cosmetics Regulation (entries 1380, 1381, 1382), so their exclusion in EU Ecolabel is not needed</p>
<p><i>Please confirm, that substances that are "Established contact allergens in humans" from the SCCS opinion are covered by criterion 3 (a) (i) [at a maximum of 0.001% (10 ppm) in leave-on products and a maximum of 0.01% (100 ppm) in rinse-off products]. If not, they should be explicitly excluded.</i></p> <p><i>Please confirm, that all the substances that are "Established contact allergens in humans" from the SCCS opinion are covered by criterion 3 (a) (i). If not, they should be explicitly excluded.</i></p>	

We would favor a full exclusion regardless of concentration, at the very list at a maximum of 0.001% (10 ppm) in leave-on products and a maximum of 0.01% (100 ppm) in rinse-off products.

"The EU Ecolabel should also take into account the substances established as contact human allergens by the SCCS opinion from 2012, as they are of equivalent concern than all 26 perfumes that are currently subject to declaration ([https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_102.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_102.pdf))

The Nordic Swan restrict the 26 substances that are currently subject to declaration plus additional fragrances.

In addition to the restriction under 3a of classified allergens, the 26 fragrance allergens which are obligatory to declare if present in products above 10 ppm or 100 ppm (for leave-on and rinse-off respectively) should be restricted in the same manner.

#### 3(d) Fragrances

The criteria on sensitizing fragrance compounds are not protective enough. The sensitizing substances listed in Annex III (with reference number 67-92) of the Cosmetics Regulation (EC) No 1223/2009 should be limited to a maximum of 0.01% in rinse-off products and 0.001% in leave-on products. The same limits should apply to sensitizing fragrance compounds listed in the SCCS opinion as established allergens of concern for humans (Table 13-1). "

Requirement 3(d) Fragrances Major We would like to support the proposition of Austria to exclude the fragrance allergens (from 0,01% (rinse-off products) and 0,001% (leave on products)) listed in Table 13-1 of the SCCS-opinion on fragrance allergens in cosmetic products, 26-27 June 2012.

We would like to have excluded the SCCS 2012 opinion substances to a limit at 0.01% in rinse-offs and 0.001% in leave-ons

We would like to exclude the SCCS 2012 opinion substances totally (regardless of their concentration in the products)

Fragrances included in the SCCS 2012 opinion should be restricted in EU Ecolabel

We are in favour of excluding the SCCS 2012 opinion substances

We would like to exclude the SCCS 2012 opinion fragrances

#### 3d fragrance

The official Danish position is to exclude fragrances in ecolabelled products, as environmental carrying people expects ecolabelled products not to contain fragrances.

As a start, Denmark proposes that:

- A fragrance substance/flavouring/fragrance substance in plant extract which is judged to be sensitising with the hazard statement H317 and/or H334, or covered by the Cosmetic regulation and subject to a declaration on the product, may not be included above 0.0010 % (10 ppm) in leave-on products (see section 2 Biodegradability and aquatic

<p>toxicity for definition) and a maximum of 0.010 % (100 ppm) in rinse-off products</p> <ul style="list-style-type: none"> <li>• Products which contains fragrances shall be clearly marked on front with "Contains fragrance/perfume"</li> <li>• HICC, chloroatranol and atranol are not permitted in the product.</li> <li>• The fragrance substances in table 2 (Swan criteria), may be included in products with a maximum of 100 ppm (0.010%) for rinse-off products and a maximum of 10 ppm (0.0010%) for leave-on products per substance.</li> </ul>	
<p>"As fragrance allergy accounts for 30-45% of reaction tp cosmetic products. A list of sensitising fragrances has been established in 2012, but nothing happened in the cosmetics regulation until now. " "We ask to add</p> <p>From 0,01% (rinse-off products) and 0,001% (leave-on products) following substances are excluded:</p> <p>Sensitizing fragrance ingredients listed in Table 13-1 of the SCCS-opinion on fragrance allergens in cosmetic products, 26-27 June 2012 (54 individual chemicals, 28 natural extracts (mixtures of chemicals), including all 26 fragrance allergens identified by SCCNFP in 1999)"</p>	
<p>Fragrance</p> <p>We wish to receive information from the JRC about other stakeholders' feedback on this criterion and on the possibility of authorizing some fragrance with additional restrictions for products marketed as designed and intended for children.</p>	<p><b>Comment clarified</b></p> <p>The list of all comments received during the written consultation period and JRC's responses is attached as an Annex to the TR3</p>
<p>"Cosmetic products that are specially developed for children under the age of 3 or allergy sufferers and marketed accordingly must not contain any fragrances." Indeed it was explained that "the more children are exposed to fragrances, the higher the risk that allergies develop", therefore stakeholders ask to ban also fragrances which have not been identified as being sensitizing up to now.</p> <p>In some of EU countries, products for children (shower gel, toothpastes, body milks...) can't be sold without fragrance.</p> <p>We totally agree to have stricter restriction for children regarding fragrance (tohave a good health security) We propose to include restriction about skin allergens in the fragrance (SCCNFP 26 allergens and SCCS 82 allergens (list 13.1) ) about H317 substances in the fragrance.</p> <p>We also can extend the fragrance restriction by excluding H412 substances in order to have better environmental profile.</p> <p>for leave on products we would like lower thresholds as well as in baby products where there should not be any fragrance.</p> <p>Finally, some stakeholders highlighted the importance of flavours in toothpaste for children, as their absence would discourage children to clean their teeth: "If flavours are considered</p>	<p><b>Comments partially accepted</b></p> <p>It is important that products marketed for children must not contain fragrances in order to limit the cumulative exposure and thus the risk that allergies develop. Therefore, the current ban on fragrances in products for children was kept. However, an exception was made for toothpaste for children.</p>

<p>to be "fragrances" in toothpaste, then they need to be included in children's toothpaste otherwise they will not tolerate using the toothpaste due to the taste, this would discourage children to clean their teeth... therefore we want to stress that flavours are needed for children's toothpaste for dental health reasons".</p>	
<p>3(d) Fragrances Multifunctional ingredients exerting notably a perfuming function, such as essential oils, should also be covered by this restriction, regardless of other possible functions declared by the applicant</p>	<p><b>Comment partially accepted</b> A new restriction has been added in the TR3 on the 82 allergens from the SCCS opinion of 2012. This list includes also multifunctional ingredients.</p>
<p>One stakeholder suggested to align with the criterion in Nordic Swan and to impose a label on the packaging warning that the product contains fragrances, when it is not possible to completely exclude them. The labelling should also state when a product contains perfume. However, one stakeholder mentioned that "products should not have to place contains fragrance on-pack since conditions for optional claims are already in place according to the rules set by the Sub-Working Group on Claims".</p>	<p><b>Comment rejected</b> The list of sentences that can be put on a product is detailed in criterion 8</p>
<p>Criterion 3e, Denmark can support the proposal</p>	<p><b>Comment acknowledged</b></p>
<p>Other comments referred to the criterion 3 (e) on preservatives, which should be banned regardless of their concentration if classified as H317 (due to the low amount in which there are used in the formulations).</p>	<p><b>Comments rejected</b></p>
<p>Preservatives which are classified with H317 according to CLP should not be permitted, regardless of concentration. "Preservatives which are classified with H317 according to CLP should not be permitted, regardless of concentration.3 (e), Preservatives (x) "The preservative must not be classified with H317 May cause an allergic skin reaction""</p>	<p>Substances H317 are already restricted according to criterion 3(a).</p>
<p>Preservatives used in toothpaste This must concern all products in contact with the mouth.</p>	
<p>Preservatives and colorants  As part of lipsticks and nail polishes can be easily swallowed by the consumer, we recommend applying the restriction on preservatives approved as food additives, according to Regulation (EC) No 1333/2008 on food additives to lipsticks and nail polishes as well.</p>	<p><b>Comment accepted</b> Mouthwash and lip care products were also added to this requirement. Additionally, nail lacquers were also included in the requirement.</p>
<p>Preservatives exemptions needed for some animal care products? No, since not all the animal care products are for biocidal functions. There are lots of normal shampoos and they do not need biocidal properties.</p>	
<p>Do we need to exempt some preservatives for use in animal care products, due to the likely higher biocidal functions required? (Annex II)  Minor  No. Biocidal products should not be covered by the ecolabel."</p>	<p><b>Comments accepted</b> No change was made to the report</p>
<p>it is proposed to keep the strictest cut-off values  Major We agree with this proposal in order to maintain the selectivity of EU</p>	<p><b>Comment acknowledged</b></p>

<p><i>Ecolabel products.</i></p> <p><i>Another stakeholder asked to remove the requirement on the approval of preservatives/colorants as food additives: "Why are preservatives and colourants singled out to be food grade while other ingredients in toothpaste are not? Cosmetic grades as well as food grade are currently used under EU law and are safe".</i></p>	
<p><i>(ii) Colorants used in toothpaste must be approved as food additives according to Regulation (EC) No 1333/2008 on food additives.</i></p> <p><i>It is foreseen that preservatives in toothpastes should have been approved as food additives. It seems not appropriate that preservatives in toothpasted should have been approved as food additives. Food additives are authorized in specific food categories with particular conditions of use which may totally differ from exposure from toothpastes. Moreover it is legally required that the ingredients of toothpastes are safe taking into consideration the fact that it is party swallowed. Delete this requirement</i></p>	<p><b>Comments rejected</b></p> <p>Regulation 1333/2008 also applies on food additives for purposes other than those covered by the Regulation. Therefore, use in cosmetics product is also covered. Moreover, colorants in toothpaste are not essential in the formulation. Finally, Nordic Swan and Blue Angel have licences for toothpaste despite the existence of this requirement. Therefore, it is proposed to keep the requirement on colourants to be used in toothpaste.</p>
<p><i>Colourants: include additional product groups (e g lipsticks): yes</i></p> <p><i>Criterion 3f is more relevant now when also decorative cosmetic is included in the scope. Denmark suggest the following changes:</i></p> <ul style="list-style-type: none"> <li><i>• Bismuth Oxychloride cannot be added to decorative cosmetics.</i></li> <li><i>• Cd, Lead, Mercury shall have a limit at 1 ppm and not 10 ppm.</i></li> </ul>	<p><b>Comments partially accepted</b></p> <p>Regulation 1333/2008 also applies on food additives for purposes other than those covered by the Regulation. Therefore, it is proposed to expand criterion 3 (f) (ii) to other products in contact with the mouth. Moreover, it is proposed to modify the requirement 3 (f) (iii) so that Lead and Mercury have a stricter limit at 1 ppm.</p>
<p><i>Colorants used in toothpaste</i> <i>This must concern all products in contact with the mouth.</i></p>	
<p><i>(iii) The use of barium, lead, mercury, cadmium, six inhalant chromium, nickel and bismuth in colourants for decorative cosmetics and hair dyes is restricted to concentrations below 10 ppm.</i></p> <p><i>"We disagree for the restriction of lead in colorant below 10ppm.</i></p> <p><i>this would exclude all organic products using ochre (which are natural colourant). if decoratives products are included in the scope of the ecolabel, the products certified as organic should be encouraged. these products might contains more than 10ppm of lead but have a safety evaluation validated a safe use of these products.</i></p> <p><i>natural colorant should not be excluded in favor of synthetic colorant. This is not consistant with ecolabel philosophy.</i></p> <p><i>As already commented, we do not agree with the level of lead defined : it would exclud all natural colorants and decorative cosmetics certified as organic which contains them.</i></p> <p><input type="checkbox"/> <i>these organic products should not be excluded from the scope of the ecolabel.</i></p>	<p><b>Comments rejected</b></p> <p>As lead is very accumulative, and social concern is raising on its content in cosmetics, especially in lipstick, it is important to set a strict limit on its presence in EU Ecolabel cosmetics. Studies found that the average content of Pb is 0.36-1.38 ppm in lipstick and eye powder, suggesting that even a limit of 1 ppm is doable.</p>
<p><i>" Colorants which are classified with H317 according to CLP should not be permitted, regardless of concentration.</i></p> <p><i>" 3 (f), Colorants (x)</i></p> <p><i>"The colorant must not be classified with H317 May cause an allergic skin reaction""</i></p>	<p><b>Comments rejected</b></p> <p>Substances H317 are already restricted according to criterion 3(a).</p>

<p><i>We are not in favour of the inclusion of decorative cosmetics because as you mentioned during the first AHWG, there is a low risk of release into water and we consider that this kind of products is not in the spirit of the EU Ecolabel.</i></p> <p><i>Moreover, regarding the restriction of heavy metals, we should not encourage this kind of products (decorative cosmetics).</i></p>	<p><b>Comment rejected</b> See the scope section in TR3</p>
<p><i>"Most of these substances (lead, mercury, ...) are forbidden in cosmetic products and cannot be used. Therefor it is better to change ""the use of barium,..."" into "" the presence of barium,..."". For contaminants/impurities, the word 'presence' is more appropriate.</i> " Change "the use of barium,..." into " the presence of barium,..."</p>	<p><b>Comment accepted</b> The wording has been changed in the criterion text. Please Check TR3.0</p>
<p><i>UV filters</i></p> <p><i>We strongly disagree with the creation of this criteria. French stakeholders have expressed a shared opinion on the fact that there exists no biodegradable alternative to UV filters. Thus, we think that the inclusion of sunscreen products in the scope represents a substantial risk for the EU Ecolabel reputation.</i></p>	<p><b>Comment rejected</b> See the scope section in TR3</p>
<p><i>We are not in favour of the inclusion of sun screens (because they contain problematic substances).</i></p> <p><i>If we keep sun screens in the scope, we don't agree to accept UV filters in all leave-on products, only in sun screens because these substances represent a danger to the environment.</i></p>	<p><b>Comment rejected</b> See the scope section in TR3</p>
<p><i>Finally, one stakeholder suggested to include a requirement on marine biodegradability for sunscreens, using existing ISO tests: "sun care products have partially an end of life in marine so marine test such as may be added: 1) Luminescence inhibition test ISO 11348-3:2007; 2) Algal growth inhibition test (ISO 10253:2006) on the marine diatom micro-algae Pheodactylum tricornutum".</i></p>	<p><b>Comment rejected</b> The JRC conducted further research on this topic, and relevant studies were found, using especially the test ISO 10253 to carry out an ecotoxicological evaluation of UV filters. However, the existing evidence does not provide enough data to set robust requirements, e.g. setting toxicity thresholds. Therefore, such methods, although potentially relevant, could not be introduced in the EUEL requirement on UV filters</p>
<p><i>"Criterion 3 (g) UV filters UV filters in general possess problematic environmental properties and should therefore only be allowed in products where they are necessary, i.e sunscreen products. "</i></p> <p><i>Criterion 3 (g) UV filters UV filters may only be added to [Delete: leave-on products] [Replace by:] sunscreen products and only to protect the user- not the product."</i></p> <p><i>Only one stakeholder shared its opinion on that topic during the 1st AHWG meeting: UV filters should only be allowed in sun care products and forbidden for all other type of cosmetics (such as daily facial creams or shampoos).</i></p> <p><i>Major "We agree with this restriction. If we keep sun screens in the scope, we don't agree to accept UV filters in all leave-on products, only in sun screens because these substances represent a danger to the</i></p>	<p><b>Comment partially accepted</b> There may be cases of products with multi functions: e.g. a leave on product which works as hydrating cream and as a sunscreen, or a foundation with UV filters included. The presence of UV filters should be allowed in these products, as long as the filter is included to protect the user. Therefore, the wording of the requirement has been modified to reflect this need.</p>

<p>environment."</p> <p>only be added to leave-on products and only to protect the user – not the product.  Minor There may be cases where UV filters do both, protecting the user and the product. In such cases it would be relevant to know whether compliance with the EU EEL criteria is still given. Please consider.</p>	
<p>Criterion 3g Denmark can support the proposal, but we would like JRC to prepare a list of UV filters passing the criteria and UV filters not passing:  All organic UV filters contained in the product:  - must not be bioaccumulating (BCF&lt;100 / log Kow&lt;3) or must have a lowest measured toxicity of NOEC/ECx &gt; 0.1 mg/l or EC/LC50 &gt; 10.0 mg/l</p>	<p><b>Comment partially accepted</b>  This task is out of the scope of the TR3. However, a non-hexhaustive list can be prepared for inclusion in the user manual.</p>
<p>As to the provisions for the use of TiO2 as UV filter (page 14), please check Annex VI of CPR. TiO2 has been classified as a CMR for inhalation route only. Currently, it is under SCCS assessment for an exemption under Article 15 of the CR.</p>	<p><b>Comment acknowledged</b></p>
<p>as far as I know the danger for the use of TiO2 concerns inhalation, so there should not be problems for its use in cosmetics. Nevertheless, could be a solution to differentiate its use, so for example no derogation for toothpaste, but possibility to derogate for sun screens where lots of eco products use it as physical barrie</p> <p>"TiO2 must be exempted.</p> <p>Its bann would exclude the sun products certified as organic from the scope of the ecolabel.</p> <p>The TiO2 is classified CMR by inhalation. TiO2 should be used according to the SCCS opinion which will be adopted at the end of the summer. "</p> <p>If a derogation is considered (TiO2), it should not be given to products where inhalation can be an exposure route (e.g. spray, powder,...). BEUC recommends narrowing the derogation only for essential uses.</p> <p>Finally, with respect to criterion 3 (g) on UV filters, one stakeholder expressed the concern that the potential exclusion of TiO2 (due to its reclassification as carcinogenic) would exclude all pure mineral sun care products.</p> <p>If TiO2 is to be derogated, it should be only for its use as UV filter in sunscreens. Another possibility would be to exclude sunscreens from the scope and not derogate TiO2</p> <p>We are in favour of derogating TiO2 if not used in sprayable products/packaging</p> <p>We may need to derogate TiO2</p> <p>If TiO2 is to be derogated, only for its use as UV filter in sunscreens, which should be included in the scope. All use in powder form should be banned</p> <p>We believe we should derogate TiO2 if not used in sprayable products/packaging</p> <p>We are in favour of derogating TiO2</p> <p>TiO2: as it is only carcinogenic by (dust) inhalation, liquid or gel products should not be affected (or they can get a derogation).</p>	<p><b>Comments partially accepted</b>  The derogation of TiO2 has been investigated in TR3.0. It was decided to derogate its use in leave on products with sun protection function, if used as UV filter, complying with the SCCS opinions published so far and not used in sprays or inhalable formats.</p>

<p>Regarding the TiO<sub>2</sub>, we recommend anticipating its classification with H351 and already prohibit it in the standard.</p>	<p><b>Comments rejected</b></p>
<p>We believe a derogation for TiO<sub>2</sub> is not needed because we are against the inclusion of sunscreens</p>	<p>Please see the rationale behind the derogation in the TR3</p>
<p>-if including nano TiO<sub>2</sub> coated with either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and triethoxycaprylylsilane (up to 3% and 9% respectively), the product must not be in the form of powders or sprayable products. Minor Editorial: Suggestion to add [...] with combinations of either silica and cetyl phosphate [...]. It is not fully clear from the current text whether you always refer to combinations of two substances or not.</p>	<p><b>Comment accepted</b> Please check TR3</p>
<p>A written confirmation Who shall write this confirmation ? Manufacturers of raw materials or applicants ? Both ?</p>	<p><b>Comments clarified</b></p>
<p>For 3(b) ii) we must require a compliance declaration from manufacturers and applicants. For 3(e) i) we must require a compliance declaration from manufacturers of preservatives.</p>	<p>Declarations and confirmations shall be filled/written by the manufacturers of the raw materials. This will be further clarified in the user manual.</p>
<p>In addition, a declaration that, if used, nano TiO<sub>2</sub> fulfils the conditions expressed in Annex VI of Regulation EC 1223/2009 and its latest amendments must be provided. This declaration shall be provided by manufacturer of UV filter.</p>	
<p>To demonstrate compliance with 3(e) (i) further documentation is need than the one described. In our opinion, the applicant shall either send in documentation concerning degradation products, or, if JRC considers it sufficient, a written confirmation that the preservatives used do not release or degrade to substances that are classified in accordance with the requirements of criterion 3 (a). " "To demonstrate compliance with 3(e) the applicant shall provide: copies of the SDS of any preservative added, and information on its BCF and/or log Kowvalues.  To demonstrate compliance with 3(e) (i), the applicant shall either send in documentation concerning degradation products, or, if JRC considers it sufficient, a written confirmation that the preservatives used do not release or degrade to substances that are classified in accordance with the requirements of criterion 3 (a)."</p>	<p><b>Comment rejected</b> The proposed definition of 'ingoing substances' includes 'substances known to be released or degraded from ingoing substances [...]'. Therefore, the whole set of criteria also applies to degradation products from preservatives, that shall therefore comply with criterion 3 (a).</p>
<p>SDS of any substance/mixture and their concentration in the final product.  The sentence "To demonstrate compliance with 3(a), 3(b) and 3(c) the applicant shall provide:(i) SDS of any substance/mixture and their concentration in the final product" indicates that assessing the SDS for the mixture is sufficient, but it may not be the case, if the substance is present below the concentration where It has to be stated in the SDS of the mixture. " "To demonstrate compliance with 3(a), 3(b) and 3(c) the applicant shall provide:(i)SDS of any substance/[delete: mixture] and their concentration in the final product. (ii)A written confirmation that 3(a), 3(b) and 3(c) is fulfilled."</p>	<p><b>Comment rejected</b> It was finally decided to keep the wording to substances/mixtures, so this must be reported as well in the assessment and verification. Please see TR3 for details</p>
<p>Editorial: It should read Isothiazolinones</p>	<p><b>Comments accepted</b></p>

<p>The word "isothiazolinone" is misspelled on page 13 of the Annex I</p> <p>DEA Minor Editorial: Please provide full text of the acronym.</p> <p>Butylated Hydroxi Toluene Minor Editorial: It should read Hydroxytoluene</p> <p>six inhalant chromium Minor Editorial: Please clarify if you refer to hexavalent chromium (Chromium VI).</p> <p>Regulation 1223/2008 Major Editorial: It should read 1223/2009. Regulation 1223/2008 refers to establishing the standard import values for determining the entry price of certain fruit and vegetables.</p>	<p>Please see specific changes in the criterion text</p>
<p>3(b) Specified excluded substances</p> <p>The reference should be to "Regulation (EC) No 1223/2009" not "Regulation 1223/2008"</p>	
<p>Annex I: Second proposal for criterion 3: Hazardous substance restrictions</p> <p>We strongly support the suggested "No-limit" threshold for these requirements, which is now clarified in the table on pages 26-27. However, the wording in criteria 3 (a) (ii), 3(b) and 3 (c) is a bit unclear. We suggest the following:</p> <p>3 (b) "The product shall not contain any substances that meet the criteria for classification with the hazard statements listed in Table 6, regardless of concentration"</p> <p>3 (b) "The product shall not contain any of the substances below, regardless of concentration"</p> <p>3 (c) "The product shall not contain, regardless of concentration, any substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation"</p> <p>"Delete: 3 (a) (ii) ""No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall be added in the final product or its ingredients, regardless of their concentration""</p> <p>and replace by: 3 (a): ""The product shall not contain any substances that meet the criteria for classification with the hazard statements listed in Table 6, regardless of concentration"".</p> <p>Delete: 3(b) ""Specified excluded substances The substances listed below shall not be added in the final product: ""</p>	<p><b>Comments partially accepted</b> Please see TR3 for the modifications implemented</p>

<p><i>and replace by 3 (b) ""The product shall not contain any of the substances below, regardless of concentration"".</i></p> <p><i>Delete 3(c): ""Restrictions on Substances of Very High Concern (SVHCs) Ingoing substances and mixtures meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation shall not be added to the product, regardless of their concentration"".</i></p> <p><i>and replace by 3 (c) The product shall not contain, regardless of concentration, any substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation."</i></p>	
<p><i>Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate;</i></p> <p><i>Shall not be added to the product, does this mean as impurities from production? For instance cosmetic substances will use phosphates in their production and these substances may be used during production (e.g. pH-adjustment).</i></p>	<p><b>Comment clarified</b> The requirement applies also to impurities.</p>
<p><i>How shall we deal with products marketed as "family products" ? Can you confirm they are considered as children's products too ?</i></p>	<p><b>Comment clarified</b> family products are considered designed and marketed also for children older than 3 years.</p>
<p><i>We are not obliged to duplicate other schemes. We can define our own restrictions for the EU Ecolabel.</i></p> <p><i>As already mentioned, it's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel, in particular for packaging because reducing plastic waste is a major environmental issue!</i></p> <p><i>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market.</i></p> <p><i>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme.</i></p>	<p><b>Acknowledged</b></p>
<p><i>In order to reduce plastic waste – a major environmental issue – it's essential to encourage applicants to provide refills because there is a huge waste of plastic whereas bottles could be refilled! At least, it must be mandatory for packagings using pumps.</i></p> <p><i>Moreover these refills must have an equivalent or higher capacity to the capacity of the bottle for refilling. Indeed providing refills with a lower capacity is not an ecological option.</i></p>	<p><b>Comment partially accepted</b> Criterion 4.a specifies that refills shall have an equivalent or higher capacity. It was additionally specified in TR2.0 that refill option shall be mandatory for products using pumps.</p>

<p><i>It's necessary to oblige applicants to provide these refills, to sell them and to promote their use by consumers thanks to information provided on labels.</i></p> <p><i>As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel, in particular for packaging because reducing plastic waste is a major environmental issue !</i></p> <p><i>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market.</i></p> <p><i>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.</i></p>	
<p><i>[the inclusion of a requirement on mandatory provision of refill bottles for some cosmetics; at least for products sold with pumps.]</i></p> <p><i>We strongly appreciate the inclusion of this requirement which must be kept mandatory.</i></p> <p><i>You can specify that for leave-on products (more viscous and thicker than products in the current scope), the refill can be the same packaging with cap and without pump in order to reuse several times this pump.</i></p> <p><i>For products sold without pump, you can encourage applicants to provide also refills with the reduction of PIR threshold.</i></p>	
<p><i>[For the products sold with pump, a refilling option should be provided in the same or higher packaging capacity.]</i></p> <p><i>We ask to remove this requirement. In some european countries, the mass market is not open to sell so much refills. Even if we propose refills, the product can not be accepted in stores. We are in favor of inciting this topic but that needs time to be accepted in stores. Waiting for this evolution, we ask to not make the criterai mandatory.</i></p> <p><i>If you want to let the criteria, I think it is important to limit the restriction for rinse-off cosmetics. For example products in spray like decorative cosmetics, body milk, sun screen products can't be proposed in refill</i></p>	<p><b>Comment partially accepted</b>          Considering the practical difficulties to refill leave on products, it has been specified that the requirement apply to rinse off products.</p>
<p><i>Primary packaging</i></p> <p><i>We support the refilling option for products sold with a pump, provided that a requirement is introduced on the difference in weight between the initial packaging and the refill, this to ensure that the refill has a lower environmental impact than the initial packaging. However, we advise to restrain this criterion to rinse-off products as it could be difficult to reach for leave-on products newly included in the scope, especially seasonal products such as sunscreen products.</i></p>	

<p>What about multipacks of products? Do they get an exemption as something has to hold them together?</p> <p>Add an exemption for multi-packs.</p> <p>Multipacks of products (such as two toothpastes sold together) need to have something to hold them together, so must have additional packaging.</p> <p>In relation to secondary packaging, a stakeholder mentioned that toothpaste cannot be refilled and suggested that secondary packaging should be allowed for toothpaste as 2-3 pack are a more sustainable solution.</p>	<p><b>Comment partially accepted</b></p> <p>An exemption has been included for toothpastes in order to allow the use of secondary packaging for multipacks of toothpastes.</p>
<p>Moreover, we suggest removing the exception on secondary packaging intended to group the product and its refill. Removing plastic packaging only used for product grouping is one of the pillars of work of the French National Pact on plastic packaging. In addition, it should be possible to purchase the refill independently from the bottle.</p>	<p><b>Comment rejected</b></p> <p>The use of secondary packaging is only allows to pack the products with its refills. This does not prevent the purchases of the refill independently of its product.</p>
<p>Small packaging are also stored in secondary packagings (it is not a case of product with its refill).</p> <p>Considering you choose to keep small packagings, the proportion of carboard (including these small bottles) should be taken into account in the calculation of W (proportion of secondary).</p> <p>Indeed, the weight of cardboard is not included in the CURRENT calculation because we consider the customer of the hotel as the final user and this cardboard is used as transport packaging but it's not only a transport packaging, it's a storage packaging too !</p> <p>Please feel free to contact me if you need more details !</p> <p>For clarification purpose, secondary packaging is also packaging (for instance cardboard) around several similar items for the purpose of transport, not just "the product and its refill" ?</p>	<p>Cardboard boxes used to transport the products to the retail stores should not be considered as secondary packaging. This has been specified in the revised text.</p>
<p>We strongly appreciate the inclusion of this requirement which must be kept mandatory.</p> <p>You can specify that for leave-on products (more viscous and thicker than products in the current scope), the refill can be the same packaging with cap and without pump in order to reuse several times this pump.</p> <p>For products sold without pump, you can encourage applicants to provide also refills with the reduction of PIR threshold.</p>	<p><b>Comment rejected</b></p> <p>Refills are not common practice for leave on products. Considering the practical difficulties to refill leave on products, it has been specified that the requirement apply to rinse off products.</p>
<p>The value of PIR shall be more restrictive and reduced.</p> <p>We sent you our values : we have only 3 products by 34 certified products with this huge value and the average is 0,15. We propose a threshold of 0,18g.</p>	<p><b>Comment partially accepted</b></p> <p>PIR values have been revised accordingly. Stricter value has been proposed.</p>

<p>Indeed, there are solutions for current products which have PIR &gt; 0,18 : providing refills, using a % of recycled materials, raising volume capacity...etc.</p> <p>It's crucial to reduce this value if we want that the criterion remains selective. As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel, in particular for packaging because reducing plastic waste is a major environmental issue !</p> <p>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market.</p> <p>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.</p>	
<p>With regards PIR calculation and values, a stakeholder suggested to align with Nordic Swan as the existing formula may not be suitable for new products under the scope. Several stakeholders supported a further restriction of PIR values. A stakeholder mentioned: "The value of PIR shall be more restrictive and reduced. We sent you our values: we have only 3 products by 34 certified products with this huge value and the average is 0,15. We propose a threshold of 0,18g."</p>	
<p>Packaging impact ratio (PIR)</p> <p>We recommend lowering even more the PIR, as the average PIR among French license holders is 15g, with 74% of PIR being below 20g.</p> <p>Criterion 4b (Packaging impact ratio) should be looked at again. The limit in the proposal is in our opinion too high and should be lowered. Also it should be considered to differentiate the requirement in regards to the new scope of the product group – especially decorative cosmetic are normally sold in smaller packaging. The Nordic Swan have a requirement with differentiated limits depending on product type.</p>	
<p>With regards the exemption of PIR requirement for products with 80% of recycled material, a stakeholder asked there is data to support such exemption.</p>	<p>According to the information provided by CB and stakeholders, there are products certified under the EU Ecolabel with a percentage of recycled or renewable materials in their content. The range goes from the 20% to 90% of material from renewable or recycled sources.</p>
<p>Oral care products often cannot use recycled materials for packaging due to food grade requirements. Can they be exempted?</p>	<p>The use of recycled material is not mandatory. The PIR calculation is mandatory unless the following exemption can be met:  <i>Primary packaging made of more than 80% of recycled materials is exempted from this requirement.</i></p>
<p>Small packaging are not an ecological option, so they should not be certified.</p> <p>[Moreover, with the expansion of the scope it should be considered the use of small packaging (for example for make-up products and toothpastes).]  We could accept them only for these specific cases (toothpastes...).</p>	<p><b>Comment partially accepted</b></p> <p>In order to avoid the use of small bottles it has been included a new requirement to limit the minimum volume for a product to be certified to 150ml.</p>

	This requirement will not apply to leave on products and toothpastes usually marketed in small volumes.
<p>[ on PIR] Metal containers should be evaluated in terms of a possible ban. We propose to evaluate plastic containers also for aerosols, since there are such available on the market</p>	<b>Comment acknowledged</b>
<p>Is it possible to change the name of this threshold and criterion in order to harmonise with the name given in Detergents, namely "Weight/utility ratio (WUR)" ?</p> <p>The definition in Detergents is "The weight/utility ratio (WUR) of the product shall be calculated for the primary packaging only and shall not exceed the following values for the reference dosage."</p>	<p><b>Comment rejected</b> Considering the approaches are a bit different for detergents and cosmetics the existing name is kept.</p>
<p>[Primary packaging made of more than 80% of recycled materials is exempted from this requirement.] What about biobased plastics? We mean plastics produced from renewable resources.</p>	This exemption only refers to recycled material due to the lack of data on renewable packaging content. In addition, despite the potential environmental advantages of using bioplastics, some impacts from vegetable oils used should be considered, especially those related to the agriculture stage. Therefore this is not easy to have a clear picture of biobased plastics as a superior environmental choice unless third party verified.
<p>Considering the table 19, the new threshold seems to be insufficiently strict.</p> <p>As mentioned during the first meeting and knowing that the residual amount of the product in the container disrupts the recycling, it's essential to reduce the value of R because this value remains too easy to achieve. Values you have already collected confirm this fact. As proposed, we will send you our values in the coming weeks (by email).</p> <p>As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel.</p> <p>We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market.</p> <p>Reducing the ambition to preserve and increase license holders does not seem the best strategy if this can question robustness of the scheme compared to other more ambitious labels.</p> <p>In relation to the residual amount, several stakeholders considered that decreasing R from 10 to 8% is not enough.</p> <p>We reckon that 8% is too much and we think that the license holders would agree. The requirement should go down to 5-6%.</p> <p>During the working group some manufacturers question that 8% was a very restrictive threshold. We were surprised because we consider 8% waste as quite a high number for consumers. Allowing bigger shared of cosmetic waste will be to the detriment of the environment and consumers.</p>	<p><b>Comments partially accepted</b> Residual amount has been decreased to 6%. According to existing data, more than 80% of existing licences will be able to reach this value. Considering that existing data is representative only for rinse off cosmetics, the existing requirement has been limited to rinse off cosmetics while for leave on products new requirements have been included in line with Nordic Swan.</p>

<p><i>Do not increase this threshold or even consider lowering it.</i></p>	
<p><i>Other stakeholder mentioned that R value will be challenging specially for toothpaste: "the shoulder section of toothpaste tubes means it's very difficult to get down to this level, we propose a higher level for toothpaste". It was remarked that the data amount of residual product come from rinse-off products and these threshold would be very difficult for viscous leave-on product and it was suggested that the restriction must be limited to the rinse-off product.</i></p>	<p><b>Comments partially accepted</b>          Considering that existing data is representative only for rinse off cosmetics, the existing requirement has been limited to rinse off cosmetics while for leave on products new requirements have been included in line with Nordic Swan.</p>
<p><i>[to ensure that at least 92% of the product can be easily removed from the container.]</i></p>	
<p><i>This limit isn't reachable for toothpastes and viscous products sold in pump (body milk, derocative cosmetics...)</i></p>	
<p><i>We ask to remove toothpastes and viscous products in pump from this criteria requirement</i></p>	
<p><i>The shoulder section of toothpaste tubes make is very difficult to get to this level of 90%.</i></p>	
<p><i>Exemption for toothpaste tubes from this requirement.</i></p>	
<p><i>Design of primary packaging</i></p>	
<p><i>We support the reduction of the residual amount of the product in the packaging to 8%. However, French stakeholders have notified that this threshold might be challenging to reach for sticky products.</i></p>	
<p><i>A stakeholder expressed: "The procedure to calculate residual amount shall be harmonized. <input type="checkbox"/>For example, we can require to test at least 5 packaging in order to calculate the residual amount."</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>Denmark suggest to change this requirement and make a requirement similar to The Nordic Swan Ecolabel, see inserted requirement 29. We made an investigation of this type of requirement when the Nordic Swan was revised, and it does not work in practice. Example a conditioner will not often not comply since the fluid will not leave the bottle just by turning the bottle upside down (as defined in the criteria) – you need to squeeze it to get fluid out. In regards to leave-on products only jars will comply with the requirement.</i></p>	<p><b>Comment accepted</b>          Residual amount has been decreased to 6%. According to existing data, more than 80% of existing licences will be able to reach this value.          Considering that existing data is representative only for rinse off cosmetics, the existing requirement has been limited to rinse off cosmetics while for leave on products new requirements have been included in line with Nordic Swan.</p>
<p><i>However, we wish to receive from the JRC information supporting the choice of the 2g of formula delivered per full press. One French stakeholder considers this threshold as too strict and informs that packaging technical documents provide information in millilitre (ml) instead of gram (g). This stakeholder thus recommends to raising the 2g threshold to 3ml. Moreover, other French stakeholders have expressed concerns about the possibility to certify containers sold as refills for dispensers, as their high opening diameter could contradict the following requirement: "The primary packaging shall be designed to make correct dosage easy (e.g. by ensuring that the opening at the top is not too wide". We wish to receive clarifications from the JRC on this point.</i></p>	<p><b>Comment partially accepted</b>          This value comes from Nordic Swan.          Considering that in many cases the information is provided in millilitres it has been included the possibility to measure this quantity also in volume (3 ml limit) in order to give flexibility to this requirement.</p>
<p><i>This quantity (2g) is arbitrary and does not necessarily correspond to all functions (for example it is not the same dosage for hand soap, shower gel or shampoo...) but it is not fair that this requirement only applies to liquid hand soap.</i></p>	

<p><i>[to ensure that at least 92% of the product can be easily removed from the container.] Does this apply if the packaging can be opened and the residue product can be extracted with adding water ?</i></p>	<p>Rinse off products that can be opened and the residue product can be extracted with adding water are proposed to be exempted from R requirement.</p>
<p><i>Design for recycling of plastic packaging</i></p> <p><i>The following comments has been collected from a French eco-organism, a public organisation in charge of managing the collection, sorting and recycling of waste, which has compared the EU Ecolabel criterion to the following standards Cotrep, EPBP and Recyclclass, which are 3 robust references in Europe:</i></p> <p><i>Closures: Caps in PS and PVC do not exist on the market, it is interesting to prohibit them, but since these materials are not suitable for caps making this requirement not relevant.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>Barrier coatings: A 3-layer of PET/Polyamide/PET coatings is the best possible barrier at the disposal of industrials to make a recyclable PET packaging barrier. Keeping the prohibition of polyamide for barriers would contradict European recommendations, as the 3 European standards agree on this point. We recommend removing this exclusion.</i></p>	<p><b>Comment rejected</b></p> <p>According to bilateral communication with RecycleresEuroe PA is admitted only if provided as multilayers and will get delaminated during the prewashing phase in PET recycling. The polyamide restriction is proposed to be kept under the EU Ecolabel</p>
<p><i>Similarly, the EVOH is the best possible barrier for industrials to make a recyclable PE or PP barrier packaging, the 3 European standards agree on this point. Moreover, EVOH is not a specific plastic but a family of different plastics, some of which are not compatible with PP or PE recycling. We thus recommend allowing EVOH regardless of their content and adding a requirement on their recycling compatibility.</i></p>	<p><b>Comment partially accepted</b></p> <p>Against this it is proposed to allow a maximum content of EVOH of 5%.</p>
<p><i>From a CB forum question about the packaging of detergents I remember that Plastics Recyclers Europe said that the adhesive used in the label can give problems for recycling of HDPE. While water soluble glues are fully compatible with the recycling process, self-adhesive labels are very difficult to separate from the body and will contaminate the final recycle. On their website they have recycling guidelines for packaging e.g. HDPE bottles. <a href="https://recyclclass.eu/wp-content/uploads/2020/04/PE-HD-natural-containers-guidelines-27-04-2020-3.pdf">https://recyclclass.eu/wp-content/uploads/2020/04/PE-HD-natural-containers-guidelines-27-04-2020-3.pdf</a></i></p> <p><i>Other guidelines can be found here <a href="https://recyclclass.eu/recyclclass/design-for-recycling-guidelines/">https://recyclclass.eu/recyclclass/design-for-recycling-guidelines/</a></i></p>	<p><b>Comment partially accepted</b></p> <p>Based on bilateral communication with RecyclersEurope it has been found that: SAL (self adhesive) or PSL (pressure sensitive) needs to be provided with a releasable adhesive without reactivation. Water/alkali soluble and water/alkali releasable adhesives without reactivation are fully compatible with PET recycling. Against this it is proposed to include a requirement on adhesives.</p>
<p><i>If the label and packaging are the same material, even if in mold labelling is done they can be recycled: need clarity on why they are being excluded.</i></p>	<p><b>Comment rejected</b></p> <p>No modifications have been included with regards this comment. The label/sleeve is printed and the inks will affect recycle quality. In the case of washable inks, at least the washing water will be contaminated.</p>
<p><i>We would like clarity on why metal caps aren't allowed.</i></p>	<p>Closures containing metal or glass are not suitable with recycling. We cannot expect all the consumers will remove the cap/closure from the bottle before to waste it. It will create loss of material in the sorting process, contaminate the recycled plastics and also create some concerns to the recycling equipment.</p>

<p><i>EU recycling bodies such as Recyclclass will allow up to 5% EVOH so we would like to understand why this has been excluded.</i></p>	<p><b>Comment partially accepted</b> Against this it is proposed to allow a maximum content of EVOH of 5%.</p>
<p><i>PETG density is similar to PET density and cannot be separated by the process. Unfortunately their thermal behaviors are quite different. Therefore PETG labels/sleeves cannot be used in any case on PET bottles. Also PET labels/sleeves cannot be used because of the printing.</i></p> <p><i>Foamed PET or foamed PETG labels/sleeves have a density lower than 1 g/cm3 and can get separated by PET in the recycling process. Even if both will not get recycled. Preferred choice for PET bottles is always PE or PP label/sleeve with small covering (&lt;50%).</i></p>	<p><b>Comment accepted</b> The text has been revised in order to harmonise with hard surface cleaners text. PETG restriction has been included.</p>
<p><i>Please have further look to hard surface cleaners text on design for recycling in order to further align as far as possible. Also because otherwise companies will get confused to see that for one product some design item is allowed and for another product the same design item is not allowed.</i></p> <p><i>An example is the use of PETC and PETG label/sleeve on PET package. PETC label/sleeve is now not allowed in case of rinse-off cosmetic products but still allowed in case of surface cleaner products. Some brands owners are asking me about that. PETC is not allowed in Europe to the legislation and the mandatory target for r-PET to be used for food contact (but allowed in US for example).</i></p>	<p><b>Comment accepted</b> A requirement based on the proposal has been included to avoid competition with food contact approved recyclates.</p>
<p><i>4d) Denmark suggests that virgin PET and rPET from already food contact approved material shall not be allowed to use. Especially food contact approved rPET should not be part of a "competition" between soap manufacturers and food/drinking manufacturers, but should be reserved to the latter as food contact materials shall live up to high standards</i></p>	<p><b>Comment accepted</b> A requirement based on the proposal has been included to avoid competition with food contact approved recyclates.</p>
<p><i>With regards take-back system, stakeholders considered the new proposal much more workable now. However, they still see problematic because of it does not consider the product chain.</i></p> <p><i>A stakeholder commented: "We are in favour of this requirement for products to be used by accommodation services in a small packaging. We would have preferred to prohibit small bottles &lt; 300ml (used for example in hotels) because it's a huge waste of plastic: a major environmental issue. Moreover, these products can be replaced by dispensers with EU Ecolabel products. Nevertheless the new requirement you propose is an acceptable alternative."</i></p> <p><i>Another stakeholder mentioned: "It's not sufficient : you need to require also 1) evidence of this take-back system such as receipt proof of these empty packaging and 2) reusing evidence of them"</i></p> <p><i>A stakeholder suggested limiting this criterion only if producer is directly dealing with hotels.</i></p> <p><i>In addition, it was expressed: "Good to try take back systems for hotels. We wonder whether setting a limit at 75 ml would not encourage bigger packaging though to avoid needing to comply with this requirement"</i></p>	<p><b>Comments accepted</b> Considering the difficulties related to the implementation in case the producer is not directly dealing with the accommodation it has been finally decided to not include this requirement.</p> <p>In order to avoid the use of small bottles it has been included a new requirement to limit the minimum volume for a product to be certified to 150ml. This requirement will not apply to leave on products and toothpastes usually marketed in small volumes.</p>
<p><i>In my opinion this is still difficult to implement in practice. To promote the circular economy</i></p>	

<p><i>and to boost the recycling of plastics we are in favor of a requirement about a certain minimum % of recycled plastic in the packaging</i></p>	
<p><i>We are in favor of the reuse reduce and recycle concept. However, for the professional market for personal hygiene, reuse is difficult to ensure. For instance hospital or hotel, refills can be source of contamination and bacterial growth. Having to always refill is not recommended. (see attachment for some examples). it could put the customers (eg hospital) at risk.</i></p> <p><i>Additionally, production of the cosmetics range is in our case under very strict conditions on the equipment, packaging, personnel and lines at the factory to prevent contamination. Having the refill done by the customers would be a breach and allow contamination of the products by uncontrolled external sources, again, it could put the customers at risk</i></p> <p><i>Some soap packagings with pump device are sealed packagings and can go into dispensing platforms, a refill would be a compromise of the design and would not allow the reuse.</i></p>	
<p><i>Take-back system</i></p> <p><i>The JRC proposal regarding the implementation of a take-back system in order to collect empty products from consumers is in contradiction with the existing schemes aiming at collecting the waste for recycling. We do not support this proposal.</i></p>	
<p><i>We are in favour of this requirement for products to be used by accommodation services in a small packagings.</i></p> <p><i>We would have preferred to prohibit small bottles &lt; 300ml (used for example in hotels) because it's a huge waste of plastic: a major environmental issue !</i></p> <p><i>Moreover, these products can be replaced by dispensers with EU Ecolabel products.</i></p> <p><i>Nevertheless the new requirement you propose is an acceptable alternative.</i></p> <p><i>We welcome this requirement for TAS. We wonder if by setting a volume limit, there could be a risk, that producers make (unnecessarily) large packages instead. For some cosmetics used only in small volumes, this might lead to extra waste, and the requirement might end up with no (or even negative) environmental benefit.</i></p>	<p><b>Comment partially accepted</b></p> <p>Considering the difficulties related to the implementation in case the producer is not directly dealing with the accommodation it has been finally decided to not include this requirement.</p> <p>In order to avoid the use of small bottles it has been included a new requirement to limit the minimum volume for a product to be certified to 150ml.</p> <p>This requirement will not apply to leave on products and toothpastes usually marketed in small volumes.</p>
<p><i>[on consumed in the accommodation. ]</i></p> <p><i>You shall complete this sentence with "in order to REUSE these small packagings".</i></p> <p><i>Indeed, if applicants collect empty products to recycle them without reusing, there will be no real benefit.</i></p>	<p>Considering the difficulties related to the implementation in case the producer is not directly dealing with the accommodation it has been finally decided to not include this requirement.</p>
<p><i>Shall we check the real number of sold refillings the following year ?</i></p> <p><i>If yes, can you indicate this precision ?</i></p>	<p>No precision included at this stage. The number will be very different depending on the company market volume.</p>
<p><i>[on the for the content of post-consumer recycled material or material from renewable</i></p>	<p><b>Comment accepted</b></p>

<p><i>origin in the packaging] This declaration of compliance shall be provided by packagings manufacturers.</i></p>	
<p><i>[on ensuring that the opening at the top is not too wide] For assessment purpose, How do you define "not too wide" ?</i></p>	<p><b>Comment accepted</b></p>
<p><i>concerning recycled content I would add to this text 'signed declaration for the content of post-consumer recycled material or material from renewable origin in the packaging' a reference to the need to fulfil the conditions of the future (January 2022) implementing act of Directive 2019/904 laying down the rules for the calculation and verification of the targets on recycled content.</i></p>	<p><b>Comment accepted</b></p>
<p><i>From an environmental perspective, PVC and other halogenated plastics should not be permitted</i></p> <p><i>PVC is associated with several problematic properties. For example, the monomer in PVC, i.e. vinyl chloride, has a harmonized classification as carcinogenic. PVC is a type of plastic that requires the many additives, some of which may be hazardous. Other halogenated plastics can be suspected of having similar problematic properties.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>In relation to packaging and contaminants, several stakeholders mentioned that it must be ensured that packaging made with recycled material should exclude contaminants and SVHCs because these substances can migrate to the product and because of the risk of greenwashing.</i></p> <p><i>When introducing recycled material in the packaging, it should be ensured, that no problematic substances are in the recycled material. I.e. heavy metals, UV-filters, etc</i></p> <p><i>It is however a must, that the use of recycled materials does not lead to contamination of the cosmetic product. The requirement could then be to use a lining or source from clean recyclables." "Recycled material in contact with the cosmetic product should only be sourced from known "clean" materials, to avoid contaminating the product with unknown and unwanted substances.</i></p> <p><i>" "The JRC has rejected our proposal arguing that the use of recycled materials is one of the key aspects of the circular economy and it is necessary providing more flexibility to manufacturers and avoiding complex verification. We plead to reconsider this assessment which lacks coherence with the European Green Deal commitment to achieve a non-toxic environment. Minimising the presence of toxic substances in recycled materials to avoid reinjecting them in the economy is also a goal of the circular economy action plan. The EU Ecolabel shall differentiate best in class products and be coherent with EU policies."</i></p> <p><i>It is of high importance for future recyclability of packaging materials to not use Substances of very high concern (SVHC), when using virgin materials in the manufacturing of packaging.</i></p> <p><i>Table 7. Materials and components excluded from packaging elements:</i></p> <p><i>The packaging shall not contain any substances that have been identified in accordance</i></p>	<p><b>Comment accepted</b> A new requirement on SHVCs on packaging has been proposed.</p>

<p>with the procedure described in Article 59(1) of Regulation (EU) No 1907/2006 which establishes the candidate list for substances of very high concern, at or above the concentration of 0.10% weight by weight.</p>	
<p>To replace this requirement (not necessary relevant) and in order to make correct dosage easy, an essential requirement in order to avoid overdosage, it's necessary to force applicants to provide a convenient dosage system or if not appropriate, to provide an effective system of delivery.</p> <p>In order to control the dosage of certified products and avoid any overdosage, we should require :</p> <p style="padding-left: 40px;">applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,</p> <p style="padding-left: 40px;">applicants shall provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery,</p> <p style="padding-left: 40px;">applicants shall indicate the correct dosage/quantity on the label and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money.</p> <p>This requirement should also replace the question « How easy is it to apply the dosage of the product in comparison with a market-leading product?» » (question 2 of test) because : it's not a scientific and reliable method and it's binding because applicants shall provide a new test when they change their packaging.</p>	<p><b>Comment partially accepted</b> A requirement on provision of information of the correct dosage has been included in primary packaging design criterion.</p>
<p>The user manual shall be available at the same time as the decision !</p>	<p><b>Comment acknowledged</b></p>
<p>We need to have clarifications and examples in the user manual, in particular for pouches, which are also concerned by this requirement a priori.</p> <p>You should add clarifications and examples in the user manual, in particular for pouches.</p>	<p><b>Comment acknowledged</b></p>
<p>Two stakeholders commented on the difficulty and lengthiness of the verification method for this requirement and ask for removing this criterion or finding alternative certification schemes:</p> <p>"With the current criterion we have no guarantee that EU Ecolabel certified products contain sustainable derivatives of palm oil (only with « segregated » certification) whereas it's particularly difficult and time-consuming to check different proofs. Since the low benefit in comparison with the high complexity, we ask for the removal of this requirement. It's necessary to find another scheme to deal with palm oil issue. Nevertheless, if you choose to keep this criterion, it's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product." Indeed, Competent Bodies have to check that the Book and Claim credits have not already been used in other products. However, another stakeholder mentioned that the verification of this criterion would become much easier, would the Book and Claim system be removed.</p>	<p><b>Comments rejected</b> The criterion has been made more stringent by accepting only the certifications stricter than a Mass Balance level. This modification will make the understanding and the verification of the requirement much easier, as CBs do not have to check different proofs. In this way, the efficacy of the requirement has also been improved, as RSPO certifications up to Mass Balance (IP, SG and MB) ensure a higher and less disputable sustainability.</p> <p>Other sustainability schemes have been looked at, but none of them has the same uptake of RSPO. Nevertheless, certifications from other schemes can be used, provided that a third-party auditor approves the equivalence.</p> <p>The option of limit the content of palm oil, palm kernel oil and their derivatives may be interesting, however a proposal cannot currently be formulated as</p>

*With the current criterion we have no guarantee that EU Ecolabel certified products contain sustainable derivatives of palm oil (only with « segregated » certification) whereas it's particularly difficult and time-consuming to check different proofs.*

*We understand and share your concern about palm oil but this scheme is very not satisfactory. Licence holders pay an extra of 20% but we have no guarantee there are derivatives from sustainable palm oil in EU Ecolabel products. This scheme doesn't guarantee no deforestation and permits to ingredients manufacturers to make profit. Don't forget this scheme is not a public label and it's much criticized.*

*Since the low benefit in comparison with the high complexity, we request again the removal of this requirement.*

*It's necessary to find another scheme to deal with palm oil issue. For example, we can limit the use of these derivatives and fix different threshold according to products types.*

*Nevertheless, if you choose to keep this criterion, it's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.*

*We request again the removal of this requirement.*

*To replace it, we can limit the use of these derivatives and fix different threshold according to products types.*

*With the current criterion we have no guarantee that EU Ecolabel certified products contain sustainable derivatives of palm oil (only with « segregated » certification) whereas it's particularly difficult and time-consuming to check different proofs.*

*We understand and share your concern about palm oil but this scheme is very not satisfactory. Licence holders pay an extra of 20% but we have no guarantee there are derivatives from sustainable palm oil in EU Ecolabel products. This scheme doesn't guarantee no deforestation and permits to ingredients manufacturers to make profit. Don't forget this scheme is not a public label and it's much criticized.*

*Since the low benefit in comparison with the high complexity, we request again the removal of this requirement.*

*It's necessary to find another scheme to deal with palm oil issue. For example, we can limit the use of these derivatives and fix different threshold according to products types.*

*We request again the removal of this requirement.*

*To replace it, we can limit the use of these derivatives and fix different threshold according to products types.*

*As already stated, with the current criterion we have no guarantee that EU Ecolabel certified*

data were made available by one Competent Body only. Moreover, substances substituting palm oil, palm kernel oil and their derivatives may have a worse environmental profile.

*products contain sustainable derivatives of palm oil (only with « segregated » certification) whereas it's particularly difficult and time-consuming to check different proofs.*

*Since the low benefit in comparison with the high complexity, we request again the removal of this requirement.*

*It's necessary to find another scheme to deal with palm oil issue. For example, we can limit the use of these derivatives and fix different threshold according to products types.*

*We request again the removal of this requirement.*

*To replace it, we can limit the use of these derivatives and fix different threshold according to products types.*

#### *Sustainable sourcing of palm oil, palm kernel oil and their derivatives*

*Based on the feedback of French stakeholders, we have the following comments:*

*Fulfilling this criterion is very complex and all French licenced products include derivates from palm oil and palm kernel oil (but none of them contains palm or palm kernel oil).*

*It is not clear which evidences are required for the assessment and verification of this criterion, and whether the third-party verification should be done annually and for each certified product or not.*

*The "mass balance" certification scheme is questionable and has been subject to controversy.*

*The improved environmental performance of certified palm oil, palm kernel oil and their derivatives has not been scientifically proven.*

*Considering the above comments and the fact that intensive cultivation of palm oil, palm kernel oil and their derivatives has a direct link with environment destruction (including deforestation, habitat destruction and associated biodiversity loss), we recommend to define an upper threshold regarding the percentage of palm oil, palm kernel oil and their derivatives contained in a product. Based on data collected from French industrials, the maximum average palm oil derivative content (average of the maximum palm oil derivative contents of all products) is the following:*

*Shampoo: 3.64%*

*Shower preperations: 5.73%*

*Liquid soaps: 2.68%*

*[on 5a]*

**Comment rejected**

<p><i>This criteria is very difficult for both of us: stakeholders to collect the good approved documents, for the CB to well understand the criteria, to verify it, and follow it every year. Annually audit are very timeconsuming for all of us.</i></p> <p><i>Some comments asked to make this criteria harder, for example by only accept segregated PKO derivative at the lightest or stricter sourcing.</i></p> <p><i>Keep in my segregated surfactant are 30% more expensive. In a rinse off cosmetic product, the incidence is very high. For all the products sold in mass market, the consumer won't accept to pay the cost difference. Moreover, if all ECOLABEL products are forced to use segregated surfactants, the surfactant producers are not able to provide segregated surfactant for all their surfactant, and even worse they won't have the asked quantity for all.</i></p> <p><i>For all this reasons we propose to remove this criteria.</i></p>	<p>The market trend shows that the availability of RSPO-certified products at the IP, SG or MB level has dramatically increased in the last years, and are expected to increase even further. Therefore, availability of quantities should not be a limitation.</p>
<p><i>We support the introduction of this criterion in general.</i></p> <p><i>This point, as written, would infer 20% of the product.</i></p> <p><i>20% of the formulation being organic is consistent with some private standards on the market (e.g. NATRUE and COSMOS). However, COSMOS itself provides a derogation to this % as follows:</i></p> <p><i>7.1.2 Total product</i></p> <ul style="list-style-type: none"> <li><i>• At least 20% of the total product must be organic.</i></li> <li><i>• By exception, for rinse-off products, non-emulsified aqueous products, and products with at least 80% minerals or ingredients of mineral origin, at least 10% of the total product must be organic.</i></li> </ul> <p><i>Moreover, organic raw materials in NATRUE and COSMOS schemes include, for example, hydro(alcoholic) extracts commonly used for skin conditioning purposes and other actives. These extracts, unlike an organic olive oil for example, are not certified under the EU Organic Regulation as organic; only within the scope of the aforementioned private standard.</i></p> <p><i>Hence, it would either be difficult to reach this threshold or would limit the number of product categories that could be achievable.</i></p> <p><i>Natural substances and derivatives from organic raw materials would also be excluded. Hence, the palette of acceptable organic substances would be restricted to food-based substances. Keeping this in mind if the aim is to encourage more use of organic raw materials but maintaining the scope of what is considered organic from a legislative perspective the content may have to be reduced; possibly by 5-10% but all products</i></p>	<p><b>Comments partially accepted</b></p> <p>To clarify the criterion as much as possible, the wording of the criterion text has been modified. Please see TR3.0. Further guidance will be given in the user manual, where the calculation will be explained with a spreadsheet.</p>

currently in the EU EcoLabel scheme but using natural ingredients would have to be evaluated if these could be upgraded to organic remain in scope with the permitted definition of an organic raw material described here.

If the inference here is 20% w/w of an ingredient in the product is organic this would not be correct either since those raw materials considered organic under EU legislation must be 95% or greater organic to be certified.

Clarify if the 20% value of organic raw materials contributing as a percentage proportion to the cosmetic product

If so, it must be clear that this calculation excludes water which cannot be considered organic except water-containing substances that are accepted as organic under EU law e.g. aloe vera juice

We think that percentage should be different according to product category.

Furthermore we suggest not to use specific Regulation.

ISO 16128-1 definition could be used:

Organic ingredients are natural ingredients originating from organic farming methods or from wild harvesting in compliance with national legislation or equivalent International Standards where applicable. The term organic farming can be defined as per individual national jurisdiction where applicable.

This criterion needs to be clarified. As it is written, it is not clear to which ingredients this criterion applies. We thus recommend that the JRC defines an exhaustive list of ingredients covered by the scope of the EU organic

Regulation (EC 834/2007) to which this criterion applies. The calculation method of the percentage of ingredients produced according to organic production and certified by a third-party should also be explained by the JRC.

Can you confirm this threshold (20%) only concerns natural ingredients (extracts etc.) and not all ingredients from natural origin (as surfactants for example)?

Please, can you add this clarification in the next draft or at least in the user manual ?

In the specific case of ingredients covered by the scope of the EU organic Regulation (EC 834/2007), 20%w/w of the ingredients used shall be produced according to organic production and certified by a third-party.

This criterion needs further clarification in order to define which ingredients that are to be considered as covered "by the scope of the EU organic Regulation (EC 834/2007)".

Stakeholders were confused as to what ingredients are covered by the scope of the EU Organic Regulation. Doubts were expressed on the covering of derivatives, of palm oil, surfactants, on-food substances like extracts used exclusively in cosmetics but produced

<p>from organic plants. The question is further complicated by the fact that a positive list of substances included in the EU Organic Regulation does not exist. JRC responded that will clarify this issue in the next technical report.</p>	
<p>Split views were recorded for the level of ambition of the proposed threshold for organic ingredients. The risk is that the consumer perceives the product as organic and feels greenwashed. However, an official definition of organic cosmetic product does not exist, also due to the presence of water: "The 20% value is because cosmetics are not food e.g. they contain formulation water which is not organic. Equally, for certain product categories functionality products will require raw materials only available in natural quality grade e.g. surfactants. Hence, except for a limited range of products (e.g. body oils) an organic cosmetic is unlikely to be 100% organic. This is certainly a step away from consumer understanding of the claim from food agreeably". One stakeholder commented that "it will be possible to assess the feasibility of this criterion only once it will be clear which ingredients are covered by this requirement".</p>	
<p>We are confused with this criteria and are not sure to well defined it.</p> <p>We are not in favour of including a minimum amount of organic substances for the ingredients covered by the EU organic regulation (nor a minimum amount at all). this would encourage the use of as it could discourage the use of this ingredients.</p>	
<p>We think that a good idea could be the introduction of biobased surfactants according to EN 17035:2018 definition</p>	
<p>Finally, stakeholders suggested to modify the requirement and to target bio-based ingredients instead, as done in Blue Angel and to accommodate the demand of consumers for natural products. Indeed, the risk is that including a requirement on the organic cultivation of plant-based ingredients would have the rebound effect to favour petrochemical substances, which under the current set of criteria would be subject to less certifications and declarations than plant-based ingredients.</p>	<p><b>Comments rejected</b> Requirements on a minimum content of bio-based ingredients cannot be set on cosmetic products, because the EU Ecolabel is technology neutral: it does not prefer one type of ingredient over the others. All ingredients are allowed, provided that are the less impacting throughout their life-cycle (e.g. in terms of their toxicity, biodegradability, etc.)</p>
<p>Moreover, another stakeholder commented that life cycle assessments found that organic products have a high land footprint and possibly other environmental impacts: "Organic is not necessarily more sustainable from our life cycle assessments - requires more land footprint. This criterion may be lead to other environmental impacts - a life cycle assessment approach should be considered to make sure the most sustainable agriculture solution overall is promoted". One suggestion referred to "setting a bio-based minimum content, which may vary by product type such as other criteria (CDV and biodegradability)".</p>	
<p>Can we state / clarify that criteria 5b is not applicable if raw material already comply with the criteria 5a ?</p>	<p><b>Comment clarified</b> Criterion 5b applies even if the ingredient complies with 5a. However, organic certifications will be accepted as equivalent to RSPO certifications, also in order to lighten the certification burden on manufacturers that would have to comply with 5a and 5b.</p>
<p>In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100% w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi-stakeholder organisation with a broad membership, including NGOs, industry and</p>	<p><b>Comments accepted</b> The share of RSPO-certified ingredients available on the market with a level stricter than Mass Balance has increased considerably in the last years. Therefore, Book and Claim credits are proposed not to be accepted anymore.</p>

<p>government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.</p> <p>It is unclear whether or not RSPO Book and Claim is accepted or not, according to this criterion. Only RSPO Mass Balance or higher should be accepted.</p> <p>Several other ecolabelling schemes, such as Bra Miljöval for Cosmetics, the Nordic Swan for Cleaning products and the Blue Angel for Laundry detergents, accepts only RSPO Mass Balance or higher.</p>	
<p>Book and Claim should not be accepted.</p>	
<p>Only IP, SG, and MB qualities are accepted by most private standards on the market with MB being the minimum quality.</p>	
<p>Remove Book and claim and independent small holder credits</p>	
<p>For your information, the most of French license holders who used B&amp;C could also buy certified ingredients, so this deletion would not significantly impact the number of certified products (by French CB at least).</p>	
<p>The marked for certified palm oil and their derivatives are developing rapidly. Book and claim should only be accepted if there is not enough available certified ingredients on the market. The EU licenses which have been certified using the Book and claim system can easily source the ingredients from other suppliers – from a technical point of view. Hence more data on the marked situation is needed. If the validity of the criteria documents is intended to be 8 years a stepwise approach to face out the Book and Claim system should also be considered</p>	
<p>The stakeholder discussion mainly addressed the issue of excluding the Book and Claim system as a certification method in the framework of the Roundtable for Sustainable Palm Oil (RSPO), as an amendment to the second Technical Report. Stakeholders highlighted that Blue Angel and the upcoming updated criteria within Nordic Swan set the Mass Balance system as a minimum requirement. Moreover, it was mentioned that the analysis should be done on existing licenses, because current data on the type of certifications available on the market justifies the feasibility of excluding the Book and Claim method. One stakeholder suggested adopting a step-wise approach and allowing for acceptance of Book and Claim credits only temporarily. Another stakeholder mentioned that "if the EU Ecolabel will set stricter RSPO levels (e.g. identity preserved, segregated) the suppliers will not be able to provide sufficient ingredients, and the cost would increase by 20% at least".</p>	
<p>In addition, stricter requirements should apply to unmodified palm and palm kernel oil, which should come from organic production.</p>	<p><b>Comment partially accepted</b> A new requirement setting that 'unmodified palm and palm kernel oil should come from organic production' was not introduced, as organic certification of these ingredients is not as developed as RSPO. However, organic certifications will be accepted as equivalent to RSPO certifications, also in order to lighten the certification burden on manufacturers that would have to comply with 5a and 5b.</p>
<p>Stakeholders asked for improved clarity as to what concern the annual audits to be</p>	<p><b>Comments partially accepted</b></p>

<p><i>performed by Competent Bodies: "In the previous draft, we indicated it's necessary to clarify what kind of proofs shall be provided by applicants and if these documents shall be checked annually by the competent body for each certified product. You mention verifications of validity RSPO certificates (only for MB certified ingredients) but you don't mention frequency for non-certified ingredients (covered by book and claim)".</i></p>	<p>The text of the assessment and verification of criterion 5 (a) was carefully revised to improve its clarity. Moreover, the exclusion of Book and Claim credits certifications simplifies the verification for CBs itself.</p>
<p><i>In the previous draft, we indicated it's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p>	
<p><i>You mention verifications of validity RSPO certificates (it only corresponds to MB certified ingredients) but you don't mention frequency for non-certified ingredients (covered by book and claim).</i></p>	
<p><i>It's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p>	
<p><i>The verification shall be done via RSPO website (<a href="https://www.rspo.org/certification/search-for-supply-chain-certificate-holders">https://www.rspo.org/certification/search-for-supply-chain-certificate-holders</a>), where the status of the Certificate is show live. As explained in the 1st WG meeting in Brussels, if the verification is done only checking the certificate that the company can provide, there is a big risk that the Certificate is NOT valid even if the end date has not reach, as the validity of the Certificate is subject to the annual audit. The only up-to-date way to check the actual validity of the RSPO Certificate is through RSPO website <a href="https://www.rspo.org/certification/search-for-supply-chain-certificate-holders">https://www.rspo.org/certification/search-for-supply-chain-certificate-holders</a>.</i></p> <p><i>To clarify that the verification is through the live platform of RSPO website, and not just checking the Certificate document that the company could provide.</i></p>	
<p><i>What is the exact requirement?</i></p> <ul style="list-style-type: none"> <li><i>- If the applicant shall claim that the product that it produces is RSPO certified, then it needs to hold itself an Supply Chain Certification.</i></li> <li><i>- if the applicant shall demonstrate that it physically sources RSPO certified material, then it needs to provide the Certificate of its supplier(s). In this case it can physically supply RSPO material, but you cannot assure that the EU ecolabel product contains that RSPO material as it is not Supply Chain Certified.</i></li> </ul> <p><i>To clarify what the exact requirement is</i></p>	
<p><i>The requirement to perform an annual audit is not absolutely clear. An audit is understood as an on-site visit which is not necessary in case of a validity check. The validity of a certificate could be easily checked every year on-line on the RSPO web site.</i></p>	
<p><i>Please check if there is no duplication of process here where audits are carried out by RSPO and documentation to prove this can be supplied by the applicant to the CB.</i></p>	

<p><i>In the previous draft, we indicated it's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p> <p><i>You mention verifications of validity RSPO certificates (it only corresponds to MB certified ingredients) but you don't mention frequency for non-certified ingredients (covered by book and claim).</i></p> <p><i>It's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p>	
<p><i>it is possible to make annual audits in order to verify the validity of RSPO certificates? NO</i></p>	
<p><i>In the previous draft, we indicated it's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p> <p><i>You mention verifications of validity RSPO certificates (it only corresponds to MB certified ingredients) but you don't mention frequency for non-certified ingredients (covered by book and claim).</i></p> <p><i>It's necessary to clarify what kind of proofs shall be provided by applicants. You must specify if these documents shall be checked annually by the competent body for each certified product.</i></p>	
<p><i>[it is possible to make annual audits in order to verify the validity of RSPO certificates?]</i>  <i>Yes, it's possible if we consider documentation audit (as we are doing for detergents products) but as explained, it's particularly difficult and time-consuming to check different proofs whereas benefits are low.</i></p>	
<p><i>An audit is not needed to check the validity of the certificates. An audit for this purpose by a CB is impossible. CBs don't have the competence for that.</i></p>	
<p><i>Independent Smallholder (IS) credits is an option inside B&amp;C (Please check the graph in <a href="https://www.rspo.org/rspo-credits/i-am-a-buyer/step-by-step">https://www.rspo.org/rspo-credits/i-am-a-buyer/step-by-step</a>). Those specific credits are named IS CSPO, IS – CSPKE and IS – CSPKO.</i></p> <p><i>To clarify in brackets that IS Credits is one of the options of the B&amp;C model of RSPO.</i></p>	<p><b>Comment accepted</b> It has been modified in the TR3</p>
<p><i>If other certification schemes than RSPO are to be accepted there should be an accompanying practice document stating which they are, at any given time.</i></p>	<p><b>Comment clarified</b> It is stated in the criterion text that "any equivalent or stricter sustainable production scheme demonstrating compliance" to RSPO shall be accepted</p>
<p><i>Please note that the text:</i></p> <p><i>"(b) Certification of plant based ingredients</i></p> <p><i>In the specific case of ingredients covered by the scope of the EU organic Regulation (EC 834/2007), 20% w/w of the ingredients used shall be produced according to organic</i></p>	<p><b>Comment accepted</b> This has been introduced in the proposed assessment and verification text</p>

*production and certified by a third-party."*

*...is inconsistent with:*

*"To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certifications for the ingredients covered by the scope of the EU Organic Regulation. Certifications accepted shall include those awarded by Competent Bodies appointed through the EU Regulation on organic production 834/2007, as well as IFOAM family of standards, COSMOS, or any equivalent scheme."*

*The last part in yellow highlight is redundancy since COSMOS is a private standard owner, like NATRUE. COSMOS and NATRUE include approved certifiers that are duly recognised by the EU for the purposes of certifying to the EU Organic Regulation, and those that are not. However, only products certified by a duly recognised control body in the EU could provide a valid certificate. Private standards re-certifying already officially certified organic raw materials, like olive oil, would be selling certificates and an official organic certificate by the duly recognised control body meet the requirements of the EU Organic Regulation should be the basis for proof.*

*Not all the raw materials on the COSMOS or NATRUE databases considered organic could therefore be used in EU EcoLabel products; only those that are certified organic agricultural extracts used in food e.g. plant oils/fats commonly but not water(/alcohol)-based extracts from, for example, calendula even if the plant was organic since the product raw material is not a food-stuff and does not fall under the scope of the EU Organic Regulation.*

*The IFOAM Family of Standards is a private reference point for schemes that meet equivalency for IFOAM. For the latter there may be more regulations, as well as private standards, that are viewed as equivalent by IFOAM than by the EU.*

*Please see suggested action.*

*Since the scope is limited to organic raw materials under the scope of the EU Organic Regulation wording:*

*"To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certificates for raw materials/ingredients certified to the EU Organic Regulation. Raw materials outside the scope of certification to the EU Organic Regulation, or Organic Regulations recognised as equivalent by the EU, are not considered organic for the purposes of the EU EcoLabel. Certificates accepted shall include those awarded by Competent Bodies duly recognised and appointed through the EU Regulation on organic production 834/2007.*

*Regarding the inclusion of antiperspirants, almost all use aluminium salts in their formulation. The extraction of bauxite used to produce aluminium raises societal (child labour, forced labour, exposure to toxic substances) and environmental (deforestation, water and soil pollution) issues that should be considered in this standard. We thus*

**Comment rejected**  
As an international standard that provides licences to sustainably sourced bauxite could not be found, this was not introduced in the criteria

<i>recommend including a sub-criterion on the origin of the bauxite used in aluminium salts.</i>	
<i>Financial institutions are key to be engaged in the production of sustainable PO too.</i>	<b>Comments accepted</b>
<i>To include FIs as a key stakeholder of the PO industry.</i>	
<i>Add FI, as the comment before.</i>	
<i>That is the previous name of the program call now PalmTrace.</i>	<b>Comments rejected</b> These corrections refer to the existing criterion text, whose wording cannot of course be changed
<i>Update the name to PalmTrace</i>	
<i>ON instead of FOR</i>	
<i>This footnote is not updated.</i>	
<i>What about social issues as land rights, human rights, workers rights and decent living wage, etc? These is a key pillar of sustainability too.</i>	<b>Comments rejected</b> The EU Ecolabel is an environmental label, and, although acknowledging the importance of the social pillar, criteria are expected to focus on the environmental aspect of sustainability
<i>Add Social and Economical impacts too.</i>	
<i>Sustainability includes environmental, social and economical. It is important to mention this, as all the text seems that it is just about environmental issues.</i>	
<i>Not accurate.</i>	<b>Comment accepted</b> The text has been rewritten
<i>RSPO started in 2004. Consider if 2004 is considered 'only recently started'.</i>	
<i>When the mentioned and 'well established' schemes started? NATRUE was founded in 2007, for example. COSMOS in 2010.</i>	
<i>If NATRUE and COSMOS are considered well established, RSPO shall be considered well established too, and not just started.</i>	
<i>Rephrase the sentences to be consistent in the idea of well establish/recently started based.</i>	
<i>Not accurate.</i>	<b>Comment rejected</b> The text refers not only to RSPO, but to other palm oil certification schemes as well.
<i>RSPO does not just minimise, but prevent/mitigate environmental impacts in the certified plantations.</i>	
<i>To rephrase to be accurate in the given message.</i>	<b>Comment accepted</b> The paragraph has been deleted
<i>Not a requirement but an aspect of sustainability, right?</i>	
<i>Amend the word.</i>	
<i>This sentence is misleading if all the EU ecolabel product manufacturing sites are NOT RSPO SC certified.</i>	<b>Comment accepted</b> The sentence has been rewritten
<i>Only an RSPO SC certified manufacturing site can claim that its manufactured product is RSPO certified.</i>	

<p><i>If an EU ecolabel product manufacturing site is NOT RSPO SC certified but it just sources RSPO certified material, then the sentence cannot state that the product is RSPO certified.</i></p> <p><i>Assess the real situation and amend the sentence accordingly.</i></p>	
<p><i>Important to include Shea butter too, as per its cultivation expansion in fragiles areas of Africa.</i></p>	<p><b>Comment accepted</b> The paragraph has been deleted</p>
<p><i>The 'moreover' gives a confusing message.</i></p> <p><i>There is data and existance of mature schemes to verify the sustainable sourcing of palm oil, palm kernel oil and their derivative. Consequently the word 'moreover' is giving the wrong message as it is wrongly connecting ideas that are not the same.</i></p> <p><i>Remove the word 'moreover' as it is wrongly used.</i></p>	<p><b>Comment rejected</b> The two sentences are indeed connected as the reasons why no other requirement was introduced on ingredients other than palm oil, palm kernel oil and their derivatives are that no mature standards exist for these ingredients AND other ecolabel schemes do not go further than that.</p>
<p><i>Incorrect statement.</i></p> <p><i>RSPO sets up the Standard for the production of sustainable palm oil. The assurance system of RSPO ensures that RSPO certified products contain PO/PKO from sustainable production.</i></p> <p><i>To rephrase to indicate the correct statement.</i></p>	<p><b>Comment accepted</b> The sentence was amended</p>
<p><i>Incorrect statement.</i></p> <p><i>As per the explanation below regarding P&amp;C2018, it is demonstrated that RSPO does effectively prohibit the conversion of rainforest to palm plantations in RSPO certified plantations.</i></p> <p><i>To correct the sentence to indicate the correct statement.</i></p>	<p><b>Comment rejected</b> The sentence indicated by the stakeholder refers to before the P&amp;C2018 was published, as indicated also in the next paragraph.</p>
<p><i>There is a new SCC Systems document endorsed 01 February 2020.</i></p> <p><i>To update the footnote</i></p>	<p><b>Comment accepted</b> The footnote has been updated accordingly</p>
<p><i>Incorrect statement.</i></p> <p><i>As per the previous comment and as per the explanation below regarding P&amp;C2018, it is demonstrated that RSPO does effectively prohibit the conversion of rainforest to palm plantations in RSPO certified plantations. Therefore, the connector 'for this reason' is incorrect.</i></p> <p><i>Remove 'for this reason', as RSPO prohibit the conversion of rain forest into palm plantations in the RSPO certified plantations.</i></p>	<p><b>Comment accepted</b></p>
<p><i>It needs amendment.</i></p> <p><i>40% of world land under oil palm production is owned by SH.</i></p>	<p><b>Comment accepted</b></p>

<p><i>Amend the sentence to indicate the correct statement.</i></p>	
<p><i>Agree that this should be included. These articles are found in a number of standards on the market with criteria for their production and the origin of their starting materials.</i></p> <p><i>The wet wipe material must be sourced sustainably from renewable raw materials, avoid the use of hazardous preparative chemicals, if flushable it must be made of materials that break apart with the mechanical flush but this is not preferable since the material enters the water system so the material has to be biodegradable in end use.</i></p> <p><i>Wet wipes have an environmental footprint but remain a common article to apply cosmetic products for consumers on the market. Consumers use a number of articles to apply and remove cosmetic products, including cotton pads etc. Cotton is a natural biodegradable material that can be sourced and disposed of responsibly. Therefore, the use of any such article should be treated responsibly in line with the principles of the EU EcoLabel. Eliminating their use would also limit what products could be made, as cosmetics, under the EU EcoLabel.</i></p>	<p><b>Comments rejected</b>  It has been decided to remove wet wipes from the scope for this revision. Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.  Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products.  In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>Denmark supports to include wet wipes into the product group, but fragrance should not be allowed in wet wipes. People expects to be clean when using a wet wipe, not having their hands smelling like a perfume.</i></p> <p><i>We also suggest including a requirement to the process water – if this is used in the production. This suggestion is taken from the Nordic Swan Ecolabel.</i></p> <p><i>Some stakeholders agreed on the inclusion of wet wipes under the scope and suggested improvements to the proposed criterion:  It was suggested to ban fragrances.</i></p> <p><i>Srong requirements of biodegradability and no environment toxicity should be defined for the formula and the fibers used.</i></p>	<p><b>Comment rejected</b>  The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>There are other available standards and these should be explored and included.</i></p>	<p>In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision.</p>
<p><i>The substrate must be biodegradable.</i></p>	
<p><i>As alreday commented, we are not in favour of the inclusion of wet wipes in the scope of th ecolabel.</i></p> <p><i>If they are included, the proposed criteria seems not adpated :</i></p> <p><i>EU Ecolabel for "Graphic paper, tissue paper and tissue products" in accordance with Commission Decision (EU) 2019/70,</i></p> <p><i>Ecolabel for "Absorbent Hygiene Products" in accordance with Commission Decision (EU) 2014/763</i></p> <p><i>specific criteria should be defined, specfied for these products.</i></p>	<p><b>Comment partially accepted</b>  Wet wipes are proposed to be removed from the scope</p>
<p><i>There is gap to fill here if you want to certify wet wipes. Fibers are not certified in the</i></p>	<p><b>Comment rejected</b></p>

<p><i>product group sanitary products, we certify the final product. A fiber can be approved/assessed according to the criteria for sanitary products. Then, we need to have a requirement on the wipe manufacturer to be sure that the right approved fiber is used in the wipe intended to become a EU Ecolabel certified wet wipe.</i></p>	<p>The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>As a minimum, the wipes must be 100% bio-based excluding petrochemicals materials.</i></p>	<p>Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.</p>
<p><i>Avoid certifying fibres made by viscose. Certify only fibres made with cellulose.</i></p>	<p>Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products.</p>
<p><i>Investigate if it is technically possible to use paper as a substrate.</i></p>	<p>In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision.</p>
<p><i>biodegradable and natural fiber should be encouraged. Viscose and plastics should be banned.</i></p>	<p>In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision.</p>
<p><i>Paper substrate can hardly be used for wet wipes. The material made of pure cellulose fiber is too frail/fragile and must be further processed by a wipe manufacturer. It is often blended with viscose or PET/PP fibers.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>The product group textile has the same requirements when it comes to fibers. They also can be used and the same as in our previous comment applies.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>There need to be requirements at the wipe level. What the manufacturers do to the fibers ust be checked? Do they use chemicals? TiO2 is used as delustrant for instance. Do they use environmentally/sensitizing hazardous preservatives in the process water?</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>We do not support the inclusion of wet wipes in the scope as they represent a large amount of waste that can be avoided by using alternatives.</i></p> <p><i>If wet wipes are to be included in the standard, the criterion on raw materials might not be adequate. Indeed, French stakeholders have pointed out that "Graphic paper, tissue paper and tissue products" and "Absorbent Hygiene Products" standards are not appropriate for wet wipes. We would thus recommend introducing a criterion on the origin of the fibre substrate of wet wipes by using other standards such as FSC or PEFC.</i></p>	<p><b>Comment partially accepted</b> Wet wipes are proposed to be removed from the scope</p>
<p><i>The requirement for Forestry in Ecolabel for AHP is really low ambition. Only 25% from sustainable managed forests compared to vs as benchmark in FSC and PEFC.</i></p>	<p></p>
<p><i>For wet wipes the EU Commission should not refer to the EU Ecolabel for Hygiene Absorbent Products because the level for forestry requirements is too low (25% vs the usual 70%). The Commission should instead align with FSC requirements (70%)</i></p>	<p></p>
<p><i>Increase the percentage of SFM in forestry requirements to the usual 70%.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>If the SFM part in the forestry rerquirements is too low (25%), it would make the EU Ecolabel legislation inconsistent and will also make the rationale of EU Ecolabel weaker.</i></p>	<p>The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>The requirements for the substrate should not be aligned with the Ecolabel for AHP. They are old requirements from 2014 which did not set a requirement of environmental excellence for the origin of fibres. Only 25% of fibres should originate from sustainable managed sources, while the reference under FSC and other Ecolabel product groups is 70%.</i></p>	<p></p>

<p>Any requirements for chemicals for wet wipes should be in line with the other requirements set within the set for cosmetics and not for AHP.</p>	
<p>Criterion 3.6 (b) User information</p> <p>The packaging shall include information on the correct disposal of the wipes.</p> <p>This criterion should be further clarified, with regards to the meaning of "correct disposal"</p> <p>Process water: a substance that is classified as sensitising with risk phase H317 and/or H334 can only be used in the process water if the residue in the non woven is &lt;0.1 ppm for each sensitizing substance</p> <p>The user manual must include details of calculation method.</p>	<p><b>Comment acknowledged</b> The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explored in next revision.</p>
<p>Other stakeholders were against the inclusion of wet wipes under the scope and suggested to remove this criterion:</p> <ul style="list-style-type: none"> <li>We're not in favour of including wet wipes on the scope. Wet wipes are a ecologic disaster (unique usage as alternatives exists), the SUP regulation is including new requirements like not flush wet wipes and not let it in environment because of many "biodegradable" claims on wet wipes packaging that create confusion on consumers. I don't think ECOLABEL has interest to promote this controversial category.</li> <li>We're not a fan from including wet wipes in the scope.</li> <li>When you give the ecolabel you sort of give a green light to these single use product</li> <li>Wet wipes generate waste. It doesn't matter whether they are biodegradable, because they have to be disposed of with household waste and then have to be incinerated.</li> </ul> <p>The best is that they are not included. But if they are, clear difference has to be made with conventional products.</p>	<p><b>Comment accepted</b> Wet wipes are proposed to be removed from the scope</p>
<p>We are not in favour of the inclusion of wet wipes because we are seriously concerned about the environmental impact the existence of them (waste increase).</p> <p>This kind of products is not environmentally friendly and we consider this inclusion risks to promote wet wipes. That's why we strongly disagree with this inclusion because we consider that this kind of products is not in the spirit of the EU Ecolabel.</p> <p>Exclude wet wipes from the scope, so this criterion must be deleted.</p>	
<p>One stakeholder suggested to remove from the criterion text the specific questions related to the consumer tests, in order to preserve flexibility.</p>	<p><b>Comments rejected</b></p>
<p>Denmark suggest to make a more product specific guidelines to the user test. This will ensure that the products will be evaluated on the same basis – inspiration can be found in the The Nordic Swan requirement for Cosmetic products (version 3.7), appendix 7.</p>	<p>The inclusion of the consumer test questions in the criterion text aims at standardizing the tests for all products. Further guidance has been given in the new version of TR3.</p>

One stakeholder stressed the importance to keep the requirement concerning the application ease of the cosmetic product and suggested to replace the question relating to the easiness of application by requiring applicants to define the correct dosage or the appropriate quantity and test it in laboratory tests. One suggestion was:  
"In order to control the dosage of certified products and avoid any overdosage, we should require :  
applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,  
applicants shall provide a convenient dosage system (as for detergents) if appropriate or a effective system of delivery,  
applicants shall indicate the correct dosage on the label and a sentence which underlines the importance of using the correct dosage/quantity in order to minimise energy and water consumption, reduce water pollution and save money.  
This requirement should replace the question « How easy is it to apply the dosage of the product in comparison with a market-leading product? » because:  
it's not a scientific and reliable method and  
it's binding because applicants shall provide a new test when they change their packaging."

The question « How easy is it to apply the dosage of the product in comparison with a market-leading product?" » (question 2 of test) should be replaced by a specific requirement concerning the dosage (or if not appropriate en effective system of delivery) because :

it's not a scientific and reliable method and

it's binding because applicants shall provide a new test when they change their packaging.

Nevertheless, if this question is kept, this ability shall be tested in laboratory tests too in order to ensure the fairness of the methods equivalence.

In order to control the dosage of certified products and avoid any overdosage, we should require :

applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,

applicants shall provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery,

applicants shall indicate the correct dosage/quantity on the label and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money.

This requirement should also replace the question « How easy is it to apply the dosage of the product in comparison with a market-leading product?" » (question 2 of test) because :

#### Comments accepted

Criterion 5 (c) has been modified and now includes the following requirement:

"Applicants shall indicate on the label of the primary packaging:

- the correct dosage or the appropriate quantity to be used by the consumer; and
- on the label of the primary packaging and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money"

In addition, in criterion 7 it has been added that the tests (both laboratory and consumer tests) shall be conducted on the dosage indicated by the applicant [1].

The question on the ease of application for leave-on products has been deleted, as it is more relevant for criterion 5.

*it's not a scientific and reliable method and*

*it's binding because applicants shall provide a new test when they change their packaging.*

*It's important to keep the requirement concerning the application ease of the cosmetic product because it's a relevant selection criterion for consumers.*

*In order to ensure the fairness of the methods equivalence, laboratory test shall also include a test for :*

*How easy is it to apply and rinse-off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?*

*If it is maintained for user tests, How easy is it to apply the dosage of the product in comparison with a market-leading product?*

*In order to control the dosage of certified products and avoid any overdosage, we should require :*

*applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,*

*applicants shall provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery,*

*applicants shall indicate the correct dosage/quantity on the label and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money.*

*This requirement should also replace the question « How easy is it to apply the dosage of the product in comparison with a market-leading product?" » (question 2 of test) because :*

*it's not a scientific and reliable method and*

*it's binding because applicants shall provide a new test when they change their packaging.*

*In order to control the dosage of certified products and avoid any overdosage, we should require :*

*applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,*

*applicants shall provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery,*

<p><i>applicants shall indicate the correct dosage/quantity on the label and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money.</i></p>	
<p><i>We support the upholding of this criterion for the following reasons:</i></p> <p><i>The requirement on the demonstration of the product's capacity to fulfil its primary function and any secondary functions claimed should be kept in order to maintain EU Ecolabel credibility;</i></p> <p><i>The test on the ease of application of the product is essential, as it is an important decision criterion for consumers.</i></p> <p><i>However, French cosmetic companies have argued that the objective and the relevance of this criterion are not clear, especially on the ease of dose delivery. The latter is highly subjective and is more linked to the equipment used than to the product itself. It is also hardly applicable to refills that can be sold wholesale or to new products included in the scope such as body balm and deodorants. Thus, we wish to receive further explanation from the JRC to justify this criterion.</i></p>	
<p><i>It's important to keep the requirement concerning the application ease of the cosmetic product because it's a relevant selection criterion for consumers.</i></p> <p><i>This ability shall be tested in laboratory tests too in order to ensure the fairness of the methods equivalence.</i></p>	
<p><i>In order to ensure the fairness of the methods equivalence, laboratory test shall also include a test for :</i></p> <p><i>How easy is it to apply and rinse-off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?</i></p> <p><i>If it is maintained for user tests, How easy is it to apply the dosage of the product in comparison with a market-leading product?</i></p>	<p><b>Comment partially accepted</b></p> <p>In the TR3 it is required that if available, a recognised standardised laboratory test (for example Commission Recommendation 2006/647 (*) for sunscreen products) must be used, and consumer tests will not be considered equivalent. However, in order to reduce the burden on applicants, only one type of test is required.</p>
<p><i>Can the list of tests for the laboratory assessment be made available in an annex for the different categories ? for clarity, simplification and alignment</i></p>	<p>A non-exhaustive list of available laboratory tests will be made available in the User Manual.</p>
<p><i>Moreover, stakeholders expressed their interest in favouring laboratory tests over consumer tests.</i></p>	
<p><i>We recommend adding:</i></p> <p><i>"instrumental tests when available shall take precedence over consumer tests".</i></p> <p><i>A compilation of a list of methods that could be used for each cosmetic product could also be helpful.</i></p>	

<p>Stakeholders should provide the program or test method. On the other hand, efficacy cannot be based in "consumer test". Use test only gives the perception of the consumer about the efficacy of the product, it is not objective. Consumer organisations experience when testing cosmetics shows that consumers normally appreciate the products and think they are effective (even when we have objective data that shows the opposite). They can only tell if they like it or not, but not if it works.</p>	
<p>Since a defect in quality/effect of toothpaste may be associated with a risk for decreased dental health, product specific requirements for this product type should be introduced.</p> <p>Toothpaste</p> <p>If there are national guidelines on fluorine content in toothpaste, they should be followed. Exceptions may be made if a fluorine-free toothpaste has been evaluated by an independent party and the conclusion is that it has the same protective effect as fluorine-containing toothpastes.</p>	<p><b>Comment accepted</b> This has been included in the criterion text</p>
<p>It's essential to require tests to prove that primary function and any secondary functions claimed on the label of certified EU Ecolabel products are fulfilled in order to maintain the credibility of the European Ecolabel.</p> <p>Secondary function claims are covered by the legislation already (cosmetics regulation and EC no 655/2013) and need not be included in the criteria. Documenting and evaluating this requirement is only time-consuming for applicants and ecolabel bodies. however, in terms of safety or "mildness" of products, a requirement for claims regarding e.g. "sensitive" products should be considered</p>	<p><b>Comments rejected</b> In the assessment and verification it is clearly stated that "Tests performed in compliance with Cosmetics Regulation and Regulation 655/2013 can be suitable to demonstrate that the product fulfils its primary function and any secondary claimed function. It is not necessary to perform new specific tests to demonstrate a function previously demonstrated."</p>
<p>Stakeholders had polarized views on the existing legislation on claims. Some stakeholders judge the EU legislation on claims not to be comprehensive and prompted the EU Ecolabel to add an extra layer of protection for the consumers and adopt stricter requirements, especially targeting products misleadingly claimed to be sensitive while containing allergens: "The cosmetics regulation has issues here, that can mislead consumers. It will be good if EU Ecolabel is very clear on this".</p>	<p><b>Comments rejected</b> The claim on gentle/sensitive is regulated by the Cosmetic Regulation, Regulation 655/2013 on the justification of claims in cosmetic products, Directive 2005/29/EC on the Unfair Commercial Practices and technical guideline for allegations. Tests like HET-CAM or a test for red blood cells will be used. If these tests demonstrate that a product containing fragrances is sensitive, it will be accepted.</p>
<p>We suggest to a requirement to ensure that products which includes fragrance can not be labelled with claims like "mild/gentle or sensitive".</p>	
<p>On claims: if fragrances are included, there should not be a claim that the cosmetic is not sensitizing.</p> <p>Also the claims "mild/gentle/sensitive" cannot be demonstrated in a User test. These claims can be documented by testing methods to document mildness, e.g. HET-CAM or a test for red blood cells.</p>	
<p>On the other hands, other stakeholders considered the requirements under the Cosmetics Regulation, Regulation 655/2013 and the Unfair Commercial Practices Directive to be sufficient: "Keep in mind fragranced product are compatible with "sensitive" or "gentle" as soon as we have strict criteria on fragrances (no H317/334 nor allergen)"; "The claim sensitive skin is already regulated by cosmetics regulation and technical guideline for allegations. ECOLABEL certification doesn't have to have a different point of view".</p>	<p><b>Comment accepted</b></p>

<p>The performance test protocols must be available as soon as possible and in the latest when the Decision will be published, in order to not lose time for the renewal process.</p> <p>The actual requests are more or less relevant for rinse-off cosmetics products but not for leave-on products. It's important to have well-defined protocols very soon.</p>	<p><b>Comment acknowledged</b></p>
<p>How statistically significant is this proportion? Unclear</p>	<p><b>Comment clarified</b> The 80% satisfaction limit for the user tests comes from Cosmetics Europe's 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products' and is in line with Nordic Swan and Blue Angel</p>
<p>The user manual shall be available at the same time as the decision.</p>	<p>Comment acknowledged</p>
<p>We are not in favour of this practice.</p>	<p><b>Comment clarified</b> This kind of certification is not requested in EU Ecolabel</p>
<p>About the sentences on the label, a stakeholder proposed to focus the sentences on criterion 3 and other stakeholder mentioned that the sentence on <b>restriction of hazardous substances</b> is used in other product groups.</p>	<p><b>Comments partially accepted</b> Text has been revised according to the suggestions received.</p>
<p>A stakeholder suggested "<b>Promoting care for the environmental</b>"</p>	
<p>Other stakeholder commented: "It's important to modify information appearing on the EU Ecolabel to add a sentence concerning <b>conducted tests</b> in order to highlight also the performance of EU Ecolabel certified products."</p>	
<p>Additionally a stakeholder mentioned: "we would prefer the criteria for claiming <b>biodegradable/lower impact on environment are not required</b>"</p>	
<p>Suggest to include in the text : Cosmetics products must contain in addition to label requirement from Cosmetics Products regulation , the following optional label with text ...."</p>	
<p>Whilst all cosmetics must support their claims related to the characteristics or functions of their product, claims made in reference to this Regulation should only be supported by hard criteria presented in the regulation. Soft claims like environmental friendliness are too vague and should be avoided / not encouraged. Those claims listed are fine to this extent.</p>	
<p>It was mentioned that the sentence about biodegradability would not apply with wet wipes if the final decision is to keep them in the scope.</p>	<p>Wet wipes have been finally excluded from the scope.</p>
<p>It was expressed: "The AGEC French law is releasing banning the words "biodegradable" are "respectful for environment" or equivalent that is totally in contradiction with ECOLABEL aim. Regarding AGEC French law "loi n°2020-105 relative à la lutte contre le gaspillage et à l'économie circulaire", EC must push to exempt ECOLABEL products from this new French law"</p>	<p><b>Comments acknowledged</b></p>
<p>We wish to inform the JRC that this criterion might be in contradiction with the French law on waste reduction and circular economy voted in February 2020. This law prohibits the use of terms "biodegradable", "respect the environment" or any equivalent wording in packaging. We recommend that the JRC request an exemption for certified products.</p>	
<p>Communication on packaging is important to inform the consumer about the efforts made on the products in order to reduce the impact on the environment.</p>	

<p>However, the french law of the waste reduction and circular economy voted in february 2020 would not let this.</p> <p>This french law is in contradiction with The criteria 8 of the ecolabel. Conditions should be the same for all countries.</p> <p>We ask for pushing for an exemption in the french law to french authorities, at least for certified products.</p>	
<p>Finally it was suggested to add a criterion about information provided on labels which requires: □- information on product's use : dosage which shall be easily achievable with the effective system of delivery (applicants shall also indicate on the label how to use it), □- applicants have to prove differents claims, □- information on the reuse – requirement connected to packaging criterion, recycling and correct disposal of packaging, □- In order to harmonise with good pratises used in detergents products &gt;&gt; A text shall appear on the primary packaging indicating the importance of avoiding overdosage and to refill the product in order to minimise energy and water consumption, reduce water pollution and save money</p> <p>In addition it's necessary to force applicants to provide provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery.</p> <p>Moreover it's necessary to add a criterion about information provided on labels which requires :</p> <p style="padding-left: 40px;">Information on product's use : dosage which shall be easily achievable with the effective system of delivery (applicants shall also indicate on the label how to use it),</p> <p style="padding-left: 40px;">Applicants have to prove differents claims,</p> <p style="padding-left: 40px;">Information on the reuse – requirement connected to packaging criterion, recycling and correct disposal of packaging,</p> <p style="padding-left: 40px;">In order to harmonise with good pratises used in detergents products &gt;&gt; A text shall appear on the primary packaging indicating the importance of avoiding overdosage and to refill the product in order to minimise energy and water consumption, reduce water pollution and save money.</p>	<p><b>Comment partially accepted</b>  Provision of dosage information and design for a proper dosage has been addressed in primary packaging criterion.</p>

## ANNEX III

Comments received after the EUEB meeting (Nov 2020). Comments refer to the third version of the revised criteria proposal.

Comments received in last open consultation	JRC Dir. B response
<p><i>we still supports the suggested scope, which includes wet wipes and sunscreen. 3Denmark also supports to include Animal care products.</i></p> <p><i>we supported this criterion in the former Draft, which was to include wet wipes into the product group, and we still see that this criterion should be included. However, we cannot support that fragrances are allowed in wet wipes. We also suggest including a requirement to the process water – if this is used in the production. This suggestion is taken from the Nordic Swan Ecolabel.</i></p> <p><b>Process water: A substance that is classified as sensitising with risk phrase H317 and/or H334 can only be used in the process water if the residue in the nonwoven is &lt;0,10 ppm for each sensitizing substance.</b></p>	<p><b>Comments rejected</b> Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers. Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products. In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p><i>2) 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes (etc.) Here it is not relevant to include "substance" because no substance can be certified as cosmetic products.</i></p>	<p><b>Comment rejected</b> Text is aligned to Cosmetic Regulation</p>
<p><i>Maybe it's necessary to add a definition for "mixture"?</i></p>	<p><b>Comment partially accepted</b> Definition proposed to be included in the User Manual. In line with Cosmetics Regulation.</p>
<p><i>The definition of "animal care products" is missing</i></p>	<p><b>Comment acknowledged</b> It is considered that the text included for animal care products under article 2 is precise enough: rinse-off substance or mixture intended to be placed in contact with animal hair to clean them or to improve the condition of it, such as shampoos and conditioners for animals</p>
<p><i>The following definitions should be added for clarification; no cross references (see p. 16) should be used: 8.) microplastic 9) Nanomaterial 10) Substances and mixtures identified to have endocrine disrupting properties This should also be the case for animal care products</i></p>	<p><b>Comment accepted</b></p>
<p><i>License holders and some competent bodies do not know from which substances arylamines come from! We suggest we write "(e.g. formaldehyde from preservatives and arylamines from azodyes and azopigments)", so there is no risk of missing hazardous azodyes and azopigments.</i></p>	<p><b>Comment accepted</b></p>
<p><i>You indicated in comments "Inorganic rubbing/abrasive agents are not included in the calculation of active content. Organic rubbing/abrasive agents should be included in the calculation of CDV toxicity. Further guidance will be given in the user manual"</i></p>	<p><b>Complementary definitions clearly states:</b> Inorganic rubbing/abrasive agents are not included in the calculation of the active content;</p>

<p>&gt;&gt; So, can you confirm (and indicate in the UM) that inorganic rubbing/abrasive agents are not included in the calculation of CDV toxicity because the calculation of CDV is connected to the calculation of AC?</p>	<p>Further guidance will be included in the UM</p>
<p>Third complementary definitions proposal Page 10 9) (empty) It is a mistake</p>	<p><b>Comment accepted</b></p>
<p>We wish to receive clarifications from the JRC on impurities concentrations. Indeed, it is specified under point 4) that "impurities in the raw materials <math>\geq 1000</math> ppm are always regarded as ingoing substances", however it is specified in point 5) that impurities "remain in the raw material/ingredient and/or in the final product in concentrations less than 100 ppm in the rinse off product and less than 10 ppm in the leave on product". Therefore, a clarification is needed on whether impurities in concentrations between 100ppm and 1000ppm for rinse off products and between 10ppm and 1000ppm for leave on products are considered as impurities or not.</p> <p>There are 2 different thresholds for impurities: <math>\geq 1000</math> ppm in the raw materials (point 4) and <math>\geq 100</math> ppm (or 10 ppm) in the final product (point 5). What threshold shall be considered?</p>	<p><b>Comment accepted</b> The definition of ingoing substances and impurities have been clarified.</p>
<p>The product group "animal care products" shall not cover products that are specifically marketed for disinfecting or anti-bacterial use. Please add the following sentence: "The product group "cosmetic products" shall not cover products that are specifically marketed for disinfection or anti-bacterial use. Anti-dandruff shampoos are allowed.</p>	<p><b>Partially accepted</b> These products fall under the Biocidal products Regulation and are therefore out of the scope of Cosmetic Regulation. It is redundant (and could be misleading) to mention that the EU Ecolabel for cosmetic products does not cover such products. However a clarifying note with this regards will be included in the user manual. In relation to the sentences: Anti-dandruff shampoos are allowed. This has not been mentioned as antidandruff products are considered under the cosmetics Regulation and therefore under the scope of this EU Ecolabel.</p>
<p>As shared in previous comments on the first and second technical reports, we believe that including sunscreen products in the scope could discredit the reputation of the EU Ecolabel because of the presence of UV filters that are not biodegradable. We would like to draw the JRC attention on the fact that studies on environmental and health impacts of UV filters are still in progress, which means that there are no validated data available to establish relevant criteria on UV filters. We thus recommend planning an intermediary revision of the technical report in order to take into account the results of current studies on UV filters and review the criterion 4(g) accordingly to make sure it promotes the use of the best alternatives in the market.</p>	<p><b>Comments rejected</b> Sunscreen needs to be used during summer to avoid solar radiation, it is an essential product. It is important to recognise better alternatives through EU Ecolabel. Nordic Swan has 58 certified sunscreen products (+ 10 sunscreens for children). It is proposed to keep sunscreens under the scope. In line with Nordic Swan UV filters are exempted of biodegradability criterion however there is a specific criterion on UV filters on criterion 4 to ensure non bioaccumulation and low toxicity for organic UV filters.</p>
<p>Regarding animal care products we are not in favour of EU Ecolabel criteria for such products as they are most of the time unnecessary. In the Austrian Ecolabel we avoid to award unnecessary products as the most sustainable way is not to use them, even if they are more environmental friendly than others.</p>	<p><b>comments rejected</b> These products are not essential but its use is very much extended. These products present licences under the Nordic Swan. It is important to give consumers the option to select better alternatives for these type of</p>

	<p>products. There are at least 12 products certified under Nordic Swan scheme for this category. It is considered important to give consumers the opportunity to choose a better option for animal care products. Although these products are not covered by the Cosmetics Regulation, this EU Ecolabel sets strict requirements for these products aligned to cosmetic products. In addition, considering the expressed concern on the animal testing, fitness for use criterion has been modified to ensure the absence of animal testing.</p>
<p><i>We are not in favour of the inclusion of any cosmetic product as we mentioned before and would prefer to stick on the group of rinse-of products. We would very welcome if at least no decorative cosmetics and hair dyes are included and are sceptical that feminine hygiene cosmetic products shall be included as those products are not very welcomed by gynecologists.</i></p> <p><i>In regard of borderline products please check following document <a href="https://ec.europa.eu/docsroom/documents/42850">https://ec.europa.eu/docsroom/documents/42850</a></i></p> <p><i>We are of the opinion that you should mention the product groups explicitly like in the draft before to prevent ambiguities.</i></p> <p><i>And especially for the borderline with biocides (ch.3.2) we ask to exclude any "antiseptic" or "antibacterial" products similar to the EU Ecolabel criteria for cleaning agents.</i></p>	<p><b>Comment partially accepted</b> At the first AHWG meeting a general agreement was expressed to extend the scope to all cosmetics included in the cosmetics Regulation. It is proposed to keep the alignment to Nordic Swan.</p> <p>In relation to antiseptic and antibacterial products the exclusion has been specified</p> <p>Tables in order to clarify which products belong rise off or leave on categories, and therefore which criteria affect to the different products are proposed to be included in the User Manual.</p>
<p><i>According to our experience dry shampoos can sometimes contain small percentages of powder surfactants. Even if not washed with water, dry shampoos are removed from hair so we propose to compare them with rinse-off products.</i></p>	<p><b>Comment rejected</b> Dry shampoos are marketed not to be rinsed off immediately, therefore they fall under the leave on category</p>
<p><i>Italy is in favour of the inclusion of pet care products in a separate annex. We are in favour of the inclusion of sunscreen since needed for protection and of the exclusion of wet wipes since not necessary and very polluting.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>A detailed list which products belong to the product group "leave-on cosmetics" is missed and should be added. All product types belonging to rinse-off-cosmetics should be added. Moreover, products that are not falling under these product groups should be added. (For some month decorative cosmetics were excluded explicitly) Alternatively, the included and excluded products could be mentioned/listed in Article 3.</i></p>	<p><b>Comment partially accepted</b> Considering that all cosmetics are covered, the scope refers to Cosmetic Regulation. Detailed list differentiating rinse off form leave on will be included in the User Manual. Reference to borderline will be also included in the User Manual.</p>
<p><i>We recommend to split this product group into two product groups: 1.) cosmetic products and 2.) animal care products. From our point of view cosmetics are products in the meaning of the cosmetic regulation ((EC) No 1223/2009). Animal care products are detergents in the meaning of the regulation no 648/2004. We suggest to assign this product group to laundry detergents.</i></p>	<p><b>Comment rejected</b> There are at least 12 products certified under Nordic Swan scheme for this category. It is considered important to give consumers the opportunity to choose a better option for animal care products. Although these products are not covered by the Cosmetics Regulation, this EU Ecolabel sets strict requirements for these products aligned to cosmetic</p>

	products. In addition, considering the expressed concern on the animal testing, fitness for use criterion has been modified to ensure the absence of animal testing.
<i>The product group 'Cosmetic products' shall include products for both private and/or professional use.</i>	<b>Comment accepted</b>
<i>The product group 'Animal care products' shall include products for both private and/or professional use.</i>	Text has been corrected
<i>Measurement thresholds: We understood from the presentation at the EUEB, that the approach now will be as in the current criteria (and in the 2nd draft technical report). Denmark supports these definitions for substances and impurities, which is in line with the Nordic Swan Ecolabel.</i>	<b>Comments acknowledged</b>
<i>We understand from feedback from JRC that "regardless of concentration" and "no limit" should have the same meaning in this table. We recommend referring only to "regardless of concentration"</i>	
For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>17</sup> <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018D1702&amp;from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018D1702&amp;from=EN</a> - <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018L0003&amp;from=EN">ntr3-L_2018285EN.01008501-E0003</a> shall be provided <i>I think it's a mistake : this link is for lubricants decision</i>	<b>Comment accepted</b>
<i>License holders inform us it is not possible for "2-in-1" or "3-in-1" product. If the product is intended for different functions (for example shampoo and shower), the highest threshold (less restrictive) shall be considered. Indeed, it's better for the environment to encourage "2-in-1" and "3-in-1" products.</i>	<b>Comments rejected</b> There is no clear evidence that a 2 in 1 product is better for the environment. Considering the impact is closely linked to the composition of each functionality (category), then the most restrictive threshold shall apply. This is horizontal approach in all EU ecolabel product groups.
Footnote 18 <i>Be careful: links are not correct because it is 2014 version instead of 2016 version.</i>	<b>Comment accepted</b>
<i>What is the rationale of having different threshold levels for leave on and rinse off cosmetics and why are all the threshold levels for leave on products stricter? We acknowledge that stricter criteria for leave-on products may be appropriate for substances with human health hazards, but it doesn't make sense for environmental properties such as i) Criterion 3. Biodegradability and aquatic toxicity of leave on cosmetic products and ii) hazards to the environment (Table 5, page 60) or properties related to the source of a substance such as criterion 6, renewable ingredients. The level for "leave on" products for fragrances should not be lower than the level for "rinse off" products for such criterion. They should both be 0.010% (100ppm). Like we argued in the previous consultation, for leave-on cosmetics the main release of the fragrance component will be evaporation from the skin into the air i.e. at the end of the day there will be no / negligible amounts remaining on the skin for subsequent wash off. Criteria related to the aquatic environment are not necessarily relevant for the fragrance substance.</i>	<b>Comment rejected</b> The criteria have been developed taking into account the thresholds set in the Cosmetic Regulation and in the Nordic Swan criteria. Please notice that criteria 1, 2 and 3 refer either to rinse off or to leave on, therefore ensuring that an appropriate safety level. While we acknowledge that criterion 4 (a) could seem a contradiction in having a stricter threshold for leave on products (that are released to water to a less extent), all other environmental schemes set the same thresholds. Setting a different threshold in the EU Ecolabel is impossible at this stage of the revision due to the availability of data. Indeed, we would not be able to verify the feasibility of a stricter threshold for rinse off products.

<p>Denmark will strongly encourage the Commission to consider the validity period again for the product group Cosmetic Products. Consumers are very focused on this product group, and it is of crucial importance for the credibility of the EU Ecolabel for Cosmetic Products that the criteria are up to date. A lot of new knowledge and focus areas will appear during an 8 year validity period, which will not be reflected in the criteria. The Commission argued at the EUEB, that a long validity period is beneficial for the license holders. This is definitely not the responses we get from license holders for the Nordic Swan Ecolabel for Cosmetic Products. They urge Nordic Ecolabelling to ensure that the criteria are revised often in order to keep up with the expectation of consumers.</p>	<p><b>Comment accepted</b> Validity period has been modified to 6 years</p>
<p>We fear that after the proposed 8 years validity the criteria will be very outdated. Because of the new and very ambitious chemicals strategy for sustainability and especially in regard of endocrine disrupting chemicals we expect considerable developments within the next years. Therefore we ask to put choose 6 years for this product group.</p>	
<p>8 years validity: in favour</p>	
<p>As already said, we would like to remind you of the importance of providing the user manual (UM) at the same time as the decision. If it is possible, our license holders would like to comment/ask some clarifications before the publication of this UM.</p>	<p><b>Comment acknowledged</b> It is expected to have the UM ready at the time of the Decision publication</p>
<p>As the raw material and packaging declarations are going to be more extensive than before for this category, it will take more time to obtain them and therefore it is necessary that they are available at the same time as the voted criteria</p>	
<p>Technical report User Manual, Spreadsheets, Availability of documentation We would like to draw the JRC's attention to the need to make all the documents (report, spreadsheet and user manual) available at the same time, in order to avoid the difficulties encountered in 2017 during the revision of the detergent report.</p>	
<p>We would like to draw the JRC's attention to the need to make all the documents (report, spreadsheet and user manual) available at the same time, in order to avoid the difficulties encountered in 2017 during the revision of the detergent report.</p>	
<p>French CB mentioned that this criterion might be in contradiction with the French law on waste reduction and circular economy voted in February 2020. This law prohibits the use of terms "biodegradable", "respect the environment" or any equivalent wording in packaging. We are the French CB, AFNOR, and it's not one of our comments. Maybe there was a confusion with ADEME.</p>	<p><b>Comment accepted</b></p>
<p>10000 for liquid soaps and shower preparations We agree with this proposal</p>	<p><b>Comments acknowledged</b></p>
<p>11000 for shampoos (liquid form) We agree with this distinction for shampoos. Indeed, we are in favour of the separation between liquid soaps/shower preparations and shampoos.</p>	
<p>We highly welcome that the CDV limits have been lowered for liquid soaps and shower preparations</p>	
<p>We welcome to reduce the CDV-values as in our experience the existing thresholds are not very demanding</p>	
<p>Criterion 1: in favour of the proposed threshold</p>	<p><b>Comments rejected</b> Nordic Swan holds 15 licences for solid soaps with a CDV value below 2000 l/g AC. While this shows that the limit is attainable, the current threshold for solid soaps</p>
<p>Denmark can support the suggested CDV values, except for Solid soap. For solid soap, we suggest to follow the Nordic Swan Ecolabel and set the limit at 2000. A present, the Nordic Swan have certified 15 different products. The argument for setting a higher limit was that two EU Ecolabelled products would not comply. We think the number of products certified with the Nordic Swan ecolabel shows the limit at 2000 is feasible.</p>	

	<p>in the EU Ecolabel criteria in force (3 300 g AC/l) could be achieved by only 4 products. Because the EU Ecolabel entails the market of the whole EU, the low uptake of EU Ecolabel licenses for solid soaps may suggest that Southern European market may need a slighter higher limit. Nevertheless, the threshold is proposed to be decreased to 2 200 g AC/l anyway (which represents a limit 33% stricter than the current in force). Considering that this limit should be valid also for solid shampoos, solid shaving soaps and solid toothpaste, which are new products under the scope, a limit of 2 200 l/g AC is considered an acceptable compromise.</p>
<p><i>You announced only 15 solid soaps are certified according Nordic Swan with this strict threshold (2.200) whereas DK communicated that at the present there are more than 2200 certified products. It represents less than 1%!</i></p> <p><i>So, you considered to promote solid soaps during the first meeting but the threshold for this kind of products seems to be too restrictive.</i></p>	<p><b>Comment rejected</b> The majority of stakeholders during the revision process have been against a relaxing of the CDV thresholds for solid soap compared to the values in Nordic Swan.</p>
<p><i>"The CDV is calculated using the following equation:" You indicated in comments "Inorganic rubbing/abrasive agents are not included in the calculation of active content. Organic rubbing/abrasive agents should be included in the calculation of CDV toxicity. Further guidance will be given in the user manual"</i></p> <p><i>&gt;&gt; So, can you confirm (and indicate in the UM) that inorganic rubbing/abrasive agents are not included in the calculation of CDV toxicity because the calculation of CDV is connected to the calculation of AC?</i></p>	<p><b>Comment clarified</b> inorganic rubbing/abrasive agents are not included in the calculation of CDV toxicity because the calculation of CDV is connected to the calculation of AC</p>
<p><i>Our comment was rejected, so we are requiring to act that it will be essential to define a new methodology for the next revision.</i></p> <p><i>In particular, it will be essential to change the definition of "weight". Because :</i></p> <ol style="list-style-type: none"> <li><i>1) it is not environmentally friendly to add substances to reduce the ratio of CDV/CA. This practise goes against principles of the European Ecolabel ;</i></li> <li><i>2) it is more complicated to deal with CDV depending on CA and</i></li> </ol> <p><i>Please also note in "commission statement" our proposal to define thresholds as in detergents products (in l/g).</i></p> <p><i>Indeed, as already commented, we don't agree with your explanation because in detergents we have also ready-to-use (RTU) products so without determined dose but in the RTU detergents decision, their thresholds are however defined per litre of product. Indeed, the reference dosage for RTU products is defined as "1 litre of RTU products". We can use the same definition of reference dosage for cosmetics products. We reiterate our request to change the current calculation to delete the fact CDV is based on the active content.</i></p> <p><i>If our proposal is accepted, it will be necessary to review thresholds. So it will be essential that JRC requires before 1st AHWG meeting values from different competent bodies with the methodology used in detergents (for example, by email).</i></p>	<p><b>Comment acknowledged</b> It will be considered before the start of the next revision process to modify the CDV calculation methodology. However, the outcome will be highly dependent on the willingness of competent bodies to share their data with JRC, as lack of data was the main problem hindering a change of methodology in this revision process</p>

<p>As explained in previous technical draft comments, this method needs to be reviewed because isn't efficient to well evaluate the real aquatic toxicity potential. With this method by calculation by active content only, if you add a non impactant active content, it automatically decrease the CDV result, while you didn't reduced the impacting raw material. That can encourage to not reducing highly impactant ingredients and add non useful ingredient to decrease the CDV result. The calculation by liter of product is completely relevant and already used for detergent (HSC category) and perfectly works. We highly recommend to ask to all competent bodies all the data of already certified product and the comparison between old calculation results and calculation by liter of product to establish new limits. This works needs much time but is highly essential. We need to anticipate this point for the next revision.</p>	
<p>As shared in previous comments on the first and second technical reports, we strongly recommend reviewing the calculation methodology of the CDV. With the current calculation methodology, the CDV of each substance is linked to the share of other substances which prevents from summing the toxicity of each ingredient. Therefore, industrials are incentivized to add substances in the product formulation in order to decrease the CDV, which is the antithesis of ecological practice and therefore goes against the fundamental principles of the European Ecolabel. We thus strongly advise the JRC to request competent bodies to provide data on CDV of existing licenses by litre of product in order to be able to express the toxicity per litre of product instead of litre of active content. If the current revision process is too advanced to modify the CDV calculation method, we recommend considering inorganic substances in the calculation of the active content for the current revision and soliciting competent bodies at the beginning of the next revision in order to anticipate the review of the CDV calculation method.</p>	
<p>Here links are correct.</p>	<p><b>Comment acknowledged</b></p>
<p>Table 3 CDV limits This table is difficult to read and should be more coherent. We suggest you write "Soaps and shower preparations (liquid form)" as well.</p>	<p><b>Comment accepted/rejected</b></p>
<p>We support that surfactants shall be biodegradable under both aerobic and anaerobic conditions</p>	<p><b>Comments acknowledged</b></p>
<p>We support that all surfactant, i.e also the ones not being classified according to CLP, have to be both anaerobically degradable and that the exemption suggested in TR2 has been removed.</p>	
<p>We supports the limits in line with the Nordic Swan Ecolabel (criteria version 3) for the foam soap, where the difference between the Nordic Swan Ecolabel and the EU ecolabel is at least 16 times higher for the aerobic conditions and 28 times higher for the anaerobic conditions. There are many products certified on the Danish market, which clearly demonstrates that the Nordic Swan Ecolabel limit is feasible.</p>	
<p>Criterion 2 and 3: in favour of the proposed threshold</p>	
<p>15 for liquid soaps and shower preparations We strongly appreciate new thresholds for "liquid soaps and shower preparations"</p>	
<p>We support that the aNBO and anNBO limits have been lowered for solid soaps/shampoos, hair conditioners, liquid soaps, and shower preparations and liquid shampoos</p>	<p><b>Comments partially accepted</b> Considering that shampoos is the category most affected by the alignment with Nordic Swan values and that a high number of current licenses could be affected. It is proposed as a first step for improvement for this revision, the compromise value of 20 mg/g AC.</p>
<p>15 for shampoos We don't agree with these new thresholds for liquid shampoos because as mentioned in our comments, the previous value of 25 should be kept. In addition, if we are considering your table 7 page 49, only 20% shampoos could be certified with this very restrictive threshold of 15!</p>	
<p>The new aNBO and anNBO limit for liquid shampoos of 15 mg/g AC is too restrictive. For a good efficiency of shampoo we need to add guar (conditioning agent) that is not biodegradable. The previous limit of 25mg/g AC was reachable while 15 isn't. If we reduce the limit at 15 mg/m AC, the shampoos won't be efficient anymore.</p>	

<p>We generally support the JRC proposal regarding biodegradability thresholds. However, the revised threshold for shampoos in liquid form seems too restrictive given the data collected from French industrials. Indeed, the average aNBO and anNBO for certified shampoos is 25mg/g AC. Lowering the threshold to 15mg/g AC would imply that only 20% of products currently certified would keep the certification. Therefore, we recommend to keeping the former threshold of 25mg/g AC. For 3-in-1 products, the less restrictive threshold should apply, this in order to valorize these products which have a reduced environmental impact. Indeed, they reduce packaging, water and raw material consumption by substituting one product for 3.</p>	<p>In relation to 3 in 1 products, there is no clear evidence that its use is environmentally preferable than single purpose products. It will depend on the composition. For these products, it is proposed to follow the precautionary approach to apply the more restrictive value as made in other EU Ecolabel product groups.</p>
<p>aNBO &amp; anNBO for Liquid soaps and 3in 1 (hair/body/hands) preparations : reduction to 15 - In our portfolio, conditioners and perfumes are the main contributors of the aNBO &amp; anNBO ratio.</p> <ul style="list-style-type: none"> <li>- If we apply the drafted threshold (15 mg/g AC), impacts would be as following: <ul style="list-style-type: none"> <li>o We wouldn't be able to add any conditioning agents &gt; so the end user experience would be affected. The products wouldn't pass the fitness for use testing.</li> <li>o We wouldn't be able to add any perfume or at the latest in a very few quantity, and we know to what extent the perfume influences the fitness for use testing as well as the aesthetic experience of the end user</li> </ul> </li> <li>- This change is affecting 8 formulas out of the 15 Ecolabelled formulas in our portfolio. Overall, we would end up with a fragrance-free portfolio only.</li> <li>- That's why we would push for <ul style="list-style-type: none"> <li>o Keeping a threshold at 25 mg/g AC at least for 3in1 products</li> <li>o Increasing as far as we can the liquid soap threshold (to 18 ?), that would protect a better part of our portfolio, including fragranced products in essence</li> </ul> </li> </ul>	
<ul style="list-style-type: none"> <li>- readily biodegradable (OECD 301 A-F),: this aspect can be assessed by our certification company</li> <li>- lowest aquatic toxicity NOEC/ECx &gt; 0.1 mg/l or EC/LC50 &gt; 10.0 mg/l and not be bioaccumulable, and/or</li> <li>- lowest aquatic toxicity NOEC/ECx &gt; 0.1 mg/l or EC/LC50 &gt; 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or</li> <li>- lowest aquatic toxicity NOEC/ECx &gt; 0.1 mg/l or EC/LC50 &gt; 10.0 mg/l and not be bioavailable (molar weight &gt; 700g/mol)</li> </ul> <p><input type="checkbox"/> all aspects can not be assessed by our certification company <input type="checkbox"/> please make another proposal</p>	<p><b>Comment rejected</b> The proposal is aligned to existing Nordic Swan criteria</p>
<p>QSARs (Quantitative Structure-Activity Relationship) methodologies are used in REACH Regulation (EC) No 1907/2006 as alternative to testing methods. However, QSARs must be used only when the substance under assessment falls into the application domain of the model. In addition, predictions must be interpreted carefully since QSARs are screening tools that can give rough estimates of fate and ecotoxicity of chemicals. To our opinion, the use of QSARs for the ecolabel should be limited as much as possible, and their results verified rigorously before any exploitation.</p>	<p>(Q)SAR methodology has been removed due to the impossibility to define the acceptance criteria for the QSAR predictions. There are not standard criteria to verify the validity of a (Q)SAR prediction. OECD has just started two projects on the matter: QSAR assessment framework and Good Computational Modelling Practices (GCMP). The former aims at establishing criteria for acceptance of QSAR predictions, the latter aims at defining criteria equivalent to GLP but</p>
<p>Technical report P51 - QSARs</p> <p>QSARs (Quantitative Structure-Activity Relationship) methodologies are used in REACH Regulation (EC) No 1907/2006 as alternative to testing methods. However, QSARs must be used only when the substance under assessment falls into the application domain of the model.</p>	

<p><i>In addition, predictions must be interpreted carefully since QSARs are screening tools that can give rough estimates of fate and ecotoxicity of chemicals. To our opinion, the use of QSARs for the ecolabel should be limited as much as possible, and their results verified rigorously before any exploitation.</i></p>	<p>for computational models. Therefore, it is suggested to explore QSAR use in the next revision, once the OECD projects are finalised and criteria of acceptance are clearly defined. At this stage it will not be possible to certify correct predictions (even by an expert toxicologist) as there is not the possibility to establish the acceptability criteria.</p>
<p><i>For French CB, it is essential to require third party certification because we are not experts of QSAR method.</i></p>	
<p><i>French stakeholders are favorable to requesting third-party certification in the case QSAR method is used and for the extrapolation for substances not listed in the DID-list.</i></p>	
<p><i>We don't consider necessary any third party certification as industry has the competence to evaluate its products in the most correct and appropriate way. Furthermore guidelines are also available in the ECHA website to help industry.</i></p>	
<p><i>We don't consider necessary any third-party verification as industry has the competence to evaluate its products in the most correct and appropriate way.</i></p>	
<p><i>We support that it has been clarified that "Q(SAR) models should only be accepted if actual test data is missing."</i></p>	
<p><i>Extrapolation for substances not listed in the DID-list This should read "is also "not" anaerobically biodegradable".</i></p>	<p><b>Comment acknowledged</b> Text corrected</p>
<p><i>There is a mistake : it is not the Table 3 (PDF page 36) but Table 4</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>a) Biodegradability of surfactants Does that mean inherently anaerobic biodegradable surfactants are ok? Or Inherently is a term used only for aerobic degradation?  What about emollients/emulsifiers and anaerobic biodegradability? They are given an exemption in the Nordic Ecolabel's criteria as it can be difficult to collect data.</i></p>	<p>Criterion on Biodegradability of surfactants is as in its current form in force. No additional exemptions are deemed necessary.</p>
<p><i>The new text regarding "Documentation on aquatic toxicity" is clear and we support that it is used.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>We would like to include third party certification for the extrapolation of not listed substances because it can be complex to determine what is equivalent or not.</i></p>	<p><b>Comment accepted</b></p>
<p><i>Is all the SCCS text (blue and black) to be put in the user manual? About the phrase "the most restrictive requirement that applies" could be better specified from whom and from which the most restrictive criterion must come from?</i></p>	<p><b>Comment rejected</b> The text within the square brackets has been finally decided not to be included in the ANNEX.. Please refer to the Technical Report for the details.</p>
<p><i>Title: please adapt this title of the criterion to earlier versions of this product group (and also to other product groups) because of harmonization: Excluded and limited substances and mixtures</i></p>	<p><b>Comment rejected</b> The title has been adapted to the Commission Decision for Detergents: "excluded and restricted substances".</p>
<p><i>In 4a,</i></p>	<p><b>Comment acknowledged</b></p>

<p>Denmark wish to minimize the use of fragrances, therefore we have proposed earlier that fragrances are excluded in ecolabelled cosmetics. Many fragrances are skin sensitizers and exposure to fragrances can therefore have serious consequences for people suffering from allergy. Denmark supports the exclusion of respiratory and skin sensitizing substances is applied at the substance level in Table 5.</p>	
<p>We appreciate the modified title to include "mixtures" and your response "The structure of the criterion referring to substances and mixtures has not been changed as to avoid any risk of cumulative effect of substances with a harmonised classification used in a cosmetic product in the form of mixtures." (+ the exception for H314 and H317)</p> <p>Thus, in order to harmonize, this sentence must be changed for "substances NOR mixtures", to insist on the fact that both must be checked. (page 60 and page 62)</p>	<p><b>Comment rejected</b></p> <p>The wording 'substances or mixtures' in the context of criterion 4 is present in the EU Ecolabel criteria in force already. The interpretation of most of the CBs, and the agreed practice is that all ingoing substances have to be checked, also all substances within a mixture. However, mixtures have to be checked only in case data are not available for a single substance (hence the presence of the word or in 'substances or mixtures'). This situation occurs only seldom. Given the definition of 'ingoing substance', the agreement at the CB level, the alignment with Nordic Swan and with the EU Ecolabel for detergents (both referring to substances only), only the word 'substance' is referenced in the criterion text.</p>
<p>As already mentioned, the criterion 4. a) (i) must be applied to SUBSTANCES AND MIXTURES. Indeed, for each "intentionally added" mixture, we need to check the classification of all the substances AND the classification of the mixture because it's essential to evaluate the cumulative effect in the product which is intended to apply on skin's humans or animals (high hazardousness level).</p> <p>So, we appreciate the modified title to include "mixtures" and your response "The structure of the criterion referring to substances and mixtures has not been changed as to avoid any risk of cumulative effect of substances with a harmonised classification used in a cosmetic product in the form of mixtures. " (+ the exception for H334 and H317)</p> <p>Thus, in order to harmonize, the sentence must be changed for "substances NOR mixtures", to insist on the fact that both must be checked.</p>	
<p>It's a mistake: it's H334. My apologies ! (page 71)</p>	<p><b>Comment acknowledged</b></p>
<p>In response to this question from JRC, IFRA position is that the criterion 4(a)(i) should be applied only to substances.</p> <p>The latest Technical Report proposed by JRC considers applying the concentration limits to ingoing substances and mixtures such as fragrances.</p> <p>We consider fragrance ingredients as ingoing substances which is aligned with Nordic Swan and Ecolabel detergents/dishwashing, where the restrictions apply on the constituents and not on the fragrance as a whole.</p> <p>Therefore, we would request to remove the wording "or mixtures" from criterion 4 (a).</p>	<p><b>Comments partially accepted</b></p> <p>The structure of the criterion refers to substances only.</p>
<p>Is criterion 4 (a) (i) to be applied to mixtures also, or only substances?</p> <p>The criterion 4 (a) (i) should be applied only to ingoing substances in alignment with the criteria provided by Nordic Swan scheme and Ecolab Detergent Decisions.</p>	
<p>French stakeholders have agreed on the necessity to apply criterion 4(a)(i) to substances and mixtures in order to consider the aggregate effect of substances in a product, except for the H334 and H317 hazard classes that should apply to substance level only as there is no aggregate effect of substances linked to those hazard classes.</p>	
<p>It was clarified by JRC that this means that it will be "permitted to use a mixture which is classified with H317 or H334, provided that each of the ingoing substances with H317/H334 do not exceed 0.01/0.001%, since an allergic reaction to substance A does not necessarily cause an allergic reaction with substance B: there is not a cumulative effect for these specific classifications."</p>	
<p>We find this acceptable, but it should only be permitted for fragrances.</p>	

<p>Apply this exemption only for fragrances. It is important not to allow the use of other sensitizing substances than necessary.</p>															
<p>Please add the right "number":</p> <p>(i) Unless derogated in Table 6, the product shall not contain substances or mixtures at or above the concentration of 0.010 % weight by weight for rinse-off products and 0.0010% weight by weight for leave-on cosmetics,</p>	<p><b>Comment partially accepted</b> A new Table 8 was created for derogations to CMR substances also, and placed after Table 7. However, two different tables have been kept for criteria 4 (a) (i) and 4 (a) (ii).</p>														
<p>Please put together table 5 and table 7 to one table. To put table 6 before table 7 is confusing. It seems that table 6 only relates to table 5 and not to table 7 as well. This would lead to more clarification.</p>															
<p>The derogation for CMR-classified TiO2 should be seen after the table about CRM substances (table 7).</p>															
<p>We find the derogations in table 6 well formulated</p>	<p><b>Comment acknowledged</b></p>														
<p>In regards to the process to discuss and evaluate proposal for derogation Denmark wishes to be included in any discussion or sub groups that might be formed the on-going revision process. Denmark can still not support any derogation on the following substance:</p> <p>Zink pyrithione: was classified as CMR 1B and may be thus only be further used in cosmetic products if an exemption is granted based on article 15.2 of Regulation 1223/2009. There is a suitable alternative ingredient (piroctone olamine) that is used in numerous antidandruff products.</p>	<p><b>Comment acknowledged</b></p>														
<p>Dandruff is a chronic, relapsing scalp condition that negatively impacts the quality of life of sufferers. Scalp dandruff affects more than 50% of the human population. Regular use of anti-fungal shampoos represents a proven therapeutic strategy to improve the most common symptoms of flakes and itch. The treatment of the cause includes use of anti-fungal agents.</p> <p>In the table below are gathered the antidandruff ingredient which are recognized as being efficient <sup>a</sup>.</p> <table border="1" data-bbox="192 1066 1267 1375"> <thead> <tr> <th data-bbox="192 1066 667 1114">Active Ingredient</th> <th data-bbox="667 1066 1267 1114">CLP ECHA classification</th> </tr> </thead> <tbody> <tr> <td data-bbox="192 1114 667 1153">1. Zinc Pyrithione</td> <td data-bbox="667 1114 1267 1153">H410/H400/H318/H301/H372/H330</td> </tr> <tr> <td data-bbox="192 1153 667 1201">2. Ketoconazole</td> <td data-bbox="667 1153 1267 1201">H301/ H360F/H373/H410/H400 b</td> </tr> <tr> <td data-bbox="192 1201 667 1249">3. Climbazole</td> <td data-bbox="667 1201 1267 1249">H400/H410/H302</td> </tr> <tr> <td data-bbox="192 1249 667 1297">4. Selenium sulphide</td> <td data-bbox="667 1249 1267 1297">H410/H400/H301/H373/H331</td> </tr> <tr> <td data-bbox="192 1297 667 1345">5. Clotrimazole</td> <td data-bbox="667 1297 1267 1345">H302/H315/H319/H410/H400</td> </tr> <tr> <td data-bbox="192 1345 667 1375">6. Piroctone Olamine</td> <td data-bbox="667 1345 1267 1375">H412/H315/H318</td> </tr> </tbody> </table>	Active Ingredient	CLP ECHA classification	1. Zinc Pyrithione	H410/H400/H318/H301/H372/H330	2. Ketoconazole	H301/ H360F/H373/H410/H400 b	3. Climbazole	H400/H410/H302	4. Selenium sulphide	H410/H400/H301/H373/H331	5. Clotrimazole	H302/H315/H319/H410/H400	6. Piroctone Olamine	H412/H315/H318	<p><b>Comment rejected</b> A derogation for piroctone olamine is not needed. Indeed, among the H classes restricted in criterion 4 (a), only class H412 is relevant for piroctone olamine. However, this class is already proposed to be derogated if the substance or mixture is a surfactant present in a concentration &lt;20% of the product formulation. Thereby piroctone olamine is already derogated (if present in a concentration &lt;20% of the product formulation).</p>
Active Ingredient	CLP ECHA classification														
1. Zinc Pyrithione	H410/H400/H318/H301/H372/H330														
2. Ketoconazole	H301/ H360F/H373/H410/H400 b														
3. Climbazole	H400/H410/H302														
4. Selenium sulphide	H410/H400/H301/H373/H331														
5. Clotrimazole	H302/H315/H319/H410/H400														
6. Piroctone Olamine	H412/H315/H318														

7. Salicylic acid	H302/H318/H361 d	
8. Coal Tar	H304/H315/H317/H350/H361/H412	
<p><sup>a</sup> AN OVERVIEW OF DANDRUFF AND NOVEL FORMULATIONS AS A TREATMENT STRATEGY, Narshana and Ravikumar, IJPSR, 2018; Vol. 9(2): 417- 431</p> <p><sup>b</sup> <a href="https://pubchem.ncbi.nlm.nih.gov/compound/456201#section=GHS-Classification">https://pubchem.ncbi.nlm.nih.gov/compound/456201#section=GHS-Classification</a></p>		
<p><i>Piroctone Olamine is a very effective anti-dandruff antifungal agent used for more than 30 years in cosmetics. Piroctone Olamine is approved by European authorities with a maximum concentration of 1% in rinsed products. According to the ECHA evaluation, the substance is not evaluated as PBT / vPvB and present the best environmental profile among the anti-dandruff agents on the market. Derogation must be granted to this ingredient to enable efficient antidandruff shampoo design.</i></p>		
<p><i>Technical Report P61 – anti dandruff ingredients</i>  <i>Dandruff is a chronic, relapsing scalp condition that negatively impacts the quality of life of sufferers. Scalp dandruff affects more than 50% of the human population. Regular use of anti-fungal shampoos represents a proven therapeutic strategy to improve the most common symptoms of flakes and itch. The treatment of the cause includes use of anti-fungal agents.</i>  <i>In the table below are gathered the antidandruff ingredient which are recognized as being efficient1.</i></p> <p><i>Active Ingredient CLP ECHA classification</i></p> <ol style="list-style-type: none"> <li>1. Zinc Pyrithione H410/H400/H318/H301/H372/H330</li> <li>2. Ketoconazole H301/ H360F/H373/H410/H4002 b</li> <li>3. Climbazole H400/H410/H302</li> <li>4. Selenium sulphide H410/H400/H301/H373/H331</li> <li>5. Clotrimazole H302/H315/H319/H410/H400</li> <li>6. Piroctone Olamine H412/H315/H318</li> <li>7. Salicylic acid H302/H318/H361 d</li> <li>8. Coal Tar H304/H315/H317/H350/H361/H412</li> </ol> <p><i>Piroctone Olamine is a very effective anti-dandruff antifungal agent used for more than 30 years in cosmetics. The substance is approved by European authorities with a maximum concentration of 1% in rinsed products. According to the ECHA evaluation, the substance is not evaluated as PBT / vPvB and present the best environmental profile among the anti-dandruff agents on the market. We believe a derogation must be granted to this ingredient to enable efficient antidandruff shampoo design.</i></p>		
<p><i>Table 5. Restricted hazard classes, categories and associated hazard statement codes</i>  <i>Piroctone Olamine (H412/H315/H318) is a very effective anti-dandruff anti-fungal agent used for more than 30 years in cosmetics. The substance is approved by European authorities with a maximum concentration of 1% in rinsed products. We believe a derogation must be granted to this ingredient to enable efficient anti-dandruff shampoo design.</i></p>		
<p><i>Derogation for surfactants should cover not only rinse-off but also leave-on cosmetic products.</i></p>		
<p><i>Leave-on products are not released into the water, so compared to rinse-off products they are not hazardous. Based on this, these classifications (H400, H410, H411, H412) should not apply to leave-on products</i></p>		<p><b>Comment accepted</b>  Surfactants have been derogated in leave-on products as well, up to a maximum 25 % w/w.</p>

<p>Leave-on products are not released into the water like rinse-off products are. Formula in Criterion 4 (iii) should not apply to leaveon products</p> <p>Leave-on products are are not released into the water, so compared to rinse-off products they are not hazardous to the aquatic environment. Based on this, these classifications (H400, H410, H411, H412) should not apply to leave-on products</p> <p>Derogation for surfactants should cover not only rinse-off but also leave-on cosmetic products.</p> <p>Hazardous to the aquatic environment – Leave-on products Leave-on products are not released into the water like rinse-off products are. Formula in Criterion 4 (iii) should not apply to leave-on products.</p>	
<p>Restriction regarding TiO2 The sentence "It needs to comply with SCCS/1516/13, SCCS/1580/16, and SCCS/1583/17. It cannot be used in powder or spray form" may be updated taking into account the last regulatory change for titanium dioxide, brought with the Regulation "Omnibus III" which will be voted on January 2021. So the restriction on TiO2 may only refer to the Cosmetic regulation (CE) n°1223/2009 which already regulate the use of TiO2 in cosmetics. Annex VI regulates the use of TiO2 (nano and not nano) as UV filter (with the exclusion of nano form in application that could lead to lung exposure). Following the final SCCS opinion on Titanium dioxide: SCCS/1617/20 of the 6 October 2020, a new entry in annex III will regulate the use of TiO2 in general taking into account the last assessment on TiO2 and the consideration of the specific form considered as safe in powders (pigmentary, anatase, surface-treated).</p>	<p><b>Comment rejected</b> The SCCS opinion SCCS/1617/20 on Titanium dioxide cannot be taken into account as it refers to the use of pigmentary TiO2, whereas in EU Ecolabel only the use as UV filter is accepted (under certain conditions). The reference to SCCS was included for clarity and precision on the cases that can be granted derogation.</p>
<p>Table 6. Derogations to restrictions on ingoing substances/mixtures classified under the CLP Regulation and applicable conditions It seems that Only TiO2 in nano-form used in sunscreens is exempted. What about its use in toothpaste? What about the non-nano-form?</p>	<p><b>Comment clarified</b> Only nano TiO2 for use as an UV filter in product with sunscreen application is exempted. The use in toothpaste is excluded. The non-nano-form is also excluded</p>
<p>Page 61 Derogation to restrictions : removing fragrances from the list - Today : we estimate that 80% of our 14 fragranced formulas would be impacted. - Fragrance houses gave their feedbacks according to which there will be real difficulties to reformulate the fragrances - There will definitely impacts on : o the quality/nature of the scents themselves : we already know that some scent categories won't be possible at all _ hesperidia notes for example. Long lasting properties will be also altered. o Timeline : the transitional period (12months ?) might be not enough to support the fragrance reformulation first and then the reformulation in our finsh goods.</p>	<p><b>Comment rejected</b> Derogations in place in the current EU Ecolabel criteria in force have been removed at the beginning of the revision process, and new evidence for the reasons behind the needs for a derogation was requested to stakeholders, which were asked to submit official derogation requests with substantiated data. No official derogation request was received for fragrances. Apart from this, the new requirements proposed to the revised criteria restrict indeed the use of substances, however without banning them. Even substances classified as H317 and H334 are accepted for inclusion in a product with a limit of 0.01% w/w in rinse-off products and 0.001% w/w in leave-on products. Considering that fragrances are generally added to products in very low amounts, this restriction will not imply that EU Ecolabel products will have to be fragrance-free. Nordic Swan has in place similar criteria and have many many products which are not fragrance free.</p>
<p>Criterion 4a: Restricted substances/mixtures For rinse-off cosmetics there is currently a derogation for fragrances for the environmental hazard statements H412 and H413. The derogation for fragrance mixtures which are classified as H412 could be kept if a maximum limit for fragrances in the final product is introduced, in order to limit environmental effects. Absence of derogation for fragrances mixtures classified H412 would highly impact the use of NCSs in fragrances as most NCS contain substances classified H410, H411 and H412.</p>	

<p><i>The fragrance and cosmetic industry use a significant number of natural substances (e.g. natural complex substances such as essential oils or extracts from botanical origin). Since many of the natural substances are classified for the environment, the limitation of the use of classified naturals would drastically impact the possibility of using natural substances. Note that many of the naturals not classified for the environment are those oils with no olfactive properties such as almond oil, canola oil, castor oil, corn oil, cottonseed oil, olive oil, peanut oil, sesame oil, soya oil... Reducing the use of naturals will result in an increase use of synthetic chemicals and it is in contradiction with the concept of naturality and renewability of ingredients in consumer products. Therefore, we propose to include a derogation for the use of natural ingredients classified for the environment.</i></p>	<p><b>Comment rejected</b> The EU Ecolabel is technology neutral, which in this case means that does not prefer natural substances over synthetic ones, especially if it has not been proven that they are environmentally better or if an agreed standardised definition of natural exists. If a substance is classified for the environment, then that substance is excluded, regardless of whether it's natural or synthetic.</p>
<p><i>We support the adjusted criteria formulation, i.e.: 62(iii)Ingoing substances or mixtures classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum: <math>100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%</math> where <math>c</math> is the fraction of the product, measured in percentage by weight, made up of the classified substance.</i></p> <p><i>Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.</i></p> <p><i>Surfactants regardless of their function classified with H412 are exempted from the requirement.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>The meaning of the following sentence is unclear: "Surfactants regardless of their function classified with H412 are exempted from the requirement."</i></p> <p><i>The function is already included in the term "surfactant"</i></p> <p><i>It was clarified from JRC that the meaning will be further specified in the next version of the report.</i></p>	<p><b>Comment clarified</b> This sentence refer to the fact that surfactants may be added to a cosmetic product because of different functions: as detergents, wetting agents, emulsifiers, foaming agents, or dispersants. All of these functions are exempted from the requirement 4 (a) (iii). For the sake of clarity, the sentence has been removed from the legal text, and added to the user manual only</p>
<p><i>It is not defined at the beginning what kind of products are included in this product group. What is the differentiation to pharmaceuticals? From our point of view is zinc ointment a pharmaceutical?</i></p> <p><i>Please delete the following sentences:</i></p> <p><i>Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.</i></p> <p><i>Surfactants regardless of their function classified with H412 are exempted from the requirement.</i></p> <p><i>This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 (*) which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product.</i></p>	<p><b>Comment rejected</b> For zinc oxide containing products, according to the literature, a pharmacological and metabolic action is demonstrated, e.g. may play a role in enzymatic processes, support of wound granulation. The pharmacological action may, however, be ancillary when the product concerned is primarily a barrier cream. In such cases the qualification of zinc-oxide containing products is defined taking into account the claims, the intended purpose and the relevant primary mode of action. In particular, if the claims give the impression, either explicitly or implicitly, that it is for the prevention or treatment of acne or skin disease, the product would not fall under the Cosmetic Regulation. On the contrary, if the product claim "suitable for acne-prone skin", it may be regarded as Cosmetic Product. Since the classification of products is decided on a case-by-case basis taking into account all of the</p>

	characteristics of the product, it may be the case that zinc ointment are regarded as cosmetic products. To take into account this case, the sentence on the exemption of zinc cremes in requirement 4 (a) (iii) has been kept.																										
<p>Regulation 1272/2008 <sup>3</sup> states that "preferably data shall be derived using the standardised test methods referred to in Article 8(3). In practice data from other standardised test methods such as national methods shall also be used where they are considered as equivalent. Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006. In general, both freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent."</p> <p>It is therefore possible to use, for marine species, the same classification criteria in the ecolabel as for freshwater species.</p> <p>At least 3 marine species <sup>4</sup> could be required to fulfil this criterion.</p> <table border="1" data-bbox="192 651 1420 895"> <thead> <tr> <th></th> <th>Acute toxicity data only</th> <th colspan="2">Available chronic toxicity data</th> </tr> <tr> <th></th> <th></th> <th>Non-rapidly degradable subst.</th> <th>Rapidly degradable subst.</th> </tr> </thead> <tbody> <tr> <td>H400</td> <td>EC50 ≤ 1 mg/L</td> <td></td> <td></td> </tr> <tr> <td>H410</td> <td>EC50 ≤ 1 mg/L + subst not rapidly degradable</td> <td>NOEC ≤ 0.1 mg/L</td> <td>NOEC ≤ 0.01 mg/L</td> </tr> <tr> <td>H411</td> <td>EC50 &gt;1 to ≤ 10 mg/L + subst not rapidly degradable</td> <td>NOEC &gt; 0.1 to ≤ 1 mg/L</td> <td>NOEC &gt; 0.01 to ≤ 0.1 mg/L</td> </tr> <tr> <td>H412</td> <td>EC50 &gt;10 to ≤ 100 mg/L + subst not rapidly degradable</td> <td></td> <td>NOEC &gt; 0.1 to ≤ 1 mg/L</td> </tr> </tbody> </table> <p>Based on the above marine and freshwater tests, it is proposed to use the same criteria as those used in the Nordic Swan, i.e.:</p> <ul style="list-style-type: none"> <li>Substances classified as environmentally hazardous according to Regulation 1272/2008 may be included in the product to a maximum: <math>100 c_{H410} + 10 c_{H411} + c_{H412} \leq 2.5\%</math> (where c is the fraction of the product, measured in percentage by weight, made up of the classified substance).</li> </ul> <p>The formula should not be classified for the environment</p> <p>Technical report P98 – substances classified as environmentally hazardous Regulation 1272/2008 states that</p>		Acute toxicity data only	Available chronic toxicity data				Non-rapidly degradable subst.	Rapidly degradable subst.	H400	EC50 ≤ 1 mg/L			H410	EC50 ≤ 1 mg/L + subst not rapidly degradable	NOEC ≤ 0.1 mg/L	NOEC ≤ 0.01 mg/L	H411	EC50 >1 to ≤ 10 mg/L + subst not rapidly degradable	NOEC > 0.1 to ≤ 1 mg/L	NOEC > 0.01 to ≤ 0.1 mg/L	H412	EC50 >10 to ≤ 100 mg/L + subst not rapidly degradable		NOEC > 0.1 to ≤ 1 mg/L	<b>Comment accepted</b>		
	Acute toxicity data only	Available chronic toxicity data																									
		Non-rapidly degradable subst.	Rapidly degradable subst.																								
H400	EC50 ≤ 1 mg/L																										
H410	EC50 ≤ 1 mg/L + subst not rapidly degradable	NOEC ≤ 0.1 mg/L	NOEC ≤ 0.01 mg/L																								
H411	EC50 >1 to ≤ 10 mg/L + subst not rapidly degradable	NOEC > 0.1 to ≤ 1 mg/L	NOEC > 0.01 to ≤ 0.1 mg/L																								
H412	EC50 >10 to ≤ 100 mg/L + subst not rapidly degradable		NOEC > 0.1 to ≤ 1 mg/L																								

<sup>3</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>4</sup> Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

<sup>4</sup> The use of existing ISO tests the Luminescence inhibition test (ISO 11348-3:2007) and the Algal growth inhibition test (ISO 10253:2006) and Urchin toxicity test such as US EPA 600/R-95-136 Section 15 or Environment Canada Reference Method for Measuring the Toxicity of Contaminated Sediment to Embryos and Larvae of Echinoids (Sea Urchins or Sand Dollars) Reference Method 1/RM/58 July 2014

<p>"preferably data shall be derived using the standardised test methods referred to in Article 8(3). In practice data from other standardised test methods such as national methods shall also be used where they are considered as equivalent. Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/20064. In general, both freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent."</p> <p>It is therefore possible to use, for marine species, the same classification criteria in the ecolabel as for freshwater species. At least 3 marine species<sup>5</sup> could be required to fulfil this criterion.</p> <p>Acute toxicity data only Available chronic toxicity data</p> <p>Non-rapidly degradable subst. Rapidly degradable subst. H400 EC50 <math>\square</math> 1 mg/L H410 EC50 <math>\square</math> 1 mg/L + subst not rapidly degradable NOEC <math>\square</math> 0.1 mg/L NOEC <math>\square</math> 0.01 mg/L H411 EC50 &gt;1 to <math>\square</math> 10 mg/L + subst not rapidly degradable NOEC &gt; 0.1 to <math>\square</math> 1 mg/L NOEC &gt; 0.01 to <math>\square</math> 0.1 mg/L H412 EC50 &gt;10 to <math>\square</math> 100 mg/L + subst not rapidly degradable NOEC &gt; 0.1 to <math>\square</math> 1 mg/L</p> <p>Based on the above marine and freshwater tests, it is proposed to use the same criteria as those used in the Nordic Swan, i.e.:</p> <ul style="list-style-type: none"> <li>- Substances classified as environmentally hazardous according to Regulation 1272/2008 may be included in the product to a maximum: <math>100 cH410 + 10 cH411 + cH412 \leq 2.5\%</math> (where c is the fraction of the product, measured in percentage by weight, made up of the classified substance).</li> <li>- The formula should not be classified for the environment.</li> </ul>	
<p>4 (a) iii</p> <p>Here it is unclear if one should look only at substances or also at mixtures. Fragrances mixtures are often classified as environmental hazardous and this calculation will make the certification of perfumed products difficult.</p> <p>We suggest that the requirement must be only on substances, whose concentrations in the final product is much lower.</p>	<p><b>Comments clarified</b></p> <p>In the formula, the parameter c indicates the total concentration of all substances/mixtures with that hazard class in the cosmetic product. If it's a mixture being classified, the total weight of the mixture needs to be included.</p>
<p>In 4b Denmark supports the exclusion of specific substances Denmark also supports the list of excluded substances.</p>	<p><b>Comment partially accepted</b></p>
<p>In regards to Endocrine disruptors Denmark, as other MS, suggests to refer to the Commissions list of ingredients with potential endocrine-disrupting properties used in cosmetic products from 2019 and excluded substances on the "EDLIST" list I, II and III (please refer to <a href="https://edlists.org/">https://edlists.org/</a>). Referring to the two lists will give a more up to date references and will not cause any more administrative burden when handling applications. It is especially relevant to have a dynamic approach to this area and in this product group since the presence of suspected endocrine disruptors in cosmetics is a key issue for many consumers. See also our remarks of the validity period. According to the reply from JRC Dir. B response: "As a conclusion, a list of 8 compounds with potential endocrine disrupting properties commonly found in cosmetic products have been added for exclusion in sub-criterion 3(b)" – can it be more specifically listed, which 8 compounds would be included? In the EUEB meeting, on November 19th, COM/JRC specified that many other substances with endocrine disrupting properties are covered by other EU Ecolabel criteria. It would be relevant to table the substances and accordingly which ecolabel criteria excludes the substances on page 84 in the technical report, where the eight substances already are listed (<a href="https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2020-10/Technical%20Report%203.0.pdf">https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2020-10/Technical%20Report%203.0.pdf</a>)</p>	<p>The 8 compounds with potential ED properties that were prohibited in TR3 (and also prohibited in this final version of the TR) are: Ethylhexyl methoxycinnamate, Recorsinol, Benzopehenones, Homosalate, Octocrylene, Butylphenyl metylpropional, Benzyl salicylate, Triphenyl phosphate.</p> <p>A direct reference to the DG GROW list is not possible from a legal point of view. Moreover, it would not make the criterion dynamic but rather add a layer of uncertainty/ambiguity, since the SCCS opinion of the assessed substances concludes that the evidence on the ED properties is inconclusive.</p> <p>Therefore, the substances listed in the DG GROW table were checked against the EU Ecolabel criteria and, when not excluded from other criteria, were added to the</p>
<p>We have taken note of your answer "As the classification of substances as identified EDs has an evolving nature,</p>	

*JRC believes that specifying a list of excluded EDCs would limit the flexibility of the label to update together with the legislation. Therefore, a list of identified EDCs will not be made available".*

*But without this comprehensive list CBs won't be able to check further this requirement (only with the declaration...).*

*We strongly recommend including the suspected EDCs by referring to the EC list published on May 2019 (including group A and B), which should be assessed by the SCCS ([https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en)).*

*Referring to this list would ensure that the EU Ecolabel follows a more dynamic and robust approach, since substances that would be assessed as safe would in that case be allowed for use under the Ecolabel.*

*However, until the scientific committee delivers its conclusions, referring to the list would also enable integration of the precautionary principle.*

*Applying the precautionary principle is at the heart of the EU Ecolabel Regulation, all the substances in the list should be excluded in the EU Ecolabel.*

*Should the EC insist in only referring to a list of substances we suggest that all the substances A + B are listed, to avoid that any potentially EDCs could be used in cosmetics.*

*In addition, the following two substances included in the National Authorities list (<https://edlists.or>) but not in the EC list should be added:*

*Ethylhexyl salicylate*

*Isoamyl P-methoxycinnamate.*

*Revise to:*

*Substances and mixtures identified to or suspected to have endocrine disrupting properties [4];*

*[4] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.*

*Substances suspected to have endocrine disrupting properties from the Commission priority list on potential endocrine disruptors [[https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine\\_en](https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine_en)]*

*Or*

*[4] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.*

*Substances suspected to have endocrine disrupting properties from the National Authorities lists of potential endocrine disruptors (EDs) <https://edlists.org/>*

*The Ecolabel would be more robust with the above proposal.*

*However, if not accepted, we suggest to name in criterion 4 (b) xviii all the substances included in the EC list*

exclusion list in criterion 4(b). See TR for more details.

*(sections A and B) and the following two substances which are additionally addressed by the National Authorities list but not the EC list:*

- *Ethylhexyl salicylate*
- *Isoamyl P-methoxycinnamate*

*By referring to the EC list and the National Authorities list a dynamic approach and robust approach is ensured, without adding any burden on the CBs and ensuring the integration of the precautionary principle.*

*Ecolabelling should fulfil the consumers wish to have cosmetics free from potentially problematic substances. If unwanted substances are accepted in the ecolabel, it will negatively impact the image of and market for the ecolabelled products.*

*Scientists increasingly link endocrine-disrupting chemicals (EDCs) to a range of severe diseases and disorders, including infertility, obesity and cancer (<https://pubmed.ncbi.nlm.nih.gov/26544531/>). Cosmetics ingredients with endocrine-disrupting (ED) properties represent a significant, potential source of cumulative consumer exposure to EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. They also have environmental impacts as they affect wildlife. EDCs are used in cosmetics, and as label for environmental excellence the EU Ecolabel should address them.*

*Considering the precautionary principle at the heart of the Ecolabel Regulation, the requirements should also cover substances that are not yet classified as EDCs but suspected of being endocrine disrupters. The Nordic Swan Ecolabel has this requirement although it refers to an old EU list and we think that considering more updated lists instead is preferable.*

*We strongly recommend referring to the EC list published on May 2019 (including group A and B), which should be assessed by the SCCS.*

*We also consider the National Authorities lists of potential endocrine disruptors (EDs) <https://edlists.org/> as a relevant reference.*

*Applying the precautionary principle at the heart of the EU Ecolabel Regulation, all the substances in the list should be excluded in the EU Ecolabel. BEUC comments on each of the substances included in this list can be found in this position paper.*

*[https://www.beuc.eu/publications/beuc-x-2019-009\\_potential\\_hormone\\_disruptors\\_in\\_cosmetics.pdf](https://www.beuc.eu/publications/beuc-x-2019-009_potential_hormone_disruptors_in_cosmetics.pdf)*

*The UN has also published a list of endocrine disrupting chemicals or potential EDCs which support the consideration of suspected EDCs by the EU Ecolabel. All the substances included in this list have gone at least through one thorough scientific assessment.*

*Test by the Danish Consumer Council THINK Chemicals have shown that many products are without suspected EDCs, for instance:*

*Bodylotion: 44 of 54 products in the test were free from suspected EDC*

*Handsoap: 55 out of 72 in the test were free from suspected EDC*

*Suncare products: 20 out of 36 in the test were free from suspected EDC*

<https://kemi.taenk.dk/english>

*(FYI the numbers listed above have been updated with substances from the EDlists.org*

*Policy background supporting the exclusion of suspected EDCs:*

*The European Parliament and Council have called for a swift preparation of the long-overdue non-toxic environment strategy, as well as action on endocrine disrupting chemicals (EDCs).*

*- European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors*

*- Council conclusions June 2019 Towards a Sustainable Chemicals Policy Strategy of the Union*

*- Council conclusions on 8th Environmental Action Program, October 2019.*

*Ethylhexyl methoxycinnamate; Recorsinol; Homosalate; Octocrylene;*

*These substances have been defined by the European Commission as substances to be evaluated for assessing potential endocrine disrupting properties.*

*The conclusion of the evaluation may be an absence of concern and safe use in cosmetics.*

*We recommend planning intermediate revision in order to update criteria with the last conclusion of the evaluation in case the substance has been considered safe.*

*Especially in the case of UV filters, if sun products remain in the scope of Ecolabel. The list of UV filters that could be use will be very short, UV filters fulfilling environmental criteria, and considered as safe for use should be able to be used to formulate ecolabel sun products.*

*What should happen with these substances that are suspected of having endocrine. What should the certification company do?*

*Substances that are suspected of having endocrine should be*

*a) excluded*

*b) not excluded?*

*The Blue Angel has formulated the following sentences:*

*3.6 General exclusion of substances with certain properties*

*The use of the following substances is not permitted in order to protect the environment and human health. In the case of mixtures e.g. fragrances where it is not possible to obtain information about the individual substances, the classification rules for mixtures shall be applied.*

*a) Substances of very high concern (SVHC), substances in end products labelled with the Blue Angel ecolabel that have been identified in accordance with Article 57 of Regulation (EC) No. 1907/2006 and listed in accordance with Article 59 of the same regulation on the list of candidates<sup>7</sup> for inclusion on the Annex of substances subject to authorisation. Impurities in substances added to the end product that correspond to the above named criteria are not permitted.*

*This requirement also applies to suspected SVHC, which are classified on the ECHA website under <https://echa.europa.eu/de/information-on-chemicals/registered-substances> on the infocard for the substance under "Properties of concern" as suspected PBT, CMR or ED and thus are subject to a substance evaluation. Impurities in the raw materials with a concentration of < 0.1% are excluded from this requirement for suspected SVHC.*

*The label holder is obligated to take into account current developments on the list of candidates and the latest publications by the ECHA*

7 <http://echa.europa.eu/web/guest/candidate-list-table>

we would appreciate the exclusion of all the 28 Suspected Endocrine Disruptors and in favour of the exclusion of phenossyethanol in children products for the precaution principle.

In our opinion it is essential to introduce the precautionary principle for EDCs in the EU Ecolabel as alarming information and studies are overwhelming and in order not to lose credibility in the eyes of consumers. Therefore we strongly recommend to exclude all substances mentioned at the „call for data on ingredients with potential endocrine-disrupting properties“ published on May 2019 (including group A and B).  
[https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en)

(xviii) In our opinion it is essential to introduce the precautionary principle for EDCs in the EU Ecolabel as alarming information and studies are overwhelming and in order not to lose credibility for consumers. Therefore we strongly recommend to exclude all substances mentioned at the „call for data on ingredients with potential endocrine-disrupting properties“ published on May 2019 (including group A and B).  
[https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disruptingproperties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disruptingproperties-used-cosmetic-products_en)

Here you find our justification for the exclusion of EDs from Nov. 2019. In addition to that strong arguments are also included in chemicals strategy for sustainability published in November this year.

#### 1 Endocrine Disrupting Chemicals EDCs

##### 1.1 Why we need strict and precautionary criteria

1.1.1 Many endocrine-related diseases and disorders are on the rise From: State of the Science of Endocrine Disrupting Chemicals 2012 Summary for Decision-Makers / WHO  
[https://apps.who.int/iris/bitstream/handle/10665/78102/WHO\\_HSE\\_PHE\\_IHE\\_2013.1\\_eng.pdf;jsessionid=A6F74B6F403DB5529AACCF05237D92BE?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/78102/WHO_HSE_PHE_IHE_2013.1_eng.pdf;jsessionid=A6F74B6F403DB5529AACCF05237D92BE?sequence=1)

□ Large proportions (up to 40%) of young men in some countries have low semen quality, which reduces their ability to father children. □ The incidence of genital malformations, such as non-descending testes (cryptorchidisms) and penile malformations (hypospadias), in baby boys has increased over time or levelled off at unfavourably high rates. □ The incidence of adverse pregnancy outcomes, such as preterm birth and low birth weight, has increased in many countries. □ Neurobehavioural disorders associated with thyroid disruption affect a high proportion of children in some countries and have increased over past decades. □ There is a trend towards earlier onset of breast development in young girls in all countries where this has been studied. This is a risk factor for breast cancer. □ The prevalence of obesity and type 2 diabetes has dramatically increased worldwide over the last 40 years. WHO estimates that 1.5 billion adults worldwide are overweight or obese and that the number with type 2 diabetes increased from 153 million to 347 million between 1980 and 2008. □ Global rates of endocrine-related cancers (breast, endometrial, ovarian, prostate, testicular and thyroid) have been increasing over the past 40–50 years.

##### 1.1.2 Consumers are worried

Apps and information from Consumer Organisations support them for making informed decisions to purchase □ General Leaflet of BEUC (The European Consumer Organisation) on EDCs [https://www.beuc.eu/publications/beuc-x-2019037\\_endocrine\\_disruptors\\_throughout\\_your\\_day.pdf](https://www.beuc.eu/publications/beuc-x-2019037_endocrine_disruptors_throughout_your_day.pdf) □ App ToxFox on Cosmetics, Germany <https://www.bund.net/themen/chemie/toxfox/> □ App Kemiluppen on Cosmetics

and Personal Care Products, Denmark <https://kemi.taenk.dk/bliv-groennere/kemiluppen-tjek-din-personlige-pleje-uoensketkemi> □ QuelCosmetic, France <https://www.quechoisir.org/application-mobile-quelcosmetic-n52804/> □ Voluntary Labelling in Austria (english version attached below the german one) <https://vki.at/hormoninfo>

Therefore, if the EU Ecolabel doesn't set strict criteria on endocrine disrupting chemicals in cosmetic products, it will lose credibility in the eyes of consumers and consumer groups.

#### 1.2 Political developments towards a regulation of EDCs

The EU Commission has been defaulting since years. In general

The EU Commission failed to meet any deadline for establishing clear rules for the identification of endocrine active chemicals. Sweden sued the EU Commission for this delay at the General Court of the European Union. The Court decided in December 2015 that "By failing to adopt measures concerning the specification of scientific criteria for the determination of endocrine-disrupting properties, the Commission has breached EU law". After this, in June 2016 – 2,5 years too late – the EU Commission submitted a draft for criteria to identify endocrine disruptors which were finally introduced in the biocidal regulation in 2017 and the regulation for plant protection products in 2018. As various other measures are missing, the European Parliament and Council have called for a swift preparation of the long-overdue non-toxic environment strategy, as well as action on endocrine disrupting chemicals (EDCs):

European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors

Council conclusions June 2019 Towards a Sustainable Chemicals Policy Strategy of the Union

Council conclusions on 8th Environmental Action Program, October 2019.

To the cosmetics regulation According to article 15 of the EU cosmetics regulation (Regulation (EC) No 1223/2009) at the latest on 11 January 2015 the Commission should have reviewed this regulation with regard to substances with endocrine-disrupting properties. This review has been published in 2018, and in May 2019 a call for data on ingredients with potential endocrinedisrupting properties used in cosmetic products has been published. In this priority list 28 substances are included, divided into in two groups including 14 substances each. [https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disruptingproperties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disruptingproperties-used-cosmetic-products_en)

But as Ursula van der Leyen mentions explicitly EDCs in her agenda for the coming presidency of the EC: „For the health of our citizens, our children and grandchildren, Europe needs to move towards a zero-pollution ambition. I will put forward a cross-cutting strategy to protect citizens' health from environmental degradation and pollution, addressing air and water quality, hazardous chemicals, industrial emissions, pesticides and endocrine disrupters." p.7, [https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-nextcommission\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-nextcommission_en.pdf) we hope that this situation will be improved.

4b(xv) only includes EDs which have been legally identified as SVHC on the Candidate list and/or as EDs under BPR and/or PPPR. We repeat our strong opinion that this is too weak for an ecolabel scheme, even when taking also 4b(xviii) into account. Very few substances have so far been identified as EDs in the legislation, while many more are potential EDs under evaluation due to explicit concerns.

The TR3.0 (Oct 2020) argues that "The presence of so many lists makes it difficult to set a clear and concrete requirement". We repeat our proposal to make use of the EU member state initiative "Endocrine Disruptor Lists" at [www.edlists.org](http://www.edlists.org) as they offer a clear, concrete and comprehensive compilation of identified and potential EDs covering all the pieces of currently relevant EU legislation (List I and II). As well as EDs which have been identified at the national level in a scientifically sound and transparent manner (List III). Moreover, since substances which are not identified as EDs are delisted, [www.edlists.org](http://www.edlists.org) addresses the issue pointed out in TR3.0 about "compounds that change their "status" on the list, e.g. from "to be assessed" to "assessed as safe".

List I, II and III ought to be included. A transition period allowing time for substitution might be necessary and should apply for substances introduced on List II and III, as well as for BPR/PPPR-co-formulants on List I (as they do not appear on List II beforehand).

As an absolute minimum List I and III ought to be included, as well as (all of!) the 28 cosmetic ingredients prioritised by the Commission in the 2019 call for data (only those of the 28 which are not covered by other requirements should be left out).

Regarding comparisons to Nordic Swan cosmetics, the ED requirement will shortly be updated to cover those substances from the Commission 2019 Call for data that are not already excluded by other requirements. In the next complete NS criteria revision, the requirement would be extended further to cover all three lists at [www.edlists.org](http://www.edlists.org), in line with a recently updated policy on EDs.

The singling out of 8 substances from the Commission's 2019 priority list is quite dubious. The prioritization has already been done by the Commission and all of the 28 substances which are not already excluded by other requirements ought to be excluded from ecolabelled cosmetics. Moreover, all 28 ought to continue to be excluded if they are found to have inherent ED properties, regardless of whether the SCCS finds them safe to use with respect to (only!) human health (just like CMR substances are excluded per their inherent properties) or not. I.e. the 28 potential EDs ought to continue to be excluded until they have been thoroughly evaluated under REACH or BPR/PPPR.

As an absolute minimum, all 28 ought to be excluded until their safe use in cosmetics has been evaluated and recommended by the SCCS.

Also, for clarity reasons, it should be considered to list all 28 substances or refer to the Commission 2019 Call for data. If only substances which are not excluded by other requirements should be listed, please note that butylphenyl methylpropional (lysmeral/lilial CAS# 80-54-6) is classified Repr. 1B in CLP ATP15, i.e. as such excluded by 4(a)(ii) (binding application from 1st March 2022).

Please specify the post "benzophenones".

This should read "Resorcinol".

(xv) Substances and mixtures identified to have endocrine disrupting properties [7];  
"Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) according to article 57(f) of REACH Regulation (Candidate List of SVHCs), in Regulation 528/2012 or in Regulation 1107/2009. [to be included in the User Manual: No list exists for ED substances in the Biocidal Products Regulation. ECHA's endocrine disruptor (ED) assessment list (<https://echa.europa.eu/ed-assessment>) can be consulted, as it includes the substances

**Comments rejected**

The reference can help CBs and applicant to understand which substances are excluded

<p>with ongoing or concluded ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group]</p> <p>From our point of view reference no 7 can be deleted because we see no added value to 4 a)</p>	
<p>Regarding substances classified as endocrine disruptors, French stakeholders have pointed out that the Candidate List of SVHC in Regulation 528/2012 and in Regulation 1107/2009 are evolving lists. Furthermore, we agree with the comments made by several CBs during the EUEB of November 19th regarding the 8 years validity period. We consider that this validity period is too long compared to the frequency of opinion's evolutions on chemical substances and especially endocrine disruptors. We thus recommend reducing the validity period of the technical report to 5 years and defining an exhaustive list of substances recognized as endocrine disruptors to be excluded, as does the Nordic Swan. It will have to be checked annually that this list is in line with the latest ECHA opinions.</p> <p>Footnote [7] Please clarify what is meant by the underlined: "identified to have endocrine disrupting properties [...] in Regulation 528/2012 or in Regulation 1107/2009".</p> <p>Moreover, where should applicants and CB:s find out what substances are EDs according to these regulations, i.e. BPR and PPPR? Especially co-formulants? The suggested ECHA ED Expert group assessment list does not give opinions on PPPR substances and they do not give opinions on all REACH/BPR substances. And of course, they do not make the legal decision whether a substance is an ED according to any regulation.</p> <p>We propose that <a href="http://www.edlists.org">www.edlists.org</a> List I is used as a comprehensive reference for EDs identified legally under REACH/BPR/PPPR. Moreover, our repeated opinion is that it's too weak for an ecolabel scheme to only exclude EDs which have been identified under the legislation. In our opinion, <a href="http://www.edlists.org">www.edlists.org</a> List II and List III ought to be included as well.</p>	<p><b>Comment partially accepted</b> The validity period has been set to six years. A list of identified substances will be provided in the UM.</p>
<p>(xv) The only way of identification of EDCs is these days the identification as „property of equivalent concern" for identification as chemical as substance of very high concern SVHC according to article 57 (f) REACH. As this is a time-consuming process up to now only 14 substances were identified in autumn 2019. <a href="https://echa.europa.eu/candidate-list-table">https://echa.europa.eu/candidate-list-table</a></p> <p>Find here the 17 substances identified as EDCs, underlined the only 3 substances which were used in cosmetics, 2 of them forbidden since a few years. The only interesting substance is butylparabene which is already excluded with another restriction in the criteria document.</p> <p>Endocrine disrupting properties (Article 57(f) - human)</p> <p>Dicyclohexyl phthalate (DCHP) 4,4'-isopropylidenediphenol (Bisphenol A; BPA) (also environment) Diisobutyl phthalate Benzyl butyl phthalate (BBP) Bis (2-ethylhexyl)phthalate (DEHP) (also environment) Dibutyl phthalate (DBP) Butyl 4-hydroxybenzoate (Butylparabene)</p> <p>Endocrine disrupting properties (Article 57(f) - environment)</p> <p>4-tert-butylphenol Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with <math>\geq 0.1\%</math> w/w of 4-nonylphenol, branched and linear (4-NP) 1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor; 3-BC) Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with <math>\geq 0.1\%</math> w/w 4-heptylphenol, branched and linear (4-HPbl) p-(1,1-dimethylpropyl)phenol 4,4'-isopropylidenediphenol (Bisphenol A; BPA) (also human) 4-heptylphenol, branched and linear p-(1,1-dimethylpropyl)phenol 4-Nonylphenol, branched and linear, ethoxylated 4-Nonylphenol, branched and linear 4-(1,1,3,3-tetramethylbutyl)phenol Bis (2-ethylhexyl)phthalate (DEHP) (also human)</p>	<p><b>Comment acknowledged</b></p>

<p>JRC clarified at the EUEB meeting that nanomaterials will be banned unless shown to be safe for both human health and the environment. We strongly support this.</p> <p>We suggest that JRC clarifies through the user manual that the intention expressed above is secured.</p> <p>Clarify in user manual.</p>	
<p>[5] As defined in article 2 of the Cosmetic Regulation  [6] Opinions will be accepted if coming from SCCS (for the assessment of the human health of the nanomaterial) or from RAC or SCHEER (for the assessment of the environmental impacts of the nanomaterial). The list of cosmetic products containing nanomaterials can be found at the online Cosmetic Products Notification Portal: <a href="https://ec.europa.eu/growth/sectors/cosmetics/cpnp/">https://ec.europa.eu/growth/sectors/cosmetics/cpnp/</a> The list of nanomaterials placed on the EU market can be found at the EU Observatory for Nanomaterials database: <a href="https://euon.echa.europa.eu/search-for-nanomaterials">https://euon.echa.europa.eu/search-for-nanomaterials</a></p> <p>Please decide for one option. Because of the product group you should decide for option 5 and use the cosmetic regulation,</p>	<p><b>Comments rejected</b>  Reference has been made to the Cosmetic Regulation, which sets down in Annexes III, IV and VI the conditions under which the nanomaterials have been found safe for human health.</p>
<p>[2] We were a bit concerned that the note "[2] also named per-and polyfluoroalkyl substances (PFASs)" could be confusing/misleading, giving the impression that not all perfluorinated and polyfluorinated substances are banned. However, it was confirmed by the JRC that all perfluorinated and polyfluorinated substances are still being banned (as in the previous criteria draft).</p>	<p><b>Comment acknowledged</b>  It will be further specified in the UM</p>
<p>Phenoxyethanol It is proposed not to ban this substance based on the SCCS opinion from 2016 which states that the allowed limit of 0.1% (according to the Cosmetic Regulation) is considered safe also for children. However, have you considered also the opinion of the French Agency for Food, Environmental and Occupational Health &amp; Safety, ANSES, discouraging the use of the substance in baby products especially those intended for the nappy area? Would it be possible to introduce a restriction on phenoxyethanol in leave on cosmetics for babies (especially the nappy area)?</p> <p>Proposal:</p> <p>Add a restriction of phenoxyethanol for cosmetics intended to be applied in the nappy area of babies.</p>	<p><b>Comment rejected</b>  A new restriction cannot be added, as the SCCS opinion was that phenoxyethanol has been found safe also for children.</p>
<p>(vii) Please correct microbaeds into microbeads</p> <p>4 (b) vii Here it should read microbeads.</p>	<p><b>Comment accepted</b></p>
<p>Need for clarification for microplastics prohibition  As the restriction on microplastics has not been finalized yet, some change and exemptions could be made. The prohibition on microplastics should not be different than the restriction defined with REACH regulation.</p>	<p><b>Comment partially accepted</b>  The reference to ECHA's definition has been removed. The new proposal has been aligned with the EU Ecolabel for detergents.</p>
<p>("Including the following substances to the exclusion list)  Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates;  Phosphonates are different substances from the phosphates which were used in the past in Europe before the introduction of "phosphate free" consumer detergents, and which were accused of contributing to eutrophication in situations where sewage collection and treatment with nutrient removal were not adequately</p>	<p><b>Comment partially accepted</b>  Based on the information submitted by industry, and in the interest of aligning with Nordic Swan, the ban on EDTA and its salts and non-readily biodegradable phosphonates has been set at 0.06 mg/g AC but only for</p>

<p><i>installed.</i>  <i>A ban of not readily biodegradable phosphonates for Ecolabel for Rinse-Off Cosmetics would mean a loss of a complete category of raw materials.</i>  <i>For more information, please refer to the attachment.</i></p>	<p>solid rinse-off products.  Indeed, according to one of the article quoted by the stakeholder, "the environmental risk of phosphonates is low in the Netherlands with properly functioning sewage treatment plants". However, not all EU areas have properly functioning sewage treatment plants.</p>
<p><i>Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate</i></p> <p><i>Re-instating the standard threshold for mixtures (0,010 % w/w) to apply also for impurities and by-products would be a logical compromise.</i>  <i>Otherwise, it would be giving the wrong message and creating confusion if criteria for e.g. phosphate or fragrances – banned whatever the concentrations are – would be stricter than for a substance that is classified as toxic, hazardous to the aquatic environment, respiratory or skin sensitizers, carcinogenic, mutagenic, or toxic for reproduction (can contain below 0,010 % w/w).</i>  <i>For more information, please refer to the attachment.</i></p>	<p><b>Comments partially accepted</b>  An exemption has been made to Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate that can be present in the product formulation only if complying with the definition of impurities.</p>
<p><i>Which regulation is valid for Nano TiO2? Or how is Nano TiO2 treated? (see also comment no 16)</i></p>	<p><b>Comment clarified</b>  Nano TiO2 is excluded regardless of the concentration (i.e. no limit, limit of detection) according to requirement 4a(ii). Indeed, according to the COMMISSION DELEGATED REGULATION (EU) 2020/217 of 4 October 2019, its classification as H351 will be effective as per 9 September 2021 (before the entry into force of the new EU Ecolabel criteria. Nano TiO2 can be used as a UV filter in leave-on products with sunscreen function if complying with the requirements listed in table 6 (now table 7).</p>
<p><i>4c SVHC</i>  <i>Denmark can support the proposal.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>4d fragrance</i>  <i>The official Danish position is to exclude fragrances in ecolabelled products, as environmentally dedicated people expect ecolabelled products not to contain fragrances.</i>  <i>Alternatively, Denmark proposes that products that contains fragrances shall be clearly marked on front with "Contains fragrance/perfume".</i></p>	<p><b>Comments rejected</b>  The total exclusion of fragrances has not been proposed because the EU Ecolabel is an environmental label, and the restrictions should focus at the improved environmental profile on cosmetic products. The restriction of sensitizing substances is in place via criteria 1, 2, 3a and 3d, which has now been made stricter, restricting 26 extra fragrance allergens. Moreover, strong sensitizers such as HICC, Atranol and Chloroatranol have been banned completely in criterion 3b. baby products have to be marketed fragrance-free. This set of criteria will limit the problem of allergic or skin reactions significantly. For the most sensitive segment of the population, minimum reactions can be ensured via those products that are developed as mild or for sensitive skins.</p>

<p>See also proposal to criterion 4d. We support, however, the new proposal widening the exclusion of 82 fragrances from the 2012 SCCS opinion.</p>	<p><b>Comment acknowledged</b></p>
<p>We understand your answer but in southern European countries products for children (shower gel, shampoos, body milks...) can't be sold without fragrance. So, it's better that children consumers can use EU Ecolabel products which have constringer formulations than non certified products (same arguments and same reasoning as for sunscreens).</p> <p>We totally agree to have stricter restrictions for children products regarding fragrance to ensure health safety. So, we propose to include restrictions about skin allergens in the fragrance (SCCNFP 26 allergens and SCCS 82 allergens (list 13.1) ) for H317 substances in the fragrance. We can also extend the fragrance restriction by excluding H412 substances in order to have better environmental profiles.</p>	<p><b>Comment clarified</b> The suggestions proposed are already present in the third version of the criteria. Please note that the SCCNFP 26 allergens are included in the SCCS opinion on the 82 allergens.</p>
<p>Fragrances We welcome the improvements of the criterion for fragrances and the restriction proposed in 4(d)ii.</p>	<p><b>Comment acknowledged</b></p>
<p>Fragrance free products are totally adapted for baby products (&lt;3years); However, we think that it may be more adapted to authorize fragrance in products marketed for children (as the restricted criteria defined already ensure their safety.) This possibility will help to develop Ecolabel products marketed for children as consumers in southern Europe are expecting products with fragrances, even for children. We totally agree that products for family should be also destined for children. However, baby products are more specific and may be distinguished. We recommend a distinction between baby products (0-3years) and children products (3-12y) in order to authorize the use of fragrances in children's products.</p>	<p><b>Comment accepted</b> The change has been added to the criterion</p>
<p>Use of fragrance in products intended and marketed for children We are happy to see the fragrance restrictions are now stricter and take into account SCCS skin allergens. That's why we strongly think it isn't relevant anymore to exclude fragrance for children's products. It might thus be very difficult to sell a fragrance-free product intended and marketed for children in southern Europe.</p>	<p><b>Comment accepted</b> The change has been added to the criterion</p>
<p>Criterion 4(d) Page 63 We understand the need to limit the cumulative exposure of babies to fragrances and thus reducing the risk that allergies develop. However, we believe that fragrances should be authorized for products intended and marketed for children as this risk is well limited through the different criteria of the technical report. Moreover, we wish to point out that northern and southern countries have different consumption habits, and that consumers in southern Europe are very sensitive to fragrance used in products. It might thus be very difficult to sell a fragrance-free product intended and marketed for children. We therefore recommend reviewing the categorization of products by distinguishing between products for babies (under 3 years old) and children's products (over 3 years old), in order to authorize the use of fragrances in children's products.</p>	<p><b>Comment accepted</b> The change has been added to the criterion</p>
<p>JRC has introduced the following paragraph to TR3: "(ii) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' [9] and listed in the Annex cannot be present in EU Ecolabel products in concentrations higher than 0.01% in rinse-off products and 0.001% in leave-on products". IFRA requests to double check that substances listed under Table 13-1 of the SCCS opinion, such as OTNE, are not also repeated in Criterion 4(b) 'Specified excluded substances'.</p>	<p><b>Comment rejected</b> Criteria 4 (b) and criteria 4 (d) are independent and cumulative and have different restriction thresholds. The exclusion of the fragrance OTNE according to criterion 4(b) is due also to the information reported by companies to ECHA in the REACH registration process, which report that this substance is very toxic to aquatic</p>

	life with long lasting effects.
<p>4 (d) We would like to suggest limiting the use of all substances classified as H317/H334 in addition to the ones listed in this report and its annex, to concentrations not higher than 0,01% in rinse-off and 0,001% in leave-on products.</p> <p>Unclear. we suggest: "Substances listed under Table 13-1 and in the Annex of the SCCS opinion on "Fragrance allergens in cosmetic products" [9] cannot be present...."</p>	<p><b>Comment clarified</b> It was a mistake. Only Table 13-1 should be mentioned.</p>
<p>Criteria 4 (d) Perfume ingredients We have noted that there will be 82 more perfume ingredients included in the SCCS list. The EU Ecolabel criteria will mean an increase in the administrative burden for companies since there will be additional work towards the perfume suppliers to check the different lists of restricted perfumes, and concentrations for these ingredients, to make sure there is a suitable alternative for the eco labelled product. The restriction will also add to the reformulation work within both perfume suppliers and cosmetic products suppliers.</p>	<p><b>Comment rejected</b> Please note that the 82 substances are not totally excluded, but restricted to concentrations not higher than 0.01% in rinse-off and 0.001% in leave-on products.</p>
<p>Criterion 4e, Denmark can support the proposal</p>	<p><b>Comment acknowledged</b></p>
<p>We strongly welcome the confirmation made by JRC at the EUEB meeting that preservatives classified with H317 will be banned regardless of concentration and that this will be adjusted in the next version of the report. Criterion 4(a) (i) sets a limit for H317 classified substances of either 0.01% (rinse-off cosmetics) or 0.001% (leave-on cosmetics). However, for preservatives these limits are not protective enough. Highly sensitizing preservatives have been shown not to be safe to use in concentrations up to these limits. For example, methylisothiazolinone is nowadays restricted to a maximum of 0.0015% in rinse-off products, and not allowed at all in leave-on products, according to the Cosmetics Regulation (EC) No 1223/2009.</p>	<p><b>Comment acknowledged</b></p>
<p>(iii) Preservatives used in products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail lacquers) must be approved as food additives, according to Regulation (EC) No 1333/2008 on food additives. Please define in commission decision what products are included and excluded; from our point of view decorative cosmetics are not included in the scope.</p>	<p><b>Comment clarified</b> Decorative cosmetics whose use is expected to be in contact with the mouth, e.g. lipsticks but also nail lacquers, must be approved as food additives, according to Regulation (EC) No 1333/2008 on food additives. This aspect will be further clarified in the user manual</p>
<p>Criterion 4f is more relevant now when also decorative cosmetic is included in the scope. Denmark suggest the following changes:</p> <ul style="list-style-type: none"> <li>Bismuth Oxychloride cannot be added to decorative cosmetics.</li> </ul> <p>Cd shall have a limit at 1 ppm and not 10 ppm.</p>	<p><b>Comment rejected</b> Studies for cadmium found that lipsticks have a Cd content between 1.83 and 412.23 ppm. Therefore, the limit of 1ppm is considered difficult to achieve. For bismuth oxychloride, no hazards have been classified to this compound, according to the notifications provided by companies to ECHA in REACH registrations. Therefore, the total ban of this compounds is not judged relevant. The limit of 10 ppm has been kept for both cadmium and bismuth oxychloride.</p>
<p>Colorants We strongly welcome the confirmation made by JRC at the EUEB meeting that colorants classified with H317 will be banned regardless of concentration and that this will be adjusted in the next version of the report.</p> <p>Criterion 4(a) (i) sets a limit for H317 classified substances of either 0.01% (rinse-off cosmetics) or 0.001% (leave-on cosmetics). However, colorants are often used below these limits. Hence, it is necessary to not permit</p>	<p><b>Comment acknowledged</b></p>

<p><i>the use, regardless of concentration, of colorants being classified with H317.</i></p>	
<p><i>We have no comment on the criteria on heavy metals but for the criteria on the lead. The restriction below 1ppm on decorative cosmetics seems too restrictive. The traces of lead found on some colorant, as ochre, for example are not a safety concern above 1ppm and may remain to 10ppm. (it does not pass the skin barrier)</i></p>	<p><b>Comment accepted</b> The limit for lead has been increased to 10 ppm</p>
<p><i>(iii) The content of barium, cadmium, hexavalent chromium (Chromium VI), nickel and bismuth in decorative cosmetics and hair dyes is restricted to concentrations below 10 ppm. The content of lead and mercury in decorative cosmetics and hair dyes is restricted to concentrations below 1 ppm.</i></p> <p><i>From our point of view (and looking back to our discussions) decorative cosmetics and hair dyes are not included in the scope of this product group. Including these products lead to other criteria for example VOC emissions that are relevant for nail lacquers and hair dyes.</i></p>	<p><b>Comment rejected</b> Decorative cosmetics and hair dyes are included in the scope of this product group and must comply with all criteria. However, a similar criterion for VOC emissions is not present in other schemes, thereby creating a challenge to find data on which calibrating the thresholds.</p>
<p><i>4 (f) (ii) We suggest that colorants must be approved as food additives no matter the use of the cosmetic product. This would guarantee that no hazardous azodyes are used.</i></p>	<p><b>Comment rejected</b> Annex IV of Regulation EC 1223/2009 set a list of colorants which are allowed to be used in cosmetic products. Azodyes are included in the Annex IV of Regulation EC 1223/2009. Moreover, none of the other environmental schemes (Nordic Swan, The good environmental choice, Blue Angel), includes a restriction for azo dyes. Therefore, there is no reason to restrict their use under the scope of this EU Ecolabel scheme.</p>
<p><i>4 (f) (iii) Nickel, Chromium and Barium are used very often in colorants in quantities higher than 10 ppm. This requirement might be too demanding and might prevent the certification of make-up and hair dyes.</i></p>	<p><b>Comment rejected</b> Nordic Swan sets the same limits and has make-up licenses under its schemes</p>
<p><i>Criterion 4g Denmark can support the proposal, but we would like JRC to prepare a list of UV filters passing the criteria and UV filters not passing: We suggest that the requirements on UV-filters should be changed into: All organic UV filters contained in the product: must not be bioaccumulating (BCF&lt;100 / log Kow&lt;3) or must have a lowest measured toxicity of NOEC/ECx &gt; 0.1 mg/l or EC/LC50 &gt; 10.0 mg/l</i></p>	<p><b>Comment rejected</b> The requirement of bioaccumulation has been set at BCF&lt;500 / log Kow&lt;4 in accordance with the CLP Regulation data. The list of UV filters will be prepared in the context of the user manual</p>
<p><i>We support the new criteria text, i.e.: "UV filters may only be added to leave-on products that target the solar protection of the user, e.g. sunscreens and multi-purpose products with a sunscreen function. UV filters shall only protect the user –not the product"</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>Comments on criteria for UV filter We would like to draw the JRC attention that criteria may be too much anticipated as new tests are in progress to evaluate the toxicity and biodegradability of UV filters in sea water. Conclusions at this time may be premature if unchanged for several years. We recommend planning intermediate revision in order to update criteria on UV filters.</i></p>	<p><b>Comment clarified</b> Mid-term evaluations are foreseen during the validity period</p>
<p><i>- if including nano TiO2, must fulfil the conditions expressed in Annex VI of Regulation EC No 1223/2009 and its amendments.</i></p> <p><i>- if including nano TiO2 coated with combinations of either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and</i></p>	<p><b>Comment clarified</b> There is no contradiction. The use of nano TiO2 has been the object of several SCCS opinions, some of which have resulted into direct amendment of the Cosmetic Regulation. Moreover, there is also criterion 4(a) (ii) to</p>

<p>triethoxycaprylylsilane (up to 3% and 9% respectively), the product must not be in the form of powders or sprayable products.</p> <p>Is there a contradiction to criterion 4 (b) viii? (See also comment no 12)</p>	<p>take into account. Therefore nano TiO2 use is accepted if used as UV filter, if complying with SCCS opinions and if not in a sprayable form.</p>
<p>For 4(b) ii) we must require a compliance declaration from MANUFACTURERS and applicants.</p> <p>For 4(e) we must also require a compliance declaration from preservatives manufacturers.</p> <p>For 4(f) we must also require a compliance declaration from colorant manufacturers.</p> <p>For 4(g) The compliance declaration must be completed by UV filters manufacturers.</p>	<p><b>Comment accepted</b></p>
<p>This assessment and verification section is not clear. Please put the assessment and verification of criterion 4 (a) to this criterion for more clarification (the same for 4(b) etc.). We know you want to safe space but it is really confusing.</p>	<p><b>Comment rejected</b> There is no need to repeat the same verification paragraph. We believe that having all sub-requirement together is clearer because it offers the differences between requirements at a glance</p>
<p>(iii) Ingoing substances or mixtures classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum:</p> $100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%$ <p>where <i>c</i> is the fraction of the product, measured in percentage by weight, made up of the classified substance.</p> <p>Surfactants regardless of their function classified with H412 are exempted from the requirement.</p> <p><del>This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/20065 which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product. Please delete these sentences because they are misleading.</del></p>	<p><b>Comment accepted</b></p>
<p>3(b) Specified excluded substances:</p> <p>Please add: as xviii: Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atronal, and Chloroatranol (because animal care products are no cosmetic products)</p>	<p><b>Comment rejected</b> The sentence "Substances and mixtures listed under Annex II to Regulation 1223/2008 shall not be present in the product, regardless of the concentration, neither as part of the formulation nor as part of any mixture included in the formulation." Ensures that all substances/mixtures prohibited under the cosmetic regulation will also be excluded in animal care formulations</p>
<p>Please change / delete: Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' [7] and</p>	<p><b>Comment accepted</b></p>

<p><i>listed in the Annex cannot be present in EU Ecolabel products in concentrations higher than 0.010% in <del>rinse-off animal care</del> products and 0.001% in <del>leave-on products</del>.</i></p>	
<p><i>Please put together table 4 and table 6 to one table. To put table 5 before table 6 is confusing. It seems that table 5 only relates to table 4 and not to table 6 as well. This would lead to more clarification.</i></p>	<p><b>Comment partially accepted</b> Table 5 was moved after Table 6. However, two different tables have been kept for criteria 4 (a) (i) and 4 (a) (ii).</p>
<p><i>One environmental issue that is always highlighted in connection with sun creme is the hazard for corals. Is this aspect already included?</i></p>	<p><b>Comment clarified</b> While there is no direct mention to corals specifically, criterion 1 on toxicity in the aquatic environment, criterion 2 and 3 on biodegradability and criterion 4(g) on UV filters ensure the safety for the marine environment.</p>
<p><i>Please do not use endnotes. It is the first time that in the awarding criteria endnotes are used. Please use "normal" footnotes at the end of the page. We are not sure if its target oriented to include so many links. Looking at the intended running time of the product group we assume that different links not work anymore.</i></p>	<p><b>Comment accepted</b> In the last version of the ANNEXES normal footnotes will be used.</p>
<p><i>The list of excluded substances should include</i></p> <p><i>With „no limit“:</i></p> <ul style="list-style-type: none"> <li>- Nanomaterials unless a SCCS opinion is published with the conclusion that they are safe (for example 3 TiO<sub>2</sub>-Monomers, SCCS, Opinion on additional coatings for Titanium Dioxide (nano form) as UV-filter in dermally applied cosmetic products, 7 March 2017, revision 22 June 2018, SCCS/1580/16)</li> <li>- CMR-substances of all categories (1A, 1B, 2)</li> <li>- Per- and polyfluoroalkyl substances (see a Swedish study from 2018: <a href="https://pubs.rsc.org/en/content/articlelanding/2018/em/c8em00368h#!divAbstract">https://pubs.rsc.org/en/content/articlelanding/2018/em/c8em00368h#!divAbstract</a> )</li> <li>- PBT and vBvP substances</li> <li>- SVHCs in accordance with the criteria for the detergent group</li> <li>- Substances suspected of being endocrine disruptors (justification see below)</li> </ul> <p><i>From 0,01% (rinse-off products) and 0,001% (leave on products)</i></p> <ul style="list-style-type: none"> <li>- all H317 and H334 substances and especially</li> <li>- Sensitizing fragrance ingredients listed in Table 13-1 of the SCCS-opinion on fragrance allergens in cosmetic products, 26-27 June 2012 (54 individual chemicals, 28 natural extracts (mixtures of chemicals), including all 26 fragrance allergens identified by SCCNFP in 1999)</li> </ul> <p><i>In this regard: please include a threshold table in the criteria in order to have all thresholds unambiguously at a glance.</i></p>	<p><b>Comment clarified</b> All the exclusions and the relative limit values listed in the comment are already proposed in the TR3.0. For the exclusion on potential EDs please refer to earlier parts of this table of comments. A table of thresholds was also already proposed in TR3.0.</p>

<p><i>Minimum volume</i> The minimum volume of 150mL for rinse off product needs to exclude toothpastes that are all generally sold on 75mL</p>	<p><b>Comment accepted</b> As mentioned in Table of Comments of previous TR3.0: In order to avoid the use of small bottles it has been included a new requirement to limit the minimum volume for a product to be certified to 150ml. This requirement will not apply to leave on products and toothpastes usually marketed in small volumes. The exemptions to leave on and toothpastes has been now specified in the text</p>
<p><i>Criterion 5: in favour of the 150 ml minimum requirement In favour of the subcriteria</i></p>	
<p><i>The minimum volume for a certified rinse off product should not be 150 ml – you would exclude for example toothpaste (mostly sold as 75 ml package) and solid soap (mostly sold as a piece of 100 g)</i></p>	
<p><i>For a rinse off product, we should require a minimum volume of 200ml because 200ml it's the usual volume for consumer products (higher for professional products) except for toothpastes.</i> <i>If you ever choose to change this minimum volume for travel products, the exemption shall be applied only to travel products and this claim ("travel product") shall appear on the label.</i> <i>For treatment products, skin care products and deodorants/antitranspirants we should also require a minimum volume.</i> <i>Our proposal is 150ml because the aim of the EU Ecolabel is to encourage more environmentally friendly products and there are a lot of these products with the capacity of 150ml, 200ml or more!</i></p>	
<p><i>The limit of 150 ml for packaging for rinse-off will be a problem for specific subgroups of criteria. In the EUEB JRC stated, that toothpaste is not considered as "rinse off". This should perhaps be mentioned, specifically, in the user manual. From products certified with the Nordic Swan Ecolabel we know that products in the following subgroups normally are marketed in packaging smaller than 150 ml (because the products are not used in big quantities on a daily basis): Intimate soap, Face wash and face masks, Body Scrub, Soaps for special purposes, Shampoo and conditioner for hotels (and in "travel sizes". Furthermore, for environmental reasons manufacturers are aiming at concentrated products, which leads to smaller packaging sizes.</i></p>	
<p><i>We suggest to authorize a volume of 100ml in order to allow products destined to be used for travel (plane) to be certified.</i></p>	<p><b>Comment rejected</b> It is considered better for the environment the use of standard refillable travel bottles that can be filled with the amount needed by the user and reused each time travelling.</p>
<p><i>This means that flight-friendly format (&lt;100 mL) cannot be certified. That is very unfortunate.</i></p>	<p><b>Comment rejected</b> The secondary packaging is not essential for that reason is only allowed to multipack the refill of the product. However in this latest revision it is proposed to allow its use also to products that include several elements for its use (e.g hair inks) Finally it has been removed the exemption for toothpastes as the multipack is an optional market strategy with no environmental benefits.</p>
<p><i>Multipacks exist for all kind of products. Why give an exemption only to toothpastes?</i></p>	<p><b>Comment accepted</b> The conditions of the future (January 2022) implementing act of Directive 2019/904 laying down the rules for the calculation and verification of the targets on recycled content will be considered in future revision.</p>
<p><i>In relation to: future (January 2022) implementing act of Directive 2019/904 How can we demand that a declaration must fulfil conditions not yet written?</i></p>	

<p><i>We disagree with the requirement to make the refill compulsory for rinse off products with pump for professional market. Refill operation can introduce contamination. It can become a health issue at customers such as hospitals, food service. Example of studies was shared in previous comments session. Comment on refill was not addressed as it was put with the question of take back system -table TR3.0 p75/101.</i></p> <p><i>Bottle with pump to be placed in dispenser cannot be open without compromising the design. Can you confirm that refill in that case does not apply?</i></p>	<p><b>Comment partially accepted</b> The mandatory refilling for products sold with pump has been limited to products for domestic use with dispenser that can be opened without compromising the design.</p>
<p><i>Criterion 5(a) Page 103</i></p> <p><i>We support the proposition of the JRC to add a requirement on the minimum volume of 150ml for a rinse off product to be certified. We support the refilling option for products sold with a pump, provided that a requirement is introduced on the difference in weight between the initial packaging and the refill, this to ensure that the refill has a lower environmental impact than the initial packaging. We also recommend to extending the refilling option to every rinse-off cosmetics, not only those that are sold with a pump</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>Applicants shall provide proofs of this number.</i></p> <p><i>You didn't answer in your comments : Shall CBs check the real number of sold refillings the following year? If yes, please indicate this precision that CB have to check the number announced by applicants?</i></p>	<p><b>Comment clarified</b> The evidence shall be provided by applicant. In this case could be refillings sales figures from previous year and foreseen production figures of the year of application. This will be further clarified in the UM.</p>
<p><i>If applicants provide refills, you shall require a sentence on the label to encourage consumers to use refills for example "apply the correct dosage and use refills in order to reduce the impact on the environment and save money"</i></p> <p><i>You shall also require where applicable (when a refill is necessary and/or provided) a sentence on the label to encourage consumers to use refills for example "apply the correct dosage and use refills in order to reduce the impact on the environment and save money"</i></p>	<p><b>Comment accepted</b> The text has been revised accordingly.</p>
<p><i>(PIR) value lowered further.</i></p> <p><i>We sent you our values: the average is 0,15. We propose a threshold of 0,18g.</i></p> <p><i>Indeed, as already said, there are solutions for current products which have PIR &gt; 0,18 : providing refills, using a % of recycled materials, raising volume capacity...etc.</i></p> <p><i>As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel, in particular for packaging because reducing plastic waste is a major environmental issue!</i></p>	<p><b>Comment partially accepted</b> Please see previous report rationale. Reduction to PIR value to 0.20g would affect 35 % of current licences (out of the 120 products assessed). The general ambition level during this revision has been raised.</p>
<p><i>We appreciate the first step to reduce this value but we think this is not sufficient. Indeed, 128 of our 132 certified product already comply with this value 6%. So we are asking for 5% (101 products are already conform) or at least, 5,5% (114 products are already conform) ; especially since you offered to exempt rinse off products which primary packaging can be manually opened and the residue product can be extracted with adding water (most of our products).</i></p> <p><i>It's crucial to reduce the value of R if we want that the criterion remains selective. As mentioned by Norwegian CB and BEUC/EEB during the 2nd AHWG, the aim of the revision isn't to keep all current licenses without improvements. It's essential to challenge all applicants to provide better solutions in order to maintain the credibility of the European Ecolabel. We share the view that the Ecolabel should incentivise improvement of environmental performance and reflect environmental excellence of products already in the market.</i></p>	<p><b>Comment partially accepted</b> The R amount has been decreased to 5%.</p>

<p>To ensure relevant results, it's essential to require a test report with results of measuring R on 10 packagings (or at least, on 5 packagings).</p>	<p><b>Comment rejected</b> It is considered a significant change at this stage of the process. There is no additional consultation to industry at this stage. In addition, there is lack of evidence on gaining on solidity of test results Vs. waste of product.</p>
<p>(on the dosage sentence) We strongly appreciate this inclusion because it's important that applicants define the correct dosage to help users to minimize their environmental impact. We strongly appreciate this inclusion but license holders warned us that labels of cosmetic products are smaller and the regulatory requirements already take up space, so maybe this mandatory sentence should be shorter as "apply the correct dosage in order to reduce the impact on the environment and save money" Indication of packaging of the correct dosage The obligation of indicate a correct dosage on the packaging isn't relevant for cosmetics. For exemple a shampoo won't be used the same dosage if you have short hair or long hair. A sunscream won't be used at the same dosage if you are a children or a adult.</p>	<p><b>Comment accepted</b> The text has been revised to consider different potential situations and exemptions.</p>
<p>The criteria "Virgin PET and rPET from already food contact approved material shall not be allowed to use" must be removed. The term "food grade" is used to describe equipment and quality suitable for use in food production. In fact, it is a certification and practical safety requirement present in many industries. This certification does not induce competition with food. With this criteria the use of recycled PET would be impossible. (d) Design for recycling of plastic packaging Table 8. Materials and components excluded from packaging elements The criteria "Virgin PET and rPET from already food contact approved material shall not be allowed to use" must be removed. The term "food grade" is used to describe equipment and quality suitable for use in food production. In fact, it is a certification and practical safety requirement present in many industries. This certification does not induce competition with food. With these criteria the use of recycled PET would be impossible.</p>	<p><b>Comment accepted</b> This restrictions has been removed.</p>
<p>Technical Report P106 Packaging The criteria "Virgin PET and rPET from already food contact approved material shall not be allowed to use" must be removed. The term "food grade" is used to describe equipment and quality suitable for use in food production. In fact, it is a certification and practical safety requirement present in many industries. This certification does not induce competition with food. With these criteria the use of recycled PET would be impossible.</p>	
<p>It is important that the criteria acknowledge the possibility to use pouches, for refill purposes or other packaging purposes. Pouches are made of different layers of plastic materials. The different layers are needed to make them possible to weld and to keep the packaging water- and airtight. Since pouches are light weight packaging, they save space when they are transported. Pouches add to the environmental benefits during transport, both when empty packaging is delivered to the cosmetic producer and when the cosmetic product is delivered for further distribution. There are no alternatives to pouches made of different layers of plastic material on the market. Several producers deliver liquid products where pouches are still needed. Plastic laminates, pouches, makes it possible to use only 16 g/l packaging compared to 100 g/l packaging with an ordinary packaging solution.</p>	<p><b>Comment clarified</b> There is no specific restriction to pouches. As soon as they comply with the criteria, they can be awarded.</p>
<p>Will you provide guidance for the SAL and PSL label to demonstrate it can be released by water?</p>	<p><b>Comment accepted</b> A Quick Test Protocol by RecyClass and EPBP is being finalised. Information will be provided in the User</p>

	<p>manual.</p>
<p><i>Can you clarify the use of label of the same material of the container? it is accepted for all the other EUEcolabel categories [detergent]. Recyclclass [from recycler plastic Europe] put it as compatible for PE or PP natural container [recyclclass factsheet for HDPE and PP containers available as attachment in the email from Diversey]</i></p>	<p>Text has been further clarified in line with Hard Surface cleaners. Being same material sleeve and bottled does not automatically means it is permitted. For instances PET label with PET bottle: The printing of the sleeves (any material) will impact on the recyclability of the PET bottle. The limit has been established in 1g/cm<sup>3</sup>, because foamed PET or foamed have a density lower than 1 g/cm<sup>3</sup> and can get separated by PET in the recycling process.</p>
<p><i>"the applicant shall submit a signed declaration of compliance specifying the material composition of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging." You shall also add "supported by manufacturer documentation"</i></p>	<p><b>Comment accepted</b></p>
<p><i>Is this requirement also relevant for raw materials that are found in concentration lower than 1% in the final product?</i></p> <p><i>The Nordic Ecolabel requires more information only for raw materials included in concentrations higher than 1% in the final product.</i></p>	<p><b>Comment rejected</b> The EU Ecolabel criterion 5(a) applies to every ingoing substance.</p>
<p><i>6. (b) Certification of plant based ingredients</i> <i>We suggest that for each organic raw material/ingredient in the cosmetic product, the following data is collected:</i></p> <p><i>a) Proportion of renewable raw materials in the raw material/ingredient on an annual basis</i></p> <p><i>b) What does the raw material consist of (e.g. palm oil, coconut oil, rapeseed oil, beeswax)? State the name of the supplier.</i></p> <p><i>c) Does the renewable raw material (other than PO/PKO and derivatives) have any sustainability certification? If yes, state which, and what level of traceability (no traceability, Identity Preserved, Segregated, mass balance, Book&amp;Claim)?</i></p>	<p><b>Comment rejected</b> A totally new structure of the criterion for palm oil would be too late to introduce at this stage of the revision, also due to the general consensus of the current proposal.</p>
<p><i>We strongly are to remove this criteria because too complicated to manage by stakeholders and competent bodies (as previously already explained) We recommend to propose a limit of palm oil/ kernel oil derivates that would be better to consider to improve the environment destruction ( that is directly linked to palm production) Nevertheless we can't avoid to use palm derivates in cosmetic industry.</i></p> <p><i>If you want to keep the actual criteria, it's really important to accept Book and claim scheme that is easier to manage for everything is the certification scheme.</i></p>	<p><b>Comment rejected</b> The option of limit the content of palm oil, palm kernel oil and their derivatives may be interesting, however a proposal cannot currently be formulated as data were made available by one Competent Body only. Moreover, substances substituting palm oil, palm kernel oil and their derivatives may have a worse environmental profile. The exclusion of Book and Claim credits have been kept as discussions with other stakeholders indicated that this type of certification complicates the verification for CBs, as CBs do not have to check different proofs.</p>

<p><i>As shared in previous comments on the first and second technical reports, we received the following feedbacks from French stakeholders: - Fulfilling this criterion is very complex and all French licensed products include derivatives from palm oil and palm kernel oil (but none of them contains palm or palm kernel oil). - The "mass balance" certification scheme is questionable and has been subject to controversy. - The improved environmental performance of certified palm oil, palm kernel oil and their derivatives has not been scientifically proven. Considering the above comments and the fact that intensive cultivation of palm oil, palm kernel oil and their derivatives has a direct link with environment destruction (including deforestation, habitat destruction and associated biodiversity loss), we recommend to define an upper threshold regarding the percentage of palm oil, palm kernel oil and their derivatives contained in a product. Based on data collected from French industrials, the maximum average palm oil derivative content (average of the maximum palm oil derivative contents of all products) is the following: - Shampoo: 3.64% - Shower preparations: 5.73% - Liquid soaps: 2.68% If such a criterion cannot be set up, we then recommend removing the criterion 6.</i></p>	<p>At the final stage of the revision it has been decided to not propose this requirement during this revision as there is not a clear picture of the feasibility of this requirement due to the lack of feedback from industry at this stage. In addition there is a risk that setting requirements on SVHCs for packaging could lead to producers moving to virgin material in order to avoid compliance with this requirement.</p> <p>It is proposed to gather data with this regards during next revision in order to set SVHC restriction once a better picture of the situation is available.</p>
<p><i>Regarding the inclusion of antiperspirants, almost all use aluminium salts in their formulation. The extraction of bauxite used to produce aluminium raises societal (child labour, forced labour, exposure to toxic substances) and environmental (deforestation, water and soil pollution) issues that should be considered in this standard. We therefor recommend including a sub-criterion on the origin of the bauxite used in aluminium salts.</i></p>	<p><b>Comment rejected</b> The suggestion is definitely relevant. However, the JRC lacks the products and market data needed to define such a requirement. Moreover, other environmental schemes do not have a similar requirement, therefore also excluding the option of aligning with other schemes. It will be taken into account in the next revision process.</p>
<p><i>Certification of plant-based ingredients. Assessment and verification. We support the suggestion to exclude B&amp;C credits from the accepted RSPO supply chain system certifications.</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>It is not clear which of the RSPO schemes are valid: only MB, SG and IP? Or also Book&amp;Claim? In some parts it seem only the first three, in other it is understood that credits (B&amp;C) are accepted. Please clarify and re-write the text accordingly</i></p>	<p><b>Comment clarified</b> Book and Claim credits are not accepted. Only identity preserved, segregated, and mass balance supply chains are accepted. The text have been revised.</p>
<p><i>Depending on the final decision of the validity period, and if more than 5 years, Denmark proposes again a stepwise approach with regards to the certification level of palm oil and palm kernel oil, where "mass-balance" shall not possible from January 1<sup>st</sup>, 2025. This will ensure coherence with the market development. Concerning derivatives from palm oil and palm kernel oil, it might be relevant still to accept mass balance.</i></p>	<p><b>Comment accepted</b> The suggested requirement has been inserted for palm oil and palm kernel oil only.</p>
<p><i>Assessment and verification Certificates are not enough to show compliance, they merely prove that the license holder/supplier is in the system.</i></p> <p><i>We suggest the following:</i></p> <p><i>"The producer of raw materials or the producer of the EU Ecolabelled product must show by means of a balance calculation and/or invoices/delivery notes that the proportion of certified raw material corresponds to the amount of certified palm oil raw materials. Alternatively, a declaration from the producer of raw materials that all purchased palm oil raw materials are certified".</i></p>	<p><b>Comment accepted</b></p>

<p><i>This requirement must also be controlled during the audit.</i></p>	
<p><i>Criterion 6: in principle we are in favour but we are afraid of the practical verification</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>The scope of the regulation 2018/848 is still very unclear, considering there is no positive list of ingredients and the secondary legislation planned for January 2022 make the assessment by the raw material manufacturers difficult to do and in time as well as screening and implementation for the cosmetic manufacturer.</i></p>	<p><b>Comments partially accepted</b>  Since the beginning of the revision process stakeholders stated that the criterion is not clear, that it is difficult to implement as a positive list of substances included does not exist, that they cannot foresee if the 20% threshold is achievable as they do not have an overview of the substances affected, that it may cause greenwashing. Finally, some stakeholders fear that this extra burden on natural substances will cause a shift towards using more chemicals.  Therefore this requirement is proposed to be removed and explored for the next revision process</p>
<p><i>French industrials have expressed their concerns on reaching the minimum threshold of 20% w/w of raw materials/ingredients to which Regulation 2018/848 applies. We thus recommend lowering this threshold or removing this criterion.</i></p>	<p><b>Comment rejected</b></p>
<p><i>Concerns over non-renewable fossil fuel supply and climate change have been driving the development of bio-based materials. Bio-based products are totally or partly derived from materials of biological origin, such as, crops, plants or other renewable agricultural, marine or forestry materials. These products provide alternative material to conventional petroleum-based materials by using renewable carbon as feedstock. The use of renewable carbon feedstock for chemical production has a clear potential to reducing the risk of climate change and reduced dependency on fossil resources and when the bio-based chemicals is produced in a sustainable manner (Sustainability certification).  Several review papers<sup>1,2</sup> on bio-based products have shown that the production of bio-based chemicals has the potential to significantly reduce the greenhouse gas (GHG) emissions and fossil resource demand of the petrochemical industry, and for the downstream users. The conclusions for other environmental impacts, such as acidification, ecotoxicity, stratospheric ozone depletion, etc. or resources such as water were inconclusive<sup>3</sup>. Also Bio-based industry is a young sector. Their production processes are not fully optimized for efficiency and there are on-going efforts to optimize those processes. The scale of the bio based processes is currently in general much smaller than for their petrochemical counterparts, this limits the scale benefits.  Petroleum-based processes from new exploration methods (e.g. tar sands, deep sea drilling, arctic exploration) as well as the extraction of heavier and more contaminated oil will unlikely achieve the same environment footprint-efficiency as current old processes.  The Ecolabel must continue to encourage the use of bio-based products produced in a sustainable manner (such a RSPO palm oil derivatives). Different options are possible such as a minimum level in the product (formula and/or packaging),  the mandatory use of the biobased ingredient when widely available (Glycerin, ethanol....) or in a first step to align to the Nordic Swan criteria O3.  O3 Renewable raw materials</i></p> <ol style="list-style-type: none"> <li><i>1. The cosmetic producer must document that they are working to increase their purchasing of renewable and sustainable raw materials.</i></li> <li><i>2. For each organic raw material/ingredient in the Nordic Swan Ecolabelled cosmetic product, the following</i></li> </ol>	<p><b>Comment rejected</b>  Requirements on a minimum content of bio-based ingredients cannot be set on cosmetic products, because the EU Ecolabel is technology neutral: it does not prefer one type of ingredient over the others. All ingredients are allowed, provided that are the less impacting throughout their life-cycle (e.g. in terms of their toxicity, biodegradability, etc.)  Moreover, there is no clear international definition of "natural" or "bio-based" ingredient, also give that the ISO definition consider as natural an ingredient with only 50% renewable part.  An improved environmental profile of EU Ecolabel product can be obtained through</p>

*data is collected:*

- a) *Proportion of renewable raw materials in the raw material/ingredient on an annual basis*
  - b) *What does the raw material consist of (e.g. palm oil, coconut oil, rapeseed oil, beeswax)? State the name of the supplier.*
  - c) *Does the renewable raw material have any sustainability certification? If yes, state which, and what level of traceability (no traceability, Identity Preserved, Segregated, mass balance, Book&Claim)?*
    - 1. *Policy or equivalent documentation of the producer's work for renewable and sustainable raw materials.*
    - 2. *Appendix 2 from the raw materials supplier.*
- 1 Weiss, M., Haufe, J., Carus, M., Brandão, M., Bringezu, S., Hermann, B. and Patel, M.K. (2012), A Review of the Environmental Impacts of Biobased Materials. *Journal of Industrial Ecology*, 16: S169-S181. <https://doi.org/10.1111/j.1530-9290.2012.00468.x>
- 2 *Bio-Based Chemicals A 2020 Update Bio-Based Chemicals A 2020 Update Published by IEA Bioenergy February 2020 Heinz Stichnothe.* <https://www.ieabioenergy.com/wp-content/uploads/2020/02/Bio-based-chemicals-a-2020-update-final-200213.pdf>
- 3 *Environmental impact assessments of innovative bio-based product* <https://op.europa.eu/s/oraB>

#### *Technical Report P129 – Bio-based materials*

*Concerns over non-renewable fossil fuel supply and climate change have been driving the development of bio-based materials. Bio-based products are totally or partly derived from materials of biological origin, such as, crops, plants or other renewable agricultural, marine or forestry materials. These products provide alternative material to conventional petroleum-based materials by using renewable carbon as feedstock. The use of renewable carbon feedstock for chemical production has a clear potential to reducing the risk of climate change and reduced dependency on fossil resources and when the bio-based chemicals is produced in a sustainable manner (Sustainability certification).*

*Several review papers<sup>67</sup> on bio-based products have shown that the production of bio-based chemicals has the potential to significantly reduce the greenhouse gas (GHG) emissions and fossil resource demand of the petrochemical industry, and for the downstream users. The conclusions for other environmental impacts, such as acidification, ecotoxicity, stratospheric ozone depletion, etc. or resources such as water were inconclusive<sup>8</sup>. Also, bio-based industry is a young sector. Their production processes are not fully optimized for efficiency and there are on-going efforts to optimize those processes. The scale of the bio-based processes is currently in general much smaller than for their petrochemical counterparts, this limits the scale benefits. Petroleum-based processes from new exploration methods (e.g. tar sands, deep sea drilling, arctic exploration) as well as the extraction of heavier and more contaminated oil will unlikely achieve the same environment footprint-efficiency as current old processes.*

*The Ecolabel must continue to encourage the use of bio-based products produced in a sustainable manner (such as RSPO palm oil derivatives). Different options are possible such as a minimum level in the product (formula and/or packaging), the mandatory use of the biobased ingredient when widely available (Glycerin, ethanol....) or in a first step to align to the Nordic Swan criteria O3.*

#### *O3 Renewable raw materials*

- 1. *The cosmetic producer must document that they are working to increase their purchasing of renewable and sustainable raw materials.*
- 2. *For each organic raw material/ingredient in the Nordic Swan Ecolabelled cosmetic product, the following data is collected:*
  - a) *Proportion of renewable raw materials in the raw material/ingredient on an annual basis*
  - b) *What does the raw material consist of (e.g. palm oil, coconut oil, rapeseed oil, beeswax)? State the name of*

<p>the supplier.</p> <p>c) Does the renewable raw material have any sustainability certification? If yes, state which, and what level of traceability (no traceability, Identity Preserved, Segregated, mass balance, Book&amp;Claim)?</p> <ol style="list-style-type: none"> <li>1. Policy or equivalent documentation of the producer's work for renewable and sustainable raw materials.</li> <li>2. Appendix 2 from the raw materials supplier.</li> </ol>	
<p>"[1] The dosage used should be the same as the one identified in criterion 5 (c)." We strongly appreciate this inclusion because it's essential to link both criteria which are connected.</p>	<b>Comment acknowledged</b>
<p>We thank you for removing the irrelevant question "How easy is it to apply the dosage of the product in comparison with a market-leading product?"</p>	<b>Comment acknowledged</b>
<p>Denmark suggest making more product specific guidelines to the user test. This will ensure that the products will be evaluated on the same basis – inspiration can be found in the Nordic Swan Ecolabel requirement for Cosmetic products (version 3.7), appendix 7.</p> <p>As proposed earlier, we suggest a requirement to ensure that products, which include fragrance, cannot be labelled with claims like "mild/gentle or sensitive".</p> <p>Also, the claims "mild/gentle/sensitive" cannot be demonstrated in a User test. These claims can be documented by testing methods to document mildness, e.g. HET-CAM or a test for red blood cells.</p>	<p><b>Comment partially accepted</b></p> <p>Guidelines will be made more specific in the user manual.</p> <p>A requirement that cannot be labelled with claims like "mild/gentle or sensitive" if including fragrances have been added.</p> <p>Finally, it was already proposed in TR3.0 that if laboratory tests are available, these should be used, and consumer tests will not be accepted.</p>
<p>This criterion only relates to rinse-off cosmetics but not to leave-on cosmetics. Please add appropriate criteria for leave-on cosmetics.</p>	<p><b>Comment clarified</b></p> <p>The criterion relates to both rinse-off and leave-on cosmetics</p>
<p>Criterion 7: we hope in a clear statement in order to understand when the consumer test is not allowed</p>	<p><b>Comment clarified</b></p> <p>If laboratory tests are available, these should be used, and consumer tests will not be accepted. More detailed info will be given in the user manual</p>
<p>If the fomula has not changed with the revision of the criteria, do we need to provide a new test? previous test was a consumer test</p>	<p><b>Comment clarified</b></p> <p>If no laboratory tests exist for that product group, and if the laboratory tests was performed on a minimum of 20 consumers (with 80% of them satisfied) and the formula of the product has not changed, it is not necessary.</p>
<p>We support the reference made to 2006/647/EC for sunscreen products</p>	<b>Comment acknowledged</b>
<p>We support the following criteria text:</p> <p>"If national guidelines on fluorine content in toothpaste are available, these shall be followed. Fluorine-free toothpastes which have been evaluated as protective as fluorine-containing toothpastes by an independent party are exempted."</p>	<b>Comment acknowledged</b>
<p>Annex II: Third proposal for criterion 6: Fitness for use for Animal Care Products We think there is a mistake : it's the criterion 7</p>	<p><b>Comment clarified</b></p> <p>It is criterion 6 (EU Ecolabel criteria for Animal Care</p>

	Products don't include leave on products, therefore criterion 3 for cosmetic products is not valid for them.
<p><i>Carrying out of animal testing of final formulations How CB can CBs ensure the effectiveness of these products?</i></p> <p><i>We don't understand why carrying out of animal testing of ANIMAL products - which will be applied to ANIMALS skins - is prohibited. What is the ethical problem with this practise?</i></p> <p><i>Regarding the assessment of the fitness for use for animal care products. Indeed, it appears difficult to assess the product's capacity to fulfill its primary and secondary functions through studies, and without testing the product on the final user, meaning animals.</i></p> <p><i>We wish to inform the JRC about concerns expressed by French industrials regarding the assessment of the fitness for use for animal care products. Indeed, it appears difficult to assess the product's capacity to fulfill its primary and secondary functions through studies, and without testing the product on the final user, meaning animals.</i></p>	<p><b>Comment clarified</b></p> <p>The ban on animal testing for cosmetic started in 2013, meaning that a number of historical data exist for ingredients that were tested on animals before that date. Moreover, databases also exist reporting information on substances and formulations. Finally, the applicants could (and should) make use of laboratory tests, which can be (and, for cosmetic products, are) not on animals.</p>
<p><i>The following information are proposed for the optional label with box:</i></p> <p><i>(a) 'Restricted hazardous substances';</i></p> <p><i>(b) 'Tested performance';</i></p> <p><i>As a reminder the general purpose of the ecolabel is to provide to the consumer the best choice in term of environmental performance. For cosmetics products, the wording is very important because it is a beauty product. This is even more important than leave-on products such as make-up and skin care products will be in the new scope of the Cosmetic Ecolabel.</i></p> <p><i>(a) 'Restricted hazardous substances' is unacceptable; the term is denigrating for other products because it implies that they contain dangerous substances in quantities which is false and the use of the term "without" or equivalent is prohibited by the cosmetic regulations. We do suggest to promote a positive wording such as "improved environmental profile", "Optimized Environmental Profile" or "Very Good Environmental Profile"</i></p> <p><i>'Tested performance' if we understand why it is important to indicate that the product is efficient because of the "bad reputation" of ecological products in terms of performance, the term is awkward because it means that the performance of other product is not tested which obviously is untrue. We do suggest to promote a positive wording such as "Optimized performance tested", "Very good performance tested" or "Very good efficacy tested"</i></p>	<p><b>Comments partially accepted</b></p> <p>Text has been revised.</p>
<p><i>'Restricted hazardous substances' We don't agree with this proposal: this sentence could worry the users! Please reintroduce the previous sentence "reduced impact on aquatic ecosystems".</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>'Tested performance' We strongly appreciate this sentence to underline the effectiveness of cosmetic products which are certified EU Ecolabel.</i></p> <p><i>Maybe you could change for "verified/proven performance"</i></p>	<p><b>Comment acknowledged</b></p>
<p><i>Page 140, Criterion 8: Information appearing on the EU Ecolabel</i></p> <p><i>We support the suggestion that the optional label should contain information about restrictions on hazardous substances, since such restrictions is a major benefit of the EU Ecolabel criteria. However, the suggested wording is a bit unclear, why we suggest: "- Fulfills strict requirements regarding hazardous substances"</i></p> <p><i>We consider that a sentence referring to the end of life impacts of products is more relevant than a reference to</i></p>	<p><b>Comment acknowledged</b></p>

<p>performance tests.</p> <p>Replace "Tested performance" by "Reduced impact on aquatic ecosystems"  Reduction of all environmental impacts of the cosmetic at the end of life is a driver for green marketing.  While test of performance is relevant, it is not the main selling point of an environmental label. Additionally, not all dimensions of efficacy may be tested in laboratory with consumers tests not being equally reliable.</p>	
<p>critterion 8 –  P141  Information appearing on packaging  We would like to draw JRC attention that the sentence "restricted Hazardous substances" is not compatible with Common criteria defined by regulation (EU) n°655/2013, especially as regards the criteria "fairness".  All cosmetics products available on the market should be compliant with Cosmetic regulation (EU) n°1223/2009 and this imply that all cosmetic products must be safe.  The sentence of the restriction of hazardous substances for Ecolabel products would implies that others products contain hazardous substances. In addition to bring confusion for the consumer, it is unfair for others cosmetics products, which are safe.  However, Ecolabel products have been developed with a specific attention to reduce environmental impact. This should be highlighted on the packaging and will add value to the products certified.  On a general matter, we defend in France the possibility to claim the reduction of environmental impact when respecting specific guidelines and standards, rather than a prohibition. The more virtuous products should be highlighted to encourage virtuous action. (As the French law on waste reduction and circular economy voted in February 2020 intend to prohibit the use of terms "biodegradable", "respect the environment" or any equivalent wording in packaging)  This is true for all products but also for Ecolabel certified products Ecolabel certified products follow strict criteria on biodegradability and to reduce environmental impact. This is important to be able to claim it.  In addition, this will help consumers understand the logo.</p>	<p><b>Comment partially accepted</b>  Text has been revised.</p>
<p>Given that the main objective of the EU Ecolabel is to award products with a reduced environmental impact, we believe it is important to underline this through a mention on the label, such as "Limited environmental impact".  Indeed, we carried out a study on the awareness of the European Ecolabel, and the result shows that consumers know the logo but do not understand its meaning. Most of the answers say that the logo means that the product complies with European regulations. It is therefore necessary to be able to inform the consumer about the added value of this label compared to other products. And do not censor the efforts that are made. It can be very discouraging for licensees not to be able to communicate on this matter. Regarding the new sentences proposed by the JRC, we do not support the use of the sentence "Restricted hazardous substances". Indeed, this mention would imply the presence of hazardous substances in cosmetic products and most importantly in certified products, whereas those substances are prohibited by the Cosmetic Regulation. We support the inclusion of a sentence concerning conducted tests, however the sentence "Tested performance" might be denigrating for non-certified products as it can suppose that they are not performing well. Therefore, we suggest rephrasing this sentence. Regarding the mentions appearing on the EU Ecolabel for animal care products, we wish to inform the JRC that, contrary to what is stated in the third technical report, it is not specified in criterion 8 that tested performance is not animal tested.</p> <p>Restricted hazardous substances' is unacceptable; the term is denigrating for other products because it implies that they contain dangerous substances in quantities which is false and the use of the term "without" or equivalent is prohibited by the cosmetic regulations.</p>	<p><b>Comments acknowledged</b></p>

<p>We do suggest promoting a positive wording such as "improved environmental profile", "Optimized Environmental Profile" or "Very Good Environmental Profile".</p>	
<p>About marketing: It seems that nothing in the criteria regulate what is ok for the companies to communicate to the consumers which is good.</p> <p>We suggest that they make this clear so that no claims added on the packaging by the company producing/selling the product looks like it has been approved by the EU Ecolabel. For instance, claims about organic ingredients.</p>	<p><b>Comments acknowledged</b></p>
<p>Technical Report P140 Information on the label The following information are proposed for the optional label with box: (a) 'Restricted hazardous substances' (b) 'Tested performance'</p> <p>As a reminder the general purpose of the ecolabel is to provide to the consumer the best choice in term of environmental performance. For cosmetics products, the wording is very important because it is a beauty product. This is even more important than leave-on products such as make-up and skin care products will be in the new scope of the Cosmetic Ecolabel.</p> <p>'Restricted hazardous substances' is unacceptable; the term is denigrating for other products because it implies that they contain dangerous substances in quantities which is false and the use of the term "without" or equivalent is prohibited by the cosmetic regulations. We do suggest promoting a positive wording such as "improved environmental profile", "Optimized Environmental Profile" or "Very Good Environmental Profile".</p>	<p><b>Comment partially accepted</b> Text has been revised.</p>