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Revision of the EU Ecolabel criteria for rinse-off cosmetics

Technical Report: Revision proposal for the EU Ecolabel criteria for rinse-off cosmetics

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Title [One-line catchy title capturing the key message of the report, which will be used as the title of the Science for Policy brief]

Abstract
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•Include also a sentence or two on the policy relevance of the work.
•These (up to) five sentences will go in the "Headlines" box of the brief as bullet points.
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1 INTRODUCTION

The objective of this project is to revise the existing EU Ecolabel criteria (Commission Decision 2014/893/EU[1]) for rinse-off cosmetic products. The criteria were for the first time adopted in 2007[2] and the Decision currently in force is valid until the end of December 2021.

This technical report is intended to provide background information for the revision of the existing EU Ecolabel criteria for rinse-off cosmetic products. The study has been carried out by the Joint Research Centre (JRC) with the technical support of LEITAT. The work is being developed for the European Commission's Directorate General for the Environment.

The main purpose of the technical report is to summarise the results of the preliminary analysis of the current criteria and to discuss if the criteria are still appropriate and up-to-date or if they should be revised, amended or some of them removed; and finally, if any new criteria should be added.

This technical report is supported and complemented by the preliminary report[3] and the first draft of the technical report (TR1.0)[4], both published in October 2019. The preliminary report includes scope and definition, market analysis, and technical analysis. The information of these reports was presented in the first Ad-hoc Working Group meeting (AHWG1) which took place in Brussels in November 2019. The discussions and comments received are included in this technical report, and form the basis for the further research done to justify the latest modification of the criteria proposal.

The content of this second technical report (TR2.0) will be discussed in the second Ad-hoc Working Group meeting (AHWG2) which is planned to take place in June 2020.

This technical report (TR2.0) consists of:

- **Introduction** (Chapter 1): this section describes the goal and content of the document, the sources of information and the next steps in the project. It also summarizes the main findings from the preliminary report and the conclusions obtained regarding the scope definition and the key environmental aspects related to the product group of 'rinse-off cosmetic products'. After the AHWG1, the chapter has been completed with new information needed to clarify the environmental profile of the products considered in the revision.

[1] Commission Decision No 2014/893/EU of the European Parliament and of the Council of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products, available online at:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014D0893

[2] Commission Decision (2007/506/EC) of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:186:0036:0045:EN:PDF

[3] Revision of the European Ecolabel criteria for rinse-off cosmetics. Preliminary Report (October 2019). Available online at: https://susproc.jrc.ec.europa.eu/Rinse-off_cosmetic_products/docs/Preliminary_Report_EUEcolabel_Cosmetics.pdf

[4] Revision of the European Ecolabel criteria for rinse-off cosmetics. Technical Report: criteria proposal for revision of EU Ecolabel for rinse-off cosmetics (October 2019). Available on line at:
https://susproc.jrc.ec.europa.eu/Rinse-off_cosmetic_products/docs/Technical_Report_EU_Ecolabel_Cosmetics.pdf

- **Assessment and verification** (Chapter 2)**:** this section includes information on the type of documentation required to show compliance with the criteria that shall be provided by applicants and recognised by Competent Bodies.
- **Criteria proposal** (Chapter 3)**:** this section presents the second revised EU Ecolabel criteria for the newly named 'cosmetic products and animal care products' product group. The proposal is written in a blue box and subsequently a rationale is given. The existing EU Ecolabel text (grey box) is included for each criterion in order to allow the reader to compare the proposals with the text in force.
  Under each criterion proposed, the following information is presented:
    - A summary of the rationale considered for the first draft of the criterion, presented during the AHWG1.
    - Summary of the main outcomes received during the AHWG1 and the written comments provided by stakeholders during the consultation period.
    - Further research carried out considering the comments received.
- **Impact of changes to criteria** (Chapter 4): this section consists of a summary of the main changes proposed for the revised criteria and potential implications on current licence holders and applicants.
- **Table of comments**: a table for all comments received at the AHWG1 and during the consultation period, together with responses and explanations on how they have been addressed in this TR2.0 report has been published as a **separated document** under: https://susproc.jrc.ec.europa.eu/Rinse-off_cosmetic_products/stakeholders.html

1.1 Methodology and source of information

The approach followed in the revision of the EU Ecolabel for rinse-off cosmetic products consists of the following main elements:

- analysis of the current scope, assessment of scope enlargement potential and a review of any relevant legislation;
- analysis of the cosmetic products market from a global and European perspective;
- technical analysis, in which environmental hotspots are identified, current criteria validity is assessed and improvement potential is analysed.

While the above-mentioned elements have been extensively addressed in the preliminary report[3], a brief description is given below:

Revision of the scope and definition: an overview of existing technical categories, and relevant legislation and standards has been done in order to identify aspects of the current criteria which may require revision. Moreover, stakeholder feedback was obtained through an initial questionnaire launched in March 2019 aimed at gathering the preliminary input about the current criteria and the potential scope extension. Product categorisation has been proposed, based on the existing product categories included in PRODCOM and Mintel data bases. Other labelling schemes and other initiatives related to cosmetics have been analysed in order to identify potential areas for harmonization. The selection of product categories to be included in the scope was done considering different relevant aspects (e.g. risk of release to the environment, market relevance, other environmental schemes….).

Market analysis: global trends related with cosmetics and global market data was assessed. The economic relevance of cosmetic products at European level and European consumption values of cosmetics has also been analysed. Finally, relevant trends, key actors, challenges, innovative products and market segmentations have been identified. Information has been extracted from PRODCOM, Euromonitor International, Cosmetics Europe association and Mintel GNPD database.

Technical analysis: the technical analysis is aimed at providing specific technical support and information on environmental, health and technical issues related to the products considered in the scope extension. An analysis of the formulations of cosmetic products is included.

Moreover, by making use of the database Mintel, a qualitative analysis of the formulations of the products available on the market was carried out. The latest developments, technical innovations and novelties regarding formulations and products functionalities have been also identified in the report, to document the high innovation and research of this sector.

Using the formulations identified, a list of the hazard classes of ingredients frequently used in cosmetic products has been done, taking REACH and CLP regulations as a basis.

A Life Cycle Assessment has been performed to identify the environmental impacts of each product and the most important (from the environmental point of view) life cycle stage for each analysed product. The impact assessment method was the ILCD 2011 Midpoint method, and the analysis was performed with Simapro software. The functional unit of the assessment has been defined as "*a common day washing action of a part of the body with the main objective of providing hygienic results and/or aesthetic improvements*". For the products currently covered by the existing scope, the previous assessment done during the last criteria revision has been used. The impact of each product was updated by using the latest version of Simapro and ecoinvent. A new LCA was performed for the product categories: skin care leave-on, sun care products (being this a special category of skin care products) and toothpastes. A full LCA was not performed on animal care products, as the formulation of this product category is very similar to the shower, bath and other body cleanser preparation category already included in the last revision process. Therefore, results for shower, bath and other body cleanser preparation products have been assumed valid also for animal care products. Similarly, feminine hygiene products are expected to be represented by such results.

Information regarding the thresholds of criteria on toxicity and biodegradability of EU Ecolabel awarded products was asked to the Competent Bodies and data have been collected to revise the existing EU Ecolabel criteria on hazardous substances (their current amendments, derogations or further modifications) and packaging requirements.

Based on all the aspects of this technical analysis, improvement potential actions to existing criteria in force were identified.

Two questionnaires have been sent out to all registered stakeholders in the initial stage of the revision process. The answers of the stakeholders have been presented in the preliminary report[3].

1.2 Summary of the preliminary report and link to the EU Ecolabel criteria

The sections below provide a summary of the findings from the preliminary report with a focus on the scope and on the key environmental aspects.

1.2.1 Product group name, scope and definitions

The following section presents the proposed revisions to the existing name, definitions and scope of the rinse-off cosmetic products.

Existing product group name
Rinse-off cosmetic products
Second product group name proposal:
Cosmetic products and animal care products

Existing product group scope and definition:
The product group 'Rinse-off cosmetic products' shall comprise any rinse-off substance or mixture falling under the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council(*) intended to be placed in contact with the epidermis and/or the hair system with a view exclusively or mainly to cleaning them (toilet soaps, shower preparations, shampoos), to improve the condition of the hair (hair conditioning products) or to protect the epidermis and lubricate the hair before shaving (shaving products). The product group 'Rinse-off cosmetic products' shall include products for both private and professional use. The product group shall not cover products that are specifically marketed for disinfecting or anti-bacterial use. Anti-dandruff shampoos are allowed. *[References: (*) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).]*
Second product group scope and definition proposal:
Article 1: 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 (soaps (liquid and solid), shampoos

(liquid, solid and dry), shower preparations, feminine hygiene cosmetic products, toothpastes (liquid and solid) and mouthwashes,
- intended to improve or style the condition of the hair (hair conditioning, hair styling and treatment products),
- intended to take care of the epidermis or to massage the skin (skin care products),
- intended to protect the epidermis or lubricate the body hair before shaving (shaving products);
- intended to prevent or mask body odours (deodorants and antiperspirants);
- intended to make-up body, face, eyes, lips or nails (decorative cosmetics);
- intended to remove polish from the nails (nail enamel remover)

The product group 'Cosmetic products' shall include products for both private and professional use. Anti-dandruff shampoos are allowed.

Feminine hygiene cosmetic products include only rinse-off products intended to wash feminine intimate parts, such as intimate cleansers.

Hair styling and treatment products include products intended to be placed in contact with hair to take care or improve its condition, to dye, model, wave or straight it.

Skin care products include creams, oils and lotions intended to be in contact with the epidermis, including massage products, lip care products, after-sun and self-tanning creams, cleansers, exfoliants and sunscreens.

Decorative cosmetics include all beauty and make-up cosmetics: body colour cosmetics, eye colour cosmetics, face colour cosmetics, lip colour cosmetics, multiuse colour cosmetics and nail colour cosmetics. Wet wipes (not covered under the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council) are included in the definition of product group, if the liquid on the wipe is intended for functions as described above.

The cosmetic products covered under this EU Ecolabel can be classified as rinse off and leave on products, where these are defined as follows:

- Rinse off products are those marketed as intended to be removed with water after use in normal conditions.
- Leave on products are those marketed as not intended to be removed with water after use in normal conditions.

The following table shows the covered products and the type (to be included in the User Manual):

Category	**Type**	**Sub-categories**
SHOWER, BATH and OTHER BODY CLEANSER PREPARATIONS	Rinse-off	Shampoo, shower preparations, liquid soaps Solid soaps and solid shampoos Hair conditioners Shaving foams, shaving gels and shaving creams Feminine hygiene cosmetic products

HAIR STYLING AND TREATMENT	Rinse-off	Hair dyes
	Leave-on	Liquids, waxes, sprays, mousses, lacquers and dry shampoos
SKIN CARE PRODUCTS	Rinse-off	Exfoliants, cleansers
	Leave-on	Lotions, creams and oils (including massage products, after-sun and self-tanning creams) Sun screen products Cleanser
MOUTHWASH	Rinse-off/leave-on	Mouthwashes and oral perfumes
TOOTHPASTE	Rinse-off	Dentifrice Dental cleanser Solid toothpastes
DEODORANTS AND ANTIPERSPIRANTS	Leave-on	Personal deodorants and antiperspirants
DECORATIVE COSMETICS	Leave-on	Body colour cosmetics, eye colour cosmetics, face colour cosmetics, lip colour cosmetics, multiuse colour cosmetics, nail colour cosmetics
NAIL ENAMEL REMOVER	Leave-on	Nail enamel removers
WET WIPES	Leave-on	Wet wipes with intended use in the scope definition

The next table shows which criteria apply to the different type of products.

Table 1. criteria requirement for rinse-off and leave-on products

Criterion	**Rinse off products**	**Leave on products**
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	x	
Criterion 2. Biodegradability	x	x
Criterion 3. Excluded or limited substances and mixtures	x	x
Criterion 4. Packaging	x	x
Criterion 5. Renewable ingredients	x	x
Criterion 6. Specific requirements for wet wipes	-	-
Criterion 7. Fitness for use	x	x
Criterion 8. Information on EU Ecolabel	x	-x

Article 2:

The product group 'Animal care products' shall comprise any rinse-off substance or mixture intended to be placed in contact with animal hair to clean them or to improve the condition of it, such as shampoos and conditioners for animals. Animal care products shall not cover products that are specifically marketed for disinfecting or anti-bacterial use.

The product group 'Animal care products' shall include products for both private and professional use.

Existing complementary definitions

1) 'ingoing substances' means preservatives, fragrances and colorants, regardless of the concentration, and other substances intentionally added, by-products and impurities from raw materials, the concentration of which equals or exceeds 0.010 % by weight of final formulation;

2) 'active content' (AC) means the sum of organic ingoing substances in the product (expressed in grams), calculated on the basis of the complete formulation of the product, including propellants contained in aerosol products. Rubbing/ abrasive agents are not included in the calculation of the active content;

3) 'primary packaging' means packaging in direct contact with the content conceived so as to constitute the smallest sales unit of distribution to the final user or consumer at the point of purchase;

4) 'secondary packaging' means packaging which can be removed from the product without affecting its characteristics and is conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale.

Second complementary definitions proposal:

1) 'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

2) '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. 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.

3)

4) '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.

5) *'active content' (AC)* means the sum of organic ingoing substances in the product excluding the water content of the ingredients (expressed in grams), calculated on the basis of the complete formulation of the final product, including propellants contained in aerosol products. Rubbing/abrasive agents are not included in the calculation of the active content;

6) *'primary packaging'* means packaging in direct contact with the content conceived so as to constitute the smallest sales unit of distribution to the final user or consumer at the point of purchase;

7) *'secondary packaging'* means packaging which can be removed from the product without affecting its characteristics and is conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale.

8) '*Infant, baby and/or children's products'* are considered to be products that are marketed for or have words such as baby and/or children (<12) on the label.

Rationale of the proposed name, scope and definitions

The existing product group definition is based on the definition contained in the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[5] (later referred to as Cosmetics Regulation), where according to article 2 a **cosmetic product** is defined as: a*ny 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.*

Nevertheless, the current EU Ecolabel scope is narrowed to certain rinse-off products, namely: toilet soaps, shower preparations, shampoos, hair conditioning products and shaving products.

[5] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products:
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223

The potential interest to expand the scope of the currently valid criteria was investigated with a preliminary scope questionnaire carried out prior to this revision process in the middle of 2018. A total of 62 respondents answered the questionnaire.

In addition, another questionnaire was launched during the revision process (March 2019) to obtain information regarding the following:

- Proposal of the scope extension
- Feasibility, ambition level and improvement potential of the existing EU Ecolabel criteria

This later questionnaire was answered by 50 respondents.

A general agreement on extending the scope was expressed by the stakeholders' in their responses to both questionnaires. For this reason, and with the aim of harmonising with other ecolabelling schemes which cover more product categories, it was considered reasonable to extend the scope to other cosmetic products not currently covered.

The different products were classified into categories considering both MINTEL[6] and PRODCOM databases. Moreover, other products out of the scope of the Cosmetics Regulation, namely wet wipes, animal care products and intimate products, were also analysed in the preliminary report[3] in order to identify their relevance to the EU Ecolabel (more information in TR1.0[4]).

For the first proposal (TR1.0), it was not considered feasible to include under the revised scope all cosmetic products. Cosmetics are a very heterogeneous and wide group covering a number of products types with different formulations and functionalities. In addition, the results of both questionnaires showed that a number of stakeholders expressed interest on focusing on products with higher environmental relevance. For this reason, an evaluation was carried out to analyse the relevance of including additional products into the revised scope, prioritizing products with higher risk to be released into water and considering other relevant aspects such as (more information can be found in the TR1.0[4] and in the preliminary report[3]):

- The potential risk of the product to be released to the environment.
- The consumption of the different products.
- Market data (to cover products with higher market share).
- The interest of the stakeholders to award their products.
- The existing type I ecolabelling schemes.
- Products having similar ingredients to those currently included in the existing scope.

The evaluation made used of a scoring system that classified the product categories as having low, medium or high potential for inclusion into the revised scope. Products classified as "low risk of release into water" were proposed to be excluded from the initial scope proposal without further assessment (deodorants and antiperspirants, perfumes, decorative cosmetics, nail enamel remover, hand sanitizers, other preparations for animal care products, and intimate gels or lubricants).

The evaluation gave the following results:

[6] MINTEL is a market intelligence agency

- The products classified with **high potential of inclusion** were suggested to be included: skin care products, toothpaste and feminine hygiene cosmetic products.
- The products ranked with **low potential of inclusion** were not proposed to be included in the revised scope: depilatory products.
- Regarding the products with **medium potential of inclusion** (hair styling and treatment products, mouthwashes, perfumed bath salts and other bath preparations and shampoos and conditioners for animal care products), only the animal care products were proposed to be included (detailed explanation can be found in the TR1.0[4] and the preliminary report[3]).

Outcomes from and after 1st AHWG meeting

The definition of "Cosmetic products" was considered inadequate by a group of stakeholders who believed that such definition should be aligned with the definition included in the Cosmetics Regulation, therefore including in the revised scope more products than those proposed in TR1.0.

Most attendants to AHWG1 agreed with the idea of expanding the current scope to all cosmetic products covered by the Cosmetics Regulation[5].

Regarding the products not covered by the Cosmetic Regulation, stakeholders commented that animal care products should not be included in the revised scope because they are not included in the Cosmetics Regulation and therefore does not follow the same restrictions of cosmetic products. Nevertheless, a group of stakeholders was in favour of their inclusion, some comments received agreed to include animal care products but in a different Commission Decision.

During the consultation period following the AHWG1, stakeholders expressed their interest for the inclusion of specific products in the new proposal of the scope:

- Mouthwash (as part of oral care hygiene)
- Decorative cosmetics
- Hair styling and treatment products
- Deodorants (aluminium salt concerns)

One stakeholder disagreed with the inclusion of sunscreen products in the EU Ecolabel scope arguing that UV filters constitute a large part of sunscreen products and they are not biodegradable.

Stakeholders asked for better clarity on the new definition of substance. Despite the fact that the definition was aligned with the one included in REACH Directive[7], stakeholders considered that it is not clear which substances are covered, especially with respect to whether preservatives or solvents are included in the product group requirements.

Other minor comments received during the consultation period are:

- The definition should include the sentence "intended to be placed in contact with the body".

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1907R(01)

- It should be specified that cosmetic products are only for external use.
- The inclusion of shampoo bars and solid toothpaste in the scope was requested.

Further research and main changes in the second proposal

In the second proposal the idea is to establish two separated annexes with criteria, namely one specific for products covered under the Cosmetics Regulation (Annex I) and one specific for animal care products (Annex II). Wet wipes with liquid intended to fulfil functions covered under the Cosmetics Regulation would also be addressed in Annex I.

Consequently, the name of the product group has been modified to "Cosmetic products and animal care products". The products included in *Annex I: EU Ecolabel criteria for awarding the EU Ecolabel to cosmetic products* are the ones covered under the Cosmetics Regulation and wet wipes using liquid intended for functions as covered under Cosmetics Regulation. The animal care products can be EU Ecolabel awarded if they comply with the specific requirements included in *Annex II: EU Ecolabel criteria for awarding the EU Ecolabel to animal care products*.

Considering the general interest expressed of stakeholders to further expand the scope, an extension of the scope to other products covered by the Cosmetic Regulation and by other environmental schemes is proposed. To enlarge the scope, the evidence from other schemes on the potential compliance of the specific requirements for the different cosmetic products considered has been considered.

The number of licences awarded by the Nordic Swan certification scheme have been studied in order to analyse the potential compliance with thresholds included in this ecolabel for categories not covered by the EU Ecolabel. There are 1496 ecolabelled products certified under the Nordic Swan ecolabel[8].

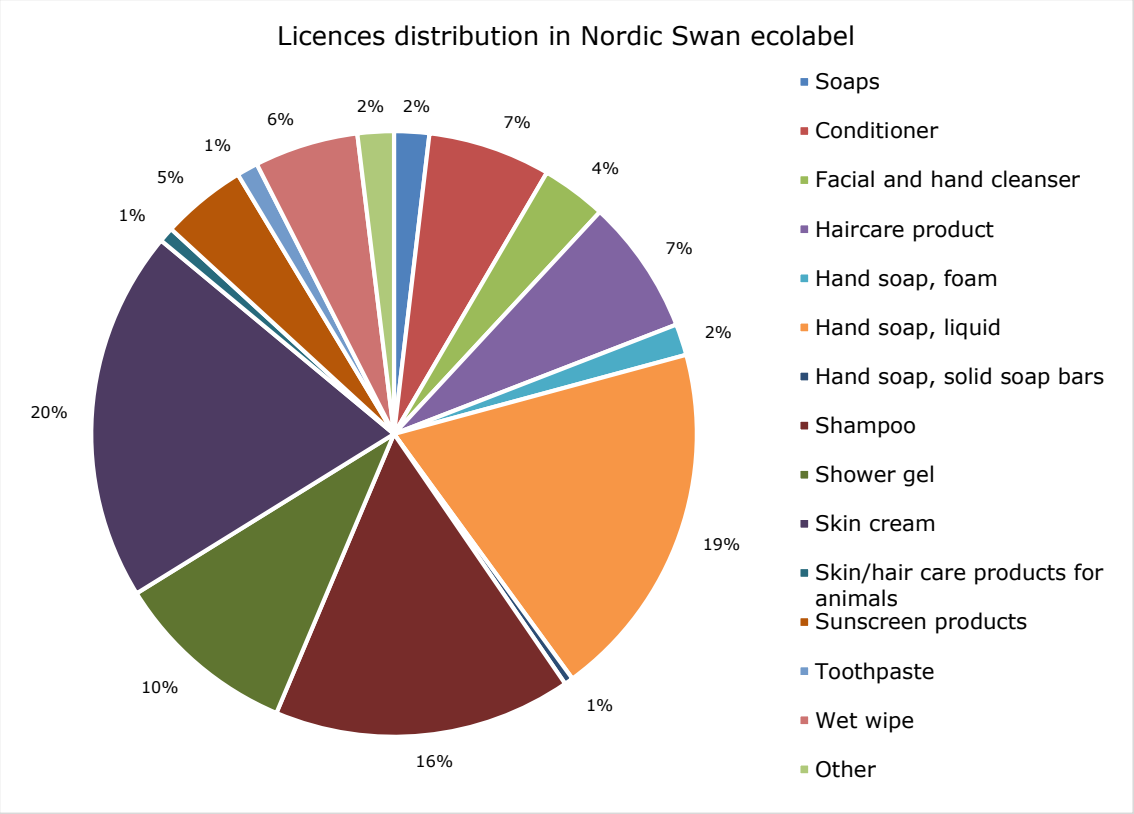
The most important group of products certified is skin care (leave on), representing 20% of the total amount of Nordic Swan-certified products (19% of such skin care products are specific for children). Hand soaps (liquid) represent the 19% of the Nordic Swan-certified products, followed by shampoos 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.

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.

Figure 1. Percentage of licences for each product category included in the Nordic Swan ecolabel. N.B.: values are rounded.

[8] 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



Note: In the legend, "Other" include: Deodorants, Hand soap, solid soap bars, Intimate wash, Lip care products, Lubricants, Makeup, Massage oil and Nail polish remover.

In Table 1, the number of products certified in each of the categories considered in the scope of the Nordic Swan ecolabel is included. Only 56% of Nordic Swan-certified products would be eligible for EU Ecolabel, considering the existing EU Ecolabel scope definition (Rinse-off cosmetics) in force.

For the second proposal it is suggested to cover most cosmetic products in order to align as much as possible with Nordic Swan Ecolabel and considering the general agreement on scope extension expressed by the stakeholders. **Products proposed to be included in the scope of TR2.0, besides the ones already included in TR1.0 scope, are: hair styling and treatment products, mouthwashes, deodorants and antiperspirants, decorative cosmetics, nail enamel removers and wet wipes.**

According to data gathered from Nordic Swan, the scope of the EU Ecolabel for Cosmetic products is proposed to be aligned with this scheme to cover also those product groups for which Nordic Swan licences exist. The proposed extension would result in almost 100% of Nordic Swan products being covered by EU Ecolabel criteria. Lubricants are the only category not proposed to be included in the scope, as they are out of the scope of Cosmetics Regulation because they are intended for internal use.

Table 1. Number of products certified in the Nordic Swan ecolabel and relation with EU Ecolabel scope. *Source: list of certified products within the product group of Cosmetic Products in Nordic Swan ecolabel*.[8]

Category	Number of products certified	Covered by existing EU Ecolabel in force	Covered by second proposal
Children soap	23	Yes	Yes
Conditioner	93	Yes	Yes
Conditioner for children	5	Yes	Yes
Deodorant	4	No	Yes
Facial cleanser	26	No	Yes
Haircare for children	1	No	Yes
Haircare product	107	No	Yes
Hair dyes	0	No	Yes
Hand cleaner	26	No	Yes
Hand soap, foam	25	Yes	Yes
Hand soap, liquid	287	Yes	Yes
Hand soap, solid soap bars	7	Yes	Yes
Intimate wash	4	No	Yes
Lip care products	6	No	Yes
Lubricants	5	No	No
Make-up	4	No	Yes
Massage oil	3	No	Yes
Nail polish remover	3	No	Yes
Shampoo	217	Yes	Yes
Shampoo for children	21	Yes	Yes
Shower gel	147	Yes	Yes
Skin cream	241	No	Yes
Skin cream for children	56	No	Yes
Skin/hair care products for animals	12	No	Yes
Soaps	5	Yes	Yes
Sunscreen products	58	No	Yes
Sunscreen products for children	10	No	Yes
Toothpaste	11	No	Yes
Toothpaste for children	6	No	Yes
Wet wipe	27	No	Yes
Wet wipe for children	56	No	Yes

The following table summarises the products proposed to be included in the scope of the revised EU Ecolabel criteria.

Table 2. Summary of product groups proposed in TR2.0 to be included in the revision of the EU Ecolabel criteria. Products in bold are already covered under the existing criteria in force

PROPOSED PRODUCT GROUPS
Annex I: Cosmetic products

SHOWER, BATH and OTHER BODY CLEANSER PREPARATIONS	Rinse-off	**Shampoo, shower preparations, liquid soaps** **Solid soaps and solid shampoos** **Hair conditioners** **Shaving foams, shaving gels and shaving creams** Feminine hygiene cosmetic products
HAIR STYLING AND TREATMENT	Leave-on	Liquids, waxes, sprays, mousses, lacquers and dry shampoos
	Rinse-off	Hair dyes
SKIN CARE PRODUCTS	Rinse-off	Exfoliants, cleansers
	Leave-on	Lotions, creams and oils (including massage products, after-sun and self-tanning creams) Sun screen products Cleanser
MOUTHWASH	Rinse-off/leave-on	Mouthwashes and oral perfumes
TOOTHPASTE	Rinse-off	Dentifrice Dental cleanser Solid toothpastes
DEODORANTS AND ANTIPERSPIRANTS	Leave-on	Personal deodorants and antiperspirants
DECORATIVE COSMETICS	Leave-on	Body colour cosmetics, eye colour cosmetics, face colour cosmetics, lip colour cosmetics, multiuse colour cosmetics, nail colour cosmetics
NAIL ENAMEL REMOVER	Leave-on	Nail enamel removers
WET WIPES	Leave-on	Wet wipes with intended use in the scope definition
Annex II: Animal care products		
ANIMAL CARE PRODUCTS[9]	Rinse-off	Shampoos Conditioners Other washing preparations

Wet wipes are not within the scope of application of the Cosmetics Regulation. However, the substance or mixture delivered on a wipe falls under the Cosmetics Regulation scope as long as it is intended to be placed in contact with external parts of the human body, with a view exclusively or mainly to cleaning them, to perfume them, to change their appearance and/or to correct body odours and/or to protect them or keep them in good conditions. Therefore, wet wipes can be awarded by the EU Ecolabel if the delivered substance/mixture fulfils the function specified in the

[9] Products with biocidal or antimicrobial activity are not eligible for EU Ecolabel and are therefore excluded.

scope of the revised criteria. The product shall comply with the specific requirements included in Annex I for Cosmetic products. Despite the fact that 20% of the stakeholders expressed their disagreement with inclusion of sunscreens in the revised scope proposal, there are 68 sunscreen products certified under the Nordic Swan scheme, showing the interest of companies and the feasibility to meet criteria thresholds. In addition sunscreens were considered relevant to be included into the revised scope due to their environmental relevance (i.e. direct release to aquatic environment under some use circumstances).

Animal care products is another product that generated controversy among the stakeholders. In the second proposal this products have been included in a separate annex because they are not covered by the Cosmetic Regulation, therefore some parts of the criteria valid for human cosmetics products do not apply to products designed for animals. The formulation of these products is very similar to the one of human shampoos and their impacts on the environment are expected to be similar to the ones caused by products manufactured for human use.

In summary, the main changes of the second version of the scope are the extension of the scope to products covered by other environmental schemes. Considering the products certified under the Nordic Swan ecolabel, the new products included in the scope of the EU Ecolabel are hair styling and treatment products, massage products and lip care products, deodorants and antiperspirants, decorative cosmetics, nail enamel remover and wet wipes with liquid intended to fulfil functions covered under the Cosmetic Regulation.

Other products included in the first revision of the scope have been maintained. In order to separate the products included in the Cosmetic Regulation from the Animal care products, two annexes have been defined:

- **Annex I: EU Ecolabel criteria for awarding the EU Ecolabel to cosmetic products**, covering products under Cosmetic Regulation and wet wipes.
- **Annex II: EU Ecolabel criteria for awarding the EU Ecolabel to animal care products**, covering animal care products.

The inclusion of new products implies the division of the products in two sub-groups: rinse-off products and leave on products. The definitions of these products have been included in the Commission Decision, as well as two tables in order to clarify which products belong to each type and which criteria affect to the different products.

The definitions of the new products included in the scope have been included in the Commission Decision, including the specific products affected by each cosmetic product.

Complementary definitions have been revised to clarify 'ingoing substances' which has been aligned to Nordic Swan, and 'active content' definition. In addition, the definitions for 'impurities' and 'children products' have been included, aligning with Nordic Swan .

Finally, in order to adapt the product group name to the products included in the scope, the second product group name proposal is **Cosmetic products and animal care products**.

Questions to stakeholders
Should we include dry shampoos?

1.2.2 Key environmental aspects and relation with the criteria proposal

The EU Ecolabel and other ecolabels of type I Ecolabels use a life cycle (LCA) approach in the process of defining criteria. The environmental performance of products should be considered throughout its life cycle, in order to cover all life cycle of cosmetics products and avoid shifting environmental problem between different product life stages or aspects. The Life Cycle Assessment allows the identification of the environmental hotspots along the life cycle of a product which could be in terms of raw material consumption, packaging, use phase, and end-of-life management.

In the first revision (TR1.0), the LCA of the products included in the criteria in force was updated[10] considering the latest version of the Simapro software and the new Ecoinvent database. In addition, three new products were analysed: toothpaste, leave-on skin care products and sun care products. Indeed, sun care products contain a completely different formulation compared to the other products suggested to be included in the scope, and are therefore worthwhile a separate assessment. A full LCA was not performed on animal care products, as the formulation of this product category was considered very similar to the shower, bath and other body cleanser preparation category already included in the last revision process. Therefore, results for shower, bath and other body cleanser preparation products have been assumed valid also for animal care products. Similarly, feminine hygiene products were expected to be represented by such results. Also, a full LCA was not performed on shaving products. The inventory data and further details on the assumptions considered to model the environmental profile of cosmetic products can be found in the preliminary report[3].

Additionally, after the 1st AHWG meeting, the LCA modelling was revised taking into account stakeholders' comments on the functional unit (for details, see the Table of comment in the appendix).

The revised functional unit defined to quantify the environmental performance of the products is "***A daily use of a cosmetic product with the main objective of providing hygienic results and/or aesthetic improvements***". The reference flow for each of the products investigated can be found in Table 3. The reference flow equals to the column "daily dosage" and was calculated by multiplying the single dosage with the frequency of application. Liquid and solid soaps were considered to be used in an equivalent way for a daily use of washing hands and showering[11].

[10] The update refers to the LCAs performed in the previous criteria revision for the product categories: soaps, shampoos and hair conditioners (criteria in force as from 2014)

[11] 5 times of hand washing and 1 shower a day.

Table 3. Data used to calculate the reference flow for each product.

Product category	Product volume (g)[12]	Single dosage (g)[13]	Frequency of application (times/day)[14]	Daily dosage (g)
Liquid soap	300ml	Washing hands: 2.3 Shower: 8.7	Washing hands: 5 Shower: 1	20.2
Solid soap	100g	Washing hands: 0.35 Shower: 4		5.8
Shampoo	250ml	10,5	1,0	10,5
Hair conditioner	200ml	14,0	0,3	3,9
Skin care	200ml	3,4	2,3	7,8
Sun care	200ml	9,0	2,0	18,0
Toothpaste	75ml	1,8	1,5[15]	2,7

The results obtained from the LCA have been normalised and weighted. The normalization factors are based on "Normalisation method and data for Environmental Footprints, 2014; Lorenzo Benini, et al.; Report EUR 26842 EN". The weighting factors are based on "European Commission, 2014, Environmental Footprint Pilot Guidance document, - Guidance for the implementation of the EU Product Environmental Footprint (PEF) during the Environmental Footprint (EF) pilot phase, v. 4.0, May 2014". According to the PEF guidance, all impact categories shall receive the same weight in the baseline approach[16].

The weighted results can be found in Figure 2. Please notice that while all products are shown in the same graph, the intention was not to compare across different products. The scope of the LCA was to identify main environmental hotspots of each product investigated with the goal of setting criteria in those areas, wherever relevant and feasible.

[12] Information from MINTEL database: most used packaging for each product category.

[13] Nordic Council of Ministers, Existing Default Values and Recommendations for Exposure Assessment, 2012. Available at: https://www.researchgate.net/publication/313383738_Existing_Default_Values_and_Recommendations_for_Exposure_Assessment_-_A_Nordic_Exposure_Group_Project_2011/link/593a50600f7e9b32b74a35f2/download;

Witlox, Keller, Jungbluth. A LCA case study of hand washing with liquid and bar soap. Available at: file:///C:/Users/faracgi/Downloads/witlox-2015-LCA-soap-poster%20(1).pdf ;

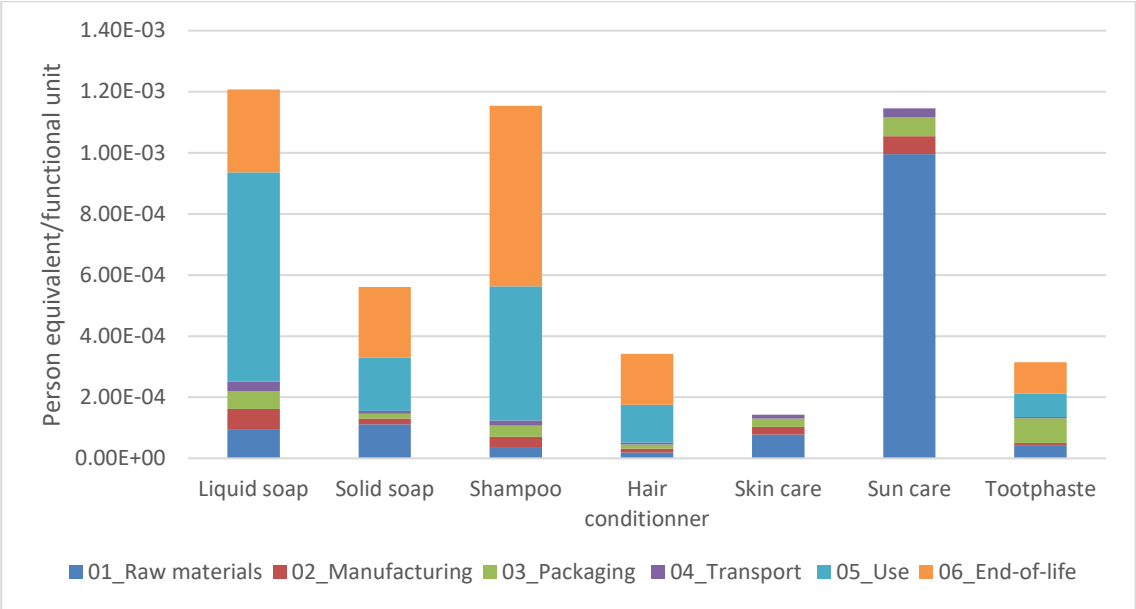
Ugaya, Brones, Corrêa. S-LCA: Preliminary results of Natura's cocoa soap bar. Available at: https://pdfs.semanticscholar.org/ca29/ae02237e7029e70ff8cc9772a16a98a2bc89.pdf

[14] The SCCS'S notes of guidance for the testing of cosmetic substances and their safety evaluation (8th revision), 2012

[15] Ficheux AS et al. (2015): Consumption of cosmetic products by the French population. First part: Frequency data, Food and Chemical Toxicology, 78, pp 159-169. Journal article available at: http://www.researchgate.net/publication/272199849

[16] http://ec.europa.eu/environment/eussd/smgp/pdf/JRC_Normalisation_method_and_data_EF_web.pdf

Figure 2. Environmental impact of each cosmetic product.



As can be seen in Figure 2, the use phase and the end-of-life are the main hotspots for liquid soap, solid soap, shampoo and hair conditioner. On the other hand, raw material extraction is the most contributing life cycle stage for skin care and sun care products. Finally, in toothpaste, packaging, use phase and end-of-life show similar contributions.

In the light of the information contained in the preliminary report, the feedback received and further evidence collected, the main environmental areas of relevance and the areas of improvement of the existing criteria that have been addressed in more detail in this technical report are summarised in Table 4:

Table 4. Link between the environmental aspects identified and the EU Ecolabel criteria

Existing EU Ecolabel criteria	Criteria proposal	Environmental aspects	
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	Hazardous substances Emission to soil/ water	It ensures that the overall aquatic toxicity is limited.
Criterion 2. Biodegradability	Criterion 2. Biodegradability		It ensures that the ingredients are biodegradable and will not persist in water.
Criterion 3. Excluded or limited substances and mixtures	Criterion 3. Excluded or limited substances and mixtures		It limits the hazardous substances that can be included in the product, limiting environmental and health risks for users.
Criterion 4. Packaging	Criterion 4. Packaging	Raw materials extraction and processing	It ensures maximum usage of the product contained in a container and promotes the minimisation of use of packaging material and plastics recyclability.
Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives	Criterion 5. Renewable ingredients		It promotes that renewable ingredients used for the cosmetic manufacturing comes from sustainable origin.
	Criterion 6: Specific requirements for wet wipes	Raw materials extraction and end of life	It guarantees that the substrate (wipe) complies with ecolabel requirements and informs consumers on the correct disposal of the product.
Criterion 6. Fitness for use	Criterion 7. Fitness for use	Efficiency during use	It guarantees that the product meets certain quality requirements and user satisfaction.
Criterion 7. Information on EU Ecolabel	Criterion 8. Information on EU Ecolabel		It informs consumers on the environmental benefits associated with the product, in order to encourage the purchase of the product.

1.3 Proposed framework for the revision of the EU Ecolabel criteria and main changes

The proposed criteria are aimed at addressing the environmental aspects of the different life stages of the products as identified in the preliminary report.

Existing criteria structure is suggested to be kept, however the content has been modified in the light of the research conducted and presented in the preliminary report and after the AHWG1. Where relevant, the names of criteria have been revised according to the changes introduced. The following table shows the changes in the criteria names proposed:

Table 5. Comparison of the criteria structure

Existing EU Ecolabel criteria	Revised proposal
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
Criterion 2. Biodegradability	Criterion 2. Biodegradability
Criterion 3. Excluded or limited substances and mixtures	Criterion 3. Excluded or limited substances and mixtures
Criterion 4. Packaging	Criterion 4. Packaging
Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives	Criterion 5. Renewable ingredients
	Criterion 6: Specific requirements for wet wipes
Criterion 6. Fitness for use	Criterion 7. Fitness for use
Criterion 7. Information on EU Ecolabel	Criterion 8. Information on EU Ecolabel

2 ASSESSMENT AND VERIFICATION

Existing assessment and verification

a) Requirements

The specific assessment and verification requirements are indicated for each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant or his supplier(s) or both.

Where possible, the testing shall be performed by laboratories that meet the general requirements of European Standard EN ISO 17025 or equivalent.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

The Appendix makes reference to the 'Detergent Ingredient Database' list (DID list) which contains the most widely used ingredients in detergents and cosmetics formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) and for the assessment of the biodegradability of the ingoing substances. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website (1) or via the websites of the individual competent bodies.

The following information shall be provided to the competent body:

(i) The full formulation of the product indicating trade name, chemical name, CAS No and INCI designations, DID No (2), the ingoing quantity including and excluding water, the function and the form of all ingredients regardless of concentration;

(ii) safety data sheets for each ingoing substance or mixture in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (3).

b) Measurement thresholds

Compliance with the ecological criteria is required for all ingoing substances as defined above, with the exception of criterion 3(b) and 3(c), where preservatives, colorants and fragrances are requested to comply when their concentration equals or exceeds 0,010 % by weight in the final formulation.

[References:

(1) http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf,

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

(2) DID No is the number of the ingoing substance on the DID list.

(3) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive

1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).]

Second proposal for assessment and verification

a) Requirements

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or his/her supplier(s) and/or their supplier(s), etc. as appropriate.

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site inspections to check compliance with these criteria.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to Competent Bodies, together with supporting information to enable verification of continued compliance with the criteria.

As a prerequisite the product shall meet all applicable legal requirements of the country or countries in which the product is placed on the market. The applicant shall declare the product's compliance with this requirement.

A list of all ingoing substances in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS No, No and INCI designations, DID No[17] (if existing), its function, form and concentration in mass percentage (including and excluding water), regardless of concentration in the final product formulation. All listed substances present in the form of nanomaterials shall be clearly indicated on the list with the word 'nano' written in brackets.

[17] *DID No is the number of the ingoing substance on the DID list*

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[18] shall be provided. 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.

The Appendix makes reference to the 'Detergent Ingredient Database' list (DID list) which contains the most widely used ingredients in detergents and cosmetics formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) (criterion 1) and for the assessment of the biodegradability (criterion 2) of the ingoing substances. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website[19] or via the websites of the individual competent bodies.

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.

b) Measurement thresholds

Compliance with the ecological criteria is required for all substances as specified in Table 2.

Table 2. Threshold levels applicable to substances for cosmetic products (% weight by weight), shown by criterion

Criterion name	Preservatives	Colorants	Fragrances	Impurities	Ingoing substances (e.g. surfactants, enzymes, UV filters)

[18] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)*

[19] *http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf,*

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) (rinse-off only)		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,010	no limit (*1)
Criterion 2. Biodegradability	Criterion 2 (a) (rinse-off and leave – on)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,010 (rinse-off) ≥ 0,001 (leave-on)	no limit (*1*2)
	Criterion 2 (b) (i) (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,010	no limit (*1)
	Criterion 2 (b) (ii) (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,001	no limit (*1*3)
Criterion 3. Excluded or limited substances and mixtures	Criterion 3 (a) (i) (rinse-off)	≥ 0,010	≥ 0,010	≥ 0,010	≥ 0,010	≥ 0,010
	Criterion 3 (a) (i) (leave-on)	≥ 0,001	≥ 0,001	≥ 0,001	≥ 0,001	≥ 0,001
	Criterion 3 (a) (ii) (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (a) (ii) (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (a) (iii) (rinse-off)	no limit (*1*4)	no limit (*1*4)	no limit (*1*4)	≥ 0,010	no limit (*1*4)

	Criterion 3 (a) (iii) (leave-on)	no limit (*1*4)	no limit (*1*4)	no limit (*1*4)	≥ 0,001	no limit (*1*4)
	Criterion 3 (b) (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (b) (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (c) (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (c) (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (d) (rinse-off)	N/A	N/A	no limit (*1)	N/A	N/A
	Criterion 3 (d) (leave-on)	N/A	N/A	no limit (*1)	N/A	N/A
	Criterion 3 (e) (rinse-off)	no limit (*1)	N/A	N/A	N/A	N/A
	Criterion 3 (e) (leave-on)	no limit (*1)	N/A	N/A	N/A	N/A
	Criterion 3 (f) (rinse-off)	N/A	no limit (*1)	N/A	N/A	N/A
	Criterion 3 (f)	N/A	no limit (*1)	N/A	N/A	N/A

	(leave-on)					
	Criterion 3 (g)	N/A	N/A	N/A	N/A	no limit (*1)
Criterion 5. Renewable ingredients	Criterion 5 (a)	N/A	N/A	N/A	N/A	no limit (*1)
	Criterion 5 (b) (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,010	no limit (*1)
	Criterion 5 (b) (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,001	no limit (*1)

(*1) 'no limit' means: regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection).

(*2) Surfactants with cleaning and/or foaming function in toothpastes are exempted

(*3) UV filters are exempted from this requirement

(*4) substances listed in Annexes IV and V to Regulation (EC) No 1907/2006 are exempted

(The assessment and verification has been slightly modified in ANNEX II for animal care products)

Rationale of the proposed general text of Assessment and Verification

The assessment and verification text refers to the different types of evidence that is considered relevant as a proof of compliance for each criterion. The text has been revised to harmonize it as far as appropriate with the text which is included in the most recently adopted EU Ecolabel criteria.

The EU Ecolabel Regulation (EC) No 66/2010 indicates that competent bodies shall preferentially recognize verifications performed by bodies which are accredited under the EN 45011. However, this standard is nowadays phased-out since it has been substituted by ISO/IEC 17065:2012: Conformity assessment - Requirements for bodies certifying products, processes and services.

For the first proposal included in TR1.0:

- Test was aligned with recently voted products.
- Where appropriate, test methods other than those indicated for each criterion may be used if the Competent Body assessing the application accepts their equivalence.
- The reference to the function and form present in the final product was maintained in order to enable traceability of nanomaterials present in products

based on a precautionary principle. The same horizontal approach has been followed in other product categories.

- A text regarding the prerequisite that the applicant shall meet all applicable legal requirements of the country/ies in which the product is placed on the market was added as this is a legal pre-requisite and applies horizontally for all EU Ecolabel products.
- Section *"(b) Measurement thresholds"* was removed from this general assessment and verification section as the applicability of each criterion is proposed to be indicated in the text of each single criteria to ensure more clarity.

Outcomes from and after the 1st AHWG meeting

No major comments were received.

Further research and main changes in the second proposal

Minor wording changes have been introduced in the second proposal in line with other product groups. In addition, in order to increase the clarity of the EU Ecolabel criteria, the 'measurement thresholds' section has been reintroduced, and the table indicating the scope of each requirement in terms of threshold limit has been included in the assessment and verification, taking the table included in Detergents product group as a reference.

3 CRITERIA PROPOSAL

3.1 CRITERION 1: Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

Existing criterion 1: Toxicity to aquatic environment

The total CDV toxicity of the product shall not exceed the limits in Table 1:

Table 1

CDV limits

Product	CDV (l/g AC)
Shampoo, shower preparations and liquid soaps	**18 000**
Solid soaps	**3 300**
Hair conditioners	**25 000**
Shaving foams, shaving gels, shaving creams	**20 000**
Shaving solid soaps	**3 300**

The CDV is calculated using the following equation:

$$\text{CDV} = \sum \text{CDV (ingoing substance i)} = \sum \text{weight (i)} \times \text{DF (i)} \times 1000/\text{TF chronic (i)}$$

Where:

weight (i)—is the weight of the ingoing substance (in grams) per 1 gram of AC (i.e. normalised weight contribution of the ingoing substance to the AC)

DF (i)—is the degradation factor of the ingoing substance

TF chronic (i)—is the toxicity factor of the ingoing substance (in milligrams/litre)

Assessment and verification: the applicant shall provide the calculation of the CDV of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website. The values of DF and TF chronic shall be as given in the DID list-part A. If the ingoing substance is not included in the DID list-part A, the applicant shall determine the values using the guidelines described in the DID list-part B and attaching the associated documentation (for more information see the Appendix).

--------Appendix (excerpt) -------

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information of the aquatic toxicity and biodegradability of ingredients typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances

present on the DID list are not automatically approved for use in EU Ecolabelled products.

Part A and Part B of the DID list can be found on the EU Ecolabel website at:

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

	Acute toxicity			Chronic toxicity			Degradation		
Ingoing substance	LC50/ EC50	SF (acute)	TF (acute)	NOEC (1)	SF (chronic) (1)	TF (chronic)	DF	Aerobic	Anaerobic
'Name'	1 mg/l	10,000	0,0001			0,0001	1	P	N

(1) If no acceptable chronic toxicity data are found, these columns are empty. In this case, TF(chronic) is defined as equal to TF(acute).

Annex I: Second proposal for criterion 1: Toxicity to aquatic environment for cosmetic products

This criterion applies to final products. This criterion applies to rinse-off products only.

The total CDV toxicity of the rinse-off product as specified in Table 3 shall not exceed the following limits:

Table 3 CDV limits

Product	CDV (l/g AC)
Shampoo, shower preparations and soaps (liquid form)	11 000
Feminine hygiene cosmetic products	12 000
Shampoos and soaps and shaving soaps (solid and dry form)	2 200
Hair conditioners	12 000
Toothpaste and mouthwash	12 000
Shaving foams, shaving gels, shaving creams	12 000
Rinse-off skin care products (exfoliants)	12 000
Rinse-off hair styling and treatment products (hair dyes)	12 000

The CDV is calculated using the following equation:

$$CDV = \Sigma CDV \text{ (ingoing substance i) (l/gAC)} = \Sigma \text{ weight (i) x DF (i) x 1000/TF chronic (i) (mg/l)}$$

Where:

weight (i)—is the weight of the ingoing substance (in grams) per 1 gram of AC (i.e. normalised weight contribution of the ingoing substance to the AC)

DF (i)—is the degradation factor of the ingoing added substance

TF chronic (i)—is the toxicity factor of the ingoing added substance (in milligrams/litre)

Assessment and verification: the applicant shall provide the calculation of the CDV of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website. The values of DF and TF chronic shall be as given in the DID list-part A. If the ingoing substance is not included in the DID list-part A, the applicant shall determine the values using the guidelines described in the DID list-part B and attaching the associated documentation (for more information see the Appendix).

--------Appendix (excerpt) -------

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information of the aquatic toxicity and biodegradability of ingredients typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabel products.

Part A and Part B of the DID list can be found on the EU Ecolabel website at:

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

	Acute toxicity			**Chronic toxicity**			**Degradation**		
Ingoing added substance	**LC50/ EC50**	**SF (acute)**	**TF (acute)**	**NOEC (1)**	**SF (chronic) (1)**	**TF (chronic)**	**DF**	**Aerobic**	**Anaerobic**
'Name'	**1mg/l**	**10,000**	**0,0001**			**0,0001**	**1**	**P**	**N**

(1) If no acceptable chronic toxicity data are found, these columns are empty. In this case, TF (chronic) is defined as equal to TF (acute).

Annex II: Second proposal for criterion 1: Toxicity to aquatic environment for animal care products

This criterion applies to final products.

The total CDV toxicity of the product shall not exceed the limits in Table 1:

Table 2 **CDV limits**

Product	**CDV (l/g AC)**
Animal care products	**12 000**

[The rest of text same as text included in annex I]

Rationale of the proposed criterion text

The Critical dilution volume (CDV) is used in the EU Ecolabel as an indicator to assess the toxicity of products with respect to the aquatic environment. This criterion is especially relevant for rinse-off products which are released to water during the use phase or after use.

The CDV represents a risk-based parameter that combines the amount used, the (aerobic) biodegradability and the aquatic toxicity of all substances present in the cosmetic formulation.

The CDV expresses the amount of water needed for the hypothetical dilution of a product down to a harmless concentration for the aquatic environment. The unit is expressed in litres per functional unit. It is calculated based on the chronic toxicity and chronic safety factors. If no chronic test results are available, the acute toxicity and safety factor must be used.

The actual CDV calculation method, as given in the currently valid criteria document, refers to 1g of "active content" (AC), which is defined as the weight of organic ingredients in the product. The AC is calculated based on the entire formulation of a product. Water is not included in the calculation of AC. Rubbing/abrasive agents are not included in the calculation of AC. So, the CDV of each substance is linked to the share (%) of other substances. As a consequence, the more substances are added, the less the CDV of dangerous substances is important and the CDV can be decreased by adding substances.

During the previous revision in 2013, to the possibility of modifying the method for CDV calculation was considered; however finally it was decided to keep the calculation as it was in criteria from 2007[2]. Details of the discussions carried out during last revision process are available in previous revision technical report[20].

Out of the EU Ecolabel questionnaire sent out to stakeholders at the beginning of this revision (march 2019), 56% of the respondents considered the current limits for CDV to be adequate, while 16% did not agree with the current criterion and thresholds:

[20]https://susproc.jrc.ec.europa.eu/Rinse-off_cosmetic_products/docs/Rinse-off%20cosmetics-TECHNICAL%20REPORT_after%20ISC%20consultation_20.05.2013.pdf

6% of the respondents considered the limits too restrictive (industry representatives), while other 10% of them think that they should be more restrictive.

In order to align the EU Ecolabel with other regional ecolabels, during the first revision (TR1.0) it was suggested that existing CDV thresholds were lowered. The threshold values for "shampoo, shower preparation and liquid soaps" were lowered to 11000 l/g AC based on the maximum value available for the EU Ecolabel certified products (more information available in TR1.0[4]).

Thresholds for other product categories (for which no EU Ecolabel products exist) were aligned to Nordic Swan. The product groups "Hair conditioners" and "shaving foams, shaving gels, shaving creams", which currently present relaxed thresholds due to the lack of data in previous revision, were also aligned to Nordic Swan. Based on available hair conditioners data, existing EU Ecolabel licences (for at least 2 products) should be able to achieve the stricter value proposed in the first proposal (TR1.0).

The newly included product categories were assigned a CDV threshold of 12000 l/g AC, in line with Nordic Swan.

Outcomes from and after 1st AHWG meeting

Different stakeholders welcomed the reduction of the threshold values. The alignment with Nordic Swan ecolabel has been well received. Specific comments on the different product categories considered have been received:

- The threshold value for shampoo, shower preparation and liquid soaps can be lowered further, considering that CDV values in Nordic Swan criteria are expected to be restricted due to the upcoming revision process.
- Differentiating between the products shampoo, shower preparations and liquid soaps can help to better define the thresholds for these products.

On the other hand, some stakeholders believed that current CDV values for solid soaps seems already to be too restrictive, as reflected by the low number of ecolabelled solid soaps, and an additional decrease in values is not feasible. Nevertheless, other comments were also received during the AHWG1 pointing that the lower number of licences for solid soaps could be related to consumers' habits. Considering the feedbacks received, further analysis on the characteristics of solid soaps is needed.

Additional data have been provided by CB and industries on CDV values of products certified with the EU Ecolabel. In total, data of 120 currently EU ecolabelled products from 7 countries (France, Austria, Spain, Estonia, Italy, Sweden, Norway) were obtained. However, these only represent 5% of the total amount of products certified with EU Ecolabel (2270 ecolabelled products are currently available on the market).

Different stakeholders pointed out that fragrances and perfumes are an important ingredient for cosmetic products; however, a high amount of perfumes in a product could lead to high CDV values. On the other hand, other stakeholders welcomed lower CDV values to enable the consumer to choose between product with or without fragrances and perfumes.

Regarding the calculation methods, the possibility of considering other alternatives than CDV values for assessing the toxicity to aquatic organism was discussed during the AHWG1 and comments were received during the subsequent consultation period.

Stakeholders proposed to define the thresholds as in detergents products: based on the use of the product or the reference dosage.

Further research and main changes in the second proposal

- *Threshold proposal*

Information provided by CBs after the 1st AHWG has been analysed in order to make a second proposal of threshold values. The new results are presented in Table 6 The category of "shampoo, shower preparations and liquid soaps" has been divided in individual products in order to differentiate the threshold values for each product. If the CDV values proposed in the first draft (TR1.0) of the criterion were adopted, the changes would affect one EU Ecolabelled product (hair conditioners category) which would not be compliant anymore.

Table 6. CDV descriptive statistics of analysed ecolabelled products and current limits of the Criterion 1. *Source: information provided by CBs*

Product	Current CDV limits (l/g AC)	TR1.0 CDV limits (l/g AC)	Range	Average	50th percentile	75th percentile
Liquid soaps (60 products)	18 000	11 000	214,9 – 10 842,4	6 374,9	6 826,3	8 388,0
Shampoos (23 products)	18 000	11 000	3 507,3 – 10 408,6	8 391,8	10 408,6	10 408,6
Shower preparations (24 products)	18 000	11 000	4 173,0 – 11 344,8	8 811,6	9 161,9	10 397,0
Solid soaps (7 products)	3 300	2 000	1 621,0 – 2 185,4	1 932,0	1 960,8	2 074,9
Hair conditioners (6 products)	25 000	12 000	2 956,9 – 19 047,0	6 797,6	4 159,7	6 528,4

For the second proposal, considering the possibility that Nordic Swan thresholds would be lowered during the upcoming revision of the scheme, **the CDV limits for "shampoo, shower preparations and liquid soaps" have been maintained as strict as in the first proposal (11 000 l/g AC)**.

The threshold value proposed in TR.1.0 for solid soaps was based on the existing limits of Nordic Swan. In the second revision, the threshold value has been slightly relaxed in order to include all the products currently certified under this product category (there are two licences with values above 2 000that would not be compliant otherwise). **The new threshold value for solid cosmetic products is 2 200 l/g AC**.

For other product categories proposed to be included in the scope, 12 000 l/g AC was proposed as CDV threshold value, aligning with Nordic Swan ecolabel.

According to the Nordic Swan approach, toothpastes are not considered rinse-off products and they do not have to comply with the Critical Dilution Volume requirement[24]. In this process revision, toothpaste is considered a rinse-off product, and the product should comply with the requirements included in Criterion 1. Data on CDV values of toothpaste will be welcomed and used to define the threshold value for these products, which are temporarily left blank.

Finally, **the threshold value for animal care products has not been modified from the first proposal**, considering that there are products currently certified under Nordic Swan ecolabel with a CDV threshold value of 12 000l/g AC.

- *Calculation method: USEtox*

Some stakeholders expressed their concern on the use of CDV as an indicator for toxicity to the aquatic environment and proposed the use of USEtox score instead. A short comparison of USEtox and CDV methods is given below.

USEtox is the UNEP/SETAC scientific consensus model for characterizing human and ecotoxicological impacts (i.e. calculating characterization factors) of chemical emissions in LCA and other comparative toxicity assessments including product environmental footprinting (PEF)[21]. The USEtox score is focused on the potential toxicity of persistent-water-soluble chemicals under a steady state assumption.

USEtox employs a multi-compartment fate model that allows emissions to receiving compartments air/water/soil to re-distribute. Conversely, emissions to air and soil cannot currently be considered in CDV, thus resulting in a less complete fate modelling.

In USEtox, a geometric mean based on all available ecotoxicity data is used to assess freshwater toxicity because this approach is considered more statistically robust to derive the effect factor. Conversely, in CDV the most sensitive trophic level is retained for the calculation of the effect factor, which may therefore result being more environmental realistic[22].

With USEtox a persistent and very toxic chemical may contribute very little to the total aquatic freshwater product toxicity score, because the model considers that the chemical will not reach in the aquatic freshwater compartment. On the other hand, CDV estimates the potential product toxicity of all chemicals in the formula of the product. For this reason, with the CDV method a persistent and vey toxic chemical will contribute heavily to the total product score (independently if the chemical reach or not the aquatic freshwater compartment).

CDV is simple to apply since only two parameters are required per substance; furthermore, the DID-list facilitate the calculation of such parameters. To calculate the USEtox, a high number of parameters is needed[22].

Both methodologies may be used complementarily. However, the introduction of the USEtox method would make the verification method more complex and costlier. For this reason, **the introduction a new methodology to assess the toxicity of the products is not proposed in this revision.**

- *Reference unit: dosage or active content*

The CDV is calculated based on the active content because the dose cannot be always determined. Only for the products with dispenser, the dosage can be controlled. Nevertheless, the consumer behaviour cannot be controlled, and the dose used in each application is not easy to estimate. Moreover, determining standard doses for

[21] ECETOC, 2016. Freshwater ecotoxicity as an impact category in life cycle assessment. Technical Report No. 127. Brussels, ISSN-2079-1526-127 (online)

[22] Fantke, P., 2017. USEtox 2.0, Documentation, ISBN: 978-87-998335-0-4, DOI: 10.11581/DTU:00000011

shampoos and hair conditioners would not be straightforward e.g. the dosage is dependent to the length of the hair washed.

- *Summary of changes*

In summary, the main changes introduced to criterion 1 in TR2.0 are:

- The CDV threshold values for solid cosmetic products have been defined as 2200 l/g AC.
- For the skin care products it has been specified that it refers to rinse off (exfoliants)
- For shaving foams, shaving gels and shaving creams, 12000 l/g AC has been proposed as CDV threshold value.
- New products on the scope have been included aligned to Nordics Swan threshold.

Question to stakeholders
Stakeholders are requested to provide data on CDV values of proposed categories, especially for toothpastes, mouthwashes, shaving products and hair dyes.

Rationale of proposed "assessment and verification"

Regarding the verification procedure, 56% of the questionnaire respondents considered the current verification procedure clear and appropriate against 16% of respondents that disagreed with the current verification method. Nevertheless, most of the problems encountered are related with the DID-list (which is considered not user friendly), and the calculation of the toxicity factor (TF) and degradation factor (DF) when a substance is not included in this list.

For the verification of the criterion, 66% of the stakeholders used the spreadsheet available on the EU Ecolabel website and 33% of them considered it was not easy to use.

No changes have been introduced in the verification text in this second revision.

3.2 CRITERION 2: Biodegradability

Existing criterion 2: Biodegradability

a) Biodegradability of surfactants

All surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.

(b)Biodegradability of organic ingoing substances

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 2:

Table 2

aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Shampoo, shower preparations and liquid soaps	**25**	**25**
Solid soaps	**10**	**10**
Hair conditioners	**45**	**45**
Shaving foams, shaving gels, shaving creams	**70**	**40**
Shaving solid soaps	**10**	**10**

Assessment and verification: the applicant shall provide documentation for the degradability of surfactants, as well as the calculation of aNBO and anNBO for the product. A spreadsheet for calculating aNBO and anNBO values is available on the EU Ecolabel website.

For both surfactants and aNBO and anNBO values, reference shall be done to the DID list. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided as described in the Appendix.

In the absence of documentation in accordance with the above requirements, an ingoing substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:

1. Readily degradable and has low adsorption (A < 25 %);
2. Readily degradable and has high desorption (D > 75 %);
3. Readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106.

--------Appendix (excerpt) -------

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1)Until 1 December 2015:

The test methods for ready biodegradability provided for in Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10 days window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

or

The test methods provided for in Regulation (EC) No 1272/2008

(2) After 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008

Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate degradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list, the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

(1)Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable

(e.g., C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)).

(2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.

(3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by 14C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.

Annex I: Second proposal for criterion 2: Biodegradability

This criterion shall be fulfilled by each ingoing added substance.

a) Biodegradability of surfactants

All surfactants shall be readily biodegradable under aerobic conditions.

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.

The following are exempt from the requirement on anaerobic biodegradability:

Surfactants with cleaning and/or foaming function in toothpastes

b) Biodegradability of organic ingoing substances

(i) Rinse-off products:

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 4:

Table 4 aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Shampoo and liquid soaps	25	25
Shower preparations	20	20
Solid soaps/shampoos	10	10
Hair conditioners	20	20
Shaving foams, shaving gels, shaving creams	70	40
Shaving solid soaps	10	10
Feminine hygiene cosmetic products	15	15
Toothpastes, mouthwashes	15	15
Rinse-off skin care products (exfoliants)	15	15
Rinse-off hair styling and treatment products (hair dyes)	15	15

(ii) Leave-on products:

At least 95% by weight of the total content of organic ingoing substances must be:

- *readily biodegradable (OECD 301 A-F), and/or*
- *lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulable, and/or*
- *lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or*
- *lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)*

Exempt are:

- *UV filters in sun products*
- *fibre material in wet wipes*

Assessment and verification: the applicant shall provide documentation for the degradability of surfactants, as well as the calculation of aNBO and anNBO for the product. A spreadsheet for calculating aNBO and anNBO values is available on the EU Ecolabel website.

For both surfactants and aNBO and anNBO values, reference shall be done to the DID list. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided as described in the Appendix.

In the absence of documentation in accordance with the above requirements, an ingoing substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:

1. Readily degradable and has low adsorption (A < 25 %);
2. Readily degradable and has high desorption (D > 75 %);
3. Readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106.

--------Appendix (excerpt) -------

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1)Until 1 December 2015:

The test methods for ready biodegradability provided for in Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10 days window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

or

The test methods provided for in Regulation (EC) No 1272/2008

or

Regulation (EC) No 1907/2006 foresees in Annex XI that the standard testing regime can be adapted by de use of non-tested methods such as qualitative or quantitative structure-activity relationship (Q(SAR) models).

(2)After 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008

or

Regulation (EC) No 1907/2006 foresees in Annex XI that the standard testing regime can be adapted by de use of non-tested methods such as qualitative or quantitative structure-activity relationship (Q(SAR) models).

Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate degradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list, the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

(1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)). 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.

(2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.

(3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by 14C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.

Documentation of bioaccumulation

The following test methods for bioaccumulation shall be used:

(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.

The OECD 305 test on fish. For a BCF < 500 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.

(2)After 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent with the requirement of < 100 or log Kow is < 3,0.

Annex II: Second proposal for criterion 2: Biodegradability for Animal Products

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.

a) Biodegradability of surfactants

Same as text included in annex I.

b) Biodegradability of organic ingoing added substances

The content of all organic intentionally added substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 3:

Table 3 aNBO and anNBO limits

Product	**aNBO (mg/g AC)**	**anNBO (mg/g AC)**
Animal care products	**15**	**15**

Assessment and verification: "Same as text included in annex I"

Rationale of the proposed criterion text

Criterion 2 is divided in two parts:

- Biodegradability of surfactants
- Biodegradability of organic ingoing substances

Basic elements used for classification of aquatic environmental impacts are: Acute aquatic toxicity; Potential for actual bioaccumulation; Degradation (biotic or abiotic) for organic chemicals; and Chronic aquatic toxicity. Substances that rapidly degrade can be quickly removed from the environment. In the absence of rapid degradation in the environment a substance in the water has the potential to exert toxicity over

a wide temporal and spatial scale[23]. Surfactants in this respect are considered relevant due to the fact that they are used in high amounts in liquid soaps, shampoos and conditioners[24].

Most surfactants affect to a greater or lower extent the product toxicity to aquatic organisms due to their surface activity which allows reaction with the biological membranes of the organisms. The biological degradability varies according to the nature of the carbohydrate chain of the surfactant.

During the last revision in 2013 main discussions arose on the issue if, from the environmental point of view, all surfactants should be readily aerobically and anaerobically biodegradable. Some participants strongly supported the requirement for all surfactants to be readily aerobically and anaerobically biodegradable; other stakeholders disagreed with the importance of the anaerobic biodegradability and questioned its environmental relevance[25] as well as the feasibility of fulfilling the respective criterion. Finally, based on the scientific evidence detailed in previous technical report[20], it was proposed to keep the proposal from the previous draft stating that all surfactants should be readily aerobically and anaerobically biodegradable.

The threshold values for aerobic and anaerobic biodegradability were extensively discussed with the stakeholders during last revision. Main concerns regarding decreasing too much the values in the criterion on biodegradability of organic substances was related to the consequences for the possibility of using perfumes in the product group under study. It was pointed out that important part of non-biodegradable substances can be assigned to fragrances; thus the concentration of perfume has direct influence on the biodegradability of the product.

According to the feedbacks received in the questionnaire launched in March 2019, in general stakeholders agree with sub-criterion a) on Biodegradability of surfactants; only 1 stakeholder considers that this criterion is not adequate claiming that only surfactants which are not anaerobically biodegradable are of relevance from the environmental point of view.

In relation to sub-criterion b) on biodegradability of organic substances, 16% of stakeholders would modify the requirement for the aerobic biodegradability and 24% of them would modify the requirement for anaerobic biodegradability of organic substances in the product. They point out that it is not possible to use some ingredients when aNBO and anNBO values are not available, as calculating the biodegradability of an ingredient is expensive; therefore manufacturers prioritize the inclusion of ingredients with biodegradability data. One stakeholder added that due to this fact the creativity level in EU Ecolabel products formulation is very limited. On the contrary, 8% of respondents consider that thresholds should be more restrictive.

[23] Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.

[24] Nordic Ecolabelling of cosmetic products Version 2.1 Background document regarding ecolabelling 16 February 2011.

[25] Scientific Committee on Health and Environmental Risks (SCHER), "Opinion on Anaerobic Degradation of Surfactants and Biodegradation of Non Surfactant Organic Ingredients", November 2008, available online at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_109.pdf.

An analysis of other ecolabels (Nordic Swan, Blue Angel and Bra Miljöval) was performed in TR1.0 to study how biodegradability and bioaccumulation was addressed in other schemes. Considering this background it was proposed:

- To reduce hair conditioner biodegradability values (aNBO and anNBO) to 15 mg/g AC.
- In line with Nordic Swan, a threshold of 15 mg/g was proposed for the rinse-off categories (feminine hygiene cosmetic products, toothpastes, rinse-off skin care products) suggested to be include in the TR1.0 scope.
- Specific restrictions were proposed for leave-on products.

Outcomes from and after 1st AHWG meeting

During the AHWG1 meeting and from gathered comments, the following issues were addressed by different stakeholders and CBs:

- It was detected a general interest to lower aNBO and anNBO limits for organic substances and to align with Nordic Swan Ecolabel.
- The possibility to divide the category "Shampoo, shower preparations and liquid soaps" into three different sub-categories to adjust better the thresholds was suggested.
- Stakeholders and CBs expressed pros and cons of the exemption for surfactants in toothpastes.
- Concern about the exemption proposed for sunscreens was detected, arguing that these products contain a high concentration of UV filters and they are not biodegradable.
- One stakeholder proposed to exempt from the requirement of anaerobic biodegradation all surfactants not classified for the environment (i.e. no H400, H410, H411, H412 or H413).

Data from 120 currently EU ecolabelled products from 7 countries (France, Austria, Spain, Estonia, Italy, Sweden and Norway) were made available by stakeholders, enabling further analysis.

Further research and main changes in the second proposal

- *Alignment of aNBO and anNBO limits with Nordic Swan scheme*

New aNBO and anNBO data has been received after the 1st AHWG meeting. The threshold values of Nordic Swan have been assessed and checked against the new information provided by CBs to identify the effects of the alignment of the aNBO and anNBO values. All rinse-off products for which data were provided include surfactants in their formulation. Regarding the compliance with the requirement on aerobic non-biodegradability of the products included in the category shampoo, shower preparations and liquid soaps currently certified as EU Ecolabel, the maximum threshold is 25.0 mg/g AC, with 21.9 mg/g AC as 75th percentile (Table 7**Error! Reference source not found.**).

Table 7. Aerobic non-biodegradability descriptive statistics of analysed ecolabelled products and current limits of the Criterion 2.

Product	Current aNBO (mg/g AC)	Information provided			
		Range	Average	50th percentile	75th percentile
Shampoo, shower preparations and liquid soaps (107 products)	25	0,0 – 25,0	13,0	12,0	21,9
Solid soaps (4 products)	10	4,5 – 7,1	6,0	6,1	6,8
Hair conditioners (6 products)	45	8,3 – 17,2	10,9	9,0	12,5
Shaving foams, shaving gels and shaving creams	70	-	-	-	-
Shaving solid soaps	10	-	-	-	-

For the anaerobic non-biodegradability, the situation is similar to that of aerobic non-biodegradability. The maximum biodegradability and the 75th percentile values are the same as for the aerobic non-biodegradability (Table 8). Nevertheless, the average of anaerobic non-biodegradable ingredients is higher than the average of aerobic non-biodegradable ingredients, indicating that the products have more ingredients with higher values of anaerobic non-biodegradability.

Table 8. Anaerobic non-biodegradability descriptive statistics of analysed ecolabelled products and current limits of the Criterion 2.

Product	Current anNBO (mg/g AC)	Information provided			
		Range	Average	50th percentile	75th percentile
Shampoo, shower preparations and liquid soaps (107 products)	25	0,0 – 25,0	15,6	16,7	23,2
Solid soaps (4 products)	10	4,7 – 9,7	6,8	6,4	7,7
Hair conditioners (6 products)	45	9,3 – 13,6	17,5	12,5	16,3
Shaving foams, shaving gels and shaving creams	40	-	-	-	-
Shaving solid soaps	10	-	-	-	-

The following table (Table 9) summarizes what would happen if aNBO and anNBO thresholds of EU Ecolabel were aligned with Nordic Swan limit values. The second column details the number of products for each category or sub-category for which information has been received. The third column summarizes the current biodegradability (aerobic and anaerobic) thresholds in EU Ecolabel, followed by the number and percentage of products within existing EU Ecolabel thresholds (100%, evidently).

Table 9. Effects of the EU Ecolabel biodegradability values alignment with Nordic Swan thresholds.

Product	Products with provided information	Current **aNBO** EU Ecolabel (mg/g AC)	Compliant products with current thresholds	Proposed **aNBO** in TR1.0 (mg/g AC)	Compliant products with proposed thresholds	Current **aNBO** in Nordic Swan (mg/g AC)	Compliant products with Nordic Swan thresholds
Shampoos	23	25	23 (100%)	25	23 (100%)	15	6 (26,1%)
Shower preparations	24	25	24 (100%)	25	24 (100%)	15	18 (75%)
Liquid soaps	60	25	60 (100%)	25	60 (100%)	15	38 (63,3%)
Solid soaps	4	10	4 (100%)	10	4 (100%)	5	1 (25%)
Hair conditioners	6	45	6 (100%)	15	5 (83,3%)	15	5 (83,3%
Product	Products with provided information	Current **anNBO** EU Ecolabel (mg/g AC)	Compliant products with current thresholds	Proposed **anNBO** in TR1.0 (mg/g AC)	Compliant products with proposed thresholds	Current **anNBO** in Nordic Swan (mg/g AC)	Compliant products with Nordic Swan thresholds
Shampoos	23	25	23 (100%)	25	23 (100%)	15	5 (21,7%)
Shower preparations	24	25	24 (100%)	25	24 (100%)	15	17 (70,8%)
Liquid soaps	60	25	60 (100%)	25	60 (100%)	15	28 (46,7%)
Solid soaps	4	10	4 (100%)	10	4 (100%)	5	1 (25%)
Hair conditioners	6	45	6 (100%)	15	4 (66,7%)	15	4 (66,7%)

The fifth column details the biodegradability values proposed in the TR1.0, followed by the number and percentage of products that would be eligible for the EU Ecolabel according to such proposal. Two products would be cut out from the EU Ecolabel, both in the hair conditioners product category. The new data gathered on hair conditioners (6 products compared to the 2 products which were available at the time of writing the TR1.0) indicate that the thresholds proposed in the TR1.0 would be too strict.

The last two columns of the tables list the current biodegradability thresholds for Nordic Swan and the number and percentage of products that would be eligible for the EU Ecolabel if a complete alignment with Nordic Swan values was proposed. According to the data obtained from 117 products certified with the EU Ecolabel, if Nordic Swan limits are applied, a substantial number of products would be excluded from the EU certification.

A complete alignment with Nordic Swan is difficult, but a compromise should be reach. Therefore, a more gentle reduction of thresholds is proposed (Table 10).

Table 10. New proposed thresholds

	Products with provided information	Proposed **aNBO** and **anNBO** EU Ecolabel (mg/g AC)	Products with proposed **aNBO** thresholds	Products with proposed **anNBO** thresholds
Shampoos	23	20	7 (30%)	6 (26,09%)
Shower preparations	24	20	21 (87,5)	20 (83,3%)
Liquid soaps	60	20	44 (73,3)	34 (56,7%)
Solid soaps	4	10	4 (100%)	4 (100%)
Hair conditioners	6	20	6 (100%)	5 (83,3%)

If the threshold of aNBO and anNBO is reduced to 20 mg/g AC, only 26% of shampoo and 56% of liquid soaps would comply with the criterion, while in the case of shower

preparations and hair conditioners would comply 83,3%. Hence, **it is proposed to reduce the thresholds of shower preparations and hair conditioners to 20 mg/g AC.**

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.**

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.**

- *Subdivide the thresholds for the category "Shampoo, shower preparations and liquid soaps"*

According to the new proposed threshold for shower preparations (20mg/g AC), the category "shampoo, shower preparations and liquid soaps" has been divided in two subcategories: "shampoo and liquid soaps" (with threshold 25mg/g AC) and "shower preparations" (with threshold 20mg/g AC).

- *Inclusion of new categories in the requirement*

Feminine hygiene products, toothpastes, rinse-off skin care products and leave-on products have been integrated in Annex I of criterion 2 according the new proposed scope, and animal care products have been integrated in Annex II.

All thresholds of aerobic and anaerobic biodegradability of rinse-off products (including animal care products) and specific requirements for leave-on products have been aligned with Nordic Swan. Licences for all these products exist in Nordic Swan Ecolabel indicating that these thresholds and requirements can be achieved.

For leave-on products, specific requirements are proposed instead of aerobic and anaerobic biodegradability as the potential risk of release into water is low.

- *Inclusion of new exemptions*

Exemption of the requirement of anaerobic biodegradability for surfactants not classified for the environment (i.e. no H400, H410, H411, H412 or H413). One stakeholder proposed this exemption in alignment with the EU Ecolabel criteria for detergents.

Biodegradability criterion ensures that ingredients are biodegradable and will not persist in the environment, what is of high importance for rinse-off products. Chemicals that degrade rapidly can be quickly removed from de environment, while in the absence of fast degradation a substance present in the environment has the potential to exert toxicity over a wide temporal and spatial scale. Consequently, Ecolabelling schemes set requirements regarding degradability of ingredients.

Anaerobic biodegradability (by analogy with aerobic) is the breakdown in the environment of complex organic compounds into basic molecular forms. Aerobic oxidation, since it is in the presence of oxygen, tends to result in highly oxidised and hence chemically stable forms. On the other hand, anaerobic oxidation results in less oxidised forms as a consequence of low or no-oxygen reactions; these products may therefore react further when exposed to an oxygen-rich environment In the last revision of EU Ecolabel criteria for detergents the exemption of this requirement was

extensively discussed.[26,27] Split views were expressed by stakeholders along the criteria revision process regarding the relevance of the requirement on anaerobic biodegradability. Finally, JRC proposed to link the requirement of anaerobic biodegradability with the hazardous profile of the surfactants, and consequently, potential environmental impacts. If surfactants are not classified for the environment (i.e. no H400, H410, H411, H412 or H413), in theory there is no negative impact on the environment and consequently it is not necessary that the surfactants be anaerobically biodegradable.

In Nordic Swan the only surfactants exempt of the requirement of anaerobic biodegradability are surfactants with emulsifying function and surfactants with cleaning function in toothpastes.

Exemption of the requirement of anaerobic biodegradability for surfactants in toothpastes. During the AHWG1 stakeholders were asked about the possibility to exempt surfactants on anaerobic biodegradability in toothpastes. The objective of this exemption is to facilitate the formulation of these products, as Sodium Lauryl Sulphate (a very used surfactant in non-Ecolabel products) is banned in EU Ecolabel according to criterion 3 (b). Being SLS a widely used surfactant it is proposed to exempt from anaerobic degradability all other surfactants with cleaning or foaming function, in line with Nordic Swan proposal, in order to increase the formulation creativity for different toothpastes.

Taking into account the definitions of surfactants the text of exempt substances from the requirement on anaerobic degradability has been clarified and is proposed as follows:

"The following are exempt from the requirement on anaerobic biodegradability:

Surfactants with cleaning and/or foaming function in toothpaste"

Summary of changes

In summary, the main changes introduced to criterion 2 in TR2.0 are:

- The aNBO and anNBO thresholds of shower preparations and hair conditioners have been lowered to 20 mg/g AC.
- The category "shampoo, shower preparations and liquid soaps" has been divided in "shampoo and liquid soaps" and "shower preparations".
- New rinse-off product categories (mouthwash, solid shampoos and hair dyes) have been included.
- Biodegradability limits for rinse-off products and specific requirement for leave-on products have been proposed according to Nordic Swan.

[26] https://susproc.jrc.ec.europa.eu/detergents/docs/ELS-DP_D2_0915.pdf

[27] https://susproc.jrc.ec.europa.eu/detergents/docs/ELS-DP_2_15-01-2015.pdf

- It is suggested that requirement on anaerobic biodegradability does not apply to surfactants not classified for the environment and surfactants with cleaning and/or foaming function in toothpastes.

Question to stakeholders
Opinions on the exemptions for criterion 2 are welcome. Stakeholders are requested to provide data on biodegradability values of newly proposed categories.

Rationale of proposed assessment and verification

According to 14% of the respondents of the questionnaire, the current verification procedure is not appropriate because the information required is not always available. Data for anaerobic non-biodegradability are difficult to obtain as they are not mandatory in REACH regulation, and in some cases suppliers of raw materials do not want to share the results of biodegradability tests.

No changes were introduced in the verification text for the first proposal.

Outcomes from and after 1st AHWG meeting

One stakeholder highlighted that although anaerobic non-biodegradability data is difficult to obtain as it is not mandatory in REACH regulation, it is important to keep this requirement. This stakeholder proposed to give incentives as a measure to generate new data.

Regarding the generation of new data, another stakeholder proposed that, in those cases where suppliers of raw materials do not want to share the results of biodegradability tests, the use of Q(SAR) calculations would allow an improved verification of this criterion.

Finally, one stakeholder asked for tests to prove the bioaccumulation of a substance.

Further research and main changes in the second proposal

- *QSAR models*

Under REACH, testing on vertebrate animals shall be used as a last resort to fulfil information requirement for registration. To avoid the use of these animals, different alternatives have been investigated, such as QSAR models. The use of quantitative structure-activity relationship (QSAR) calculations are mathematical models that can be used to estimate physicochemical properties, and for some environmental toxicity and fate properties of substances from the knowledge of their chemical structures. The QSAR has to be scientifically validated and the analysed substance has to fall within the applicability domain of the model. The assessment depends on the software and on the target endpoint. Example of endpoints are log K_{ow}, ready

biodegradability, short-term toxicity to fish and acute mammalian toxicity, which are endpoints of requirements of REACH Annexes VII or VIII[28].

Therefore, the use of QSAR models to predict biodegradability could be one possibility in the cases where suppliers of raw material do not have the information or do not want to share it. Therefore, **QSAR models are proposed as new methodology to document biodegradability and bioaccumulation of raw materials.**

QSAR models were also accepted in the last EU Ecolabel revision for lubricants to obtain biodegradability information when these data are not available from raw material suppliers.

- *Bioaccumulation tests*

According to Regulation No. 1272/2008 bioaccumulation means the net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e. air, water, sediment/soil and food).

Bioaccumulation of substances within aquatic organisms can give rise to toxic effects over longer time scales, even when actual water concentrations are low. For organic substances the potential for bioaccumulation shall normally be determined by using the octanol/water partition coefficient, usually reported as a log K_{ow}. The relationship between the log K_{ow} of an organic substance and its bioconcentration as measured by the bioconcentration factor (BCF) in fish has considerable scientific literature support. Using a cut-off value of log $K_{ow} \geq 4$ is intended to identify only those substances with a real potential to bioconcentrate.

Nordic Swan Ecolabel has established that substances are bioaccumulating if log $K_{ow} \geq 4.0$ under the OECD's guidelines 107 or 117[29,30] or equivalent. Such a substance may be tested on fish in line with the OECD's testing instructions 305 A-E. However, as animal testing of ingredients for cosmetic products is banned from March 2009, only OECD test guideline no. 305 results obtained before this data may be used. If the substance has a biological concentration factor (BCF) ≥ 500 the substance is considered to be bioaccumulative, and if the BCF < 500 the substance is considered not to be bioaccumulative. If there is some measured BCF values, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

In Nordic Swan, results from data models (such as BIOWIN) are accepted, but if such results are close to the threshold values or if Nordic Swan Ecolabelling has contradictory data, further information may be required.

[28] Practical guide: How to use and report (Q)SARs, available online at: https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf/407dff11-aa4a-4eef-a1ce-9300f8460099

[29] https://www.oecd-ilibrary.org/environment/test-no-107-partition-coefficient-n-octanol-water-shake-flask-method_9789264069626-en

[30] https://www.oecd-ilibrary.org/environment/test-no-117-partition-coefficient-n-octanol-water-hplc-method_9789264069824-en

Summary of changes

In summary, the main changes introduced to assessment and verification of criterion 2 in TR2.0 are:

- **QSAR models and bioaccumulation tests have been introduced in the criterion text of this second proposal** as new methodologies to document biodegradability and bioaccumulation of raw materials.
- Furthermore, the following clarification has been added in the extrapolation approach: "Nevertheless, vice-versa if a structurally similar surfactant has been shown not to be anaerobically degradable", to confirm the no anaerobic biodegradability of a structurally related compound.

3.3 CRITERION 3: Excluded or limited substances and mixtures

Existing criterion 3: Excluded or limited substances and mixtures

(a) **Specified excluded ingoing substances and mixtures**

The following ingoing substances and mixtures shall not be included in the product, neither as part of the formulation nor as part of any mixture included in the formulation:

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives;
(ii) Nitrilo-tri-acetate (NTA);
(iii) Boric acid, borates and perborates;
(iv) Nitromusks and polycyclic musks;
(v) Octamethylcyclotetrasiloxane (D4);
(vi) Butylated Hydroxi Toluene (BHT);
(vii) Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates;
(viii) The following preservatives: triclosan, parabens, formaldehyde and formaldehyde releasers.
(ix) The following fragrances and ingredients of the fragrance mixtures: Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atranol and Chloroatranol;
(x) Micro-plastics;
(xi) Nanosilver.

Assessment and verification: the applicant shall provide a signed declaration of compliance supported by declarations from manufacturers of mixtures, as appropriate, confirming that the listed substances and/or mixtures have not been included in the product.

(b) Hazardous substances and mixtures

According to Article 6(6) of Regulation (EC) No 66/2010, the EU Ecolabel may not be awarded to any product that contains substances meeting criteria for classification with the hazard statements or risk phrases specified in Table 3 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (4) or Council Directive 67/548/EC (5) or substances referred to in Article 57 of Regulation (EC) No 1907/2006. In case the threshold for classification of a substance or mixture with a hazard statement differs from the one of a risk phrase than the former prevails. The risk phrases in Table 3 generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

Substances or mixtures which change their properties through processing and thus become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard are exempted from criterion 3(b).

Table 3

Hazard statements and Risk Phrases

Hazard Statement	Risk Phrase
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

For rinse-off cosmetic products, the substances in Table 4 are exempted from the obligation in Article 6(6) of Regulation (EC) No 66/2010 following application of Article 6(7) of the same Regulation.

Table 4

Derogated substances

Substances	Hazard statements	Risk phrases
Surfactants (in total concentrations < 20 % in the final product)	**H412: Harmful to aquatic life with long-lasting effects** **H413: May cause long-term adverse effects to aquatic life**	**R52-53** **R53**
Fragrances (6)	**H412: Harmful to aquatic life with long-lasting effects** **H413: May cause long-term adverse effects to aquatic life**	**R52-53** **R53**
Preservatives (7)	**H411: Toxic to aquatic life with long-lasting effects** **H412: Harmful to aquatic life with long-lasting effects** **H413: May cause long-term adverse effects to aquatic life**	**R51-53** **R52-53** **R53**
Zinc pyrithione (ZPT) used in anti-dandruff shampoos	**H400 Very toxic to aquatic life**	**R50**

Assessment and verification: the applicant shall demonstrate compliance with criterion 3(b) for any ingoing substance or mixture present at concentrations greater than 0,010 % in the product.

A declaration of compliance shall be provided by the applicant supported, where appropriate, by the declarations from producer(s) of the raw materials that none of these ingoing substances and/or mixtures meet the criteria for classification with one or more of hazard statements or risk phrases listed in Table 3 in the form(s) and physical state(s) they are present in the product.

The following technical information related to the form(s) and physical state(s) of the ingoing substances and/or mixtures as present in the product shall be provided to support the declaration of non-classification:

(i) For substances that have not been registered under Regulation (EC) No 1907/2006 and/or which do not yet have a harmonised CLP classification: Information meeting the requirements listed in Annex VII to that Regulation;

(ii) For substances that have been registered under Regulation (EC) No 1907/2006 and which do not meet the requirements for CLP classification: Information

based on the REACH registration dossier confirming the non-classified status of the substance;

(iii) For substances that have a harmonised classification or are self-classified: safety data sheets where available. If these are not available or the substance is self-classified then information shall be provided relevant to the substances hazard classification according to Annex II to Regulation (EC) No 1907/2006;

(iv) In the case of mixtures: safety data sheets where available. If these are not available then calculation of the mixture classification shall be provided according to the rules under Regulation (EC) No 1272/2008 together with information relevant to the mixtures hazard classification according to Annex II to Regulation (EC) No 1907/2006.

For substances listed in Annexes IV and V to Regulation (EC) No 1907/2006, which are exempted from registration obligations under point (a) and (b) of Article 2(7) of that Regulation, a declaration to this effect by the applicant shall suffice to comply with criterion 3(b).

A declaration on the presence of ingoing substances that fulfil the derogation conditions shall be provided by the applicant, supported, where appropriate, by declarations from the producer(s) of the raw materials. Where required for the derogation, the applicant shall confirm the concentrations of these ingoing substances in the final product.

(c) Ingoing substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 shall be given concerning ingoing substances identified as substances of very high concern and included in the list provided for in Article 59(1) of Regulation (EC) No 1907/2006 (8), present in the product in concentrations higher than 0,010 % (weight by weight).

Assessment and verification: reference to the list of substances identified as substances of very high concern shall be made on the date of application. The applicant shall provide the full formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with criterion 3(c), together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant safety data sheets for substances or mixtures.

(d) Fragrances

(i) Products marketed as designed and intended for children shall be fragrance-free.

(ii) Any ingoing substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on the IFRA website: http://www.ifraorg.org. The recommendations of the IFRA Standards concerning

prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

Assessment and verification: the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

(e) Preservatives

(i)Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 3(b).

(ii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 100 or log Kow < 3,0. If both BCF and log Kow values are available, the highest measured BCF value shall be used.

Assessment and verification: the applicant shall provide a signed declaration of compliance, together with copies of the safety data sheets of any preservative added, and information on its BCF and/or log Kow values.

(f) Colorants

Colorants in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 100 or log Kow < 3,0. If both BCF and log Kow values are available, the highest measured BCF value shall be used. In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

Assessment and verification: the applicant shall provide copies of the safety data sheets of any colorant added together with information on its BCF and/or log Kow value, or documentation to ensure that the colouring agent is approved for use in food.

[References:

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

(5) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

(6) Derogation is only for criterion 3(b). Fragrances shall comply with criterion 3(d).

(7) Derogation is only for criterion 3(b). Preservatives shall comply with criterion 3(e).

(8) http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.]

Annex I: Second proposal for criterion 3: Hazardous substance restrictions

[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.] (text to be included in the User Manual)

3(a) Restrictions on ingoing substances/mixtures classified under the Classification, Labelling and Packaging (CLP) Regulation

(i) Unless derogated in Table X, the product shall not contain substances or mixtures at or above the concentration of 0.010 % weight by weight for rinse-off products and 0.001% weight by weight for leave-on cosmetics, that are assigned any of the following hazard classes, categories and associated hazard statement codes, in accordance with Regulation (EC) No 1272/2008 (*).

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall take precedence.

Table 5 Restricted hazard classes, categories and associated hazard statement codes

Acute toxicity	
Categories 1 and 2	**Category 3**
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target on organ toxicity	
Category 1	**Category 2**
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1[a]	**Category 1B**
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Hazardous to the aquatic environment	
Categories 1 and 2	**Category 3 and 4**
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	
Hazardous to the ozone layer	
H420 Hazardous to the ozone layer	

Table X. **Derogations to restrictions on ingoing substances/mixtures classified under the CLP Regulation and applicable conditions** (No substantiated derogation request using template in annex I received)

Substance /mixture type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Industry must submit derogations during 2020 in order to be evaluated			

(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.

Table 6 Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	**Category 2**
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	

(iii) Ingoing substances or mixtures classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum:
100·c [H410] +10·c [H411] +c [H412] ≤ 2.5%
where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.

This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 (*) which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product.

3(b) Specified excluded substances

The substances listed below shall not be added in the final product:

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];

(ii) Perfluorinated and polyfluorinated substances;

(iii) Nitromusks and polycyclic musks;

(iv) Butylated Hydroxi Toluene (BHT) and Butylated hydroxyanisole (BHA);

(v) Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates;

(vi) The following preservatives: triclosan, parabens, formaldehyde releasers, benzalkonium chloride, phenoxyethanol [2];

(vii) Microplastics [3];

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

(ix) The fragrance tetramethyl acetyloctahydranophthalenes (OTNE);

(x) Sodium hypochlorite, chloramine and sodium chlorite;

(xi) ETPA (diethylenetriaminepentaacetic acid and its salts);

(xii) Cocamide DEA;

(xiii) Sodium Lauryl Sulphate (SLS) on toothpaste products;

(xiv) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate;

(xv) Substances and mixtures identified to have endocrine disrupting properties [4];

(xvi) Aluminium and its salts [5];

(xvii) Phthalates;

(xviii) Isothiazolines.

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[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.

[31] *OJ L 396, 30.12.2006, p. 1*

3(d) Fragrances

(i) Products marketed as designed and intended for children shall be fragrance-free.

(ii) Any substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on the IFRA website: http://www.ifraorg.org. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

3(e) Preservatives

(i) Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 3(a).

(ii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 100 or log K_{ow} < 3. If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used.

(iii) Preservatives used in toothpaste must be approved as food additives, according to Regulation (EC) No 1333/2008 on food additives.

3(f) Colorants

(i) Colorants in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 100 or log K_{ow} < 3. If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used. In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

(ii) Colorants used in toothpaste must be approved as food additives according to Regulation (EC) No 1333/2008 on food additives.

(iii) The use of barium, lead, mercury, cadmium, six inhalant chromium, nickel and bismuth in colourants for decorative cosmetics and hair dyes is restricted to concentrations below 10 ppm.

3(g) UV filters

UV filters may only be added to leave-on products and only to protect the user – not the product.

All organic UV filters contained in the product:

- 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

-if including nano TiO_2, must fulfil the conditions expressed in Annex VI of Regulation EC No 1223/2009 and its amendments.

-if including nano TiO_2 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.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with all above sub-requirements, supported by declarations from suppliers, if appropriate; and the following supporting evidence:

To demonstrate compliance with 3(a) the applicant shall provide the SDS of the final product.

To demonstrate compliance with 3(a), 3(b) and 3(c) the applicant shall provide:

(i) SDS of any substance/mixture and their concentration in the final product.

(ii) A written confirmation that 3(a), 3(b) and 3(c) is fulfilled.

For substances exempted from requirement 3(a) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to comply.

For requirement 3(c) reference to the latest list of substances of very high concern shall be made on the date of application.

To demonstrate compliance with 3(d) the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

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 K_{ow} values.

To demonstrate compliance with 3(f) the applicant shall provide: copies of the SDS of any colorant added together with information on its BCF and/or log K_{ow} value, or documentation to ensure that the colouring agent is approved for use in food.

To demonstrate compliance with 3(g) the applicant shall provide: copies of the SDS of any UV filter added together with information on its BCF and/or log K_{ow} value, or lowest available NOEC/EC_x/EC/LC50 value. 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.

The above evidence can also be provided directly to Competent Bodies by any supplier in the applicant's product supply chain.

Notes:

[1] Substance name = "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals

[2] The restriction for phenoxyethanol only applies to leave-on products for children under 12 years old.

[3] The definition of 'microplastic' can be found in "Annex XV report" for its registry of restriction intention: https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[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.

[5] The restriction for aluminium and its salts only apply to leave-on products if the concentration in the final product is higher to 0.6% (w/w).

[References:

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

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(*) http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.]

Annex II: Second proposal for criterion 3: Hazardous substance restrictions for animal care products

3(a) Restrictions on ingoing substances/mixtures classified under the Classification, Labelling and Packaging (CLP) Regulation

Same as Annex I.

3(b) Specified excluded substances

Substances and mixtures listed under Annex II to Regulation 1223/2008 shall not be added to the product In addition, the substances listed below shall not be added in the final product:

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];

(ii) Perfluorinated and polyfluorinated substances;

(iii) Nitromusks and polycyclic musks;

(iv) Butylated Hydroxi Toluene (BHT) and Butylated hydroxyanisole (BHA);

(v) Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates;

(vi) The following preservatives: triclosan, parabens, formaldehyde releasers, benzalkonium chloride.

(vii) Microplastics [2];

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

(ix) The fragrance tetramethyl acetyloctahydranophthalenes (OTNE);

(x) Sodium hypochlorite, chloramine and sodium chlorite;

(xi) ETPA (diethylenetriaminepentaacetic acid and its salts);

(xii) Cocamide DEA;

(xiii) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate;

(xiv) Substances identified to have endocrine disrupting properties [3].

(xv) Phthalates;

(xvi) Isothiazolines.

3(c) Restrictions on Substances of Very High Concern (SVHCs)

Same as Annex I.

3(d) Fragrances

Same as Annex I.(only ii)

3(e) Preservatives

Same as Annex I.(except iii)

3(f) Colorants

Same as Annex I. (Only 3 (f) (i) is relevant)

Assessment and verification:

Same as Annex I.

Notes:

[1] Substance name = "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals

[2] The definition of 'microplastic' can be found in "Annex XV report" for its registry of restriction intention: https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[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

Rationale of the proposed criterion text

The technical analysis included in the preliminary report[3] showed that the chemicals used in the formulation of the cosmetic products contribute significantly to their overall environmental impact. The aim of the existing criterion in force (i.e. 3. *Excluded or limited substances and mixtures)* is to limit toxic or harmful substances, thus ensuring that the EU Ecolabel is only awarded to the least environmentally impacting products.

The **revised criteria proposal** keeps the former EU Ecolabel criteria structure, with three more general sub-requirements (a, b and c) and three substance group specific ones (d, e and f, i.e. for preservatives, fragrances and colorants, respectively), as detailed below:

1. Sub-criterion (a): hazardous substances
2. Sub-criterion (b): specified excluded substances
3. Sub-criterion (c): substances of very high concern (SVHCs)
4. Sub-criterion (d): fragrances
5. Sub-criterion (e): preservatives
6. Sub-criterion (f): colorants

In addition, a new sub-requirement on UV filters was added in the first proposal:

7. Sub-criterion (g): UV Filters

In the first proposal (TR1.0), the wording of the existing criteria was slightly modified to align it with the wording of the most recently adopted EU Ecolabel criteria. Moreover, several major changes were introduced.

In the below sections the rationale and relevant changes to the single criteria are presented separately for each sub-criterion.

- Requirement 3(a) Hazardous substances (Restrictions on substances/mixtures classified under the Classification, Labelling and Packaging (CLP) Regulation)

Rationale of proposed requirement

This criterion corresponds to the existing criterion 3 (b) Hazardous substances and mixtures, currently in force. It is directly linked to the requirements given in the EU Ecolabel Regulation (EC) No 66/2010 in Article 6(6) which states: "*the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008".*

The current criterion grants derogation to four substances/substance groups, namely surfactants, fragrances, preservatives and zinc pyrithione used in anti-dandruff shampoos (Table 4 of the existing criteria), which are exempted from the obligation of this sub-criterion.

There was no agreement among the revision questionnaire respondents (March 2019) regarding the validity of the currently given derogations. While some of them pointed out that there are certain substances not included in the derogation list that should be exempted, e.g. fragrance mixtures (which are classified as sensitizers, but are used in small quantities), there was another group of stakeholders that considered that even the existing exemption should be removed.

An analysis of other ecolabels was performed in order to study how the exclusion of certain hazardous substances and mixtures according to their hazard classification is addressed in other schemes. These schemes include criteria equal to or less stringent than the EU Ecolabel. (See TR1.0 for details)

In the initial stage of the revision process, for the first proposal, the following changes in the current 3 (b) Hazardous substances and mixtures criterion (revised 3 (a) Hazardous substances) were proposed:

- Aligning the wording of the requirement to the latest voted EU Ecolabel products.
- Removing the derogation on Zinc pyrithione (ZnPT) used in anti-dandruff shampoos.
- Exploring the elimination of the other derogations (table 4 of existing criterion 3b), depending on the results of the derogation evaluation process.

Granting derogation is ruled by the provision of the EU Ecolabel Regulation and certain conditions must be met before a substance can be placed on the derogation list. Namely only:

- when it is not technically feasible to substitute these substances as such, or via the use of alternative materials or designs,
- or in the case of products which have a significantly higher overall environmental performance compared with other goods of the same category

In the first revised proposal, removing the derogation for ZnPT used in anti-dandruff shampoos was suggested based on the scientific opinion given in 2018 by ECHA's Committee for Risk Assessment (RAC)[32] to include ZPT in Annex VI of CLP, if agreed by COM, and classify it according to the dossier submitters' proposal. More

[32] https://echa.europa.eu/documents/10162/6405ddd0-2429-9e13-31bd-4e0752fe7430

information on the withdrawal of the derogation for ZnPT can be found in TR1.0. For the remaining substances/substance groups currently derogated in the existing criterion 3(b), it was suggested for such derogations to be removed unless industry can provide new/up-to-date evidence for substances or substance groups, which, according to their knowledge, would require keeping the existing derogations or should additionally be derogated from the provision of the sub-criterion 3(a).

Outcomes from 1st AHWG meeting

During the 1st AHWG meeting, the following discussions were raised:

- Concern was expressed that the wording for the first proposal of sub-criterion 3(a) would allow the use of CMR substances in cosmetic formulations in a concentration up to 0.010%. Such substances are generally used in very low concentrations. Additionally, it was proposed to ban all problematic substances, regardless of their concentration. Concerns were also raised with respect to the way impurities are addressed.
- It was pointed out that criterion 3 and criterion 5 (b) "Certification of plant based ingredients" must be aligned in order to ensure the fulfilment of both criteria. The main concern is to reach the minimum content of organic ingredients if CLP-classified complex mixtures of natural substances are banned due to their concentration in the final product (greater than 0.01%). It is required to take into consideration that several natural ingredients are considered as UVCB (unknown or variable composition, complex reaction products or of biological materials) under Regulation EC nº 1907/2006 [REACH Regulation].
- In regard to sub-criterion on final product clasification, stakeholders reported that CLP final product classification does not cover cosmetic products which falls under the Cosmetics Regulation.

Additionally, several comments were received through the procedure for revision of this criterion:

- It was proposed to include SCCS opinions which could occur during the validity of the revised criteria.
- It was suggested to include the term "mixtures".
- It was requested to differentiate thresholds for the content of the considered substances and mixtures between rinse-off and leave-on products.
- It was proposed to add a sub-criterion to further restrict CMR substances.

A number of substances in need of derogation from sub-criteria 3 (a) (i) and 3 (a) (ii) were suggested. However, at this stage, no derogation request was submitted.

Further research and main changes in the second proposal

Reference to SCCS opinions

In order to make sure that licenced products are up to date with new assessments, knowledge from published SCCS opinions should be taken into consideration, when the conclusion of the opinion is unambiguous. So, reference to compliance with SCCS opinions published during the validity of the criteria has been made. In line with general requirement included in Nordic Swan, a text referring to SCCS opinions has been proposed. It is suggested that this guidance text is included in the User Manual. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.

Concentration thresholds of substances/mixtures

Criterion 3(a) was modified in terms of the concentration thresholds that substances/mixtures present in the product have to fulfil. It is proposed that 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. The stricter threshold for leave-on products stems from the Cosmetics Regulation, which refers to such concentration of 0.001% w/w when banning substances/mixtures in leave-on products.

In addition, substances and mixtures presenting CMR hazards have been further restricted in both rinse-off and leave-on products. CMR substances/mixtures are banned regardless of their concentration.

CLP classification of final cosmetic products

Regulation EC 1272/2008 (CLP Regulation) only impacts chemical substances/mixtures that are used to manufacture cosmetic products. Finished cosmetics products are exempt from this Regulation. Due to this fact, the structure of criterion 3 (a) has been rearranged, exclusively focusing in the substances and mixtures as ingredients for the final cosmetic formulation.

Blue Angel Ecolabel for "Shampoos, shower gels, soaps and other so-called "rinse-off" cosmetic products" (DE-UZ 203) sets a criterion to calculate the theoretical classification of the end product (section 3.10 of DE-UZ 203), only considering the environmental hazards statements (H410, H411 and H412) from the substances and mixtures used for the manufacturing of the final cosmetic product.

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.

In the second revision of the technical report, it is proposed to include such requirement for the substances/mixtures added to the product, in order to be aligned with other EU Ecolabel schemes.

Possible derogations to CLP restrictions

After the 1st AHWG meeting, some stakeholders showed interest on including several derogations for the substances and mixtures which are affected by criteria 3 on hazard phrases. Further research was conducted on those substances and mixtures that stakeholders believe necessary to be allowed into products. As no official derogation request was submitted at this stage, no final decision was taken on such substances/mixtures. **The derogation decision will be made upon receipt of the derogation requests from stakeholders, using the template which is stated under Annex I of this document.**

Surfactants (in total concentrations < 20% in the final product) and fragrances [H412 and H413]

These two groups of chemical products are granted derogations from sub-criterion 3 (a) in the current EU Ecolabel criteria for Rinse-off cosmetic products.

Surfactants are used for cleansing, foaming, thinckening, emulsifying, solubilizing, penetration enhancement, antimicrobial effects and other special effects in cosmetics products. Some commonly added surfactants in cosmetic products are: Sodium Lauryl Sulfate, Ammonium Laureth Sulfate, Disodium Lauryl Sulfosuccinate, Cocoamphocarboxyglycinate, Decyl Polyglucoside, Cetearyl Alcohol, Stearyl Alcohol, Cocamidopropyl Betaine, Decyl Glucoside, Glyceryl Cocoate, Sodium Cocoyl Isethionate, Almond Glycerides, Sodium Lauryl Sulfoacetate, Sodium Lauroyl Sarcosinate, Sodium Methyl Cocoyl Taurate and Sucrose Cocoate. The derogation for the ones which are classified with H412 (most of the commonly used in cosmetics) could be justified in case alternatives cannot be substituted in all applications. However, it should only apply to surfactants that are both aerobically and anaerobically degradable.

In the context of EU Ecolabel for hard surface cleaning products, dishwater detergents and laundry detergents, it exists the derogation for surfactants which meet the criteria to be classified as H400 and/or H412 according to CLP Regulation.

The derogation for fragrances which are classified as H412 could be kept if a maximum limit for fragrances in the final product is introduced, in order to limit environmental effects.

Benzoic acid

Considering the proposal to remove the derogation for preservatives which meet the criteria to be classified as H411, H412 or H413, one stakeholder pointed to the possibility to use "benzoic acid" as an alternative to those non-derogated preservatives.

Benzoic acid has a harmonized classification according to Annex VI of Regulation EC No 1272 / 2008 (CLP Regulation), which states the hazard categories: H315 (Causes skin irritation), H318 (Causes serious eye damage), H372 (Causes damage to organs (lungs) through prolonged or repeated exposure).

It could be considered to derogate benzoic acid in products where inhalation is not a relevant route of exposure. However, stakeholders are requested to submit relevant information substantiating its derogation.

Sodium fluoride

Another stakeholder pointed to the possibility to derogate "sodium fluoride" for use in toothpaste products. The inclusion of fluorine is supported by its documented positive effect on dental health. The Swedish National Board of Health and Welfare (Socialstyrelsen) recommends the use of toothpaste containing fluorine.

However, sodium fluoride has a harmonized classification according to Annex VI of Regulation EC No 1272/2008 (CLP Regulation), which states the hazard categories H301 (Toxic if swallowed), H315 (Causes skin irritation, H319 (Causes serious eye irritation).

Due to the classification as H301, and the likely ingestion of part of toothpaste, the derogation of sodium fluoride is not considered.

Ethyl N^2-dodecanoyl-.sc.l.sc.-argininate hydrochloride

A stakeholder suggested the derogation of Ethyl Lauroyl Arginate HCl (LAE). This substance is included in Annex V of Commission Regulation (EU) No 1223/2009 as a preservative for cosmetic products.

LAE has a harmonized classification according to Annex VI of CLP Regulation which states the hazard categories H318 (Causes serious eye damage), H400 (Very toxic to aquatic life). Additionally, it accepts a self-classification as H412 (Harmful to aquatic life with long lasting effects).

This substance is included in some formulations which are already certified by ECOCERT, COSMOS and NATRUE. In order to consider a derogation for LAE, stakeholders should submit a derogation request.

Zinc pyrithione for anti-dandruff shampoos

Anti-dandruff agents are intended to reduce the formation of dandruff flakes. Dandruff appearance is due to abnormal desquamation of cells of epidermis at scalp level. Proliferation of the fungi Malassezia enhances the phenomenon since it provokes inflammations as very unpleasant itching, irritations or sebum excess. Also, many factors can favour dandruff appearance as stress, hormones unbalance, excessive sudation or repeated aggressions to scalp. The anti-dandruff treatment involves the use of a number of "actives" that function either as antimicrobial agents or as anti-mitotic agents.

The most popular alternatives to "zinc pyrithione" are "selenium sulphide", "salicylic acid" and "coal-tar solution". Additionally, a botanical-derived ingredient was presented in 2014 that is claimed to be active against dandruff within 72 hoursIt is a complete dandruffs reducer agent, which has been developed from the bark of Ziziphus joazeiro, a tree native from North-eastern Brazil.

Among these alternatives, it is not recommended the use of salicylic acid (harmonised classification as Repr. 2 - H361d) nor coal-tar solution (harmonised classification as Carc. 1A - H350) in the scope of this EU Ecolabel criteria because of their CLP classification as CMR substances. However, selenium sulphide or other natural ingredients can be used. For more information on the background to the ban of ZnP please refer to TR1.0.

The derogation of ZnP is not proposed for this second version of the TR.

Compatibility between criterion 3 and criterion 5 (b) "Certification of plant based ingredients"

During 1st AHWG meeting, it was pointed out that criterion 3 and criterion 5 (b) must be aligned in order to ensure the fulfilment of both criteria. The main concern was to reach the minimum content of organic ingredients (as required by criterion 5 (b)) if CLP-classified complex mixtures of natural substances are banned due to their concentration in the final product (greater than 0.01%). It is required to take into consideration that several natural ingredients are considered as UVCB (unknown or variable composition, complex reaction products or of biological materials) under Regulation EC nº 1907/2006 [REACH Regulation].

Further research has been carried out in order to identify the main natural organic ingredients which are used in the product groups the scope of this EU Ecolabel covers. The following table includes the main ingredients, their CAS number and their CLP classification.

Table 11: Main natural organic ingredients used in cosmetics products. Source: own compilation

Ingredient	CAS number	CLP Classification	Source	Comments
ALOE VERA (Aloe Barbadensis Miller)	85507-69-3	Not classified	REACH registration dossier	UVCB
APPLE CIDER VINEGAR (Acetic acid)	64-19-7	H226, H314	CLP Regulation (Annex VI)	
ARGAN OIL (Argania Spinose)	223747-87-3	Not classified	C&L Inventory	
AVOCADO OIL (Persea Gratissima)	8024-32-6	Not classified	C&L Inventory	
BENTONITE CLAY	1302-78-9	Not classified	C&L Inventory	
CEDAR WOOD OIL (Cedrus Atlantica)	8000-27-9	H304, H400, H410	C&L Inventory	
CETEARYL ALCOHOL	8005-44-5	Not classified	REACH registration dossier	Belongs to "Alcohol, C16-18" (CAS 67762-27-0)
CHAMOMILE (Matricaria chamomilla / Anthemos chamomilla)	84082-60-0	H304, H315, H317, H319 and H411	REACH registration dossier	

CHARCOAL	7440-44-0	Not classified	REACH registration dossier	
COCOA (Theobroma Cacao)	84649-99-0	Not classified	REACH registration dossier	UVCB
COCONUT (Cocos Nucifera)	8001-31-8	Not classified	C&L Inventory	
ETHYL MACADAMIATE	214495-31-5	Not classified	C&L Inventory	
FRANKINCENSE (Boswellia Carterii)	8016-36-2	H304, H315, H317 and H411	C&L Inventory	
GLYCERIN / GLYCEROL	56-81-5	Not classified	REACH registration dossier	
GREEN TEA (Camellia Sinensis)	84650-60-2	H225	C&L Inventory	
HEMP SEED OIL (Cannabis Sativa)	89958-21-4	H226, H304, H315, H317, H319 and H411	C&L Inventory	
HIMALAYAN SALT / SEA SALT (Sodium Chloride)	7647-14-5	Not classified	REACH registration dossier	
JOJOBA OIL (Simmondsia Chinensis)	61789-91-1	H332	REACH registration dossier	
LIQUORICE ROOT EXTRACT (Glycyrrhiza glabra)	68916-91-6	H226	C&L Inventory	
L-ASCORBIC ACID (Vitamin C)	50-81-7	Not classified	C&L Inventory	
LAVANDER OIL (Lavandula)	8000-28-0	H319, H317, H304, H412	REACH registration dossier	UVCB
MARIGOLD (Calendula Officinalis)	84776-23-8	H226	REACH registration dossier	
OLIVE OIL (Olea Europaea)	8001-25-0	Not classified	C&L Inventory	
POMEGRANATE EXTRACT (Punica Granatum)	84961-57-9	Not classified	C&L Inventory	
PRIMROSE OIL (Oenothera Biennis)	90028-66-3	Not classified	C&L Inventory	
ROSE HIP OIL (Rosa Canina)	84603-93-0	Not classified	C&L Inventory	
ROSEMARY EXTRACT (Rosmarinus Officinalis)	84604-14-8	H226, H304, H315, H317, H319, H371 and H411	REACH registration dossier	UVCB
SEA BUCKTHORN OIL (Hippophae Rhamnoides)	90106-68-6	Not classified	C&L Inventory	
SHEA BUTTER (Butyrospermum Parkii)	194043-92-0	Not classified	C&L Inventory	

SUNFLOWER SEED OIL (Helianthus Annus)	8001-21-6	Not classified	C&L Inventory	
TEA TREE OIL (Melaleuca Alternifolia)	68647-73-4	H302	C&L Inventory	
TURMERIC (Curcuma Longa)	84775-52-0	H304, H317 and H412	C&L Inventory	
UBIQUINONE (Coenzyme Q10)	303-98-0	Not classified	C&L Inventory	

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.

According to proposed criterion 5 (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. The presence of the 7 above mentioned ingredients in cosmetics formulations could be a challenge for EU Ecolabel potential license holders in order to fulfil both criteria 3 and 5 (b), but it is still considered achievable.

Summary of main implemented changes under criterion 3 (a)

Based on the comments received after 1st AHWG meeting, the following changes have been implemented in this second revised criteria proposal:

- Wording has been adjusted to avoid any misunderstanding as to the limit thresholds to be met by substances/mixtures and to align with other recently voted EU Ecolabel product groups.
- Concentration thresholds has been specified for rinse-off products and leave-on cosmetics. Such thresholds equal to 0.01% w/w in rinse-off products and 0.001% w/w in leave-on products in line with Cosmetics Regulation.
- The criterion 3(a) (i) proposed in TR1.0 for final products has been deleted. In replacement, substances classified as environmentally hazardous according to Regulation EC 1272/2008 may now be included in the product to a maximum: $100 \cdot c[H410] + 10 \cdot c[H411] + c[H412] \leq 2.5\%$, in accordance with Blue Angel labelling scheme.
- CMR substances/mixtures have been further restricted in both rinse-off and leave-on products. CMR substances/mixtures are excluded in cosmetic products, regardless of their concentration.

Question to stakeholders
• **Stakeholder are requested to further substantiate the derogation needs using the derogation request template included in Annex I.** • Stakeholders and competent bodies are requested to provide their opinions on the acceptance of the possible derogations • Possibility to fulfil criteria 3 and 5(b) by potential license holder?

- ***Requirement 3(b) Specified excluded substances***

Rationale of proposed requirement

This criterion lists substances that shall not be included in the product (as part of the formulation or as a part of a mixture included in the formulation) as defined in the existing criteria in force (3 (a) Specified excluded ingoing substances and mixtures).

The results from the survey (March 2019, before the TR1) revealed that 62% of the stakeholders agreed with the current formulation of the criterion on substances and mixtures not allowed in the product formulation. Moreover, 18% of stakeholders indicated it is necessary to add other substances or mixtures in the revised criterion.

Regarding specific substances, respondents stated the following opinions:

- *Butylated Hydroxi Toluene (BHT) should be allowed as antioxidant because it is extensively used in raw material formulations,*
- *Nitrilo-tri-acetate (NTA) does not fulfil the Cosmetics Regulation, so it can be excluded from the list,*
- *All ingredients regulated already through the Cosmetics Regulation should not be included in the specified excluded substance list,*
- *This criterion should be aligned with the list of excluded ingoing substances and mixtures contained in the EU Ecolabel for hand dishwashing detergents*.

Moreover, some ingredients were proposed by the stakeholders to be included in the list of specific excluded ingoing substances and mixtures, namely:

- Substances that meet the criteria for PBT or vPvB substances in accordance with Annex XIII of the REACH Regulation (EC) No. 1907/2006, or substances included in the Candidate list.
- Per- and polyfluoroalkyl substances (PFAS) and other organic halogen compounds.
- Endocrine disrupting chemicals.
- Cyclic siloxanes.
- Isothiazolinones.
- Evernia furfuracea extract and Evernia prunastri extract.
- The fragrance Tetramethyl acetyloctahydranophthalenes (OTNE)
- Nanoparticles, unless proved not to be harmful

• During the first revision process (TR1.0), an analysis of other ecolabels was performed and EU Ecolabel sub-criterion 3(b) was proposed to be aligned to

those certification schemes that are currently stricter than EU Ecolabel. For each substance mentioned by stakeholders as worth of consideration, or excluded in other certification schemes but allowed in EU Ecolabel criteria, further research was conducted prior to the proposal in TR1. The decision of excluding or including a substance (or group of substances) was based on the following approach:Substances (or group of substances) excluded according to existing criterion 3 (a) on specified exclusions and that are excluded according to the Cosmetics Regulation.

Substances proposed to be removed in the revised criterion in TR1.0:

- Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atranol and Chloroatranol.
  These three substances (currently excluded under current criterion 3(a)) were included in Annex II of Cosmetics Regulation (entries 1380, 1381, 1382) and their exclusion in cosmetic products will be effective before the revision of the EU Ecolabel will come into force. Therefore, these substances were removed in sub-criterion 3(b) because their use is prohibited in cosmetics and do not need to be specified by the EU Ecolabel.
- Nitrilo-tri-acetate (NTA); Boric acid, borates and perborates; Octamethylcyclotetrasiloxane (D4); Formaldehyde.
  These substances (currently excluded under current criterion 3(a)) were added to Annex II of Cosmetics Regulation by the 'Omnibus Act', published on 22 May 2019, that amends Annexes II, III and V of the Cosmetics Regulation. It applies without any transition period, just 20 days after its publication. Therefore, these substances were removed form revised criterion in TR1.0.

- Substances (or group of substances) suggested by stakeholders or included in other schemes:

  Proposed to not be specified in revised criterion 3(b) in TR1.0:

  - Evernia furfuracea (Tree moss) and Evernia prunastri (Oak moss)
    The Commission Regulation (EU) 2017/1410 of 2 August 2017 amended Annexes II and III to Regulation (EC) No 1223/2009, excluding these substances from use in cosmetic products. Therefore, these substances were not specified in the revised criterion.
  - Halogenated and/or aromatic solvents
    Most halogenated and aromatic solvents (e.g. aniline, its salts and its halogenated and sulphonated derivatives; Toluidines, their isomers, salts and halogenated and sulphonated derivatives; Xylidines, their isomers, salts and halogenated and sulphonated derivatives) are prohibited in cosmetics according to Cosmetics Regulation (EC) 1223/2209. Furthermore, these substances have a harmonised classification under CLP Regulation (EC) 1272/2009. Therefore, these substances were not specified in revised sub-criterion 3(b).
  - 5-bromo-5-nitro-1,3-dioxane

Being this substance a formaldehyde releaser, it is already excluded by revised sub-criterion 3(b). Therefore, it was not specified in the revised sub-criterion 3(b).

- Cyclic siloxane compounds (D5 and D6)
  The compounds D5, D6 as well as Cyclomethicone (a mixture of low molecular weight volatile cyclic siloxanes, the principal ingredients of which are D4, D5 and D6, in varying proportions), do not have a harmonised classification under CLP, but are included in REACH SVHC Candidate List, being classified as vPvB substances. Therefore, they are restricted by revised sub-criterion 3(c) on SHVCs. Moreover, the use of D5 and D6 has been restricted for rinse-off products where their concentration is greater than or equal to 0.1 % by weight of either substance[33]. Finally, ECHA is currently working on a further proposal[34] to restrict D4, D5 and D6 in leave on personal care products and other consumer/professional products (such as dry-cleaning products, waxes and polishes, and other washing and cleaning products) in a concentration equal to or greater than 0.1 %. Therefore, these substances were not included in sub-criterion 3(b) in TR1.0.

- Endocrine disruptors
  The Cosmetics Regulation does not contain specific provisions for endocrine disruptors. In REACH, substances with endocrine disrupting effects are considered under Article 57, as substances which should be included in Annex XIV (i.e. List of substances subject to authorisation). Article 57 states the following: substances — such as those having endocrine disrupting properties (…) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) [of the article 57 of REACH] and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. Thus, the substances categorised as endocrine disruptors under REACH, are already excluded from EU Ecolabel products through sub-criterion 3(c) on SVHCs. Therefore, these substances were not included in sub-criterion 3(b) in TR1.0.

- Calcium and sodium hypochlorite
  These substances have a harmonised classification under Regulation (EC) No 1272/2008 with hazard classes included in those listed under criterion 3(a). These substances are therefore restricted from EU Ecolabel products through revised criterion 3(a) to 0.01% in final product. Thus, these substances were not included in sub-criterion 3(b).

- Nano-silver

[33] https://echa.europa.eu/documents/10162/50e79685-efaf-ac9a-4acb-d8be3f0e9ddc
[34] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22920/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=208-762-8&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

This substance has a harmonised classification under Regulation (EC) No 1272/2008 with hazard classes included in those listed under revised criterion 3(a) (aquatic toxicity). This substance is therefore restricted from EU Ecolabel products through revised criterion 3(a) to 0.01% in final product. Thus, these substances were not included in sub-criterion 3(b).

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- PBT or vPvB substances
  Substances classified as PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) in accordance with Annex XIII of the REACH Regulation (EC) No. 1907/2006 are included in the list of SHVCs, and therefore excluded from EU Ecolabel products according to revised criterion 3 (c) on SVHCs. Thus, these substances were not included in sub-criterion 3(b in TR1.0.

- Perfluorinated compounds
  Most common perfluorinated compounds such as Perfluorooctane sulfonic acid (PFOS), Perfluorooctanoic acid (PFOA), Perfluorononanoic acid (PFNA), and Perfluorooctane sulfonaminde (PFOSA) have a harmonised classification under the CLP Regulation (EC) 1272/2008 with hazard classes included in those listed under criterion 3(a). These substances are therefore restricted in EU Ecolabel products through revised criterion 3(a). Thus, these substances were not included in sub-criterion 3(b).

- Phosphonates which are aerobically not readily biodegradable
  Substances that are not aerobically readily biodegradable cannot be used in EU Ecolabel products according to current criteria 2. Thus, these substances were not included in sub-criterion 3(b).

- Bis(2-ethylhexyl)phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), and Dicyclohexyl phthalate (DCHP)
  These substances have a harmonised classification with hazard classes included in those listed under criterion 3(a). These substances are therefore restricted in EU Ecolabel products through revised criterion 3(a). Thus, these substances were not included in sub-criterion 3(b).

Proposed to be included in sub-criterion 3(b) in TR1.0:

- Benzalkonium chloride
  According to the information provided by companies to ECHA, this substance causes severe skin burns and eye damage, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is harmful if swallowed, is harmful in contact with skin, is harmful if inhaled and causes serious eye damage. Moreover, this substance is excluded in Nordic Swan scheme. Therefore, it was proposed to include it in sub-criterion 3(b).

- Butylated hydroxyanisole (BHA)
  According to the information provided by companies to ECHA in the REACH registration process, this substance is toxic to aquatic life with long lasting effects, causes serious eye irritation, is suspected of causing cancer, is

suspected of damaging fertility or the unborn child, is harmful if swallowed and causes skin irritation. Moreover, this substance is excluded in Nordic Swan scheme. Finally, the evaluation of this substance being an endocrine disruptor is ongoing. Therefore, considering that endocrined disruptors were already mentioned in the list, this substance was not specified in sub-criterion 3(b).

- Cocamide DEA
  According to the information provided by companies to ECHA, this substance causes serious eye damage, is harmful to aquatic life with long lasting effects and causes skin irritation. Therefore, it was proposed to include it in sub-criterion 3(b).

- ETPA (diethylenetriaminepentaacetic acid and its salts)
  According to the information provided by companies to ECHA, these substances causes serious eye irritation, cause skin irritation, may cause respiratory irritation, are harmful if swallowed, are harmful in contact with skin, are harmful if inhaled and are suspected of damaging fertility or the unborn child. Therefore, these substances were included in sub-criterion 3(b).

- Sodium hypochlorite, chloramine and sodium chlorite
  According to the information provided by companies to ECHA, these substances causes severe skin burns and eye damage, are very toxic to aquatic life, very toxic to aquatic life with long lasting effects, causes serious eye damage, may intensify fire (oxidiser), and are harmful if swallowed. Therefore, these substances were included in sub-criterion 3(b).

- Phosphates
  According to the information provided by companies to ECHA, Sodium phosphate, Disodium Phosphate and Trisodium Phosphate cause severe skin burns and eye damage, cause serious eye damage, cause serious eye irritation, cause skin irritation and may cause respiratory irritation. Therefore, these substances were included in sub-criterion 3(b).

- Phthalates
  Phthalates with CLP hazards reported in individual entries are:
  - DNOP (Di-n-Octyl-Phthalate), suspected H361, H317, and H413, used in cosmetics,
  - DINP (Di-Isononyl Phthalate), suspected H400 and H361, not directly used in cosmetics,
  - DIDP (Di-Isodecyl-Phthalate), suspected H400, H410 and H411, not directly used in cosmetics, and
  - DEP (Diethyl phthalate), suspected H319, H331 and H373, used in perfumes).

Of these, DNOP and DEP are of interest for the products included in the scope of the first revision. Phthalates are already excluded in Nordic Swan and Bra Mijoval schemes. Therefore, it was proposed that these substances were included in the revised criterion 3 (b) as excluded substances in EU Ecolabel products.

- Sodium Lauryl Sulphate (SLS)

According to the information provided by companies to ECHA in REACH registrations, this substance is harmful if swallowed, causes serious eye damage, is harmful to aquatic life with long lasting effects, is a flammable solid, is harmful if inhaled, causes skin irritation and may cause respiratory irritation. Nordic Swan ecolabelling bans the use of SLS in toothpaste, promoting the use of alternative surfactants such as sodium-C14-C16 oleofin sulphonate, sodium lauryl sarcosinate, cocamidopropyl betaine or Stearath 30, all of which are less irritating to the skin. Therefore, SLS was included in sub-criterion 3(b) and excluded in EU Ecolabel.

- Tetramethyl acetyloctahydranophthalenes (OTNE)

According to the information provided by companies to ECHA in the REACH registration process, this substance causes skin irritation, may cause an allergic skin reaction and is very toxic to aquatic life with long lasting effects. Therefore, it was included in sub-criterion 3(b) and excluded in EU Ecolabel.

In summary, for the first proposal, the following changes to the current criterion 3 on *Specified excluded ingoing substances and mixtures,* were proposed:

- Eliminating the following substances from the exclusions list:
  - *(ix) Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atranol and Chloroatranol*.
  - *(ii) Nitrilo-tri-acetate (NTA);*
  - *(iii) Boric acid, borates and perborates;*
  - *(v) Octamethylcyclotetrasiloxane (D4);*
  - *(viii) Formaldehyde*.
- Including a definition of 'microplastic', in accordance with the definition of 'microplastic'[35] laid down in EU Ecolabel criteria for detergents[36]. This definition is also in line with the definition proposed in the scope of the proposal for restricting the use of intentionally added microplastic particles in consumer or professional use products of any kind, under REACH Regulation (process ongoing)[37]
- Including the following substances to the exclusion list:
  - Butylated hydroxyanisole (BHA);
  - The preservative benzalkonium chloride;
  - The fragrance tetramethyl acetyloctahydranophthalenes (OTNE);
  - Sodium hypochlorite, chloramine and sodium chlorite;

[35]'microplastic' means particles with a size of below 5 mm of insoluble macromolecular plastic, obtained through one of the following processes: (a) a polymerisation process such as polyaddition or polycondensation or a similar process using monomers or other starting substances; (b) chemical modification of natural or synthetic macromolecules; (c) microbial fermentation.
[36] COMMISSION DECISION (EU) 2017/1214 of 23 June 2017 establishing the EU Ecolabel criteria for hand dishwashing detergents.
[37]https://echa.europa.eu/es/restrictions-under-consideration/-/substance-rev/22921/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=-&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

- ETPA (diethylenetriaminepentaacetic acid and its salts);
- Cocamide DEA;
- The phthalates Di-n-Octyl-Phthalate (DNOP) and Diethyl phthalate (DEP);
- Sodium Lauryl Sulfate (SLS);
- Sodium phosphate, Disodium phosphate and Trisodium phosphate.

Outcomes from 1st AHWG meeting

Stakeholders were concerned about the wording which has been proposed to sub-criteria 3(a), 3(b) and 3(c) and asked for clarification regarding the thresholds applying to the whole criterion 3. It was pointed out that the wording introduced in TR1.0 for sub-criteria 3(a) and 3(c) would apply to substances at or above a concentration of 0.010 % in the final product, while criterion 3(b) would apply to substances regardless their concentration. In that sense, substances which are included in the Candidate List of Substances of Very High Concern (SVHC) would be allowed to be used in higher concentrations in comparison to the ones which are included under sub-criterion 3(b), which do not have a harmonised classification according to CLP.

Regarding Endocrine Disruptors, it was pointed out by different stakeholders that:

- The EC Priority List of substances for further evaluation of their role in Endocrine Disruption should be taken into consideration. Endocrine Disruptor Assessment List and PBT Assessment List could be possible lists to consider for that purpose.
- EU Ecolabel should follow the precaution's principle and include the substances which are suspected of being Endocrine Disruptors.
- The wording should be amended to "identified and/or suspected to be Endocrine Disruptor", instead of "classified as Endocrine Disruptor".
- The assessment and verification would be difficult without having a list of substances which fall under this category.

In terms of nanomaterials, it was proposed to either ban their use unless it is proved to be safe or evaluate their use on a case-by-case basis.

Due to the lack of harmonized classification according to CLP Regulation for certain groups of substances which were included in the first proposal of the revised criteria, some stakeholders disagreed on including them under sub-criterion 3(b). Furthermore, consistency regarding the criteria of selection of restricted substances was asked by the participants in the 1st AHWG meeting, paying special attention to substances which belong to the same chemical family.

Some stakeholders requested to include additional categories to this sub-criterion: PFOA and derivates, cyclic siloxanes and phosphates.

It was pointed out that BHT and phthalates are already included in the "Substitute It Now!" List (also known as SIN List) and, therefore, the inclusion of these substances under sub-criterion 3(b) is justified.

Other comments received in written format are summarized below:

- Other groups to be included in the Specified Excluded List are: mineral oils (MOSH and MOAH), phenoxyethanol (in leave-on products for children), PBT and vPvB which are still under evaluation (a list will be required)
- Some of the proposed groups should be considered to be removed from the Specified Excluded List: Benzalkonium chloride, SLS and Cocamide DEA.
- The definition of "microplastic" must be adjusted. As it can still suffer modifications until an opinion is adopted for its restriction intention, it is preferred to refer to the document which this definition appears.
- Phosphates were asked for inclusion under criterion 3(b), based on the CLP classification included in their submitted REACH Registration dossier and their form in the final cosmetic formulation.

Further research and main changes

Substances suggested by stakeholders to be deleted from sub-criterion 3(b)

Benzalkonium chloride

Benzalkonium chloride, additionally having 4 different IUPAC names (Alkyldimethylbenzylammonium chloride; Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides; Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides; Benzyl-C12-14-alkyldimethylammonium chlorides) was requested by one stakeholder to be removed from sub-criterion 3(b).

A further collection of data which is related to the hazardousness of these 4 groups of chemicals has been performed, in order to evaluate their inclusion into the Specified excluded substances List.

Table 12: CLP Classification for Benzalkonium chloride

Substance	CAS No	EC No	CLP Classification	Source
Alkyldimethylbenzylammonium chloride	8001-54-5	616-786-9	H302, H312, H314, H318 and H332.	C&L Inventory
Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides	68391-01-5	269-919-4	H302, H314 and H400.	C&L Inventory
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	63449-41-2	264-151-6	H302, H312, H314 and H400.	Annex VI of Regulation EC No 1272/2008
Benzyl-C12-14-alkyldimethylammonium chlorides	-	939-350-2	H302, H314, H318, H400 and H410.	REACH registration dossier

Based on the collected information, the following substances meet the criteria to be classified and, therefore, it is proposed in the 2nd revision to **keep the listing of these 4 groups of substances under sub-criterion 3 (b)**.

Sodium Lauryl Sulphate and alternative surfactants

It exists a REACH registration submission dossier[38], which tonnage band is 1.000 – 10.000 tonnes per year. Two classifications according to CLP Regulation have been reported in this submission dossier:

Table 13: CLP submitted classifications for Sodium Lauryl Sulphate in the REACH Registration dossier

Substance	CAS No	EC No	CLP Classification	Source
Sodium Lauryl Sulphate. Solid material of bulk density < 400 g/L.	151-21-3	205-788-1	H228, H302, H315, H318 (C ≥ 20%), H319 (10 % ≤ C < 20%), H332, H335 and H412.	REACH registration dossier
Sodium Lauryl Sulphate. Solid material of bulk density ≥ 400 g/L.	151-21-3	205-788-1	H302, H315, H318 (C ≥ 20%), H319 (10 % ≤ C < 20%) and H412.	REACH registration dossier

Nordic Swan ecolabelling bans the use of SLS in toothpaste, promoting the use of the following alternatives to be used as surfactants in cosmetic products (less irritating to the skin):

- Sodium-C14-C16 olefin sulphonate.
- Sodium N-lauroylsarcosinate.
- Cocamidopropyl betaine.
- Steareth-30.

Table 14: CLP classification for the alternatives for SLS

Substance	CAS No	EC No	CLP Classification	Source
Sodium-C14-C16 olefin sulphonate	**68439-57-**	**270-407-8**	**H315, H319 and H411.**	**C&L Inventory**
Sodium N-lauroylsarcosinate	**137-16-6**	**205-281-5**	**H315 (C > 30%), H318 (C > 30%), H319 (1% ≤ C ≤ 30%) and H330.**	**REACH registration dossier**

[38] https://echa.europa.eu/es/registration-dossier/-/registered-dossier/2126/1

1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts [Cocamidopropyl betaine]	**61789-40-0**	**263-058-8**	**H315, H317, H319 and H412.**	**REACH registration dossier**
Octadecan-1-ol, ethoxylated [Steareth-30]	**9005-00-9**	**500-017-8**	**H411**	**REACH registration dossier**

Sodium Lauryl Sulphate (SLS) is produced in liquid form and powder is obtained as result of additional steps; therefore, inhalation on the molecule as produced should not be a reason of concern for the cosmetic formulators. The irritation potential and environmental impact are comparable to the ones for other anionic surfactants in the market which are not prohibited. Flammability depends on powder bulk density and other characteristics are the same for the main part of surfactants.

In addition to that, the proposed alternatives by Nordic Swan Ecolabel scheme are classified with a similar or higher level of concern in terms of hazard categories.

That is why it is proposed in the 2nd revision of the criterion to **only prohibit the use of Sodium Lauryl Sulphate for toothpaste applications**, as Nordic Swan Ecolabel scheme does.

Substances suggested by stakeholders to be included in sub-criterion 3(b)

Phenoxyethanol

Phenoxyethanol was proposed to be added to sub-criterion 3(b). This substance is used as preservative or stabilizer for other ingredients that might otherwise deteriorate, spoil or become less effective too quickly, in many cosmetics and personal care products. It is also used in other industries, including in vaccines and textiles. In perfumes, fragrances, soaps and cleansers, phenoxyethanol works as stabilizer. In other cosmetics, it is used as an antibacterial and/or preservative to prevent products from losing their potency or spoiling. Manufacturers who want to avoid using parabens might use phenoxyethanol in their products as a substitute.

Most of the concern regarding its safety stems from recorded incidents of bad skin reactions and nervous system interaction in infants.

Scientific Committee on Consumer Safety adopted its opinion on phenoxyethanol on October 2016 (SCCS/1575/16). They considered safe the use of phenoxyethanol as a preservative in cosmetics with a maximum concentration of 1.0%. However, this report notes that using several products all containing a low dose could result in overexposure.

Other Ecolabels schemes, such Nordic Swan and Blue Angel, do not set a restriction on the use of phenoxyethanol on the products which fall under the scope of this EU Ecolabel.

An entry under Annex VI of Regulation EC 1272/2008 sets the categories which are met under the criteria of CLP Regulation for "phenoxyethanol": H302 (Harmful if swallowed) and H319 (Causes serious eye irritation).

Due to the potential risk of swallowing, it is proposed to **include phenoxyethanol in the subc criterion 3 (b) Specified Restricted Substance List, but only applying to leave-on products addressed to children.**

Nanomaterials

According to Article 16 (10) (a) of Regulation (EC) No 1223/2009 on cosmetic products, the Commission shall make available a catalogue of all nanomaterials in cosmetics placed on the market, including those used as colorants, UV-filters and preservatives in separate sections, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions.

The present catalogue may be found under the European Commission website[39]. This catalogue is subject to modifications and will be updated regularly. Version 2 of the catalogue (last update: 31.12.2018) lists the functions of 29 nanomaterials (3 colorants, 4 UV-filters and 22 fulfilling other functions).

In the first proposal for criteria modification, it was stated that use of nanomaterials would be evaluated on a case-by-case basis. At the moment, there is considerable uncertainty about the effects of nanomaterials on health and the environment. Given the existing concern on potential hazardous properties of nanomaterials and methodology gaps to assess them, and based on the precautionary principle, it is proposed to **add nanomaterials to the Specified Excluded Substances List**. This implementation allows EU Ecolabel to be in-line with other Ecolabel schemes, as Nordic Swan and Bra Miljöval. **For the second proposal, it has been suggested that the use of a specific nanomaterial shall be allowed only if an EU regulatory authority has evaluated its use and found that it is safe from health and environmental perspective.**

Phosphates

According to the information provided by companies to ECHA, Sodium phosphate, Disodium Phosphate and Trisodium Phosphate are the main type of phosphates which are used in cosmetics.

Table 15. CLP Classification for Sodium phosphate, disodium phosphates and trisodium phosphates.

Substance	CAS No	EC No	CLP Classification	Source
Phosphoric acid, monosodium salt, monohydrate [Sodium phosphate]	**10049-21-5**	**600-102-0**	**Not classified**	**C&L Inventory**
Sodium phosphate, dihydrate [Disodium phosphate]	**10028-24-7**	**600-053-5**	**H319**	**C&L Inventory**

[39] https://ec.europa.eu/docsroom/documents/38284

Disodium phosphate, heptahydrate [Disodium phosphate]	**7782-85-6**	**616-512-8**	**H315 and H319**	**C&L Inventory**
Phosphoric acid, sodium salt, hydrate (1:2:12) [Disodium phosphate]	**10039-32-4**	**600-088-6**	**Not classified**	**C&L Inventory**
Trisodium orthophosphate	**7601-54-9**	**231-509-8**	**H315, H319 and H335**	**REACH registration dossier**
Phosphoric acid, trisodium salt, dodecahydrate [Trisodium phosphate]	**10101-89-0**	**600-151-8**	**H315 and H319**	**C&L Inventory**

"Phosphoric acid, monosodium salt, monohydrate" and "Phosphoric acid, sodium salt, hydrate (1:2:12)" do not meet the criteria to be classified as hazardous according to CLP Regulation. Therefore, there is no reason to include them in the Specific Excluded List.

"Sodium phosphate, dihydrate", "Disodium phosphate, heptahydrate", "Trisodium orthophosphate" and "Phosphoric acid, trisodium salt, dodecahydrate" meet the criteria to be classified, at least, to one of the following categories, according to CLP Regulation: H315 (Causes skin irritation), H319 (Causes serious eye irritation), H335 (May cause respiratory irritation, by inhalation).

That is why it is proposed in the 2nd revision of the criterion to **only prohibit the use of these 4 substances and include them under sub-criterion 3 (b)**.

Phthalates

Phthalates are used in cosmetics in different functions, such as film formation, masking and solvents.

Many phthalates have negative effects on health and the environment:

- Some phthalates are inscribed on the EU's priority list of substances that should be investigated more closely for endocrine disruption – and some have already been identified as endocrine disruptors. Examples of recognised phthalates with endocrine disrupting properties are Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate, Dibutyl phthalate, Dicyclohexyl phthalate (DCHP) and Diisobutyl phthalate.

- Some phthalates can be found on the EU's Candidate List of substances of Very High Concern: Benzyl butyl phthalate (BBP), bis (2-ethylhexyl)phthalate (DEHP), Bis(2-methoxyethyl)phthalate, Dibutyl phthalate (DBP), Dicyclohexyl phthalate (DCHP), Dihexyl phthalate, Diisobutyl phthalate, Diisopentylphthalate, Dipentyl phthalate (DPP), Diisohexyl phthalate, n-pentyl-isopentylphthalate, Diisoheptyl phthalate, Dialkyl (C7-11-branched and linear) phthalate, Branched and linear dihexyl phthalate, Diisopentyl phthalate and Dibasic lead phthalate.
- Some phthalates are prohibited in cosmetics (according to Annex II of Regulation EC 1223/2009): Dibutyl phthalate (DBP), Diethylhexyl phthalate,

bis(2-Methoxyethyl)phthalate, n-pentyl-isopentylphthalate, di-n-pentyl phthalate, diisopentylphthalate, Benzyl butyl phthalate (BBP).

Historically, the primary phthalates used in cosmetic products have been dibutylphthalate (DBP), used as a plasticizer in products such as nail polishes (to reduce cracking by making them less brittle); dimethylphthalate (DMP), used in hair sprays (to help avoid stiffness by allowing them to form a flexible film on the hair); and diethylphthalate (DEP), used as a solvent and fixative in fragrances (including baby wipes) and deodorants. In some regions, di-n-octylphthalate (DNOP), a man-made substance used to keep plastics soft or more flexible (plasticiser), is also used in cosmetics. According to FDA's latest survey of cosmetics, conducted in 2010, however, DBP and DMP are now used rarely. DEP is the only phthalate still commonly used in cosmetics.

After the 1s^{t} AHWG meeting, several product groups have been included under the scope of this EU Ecolabel: CLEANSER PREPARATIONS (Feminine hygiene cosmetics), HAIR STYLING AND TREATMENT, SKIN CARE PRODUCTS, MOUTHWASH, TOOTHPASTE, DEODORANTS AND ANTIPERSPIRANTS, DECORATIVE COSMETICS, NAIL ENAMEL REMOVER, WET WIPES and ANIMAL CARE PRODUCTS. Despite the inclusion of these categories in the scope, there is no need to consider additional phthalates for the purpose of this analysis.

Based on the order used to determine the classification of the substances of interest for this criterion, DEP and DNOP does not meet the criteria to be classified as hazardous substances according to CLP Regulation.

Table 16: CLP Classification for DEP and DNOP

Substance	CAS No	EC No	CLP Classification	Source
Diethyl phthalate (DEP)	**84-66-2**	**201-550-6**	**Not classified**	**REACH Registration dossier**
Di-n-octyl phthalate (DNOP)	**117-84-0**	**204-214-7**	**Not classified**	**C&L Inventory**

As a precaution and as it was mentioned in the first technical report, Nordic Swan Ecolabelling and Bra Mijoval restrict the use of phthalates in cosmetic products. In case of EU Ecolabel schemes, several phthalates of concern are either covered by other criteria (3 (b) on Substances identified to have endocrine disrupting properties, and 3 (c) – Substances of Very High Concern) or prohibited their use by Regulation EC 1223/2009. However, as a safety net and in order to align with other labelling schemes as much as possible, **it is proposed to include all phthalates under criterion 3 (b).**

Substances identified and suspected to have Endocrine Disrupting properties.

A large group of stakeholders requested stricter requirements towards presence of identified or suspected EDs in EU Ecolabelled cosmetics.

Scientists increasingly link endocrine-disrupting chemicals (EDCs) to a range of severe diseases and disorders, including infertility, obesity and cancer. Cosmetic ingredients with endocrine disrupting properties represent a significant, potential source of cumulative consumer exposure to EDCs, including for vulnerable groups, such as pregnant and breastfeeding women, children and people with compromised immune responses. They also have environmental impacts as they affect wildlife.

The "State of the Science of Endocrine Disrupting Chemicals 2012. Summary for Decision-Makers"[40] (World Health Organisation (WHO) and United Nations Environment Programme (UNEP)) recapitulates many endocrine-related diseases and disorders which are on the rise:

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

40 https://apps.who.int/iris/bitstream/handle/10665/78102/WHO_HSE_PHE_IHE_2013.1_eng.pdf;jsessionid=A6F74B6F403DB5529AACCF05237D92BE?sequence=1

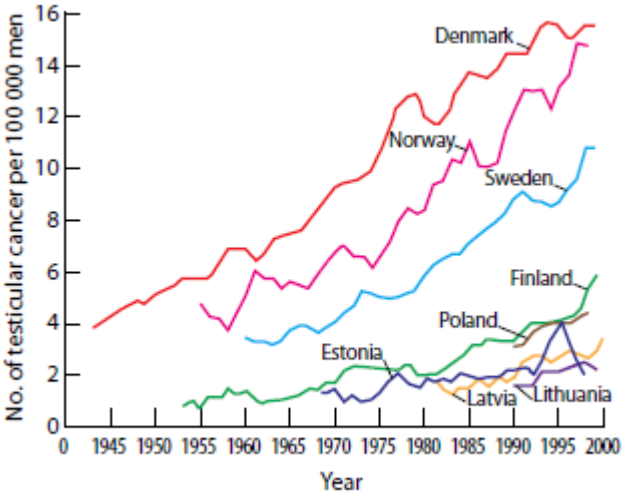


Figure 3: Testicular cancer rates across northern Europe (from Richiardi et al., 2004; used with permission of the publisher)

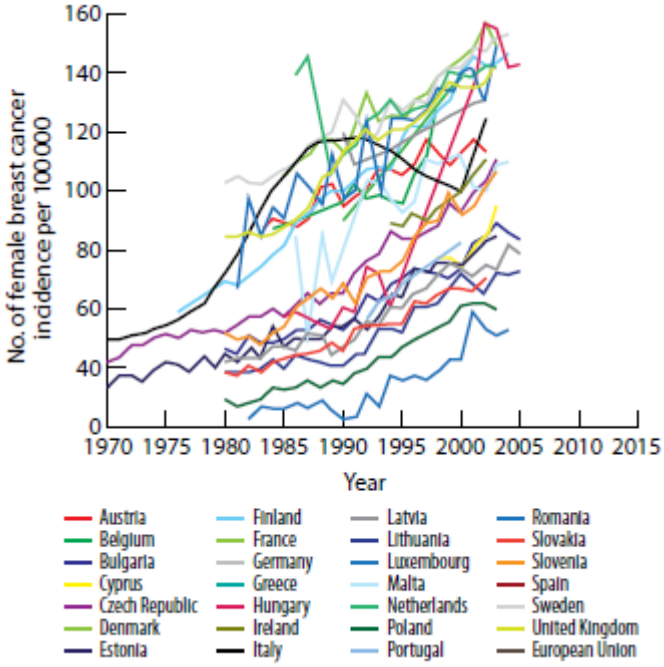


Figure 4: Female breast cancer incidence across Europe (data from http://data.euro.who.int/hfadb/)

Close to 800 chemicals are known or suspected to be capable of interfering with hormone receptors, hormone synthesis or hormone conversion. However, only a small fraction of these chemicals has been investigated in tests capable of identifying over endocrine effects in intact organisms.

According to Article 15 of the Cosmetics Regulation, at the latest by 11 January 2015 the Commission should have reviewed this regulation regarding substances with endocrine-disrupting properties. This review has been published in 2018, and a "Call

for data on ingredients with potential endocrine-disrupting properties used in cosmetic products"[41] has been published on May 2019.

In REACH, substances with identified endocrine disrupting effects are considered under Article 57, as substances which should be included in Annex XIV (i.e. List of substances subject to authorisation). Article 57 states the following: substances — such as those having endocrine disrupting properties (…) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) [of the article 57 of REACH] and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. Based on the update of the Candidate List of Substances of Very High Concern for Authorization from 16 January 2020, there have already been identified 6 entries under Endocrine disrupting properties (human health) and 12 entries under Endocrine disrupting properties (environment).

Currently, a specific list with all identified endocrine disruptors and substances which are suspected to have endocrine disrupting properties does not exist.

The lack of a unique list where all EDCs are identified makes the definition of this requirement more complex.

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.**

Cyclic siloxanes

After the 1st AHWG meeting, it was raised the concern to ban the use of all cyclic siloxanes for the purpose of this EU Ecolabel scheme. The provided reason to include all cyclic siloxanes under criterion 3 (b) is that cyclic siloxanes which are used in cosmetic products will most likely possess similar properties as D4, D5 and D6.

The cyclic siloxanes octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) have already been included in the Candidate List of Substances of Very High Concern, due to the fact that they meet the criteria to be considered as PBT and vPvB (according Articles 57d and 57e of REACH Regulation).

[41] https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

[42] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0528

[43] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

Another cyclic siloxane that may be present in cosmetic products is hexamethylcyclotrisiloxane (D3). This substance has no harmonized classification according Annex VI of CLP Regulation. A REACH registration dossier has been submitted and, according the PBT assessment, "Hexamethylcyclotrisiloxane and its hydrolysis product (dimethylsilanediol) do not meet the criteria for PBT or vPvB. But a degradation product meets the P criterion".

Based on this information, **it is proposed not to include all cyclic siloxanes in the Specified Excluded Substances List under criterion 3 (b)**, since they are already covered by criterion 3(c) which applies regardless of the concentration of these substances/mixtures.

Mineral oil hydrocarbons (MOAH and MOSH)

Cosmetic products can contain mineral oils. These are complex mixtures of hydrocarbons of different structures and sizes. A distinction should be made between mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH). The latter could potentially contain carcinogenic substances, such as polycyclic aromatic compounds (PAHs). Before being used in cosmetic products, they are technologically processed in such a way, through refining processes such as distillation, extraction and hydrogenation, that the number of potentially carcinogenic aromatic compounds are minimised. The technological purification steps have to be optimised, depending on the origin and composition of the crude oil.

These highly purified mineral oils have various functions in cosmetic products, where they can serve as static inhibitors, plasticisers, skin protection, solvents or viscosity regulators. According to their multiple functions, mineral oils are to be found in skin creams, skin lotions, body and face cleansing agents, sunscreens, self-tanning lotions, deodorants and antiperspirants, lip care products, make-up, nail care products, hair gels, skin and eye ointments, Vaseline and baby oil. The concentrations range from 1 to 99%, depending on the product.

According to Annex II of EU Cosmetics Regulation No. 1223/2009, mineral oils / waxes / distillates are only permitted in cosmetics if the full refining history is known and the starting material is not carcinogenic, or if the distillate fulfils the requirement of method IP346, which means that less than 3% (w/w) of substances are extractable with dimethyl sulphoxide (DMSO). In practice, the IP346 method is an initial test for those minerals oils which are to undergo further purification steps, such as catalytic hydrogenation in order to minimise the residual aromatic content, for subsequent use in cosmetic products. This should prevent the use of mineral oils which are of concern to health.

The health risks of dermal absorption of MOSH and MOAH from mineral oils via cosmetics was evaluated by the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR). Highly refined mineral oils and microcrystalline waxes, which comply with the purity requirements for pharmaceuticals, are used in cosmetic products for dermal application. The MOAH levels in these mineral oils are reduced through the corresponding technical refinement. As MOSH are hardly absorbed by the skin, the dermal application of cosmetic products containing mineral oils does not result in systemic exposure.

According to the currently available data and under consideration of clinical experiences and a lack of epidemiological indications, no health risks are to be expected for consumers who apply cosmetic products to their skin. There are also no indications at the moment of a health risk to the consumer through dermal absorption of the MOSH fraction in cosmetics. Existing data on skin penetration suggest that higher viscosity oils hardly become systemically available via dermal exposure route, even though small quantities of shorter chain n-alkanes, which were tested as the model substances for MOSH, are occasionally detected in the epidermis as well as the dermis.

Additionally, oral exposure has to be considered, especially with lip care products, which can also contain mineral oils. As low-viscosity mineral oils can easily be absorbed orally, medium- and high-viscosity mineral oils and microcrystalline waxes are recommended for the use in lip care products. Certain highly purified food grade medium- and high-viscosity mineral oils and microcrystalline waxes were subjected to a health risk assessment by the European Food Safety Authority (EFSA) and approved for the use in the food sector. Values for acceptable daily intake (ADI) were derived for these mineral oils and waxes by the Joint FAO / WHO Expert Committee on Food Additives (JECFA) and by EFSA. Cosmetics Europe (Europe trade association for cosmetics and personal care industry) has advised manufacturers of lip care products only to use those mineral oil fractions for which ADI values apply.

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.[44]

Based on this rationale, **it is proposed not to include MOSHs and MOAHs under the list of Specified Excluded Substances (criterion 3 (b)).**

Perfluorinated and polyfluorinated compounds

Per- and polyfluoroalkyl substances (PFASs) are a diverse class of compounds, which comprise more than 4700 chemicals, used in technical applications and consumer products, and some of them have been detected globally in human and wildlife biomonitoring studies. Concerns surrounding PFASs are principally due to their widespread occurrence in humans and the environment and links to adverse health effects. It is thought not commonly known that these compounds are also used in cosmetic products which come into contact with the skin (e.g. hair products, powders, sunblocks).

PFASs are man-made chemicals that contain, at least, one perfluoroalkyl moiety (-C_nF_{2n}-). PFASs are highly persistent, as they contain prefluorinated chains that only degrade very slowly, if at all, under environmental conditions. Due to that fact, human and environmental exposure to PFASs will be a long-term source of concern.

[44] BfR Opinion No. 008/2018 of 27 February 2018

It is documented that some polyfluorinated chemicals break down to form perfluorinated ones (D'Eon and Mabury, 2007).

Some PFASs such as perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) have been investigated extensively and thus regulated, but for many other PFASs, knowledge about their current uses and hazards is still very limited or missing entirely. The large number and structural diversity of PFASs make it difficult to comprehensively assess environmental emissions and human exposure to this class of contaminants.

Although some of the long-chain PFASs are being regulated or phased out, the most common replacements are short-chain PFASs with similar structures, or compounds with fluorinated segments joined by ether linkages. While some shorter-chain fluorinated alternatives seem to be less bioaccumulative, they are still as environmentally persistent as long-chain substances or have persistent degradation products. In addition, because some of the shorter-chain PFASs are less effective, larger quantities may be needed to provide the same performance.

Even though many fluorinated alternatives are being marketed, limited information is publicly available on their chemical structures, properties, uses and toxicological profiles. Increasing the use of fluorinated alternatives will lead to increasing levels of stable perfluorinated degradation products in the environment, and possibly also in biota and humans. This would increase the risks of adverse effects on human health and the environment.

Initial efforts to estimate overall emissions of PFASs into the environment have been limited due to uncertainties related to product formulations, quantities of production, production locations, efficiency of emission controls and long-term trends in production history (Wang et al., 2014).

Several regulatory restrictions and substitution measures have been implemented over the last decade with the aim of reducing environmental emissions and human exposure to per-and polyfluoroalkyl substances. Nine perfluorinated chemicals are already included in the Candidate List of Substances of Very High Concern for Authorisation, but only PFOA and its salts is included in the Restricted List (Entry 68 in Annex XVII to REACH).

Additionally, due to the high persistence, global distribution, bioaccumulation potential, and toxicity, some PFASs have been listed under Stockholm Convention (United Nations Environment Programme 2009) as persistent organic pollutants (POPs).

Although initially in TR1.0 the exclusion of perfluoriated substances was not considered relevant because they were already covered by CLP restriction, based on the above information, it is proposed to **include all "perfluorinated and polyfluorinated substances" in the Specified Excluded Substance List under criterion 3 (b).**

PBT or vPvB substances in accordance with Annex XIII of REACH Regulation

According to ECHA website[45], there are 27 substances which have already been recognised as PBT according to Annex XIII of REACH Regulation, 130 substances are under assessment, 38 substances have a broad agreement to be considered as PBT and 59 substances could be considered as PBT due to minority position.

The 27 substances which have been already recognised as PBT are included in the Candidate List of Substances of Very High Concern and, therefore, are covered by the criterion 3 (c) of this proposal.

It is considered that including a category addressing substances/mixtures suspected to be PBT or vPvB would be challenging and costly in terms of assessment and verification, on top of potentially exposing the EU Ecolabel to the subjective evaluation of the CB that would have to assess whether a substance is suspected to be PBT or vPvB or not. Therefore, it is proposed **not to include an extra category under criterion 3 (b) to restrict their use.**

Aluminium and its salts

Aluminium (Al) is a silvery-white, soft, nonmagnetic metal. Aluminium is the third most abundant element (after oxygen and silicon), and the most abundant metal in the Earth's crust. It makes up about 8% by mass of the crust. Aluminium metal is so chemically reactive that native specimens are rare, and it is usually found combined in over 270 different minerals. The chief ore of aluminium is bauxite.

Aluminium-containing raw materials are used safely and extensively in cosmetics. They function, mainly, as pigments and thickening agents.

Aluminium salts are used as antiperspirants to control sweat. These salts work by dissolving in sweat and temporarily inhibiting the flow of sweat to the surface of the skin. This reduces the amount of sweat on the skin for a number of hours after the antiperspirant is applied. Aerosol and roll-on antiperspirants products typically contain ACH (Aluminum Chlorohydrate), whereas sticks, gels and other solid products are most likely to contain an Aluminum salt referred to as AZAG (Aluminum Zirconium Tetrachlorohydrex GLY). In the European Union (EU), aluminum zirconium chloride hydroxide complexes and the aluminum zirconium chloride hydroxide glycine complexes are permitted within certain concentration limits for use in antiperspirant products, per Annex III of the Cosmetics Directive.

Aluminium may also be present in cosmetic colours. Aluminium powder is FDA approved and may be safely used in colouring externally applied cosmetics, including cosmetics intended for use in the area of the eye. In addition, aluminium is a common component in other cosmetic colours where it may be used as a substrate upon which another colour is precipitated. Because the resulting colour is not water-soluble, this

[45] Information obtained from https://echa.europa.eu/es/advanced-search-for-chemicals

can prevent 'bleeding', for example with lipstick. There are other uses of aluminium-containing ingredients in cosmetics, such as use as thickening agents.

The Scientific Committee on Consumer Safety (SCCS) adopted its opinion the safety of Aluminium in cosmetic products (Submission II) in October 2019 (SCCS/1613/1946). The SCCS concluded that, based on the data provided:

- The use of aluminium at concentrations of 6.25% and 10.60% in non-spray antiperspirants and spray antiperspirants, respectively is safe.
- The use of aluminium at concentrations of 2.65% in toothpaste and 0.77 % in lipstick per se is safe.
- The systemic exposure to aluminium via daily applications of cosmetic products does not add significantly to the systemic body burden of aluminium from other sources. Exposure to aluminium may also occur from sources other than cosmetic products, and a major source of aluminium in the population is the diet.

Following table contains a list of cosmetics ingredients which were taken into account for the made decision by SCCS.

Table 17: Cosmetics ingredients containing aluminium

Chemical Name	CAS number
Simple Inorganic Salts	
Aluminium sulphate	10043-01-3
Aluminium potassium sulphate	10043-67-1
Aluminium ammonium sulphate	7784-25-0
Simple Organic Salts	
Aluminium Lactate	18914-91-4
Aluminium Citrate	31142-56-0
Aluminium Glycinate	13682-92-3
Aluminium Benzoate	555-32-8
Chlorohydrates	
Aluminium chloride hexahydrate	7784-13-6
Aluminium chlorohydrate (ACH)	1327-41-9
Aluminium chlorohydrate 80% solid	-
Aluminium sesquichloro-hydrate	173763-15-0
Zirconium – aluminium – glycine complexes (ZAG)	
Aluminium Zirconium Trichlorohydrate Glycine	134375-99-8
Aluminium Zirconium Tetrachlorohydrate Glycine	134910-86-4
Aluminium Zirconium Octachlorohydrate Glycine	174514-58-0
Zirconium-aluminium complexes (ZACH)	
Aluminium Zirconium Tetrachlorohydrate	-

[46] https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf

Aluminium Zirconium Pentachlorohydrate	173762-83-9
Water insoluble Minerals, Glasses and Clays	
Aluminium hydroxide (Gibbsite)	21645-51-2
Aluminium magnesium hydroxide	39366-43-3
Aluminium oxide (Alumina, aluminium sesquioxide)	1344-28-1
Perlite (Volcanic Glass, 12-15% Al_2O_3)	93763-70-3 / 130885-09-5
Bentonite (volcanic ash derived clay; E 558)	1302-78-9
Hectorite ($Na_{0:3}(Mg;Li)_3Si_4O_{10}(OH)_2$; 0.6% Al_2O_3)	12173-47-6
Synthetic Sapphire	-
Cobalt Aluminium Oxide	1345-16-0
Aluminium silicate (Kaolin and clay minerals; E559; CI 77004)	1332-58-7
Kaolin (Al2Si2O5(OH)4; Clay silicate mineral)	1332-58-7
Topaz (Silicate of aluminium and fluorine; $Al_2SiO_4(F,OH)_2$)	1302-59-6
Aluminum calcium sodium silicate (Andesine)	-
Sodium potassium aluminium silicate	66402-68-4 / 12736-96-8
Sodium silver aluminium silicate	-
Aluminium Calcium Sodium Silicate	1344-01-0
Magnesium aluminium silicate (Argila)	1327-43-1
Aluminium Magnesium Silicate	1327-43-1
Alumina Magnesium Metasilicate	50958-44-6
Potassium Aluminium Silicate (Moonstone Powder)	12001-26-2
Ammonium Silver Zinc Aluminium Silicate	-
Pumice (volcanic glass)	1332-09-8
Loess (aeolian / wind-blown silt)	-
Calcium aluminium borosilicate	65997-17-3
Talc (Magnesium Silicate, containing a small portion of aluminium silicate)	14807-96-6
Mica (CI 77891; silicate minerals of varying chemical composition)	13463-67-7
Carbohydrates	
Aluminium starch octenylsuccinate (E1452)	9087-61-0
Aluminium Sucrose Octasulfate	54182-58-0
Fatty acids salts	
Aluminium dimyristate	56639-51-1
Aluminium distearate	300-92-5
Aluminium stearate	7047-84-9
Aluminium tristearate	637-12-7
Aluminium octadecenoate	637-12-7
Hydroxyaluminium Distearate	300-92-5
Aluminum Magnesium hydroxystearate	-
Aluminium stearoyl glutamate	-

Nordic Swan restricts the use of Aluminium in leave-on products to a maximum level of 0.6%, based on the SCCS opinion (Submission I, in 2014), the recommendations

from CosIng and French Ansm and the precautionary principle to extend this requirement to all leave-on products even if exposure is perhaps less and less frequent than in antiperspirants and deodorants.

Based on collected data for this analysis, it is not recommended to set a completely ban to aluminium and aluminium salts for products under the scope of this EU Ecolabel schemes. Efficient alternatives to these substances do not exist at the moment. Therefore, in order to align to Nordic Swan, **it is suggested to include them under criterion 3 (b), but the restriction only applies to leave-on products when their concentration in the final product is higher than 0.6% (w/w).**

Isothiazolines

Isothiazolines, being classified as H317, are allowed for use in EU Ecolabel products up to 0.01% w/w in rinse-off products and up to 0.001% w/w in leave-on products. However, since Nordic Swan prohibits their addition regardless of the concentration, it is proposed to exclude these substances/mixtures to the list of excluded substances (criterion 3(b)).

Definition of microplastics

ECHA is responsible for receiving the intentions and Annex XV of Regulation EC No 1907/2006 (REACH) restriction proposals. These intentions and proposals are listed in the "registry of restriction intentions until outcome", under ECHA website.

A restriction proposal may be prepared by a Member State or by ECHA at the request of the Commission or on its own initiative for substances in the Authorisation List (Annex XIV of REACH Regulation). It is a legal requirement for a Member State to notify ECHA of its intention to prepare a restriction dossier.

On 11 January 2019, ECHA assessed the health and environmental risks posed by intentionally added microplastics and concluded that an EU-wide restriction would be justified. This restriction could result in a reduction in their emissions of about 400.000 tonnes over 20 years.

ECHA's assessment found that intentionally added microplastics are most likely to accumulate in terrestrial environments, as the particles concentrate in sewage sludge that is frequently applied as fertiliser. A much smaller proportion of these microplastics is released directly to the aquatic environment.

ECHA's proposed restriction targets intentionally added microplastics in products from which they will inevitably be released to the environment. The definition of microplastic is wide, covering small, typically microscopic (less than 5mm), synthetic polymer particles that resist (bio)degradation. The scope covers a wide range of uses in consumer and professional products in multiple sectors, including cosmetic products, detergents and maintenance products, paints and coatings, construction materials and medicinal products, as well as various products used in agriculture and horticulture and in the oil and gas sectors.

The proposal for a regulatory definition of a microplastic under REACH by the Dossier Submitter can be found under Section 1.2.2.1 of Annex XV report for intentionally added microplastics restriction proposal:

"microplastic" means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of > 3. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable.

This definition is under evaluation and could be modified in the future. For the purpose of criterion 3 (b), **it is proposed to refer to the definition in Annex XV to REACH Regulation** instead of fixing a definition for microplastic in the legal criteria text, until the final version is available.

Criterion 3(b) for animal care products

It was highlighted by several stakeholders the need for restricting in animal care products the same substances/mixtures that are restricted in cosmetic products for humans. However, extra care should be put to take into account that animal care products are not covered by the Cosmetics Regulation.

In the interest of harmonizing criterion 3(b) for the two annexes, in order to restrict the same substances/mixtures for the two product groups, specific reference to the Annex II of the Cosmetics Regulation has been added to the criterion text). Therefore, substances/mixtures listed under such Annex II are prohibited in animal care products.

Summary of main implemented changes under criterion 3 (b)

Based on the analysis of comments, which were received from stakeholders and competent bodies after 1st AHWG meeting, and further research conducted, the following changes have been implemented in the proposal of this criterion:

- The following substances have been proposed to be included to sub-criterion 3(b):
    - phenoxyethanol (only in leave-on products targeting children);
    - nanomaterials,
    - "sodium phosphate, dihydrate", "disodium phosphate, heptahydrate", "trisodium orthophosphate" and "phosphoric acid, trisodium salt, dodecahydrate",
    - identified endocrine disruptor substances,
    - perfluorinated and polyfluorinated substances,
    - aluminium and aluminium salts (restricted if in concentration higher than 0.6% w/w in leave-on products);

- phthalates;
- isothiazolines.

- The restriction of SLS has been limited to its use in toothpaste only;
- The following substances have been proposed to be deleted to sub-criterion 3(b):
  - nanosilver (now covered by the general restriction for nanomaterials),
  - the phthalates DEP and DOHP (now covered by the general restriction for phthalates);
- The definition of microplastics has been linked to the one that appears under REACH, Annex XV report on the submission for restriction outcome.

In Annex II, the following sentence was added to criterion 3(b): "substances and mixtures listed under Annex II to Regulation 1223/2008 shall not be added to the product". Substances and mixtures listed in criterion 3(b) for cosmetic products that are not relevant for animals were removed from criterion 3(b) for animal care products.

Question to stakeholders
Would it be necessary to better specify "EU regulatory authorities" on nanomaterials exclusion criterion? Isothiazolines exclusion doable?

- Requirement 3(c) Substances of very high concern (SVHCs)

Rationale of proposed requirement

Sub-criterion (c) is directly linked to the EU Ecolabel Regulation (EC) No 66/2010, which states that no substances of very high concern (SVHC) can be present in EU Ecolabel products. "*No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 (REACH) and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight)*".

The updated list of SVHCs is available on the European Chemicals Agency website: http://echa.europa.eu/web/guest/candidate-list-table. The applicant is asked to refer to the latest version of this list at the date of application.

No content-wise changes were introduced in this criterion in the first revised proposal; however the text was aligned with the same criterion used in the most recently adopted EU Ecolabel criteria.

Outcomes from 1st AHWG meeting

After the 1st AHWG meeting, most stakeholders considered that the criterion is not restrictive enough and asked to restrict the use of the substances of very high concern regardless of concentration in the final product.

Further research and main changes

Sub-criterion 3 (c) is linked to the Articles 6(6) and 6 (7) from EU Ecolabel Regulation (EC) No 66/2010.

Article 6 (6) states that "The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic[47], hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parlament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parlament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency."

Article 57 of Regulation (EC) No 1907/2006 (REACH) defines the criteria for inclusion of substances in Annex XIV of the REACH Regulation (Authorization List), in relation

[47] The term "toxic" refers to substances or preparations/mixtures meeting the criteria for classification as Acute Toxicity, Specific Target Organ Toxicity Single Exposure and / or Specific Target Organ Toxicity Repeated Exposure.

to their classification according to Regulation (EC) No 1272/2008 (CLP Regulation) as follow:

a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B;

b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B;

c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development;

d) substances which are persistent, bioaccumulative and toxic (PBT);

e) substances which are very persistent and very bioaccumulative (vPvB);

f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 59 sets the procedure for the identification of substances referred to in Article 57.

Taking Article 6(6) of EU Ecolabel Regulation as reference, it is proposed to **modify the wording of sub-criterion 3(c) in order to restrict the use of substances which are included in the Candidate List of Substances of Very High Concern regardless their concentration**, neither in the final product nor in the ingredients used in the cosmetic formulation.

Question to stakeholders
Do stakeholders agree with the increase of ambition level with regards SVHCs?

- ***Requirement 3(d) Fragrances***

Rationale of proposed requirement

According to the current criterion, fragrances should be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). Moreover, products designed and intended for children shall be fragrance-free.

The results of the survey to stakeholders revealed that 44% of respondents of the revision questionnaire agreed with the requirements set in the current criterion, while 28% of them would modify the criterion. From the latter group half of the respondents considered that the restriction for fragrances should be stricter. There

are also some stakeholders who considered it necessary to use fragrances in baby products, accepting the inclusion of specific restrictions for this product type.

An analysis of other ecolabels was performed and its results presented in the the first technical report4 showing how the presence of fragrances is addressed in other schemes. Both, Blue Angel and Nordic Swan ecolabels establish that classified fragrances of fragrances subject to declaration obligation (Annex III of the Regulation 1223/2009) must not be contained in rinse-off products in concentrations ≥ 0.010 % per substance. The working group of Nordic Swan reported that the demand for fragrance-free cosmetics is limited and the range of fragrances that do not contain allergens is also very limited. Most of the fragrances identified are classified as sensitizers (H317) under CLP Regulation and are therefore excluded for use in EU Ecolabel products according to criterion 3 (a). See TR1 for further details.

No changes were introduced in this sub-requirement in the first revision.

Outcomes from 1st AHWG meeting

During the 1st AHWG meeting, the following topics were taken into account:

- It was discussed that the sensitivity to allergenic substances increases in general population in the last years. Due to that fact, stakeholders demanded low thresholds for leave-on products as well as the exclusion of substances with allergenic properties.
- It was announced that IFRA will publish the 49th amendment to IFRA Standards in 2020.

No changes were introduced in this sub-requirement in the second revision.

- ***Requirement 3(e) Preservatives***

Rationale of proposed requirement

There are some specific requirements for preservatives included in the existing criterion in force:

- *Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 3(b).*
- *The product may contain preservatives provided that they are not bioaccumulating.*

A preservative is not considered bioaccumulating if BCF < 100 or log K_{ow} < 3,0. If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used.

The results of the survey to stakeholders revealed that around 60% of the respondents supported the current criterion formulation, with only 8% of the respondents being against it.

An analysis of other ecolabels was performed in order to study how the presence of preservatives is addressed in other schemes. Nordic Swan and Bra Miljöval apply less

stringent thresholds for BCF and log K_{ow} than the EU Ecolabel (see TR1 for further details).

One more consideration regarding preservatives refers to the restriction on the use of isothiazolinones. Isothiazolinones are widely used in cosmetics because of their high efficacy and the broad spectrum of pH at which they are effective even at low concentrations. This makes them very difficult to be replaced by authorised alternatives. The most commonly used isothiazolinones are Chloromethylisothiazolinone (CMIT) and methylisothiazolinone (MIT), which is a powerful biocidal reported as a sensitizing agent by SCCS[48] with suspected toxicity to the aquatic environment. The Regulation (EC) 1223/2009 prohibits the use of MIT in leave-on products (as no safe concentration is possible) and limits its presence at 15 ppm (0.0015 %) in rinse-off products. The combination of CMIT/MIT in a 3:1 ratio can be used up to 15 ppm. Further restrictions appear difficult to be achieved by the EU Ecolabel cosmetic industry. In 2013, during the process of drafting the criteria which are in force now, such restrictions were discussed extensively with the stakeholders[49]. Split views were expressed, with the industry firmly rejecting the possibility of excluding isothiazolinones for the sake of the stability of cosmetic products and the safety of consumers, which can show higher sensitizing reactions to one preservative than if more substances are used simultaneously. As research may have developed new solutions for preservatives without toxic and/or sensitizing properties, further analysis is required to understand the feasibility of a possible restriction of exclusion. Examples include organic acids, sodium benzoate, potassium sorbate, essential oils, antioxidants and phenoxyethanol. However, these alternatives ensure lower protection, are only effective against yeasts, bacteria OR fungi, and/or may form carcinogenic by-products with other ingredients in the formulation.

Outcomes from 1st AHWG meeting

During the 1st AHWG meeting, the following topics were considered:

- It was indicated that the use of isothiazolinones is restricted in the EU Ecolabel for detergents, contrary to the EU Ecolabel for rinse-off cosmetic products. This situation could generate confusion in consumers. Additionally, due to the used low amount typically used in cosmetic formulations, it was also proposed to prohibit them regardless of the concentration.

Afterwards, an additional comment was received:

- Due to the risk of swallowing toothpaste products, it is suggested sharpening the requirement, in order only to use preservatives which are approved due to Food Additives Regulation.

[48] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf
[49] https://susproc.jrc.ec.europa.eu/soaps_and_shampoos/docs/Rinse-off%20cosmetics-TECHNICAL%20REPORT_after%20ISC%20consultation_20.05.2013.pdf

- The conditions for bioaccumulating (BCF and partition coefficient octanol-water - K_{ow}) should be aligned with CLP Regulation, despite the cut-off values from that Regulation are less restrictive than the existing ones (coming from DSD Directive).
- Several stakeholders requested the ban for isothiazolinones under this criterion.

Further research and main changes

Definition of bioaccumulating thresholds

According to sub-criterion 3 (e), a preservative is not considered bioaccumulating if BCF < 100 or log K_{ow} < 3.0. If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used. These cut-off values come from Dangerous Substances Directive (DSD), which was replaced by Regulation EC 1272/2008 (CLP Regulation). The cut-off values which are defined at the current legislation are less restrictive (BCF < 500 or log K_{ow} < 4,0). Therefore, **it is proposed to keep the strictest cut-off values.**

Thresholds for toothpaste products

Due to the risk of swallowing toothpaste products, it is considered reasonable to **insert a new clause which restricts the use of preservatives in toothpastes** only to those preservatives which are approved by Regulation (EC) No 1333/2008 on food additives.

Question to stakeholders
Do we need to exempt some preservatives for use in animal care products, due to the likely higher biocidal functions required? (Annex II)

- ***Requirement 3(f) Colorants***

Rationale of proposed requirement

It is currently required that colorants in the product must not be bioaccumulating. The definition of what is considered as not bioaccumulating is the same as in the case of preservatives, i.e. if BCF < 100 or log K_{ow} < 3.0.

In the case of colouring agents approved for use in food, it is not necessary to submit documentation of their bioaccumulation potential.

The results of the survey to stakeholders (March 2019) revealed that more than 50% of the revision questionnaire respondents agreed with the current criterion, while 5%

indicated that the criterion should also establish a maximum content of colorants in the final product.

An analysis of other ecolabels was performed prior to TR1.0. Both Nordic Swan and Bra Miljöval set that the colorant must be approved as a food additive. The requirement excludes about ten colorants with log K_{ow} values up to 17, which are approved under the Cosmetics Regulation. Some colorants are also excluded in these labelling schemes for decorative cosmetics.

No changes were introduced in the first revised proposal for this requirement.

Outcomes from 1st AHWG meeting

One stakeholder indicated during the 1st AHWG meeting that colorants should be allowed only if approved by the Regulation on food additives[50].

Several comments were also received in written form:

- Due to the risk of swallowing toothpaste products, a stakeholder suggested sharpening the requirement, in order only to use colorants which are approved due to Food Additives Regulation.
- The conditions for bioaccumulating (BCF and partition coefficient octanol-water - K_{ow}) should be aligned with CLP Regulation, despite the cut-off values from that Regulation are less restrictive than the existing ones (coming from DSD Directive).

Further Research and main changes

Colorants in decorative cosmetics

The expansion of the scope to cover also decorative cosmetics implied the need for further research.

The colouring agents used in the development and manufacture of decorative cosmetics are vital for them to perform their primary function, colouring the skin of the user. Many of the colours used in these products are not used elsewhere in the cosmetics and toiletries field although they are often derivatives of those colours. The chemistry of the colours used in decorative cosmetics has a large bearing on the type of products in which they are used. Some are not suitable for aqueous media but are widely used in anhydrous systems such as lipsticks and powder products.

Colours are heavily regulated in all areas of the world, and unfortunately the regulations vary from country, or regional area, to country. Those within the EU are quite different from those in force in the USA and different again from those in force

[50] Regulation (EC) No 1333/2008 on food additives

in Japan. Specifications for the individual colours may be needed in some places and also batch certification may be required.

Among the colouring agents, dyes, natural colours and pigments are the main categories of substance used for that purpose.

A **dye** is defined as a colorant which is soluble in a solvent or range of solvents (this includes water). For obvious reasons, dyes themselves are rarely used in decorative cosmetics, because the beautifying effect required is temporary, and stain ('dye') on the skin is not needed; but derivatives of the most common dyes are widely used in toiletries. There is however one area where dyes are used. This is in some lipsticks where a claim of 'long-lasting' is required and a particular group of them is used called the 'Eosin' dyes. One drawback of these colourants is that the colour that 'lasts' on the lips often bears no relationship to the initial colour of the lipstick. Another drawback is that they are potential allergens.

Natural colours are fully permitted (in the EU anyway) for use in cosmetics provided that the materials used meet the required purity. They are not particularly stable, however, especially with regard to heat, light and pH. Only one natural colour, or rather its aluminium lake, is widely used and this is carmine. It is obtained from the 'Coccus cacti' insect (a type of beetle), by aqueous alkaline extraction. The pigment is achieved by forming the aluminium lake of carminic acid. Carmine provides a bright strawberry red shade. Chemically it is very stable and is unaffected by oxygen, light, sulphur dioxide, heat and water. Carmine is one of the few organic colours permitted for use around the eye. Its major disadvantage, however, is its price.

Pigments can be defined as coloured or white chemical compounds insoluble in the liquids in which they are used. Chemically they can be divided into two main groups: the very bright, organic pigments and the relatively dull inorganic pigments.

- **Organic colorants** include lakes, toners and true pigments. They are all transparent on the skin, with various levels of chemical and physical stability. They are capable of producing a range of bright colors for a variety of visual effects. They achieve best stability in the pH range of 4 to 9 and are often unstable in the presence of metal ions. Chelating agents can be a good addition to formulas where metal ions might be otherwise present, so long as the chelating agent does not have a detrimental effect on other components of the formulation (such as some fake tanning agents). Organic colorants can also be classified chemically by their structures with varying stability, such as azo colorants, xanthenes, triarylmethanes, quinoline and indigoid. Certain organic colorants can also be used to stain the skin or the lips, for various effects. So called ‘bronzers’ used in fake tanning products usually use a combination of dyes that are able to stain the skin and are resistant to easy wash off. While some colorants would normally be used only in wash off products, in bronzers, the ‘stain’ effect is desirable to give an instant ‘tanned’ appearance. Examples of colorants used to obtain a tanned stain in the skin include FD&C Blue 1, FD&C Yellow 5 and D&C Red 33. Other skin staining dyes that may be used include those that are oil soluble and stain the lips. These typically include D&C Red 21, D&C Red 27 and D&C Orange 5. All skin staining colorants are prone to risks of causing allergic reactions. Particularly the oil-

based colorants used in lipsticks. Appropriate consumer safety tests should be conducted to confirm safety before products move beyond the sample and development stage

- **Inorganic pigments** consist of iron oxides, chromium dioxides, ultramarines, manganese violet, white pigments and pearlescent effects. They are used for their opaque colour coverage, making their use particularly suitable in face and eye make ups. They are usually duller in appearance than organic pigments. However, they have much better stability and can be enhanced through various coatings for decorative effects (pearlescent colours). They are stable to heat and light but may be sensitive to extremes of pH. Main groups of inorganic pigments are:
    - Iron oxides: It has three basic shades - yellow (CI 77492), red (CI 77491) and black (CI 77499). Through careful blending, these three colours are able to produce a vast array of Tans, Umbers, Browns and siennas, making them ideal for use in foundations, blushes and lip products.
    - Chromium oxides: It has two basic types: One provides a dull yellow/green hue and the other a bright bluish/green hue.
    - Ultramarines: They can vary significantly in colour, from blues and violets through to pinks and greens. No matter the colour, they all have the same CI number and INCI designation. Also, they are unstable to low pH conditions.
    - Titanium dioxide: It is widely used in colour cosmetics where opacity and coverage is required. It is extremely stable to heat and light and easily incorporated into a variety of coloured cosmetic and personal care products.
    - Zinc oxide: It has a lower intensity of 'whiteness' than titanium dioxide and less coverage. It does impart antibacterial and fungicidal properties and has good heat and light stability.

Annex IV of Regulation EC 1223/2009 set a list of colorants which are allowed to be used in cosmetic products. The above-mentioned categories are included in the Annex IV of Regulation EC 1223/2009. **Therefore, there is no reason to restrict their use under the scope of this EU Ecolabel scheme.**

On the other hand, heavy metals are banned in decorative cosmetics under EU law, but traces are allowed if the amount is small enough to be technically unavoidable and does not present a danger to human health. Germany conducted a Risk Assessment to evaluate the skin absorption. The concentration values of heavy metals that can be tolerated in a different kind of cosmetic were determined using the SCCS models, which consider absorption data oral and non-cutaneous. The conclusion was that the estimated values were consider as safe, and we can consider even safer for skin absorption, as these values are even much lower than oral absorption.

Nordic Swan restricts the use of barium, lead, mercury, cadmium, six inhalant chromium, nickel and bismuth in colourants for decorative cosmetics and hair dye in concentrations above 10 ppm. The reasons to include this specific requirement are:

- The content of lead and cadmium which was found on lipsticks.
- Nickel and lead are banned under Cosmetics Regulation, but residues may be found in colorants.
- Some companies notified bismuth chloride oxide, which is used in make-up as colour with the aim of providing shimmering surface, as irritant to skin and eyes (H315 and H319) in the C&L Inventory. Despite of that, the submitted REACH registration dossier states that this substance does not meet the criteria to be classified as hazardous according to CLP Regulation.

This requirement only concerns colorants in decorative cosmetics and hair dye. For other products the requirement is not considered to be relevant: soap and other cosmetic products contain very small amounts of colours (normally <1%).

Based on these evidences, **it is suggested to add a specific requirement for heavy metals under criterion 3 (f),** aligning with Nordic Swan.

Definition of bioaccumulating thresholds

Regarding the definition of the thresholds to bioaccumulating, a colorant is not considered bioaccumulating if BCF < 100 or log K_{ow} < 3.0 (as it was the case for a preservative). If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used. These cut-off values come from Dangerous Substances Directive (DSD), which was replaced by Regulation EC 1272/2008 (CLP Regulation). The cut-off values which are defined at the current legislation are less restrictive (BCF < 500 or log K_{ow} < 4.0). Therefore, **it is proposed to keep the strictest cut-off values.**

Summary of main implemented changes to criterion 3 (f).

In summary, the following changes have been made:

- Criterion 3(f) has been sharpened in order to state that colorants used in toothpaste must be approved under the Regulation (EC) No 1333/2008 on food additives.
- The use of barium, lead, mercury, cadmium, six inhalant chromium, nickel and bismuth in colourants for decorative cosmetics and hair dyes is proposed to be restricted to concentrations below 10 ppm.

Question to stakeholders
- Apart from sharpening the criterion for toothpaste products, would it be necessary to include additional product groups (e.g. lipsticks)? - Acceptance of restriction for some heavy metals in decorative cosmetics and hair dye.

- ***Requirement 3(g): UV filters***

Rationale of proposed requirement

In the research prior to the TR1.0 it was found that other ecolabelling schemes include requirements on the use of UV filters.

Nordic Swan sets a number of requirements for the use of UV filters added to the formulation as sun protection for the user. Sun care products are a special class of leave-on skin care products, as these, under specific circumstances, can be released directly to the sea, without previous treatment in a wastewater treatment plant, causing potentially serious environmental and health problems.

In TR1 it was proposed to include a new requirement in EU Ecolabel in line with Nordic Swan specifications.

A requirement of UV filters targeting exclusively the protection of the user is ensured in Cosmetics Regulation (Annex VI). Therefore, the number of available UV filters allowed in cosmetic products is limited.

The proposed limits on the bioaccumulation and toxicity of UV filters aims at restricting the use of UV filters even more, accepting only marketed products, which have a better environmental performance. Since providing stability of organic UV filters in the product is not necessarily compatible with rapid degradability of the substances, the lowest toxicity must be ensured in this case. Such requirement makes sure that the use of 4-methylbenzylidene camphor (4-MBC, used as a chemical organic filter, possibly having endocrine disrupting properties) is excluded in EU Ecolabel products, since it has a log K_{ow} = 5.92 and a LC50 = 0.13 mg/l. However, some minor modifications to the Nordic Swan requirement are proposed, thus aligning the thresholds for BCF and log K_{ow} to the most recently voted EU Ecolabel products (i.e. BCF<100 and log K_{ow} < 3).

Titanium Dioxide (TiO_2) used as a UV-filter in a concentration up to 25% in cosmetic products is currently allowed under the Cosmetics Regulation (entry 27 in the Annex VI to this Regulation). This refers to all forms of TiO_2.

With respect to the nano-form of TiO_2, the SCCS (the Scientific Committee on Consumer Safety) published in recent years three opinions on the safe use of nano-

TiO_2 in cosmetics. The first SCCS opinion[51] (from 2013) considers as safe for humans the use in UV-filters of up to 25% nano TiO_2 with the following characteristics:

- With a purity greater than or equal to 99%,
- In the rutile form, or rutile with up to 5% anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes,
- With a median particle size based on number size distribution of 30 to 100 nm,
- With an aspect ratio from 1.0 and up to 4.5, and volume specific surface area up to 460 m^2/cm^3,
- Coated with one of the coating materials described in Table 1 of the SCCS/1516/13 opinion, the coatings being stable in the final formulation and during use,
- Being photostable in the final formulation,
- Having up to 10% photocatalytic activity compared to corresponding non-coated or non-doped reference.

The second SCCS opinion[52] relates to three nano-forms of TiO_2 materials 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). These materials can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. This, however, does not apply to applications that might lead to exposure of the consumer's lungs to the TiO_2 nanoparticles through the inhalation route (such as powders or sprayable products). A third study[53] concluded that the safety of the use of nano-TiO_2 in spray applications with respect to exposure of the consumer's lungs could not be assessed because of insufficient information provided.

Finally, TiO_2 in inhalable powder form has been included as a Carc 2 (Only TiO2 placed on the market in powder form and consisting of 1% or more of particles with an aerodynamic diameter <= 10µm) in the 14th ATP (adaptation to technical progress) to CLP, which adds a number of substances to Annex VI of CLP. The 14th ATP was adopted by the Commission on 4th of October 2019. The delegated act is expected to be published early 2020, with the changes becoming a legal requirement 18 months later. TiO_2 (placed on the market in powder form and consisting of 1% or more of particles with an aerodynamic diameter <= 10µm) would then be excluded in EU Ecolabel products according to criterion 3 (c). Current EU Ecolabel criteria are

[51] Scientific Committee on Consumer Safety Opinion on Titanium Dioxide (nano form), COLIPA n° S75, SCCS/1516/13, 2014, available online under: https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf

[52] Scientific Committee on Consumer Safety (SCCS) Opinion on Titanium Dioxide (nano form) coated with Cetyl Phosphate, Manganese Dioxide or Triethoxycaprylylsilane as UV-filter in dermally applied cosmetic, SCCS/1580/16, 2018, available online under: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_202.pdf

[53] Scientific Committee on Consumer Safety (SCCS) Opinion on Titanium Dioxide (nano form) as UV-Filter in sprays. https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_206.pdf

valid until 31 December 2021; then, the prohibition of use in cosmetic products will have fully entered into force when the revised criteria are published.

For mixtures, only mixtures placed on the market in powder form and containing 1% or more of TiO_2 which is in the form of or incorporated in particles with aerodynamic diameter <= 10µm need to be classified as Carc.2., i.e. liquid and solid mixtures containing such TiO_2 do not need to be classified (but they do need to carry a warning statement).

In several studies there is clear evidence that nano- TiO_2 is considerably more toxic than micro-sized TiO_2[54], with the anatase form expected to be more toxic than the rutile form[55]. However, although nano-TiO_2 is one of the most well investigated nano substances, several data gaps still exist in relation to its toxicological evaluation. As for consumers the highest direct exposure to nano-scale TiO_2 is expected to be through the use of sunscreens, in TR1.0 it was proposed to restrict the presence of nano- TiO_2 in EU Ecolabel products through new set of requirements in the proposed sub-criterion 3 (g) UV filter, according to the latest findings of SCCS.

Outcomes from 1st AHWG meeting

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).

Afterwards, several comments were received:

- To harmonize with CLP, there should be a tenfold difference between NOEC/EC_x and LC50/EC50.
- The conditions for bioaccumulating (BCF and partition coefficient octanol-water - K_{ow}) should be aligned with CLP Regulation, despite the cut-off values from that Regulation are less restrictive than the existing ones (coming from DSD Directive).
- The conditions under Annex VI of cosmetic products regulation and its amendments must be fulfilled under this criterion, instead if the opinion SCCS/1516/13.

Further research and main changes

Definition of bioaccumulating thresholds

Regarding the definition of the thresholds to bioaccumulating, a colorant is not considered bioaccumulating if BCF < 100 or log K_{ow} < 3.0 (as it was the case for a preservative). If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used. These cut-off values come from Dangerous Substances Directive (DSD), which was replaced by Regulation EC 1272/2008 (CLP Regulation).

[54] Ferin et al., 1992; Renwick et al., 2004; Chen et al. 2006; Inooue et al. 2008
[55] Warheit et al., 2007

The cut-off values which are defined at the current legislation are less restrictive (BCF < 500 or log K_{ow} < 4.0). Therefore, **it is proposed to keep the strictest cut-off values.**

Legislative reference

Annex VI of the Regulation EC No 1223/2009 (Cosmetics Regulation) states a list of the UV filters which are allowed in Cosmetic products and their conditions of use (maximum concentration in ready for use preparation).

Entry 27 of this Annex sets a maximum concentration of 25 % for Titanium Dioxide.

Different amendments have been published for this entry under Annex VI of Cosmetics Regulation. Based on the analysis of collected information, **there is no need to mention neither SCCS/1516/13 nor SCCS/1580/16 as part of the required documentation of compliance for criterion 3 (g), but the requirements from Annex VI of Regulation EC No 1223/2009 and its latest amendments** (Regulation EC No 2016 / 1143 and Regulation EC No 2019 / 1857).

TiO2 reclassification

After 1st of October 2021, titanium dioxide [in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 μm] will be classified Hazard class: Carc. 2, Hazard Phrase : H351(by inhalation). The SDS of the TiO2 used as an ingredient will report, in its section 3, the above mentioned hazard and therefore **it won't be possible to use TiO2 (CMR are excluded according to criterion 3 (a) ii.**

Summary of main changes

The following changes have been proposed for this criterion:

- If nano TiO_2 is used, the conditions under Annex VI of cosmetic products regulation and its amendments must be fulfilled, instead of referring to the opinion SCCS/1516/13.

- ***Assessment and verification***

Rationale of proposed assessment and verification

Regarding the verification procedure, most respondents to the revision questionnaire considered the current verification system as appropriate (nearly 60% of the respondents), whereas 14% of the respondents requested to improve the procedure. Respondents asked for a verification procedure specific for each sub-chapter of criterion 3 and a harmonization of the verification methods. Respective improvements were proposed in the criteria text for the first revision. In addition, the text formulation was aligned to the recently adopted EU Ecolabel criteria for other product groups.

Outcomes from 1st AHWG meeting

It was pointed out safety data sheets are a mean of proof for the assessment, but it is not mandatory to mention all the ingredients in the formulation in this type of documents. JRC clarified that declarations from suppliers are also required to prove compliance to the different sub-criteria.

Further research and main changes

Wording of the assessment and verification has been slightly modified according to changes in criterion text.

Question to stakeholders
- Stakeholders are requested to provide information in the on the use of TiO_2 in cosmetics (type of cosmetics, function and concentration). - **In case the TiO2 is used in cosmetics and the ingredient cannot be replaced, a derogation request from criterion 3 (a) needs to be submitted (Using derogation template in annex 1).**

3.4 CRITERION 4: Packaging

Existing criterion 4: Packaging

a) Primary packaging

Primary packaging shall be in direct contact with the contents.

No additional packaging for the product as it is sold, e.g. carton over a bottle, is allowed, with the exception of secondary packaging which groups two or more products together (e.g. the product and refill).

Assessment and verification: the applicant shall provide a signed declaration of compliance.

(b) Packaging Impact Ratio (PIR)

The Packaging Impact Ratio (PIR) must be less than 0,28 g of packaging per gram of product for each of the packaging in which the product is sold. Pre-shaving products packed in metal aerosol containers are exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$PIR = (W + (Wrefill \times F) + N + (Nrefill \times F))/(D + (Drefill \times F))$$

Where:

W —weight of packaging (primary + proportion of secondary (1), including labels)(g)

Wrefill —weight of refill packaging (primary + proportion of secondary (1), including labels) (g)

N —weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g)

Nrefill —weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g)

D —weight of product contained in the 'parent' pack (g) Drefill —weight of product delivered by the refill (g)

F —number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R/Vrefill$$

Where;

V —volume capacity of the parent pack (ml)

Vrefill —volume capacity of the refill pack (ml)

R —the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number it should be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$PIR = (W + N)/D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard.

Assessment and verification: the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall document that the refills shall be available for purchase on the market.

c) Design of primary packaging

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) and to ensure that at least 90 % of the product can be removed easily from the container. The residual amount of the product in the container (R), which must be below 10 %, shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100 \ (\ \%)$$

Where:

m1 —Primary packaging and product (g)

m2 —Primary packaging and product residue in normal conditions of use (g)

m3 —Primary packaging emptied and cleaned (g)

Assessment and verification: the applicant shall submit a description of the dosage device and test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging. The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.

(d) Design for recycling of plastic packaging

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 5.

Table 5

Materials and components excluded from packaging elements

Packaging element	Excluded material or component*
Label or sleeve	- PS label or sleeve in combination with a PET, PP or HDPE bottle - PVC label or sleeve in combination with a PET, PP or HDPE bottle - PETG label or sleeve in combination with a PET bottle - Sleeves made of different polymer than the bottle - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling)

Closure	- PS closure in combination a with a PET, PP or HDPE bottle PVC closure in combination with a PET, PP or HDPE bottle PETG closures and/or closure material with density of above 1 g/cm3 in combination with a PET bottle - Closures made of metal, glass, EVA - Closures made of silicone. Exempted are silicone closures with a density < 1 g/cm3 in combination with a PET bottle and silicone closures with a density > 1g/cm3 in combination with PP or HDPE bottle - Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	- Polyamide, EVOH, functional polyolefins, metallised and light blocking barriers

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephtalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinylchloride,

Pumps and aerosol containers are exempted from this requirement.

Assessment and verification: the applicant shall submit a signed declaration of compliance specifying the material composition of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.

Annex I: Second proposal for criterion 4: Packaging for cosmetic products

a) Primary packaging

Primary packaging shall be in direct contact with the contents.

No additional packaging for the product as it is sold, e.g. cardboard over a bottle, is allowed, with the exception of secondary packaging which groups the product and its refill. For the products sold with pump, a refilling option should be provided in the same or higher packaging capacity.

Assessment and verification: the applicant shall provide a signed declaration and relevant evidence (e.g. pictures of the products as marketed).

(b) Packaging Impact Ratio (PIR)

The Packaging Impact Ratio (PIR) must be less than 0.24 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers are exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$PIR = (W + (W_{refill} \times F) + N + (N_{refill} \times F))/(D + (D_{refill} \times F))$$

Where:

W —weight of packaging (primary + proportion of secondary (1), including labels)(g)

W_{refill} —weight of refill packaging (primary + proportion of secondary (1), including labels) (g)

N —weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g)

N_{refill} —weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g)

D —weight of product contained in the 'parent' pack (g) D_{refill} —weight of product delivered by the refill (g)

F —number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R/Vrefill$$

Where;

V —volume capacity of the parent pack (ml)

V_{refill} —volume capacity of the refill pack (ml)

R —the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number it should be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$PIR = (W + N)/D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard.

Primary packaging made of more than 80% of recycled materials is exempted from this requirement.

(1) Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

Assessment and verification: the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall document that the refills shall be available for purchase on the market.

c) Design of primary packaging

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) and to ensure that at least 92% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 8%, shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100 \ (\ \%)$$

Where:

m1 —Primary packaging and product (g)

m2 —Primary packaging and product residue in normal conditions of use (g)

m3 —Primary packaging emptied and cleaned (g)

*For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press.

Assessment and verification: the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures…) and test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging. The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.

(d) Design for recycling of plastic packaging

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 7.

Table 7. Materials and components excluded from packaging elements

Packaging element	Excluded material or component*
Label or sleeve	- Full sleeves [1] are not permitted. - PS label or sleeve in combination with a PET, PP or HDPE packaging - PVC label or sleeve in combination with a PET, PP or HDPE packaging - Any PET label or sleeve in combination with a PET packaging - Sleeves made of different polymer than the packaging - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling)
Closure	- PS closure in combination a with a PET, PP or HDPE packaging - PVC closure in combination with a PET, PP or HDPE packaging - PETG closures and/or closure material with density of above 1 g/cm3 in combination with a PET packaging - Closures made of metal, glass, EVA - Closures made of silicone. Exempted are silicone closures with a density < 1 g/cm3 in combination with a PET packaging and silicone closures with a density > 1g/cm3 in combination with PP or HDPE packaging - Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened

Barrier coatings	- Polyamide, EVOH (maximum content of 3% by weight), functional polyolefins, metallised and light blocking barriers

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephtalate, PETC – crystalline polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinylchloride

[1] full sleeves are labels that cover the entire bottle/packaging

Toothpaste tubes, pumps and aerosol containers are exempted from this requirement.

Assessment and verification: the applicant shall submit a signed declaration of compliance specifying the material composition of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.

(e) Take-back system

For products to be used by accommodation services in a packaging lower than 75ml of capacity, the applicant shall offer a take back service in order to collect empty products consumed in the accommodation.

Assessment and verification: the applicant shall submit a description of the service conditions and a declaration of compliance.

Annex 2: Second proposal for criterion 4: Packaging for animal care products

(a) Primary packaging

Same as text included in annex I.

(b) Packaging Impact Ratio (PIR)

Same as text included in annex I.

(c) Design of primary packaging

Same as text included in annex I.

(d) Design for recycling of plastic packaging

Same as text included in annex I.

Rationale of proposed criterion text

Packaging makes an important contribution to the overall life cycle impact of product. The packaging of the product contributes in a range of 5 to 10% for most of the products covered, and up to 30% for toothpaste. Impacts from packaging come mainly from the material used (derived from resources and energy used for producing packaging materials). While nowadays more and more natural raw materials are used to produce cosmetics containers and energy efficiency increases, their recycling still

proves complicated due to the multi-material combinations that are frequently used. It is thus very important to address the weight, reuse, type of materials and characteristics of packaging in the Ecolabel criteria in order to minimize its environmental impact.

A recent report by Ellen McArthur Foundation on circular economy states: *If 'refill' bottle designs and models were to be applied to all bottles in beauty and personal care as well as home cleaning, packaging and transport savings would represent an 80–85% reduction in GHG emissions compared to today's traditional single-use bottles*[56].

In 2018, the European Commission published the European strategy for plastics in a circular economy[57] where one of its aims is to boost the uptake of the recycled plastics and create a solid market for this type of plastics. According to estimates, 95% of the value of plastic packaging material, i.e. between € 70 and 105 billion annually, is lost to the economy after a very short first-use cycle². The demand for recycled plastics today accounts for only 6% of the plastics demand in Europe. To boost the uptake of recycled plastic, the European Commission is taking action to ensure that by 2030 all plastic packaging placed on the EU market is either reusable or can be recycled in a cost-effective manner. Criterion 4 was drafted in line with the objectives of the European strategy for plastics in order to facilitate the transition to a more circular economy by: (a) encouraging recycling-oriented design and (b) incentivising the demand for recycled materials. Introducing the requirement of recycled content in the packaging of cosmetics is also beneficial for the image and CSR of the companies that are producing the EU Ecolabel cosmetics due to the constantly increasing public awareness to this topic.

The introduction of recycled plastics in the manufacturing process reduce dependence on the extraction of fossil fuels. Nevertheless, the demand for recycled plastics is still very limited. According to the European strategy for plastics in circular economy, only 6% of the overall plastic demand is met by recycled plastics[58]. The introduction of the requirement for 20% of recycled material in the packaging design may result in a 30% reduction of environmental impacts in terms of climate change[59].

In the first revision of the EU Ecolabel, the 4 sub-criteria on packaging (primary packaging, Packaging Impact Ratio (PIR), design of primary packaging and design for recycling of plastic packaging) where complemented by a fifth sub-criterion on the take back of empty packaging. Each sub-criterion will be addressed individually in the following sections.

a) Primary packaging

The majority of the questionnaire (March 2019) respondents found this criterion adequate. Only 6% of respondents considered this requirement inappropriate because not strict enough. Proposals to improve the criterion were collected, as for example:

[56] https://www.ellenmacarthurfoundation.org/assets/downloads/Completing_The_Picture_How_The_Circular_Economy-_Tackles_Climate_Change_V3_26_September.pdf
[57] https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf
[58] https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf
[59] According to our calculations, with Simapro software and ILCD method.

- request that refills should always be provided by the license holders,
- prohibition of small bottles.

Such type of restrictions had not been found in other schemes. No changes were proposed in the first version of the revision.

Outcomes from and after 1st AHWG meeting

Data have been gathered from 120 currently EU ecolabelled products, including information about the refilling options available for currently licenced products.

One stakeholder requested the removal of the exemption for the secondary packaging.

Different stakeholders agreed with the inclusion of a requirement on mandatory provision of refill bottles for some cosmetics; at least for products sold with pumps.

Further research and main changes in the second proposal

Majority of the products certified is sold without secondary packaging. Despite the new group of products included in the expansion of the scope could be sold with secondary packaging, this packaging is not needed to preserve the product characteristics. In order to improve the criterion and avoid unnecessary packaging, the criterion has been modified. Secondary packaging will be only allowed to group the product and its refill.

Pumps are made of a number of different materials: apart from plastic, aluminium or bronze can be used in pump construction. Usually and in a common use of the packaging, pumps have a longer life than the content of the packaging.

In order to reduce the number of pumps produced and used in the cosmetic industry, **the refilling option for these products sold with pump is proposed to be mandatory**.

b) Packaging Impact Ratio (PIR)

The PIR calculation as in the existing criterion considers the quantity of renewable and recycled materials in the packaging, as well as whether the product is refillable.

In the current scope of the formula, primary and secondary packaging is included. Tertiary packaging is excluded from calculation, as this will be specific to individual business customer requirements such as order quantity, stock control and shipping methods.

With regards to this requirement, 24% of questionnaire respondents considered the PIR difficult to calculate and/or the requirement of PIR=0.28 g of packaging/g of product difficult to achieve (62% of them from industry). Different problems have been indicated, as follows:

- In some cases, data to calculate the PIR are difficult to obtain, since the suppliers are not able to provide the information,
- There are products which require packaging with heavy closing systems (foam pumps) which are not able to comply with the current requirement,

– Small packaging for sample use has more difficulties to comply with the criterion, and an exemption should be included for this type of product.

46% of the stakeholders have used the spreadsheet available on the EU Ecolabel website to calculate the PIR of the packaging and 87% of them find it easy to use. However, stakeholders identified some errors in the spreadsheet.

CBs provided information concerning current EU Ecolabel licences:

- Regarding the PIR values, the values range from 0.019g to the maximum allowed in the existing criterion: 0.280g.
- 33% of the packaging for which data have been received contain recycled or renewable materials. The percentage of recycled or renewable materials range from the 18.4% to 98.9%.
- 10.9% of the products can be refilled.

Considering data available for current ecolabelled products, the reduction of the PIR was not considered appropriate and no changes were made.

Outcomes from and after 1st AHWG meeting

Data have been gathered from 120 currently EU ecolabelled products, including information on Packaging Impact Ration and the content of recycled material.

Stakeholders asked for the reduction of the PIR value. The average value of the PIR, according them, is lower than current threshold value. The reduction of the PIR is needed in order to remain the excellence of the EU Ecolabel.

The proposal of the inclusion of a requirement for certain cosmetic products on a mandatory provision of refill bottles was welcomed by some stakeholders. It was commented that it should be mandatory provide refill bottles at least for products sold with pump. Moreover, the refill packaging should have an equivalent or higher capacity to the capacity of the first packaging.

A problem with the amenities consumed in accommodations was identified: "the small bottles should be prohibited because they are not an ecological option. Moreover, these products can be replaced by dispensers with certified cosmetics."

Further research and main changes in the second proposal

The reduction of the PIR has been analysed in order to identify the number of products that will be out of the new approach if the value is modified. Table 18 shows how the percentage of licenced products would decrease with decreasing PIR.

Table 18. Percentage of products in compliance with the different PIR values proposed. *Source: data provided by CBs*

PIR value	**0,280**	**0,260**	**0,240**	**0,220**	**0,200**
% of compliant products	**100%**	**85,1%**	**81,4%**	**70,3%**	**64,4%**

A restriction of the PIR to 0.240 would affect the 20% of the certified products. Such a stricter value would promote the use of recycled and renewable sourced materials in packaging and the reuse of packaging. As packaging characteristics have been improved during the last years, **it is proposed to decrease the PIR value from 0.28 to 0.24.**

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.

The EU Ecolabel criteria for detergents and cleaning products include an exemption for packaging of those products that are made of more than 80% of recycled materials. These products are exempted from the calculation of the weight/utility ratio (WUR). **An exemption to comply with this sub-criterion is proposed to be introduced for this product group as well.**

Small packaging has not been prohibited in this revision due to two reasons:

- From the last revision process, stakeholders were not in favour of banning these products.
- Moreover, with the expansion of the scope it should be considered the use of small packaging (for example for make-up products and toothpastes).

Nevertheless, a new creation has been included to reduce the use of unnecessary small packaging. The criterion (e) Take-back system aims to reduce the environmental impact of the products sold in small bottles in accommodations, where are extensively used.

c) Design of primary packaging

20% of respondents consider the current requirement difficult to achieve.

According to the opinion of one respondent, the residual quantity of a rinse-off cosmetic product in the packaging depends not only on the dosage system, but also on the material and the viscosity of the product. Also products sold in bottles of lower capacity may have problems to achieve the requirement of 10%.

CBs could not provide information on the residual amount of product in the primary packaging for all the licenced products. The maximum reported residual amount of product remaining in the container is 7.8%.

No major changes were proposed to be made in the first version of the criterion. Nevertheless, it was proposed to specify further the sentence *"packaging shall be designed to make correct dosage easy (e.g. by ensuring that the opening at the top is not too wide)"* for the specific case of whether liquid soap is sold with pump or dispenser, in line with Nordic Swan requirement, requesting for a maximum amount of product dispensed.

Outcomes from and after 1st AHWG meeting

Data have been gathered from 120 currently EU ecolabelled products, including information on the residual amount of product in its packaging.

Regarding the residual amount of product in the container, different stakeholders commented that the current value (10% of residual amount of product in the container) is unambitious. In order to improve the recycling process, it should be ensured the lowest residual product in the packaging.

Further research and main changes in the second proposal

Information about the residual amount of the product in the container has been collected from 74 licenced products. The average value of R is 3.75%. The reduction of the value R has been analysed in order to consider the proposal of a stricter percentage of residual product.

Table 19 shows how the percentage of licenced products would decrease with decreasing R.

Table 19. Percentage of products in compliance with the different R values proposed. *Source: data provided by CB*

R value	10%	9%	8%	7%	6%	5%
% of compliant products	100%	97,0%	96,0%	91,6%	82,8%	72,3%

Considering the values available and to ensure the recyclability of the product, for the second proposal **the residual amount of the product in the container is suggested to be set to 8%.**

d) Design for recycling of plastic packaging

Recyclability of waste packaging is of high importance. From a life cycle perspective, it would generally be favourable to increase the amount of recycled material entering new life cycles in order to minimize the impact coming from new materials. The impacts of producing virgin materials can be decreased by substituting some of the virgin material with recycled material.

Recycling rates in EU are generally higher for paper and cardboard packaging waste than for plastic packaging waste. Among packaging plastics, PET is the polymer with the highest recycling rates, whereas PVC is the polymer less recycled in this application (nevertheless, used in low amounts for this product group).

For cosmetic products, plastics constitute the main packaging material. Labels (and to a significantly lower extent, especially for this product group, sleeves) are essential elements of packaging. Labels can be made e.g. of aluminized paper or plastic. Some labels are fixed to the packaging using different kinds of adhesives, while sleeves are

made of plastic (shrink or stretch options) and do not require fixing by glue. Currently, the main plastics used in labels and sleeves are: oriented polypropylene (OPP), polypropylene (PP), polystyrene (PS), polyvinylchloride (PVC) and Polyethylene Terephtalate Glycol-modified (PETG).

The French Comité Technique pour le Recyclage des Emballages Plastiques (COTREP) conducted studies which were aimed to analyse different design options (i.e. combinations of packaging and label materials and designs) with the goal of setting recommendations on the design for recycling of plastic packaging[60]. General guidelines were prepared, explaining the behaviour of different types of labels and sleeves with various packaging materials in sorting and recycling processes.

WRAP is a not-for-profit company financed by government funding from Defra (Department for the Environment, Food and Rural Affairs), Scottish Government, the Welsh Government, the Northern Ireland Executive, and the European Union to help businesses, local authorities, communities and individuals with reducing waste, developing sustainable products and using resources in an efficient way. In the framework of its work, tools supporting sustainable practices in waste management are being developed. Among them there are HDPE and PET categorisation matrixes, which can be defined as tools supporting design for recycling.

The above mentioned studies were used for the existing proposal of materials and components excluded from packaging elements. Detailed information can be found in the previous revision report[20].

44% of the respondents considered existing criterion clear enough. Nevertheless, some of them requested to update and make clearer the list of materials concerned.

Considering the requirements of the packaging criterion of Blue Angel, in the first revision it was proposed that PETG and PETC label or sleeve in combination with a PET bottle should be avoided.

Outcomes from and after 1st AHWG meeting

Different comments were received about current restrictions on PVC used in labels or closure. The stakeholders defended the use of PVC in combination with PP and HDPE.

On the other hand, one stakeholder commented that the PVC and other halogenated plastics should not be permitted, considering the minor recyclability of these materials.

Moreover, minor comments were received asking for the modification of the restrictions on the use of CPET on labels and the restrictions of materials for the barriers.

Further research and main changes in the second proposal

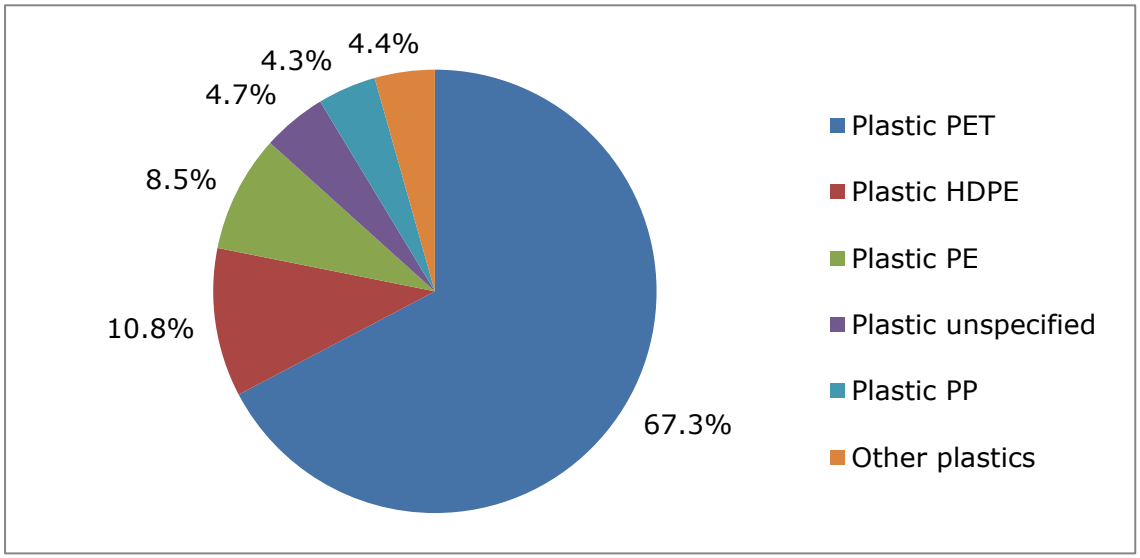
According the European strategy for plastics in a Circular Economy, by 2030 all plastics packaging placed on the EU market is either reusable or can be recycled in a cost-effective manner[57]. The design for recyclability is a strategy that the industries

[60] These guidelines are available on the website COTREP: www.cotrep.fr.

are including in their products. Plastics and packaging are made from a rage of polymers, with specific additives to meet the functionalities and properties of the product considered. The diversity of materials can complicate the recycling process, make it more costly, and affect the quality and value of the recycled plastic.

The most used plastic material for liquid soaps is the PET, 67% of the liquid soaps sold in plastic materials are sold with PET, followed by HDPE and PE (see Table 5). The use of PVC (and other plastic materials) in labels or closures will difficult the recycling process of the packaging.

Figure 5. Most common plastic materials used in liquid soap packaging



The requirement of the PVC has been deleted from the Nordic Swan because it was considered that the use of PVC in the cosmetic sector is small[24]. Nevertheless, and in order to promote the design for recyclability in the packaging sector, the prohibition of using PVC labels and closures is maintained.

Information about the sleeves and the barriers has been gathered to adjust the proposal to the newest techniques[61].

- PET labels and sleeves are always a bad choice, because of the adhesive or the inks that always strongly reduce the r-PET quality. New concepts of PET bottles equipped with PET sleeves (with washable inks) are appearing on the market. However, the fate of the washable ink is uncertain.
- The sorting of the plastic packaging is affected by the percentage of packaging covered by the sleeve. The material used in full sleeves (i.e. labels that cover the entire packaging) can affect the sorting process of the waste and classify the packaging incorrectly. This is because the sleeve covers the entire packaging, "hiding" the material used for the bottle/packaging.
- EVOH can influence the recyclability in different way. It is not admitted at all in the case of clear/light blue PET bottles, for preserving the high recyclate

[61] Information provided by Plastic Recyclers Europe

quality and avoid yellowing effects, but a 3% threshold value was set for transparent coloured PET bottles. Indeed, extensive results of lab tests demonstrated that if the EVOH is applied with ad hoc tie layers its presence does not compromise the recycling quality.

Considering the information gathered, modifications have been included in the table of the criterion. Regarding the labels or sleeves, the introduction of the following text has been done: "Full sleeves are not permitted" and "Any PET label or sleeve in combination with a PET packaging" in order to limit the use of labels that could compromise the bottle sortability.

On the other hand, the EVOH material in barrier coatings has been permitted in small quantities (with a maximum of 3% by weight). The definitive results of the tests developed during this year can result in a removing of this material from the table in future revisions.

An exemption for toothpaste tubes has been included in order to allow the certification of these products, commonly commercialized with multi-laminate packaging: 54.7% of the products are sold with multi laminate plastic packaging according information gathered from MINTEL database.

Finally, minor wording modifications have been done to clarify that all type of plastic packaging is included in the criterion.

e) Take-back system

Some cosmetics companies have offered to their shoppers the option of returning their empties by setting a diversified variety of return schemes: L'Oreal, Vichy, Garnier, Henkel, Unilever, dm, MAC Cosmetics, Farfalla, Ringana. More information on available return schemes can be found in TR1.0.

For the first proposal it was suggested to explore the possibility to include a take back system requirement.

Outcomes from and after 1st AHWG meeting

The new proposal generated controversy over the benefits of the implementation of the take back system. During the AHWG1 stakeholders were asked for their opinion concerning the feasibility of the take back system.

A group of stakeholders agreed with the proposal, nevertheless the system need to be better defined to be implemented. On the other hand, most of the stakeholders did not see it feasible to include a requirement on a take back system (6 responses). Moreover, the stakeholders are concerned about its compliance when the end user is a consumer (and not a business).

Different problems related with the inclusion of the requirement:

- The system could be suitable for big packaging (such as tanks). The products labelled under this decision are sold in small formats.
- It is not easy to implement a take back system in consumer markets, because the behaviour of the end user cannot be controlled.
- The implementation of a take back system in SME will be costly.

- Nordic Swan included this requirement to assess the detergents for professional dishwashers and professional laundry. The criterion was removed because it didn't work in the scheme.

Finally, one stakeholder commented that to promote the circular economy of the criterion, a better solution is to encourage a percentage of recycled plastic in the packaging.

Further research and main changes in the second proposal

A new requirement has been proposed, considering the most conflictive packaging: the amenities. The weight of a 75ml bottle can be of 18.6g, while the weight of 300ml bottle can be of 25g. Considering this data, the consumption of plastic packaging is bigger in lower packaging capacity.

Table 20. Relative plastic consumption considering different packagings

	75 ml packaging	**300 ml packaging**
Total weight (g)	18,6	25
Relative weight (g): per 100g of product	24,8	8,33

It is proposed that **if the product is sold in packaging lower than 75ml, a take back system should be implemented** to collect the empty packaging. These products are commonly sold in accommodations, facilitating the implementation of the system.

As the take back system is only considered in accommodations, the requirement has not been included in the Annex II.

Question to stakeholders
• Stakeholders are requested to provide their views on the proposal. • Information concerning the feasibility of the new proposal for the take back requirement is welcome.

Rationale of proposed "assessment and verification"

Few comments against the current verification procedure for the packaging criterion have also been received: problems with the verification procedure of the maximum residual amount of product exist. One stakeholder commented the absence of a method that harmonises the proofs for the different criteria.

Some minor wording clarifications were included in the first revision.

No changes have been introduced during the second revision.

3.5 CRITERION 5: Renewable ingredients

Existing criterion 5: Sustainable sourcing of palm oil, palm kernel oil and their derivatives

Palm oil and palm kernel oil and their derivatives used in the product must be sourced from plantations that meet criteria for sustainable management that have been developed by multi-stakeholder organisations that have a broad- based membership including NGOs, industry and government.

Assessment and verification: the applicant shall provide third-party certifications that the palm oil and palm kernel oil used in the manufacturing of the product originates from sustainably managed plantations. Certifications accepted shall include RSPO (by identity preserved, segregated or mass balance) or any equivalent scheme based on multi-stakeholder sustainable management criteria. For chemical derivatives of palm oil and palm kernel oil ([62]), it is acceptable to demonstrate sustainability through book and claim systems such as GreenPalm or equivalent.

Annex II: Second proposal for criterion 5: Renewable ingredients for cosmetic products

(a) Sustainable sourcing of palm oil, palm kernel oil and their derivatives

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.

(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.

Assessment and verification

To demonstrate compliance with sub-criterion (a) evidence through third-party chain of custody certificating that the input materials used in the manufacturing originate from sustainably managed plantations shall be provided. For palm oil and palm kernel oil, Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance, and independent smallholders credits shall be accepted.

[62] As defined by the RSPO in the 'RSPO Rules for Home and Personal Care Derivatives', available at: http://www.greenpalm.org/upload/ files/45/RSPO_Guiding_Rules_for_HPC_derivativesV9.pdf.

For palm oil and palm kernel oil derivatives, RSPO certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance, book and claim, and independent smallholders credits shall be accepted. Additionally, to demonstrate compliance in the case of the Book and Claim supply chain model, the amounts of RSPO credits purchased and claimed in the RSPO PalmTrace system model corresponding to that specific derivatives during the most recent annual trading period shall be provided. Competent Bodies should make annual audits in order to verify the validity of RSPO certificates.

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.

Annex II: Second proposal for criterion 5: Renewable ingredients for animal care products

(a) Sustainable sourcing of palm oil, palm kernel oil and their derivatives

Same as text included in annex I.

(b) Certification of plant based ingredients

Same as text included in annex I.

Rationale of the proposed criterion text

In the last years, public concern with respect to conservation of habitat biodiversity, exploitation of forests and use of chemical fertilizers has been increasing. Citizens' awareness has created a demand for products that do not harm the natural environment. Because the manufacture of products generally involves more than one stakeholder and tracing the ingredients is difficult, certification schemes have arisen, verifying the brand's claims on sustainable production throughout the production chain. The concept of organic farming of renewable ingredients is now well established and many certification schemes exist (e.g. Ecocert[63], COSMOS[64], NATRUE[65]). On the contrary, sustainable cultivation of palm forests has only recently started to be monitored and verified through the creation of certification schemes, the main one being RSPO[66]. Finally, for some ingredients certification schemes assessing their sustainability are not available yet (for example coconut oil).

Criterion 5 is divided in two parts:

[63] https://www.ecocert.com/en/expertise/organic-farming
[64] https://cosmos-standard.org/
[65] https://www.natrue.org/our-standard/natrue-criteria-2/
[66] https://www.rspo.org/

(a) Sustainable sourcing of palm oil, palm kernel oil and their derivatives

(b) Certification of plant based ingredients

Requirement (a) - Sustainable sourcing of palm oil, palm kernel oil and their derivatives

Rationale of the proposed criterion text

During last decades environmental concerns related to the use of fossil based ingredients versus vegetable based ingredients in products has arisen. This issue is relevant considering the future limitations on fossil fuels and the concern of global warming, related directly to the use and the combustion of fossil fuels.

Vegetable oils have environmental advantages over mineral or non-bio-based synthetic oils in terms of biodegradability and toxicity. However, these advantages can be counterbalanced by the environmental impacts associated with non-sustainable agricultural practices.

To address the socio-economic issues and minimise the environmental impacts related to the cultivation of these oil-producing plants, some voluntary sustainability certification schemes have been developed. These include: ISCC (International Sustainability and Carbon Certification), RSPO (Round Table on Sustainable Palm Oil), RSB (Roundtable on Sustainable Biomaterials) bioproduct standard, as well as several others.

In the existing EU Ecolabel criteria for rinse-off products, after many discussions, only a requirement for the ingredients from palm cultivation was decided to be included, as this was one of the renewable raw materials of high visibility and linked to important environmental concerns[67].

According to the information provided by the Competent Bodies, 11% of the products contain palm or palm kernel oils and 93,5% of the products contain derivatives from palm oil and palm kernel oil. All EU Ecolabel awarded products including palm or palm kernel oil are RSPO certified.

22% of the respondents to the revision questionnaire considered that the criterion should be extended to other sustainable sources of raw materials indicating that there are other certifications to proof the sustainable origin of the ingredients. Such an extension of the criterion would promote the use of other sustainable ingredients based on coco, rape oil or soya oil.

Following a deep analysis of certification schemes for sustainable sourcing of ingredients, it was concluded that the lack of data and the absence of mature schemes to verify the sustainable sourcing of all types of renewable ingredients were the main reasons behind the unfeasibility to set a prescriptive requirement on all type

[67] Revision of European Ecolabel Criteria for Soaps, Shampoos and Hair conditioners, Technical Report. August 2012.

of ingredients. Moreover, other ecolabelling schemes set the same criteria on palm oil, palm kernel oil and their derivatives as the EU Ecolabel.

Therefore, during the first revision of the criterion mainly wording adjustments were made. In addition, reference was made to the fact that the certification scheme must take into account environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.

Outcomes from and after 1st AHWG meeting

Other certification scheme was mentioned during the meeting: Roundtable for Sustainable Biomass.

Additionally, a discussion was held on whether the RSPO criteria covered a no deforestation requirement.

Further research and main changes in the second proposal

Additional certification schemes

More information was gathered about the certification RSB, considering the request of one stakeholder.

The RSB standard recognizes biomass and biofuel producers and processors who adhere to stringent social responsibility and environmental stewardship criteria, reaching well above minimum levels of compliance established in the Directive 2009/28/EC64.

RSB certification applies to the production, processing, conversion, trade and use of biomass and biofuels, and can be sought by feedstock and biofuel producers and processors, as well as biofuel blenders. It is applicable globally and to all types of biomass and its derivatives. It can be applied to legal organizations or natural persons producing, converting, processing, blending, trading, using or otherwise handling biomass or biomaterials (or both).

Its original name (Roundtable on Sustainable Biofuels) was changed in 2013 to Roundtable on Sustainable Biomaterials, in line with the expansion of its scope to a wide range of biomass derived products other than biofuels.

A multi-stakeholder governance system, it aims to improve the production and processing of biomass and biomaterials, and to ensure:

- Compliance with all applicable laws and international conventions.
- That production and processing are undertaken following a proper environmental and social impact assessment.
- That free prior and informed consent of local communities, especially regarding land and water rights is carried out.
- Achievement of significant GHG savings compared to the fossil-based products used for similar purposes (e.g. gasoline, plastics, coal, etc.).
- Upholdment and respect of workers' rights and human rights.

- Contribution to the economic development of rural and under privileged areas, especially in developing countries.
- Local food security.
- Conservation of areas with high biodiversity value or areas providing important ecosystem services
- Conservation of water resources and preservation of its quality, as well as the quality of soil and air
- Moderate and controlled use of hazardous technologies such as chemical inputs, genetically modified material and waste.

The inclusion of the requirement would imply that renewable ingredients should comply with higher severity requirements.

The existing verifications cannot be considered equivalents. A comparative study concluded that the RSPO standard provides the most robust scheme for palm oil certification[68]. Therefore, the inclusion of other schemes has not been considered in this revision.

Deforestation criterion in RSPO

RSPO aims to ensure to the costumer that the standard of palm oil production is sustainable. It has been observed that RSPO (and other recognised certification schemes) do not effectively prohibit their members from converting rainforest into palm plantation. For this reason, it is considered that this certification schemes have been unable to prevent massive forest and peat fires[69].

Nevertheless, the 2018 RSPO P&C[70] included new requirements to ensure the effective contribution of RSPO to halting deforestation. The standard introduced the High Carbon Stock Approach (HCSA) Toolkit and a specific criterion on deforestation:

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

The certification scheme includes different definitions of HCV areas:

- HCV 1 – Species diversity; Concentrations of biological diversity including endemic species, and rare, threatened or endangered (RTE) species, that are significant at global, regional or national levels.
- HCV 2 – Landscape-level ecosystems, ecosystem mosaics and Intact Forest Landscapes (IFL); Large landscape-level ecosystems, ecosystem mosaics and

[68] A comparison of leading palm oil certification standards. Forest Peoples Programme. https://www.forestpeoples.org/sites/default/files/documents/Palm%20Oil%20Certification%20Standards_lowres_spreads.pdf
[69] European Parliament resolution of 4 April 2017 on palm oil and deforestation of rainforests: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017IP0098&rid=7
[70] RSPO. Principles and criteria for the production of Sustainable Palm Oil 2018.

IFL that are significant at global, regional or national levels, and that contain viable populations of the great majority of the naturally occurring species in natural patterns of distribution and abundance.

- HCV 3 – Ecosystems and habitats; RTE ecosystems, habitats or refugia.
- HCV 4 – Ecosystem services; Basic ecosystem services in critical situations, including protection of water catchments and control of erosion of vulnerable soils and slopes.
- HCV 5 – Community needs; Sites and resources fundamental for satisfying the basic necessities of local communities or indigenous peoples (for livelihoods, health, nutrition, water, etc.), identified through engagement with these communities or indigenous peoples.
- HCV 6 – Cultural values; Sites, resources, habitats and landscapes of global or national cultural, archaeological or historical significance, and/or of critical cultural, ecological, economic or religious/sacred importance for the traditional cultures of local communities or indigenous peoples, identified through engagement with these local communities or indigenous peoples.

No modifications have been included in the criterion text in the 2nd revision.

Rationale of proposed assessment and verification

The assessment and verification of existing criterion 5 has the support of 60% of the revision questionnaire´s respondents, while 24% of them consider it difficult to check the proofs to guarantee the sustainable origin of the raw material, as not all ingredients are RSPO-certified.

Several stakeholders indicated that the Book and Claims[71] should be removed as a verification method. Moreover, it is considered necessary to improve the explanation and better define the evidence required for the verification.

For the first proposal the sub-criterion 5 a) formulation of the was aligned with the recently voted criteria for lubricants in order to ensure harmonisation across different EU Ecolabels.

Outcomes from and after 1st AHWG meeting

A stakeholder mentioned publications have pointed out that palm oil certification does not guarantee the absence of deforestation.

The acceptance of the Book and Claim system as a verification was questioned by different stakeholders. The book and claim supply chain model provides tradable certificates for RSPO certified oil palm to actors in the palm oil supply chain, which

[71] RSPO Supply Chains: https://rspo.org/certification/supply-chains

allows for the transfer of RSPO certified oil palm products volume credits from the mill and its supply base to the end user independently of the physical supply chain. However, it was claimed that this verification system is much weaker and can be misleading for consumers in relation to other supply chain types: identity preserved, segregated and mass balance. The Blue Angel, for example, has removed this system from the certifications possibilities.

One stakeholder commented that the verification of the RSPO certificate should be done checking the RSPO website, because it is updated in real time. In addition several comments suggested that Competent Bodies should make annual audits in order to verify the validity of RSPO certificates.

Further research and main changes in the second proposal

RSPO certification scheme includes different supply chain systems[72]:

- Identity Preserved: assures that the RSPO certified oil palm product delivered to the end user is uniquely identifiable to a single RSPO certified mill and its certified supply base.
- Segregated: assures that RSPO certified oil palm products delivered to the end user come only from RSPO certified sources.
- Mass Balance: allows certified claims to be transferred from one oil palm product to another either through physical blending or administratively under strictly controlled circumstances.
- Book and Claim (B&C): supports the production of RSPO-certified sustainable oil palm products through the sale of RSPO Credits. One RSPO credit represents one metric tonnes of RSPO certified sustainable oil palm product.

The B&C supply chain system has been questioned by stakeholders. If the licence holder has a supplier consuming palm based ingredients, the applicant has to purchase and claim enough RSPO credits to cover the part of palm oil based product.

According data provided from Competent Bodies, currently, there are 50% of the licences including ingredients certified with B&C credits. The deletion of this reference would significantly impact the number of products certified. Therefore, **B&C supply chain is proposed not to be deleted from the accepted method of compliance.** The text in the assessment and verification was revised to clarify that the Book and Claim supply chain model is accepted only in the case of palm oil and palm kernel oil derivatives.

An alternative system mentioned by a stakeholder is the Independent Smallholders Credits. Smallholder farmers produce 40% of the world's palm oil: the supply of palm oil certificated by these farmers would improve their livelihood.

[72] RSPO Supply Chain Certification Systems. RSPO-PRO-T05-002 V1.1 ENG. Adopted by the RSPO Board of Governors on 21 November 2014 Revised 14 June 2017.

Questions to stakeholders
Stakeholder are requested to provide their opinion on the potential inclusion of Independent Smallholders Credits. To Competent Bodies: it is possible to make annual audits in order to verify the validity of RSPO certificates?

Requirement (b) - Certification of plant based ingredients

Rationale of the proposed criterion text

Organic ingredients production is a form of cultivation that focuses on soil fertility management, choice of species and varieties, multiannual crop variation, recycling of organic materials and responsible use of energy and materials. Organic production respects nature's systems and cycles, excluding the use of GMOs and limiting the input of chemically synthetized materials, and contributes to a high level of biological diversity[73].

According to EU Regulations EC 1223/2009 and EU 655/203, claims present in a cosmetic product label shall be justified. Moreover, the EU organic legal framework (Regulation 2018/848 repealing regulation 834/2007) includes also raw materials used for non-food products intended to be produced, prepared, labelled, distributed, placed on the market and imported into or exported from the Union, such as: yeasts used as food or feed; maté, sweetcorn, vine leaves, palm hearts, hop shoots, and other similar edible parts of plants and products produced therefrom; sea salt and other salts for food and feed; silkworm cocoon suitable for reeling; natural gums and resins; beeswax; essential oils; cork stoppers of natural cork, not agglomerated, and without any binding substances; cotton, not carded or combed; wool, not carded or combed; raw hides and untreated skins; plant-based traditional herbal preparations.

The analysis of other schemes suggested the possibility of a requirement focusing on the certification of organic ingredients. Moreover, as market trends indicate that the cosmetic sector is going toward conscious sourcing of ingredients, the proposed method would support such increasing trend.

With regards other available certification schemes, Eco-cert certification includes two different labels: Organic Cosmetics (a minimum of 20% of organic ingredients in leave-on products, or 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 by weight must come from organic farming) and Natural Cosmetics (a minimum of 5% of all ingredients by weight must come from organic farming).

[73] Council Regulation (EC) No 834/2007

In relation to NATRUE, 95% of the natural substances of plant and animal origin and of derived natural substances contained in the product must come from controlled organic farming and/or wild collection, certified by a duly recognized certification body or authority to an organic standard or regulation approved in the IFOAM Family of Standards[74].

In the framework of a multi-year collaboration IFOAM - Organics International developed together with his UN partners, the Food and Agriculture Organization (FAO) and the United Nations Conference on Trade and Development (UNCTAD), a set of standard requirements that functions as an international reference to assess the quality and equivalency of organic standards and regulations.

The COSMOS-standard is a new cosmetic certification developed to harmonise various certifications and labels in order to create one standard that is internationally recognised for natural and organic cosmetics. The "COSMetic Organic Standard" was officially launched in February 2011, and as a result of Europe's leading natural cosmetic certifiers coming together and forming a non-profit association, COSMOS-standard AISBL. The COSMOS-standard association consists of five founding members who now authorise and oversee the certification, including the Soil Association (UK), Ecocert (France), Cosmebio (France), BDIH (Germany) and AIAB/ICEA (Italy). The COSMOS certification includes two type of ingredients: the certified ingredients (with organic content) and the approved raw materials (with no organic content which are not covered by the EU Organic Regulation). The approved raw materials have no organic content but are acceptable for use in the COSMOS-standard because they use only the chemical processes and reagents that the standard allows.

Nordic Swan requests that a certification of the organic production of ingredients is provided in all cases where organic production is claimed on the label/package. However considering that EU Ecolabel should go beyond legislation it was suggested for the first revised proposal to discuss the possibility to request a minimum content of organic certified ingredients when plant based ingredients (covered by the EU organic regulation) are used.

Outcomes from and after 1st AHWG meeting

The proposal of including the minimum content of organic certified ingredients has generated controversy. There are stakeholders who agree with the proposal, however the majority of stakeholders do not accept the requirement. They provide the following rationale and reasons:

- The traceability of the products will be difficult to obtain.
- The cost of the product will increase. In fact, nowadays, the proportion of products using certified organic soaps is small due to the cost of these ingredients.

[74] https://www.ifoam.bio/pt/ifoam-family-standards-0

- The additional requirements should be applied to mineral based ingredients, and not to impose additional criteria to plant based ingredients.

Moreover, one stakeholder commented that since most organic fragrances are classified as H317, the criterion seems to enter in a contradiction with Criterion 3.

Further research and main changes in the second proposal

The COSMOS Standard covers two levels of finished products: cosmetic products under organic certification and cosmetic products under natural certification. According the COSMOS- standard[75], a product can be included under the organic certification if at least 20% of the total product is organic. There is an exception: for rinse-off products, non-emulsified aqueous products, and products with at least 80% mineral or ingredients of mineral origin, only the 10% of the total product must be organic.

Considering these requirements, the list of COSMOS-Certified cosmetic products has been analysed in order to identify the number of products certified under these conditions. There are more than 13200 certified products under the organic certification according the requirements of the COSMOS-Standard[76]. The products certified are very diverse, including shampoos and soaps, creams and lotions, toothpastes, toners and serums, and make up products like lipstick, eyeshadows, make-up powders, etc.

Considering the number of certified products under COSMOS, the inclusion of a minimum content of organic certified ingredients is maintained in the second version of the criterion. It is suggested that t**he 20% of the ingredients covered by the EU organic Regulation (EC 834/2007) shall be produced according to organic production and certified by a third-party.**

Rationale of proposed assessment and verification

For the first proposal, it was suggested that a proof of organic certification for the relevant ingredients is provided, awarded by Competent Bodies designated according to the EU Regulation No 834/2007 on organic production, IFOAM family of standards, COSMOS scheme or equivalent schemes.

No modifications have been included in the Assessment and verification text of the sub-criterion 5 (b) (Plant-based ingredients) in the 2nd revision.

[75] COSMOS-standard. Cosmetics Organic and Natural Standard. Version 3.0, 1 January 2019
[76] COSMOS- Certified cosmetic products: http://cosmos-standard-rm.org/data/indexcp.php

3.6 CRITERION 6: Specific requirements for wet wipes

Annex I: Criterion 6: Specific requirements for wet wipes
This criterion only applies to wet wipes **(a) Raw materials** *(i) Paper materials* The paper substrate shall bear the EU Ecolabel for "Graphic paper, tissue paper and tissue products" in accordance with Commission Decision (EU) 2019/70, Annex II. *(ii) Fibres materials* The fibre substrate shall bear the EU Ecolabel for "Absorbent Hygiene Products" in accordance with Commission Decision (EU) 2014/763. **(b) User information** The packaging shall include information on the correct disposal of the wipes. *Assessment and verification*: The applicant shall provide a copy of a valid EU Ecolabel certificate for the substrate used in a final product and a signed declaration of compliance along with a sample of the product packaging design.

Despite wet wipes are not included in the Cosmetic Regulation for definition (a wipe is neither a substance nor a mixture), they can be considered the substrate of the substance or mixture intended to be placed in contact with the external parts of the human body[77]. Wet wipes have become a serious environmental problem when they ends up in the sewage system. Unlike paper, this product is not biodegradable and generates obstructions in tubs and pipes and problems in the waste water treatment system.

For all this reasons, the inclusion of this product need a specific criterion to minimise the environmental impact of the wet wipes.

Specific requirements for wet wipes have been included in order to avoid the certification of non-environmental friendly products. These requirements apply to cosmetic products destined to humans only (Annex I).

Two different requirements have been included. The first one is related with the substrate used in order to minimize the environmental impacts generated due to the raw material consumption. In line with the Nordic Swan Ecolabel, which includes a specific requirement about the materials and fibres used in wet wipes:, the wipe should be certified by the EU Ecolabel. A distinction between paper products and

[77] Manual of the working group on cosmetic products (sub-group on borderline products) on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)). Version 2.2 (February 2016).

other substrates has been made in order to cover the type of substrates commonly used.

The second requirement refers to the end-of-life of the product. The adequate disposal of the wipe is very important to reduce the environmental impact of the product. The user information requirement can influence the customer behaviour during the use phase and the end-of-life of the product.

Other EU Ecolabels (detergents EU Ecolabel, for example) include a specific requirement on user information, in order to include information about dosage instructions, packaging disposal information and environmental information. In order to minimise the environmental impact of the wipes when they arrive to the environment. It is therefore suggested that the packaging of the product should include information about the correct disposal of the wipes.

3.7 CRITERION 7: Fitness for use

Existing criterion 6: Fitness for use

The product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall be conducted following the 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products'(12) and the instructions given in the user manual available on the EU Ecolabel website.

Assessment and verification: the applicant shall document the test protocol that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging.

[References:

(12) Available at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23 and the EU Ecolabel website.]

Annex I: Second proposal for criterion 7: Fitness for use for Cosmetic Products

The product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall be conducted following the 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products'(*) and the instructions given in the user manual available on the EU Ecolabel website.

For consumer tests, the consumers must be asked about the product's efficiency compared to a market-leading product. The questions to the consumers must cover at least the following aspects:

1) How well does the product perform in comparison with a market-leading product using the same dosage?
2) How easy is it to apply the dosage of the product in comparison with a market-leading product?
3) How easy is it to apply and rinse-off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?

A minimum of 20 consumers are requested and at least 80% must be at least as satisfied with the product as with a market-leading product.

Assessment and verification: The applicant shall document the test protocol (laboratory test(s) or consumer test) that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that

demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging.

Laboratory test performed to comply 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.

[References:

(*) Available at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23 and the EU Ecolabel website.]

Annex II: Second proposal for criterion 6: Fitness for use for Animal Care Products

The animal care product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. colour protection, moisturizing) shall be supported by adequate and verifiable studies, data and information of ingredients.

Assessment and verification: The applicant shall present studies, data and information of ingredients or final formulation to demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging.

Rationale of the proposed criterion text

The environmental assessment conducted in this study showed that a high percentage of total environmental impact of certain rinse-off cosmetic products is due to the use phase (up to 50% of total impacts, depending on the product and on the impact category). Some characteristics of the product, such as the ease for being rinsed-off or long-lasting results, would contribute to saving the amount of water consumed during the use phase, minimizing the overall environmental impact of the products. If the energy needed to heat the water is included in the studied system, the use stage could be responsible for up to 82% of the total environmental impact of the product (for the case of liquid soap, and in similar extent for other products).

The quality of products awarded with the EU Ecolabel is one of important aspects of the scheme, which must be considered in order to prevent creating the image that EU Ecolabel products are environmentally friendlier but poor in performance/inefficient. For that reason, performance tests should address all important characteristics and functions of the product.

The criterion on fitness for use addresses currently the aspects of performance, dosage and application. Cosmetic Europe's "Guidelines for the evaluation of the

efficacy of Cosmetics Products"[78] (revised in May 2008) contain the general principles for all efficacy tests and the information which should appear on all test reports. Human and non-human testing methods for efficacy assessment are also explained in this document. In addition, there is a "Technical document on cosmetic claims"[79] agreed by the Sub-Working Group on Claims and endorsed by the Working Group on Cosmetic Products[80], published in July 2017 and based on Regulation (EC) 655/3013 on laying down common criteria for the justification of claims used in relation to cosmetic products.

There are different types of studies, which can be used to provide data on the performance of cosmetic products:

- The sensorial approach (sight, touch, olfaction) by consumers or experts,
- The instrumental approach which favours specific criteria measured using in vivo, ex-vivo or in vitro approaches, which do not reproduce normal conditions of the use of products but allow objective analysis of specific activities.

Due to the absence of harmonized tests for specific product groups, user tests are often used. In a consumer test required by the current Ecolabel the minimum number of participants is 15. The product is compared with a referenced market-leading product. At least 80% of the consumers must be satisfied with the product as with a market-leading product.

In general, the use tests by consumers evaluate the consumers' perception of product efficacy and cosmetic properties based on parameters they can observe or feel. There are two main types of use tests[81]:

- Blind use test: Tests without providing any information such as brand, decor, communication which could influence the consumers´ judgement and alter their perception of the effect of the product alone.
- Concept use tests: Product tests combined with elements of communication that help to check whether the concept, the communication and the effect of the product as perceived by the consumers match; information from concept use tests are used to complement that contained in the product efficacy dossier.

There are specific guidelines for certain product categories, but for some of them only. For instance the European Commission adopted recommendations on the

[78] Available online under: https://www.cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf
[79] Available online under: https://ec.europa.eu/docsroom/documents/24847/attachments/1/
[80] The Working Group is chaired by the European Commission and is composed of representatives of all Member States of EU and EFTA, the European Consumer Organisation (BEUC), The Personal Care Association (Cosmetics Europe), the European Federation for Cosmetic Ingredients (EFfCI), the International Fragrance Association (IFRA), the European Organisation of Cosmetic Ingredients Industries and Services (Unitis), the European Association of Craft, Small and Medium-sized Enterprises (UEAPME), the International Natural and Organics Cosmetics Association (NATRUE), and the European Cosmetics Responsible Person Association (ERPA).
[81] Practical guidance on methodology for cosmetic claim substantiation, Cosmetics Europe, May 2008.

efficacy of sunscreen products and related claims (Commission Recommendation 2006/647/EC)[82], which apply universally across the EU.

The guideline provided by Cosmetics Europe advice also which information should be included in the test protocols and test reports[83], e.g. information that can assure the reliability of the study.

According to Commission Regulation (EU) No 655/2013[84] claims on cosmetic products should conform to the following common criteria: legal compliance, truthfulness, evidential support, honesty, fairness, informed decision making.

These criteria should be taken into account when it comes to best-practice verification for personal care and cosmetic products. Ensuring adequate testing for products should then be a key concern for the industry, regardless of the mere regulatory requirements.

In the current EU Ecolabel for cosmetic products it is required that the product shall be tested to demonstrate its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e. g. anti-dandruff, colour protection).

55% of respondents of the revision questionnaire considered the current criterion adequate. However, some point out that the criterion is subjective and the current limit of the consumer test (80% of testers considering at least as good as a market-leading product[85]) is difficult to achieve.

Regarding the verification procedure, 10% of the respondents disagreed with the currently set method. They argue that for confidentiality reasons it is not appropriate to provide the contact details of the consumers. Moreover, a generic formulation like IKW (Industrieverband Körperpflege- und Waschmittel e.V) tests should be considered.

Even though the majority of stakeholders agreed with current criteria (52%), they point out improvement potential in the verification process. The use of a generic formulation as reference could be considered, as it is used for example in laundry detergents or automatic dishwashing products to be awarded with EU Ecolabel. Moreover, a standard procedure could be studied to allow a more objective test.

An analysis of other ecolabels was performed in order to study how fitness for use is addressed in other schemes. These ecolabelling schemes suggest that EU Ecolabel applicants could perform a consumer or laboratory test to demonstrate the functionality of the product, like the Nordic Swan and Blue Angel Ecolabels do. Nevertheless, Nordic Ecolabel allows for existing products that have been on the

[82] Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, OJ L 265, 26.9.2006, p. 39–43, available online under: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006H0647

[83] The following indications given below are not exhaustive and might not all be relevant depending the test under consideration.

[84] Commission Regulation No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetics products. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2013%3A190%3A0031%3A0034%3AEN%3APDF

[85] COSMETICS EUROPE: Guidelines for the evaluation of the efficacy of cosmetics products https://www.cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf

market for at least 3 years, the use of sales as documentation of the primary functions. Sales must be increasing or stable to demonstrate their fitness for use.

During the first revision (TR1.0) and the 1st AHWG the project team gathered as much information as possible on the specific product testing, to aid defining of the most possibly practical approach to performance testing of cosmetics products.

Outcomes from and after 1st AHWG meeting

During the 1st AHWG meeting and from the comments gathered after, it was detected that stakeholders are concerned about the efficacy and the safety of the products. They highlighted that this criterion is necessary to maintain the credibility of the EU Ecolabel and it is important to follow standardized methodologies to test the efficacy of the products.

However, one stakeholder commented that this criterion is a duplicity, as efficacy is regulated by Regulation (EC) No 1223/2009 on cosmetic products and Regulation (EC) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

Nordic Swan Ecolabel includes the possibility for existing products that have been on the market for at least three years, the use of sales as documentation of the primary functions. Sales must be increasing or stable to demonstrate their fitness for use. However, one stakeholder indicated that they do not agree to adopt this practise in EU Ecolabel.

Some comments and proposals received from different stakeholders and related with consumer tests are:

- It was proposed to require a minimum of 30 people.
- One stakeholder commented that it is difficult to achieve a level of 80% of the consumers at least as satisfied with the product as with a market-leading product. Therefore, the stakeholder proposed to reduce it to 70%.
- A general opinion was that the test is very subjective. Two stakeholders indicated that fragrances, for example, can influence the opinion of consumers.
- A stakeholder suggested that instrumental tests are more objective than user tests.

Different stakeholders commented the importance of the requirement "ease of application" (detailed in the user manual available on the EU Ecolabel website) related with the correct dosage and a convenient dosage system. However, one stakeholder proposed to replace the requirement "How easy is it to apply the desired dosage of the product in comparison with a market-leading product?" by:

- defining correct dosage and indicating it on the label
- providing a convenient dosage system
- labelling in the packaging the importance of use a correct dosage to reduce the environmental impact
- highlighting that the test should be more robust with this modification.

Further research and main changes in the second proposal

Any cosmetic product (Ecolabel awarded or not) must comply with current legislation (Cosmetics Regulation and Commission Regulation 655/2013), consequently claims on products must be supported by sufficient proof and verifiable documentation.

Criterion 6 is necessary to demonstrate that EU Ecolabel products have a good performance in order to maintain their credibility. However, because of recent enlargement of EU Ecolabel scope with the objective to cover the maximum number of cosmetic products, there is a wide range of products and there are no international standardized methodologies to test their performance, except for sunscreens. The labelling of sunscreen products with information text and SPF factor have to follow Commission Recommendation 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto.

Due to the absence of harmonized tests, user tests are often used allowing a subjective evaluation of the product, where the panellist has to make an active effort to judge the performance of the product. This kind of test is very useful to rate the attractiveness of a product in the market, assessing for example how easy it is to spread a cream on the skin or its greasy feeling, or how easy it is to spread or rinse-off a shampoo on the hair. The fragrance can be a key player, as it can affect negatively or positively the answer of a tester, especially tests performed by consumers, which are not trained experts. However, if the efficacy feelings of most consumers of a panel test are negatively affected by the parfum, they need to be also considered. Independently of the source of feeling the product needs good performance opinions to be attractive in the market. Furthermore, the ease of application and/or a convenient dosage system of a product can also modify the perception of the consumer.

The current user manual specifies that the questions to the consumers must cover at least the following aspects:

1. How well does the product perform in comparison with a market-leading product, using the same dosage?

2. How easy is it to apply the desired dosage of the product in comparison with a market-leading product?

3. How easy is it to apply and rinse-off the product to/from the hair and/or skin in comparison with a market-leading product?

Considering that these questions are a must and the user manual will need to be updated after this revision, the inclusion of these questions in the criterion text is proposed.

In consumer tests, at least 80% of the consumers must be at least as satisfied with the product as with a market-leading product. It is important to highlight that 80% of panellist do not have to be more satisfied with the test product, but equally satisfied at least. Nordic Swan and Blue Angel have the same threshold of satisfied testers, in order to be aligned with these labelling schemes, 80% is a good level to achieve.

In order to perform as more objective test as possible, "Guidelines for the Evaluation of the Efficacy of Cosmetic Products" must be followed. Furthermore, a minimum of **20 participants**, instead of 15, has been proposed for the consumer tests to increase the objectivity.

The use of sales as documentation of the primary functions is a practise used in Nordic Swan Ecolabel. However, incrementation or stabilization of specific product sales can be related with marketing campaigns more than efficacy of primary function. Therefore it is proposed not to include such a requirement.

Criterion 7 has been modified in this revision (TR2.0) in order to consider the "ease of application" reflecting questions included in current user manual. Furthermore, the number of participants in a panel test has been increased to 20 people and the percentage of satisfied panellists to fulfil the criterion has been reflected in the criterion text.

Animal care products have to demonstrate their performance, for this reason the text of criterion 6 has been modified to include this requirement. It is also important to justify the efficacy of these products to demonstrate to the consumers that they have a good performance as well as a good environmental profile.

Rationale of proposed assessment and verification

At present it is required that the applicant shall provide results from testing, which demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging. They need to document the test protocol that has been followed in order to test the product's efficacy. In the first proposal (TR1.0) no changes were made to the text.

Outcomes from and after 1st AHWG meeting

One stakeholder expressed the fear of this criterion unnecessarily duplicating existing legislation.

Further research and main changes in the second proposal

Efficacy tests (laboratory tests) performed to comply 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. However, panel tests are a good methodology to assess the captivating ability of the product in the market.

Adequate and verifiable studies as can be panel tests, or data and information of ingredients have been proposed for the assessment and verification of animal care products.

Question to stakeholders
Stakeholders are requested to provide information on testing protocols, methodologies for general and specific cosmetic products, as well as additional proposals of improvement for the currently valid criterion.

3.8 CRITERION 8: Information appearing on the EU Ecolabel

Existing criterion 7: Information appearing on the EU Ecolabel
The optional label with text box shall contain the following text: — Reduced impact on aquatic ecosystems, — Fulfils strict biodegradability requirements, — Limits packaging waste. The guidelines for the use of the optional label with text box can be found in the 'Guidelines for use of the Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: the applicant shall provide a sample of the product label or an artwork of the packaging where the EU Ecolabel is placed, together with a signed declaration of compliance.
Annex I: Second proposal for criterion 8: Information appearing on the EU Ecolabel for cosmetic products
The optional label with box shall contain the following information: - Limited impact on aquatic environment - Fulfils strict biodegradability requirements - Limits packaging waste The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: The applicant shall provide a declaration of compliance with this criterion, supported by a high resolution image of the product packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.
Annex II: Second proposal for criterion 8: Information appearing on the EU Ecolabel for animal products
Same as text included in annex I.

Rationale of proposed criterion text

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the EU Ecolabel product may be displayed in the optional label with text box. The guidelines for the use of the optional

label with text box can be found in the "Guidelines for the use of the EU Ecolabel logo" on the website[86].

Information about the EU Ecolabel on the product helps to inform the consumer on the environmental preference of this product and make easy the environmentally friendly decision. For this reason, this criterion is included in all EU Ecolabels.

The choice of phrases to be displayed on the EU Ecolabel will depend on the final shape of the criteria therefore for the moment only minor changes are being proposed and more important modification may be made, when the final criteria is better known.

According to the feedback received from the revision questionnaire (see Preliminary Report[20] for more details) the majority of the respondents agree with the current text appearing on the EU Ecolabel.

No relevant changes were included in the first revision.

Outcomes from and after 1st AHWG meeting

Few outcomes were gathered for this criterion.

Regarding the three sentences for the optional label, one stakeholder proposed to remove the sentence "limited impact on aquatic environment" as it may be confusing to consumers and it can be hard to understand what the improvement in relation to unlabelled products is. Nevertheless, a new sentence related to hazardous substances was proposed: "fulfils strict requirements regarding hazardous substances".

However, other stakeholder highlighted that it is recommended not to include any reference to health or safety since this approach has the potential to undermine the fact that all cosmetics must be safe by law.

One stakeholder proposed to add a sentence related with efficacy in order to highlight the performance of EU Ecolabel certified products.

Further research and main changes in the second proposal

The use of hazardous substances is regulated in cosmetic products by Cosmetics Regulation. Their use can be prohibited or restricted according their concentration in the final product or the type of product or their intended use. However, the final product must be safe for humans.

The proposed sentence by a stakeholder "fulfils strict requirements regarding hazardous substances" can confuse consumers, which could interpret that non-Ecolabelled products contain hazardous substances and could be unsafe. According to Regulation 655/2013 claims must be fair:

[86] http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

- Shall be objective and shall not denigrate the competitors, nor shall they denigrate ingredients legally used.
- Shall not create confusion with the product of a competitor.

No modifications have been included in the second revision of the document.

Question to stakeholders
Stakeholders are requested to provide information about possible modifications of the statements included in the criterion (e.g. one related with the verified performance).

4 IMPACT OF CHANGES TO CRITERIA

This section consists of a summary of the main general changes proposed for the revised criteria and potential implications for current license holders and possible applicants.

At this stage of the process the main fundamental changes consist of the extension of the scope and of the increased strictness of the requirements.

This chapter will be further developed in the following versions of this technical report once the proposals are further discussed.

5 ANNEX I. SUBSTITUTION INFORMATION AND DEROGATION REQUEST FORM

Stakeholders should fulfil to communicate the derogation from of substances that cannot be replaced and are not able to comply with article 6 (6) of the EU Ecolabel Regulation.

1. Common information requirements

To be treated as confidential?	☐Yes ☐No

Contact name	
Organisation	
Email	
Telephone No.	
Supplementary documents attached	

1a. Chemical substance name(s)	
1b. CAS, EC or Annex VI numbers	
1c. Current EU regulatory status	
1d. CLP Classifications from the EU Ecolabel hazard listing	

1e. Proportional contribution to final product classification (for mixture ingredients)	
1f. Existing scientific evidence and risk assessments relating to the substance	
1g. Functional need and significance to the final product	
1h. Typical concentration in the final product and specific components or articles	

2. Additional information required for <u>derogation requests</u>

2a. The relevance of the hazard classification(s) along the life cycle of the product (e.g. manufacturing, use, disposal)	
2b. Market availability of alternatives and the potential for substitution	

3. Additional information required about substitutes

3a. Comparative evaluation of environmental performance	
3b. The relevance of the hazard substitution along the life cycle of the product (e.g. manufacturing, use, disposal)	
3c. Compliance with product performance and functional requirements	
3d. Market diffusion and technical maturity	

6 ANNEX II. Substances under “call for data on ingredients with potential endocrine-disrupting properties used in cosmetic products”.

Group A:

Substance	CAS number	EC number
2-hydroxy-4-methoxybenzophenone	131-57-7	205-031-5
5-hydroxy-2-hydroxymethyl-4-pyrone	501-30-4	207-922-4
(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one	36861-47-9	253-242-6
Propyl 4-hydroxybenzoate	94-13-3	202-307-7
5-chloro-2-(2,4-dichlorophenoxy)phenol	3380-34-5	222-182-2
1,3-benzenediol	108-46-3	203-585-2
2-Cyano-3,3-Diphenyl Acrylic Acid 2-Ethylhexyl Ester	6197-30-4	228-250-8
1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea	101-20-2	202-924-1
2,6-Di-tert-butyl-p-cresol	128-37-0	204-881-4
Benzophenone	119-61-9	204-337-6
2-hydroxybenzoic acid (3,3,5-trimethylcyclohexyl) ester	118-56-9	204-260-8
Benzyl salicylate	118-58-1	204-262-9
5,7-dihydroxy-3-(4-hydroxyphenyl)-4-benzopyrone	446-72-0	207-174-9
4’,7-Dihydroxyisoflavone	486-66-8	207-635-4

Group B:

Substance	CAS number	EC number
Butylparaben	94-26-8	202-318-7
Tert-butylhydroxyanisole / Butylated hydroxyanisole / BHA	25013-16-5	246-563-8
Ethylhexyl methoxycinnamate (EHMC) / octylmethoxycinnamate (OMC) / octinoxate	83834-59-7	629-661-9
Benzophenone-1 / BP-1	131-56-6	205-029-4
Benzophenone-2 / BP-2	131-55-5	205-028-9
Benzophenone-4 / BP-4	4065-45-6	223-772-2
Benzophenone-5 / BP-5	6628-37-1	613-918-7
Methylparaben	99-76-3	202-785-7
Cyclopentasiloxane / decamethylcyclopentasiloxane / D5	541-02-6	208-764-9
Cyclomethicone	69430-24-6	614-966-1
Salicylic acid	69-72-7	200-712-3
Butylphenyl methylpropianal / BMHCA	80-54-6	201-289-8
Triphenyl phosphate	115-86-6	204-112-2
Deltamethrin	52918-63-5	258-256-6

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