

Scope and definitions

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><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>Comments partially accepted</p> <p>There are at least 12 products certified under Nordic Swan scheme for this category.</p> <p>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>Other stakeholders welcomed the inclusion of these products (animal products) which are very successful under other schemes.</i></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> <p style="padding-left: 40px;"><i>Ingredients used in cosmetic products;</i></p> <p style="padding-left: 40px;"><i>The development of cosmetic specialities;</i></p> <p style="padding-left: 40px;"><i>Tests on finished product."</i></p>	<p>Comments partially accepted</p> <p>Fitness for use has been modified accordingly: Ingredients and finished product for animal care products shall not be tested on animals.</p>

Also, it should be ensured that the thresholds are the same between animal products and cosmetics, particularly in terms of biodegradability.	
Denmark also supports to include Animal care products	
We strongly disagree with the inclusion of wet wipes.	<p>Comments accepted</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>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>
We do not support the inclusion of wet wipes in the scope of the ecolabel as these products are discordant with ecolabel philosophy.	
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.	
We are not in favor of including wet wipes into the scope.	
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.	
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). 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.	
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. 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. Considering alternatives available on the market, we do not support the inclusion of wet wipes in the scope.	

<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>Comments rejected Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.</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>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 explored 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>Comments rejected Sunscreens need 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><i>We are not in favor of the inclusion of sun screen products. They contain 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 respectful 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 products 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>Comment acknowledged</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 & 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>Comments partially accepted</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 ecolabel¹.</p>
<p><i>We are in favour of this extended scope.</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><i>We agree to keep in the new scope :</i></p> <ul style="list-style-type: none"> <i>- lotions, creams and oils (including massage products and after-sun creams) ;</i> <i>- cleanser.</i> <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</i></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>

¹ 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>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 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>It is proposed to keep the alignment to Nordic Swan.</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><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 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> <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>Comment partially accepted</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>Comment partially accepted</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>Comment rejected</p>

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. □	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.
Toothpaste can be liquid or solid. Shouldn't the limits be different as in solid and liquid soap?	There is no available data to allow us differentiate among solid and liquid toothpaste.
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 ?	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.
Suggest to replace " oral care perfume " by " mouth spray "	Comment acknowledged
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: https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en	Comment accepted Reference to borderline manual will be included in the User Manual.
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 ?	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 Sawn. 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.
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	

<p>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.</p>	
<p>The use of the word 'impurities' could be linked to how this is used in the EU Cosmetic Regulation cf.: Art.17</p> <p>"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."</p> <p>Possible rephrasing suggestion:</p> <p>'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 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</p> <p>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 you 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>	

<i>'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 ≥ 1000 ppm (≥ 0.1000 w-% ≥ 1000 mg/kg) are always regarded as ingoing substances, regardless of the concentration in the final product.</i>	
<i>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.</i>	
<i>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.</i>	
<i>"The limit on 0,1% impurities seem quite high. Can we lower this?"</i>	
<i>excluding the water content of the ingredients We strongly appreciate this clarification</i>	Comment acknowledged
<i>How shall we deal with products marketed as "family products" ? Can you confirm they are considered as children's products too ?</i>	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.
<i>No definition at point 3 is present.</i>	Clarified 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>	Comment partially accepted 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>	
<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 question is though, is it a rinse or leave on product.</i>	Comment partially accepted 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 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>	Comment acknowledged
<i>1) 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> <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.</i>	Comment partially accepted 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.

Note: Teeth and mucous membranes are not considered external parts of the human body.

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:

(...)

- 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

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.

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 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:

[Borderline products manual on the scope of application of the Cosmetics Regulation \(EC\) No 1223/2009 \(Art. 2\(1\)\(a\)\)](#) (February 2020, version 5.1) (1 MB)

[Guidance document on the relationship between the General Product Safety Directive \(GPSD\) and certain sector directives with provisions on product safety](#) (500 kB)

[Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products](#) (450 kB)

[Guidance document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83](#) (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>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</p> <p>217. Question: Are massage products cosmetic products?</p> <p>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".</p> <p>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.</p> <p>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>Comment accepted 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):</p> <ul style="list-style-type: none"> - Art. 1: straighten it <ul style="list-style-type: none"> o (soaps (liquid and solid), shampoos (liquid, solid and dry), shower preparations, feminine hygiene cosmetic products, toothpastes (liquid and solid) and mouthwashes); o intended to take care of the epidermis or to massage the skin (skin care products),; o intended to remove polish from the nails (nail enamel remover). - 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 - rinse-off cosmetics, leave-on cosmetics – throughout the Decision used with or without a hyphen) <p>Draft Annex I:</p> <ul style="list-style-type: none"> - In particular, the criteria aim to promote products that are have limited impacts - set requirements to ensures 	<p>Comment accepted Clerical mistakes have been corrected in the ACT.</p>

<ul style="list-style-type: none"> - and promotes plastics recyclability and the minimisation of use of packaging material and plastics recyclability; - sSet requirement that guarantees that the substrate (wipe) complies with EU ecolabel requirements and informs consumers on the correct disposal of the product; - guarantees that the product 	
<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> <i>30. Question: Is a wipe which releases a substance or a mixture a cosmetic product?</i> <i>31. 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>Comment acknowledged</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>

Assessment and verification

Comments received in AHWG1/written form	JRC Dir. B response
<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></p> <p><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><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>Comment accepted</p> <p>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>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>Comment rejected</p> <p>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 >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: $\geq 0,010$</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 >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: $\geq 0,001$</i></p> <p><i>Some raw materials contain those substances as antioxidants, impurities >1000ppm and are then considered as ingoing substances... We should allow those to a maximum limit of $\geq 0,010$, as in criteria above</i></p>	<p>Comments rejected</p> <p>The limit in this case in the analytical detection limit; no detectable presence of these substance should be found</p>

<p><i>'no limit' means: regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection). 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>Comments partially accepted 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>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><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><i>Add « requirements apply" to the definition provided for no limit:</i></p> <p><i>« 'no limit' means: Requirements apply regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection).</i></p>	
<p><i>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.</i></p> <p><i>Add</i></p> <p><i>"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"</i></p> <p><i>(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).)</i></p>	<p>Comment accepted The suggested text has been included.</p>

General comments

Comments received in AHWG2/written form	JRC Dir. B response
<p><i>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:</i></p> <p><i>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).</i></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></p> <p><i>The following problematic groups of substances are fully excluded in line with our demands:</i></p> <p><i>SVHC and CMRs at any concentration (i.e. previous tolerance thresholds are now removed).</i></p> <p><i>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</i></p> <p><i>Perfluorinated and polyfluorinated substances</i></p> <p><i>Isothiazolinones</i></p>	<p>Comment acknowledged Comments addressed in the relevant criteria section.</p>
<p><i>We wish to emphasise the following positions which are further described in the document:</i></p> <p><i>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.</i></p> <p><i>We strongly recommend reviewing the calculation methodology of the CDV;</i></p> <p><i>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;</i></p> <p><i>We recommend implementing a maximum threshold regarding the percentage of palm oil, palm kernel oil and their derivatives contained in a product.</i></p>	<p>Comment acknowledged Comments addressed in the relevant criteria section.</p>
<i>We would like to emphasise that the transition period must last at least 18 months.</i>	
<i>The user manual shall be available at the same time as the decision !</i>	Comment Accepted

<p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>It's really important if all essential document are not available to postpone the application of the new decision</i></p>	
<p><i>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</i></p>	<p>Comment accepted The thresholds have been revised</p>
<p><i>We would welcome an alignment with the strictness of the criteria of Nordic Swan</i></p>	
<p><i>We would welcome an alignment with Nordic Swan</i></p>	

Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

Comments received in AHWG2/written form	JRC Dir. B response
<p><i>We should harmonize the requirements (strictness level) with the Nordiic Ecolabel. Nordic Ecolabel allows moderate use of fragrances.</i></p> <p><i>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:</i></p> <p style="padding-left: 40px;"><i>Average CDV for liquid soaps: 5558 l/g AC</i></p> <p style="padding-left: 40px;"><i>Average CDV for shampoos: 10409 l/g AC</i></p> <p style="padding-left: 40px;"><i>Average CDV for shower preparations: 9234 l/g AC</i></p> <p><i>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.</i></p>	<p>Comments partially accepted</p> <p>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.</p>
<p><i>OK with the new threshold because our average for :</i></p> <ul style="list-style-type: none"> <i>- liquid soaps : it is 7.785</i> <i>- shampoos it is 10.410</i> <i>- shower preparations : is is 9.230</i> <p><i>However, for liquid soaps, you could reduce again the threshold.</i></p> <p><i>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.</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>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>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:</i></p> <p><i>Liquid soaps: 8000</i></p> <p><i>Shampoos: 10.000</i></p> <p><i>Shower preparations: 10.000</i></p>	
<p><i>We agree in not further reducing CDV limits</i></p>	
<p><i>2200</i></p> <p><i>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.</i></p>	
<p><i>How many solid soaps are certified according Nordic Swan with this strict threshold (2.200) ? 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>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>Comments partially accepted</p> <p>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.</p>
<p><i>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. At 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.</i></p>	
<p><i>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</i></p>	
<p><i>The current CDV calculation methodology encourages to add substances in order to decrease the CDV. this is not in line with the ecolabel philosophy.</i></p> <p><i>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.</i></p>	<p>Comments rejected</p> <p>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.</p>
<p><i>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".</i></p>	

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).

<p><i>It's really important to change the CDV calculation method by aligning to detergent calculation by removing the AC.</i></p> <p><i>We have COLIPA dosing in all the cosmetics category to have average dosage to put it on a base of the calculation.</i></p> <p><i>If you disagree to use COLIPA dosage, you can use the same method as RTU HSC cleaners and use "for 1L of product"</i></p> <p><i>That will permit to have a real impact on the ingoing substances.</i></p> <p><i>With the actual calculation, if you are above the limit, you only have to put more ingoing substance to automatically decrease the CDV.</i></p>	
<p><i>Usetox seemed not to have the support of the participants, as exemplified by the following comment:</i> <i>"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.</i></p> <ul style="list-style-type: none"> <i>• (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).</i> <i>• Some dangerous properties, at least PBT and vPvB , mutagenic, reprotoxic and endocrine disrupting chemicals seem not adequately captured."</i> 	<p>Comment accepted USEtox is not proposed to be used as an indicator of the aquatic toxicity of the product.</p>
<p><i>One stakeholder asked on the rationale behind not setting CDV limits on leave on products.</i></p>	<p>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.</p>
<p><i>One stakeholder suggested considering toothpaste as leave on products (in line with Nordic Swan and due to the lack of data).</i></p>	<p>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.</p>
<p><i>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)</i></p>	<p>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)</p>

<p><i>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.</i></p> <p><i>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.</i></p>	<p>Comment clarified</p> <p>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</p>
<p><i>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 re-quires 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 in-formation up front. This may be difficult for the CGCs to do because of the complex nature of the CDV calcula-tion. 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.</i></p>	<p>Comment acknowledged</p> <p>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.</p>
<p><i>What is considered as the final product ? Is there a minimum concentration to consider a substance as a "intentionally added substance" or not ?</i></p> <p><i>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)?</i></p> <p><i>If not, it is a problem because any solvent (except water) has an impact on the user and/or the environment.</i></p>	<p>Comment clarified</p> <p>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.</p>
<p><i>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 ?</i></p>	<p>Comment clarified</p> <p>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</p>

<i>Add shower preparations in solid and dry form in the category limit</i>	Comment accepted
<i>We would like to know if a new DID-list is on its way to be published.</i>	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.
<i>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.</i>	
<i>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)."</i>	

Criterion 2. Biodegradability

Comments received in AHWG2/written form	JRC Dir. B response
<p><i>strongly support the continued inclusion of fragrances in ecolabel products.</i></p> <p><i>Many fragrance ingredients are biodegradable and perfumes typically contain relatively high % w/w of biodegradable ingredients (e.g. typically > 75% for detergents based on a recent IFRA survey)</i></p> <p><i>However, the default values for a perfume in the DID list in relation to biodegradation do not reflect this:</i></p> <p><i>aerobic degradation = Inherently biodegradable</i></p> <p><i>anaerobic degradation = Not biodegradable under anaerobic conditions.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Anaerobic biodegradation data for fragrance ingredients is rare but some would be exempt from the requirement based on "readily biodegradable and non bioaccumulating"</i></p>	<p>Comment acknowledged</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"> • Provided that specific data for the ingoing substances are known and valid they can be used; • 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. <p>It is suggested to include this information in the User manual.</p>

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. However, the 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.

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

<p><i>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 anNBo 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 EUCL. 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</i></p>	<p>Comments acknowledged</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 < 500 and log Kow< 4). The values have been amended and harmonized across the entire document.</p>

<p>REGULATION (EC) No 1272/2008.” and several stakeholders supported to continue using the strict value of the EU ecolabel.</p>	
<p>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.</p> <p>1)Until 1 March 2009:The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent. The pass levels shall be < 100 or log Kow is < 3,0.</p> <p>The OECD 305 test on fish. For a (replace BCF < 500 by) BCF < 100 the substance is 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.</p>	
<p>Clarity on the non-bioaccumulating criterion is required for exemption of anaerobic degradation. A log Kow of < 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).</p>	
<p>Clarity on the non-bioaccumulating criterion is required for exemption of anaerobic degradation. Our recommendation is BCF < 500 (or if unavailable, log Kow< 4, which is in line with the EU CLP classification criterion for bioaccumulation potential).</p>	
<p>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.</p>	<p>Comments partially accepted</p> <p>The values have been revised and made stricter as a result of the general request from stakeholders to further reduce the values.</p>
<p>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.</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"> <i>- liquid soaps : the average is 12 mg/g of AC for aNBO and anNBO</i> <i>- shampoos : values of 25 for aNBO and anNBO must be kept.</i> <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 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 liquid soap if we want that the criterion remains selective.</i></p>	
<p><i>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.</i></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 :*

aNBO (mg/g AC): 15

anNBO (mg/g AC): 15

Solid soap:

aNBO (mg/g AC): 5

anNBO (mg/g AC): 5

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 in TR1 , 15 (aNBO) is above the 50-percentile value for products currently certified with EU Ecolabel.

We appreciate the first step to subdivide categories but we think this is not sufficient.

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 :

- liquid soaps : the average is 12 mg/g of AC for aNBO and anNBO,

- shower preparations : the average is 6 mg/g of AC for aNBO and anNBO

- shampoos : values of 25 for aNBO and anNBO must be kept.

It's crucial to reduce values for liquid soap and shower preparations 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. 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. It's crucial to reduce values for liquid soap and shower preparations if we want that the criterion remains selective.

We appreciate the first step to reduce these thresholds (25 in the first draft) but we think this is not sufficient.

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.

It's crucial to reduce the value for shower preparations 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. 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. It's crucial to reduce the value for shower preparations if we want that the criterion remains selective.

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.

As mentioned above, 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).	Comment rejected 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)
How many leave-on products are certified according to Nordic Swan (NS) ? 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.	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) 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). 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.
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 ? It's important to have this information in order to determine if these requirements are attainable.	
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 ? It's important to have this information in order to determine if these requirements are attainable."	
by de use Mistake ?	Comment accepted The text has been corrected.
Documentation of bioaccumulation We appreciate this adding.	Comment acknowledged
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. Why is this sentence different from the sentence from cosmetic products (Annexe I) ?	Comment accepted The text has been revised and harmonised for both annexes.
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	Comment accepted

<p><i>the European Parliament and of the Council shall be in addition anaerobically biodegradable.</i></p> <p><i>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>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 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>Comment acknowledged</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><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>Comments rejected</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>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>Comment acknowledged</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>Comments rejected</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>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><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>Comment accepted 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>Comment rejected QSAR method is included in other EU Ecolabel group (EU Ecolabel for 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 be 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>Comment accepted The text has been revised accordingly</p>
<p><i>Readily degradable and has high desorption ($D > 75\%$); Data on adsorption and desorption can be hard to find or hard to grasp in ECHA's 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>Comment clarified Adsorption/desorption is a standard information requirement for Annex VIII registrations (10 tonnes and above) and is provided under the 'Environmental fate & 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: https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f)</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>Comment partially accepted A question box has been included in relation to this comment to further explore if CBs will consider 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>Comment accepted</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>Comment partially accepted</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"> • Provided that specific data for the ingoing substances are known and valid they can be used; • 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. <p>It is suggested to include this information in the User manual.</p> <p>Testing is not a requirement but if the applicant is not satisfied with the DID data a test will be needed.</p>
<p><i>What is the difference between liquid soaps and shower preparations? There should be more detailed definitions</i></p>	<p>There is not a clear distinction under Cosmetic Regulation for this products:</p> <p><i>"bath and shower preparations (salts, foams, oils, gels)".</i> Thresholds have been unified for these products.</p>

Criterion 3. Excluded or limited substances and mixtures

Comments received in AHWG2/written form	JRC Dir. B response
<p><i>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.</i></p> <p><i>unambiguous conclusion from SCCS Major Please provide some further description as to how 'unambiguous' is defined.</i></p> <p><i>We don't understand the meaning of the word unambiguous.</i></p> <p><i>SCCS opinions should be adopted</i></p>	<p>Comments accepted</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><i>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><i>To consider restriction/ prohibit only when final SCCS opinions are published in Cosmetic Products Regulation.</i></p>	<p>Comment rejected</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><i>In 3a, as mentioned above, Denmark suggest that the limit for verification shall be "no limit".</i></p>	<p>Comment rejected</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><i>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".</i></p>	<p>Comment rejected</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><i>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".</i></p> <p><i>Restrictions on ingoing substances/mixtures classified under the Classification, Labelling 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>Comments accepted</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. The criterion text has been changed for the hazard classes H314 and H317, that now targets substances only.</p>

<p>We appreciate the modified title to include "mixtures".</p> <p>We don't agree with CB Austria to exclude mixtures.</p> <p>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>This sentence must be changed for "NEITHER substances NOR mixtures".</p> <p>We don't agree with CB Austria to exclude mixtures.</p> <p>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>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.</p>	
<p>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 ?</p>	<p>Comment clarified</p> <p>If the details of the mixture are available, the assessment should be carried on on the overall mixture.</p> <p>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>Stakeholders asked on the procedure to follow for derogating substances</p>	<p>Comment clarified</p> <p>The template for derogating substances can be found in the Annex I to the technical report</p>
<p>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.</p>	<p>Comment partially accepted</p> <p>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>At present Denmark can not support any derogation on the following substances:</p> <ul style="list-style-type: none"> • Fragrances • Zink pyrithione 	<p>Comment acknowledged</p>
<p>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</p>	<p>Comment rejected</p> <p>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</p>

<p>ingredients) used as alternatives to ZPT and having equivalent efficacy are also classified for the environment and require a derogation request.</p>	<p>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 Dandrilyl 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>Zinc pyrithione for anti-dandruff shampoos " Zinc pyrithione is replaced mainly by Piroctone Olamine in dandruff shampoos (This information is retrieved from the app Kemiluppen)" " We suggest adding to the technical report that Piroctone Olamine is used widely as a replacement."</p>	<p>Comment accepted This substance was added to the Technical Report</p>
<p>Additionally, we wish to point out that French industrials have expressed the following comments:</p> <p style="padding-left: 40px;">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;</p> <p>Table X. Derogations to restrictions on ingoing substances/mixtures classified under the CLP Regulation and applicable conditions Major 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.</p> <p>Fragrances A derogation for environmental classified fragrances (H412-H413) should be done, otherwise too many fragrances could be involved</p> <p>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.</p> <p>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?</p>	<p>Comments partially accepted 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 granted for H412 surfactants in rinse-off products, provided that the total concentration is below 20%</p>
<p>Dear Sir/Madam,</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.</p> <p>Its harmonized classification is Eye Dam.1 H318 and Aquatic Acute 1 H400 and self-classification Aquatic Chronic 2 H412.</p>	<p>Comment rejected 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>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.</i></p> <p><i>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>Clarified</p> <p>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.</i></p> <p><i>"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>Comment rejected</p> <p>In order to fully align with Nordic Swan, as the majority of the stakeholders requested, we prefer to keep the wording proposed in TR2:</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>

CMR substances are already regulated by the Cosmetic Regulation through Cosmetic Acts called Omnibus Acts which are aligned with the CLP adoption classification.	
"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.	Comment partially accepted 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)
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.	Comments rejected 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>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>https://www.thebluelabel.eu/documents/12151/342794/Criteria+Hygiene+and+Tissue+16.10.2017.pdf/7f4ae0ee-466e-4f6f-a09a-fa0d78a00980</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>	Comment accepted 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>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>	Comment rejected. 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><i>(iii) 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>The JRC justifies this proposal on an alignment with the Blue Angel requirements. However,. this opens a wider acceptance of hazardous substances than necessary.</i></p> <p><i>"Delete: Substances classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum: $100 \cdot c[H410] + 10 \cdot c[H411] + c[H412] \leq 2.5\%$, 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>Comments rejected</p> <p>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. 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>Thi 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. 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. 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>$100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%$ Major "Calculation is too restrictive."</p> <p>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.</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 level must be 25%.</p> <p>2.5% of H412 substances is impossible to reach (even more for 10x H411 + 100x H410)</p> <p>Most of anionic surfactants are classified H412. So the limit of 2.5% isn't reachable.</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>$100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%$</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.</p> <p>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 c 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>Comment partially accepted</p> <p>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>$100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%$ 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>Comment clarified</p> <p>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>Comment acknowledged</p>
<p>Criterion 3b: maybe you should align with detergents PG where it is stated:</p> <p>The substances indicated below shall not be included in the product formulation regardless of concentration:</p> <p>The substances listed below shall not be added in the final product:</p>	<p>Comments accepted</p> <p>The sentence was modified to clarify that the sub-criterion refers to all ingoing substances, irrespective of when and how they are added.</p> <p>The criterion text is kept the same as in the existing criterion in force.</p>

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)	
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	Comment rejected 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.
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 EU Ecolabel would probably need more clarity on the substances covered to be able to ensure that they comply with the EU Ecolabel criteria. The same applies to authorities checking the compliance. For this reason, ideally the EU Ecolabel criteria should already provide sufficient clarity.	Comment acknowledged
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.	Comment partially accepted 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.
we welcome the exclusion of endocrine disruptors	Comment acknowledged
Endocrine disruptors: Cefic supports including "if they are identified as ED according to Article 57(f)", also for legal clarity.	Comment accepted This reference was included in the note [4] to the criterion text.
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.	Comment rejected 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.
"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 identified under EU legislation (REACH, BPR, PPPR, CR) we propose to use list I at the website www.edlists.org . Please also note that we think the criterion for EDs is too weak in this TR2.0 proposal, see earlier comment.	Comment clarified It is proposed to insert in the user manual the following paragraph: <i>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 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</i>

<p>On EDs</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>Comments rejected</p> <p>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.</p> <p>Therefore, a list of identified EDs will not be made available</p>
<p><i>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.</i></p> <p>Major <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>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 endocrine disruptors 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."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>are not appropriate :</i></p> <ul style="list-style-type: none"> <i>- the regulation 528/2012 and 1107/2009 can not be used as a reference as the substances identified may be not appropriate (except for essential oil, which can be used safely).</i> <i>- exclusion have to be considered for the ED ""confirmed"", and well identified, but can not include the substances only presumed nor suspected.</i> <i>- the list should be well defined in the ecolabel</i> 	
<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>Comment rejected</p> <p>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 ingredient we disagree, namely salicylic acid because a recent opinion of the SCCS exists already</i> https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf "</p> <p>3(b) Specified excluded substances</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 (https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en). 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 position paper (https://www.beuc.eu/publications/beuc-x-2019-009_potential_hormone_disruptors_in_cosmetics.pdf).</i></p>	<p>Comments partially accepted</p> <p>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>

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.

These substances are found in many cosmetic products (based on consumer organisations tests) and are already not allowed under the current proposal:

BHT/Butylated Hydroxytoluene (antioxidant)

Cyclopentasiloxane (wide use in many products, for instance cream and hair products).

Cyclomethicone (Possible content of cyclopentasiloxane)

Ethylparaben (preservative, wide use)

Methylparaben (preservative, wide use)

Propylparaben (preservative, wide use)

Butylparaben (preservative, wide use)

Salicylic acid (mainly shampoo & anti blemish products)

The below substances are found in many cosmetics but are not currently excluded:

Ethylhexyl Methoxycinnamate (UV filter, decorative cosmetics, lipcare, sunlotions, perfume etc)

Resorcinol (haircolor)

Benzophenone-1 (UV filter, mainly nailpolish)

Benzophenone-3 (UV-filter, Lipcare, suncare etc)

Benzophenone-4 (UV-filter, wide use, for example shampoo and hand soap)

Butylphenyl methylpropional (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-voensket-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]*

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 poslish*

[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 applications 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. "

(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

until the publication of an evaluation of the SCCS. After a substance 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](http://www.edlists.org):

<p>https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption?page=1</p>	
<p>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.</p>	
<p>We could support the exclusion of suspected EDs but we would welcome more info from the JRC</p>	
<p>Suspected EDs have to be banned. We will vote negative if not banned</p>	
<p>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</p>	
<p>We cannot support the criteria if Suspected EDs are not banned.</p>	
<p>Suspected EDs have to be banned</p>	
<p>We are in favour of excluding suspected EDs</p>	
<p>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>	
<p>agrees that only substances and mixtures identified to have endocrine disrupting properties are included in sub-criterion 3(b) (based on the SVHC list)</p>	
<p>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.</p>	
<p>[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</p>	
<p>Please consider amending the footnote accordingly. Despite we understand the preference to include also suspected EDs in the EUEL criteria, we would like to reiterate our concerns on this approach: There is no current list of suspected EDs</p>	<p>Comments partially rejected</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>

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.	
Since these substances will be listed, what happens when these substances are delisted and recognised as 'safe' e.g. by SCCS review?	Comment clarified An amendment would be needed in those cases
This implementation allows EU Ecolabel to be in-line with other Ecolabel schemes, as Nordic Swan and Bra Miljöval	Comments acknowledged
Minor Might be relevant to add here that the Organic Regulation also has in place an exclusion of nanomaterials. 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.	
<p>" 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.</p> <p>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).</p> <p>The EU Ecolabel could take inspiration from the wording of the Nordic Swan Ecolabel:</p> <p>O5 Prohibited substances</p> <p>[...]</p> <p>Nanomaterials/particles as defined in the Cosmetics Regulation**** An exception is made to this requirement for</p> <p>a) Synthetic amorphous silica, which is used as an abrasive in toothpaste.</p> <p>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</p>	Comments partially accepted The criterion text was further defined clarifying that, for the assessment of the safety of the nanomaterial, accepted opinions will be those coming from SCCS for human health and from RAC or SCHEER for environmental impacts.

<p>c) TBPT as UV-filter as approved in SCCS opinion SCCS/1429/11. D.v.s. inte i sprayprodukter. [not spray products]</p> <p>d) MBBT som UV-filter i godkänt i SCCS opinion SCCS/1546/15. D.v.s. inte i sprayprodukter.[not spray products]</p> <p>The update below on political process, makes it even more relevant the exclusion of nanomaterials using a precautionary approach:</p> <p>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.</p>	
<p>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>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)</p>	
<p>EU regulatory authority</p> <p>Please name more specific the EU regulatory authority that is meant?</p>	
<p>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>The competent body is SCCS and ist decision is adopted by DG Grow</p>	
<p>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>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. Our suggestion is SCCS for human health and RAC and SCHEER for environmental aspects.</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 explicated 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 excluder 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>Comment rejected 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>Comments partially accepted 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>"We should use ECHA definition and biodegradability criteria when fixed.</p> <p>We must also remember that not all polymers are microplastics."</p>	
<p>Microplastics [3];</p> <p>The current definition of microplastics written by ECHA might not be its final version. What will happen to this requirement if the definition changes?</p>	<p>Comment clarified</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>Cocamide DEA is classified as H411, and hence excluded by Criterion 3 a (i).</p> <p>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.</p>	<p>Comment rejected</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>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.</p> <p>"BEUC welcomes the exclusions of isothianolinones and call on the Commission to maintain this restriction.</p> <p>" Keep the exclusion</p> <p>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.</p> <p>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 https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.results&annex_v2=V&search</p> <p>The use of isothiazolinones is being reduced, and test have shown, that it is not a problem to make products without them.</p> <p>A test of shampoos from the Danish market in 2019 showed that only 10 out of 87 contained isothiazolinones: https://kemi.taenk.dk/bliv-groennere/test-25-shampoos-without-unwanted-chemicals</p> <p>Similarly, only 4 out of 79 liquid hand soaps contained Methylisothiazolinone https://kemi.taenk.dk/bliv-groennere/test-chemicals-liquid-hand-soap</p> <p>Isothiazolines exclusion doable? Major yes</p> <p>Isothiazolines exclusion doable? Yes</p> <p>Isothiazolines.</p> <p>Please don't not forget the preservative DTBMA in this case. It should be regarded as an isothiazoline.</p>	<p>Comments accepted</p> <p>The exclusion of isothianolinones is kept.</p>

<p><i>BEUC finds it positive to add extra protection for the consumers in special products groups 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><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). https://www.cosmetics europe.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf 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>Comments partially accepted</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>"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. https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/lippenbalsem 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 https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/merendeel-lippenbalsems-mogelijk-schadelijk "</i></p> <p><i>Tests show that problematic mineral oils can be found in lip care products: A Danish declaration test showed that 35 out of 50 contained ingredients based on mineral oils or similar synthetic substances. https://kemi.taenk.dk/bliv-groennere/test-lipsticks-may-contain-perfume-mineral-oils-and-suspected-endocrine-disrupting</i></p> <p><i>BfR emphasises, that the recommendations are not always complied with</i></p>	

<p>« 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. « 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</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>https://www.beuc.eu/publications/beuc-x-2017-128_problematic_mineral_oils_in_lip_care_products.pdf</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>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 childs/baby.</p> <p>Thre 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>Comments accepted</p> <p>In line with the SCCS opinion of 2016, the ban on phenoxyethanol in requirement 3(b) was removed.</p>
<p>We agree with the exclusion of phenoxyethanol in leave on products for children).</p>	<p>Comment rejected</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>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>Comment accepted</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>formaldehyde releasers,</p>	<p>Comment rejected</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>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 (regardless the limit) according to sub-criterion 3(a) (ii)</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>Comment rejected</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 keep the ban on the substance. Relevant data from the industry will be welcomed and analysed.</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 important, to ensure there is more transparency on why these ingredients are included and provide industry stakeholders a chance to comment and provide addition 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.</p>	
<p>Sodium fluoride</p> <p>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.</p> <p>"We recommend derogating sodium fluoride in toothpaste.</p>	<p>Comment partially accepted</p> <p>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>possibility to derogate "sodium fluoride" for use in toothpaste products.</p> <p>"We support the derogation of Sodium Fluoride and Sodium Monofluorophosphate as active ingredients in toothpaste and mouthrinse products, as these active substances contribute to carries prevention. These are multiple studies to proof safety use of these products containing fluoride. "</p>	
<p>Due to the classification as H301, and the likely ingestion of part of toothpaste, the derogation of sodium fluoride is not considered.</p> <p>A toothpaste with sodium flouride protects the teeth. There is more harm caused by a toothpaste lacking fluoride, than what is caused in terms of possible irritation or intoxication.</p>	
<p>"SCCS has published a new opinion on the use of Aluminium in cosmetics: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf</p> <p>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."</p>	<p>Comments accepted</p> <p>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>"Exclusion of aluminium and all its salts has no scientific basis. Please refer to the latest SCCS opinion: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf</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 review 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 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></p>	
<p><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></p>	
<p><i>Substances that are not aerobically readily biodegradable cannot be used in EU Ecolabel products according to current criteria 2.</i></p> <p><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></p>	<p>Comment clarified Phosphonates which are aerobically not readily biodegradable have already been included in the exclusion list in TR2.0</p>
<p><i>Table 14: CLP classification for the alternatives for SLS</i></p> <p><i>Excepted for Sodium N-lauroylsarcosinate, all the proposed alternative are either H411 either H317 that is worst than SLS classification</i></p>	<p>Comment rejected 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.</p>
<p><i>We are against the exclusion of all phthalates. DEP is not classified and it should be exempted from the requirement.</i></p> <p><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></p> <p><i>Additionally we would like to understand the complete ban of all phthalates (incl. Diethylphthalate)"</i></p>	<p>3(b) - phthalates Accepted Only phthalates classified with one or more H phrases listed in Table 3a are banned</p>
<p><i>H alogenated and/or aromatic solvents: only if classified with one or more "forbidden" H phrases.</i></p>	<p>Comment rejected 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.</p>
<p><i>P lease give a definition on "perfluorinated and polyfluorinated compounds" (preferably REACH-based)</i></p>	<p>Comment partially accepted 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</p>

<p><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></p>	<p>Comment clarified 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</p>
<p><i>N anosilver is a biocide, as far as I am aware, would it not be excluded from the beginning?</i></p>	<p>Comment clarified Nanosilver is an antimicrobial agent that can be seen as a biocidal under certain condition. To be on the safe side, nanosilver is mentioned</p>
<p><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 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>Comment rejected While it would make sense to add SVHCs to the 3(b) list, in the interest of 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.</i> <i>SVHCs are fully restricted in the Ecolabel Nordic Swan showing that the restriction is doable.</i></p> <p><i>Based on the EU Ecolabel Regulation SVHC shall not be present in any Ecolabelled products!</i></p>	<p>Comments acknowledged</p>
<p><i>Do stakeholders agree with the increase of ambition level with regards SVHCs?</i> Major YES!</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.</i> <i>Denmark can support the proposal.</i></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>Comment clarified 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>

"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.

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:

(a) they comply with the food safety requirements as defined in Regulation (EC) No 178/2002

(b) there are no suitable alternative substances available, as documented in an analysis of alternatives;

(c) the application is made for a particular use of the product category with a known exposure; and

(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."

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.

On the other hand, according to Article 17 "Traces of prohibited substances" of the CPR:

"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

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.

<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>Accepted 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: "Regarding the fragrances, we ask for exclusion from 0,01% (rinse-off products) and 0,001% (leave on products) - all H317 and H334 substances and especially - 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)" "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>Comments partially accepted 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>	
<p><i>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.</i></p> <p><i>"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)</i></p> <p><i>The Nordic Swan restrict the 26 substances that are currently subject to declaration plus additional fragrances.</i></p>	
<p><i>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</i></p>	

100 ppm (for leave-on and rinse-off respectively) should be restricted in the same manner.	
3(d) Fragrances	
<i>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). "</i>	
<i>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.</i>	
<i>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</i>	
<i>We would like to exclude the SCCS 2012 opinion substances totally (regardless of their concentration in the products)</i>	
<i>Fragrances included in the SCCS 2012 opinion should be restricted in EU Ecolabel</i>	
<i>We are in favour of excluding the SCCS 2012 opinion substances</i>	
<i>We would like to exclude the SCCS 2012 opinion fragrances</i>	
<p>3d fragrance</p> <p><i>The official Danish position is to exclude fragrances in ecolabelled products, as environmental carrying people expects ecolabelled products not to contain fragrances.</i></p> <p><i>As a start, Denmark proposes that:</i></p> <ul style="list-style-type: none"> <i>• 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 toxicity for definition) and a maximum of 0.010 % (100 ppm) in rinse-off products</i> <i>• Products which contains fragrances shall be clearly marked on front with "Contains fragrance/perfume"</i> <i>• HICC, chloroatranol and atranol are not permitted in the product.</i> <i>• 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.</i> <p><i>"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.</i></p> <p><i>" We ask to add</i></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><i>Fragrance</i></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>Comment clarified</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 (to have 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 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>Comments partially accepted</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>3(d) Fragrances</p> <p>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>Comment partially accepted</p> <p>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</p>	<p>Comment rejected</p> <p>The list of sentences that can be put on a product is detailed in criterion 8</p>

<i>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".</i>	
<i>Criterion 3e, Denmark can support the proposal</i>	Comment acknowledged
<i>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).</i>	Comments rejected Substances H317 are already restricted according to criterion 3(a).
<i>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"</i>	
<i>Preservatives used in toothpaste This must concern all products in contact with the mouth.</i>	Comment accepted Mouthwash and lip care products were also added to this requirement. Additionally, nail lacquers were also included in the requirement.
<i>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.</i>	
<i>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.</i>	Comments accepted No change was made to the report
<i>Do we need to exempt some preservatives for use in animal care products, due to the likely higher biocidal functions required? (Annex II)</i>	
<i>Minor No. Biocidal products should not be covered by the ecolabel."</i>	
<i>it is proposed to keep the strictest cut-off values Major We agree with this proposal in order to maintain the selectivity of EU Ecolabel products.</i>	Comment acknowledged
<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>	Comments rejected 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

<p>(ii) <i>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 toothpastes 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 partly swallowed.</i></p> <p><i>Delete this requirement</i></p>	<p>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"> <i>Bismuth Oxichloride cannot be added to decorative cosmetics.</i> <i>Cd, Lead, Mercury shall have a limit at 1 ppm and not 10 ppm.</i> 	<p>Comments partially accepted</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></p> <p><i>This must concern all products in contact with the mouth.</i></p>	
<p>(iii) <i>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 decorative products are included in the scope of the ecolabel, the products certified as organic should be encouraged. these products might contain 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 consistent with ecolabel philosophy.</i></p> <p><i>As already commented, we do not agree with the level of lead defined : it would exclude 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>Comments rejected</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><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</i></p>	<p>Comment rejected</p> <p>See the scope section in TR3</p>

<p><i>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><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></p> <p><i>" Change "the use of barium,... " into " the presence of barium,..</i></p>	<p>Comment accepted</p> <p>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>Comment rejected</p> <p>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><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>Comment rejected</p> <p>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 EU Ecolabel requirement on UV filters</p>
<p><i>"Criterion 3 (g) UV filters</i></p> <p><i>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>"</i></p> <p><i>Criterion 3 (g) UV filters</i></p> <p><i>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>Comment partially accepted</p> <p>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><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.</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>	

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 EUCL criteria is still given. Please consider.	
<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:</p> <p>All organic UV filters contained in the product:</p> <ul style="list-style-type: none"> - must not be bioaccumulating ($BCF < 100$ / $\log K_{ow} < 3$) or must have a lowest measured toxicity of $NOEC/ECx > 0.1$ mg/l or $EC/LC50 > 10.0$ mg/l 	<p>Comment partially accepted</p> <p>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>
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>Comment acknowledged</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 suncare 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>Comments partially accepted</p> <p>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>

<i>TiO2: as it is only carcinogenic by (dust) inhalation, liquid or gel products should not be affected (or they can get a derogation).</i>	
<i>Regarding the TiO2, we recommend anticipating its classification with H351 and already prohibit it in the standard.</i>	Comments rejected Please see the rationale behind the derogation in the TR3
<i>We believe a derogation for TiO2 is not needed because we are against the inclusion of sunscreens</i>	
<i>-if including nano TiO2 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.</i>	Comment accepted Please check TR3
<i>A written confirmation Who shall write this confirmation ? Manufacturers of raw materials or applicants ? Both ?</i>	Comments clarified Declarations and confirmations shall be filled/written by the manufacturers of the raw materials. This will be further clarified in the user manual.
<i>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.</i>	
<i>In addition, a declaration that, if used, nano TiO2 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.</i>	
<i>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)."</i>	Comment rejected The proposed definition of 'ingoin substances' includes 'substances known to be released or degraded from ingoin substances [...]'. Therefore, the whole set of criteria also applies to degradation products from preservatives, that shall therefore comply with criterion 3 (a).
<i>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</i>	Comment rejected 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><i>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.</i></p> <p><i>"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.</i></p> <p><i>(ii) A written confirmation that 3(a), 3(b) and 3(c) is fulfilled."</i></p>	
<p><i>Editorial: It should read Isothiazolinones</i></p>	<p>Comments accepted Please see specific changes in the criterion text</p>
<p><i>The word "isothiazolinone" is misspelled on page 13 of the Annex I</i></p>	
<p><i>DEA Minor Editorial: Please provide full text of the acronym.</i></p> <p><i>Butylated Hydroxi Toluene Minor</i> <i>Editorial: It should read Hydroxytoluene</i></p> <p><i>six inhalant chromium Minor</i> <i>Editorial: Please clarify if you refer to hexavalent chromium (Chromium VI).</i></p> <p><i>Regulation 1223/2008 Major Editorial: It should read 1223/2009.</i> <i>Regulation 1223/2008 refers to establishing the standard import values for determining the entry price of certain fruit and vegetables.</i></p> <p><i>3(b) Specified excluded substances</i></p> <p><i>The reference should be to "Regulation (EC) No 1223/2009" not "Regulation 1223/2008"</i></p>	
<p><i>Annex I: Second proposal for criterion 3: Hazardous substance restrictions</i></p> <p><i>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.</i> <i>We suggest the following:</i></p> <p><i>3 (b)</i> <i>"The product shall not contain any substances that meet the criteria for classification with the hazard statements listed in Table 6, regardless of concentration"</i></p> <p><i>3 (b)</i> <i>"The product shall not contain any of the substances below, regardless of concentration"</i></p> <p><i>3 (c)</i> <i>"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</i></p>	<p>Comments partially accepted Please see TR3 for the modifications implemented</p>

<p><i>the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation"</i></p> <p><i>"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""</i></p> <p><i>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"".</i></p> <p><i>Delete: 3(b) ""Specified excluded substances The substances listed below shall not be added in the final product: ""</i> <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>Comment clarified 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>Comment clarified family products are considered designed and marketed also for children older than 3 years.</p>

Criterion 4. Packaging

Comments received in AHWG2/written form	JRC Dir. B response
<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>	Acknowledged
<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><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>Comment partially accepted</p> <p>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>[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>Comment partially accepted</p> <p>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><i>What about multipacks of products? Do they get an exemption as something has to hold them together?</i></p> <p><i>Add an exemption for multi-packs.</i></p> <p><i>Multipacks of products (such as two toothpastes sold together) need to have something to hold them together, so must have additional packaging.</i></p>	<p>Comment partially accepted</p> <p>An exemption has been included for toothpastes in order to allow the use of secondary packaging for multipacks of toothpastes.</p>
<p><i>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.</i></p>	
<p><i>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.</i></p>	<p>Comment rejected</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><i>Small packaging are also stored in secondary packagings (it is not a case of product with its refill).</i></p> <p><i>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).</i></p> <p><i>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 !</i></p> <p><i>Please feel free to contact me if you need more details !</i></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><i>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" ?</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>Comment rejected 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><i>The value of PIR shall be more restrictive and reduced.</i></p> <p><i>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.</i></p> <p><i>Indeed, there are solutions for current products which have PIR > 0,18 : providing refills, using a % of recycled materials, raising volume capacity...etc.</i></p> <p><i>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 !</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>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.</i></p> <p><i>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."</i></p> <p><i>Packaging impact ratio (PIR)</i></p> <p><i>We recommend lowering even more the PIR, as the average PIR among French license holders is 15g, with 74% of PIR being below 20g.</i></p>	<p>Comment partially accepted PIR values have been revised accordingly. Stricter value has been proposed.</p>

<i>Criterion 4b (Packaging impact ratio) should be looked at again. The limit in the proposal is in in our opinion too high and should be lowered. Also is should be considered to differentiate the requirement in regards to the new scope of the product group – especially decorative cosmetic are normally sold is smaller packaging. The Nordic Swan have a requirement with differentiated limits depending on product type.</i>	
<i>ith regards the exemption of PIR requirement for products with 80% of recycled material, a stakeholder asked there is data to support such exemption.</i>	According 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.
<i>Oral care products often cannot use recycled materials for packaging due to food grade requirements. Can they be exempted?</i>	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>
<i>Small packagings are not an ecological option, so they should not be certified.</i>	Comment partially accepted 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.
<i>[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...).</i>	
<i>[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</i>	Comment acknowledged
<i>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)" ? 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."</i>	Comment rejected Considering the approaches are a bit different for detergents and cosmetics the existing name is kept.
<i>[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.</i>	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><i>Considering the table 19, the new threshold seems to be insufficiently strict.</i></p> <p><i>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).</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.</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>In relation to the residual amount, several stakeholders considered that decreasing R from 10 to 8% is not enough.</i></p> <p><i>We reckon that 8% is too much and we think that the license holders would agree. The requirement should go down to 5-6%.</i></p> <p><i>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.</i></p> <p><i>Do not increase this threshold or even consider lowering it.</i></p>	<p>Comments partially accepted</p> <p>Residual amount has been decreased to 6%. According to existing data, more than 80% of existing licences will be able to reach this value.</p> <p>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>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><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>Comments partially accepted</p> <p>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>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."</p>	<p>Comment acknowledged</p>
<p>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.</p>	<p>Comment accepted 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>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 informes 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.</p>	<p>Comment partially accepted 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>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.</p>	
<p>[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 residu product can be extracted with adding water ?</p>	<p>Rinse off products that can be opened and the residue product can be extracted with adding water are proposed to be exempted form R requirement.</p>
<p><i>Design for recycling of plastic packaging</i></p> <p>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:</p> <p>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.</p>	<p>Comment acknowledged</p>
<p><i>Barrier coatings:</i> 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.</p>	<p>Comment rejected 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 restiction is proposed to be kept under the EU Ecolabel</p>

<p>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.</p>	<p>Comment partially accepted Against this it is proposed to allow a maximum content of EVOH of 5%.</p>
<p>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 recyclate. On their website they have recycling guidelines for packaging e.g. HDPE bottles. https://recyclclass.eu/wp-content/uploads/2020/04/PE-HD-natural-containers-guidelines-27-04-2020-3.pdf</p> <p>Other guidelines can be found here https://recyclclass.eu/recyclclass/design-for-recycling-guidelines/</p>	<p>Comment partially accepted 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>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.</p>	<p>Comment rejected No modifications have been included with regards this comment. The label/sleeve is printed and the inks will affect recyclate quality. In the case of washable inks, at least the washing water will be contaminated.</p>
<p>We would like clarity on why metal caps aren't allowed.</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>EU recycling bodies such as Recyclclass will allow up to 5% EVOH so we would like to understand why this has been excluded.</p>	<p>Comment partially accepted Against this it is proposed to allow a maximum content of EVOH of 5%.</p>
<p>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.</p> <p>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 (<50%).</p>	<p>Comment accepted 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><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>Comment accepted</p> <p>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 < 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>Comments accepted</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. 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 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, personel 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 plateforms, 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 < 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>Comment partially accepted</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. This requirement will not apply to leave on products and toothpastes usually marketed in small volumes.</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><i>[on consumed in the accommodation.]</i> <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 origin in the packaging] This declaration of compliance shall be provided by packagings manufacturers.</i></p>	<p>Comment accepted</p>
<p><i>[on ensuring that the opening at the top is not too wide]</i> <i>For assessment purpose, How do you define "not too wide" ?</i></p>	<p>Comment accepted</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>Comment accepted</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.</i></p> <p><i>PVC is a type of plastic that requires the many additives, some of which may be hazardous.</i></p> <p><i>Other halogenated plastics can be suspected of having similar problematic properties.</i></p>	<p>Comment acknowledged</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."</i></p> <p><i>"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>Comment accepted A new requirement on SHVCs on packaging has been proposed.</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 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><i>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.</i></p> <p><i>In order to control the dosage of certified products and avoid any overdosage, we should require :</i></p> <p><i>applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,</i></p> <p><i>applicants shall provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery,</i></p> <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>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 :</i> <i>it's not a scientific and reliable method and</i> <i>it's binding because applicants shall provide a new test when they change their packaging.</i></p>	<p>Comment partially accepted A requirement on provision of information of the correct dosage has been included in primary packaging design criterion.</p>
<p><i>The user manual shall be available at the same time as the decision !</i></p>	<p>Comment acknowledged</p>
<p><i>We need to have clarifications and examples in the user manual, in particular for pouches, which are also concerned by this requirement a priori.</i></p> <p><i>You should add clarifications and examples in the user manual, in particular for pouches.</i></p>	<p>Comment acknowledged</p>

Criterion 5. Renewable ingredients

Comments received in AHWG1/written form	JRC Dir. B response
<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>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.</p> <p>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.</p> <p>Since the low benefit in comparison with the high complexity, we request again the removal of this requirement.</p> <p>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.</p> <p>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.</p> <p>We request again the removal of this requirement.</p> <p>To replace it, we can limit the use of these derivatives and fix different threshold according to products types.</p>	<p>Comments rejected</p> <p>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 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.</p>

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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.

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

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

<p><i>Sustainable sourcing of palm oil, palm kernel oil and their derivatives</i></p> <p><i>Based on the feedback of French stakeholders, we have the following comments:</i></p> <p><i>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).</i></p> <p><i>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.</i></p> <p><i>The "mass balance" certification scheme is questionable and has been subject to controversy.</i></p> <p><i>The improved environmental performance of certified palm oil, palm kernel oil and their derivatives has not been scientifically proven.</i></p> <p><i>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:</i></p> <p><i>Shampoo: 3.64%</i></p> <p><i>Shower preparations: 5.73%</i></p> <p><i>Liquid soaps: 2.68%</i></p>	
<p><i>[on 5a]</i></p> <p><i>This criteria is vey diffult 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 timeconsoming 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 accpet 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>Comment rejected</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>

We support the introduction of this criterion in general.

This point, as written, would infer 20% of the product.

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:

7.1.2 Total product

- At least 20% of the total product must be organic.*
- 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.*

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.

Hence, it would either be difficult to reach this threshold or would limit the number of product categories that could be achievable.

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 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

Comments partially accepted

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>We think that percentage should be different according to product category.</p> <p>Furthermore we suggest not to use specific Regulation.</p> <p>ISO 16128-1 definition could be used:</p> <p>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.</p>	
<p>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.</p>	
<p>Can you confirm this threshold (20%) only concerns natural ingredients (extracts etc.) and not all ingredients from natural origin (as surfactants for example)?</p> <p>Please, can you add this clarification in the next draft or at least in the user manual ?</p>	
<p>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.</p> <p>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)".</p>	
<p>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 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 these ingredients.</p>	<p>Comments rejected</p> <p>Requirements on a minimum content of bio-based ingredients cannot be set on cosmetic products, because the EU Ecolabel is technology neutral: it</p>

<p><i>We think that a good idea could be the introduction of biobased surfactants according to EN 17035:2018 definition</i></p>	<p>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><i>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.</i></p>	
<p><i>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)".</i></p>	
<p><i>Can we state / clarify that criteria 5b is not applicable if raw material already comply with the criteria 5a ?</i></p>	<p>Comment clarified 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><i>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 government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.</i></p>	<p>Comments accepted 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><i>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.</i></p>	
<p><i>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.</i></p>	
<p><i>Book and Claim should not be accepted.</i></p>	
<p><i>Only IP, SG, and MB qualities are accepted by most private standards on the market with MB being the minimum quality.</i></p>	
<p><i>Remove Book and claim and independent small holder credits</i></p>	
<p><i>For your information, the most of French license holders who used B&C could also buy certified ingredients, so this deletion would not significantly impact the number of certified products (by French CB at least).</i></p>	

<p><i>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 marked. 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</i></p>	
<p><i>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 able to provide sufficient ingredients, and the cost would increase by 20% at least".</i></p>	
<p><i>In addition, stricter requirements should apply to unmodified palm and palm kernel oil, which should come from organic production.</i></p>	<p>Comment partially accepted 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><i>Stakeholders asked for improved clarity as to what concern the annual audits to be 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><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>Comments partially accepted 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>The verification shall be done via RSPO website (https://www.rspo.org/certification/search-for-supply-chain-certificate-holders), 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 comapny 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 though RSPO website https://www.rspo.org/certification/search-for-supply-chain-certificate-holders.</p> <p>To clarify that the verification is through the live platfrom of RSPO website, and not just checking the Certificate document that the company could provide.</p>	
<p>What is the exact requirement?</p> <p>- If the applicant shall claim that the product that it produces is RSPO certified, then it needs to hold itself an Supply Chain Certification.</p> <p>- 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.</p> <p>To clarify what the exact requirement is</p>	
<p>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.</p>	
<p>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.</p>	
<p>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.</p> <p>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).</p> <p>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.</p>	
<p>it is possible to make annual audits in order to verify the validity of RSPO certificates? NO</p>	
<p>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.</p> <p>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).</p> <p>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.</p>	

<p><i>[it is possible to make annual audits in order to verify the validity of RSPO certificates?]</i></p> <p><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&C (Please check the graph in https://www.rspo.org/rspo-credits/i-am-a-buyer/step-by-step). 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&C model of RSPO.</i></p>	<p>Comment accepted 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>Comment clarified It is stated in the criterion text that “any equivalent or stricter sustainable production scheme demonstrating compliance” to RSPO shall be accepted</p>

Please note that the text:

"(b) Certification of plant based ingredients

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."

...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.

Comment accepted

This has been introduced in the proposed assessment and verification text

<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 thus recommend including a sub-criterion on the origin of the bauxite used in aluminium salts.</i>	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>Finantial institutios are key to be engaged in the production of sustainable PO too.</i>	Comments accepted
<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>	Comments rejected 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, humand rights, workers rights and decent living wage, etc? These is a key pillar of sustainability too.</i>	Comments rejected 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 enviromental issues.</i>	Comment accepted The text has been rewritten
<i>Not accurate.</i>	
<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 wel establish/recently started based.</i>	Comment rejected The text refers not only to RSPO, but to other palm oil certification schemes as well.
<i>Not accurate.</i>	
<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>	Comment accepted The paragraph has been deleted
<i>Not a requirement but an aspect of sustainability, right?</i>	
<i>Amend the word.</i>	

<p><i>This sentence is misleading if all the EU ecolabel product manufacturing sites are NOT RSPO SC certified.</i></p> <p><i>Only an RSPO SC certified manufacturing site can claim that its manufactured product is RSPO certified.</i></p> <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>Comment accepted The sentence has been rewritten</p>
<p><i>Important to include Shea butter too, as per its cultivation expansion in fragiles areas of Africa.</i></p>	<p>Comment accepted 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>Comment rejected 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>Comment accepted The sentence was amended</p>
<p><i>Incorrect statement.</i></p> <p><i>As per the explanation below regarding P&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>Comment rejected The sentence indicated by the stakeholder refers to before the P&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>Comment accepted 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&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>Comment accepted</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><i>Amend the sentence to indicate the correct statement.</i></p>	<p>Comment accepted</p>

Criterion 6. Specific requirements on wet wipes

Comments received in AHWG1/written form	JRC Dir. B response
<p>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.</p> <p>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.</p> <p>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.</p>	<p>Comments rejected</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>Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products.</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>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. 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.</p>	<p>Comment rejected</p> <p>The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explores in next revision.</p>
<p>Some stakeholders agreed on the inclusion of wet wipes under the scope and suggested improvements to the proposed criterion:</p> <ul style="list-style-type: none"> It was suggested to ban fragrances. 	
<p>Strong requirements of biodegradability and no environment toxicity should be defined for the formula and the fibers used.</p> <ul style="list-style-type: none"> There are other available standards and these should be explored and included. 	
<ul style="list-style-type: none"> The substrate must be biodegradable. 	<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>As already commented, we are not in favour of the inclusion of wet wipes in the scope of the ecolabel.</p> <p>If they are included, the proposed criteria seems not adapted :</p> <p>EU Ecolabel for "Graphic paper, tissue paper and tissue products" in accordance with Commission Decision (EU) 2019/70,</p> <p>Ecolabel for "Absorbent Hygiene Products" in accordance with Commission Decision (EU) 2014/763</p> <p>specific criteria should be defined, specified for these products.</p>	<p>Comment partially accepted</p> <p>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 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>Comment rejected The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explored in next revision.</p>
<ul style="list-style-type: none"> <i>As a minimum, the wipes must be 100% bio-based excluding petrochemicals materials.</i> <i>Avoid certifying fibres made by viscose. Certify only fibres made with cellulose.</i> 	<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>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.</p>
<p><i>Investigate if it is technically possible to use paper as a substrate.</i></p>	
<p><i>biodegradable and natural fiber should be encouraged. Viscose and plastics should be banned.</i></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>Comment acknowledged</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>Comment acknowledged</p>
<p><i>There need to be requirements at the wipe level. What the manufacturers do to the fibers must 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>Comment acknowledged</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>Comment partially accepted Wet wipes are proposed to be removed from the scope</p>
<ul style="list-style-type: none"> <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>Comment acknowledged The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explored in next revision.</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><i>Increase the percentage of SFM in forestry requirements to the usual 70%.</i></p> <p><i>If the SFM part in the forestry requirements 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><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><i>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.</i></p>	
<p><i>Criterion 3.6 (b) User information</i></p> <p><i>The packaging shall include information on the correct disposal of the wipes.</i></p> <p><i>This criterion should be further clarified, with regards to the meaning of "correct disposal"</i></p> <p><i>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 <0.1 ppm for each sensitizing substance</i></p> <ul style="list-style-type: none"> <i>The user manual must include details of calculation method.</i> 	<p>Comment acknowledged</p> <p>The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explored in next revision.</p>
<p><i>Other stakeholders were against the inclusion of wet wipes under the scope and suggested to remove this criterion:</i></p> <ul style="list-style-type: none"> <i>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.</i> <i>We're not a fan from including wet wipes in the scope.</i> <i>When you give the ecolabel you sort of give a green light to these single use product</i> <i>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.</i> <i>The best is that they are not included. But if they are, clear difference has to be made with conventional products.</i> 	
<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><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><i>Exclude wet wipes from the scope, so this criterion must be deleted.</i></p>	<p>Comment accepted</p> <p>Wet wipes are proposed to be removed from the scope</p>

Criterion 7. Fitness for use

Comments received in AHWG2/written form	JRC Dir. B response
<p><i>One stakeholder suggested to remove from the criterion text the specific questions related to the consumer tests, in order to preserve flexibility.</i></p>	<p>Comments rejected</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>
<p><i>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.</i></p>	
<p><i>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:</i> <i>"In order to control the dosage of certified products and avoid any overdosage, we should require :</i> <i>applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,</i> <i>applicants shall provide a convenient dosage system (as for detergents) if appropriate or a effective system of delivery,</i> <i>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.</i> <i>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:</i> <i>it's not a scientific and reliable method and</i> <i>it's binding because applicants shall provide a new test when they change their packaging."</i></p>	<p>Comments accepted</p> <p>Criterion 5 (c) has been modified and now includes the following requirement:</p> <p>"Applicants shall indicate on the label of the primary packaging:</p> <ul style="list-style-type: none"> • 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" <p>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].</p> <p>The question on the ease of application for leave-on products has been deleted, as it is more relevant for criterion 5.</p>
<p><i>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 :</i> <i>it's not a scientific and reliable method and</i> <i>it's binding because applicants shall provide a new test when they change their packaging.</i></p> <p><i>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.</i></p>	
<p><i>In order to control the dosage of certified products and avoid any overdosage, we should require :</i></p>	

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.

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 :

<p><i>it's not a scientific and reliable method and</i></p> <p><i>it's binding because applicants shall provide a new test when they change their packaging.</i></p> <p><i>In order to control the dosage of certified products and avoid any overdosage, we should require :</i></p> <p><i>applicants shall define the correct dosage or the appropriate quantity, then they shall test the product with this dosage/quantity,</i></p> <p><i>applicants shall provide a convenient dosage system (as for detergents) if appropriate or if not, a effective system of delivery,</i></p> <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>Comment partially accepted</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.</p> <p>However, in order to reduce the burden on applicants, only one type of test is required.</p> <p>A non-exhaustive list of available laboratory tests will be made available in the User Manual.</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>	

Can the list of tests for the laboratory assessment be made available in an annex for the different categories ? for clarity, simplification and alignment	
Moreover, stakeholders expressed their interest in favouring laboratory tests over consumer tests.	
<p>We recommend adding:</p> <p>"instrumental tests when available shall take precedence over consumer tests".</p> <p>A compilation of a list of methods that could be used for each cosmetic product could also be helpful.</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>Comment accepted</p> <p>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>Comments rejected</p> <p>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>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>Comments rejected</p> <p>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.</p> <p>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>

<i>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.</i>	
<i>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 if view".</i>	Comment accepted
<i>The performance test protocols must be available as soon as possible and in the latest when the Decision will be publisher, in order to not loose time for the renewal process.</i> <i>The actual request are more or less relevant for rinse off cosmetics product but not for leave on products. It's important to have well defined protocols very soon</i>	Comment acknowledged
<i>How statistically significant is this proportion? Unclear</i>	Comment clarified The 80% satisfaction limit for the user tests comes from CosmeticsEurope's 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products' and is in line with Nordic Swan and Blue Angel
<i>The user manual shall be available at the same time as the decision.</i>	Comment acknowledged
<i>We are not in favour of this practise.</i>	Comment clarified This kind of certification is not requested in EU Ecolabel

Criterion 8. Information appearing on the EU Ecolabel

Comments received in AHWG1/written form	JRC Dir. B response
<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 restriction of hazardous substances is used in other product groups.</p>	<p>Comments partially accepted Text has been revised according to the suggestions received.</p>
<p>A stakeholder suggested "Promoting care for the environmental"</p>	
<p>Other stakeholder commented: "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."</p>	
<p>Additionally a stakeholder mentioned: "we would prefer the criteria for claiming biodegradable/lower impact on environment are not required"</p>	
<p>Suggest to include in the text : Cosmetics products must contains in addition to label requirement from Cosmetics Producers regulation , the following optional label with box"</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>Wet wipes have been finally excluded from the scope.</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>It was expressed: "The AGECE french law is releasing banning the words "biodegradable" are "respectful for environment" or equivalent that is totally in contradiction with ECOLABEL aim. Regarding AGECE 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>Comments acknowledged</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><i>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 different claims, □- information on the reuse – requirement connected to packaging criterion, recycling and correct disposal of packaging, □- In order to harmonise with good practices used in detergents products >> 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</i></p>	<p>Comment partially accepted Provision of dosage information and design for a proper dosage has been addressed in primary packaging criterion.</p>
<p><i>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.</i></p> <p><i>Moreover it's necessary to add a criterion about information provided on labels which requires :</i> <i>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),</i></p> <p><i>Applicants have to prove different claims,</i></p> <p><i>Information on the reuse – requirement connected to packaging criterion, recycling and correct disposal of packaging,</i></p> <p><i>In order to harmonise with good practices used in detergents products >> 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.</i></p>	